11TH ITU ACADEMIC CONFERENCE

ICT for Health: Networks, standards and innovation

> 4-6 December Atlanta, Georgia, USA

Hosted by

Technically co-sponsored by







THE LANCET Digital Health In collaboration with



Organized by



ISBN: 978-92-61-28401-5 (electronic version)

Disclaimer

The opinions expressed in these Proceedings are those of the paper authors and do not necessarily reflect the views of the International telecommunication Union or of its membership.

© ITU 2019

All rights reserved. No part of this publication may be reproduced, by any means whatsoever, without the prior written permission of ITU.



Foreword

Chaesub Lee

Director ITU Telecommunication Standardization Bureau

The ITU Kaleidoscope academic conference has gained a reputation for providing an in-depth discussion on matters relevant to the ITU membership. This year, in collaboration with the World Health Organization (WHO), Kaleidoscope 2019: *ICT for Health: Networks, standards and innovation* provided a forward-looking perspective on the future developments for better healthcare delivery.

Kaleidoscope is ITU's flagship academic event. Now in its eleventh edition, the conference supports productive dialogue between academics and standardization experts. I wish to thank the Georgia Institute of Technology for stimulating this dialogue and providing the space for such engagement in the hosting of Kaleidoscope 2019 in Atlanta, Georgia, USA.

The research presented at this conference focused on how information and communication technologies (ICTs) are set to further revolutionize the heath sector, looking into the technical aspects such as digital health strategies, smart technologies and access networks for healthcare, as well as issues of safety, security and data protection. The various sessions, including the special panel designed by the WHO Department of Evidence and Intelligence for Action in Health, highlighted how we can use ICT developments to ensure that the goal towards universal, quality health coverage is achieved. These discussions also aided in the understanding of how ITU's work on standardization can advance the digitization of the health sector.

I would like to express my great appreciation to the Kaleidoscope community and the larger ITU Academia membership for their enduring support to this series of conferences. With over 160 academic and research institutes now members of ITU, the Kaleidoscope series is certain to continue growing in strength.

My sincerest thanks go to WHO for collaborating with us on Kaleidoscope 2019, to our host, the Georgia Institute of Technology, Atlanta, Georgia; our technical co-sponsors, the Institute of Electrical and Electronics Engineers (IEEE), the IEEE Communications Society and *The Lancet Digital Health*. I would also like to thank our academic partners and longstanding ITU members, Waseda University, the Institute of Image Electronics Engineers of Japan (I.I.E.E.J.), the Institute of Electronics, Information and Communication Engineers (IEICE) of Japan, the Chair of Communication and Distributed Systems at RWTH Aachen University, the European Academy for Standardization (EURAS), and the University of the Basque Country.

I would especially like to thank the members of the Kaleidoscope 2019 Technical Programme Committee (TPC) and the members of our Steering Committee: Michael Best, Georgia Tech; Christoph Dosch, IRT GmbH; Kai Jacobs, RWTH Aachen University; Mistuji Matsumoto, Professor Emeritus Waseda University; Sameer Pujari, WHO; Rupa Sarkar, *The Lancet Digital Health*; Mostafa Hashem Sherif, USA (also TPC Chair) and Daidi Zhong, Chongqing University. I would also like to thank the distinguished General Chairman of Kaleidoscope 2019 and Executive Vice Director of Research at Georgia Tech, Chaouki Abdallah.

Chaesub Lee Director ITU Telecommunication Standardization Bureau

Chairman's message

Chaouki Abdallah

General Chairman

The use of innovative applications and advanced information and communication technologies (ICTs) are set to continue to affect the health sector globally, providing significant developments and ensuring that communities around the world are capable of providing necessary and efficient healthcare.



Georgia Institute of Technology is proud to provide a space for the presentation and discussion of essential research towards this year's ITU Kaleidoscope academic conference on *ICT for Health: Networks, standards and innovation,* at our campus in Georgia, Atlanta, USA, 4-6 December 2019.

The establishment of the ITU Academia membership category in 2011 brought greater significance to Kaleidoscope's role in fostering academic engagement in the work of ITU. As a member within this category, Georgia Tech is committed to continuing its support to the Union, and particularly in the pursuit of research and academic engagement.

The Technical Programme Committee chaired by Mostafa Hashem Sherif selected 20 papers through a double-blind peer-review process supported by 75 international experts. I would like to thank the Committee and the reviewers for selecting high-caliber papers for presentation at the conference and identifying papers eligible for awards.

Among the various keynotes presented in this year's programme, the first by Valerie Montgomery Rice, President and Dean of the Morehouse College of Medicine, explored the possibilities of leveraging digital health technology to advance health equity. Ian F. Akyildiz, the Kenneth G. Byers Professor in the School of Electrical and Computer Engineering here at Georgia Tech, offered insightful research into the technical aspects of health applications in the context of an Internet of Bio-Nanothings. Both keynotes emphasized the importance of investigating the convergence of engineering and medical research in the pursuit of the global good. John Vertefeuille, of the US Centers for Disease Control and Prevention, delivered his keynote speech titled, "*Polio eradication and how technology is reaching the last mile*," discussing how digital health plays a key role in combatting disease.

The first Kaleidoscope 2019 invited paper, "*Towards international standards for the evaluation of Artificial Intelligence for health*," co-authored by Markus A. Wenzel and Thomas Wiegand, from Fraunhofer Heinrich Hertz Institute, explored how international standards are necessary for thoroughly validating AI solutions for health, and how such standards could create trust among stakeholders. This presentation also highlighted the achievements of the ITU/WHO focus group on "AI for Health."

Kaleidoscope 2019 was developed as a joint collaboration between ITU and the World Health Organization (WHO). In light of this partnership, Marcelo D'Agostino, WHO's Senior Advisor on Information Systems and Digital Health, delivered a keynote speech as part of the opening plenary on "*Digital Health in the Information Society: Working together to leave no one behind.*" Mr. D'Agostino also moderated the WHO special panel session titled, "*Digital transformation of the health sector: The power of Artificial Intelligence and the potential of unstructured and Big Data for public health.*" Yuri Quintana from Harvard Medical School discussed the potential power of Artificial Intelligence to support patients, families and healthcare providers. Ian Brooks of NCSA University of Illinois explored what potential there might be for public health, given the uses of unstructured data and Big Data today, and Jennifer Nelson from the Interamerican Development Bank in the United States focused on the challenges and opportunities surrounding digital transformation in Latin America.

Brian Scarpelli, presented part of the second special panel on "*Essential considerations for policymakers addressing the role of Artificial Intelligence in healthcare*," from Connected Health Initiative, USA. Ilise Feitshans, Fellow in Law at the European Scientific Institute in France, presented her research on "*Global health impacts of personal data protections under European laws and beyond*." This presentation focused on understanding the role of privacy in society as well as its influence on personal health, including whether health concerns affect the application, use and disclosure of personal data in light of the GDPR provisions.

Selected papers from each year's Kaleidoscope conference are considered for publication in a specialfeature section of IEEE Communications Standards Magazine. In addition, special issues of the International Journal of Technology Marketing (IJTMKT), the International Journal of IT Standards and Standardization Research (IJITSR) and the Journal of ICT Standardization may publish extended versions of selected Kaleidoscope papers. Authors of outstanding Kaleidoscope 2019 papers have also been invited to contribute to the work of the ITU/WHO Focus Group on 'AI for Health.'

All papers accepted and presented at the conference will be submitted for inclusion in the IEEE *Xplore* Digital Library. The Conference Proceedings from 2009 onwards can be downloaded free of charge from http://itu-kaleidoscope.org.

I would like to thank our technical co-sponsors, supportive partners and Alessia Magliarditi and her team at the ITU for their role in ensuring the continued success of the Kaleidoscope series of academic conferences.

Chaouki Abdallah

Chaouki Abdallah General Chairman

Foreword	1
Chairmar	ı's Message
Committe	es
Keynote	Summary
P	ANACEA: An Internet of Bio-NanoThings application for early detection and mitigation
O	infectious diseases
Ic	n F. Akyildiz (Georgia Institute of Technology, USA)
ession 1	: ICT infrastructure for healthcare
S	1.1 5G-enabled health systems: Solutions, challenges and future research trends Di Zhang; Teng Zhang; Yunkai Zhai; Joel J. P. C. Rodrigues; Dalong Zhang; Zheng Wen; Keping Yu; Takuro Sato
S	1.2 Community healthcare mesh network engineering in white space frequencies Hope Mauwa; Antoine Bagula; Emmanuel Tuyishimire; Tembisa Ngqondi
S	1.3 Exploration of the non-intrusive optical intervention therapy based on the indoor smart lighting facility <i>Jian Song; Xiaofei Wang; Hongming Zhang; Changyong Pan</i>
S	1.4 Access technologies for medical IoT systems Junaid Ahmed Siddiquee
Session 2	: Medical ICT
S	2.1 Module structure for foot prosthetic and interface standardization Yoshitoshi Murata; Tomoki Yamato
S	2.2 Development of hearing technology with personalized safe listening features Shayan Gupta; Xuan Xu; Hongfu Liu; Jacqueline Zhang; Joshua N. Bas; Shawn K. Kelly
ession 3	: Medical IoT
S	3.1 Facilitating healthcare IoT standardization with open source: A case study on OCF and IoTivity
S	 Bongki Cha; Tounghwan Choi; Kangchan Lee Empirical study of medical IoT for patients with intractable diseases at home Kentaro Yoshikawa; Masaomi Takizawa; Akinori Nakamura; Masahiro Kuroda
Session 4	: Digital health strategies
S	4.1 Invited paper - Towards international standards for the evaluation of artificial intelligence for health
S	 Markus A. Wenzel; Thomas Wiegand 4.2 Redesigning a basic laboratory information system for the global south Jung Wook Park; Aditi Shah; Rosa I. Arriaga; Santosh Vempala

TABLE OF CONTENTS

S4.3	#RingingTheAlarm: Chronic "Pilotitis" stunts digital health in Nepal
	Ichhya Pant; Anubhuti Poudyal
S4.4	Designing national health stack for public health: Role of ICT-based knowledge
	management system
	Charru Malhotra; Vinod Kotwal; Aniket Basu
sion 5: Sm	art technologies for caregivers
S5.1	Elderly health monitoring system with fall detection using multi-feature based
	person tracking
	Dhananjay Kumar; Aswin Kumar Ravikumar; Vivekanandan Dharmalingham;
	Ved P. Kafle
S5.2	A healthcare cost calculator for older patients over the first year after renal
	transplantation
	Rui Fu; Nicholas Mitsakakis; Peter C. Coyte
S5.3	Automatic plan generating system for geriatric care based on mapping similarity
	and global optimization
	Fei Ma; Chengliang Wang; Zhuo Zeng
ion 6: Dat	a and artificial intelligence era
S6.1	Invited paper - Preparing for the AI era under the digital health framework
	Shan Xu; Chunxia Hu; Dong Min
S6.2	Operationalizing data justice in health informatics
	Mamello Thinyane
ion 7: Saf	ety and security in healthcare
S7.1	Thought-based authenticated key exchange
	Phillip H. Griffin
S7.2	Cyber-safety in healthcare IoT
	Duncan Sparrell
sion 8: Dat	a protection and privacy in healthcare
S 8.1	Technical and legal challenges for healthcare blockchains and smart contracts
	Steven A. Wright
S8 2	Design of a credible blockchain-based e-health records (CB-EHRs) platform
50.2	Linovy Xu: Antoine Bagula: Omowunmi Isafiade: Kun Ma: Taniwa Chiwewe
a c a	Emgya Xa, Muone Bagaia, Onowanna Isajiaae, Kan Ma, Tapiwa Chiwewe
S8.3	The GDPR transfer regime and modern technologies
	Melania Tudorica; Trix Mulder
tracts	
x of Autho	DrS

COMMITTEES

Steering Committee

- General Chairman: Chaouki Abdallah (Georgia Institute of Technology, USA)
- Michael Best (Georgia Institute of Technology, USA)
- Christoph Dosch (ITU-R Study Group 6 Vice-Chairman; IRT GmbH, Germany)
- Kai Jakobs (RWTH Aachen University, Germany)
- Mitsuji Matsumoto (Waseda University Emeritus Professor, Japan)
- Sameer Pujari (World Health Organization (WHO))
- Rupa Sarkar (The Lancet Digital Health, UK)
- Mostafa Hashem Sherif (Consultant, USA)
- Daidi Zhong (Chongqing University, China)

Host Committee

- Co-Chairs: Michael Best (Georgia Institute of Technology, USA) Elizabeth Mynatt (Georgia Institute of Technology, USA)
- Jennifer Hirsch (Georgia Institute of Technology, USA)
- Pinar Keskinocak (Georgia Institute of Technology, USA)
- Leigh McCook (Georgia Institute of Technology, USA)
- Sebnem Ozkan (Georgia Institute of Technology, USA)
- Alasdair Young (Georgia Institute of Technology, USA)

Secretariat

- Alessia Magliarditi, ITU Kaleidoscope Coordinator
- Erica Campilongo, Collaborator
- Nolwandle Simiso Dlodlo, Collaborator
- Marine Kern, Collaborator
- Emer Windsor, Executive Assistant
- Pascal Borde, Promotional support

Technical Programme Committee

- Mostafa Hashem Sherif (Consultant, USA)
- Marco G. Ajmone Marsan (Polytechnic University of Turin and Institute IMDEA Networks, Italy)
- Ahmad Alaiad (Jordan University of Science and Technology, Jordan)
- Rafael Asorey-Cacheda (Technical University of Cartagena, Spain)
- Chaodit Aswakul (Chulanlongkorn University, Thailand)
- Luigi Atzori (University of Cagliari, Italy)
- Antoine Bagula (University of the Western Cape, South Africa)
- Paolo Bellavista (University of Bologna, Italy)
- Michael Bove (Massachusetts Institute of Technology, USA)
- Marcelo Carvalho (University of Brasilia, Brazil)
- Shelly Chadha (WHO, Switzerland)
- Periklis Chatzimisios (Alexander TEI of Thessaloniki and Bournemouth University, Greece)
- Kejia Chen (Nanjing University of Posts and Telecommunications, China)
- Luca Chiaraviglio (University of Rome Tor Vergata, Italy)
- Mahmoud Daneshmand (Stevens Institute of Technology, USA)
- Alessio Diamanti (Orange & Cnam, France)
- Christoph Dosch (ITU-R Study Group 6 Chairman; IRT GmbH, Germany)
- Tineke Mirjam Egyedi (Delft University of Technology, The Netherlands)
- Marcos Fagundes Caetano (University of Brasilia, Brazil)
- Erwin Folmer (University of Twente, The Netherlands)
- Luca Foschini (University of Bologna, Italy)
- Ivan Ganchev (University of Limerick, Ireland / University of Plovdiv "Paisii Hilendarski", Bulgaria)
- Joan Garcia-Haro (Universidad Politécnica de Cartagena, Spain)
- Antonio Javier Garcia-Sanchez (Technical University of Cartagena, Spain)
- Katja Gilly (Miguel Hernandez University, Spain)
- William J. Gordon (Brigham and Women's Hospital, USA)
- Smrati Gupta (Microsoft Corporation, USA)
- Dijiang Huang (Arizona State University, USA)
- Eva Ibarrola (University of the Basque Country, Spain)
- Kai Jakobs (RWTH Aachen University, Germany)
- Ved P. Kafle (National Institute of Information and Communications Technology, Japan)
- Tim Kelly (World Bank, USA)
- Katarzyna Kosek-Szott (AGH University of Science and Technology, Poland)
- Ken Krechmer (IEEE, USA)
- Dhananjay Kumar (Anna University, India)
- Andreas Kunz (Lenovo, Germany)
- Tsung-Ting Kuo (University of California San Diego, USA)
- Mark Leeson (University of Warwick, UK)

- Jie Li (Shanghai Jiaotong University, China)
- Fidel Liberal (University of the Basque Country, Spain)
- Luigi Logrippo (Université du Québec en Outaouais, Canada)
- Rafael Marin-Perez (OdinS, Spain)
- Mitsuji Matsumoto (Waseda University, Japan)
- Arturas Medeisis (ITU Arab Office, Riyadh station)
- Ahmed Mohammed Mikaeil (Shanghai Jiao Tong University, China)
- Alejandro Molina Zarca (University of Murcia, Spain)
- Yoshitoshi Murata (Iwate Prefectural University, Japan)
- Kazuhide Nakajima (NTT Corporation, Japan)
- David Palma (Norwegian University of Technology and Science, Norway)
- Vitaly Petrov (Tampere University of Technology, Finland)
- RangRao Venkatesha Prasad (Delft University of Technology, The Netherlands)
- Alexander Raake (Technische Universität Ilmenau, Germany)
- Julia Rauscher (University of Augsburg, Germany)
- Anna Riccioni (Università degli Studi di Bologna, Italy)
- Domenico Rotondi (FINCONS SpA, Italy)
- Mihoko Sakurai (Keio University, Japan)
- Andreas Sciarrone (University of Genoa, Italy)
- Stefano Secci (Cnam, France)
- Cristina Serban (AT&T Security Research Center, USA)
- Mostafa Hashem Sherif (Consultant, USA)
- Minrui Shi (Shanghai Telecom, China)
- Antonio Skarmeta (University of Murcia, Spain)
- Michele Solimando (University of Bologna, Italy)
- Jian Song (Tsinghua University, China)
- Duncan Sparrell (sFractal Consulting LLC, USA)
- Christian Timmerer (Information Technology (ITEC) Alpen-Adria-Universität Klagenfurt, Austria)
- Marco Torello (University of Bologna, Italy)
- Valerio Torti (European University of Rome, Italy)
- Taavi Valdlo (Estonian IT Standardization Technical Committee, Estonia)
- Riccardo Venanzi (University of Bologna & University of Ferrara, Italy)
- Honggong Wang (University of Massachusetts, Dartmouth & College of Engineering, USA)
- Jinsong Wu (University of Chile, Chile)
- Keping Yu (Waseda University, Japan)
- Richard Yu (Carleton University, Canada)
- Daidi Zhong (Chongqing University, China)

KEYNOTE SUMMARY

PANACEA: AN INTERNET OF BIO-NANOTHINGS APPLICATION FOR EARLY DETECTION AND MITIGATION OF INFECTIOUS DISEASES

Ian F. Akyildiz

Georgia Institute of Technology, USA

The state-of-the-art diagnostics, monitoring, and therapy are limited by the imprecise nature of current methods and use of devices that are either external, or when implanted, suffer from large size. A breakthrough is eminent since we are at a critical crossroad in biomedical research in which our ability to miniaturize sensors and electronics is unprecedented, and our understanding of biological systems enables fine-grained manipulation and control of behavior of cells down to the molecular level. These technologies will be leveraged to create **Internet of Bio-NanoThings (IoBNT)**, which is envisioned to be a heterogeneous network of nanoscale bio-electronic components and engineered biological cells, so called Bio-NanoThings (BNT), communicating via electromagnetic waves, and via molecular communication. The objective of this concept is to directly interact with the cells enabling more accurate sensing and eventually control complicated biological dynamics of the human body in real time.

As the enabler of IoBNT, **Molecular Communication** (**MC**) arises from the observation of chemical communications in and among the basic units of life, i.e. biological cells, where the information is represented, exchanged and stored in the form of molecules. The key processes of chemical reactions and molecular transport are at the basis of encoding, propagation, and processing of information bearing molecular signals. The focus of this discipline is on the modeling, characterization, and engineering of information transmission through molecule exchange, with immediate applications in biotechnology, medicine, ecology, and defense, among others. In the past decade of MC research, the first studies focused on the physical layer characteristics of communication channels where MC techniques are defined based on the transport mechanism such as diffusion-based and flow-based MC, chemotaxis, and molecular motors. However, there is still limited investigation on the definition of technologies for practical applications of MC. Here, we present a novel perspective on the theory of MC by expanding on existing and future studies for its application to healthcare.

To illustrate how MC brings together biological and cyber worlds for healthcare applications, we introduce the concept of a new cyber-physical system called, PANACEA (a solution or remedy for all difficulties or diseases in Latin), which is a closed-loop solution to the problem of monitoring infections. PANACEA leverages cutting-edge technologies in the cyber (i.e. machine learning, big data analytics, cloud computing, security) and physical (i.e. bio-nanosensors, magnetic and wireless communications) domains to continuously monitor the tissues at risk of serious infection for early detection and mitigation of infections. By tapping into cell-to-cell communication mechanisms of bacteria infecting human body, it is possible to estimate the increase in the population of the bacteria indicating an infection even before the patient shows symptoms. Bio-nanosensors sense communication molecules, so-called quorum sensing molecules, exchanged among the infectious bacteria. Quorum sensing is the major cell-to-cell communication mechanism where bacteria produce and release chemical signal molecules whose external concentration increases as a function of increasing cell-population density. Therefore, by sensing the concentration of its quorum sensing molecules, it is possible to estimate the density of the infectious bacteria population. This can be used to detect infection, which is the invasion of various healthy human tissues by pathogenic bacteria that are multiplying and disrupting tissues' operation, causing diseases.

The physical domain of PANACEA will comprise all the bio-nanosensors and actuators (e.g. drug delivery devices, pacemakers, etc.) embodied by the RIMOR (explorer in Latin) subsystem, which consists of 3 parts: bio-nanosensor, sensor interface chip, and a coil/inductor for wireless communication to wearable hub outside of the body. The bio-nanosensor can be diversified by sensing quorum sensing signals directly or via a reporter bacteria. Moreover, the signals generated by bacteria can be sensed by utilizing electro-chemical or fluorescence methods. The bio-nanosensor of RIMOR, has two parts, namely, the bacterial sensor and the physical sensor. The bacterial sensor senses molecular communication signals generated by the bacteria in the body, and produces light detected by the physical sensor which converts light to electrical current. This way, MC signals are transduced to electrical signals to be further relayed to the wearable hub. Interactions between physical and cyber domains are established by heterogeneous wireless communication modules that utilize radio-frequency (RF), ultrasonic and molecular communications through RIMOR and wearable devices.

The cyber part of the PANACEA is in charge of collecting sensing data and performing complex data processing and learning procedures for the early detection of diseases and infections. The access to PANACEA is made possible by the Human-Machine Interface (HMI), which provides an easy and intuitive Data Visualization Interface (DVI) enabling the visualization of relevant information of each patient and provides alert message management to notify both caregivers and patients when an infection occurs. The DVI allows human-in-the-loop control thus making it possible for caregivers to dynamically and actively interact with the system and to regulate drug delivery through ad-hoc control primitives and APIs exposed by actuator devices. PANACEA not only facilitates interactions with humans, but it also enables advanced automated drug delivery systems that rely on supervised machine learning. The learning block is fed with both data collected by the physical system and supervised input data generated by caregivers. Such an approach makes it possible to train PANACEA with patient-dependent data so that individual medical treatments can be achieved for each patient.

Even though applications such as PANACEA are very promising since they are based on the better defined and more studied MC technique of bacterial communication, a plethora of biomedical applications can be enabled by the rest of the MC techniques such as calcium signaling, nervous networks, endocrine network, and molecular motors. The standardization efforts in molecular communication started in 2014 with the IEEE P1906.1.1 - Standard Data Model for Nanoscale Communication Systems and they have released IEEE 1906.1-2015 - IEEE Recommended Practice for Nanoscale and Molecular Communication Framework. Although this standard is a step towards developing MC as an implementable technology, it only covers the basic diffusion-based molecular communication and it also includes THz band communication under the nano-communication umbrella which overlooks underlying challenges arising from the biological nature of MC. Despite the prior work in the field on the channel characterization, estimation, and capacity calculations of these aforementioned techniques, a unifying information-theoretic framework that captures the peculiarities of an MC channel over classical communication systems for all the various MC techniques, is currently missing.

We aim at filling the aforementioned research gap by providing a mathematical framework rooted in chemical kinetics and statistical mechanics to define the main functional blocks of MC, to abstract any MC system and determine or estimate the information capacity of their communication channels. By using the general formulation of the Langevin equation of a moving nanoscale particle subject to unavoidable thermally driven Brownian forces as a unifying modeling tool for molecule propagation, we build a general mathematical abstraction of an MC system. Then, we derive a methodology to determine (or estimate, whenever closed-form analytical solutions are intractable) the MC channel capacity based on the decomposition of the Langevin equation into two contributions, namely, propagation according to the Fokker–Planck equation followed by a Poisson process.

We classify diverse implementations of MC based on their underlying physical and chemical processes and their representation in terms of the Langevin equation. MC systems based on random

walk, such as calcium signaling in cell tissues, neuron communication by means of neurotransmitters, and bacterial quorum sensing, include only the contribution of the Brownian stochastic force f. MC systems based on drifted random walk, such as MC in the cardiovascular system, microfluidic systems, and pheromone communication between plants, include both f and a drift velocity $v_{n(t)}$ as function of the time t for each molecule n, which is independent of the Brownian motion. MC systems based on active transport, such as those based on molecular motors and bacteria chemotaxis, include instead a deterministic force $F_{n(t)}$ added to f. For each of these categories of MC systems, and based on the aforementioned Langevin equation decomposition, we provide a general information capacity expression under simplifying assumptions and subsequently discuss these results in light of the functional blocks of more specific MC system models, including cases where a closed-form capacity expression cannot be analytically derived. This statistical-mechanics-based framework provides a common ground that not only allows existing researchers in this field to formalize their direction taken in the last decade in this high-level framework but also provides future researchers with a welldefined methodology to evaluate the performance of the existing and to-be-discovered MC systems. We believe this contribution will be foundational for this discipline on the way to standardization, and an important milestone for the engineering of future MC systems.

MC promises to better understand communications in biological systems, and reciprocally develop biologically-inspired approaches for communication systems. Since it provides a disruptive technology based on interfacing directly with living cells and organisms which enables an unprecedented way of reaching health information in the living body, which we believe will be at the core of next-generation ICT technologies for human health.

This talk is based on the following three papers:

^{1.} Akyildiz, I. F., Guler, U., Ozkaya-Ahmedov, T., Sarioglu, A. F., Unluturk, B. D., "PANACEA: An Internet of Bio-NanoThings Application for Early Detection and Mitigation of Infectious Diseases," submitted to *IEEE Access*, 2019.

Akyildiz, I. F., Pierobon, M., Balasubramaniam, S., "An Information Theoretic Framework to Analyze Molecular Communication Systems Based on Statistical Mechanics," *Proceedings of the IEEE*, vol. 107, no. 7, pp. 1230-1255, 2019.

^{3.} Akyildiz, I. F., Pierobon, M., Balasubramaniam, S., and Koucheryavy, Y., "Internet of BioNanoThings," IEEE Communications Magazine, vol. 53, no. 3, pp. 32-40, March 2015.

Session 1

ICT INFRASTRUCTURE FOR HEALTHCARE

- S1.1 5G-enabled health systems: Solutions, challenges and future research trends
- S1.2 Community healthcare mesh network engineering in white space frequencies
- S1.3 Exploration of the non-intrusive optical intervention therapy based on the indoor smart lighting facility
- S1.4 Access technologies for medical IoT systems

5G-ENABLED HEALTH SYSTEMS: SOLUTIONS, CHALLENGES AND FUTURE RESEARCH TRENDS

Di Zhang¹; Teng Zhang²; Yunkai Zhai^{3,4}; Joel J. P. C. Rodrigues^{5,6}; Dalong Zhang¹; Zheng Wen⁷; Keping Yu⁷; Takuro Sato⁷

¹School of Information Engineering, Zhengzhou University

²Interventional Operating Theater, the First Affiliated Hosital of Zhengzhou University

³School of Management Engineering, Zhengzhou University

⁴National Engineering Laboratory for Internet Medical Systems and Applications, China

⁵Federal University of Piauí (UFPI), Brazil

⁶Instituto de Telecomunicações, Portugal

⁷Waseda University, Japan

ABSTRACT

In the literature, Information communication technology (ICT)-assisted health systems have been intensively discussed. However, it has seldom become a reality. This is mainly due to the current wireless technologies' limited transmission rate, few connected devices and high latency. On the contrary, the fifth generation (5G) wireless communications can connect more devices, provide faster transmission rates and a lower latency. In this article, we first introduce the 5G-enabled health systems and our specific implementation in the first affiliated hospital of Zhengzhou University (FAHZZU). Afterwards, the potential challenges and future research trends on demonstrating the 5G-enabled health systems are discussed.

Keywords - 5G, health systems, smart hospital, telemedicine

1. INTRODUCTION

High-quality hospitals mostly locate in big cities, whereas the villages and remote areas lack such medical institutions. The rapid siphon effect of big cities makes the remote area's health conditions even worse. With technology advancing, the digital division between big cities and remote areas is getting bigger. The young and middle-aged people can move to big cities, but it is hard for the elderly, ill and disabled people to do this.

On the other hand, for the digital-technology development such as fifth generation (5G) Internet of things (IoT) [1] [2], most of our attention is confined to the big cities, and our effect is to deliver a faster transmission speed, better cellular coverage and larger number of connected devices for these dense area. Less attention has been paid to the remote areas. This is mainly due to its less potential revenue compared to the potential revenue for more dense areas. It is the society's responsibility to provide people in remote areas with better health services. However, it is unfair and unrealistic to force medical doctors to move to remote areas. It is also inhumane to force the people in remote areas to move to big cities. In this case, leveraging some technical methods will be a good choice, for instance, Information communication technologies (ICT)-assisted health systems.

In literature, ICT-assisted health systems is not a new topic. For example, the cloud computing paradigm for e-health and the leak risks of patient's sensitive health information were discussed in [3]. The conclusion from this study is that the precautions must be taken into consideration before storing the sensitive data in the cloud. In the study of [4], authors reviewed the diffusion of telemedicine and analyzed the factors influencing the diffusion. It was found that going back to 2007, residents and doctors in China living in remote areas mostly had less knowledge about information technology (IT), and they were unwilling to use telemedicine [4]. It was thus hard for the implementation of telemedicine at that time period. Authors suggested that a comprehensive force from both central government and local government, and various methods not only limited to education and scientific popularization, were needed. On the other hand, authors in [5] demonstrated the real-time off-the-shelf integrated telemedicine devices for emergency medical cases in Germany.

Nowadays since ICT technologies have been widely used, people has more positive attitude to telemedicine. However, wireless connections of existing ICT-assisted health systems are based on the previous wireless technologies (for instance, long term evolution (LTE) and Wi-Fi). Limited connected device number, lower transmission rate and higher latency may be risky issues for the implementation of ICT-assisted health systems. On the other hand, as fifth generation (5G) and beyond has claimed, compared to LTE systems, it can connect more than 1000 times of the number of devices, support more than 1000 times of the devices, support more than 100 times the traffic volumes and provide 1 out of 10 latency performance (less than 1 ms) [1]. All these characteristics match the requirements of ICT-assisted health systems perfectly. In 5G, massive multi-input multi-output (MIMO) [6], non-orthogonal multiple access (NOMA) [7], and full duplex (FD) are emerging technologies for these claimed targets.

The 5G and beyond wireless technologies provide perfect solutions to ICT-assisted health systems, which inspires 5G-enabled health systems. For example, with the help of ultra-reliable low latency communications (URLLC), a 5G-enabled ambulance can provide remote diagnosis and operation. 5G-enabled ambulance can also automatically respond to an emergency call and plan an optimal route in advance to save precious rescue time. Besides, URLLC is also a critical issue for remote surgery. Otherwise, the wound area will be big and might cause some risks to the patient's life. 5G's large volume real-time medical image transmission also makes remote expert consultation a reality. Moreover, in general and specialist hospitals, patients or their escorts need to press the widely used emergency call-buttons to call the medical staff whenever an emergency happens. It is time-consuming and might even waste precious rescue time. The 5G-enabled monitoring systems, on the other hand, can reduce the consumed time and save the patient's life especially in emergency conditions. The 5G-enabled monitoring systems can also provide remote ward-round and real-time vital signs monitoring services.

In this study, we first discuss the solutions and introduce the demonstrations of our 5G-enabled health systems, i.e., 5G-enabled remote diagnosis and treatment, 5G-enabled remote surgery and 5G-enabled smart monitoring. Based on these works, we discuss the challenging issues and potential future research trends on implementing 5G-enabled health systems. The rest of this paper is organized as follows: we introduce the demonstration of 5G-enabled health systems in section 2. The challenging issues on achieving the 5G-enabled health systems are discussed in section 3. Section 4 is the future research trends. We finally conclude this paper in section 5.

2. SOLUTIONS OF 5G-ENABLED HEALTH SYSTEMS

The specific demonstrations and implementations of 5G-enabled health systems in the first affiliated hospital of Zhengzhou University (FAHZZU) will be discussed in this section. We categorize the 5G-enabled health systems into three 5G-enabled remote diagnosis and treatment, 5G-enabled remote surgery, and 5G-enabled smart monitoring.

As mentioned before, currently there are less people living in remote areas as more people move to the big cities. In addition, most of the people living in remote areas are the elderly and the young that urgently need the high-quality medical services. In order to eliminate the difference between big cities and remote areas, 5G-assisted health systems is a more realistic choice. In literature, the ICT-assisted health systems have been discussed a lot. However, due to the current restrictions of latency, transmission speed and number of connected devices, the telemedicine services are inefficient.

The 5G-enabled health systems, on the contrary, can solve these problems. The most promising technologies of 5G being applied to the health systems is the URLLC. Additionally, the massive machine type communications (mMTC) and enhanced mobile broadband (eMBB) characteristics can further improve the experience of ICT-assisted health systems [7, 8]. As is known to all, compared to the fourth generation wireless communications (4G), 5G aims to offer less than 1 ms latency, more than 20 billion connected devices and up to 1 Gb/s experienced transmission speed. All these features make remote diagnosis and treatment a reality.

2.1 5G-enabled remote diagnosis and treatment



Figure 1 – 5G-enabled health systems for remote areas.

5G-enabled remote diagnosis and treatment is first discussed. As demonstrated in Figure 1, with 5G network's help, we can offer better service for remote diagnosis and treatment to residents in remote areas. We can also offer remote operations with 5G URLLC?s less than 1 ms latency. On the other hand, the district hospital and the general hospitals can mutually share the digital medical information. The automatic ambulance vehicles can respond to emergency calls and provide in-vehicle remote diagnosis and treatment services with wireless connections to the hospitals.

Figure 2 demonstrates remote diagnosis in FAHZZU. The remote community clinic is connected with FAHZZU via 5G wireless networks. In this case, the remote community clinic can share the high-quality medical resources from FAHZZU. According to our test, by leveraging the 5G's fast transmission speed, the high-definition 1080P consultation video was successfully transmitted. In our test, the downlink peak speed is about 1 Gb/s, 15 times that of the 4G wireless



Figure 2 – Remote diagnosis demonstration of 5G-enabled remote diagnosis in FAHZZU.

transmissions; and the uplink peak speed is about 100 Mb/s, 10 times that of the 4G wireless transmissions. The latency at the remote user side is about 7.6 ms according to our test, which is reduced by 73% compared to the 4G wireless connections. With the help of 5G-enabled diagnosis and treatment, patients can be remotely diagnosed by the FAHZZU?s specialists while sitting in the remote community clinic without actually traveling there.

5G-enabled ambulances is another application scenario of 5G-enabled remote diagnosis and treatment. It connects the first-aider, ambulance, command center, remote clinic and the specialist and general hospital via 5G wireless networks. In this case, the 5G-enabled ambulance can act as the mobile hospital and share the information with remote specialized doctors. It can check the patient?s vital signs and share these results in nearly real time. Moreover, it can provide remote diagnosis and treatment services with the help of equipped high-definition cameras. Compared to existing methods, the 5G-enabled ambulance has better latency performance and even faster uplink transmission speed, which are vital for the high-definition streaming media information transmission. As shown in Figure 3, medical staff can remotely look up the electronic medical record, monitor and upload the patient?s vital signs, communicate with the specialized medical doctor to save the precious rescue time. The 5G-enabled ambulance can also be used in an emergency rescue scenario while connecting to the remote control center.



Figure 3 – Demonstration of the 5G-enabled ambulance in FAHZZU.

2.2 5G-enabled remote surgery



Figure 4 – 5G-enabled remote surgery system.

Moreover, 5G's faster transmission speed (especially in the uplink) and URLLC merits make the remote surgery robot a reality. This is because that in previous generations of ICT-assisted remote surgery systems, the network reliability is a big challenge. A moment's disconnection or even a bad connection quality will result in surgery failure, which might take away the patient's life. In prior ICT-assisted remote surgery, the operating doctor relied on the two-dimensional streaming media information, they were unable to clearly see the wound or distance. This is an arduous task, any mistake or miscalculation will result in serious consequences. The argument is that reality/virtual reality (AR/VR) technology can remedy this disadvantage with its three dimensional scene reconstruction ability to assist the surgery [9]. The VR application also relies greatly on 5G's higher transmission speed URLLC merits. In this case, compared to prior wireless solutions such as LTE, 5G is an ideal choice for ICT-assisted health systems.

As depicted in Figure 4, in our considered 5G-enabled remote surgery system, 5G networks and AR/VR technologies are used. The control center and the remote surgery robot workbench are connected via 5G wireless networks. We divide the remote surgery robot system into two scenarios, i.e., the ambulance scenario

and the remote clinic (hospital) scenario. The control center is in FAHZZU, whereas the remote surgery robot workbench can be installed at either the ambulance side (Figure 3) or the remote clinic (hospital, control center, etc.) side. In order to offer reliable connections between the control center and the surgery robot workbench, we employ both the 5G wireless and extranet connections. The 5G wireless connections are used for the ambulance scenario because of the frequently moving demands. On the other hand, the extranet connections are used for the remote clinic (hospital) scenario. Different from the 5G wireless networks, the extranet network can offer more reliable connections.

Asides from the remote diagnosis and treatment, specialized doctors can remotely operate the surgery if needed. Severely injured patients do not need to travel to the big hospitals in case of long distance traveling may cause serious damage. Additionally, it can save precious rescue and operation time. The remote clinic scenario, on the other hand, can provide remote surgery operations with less risk compared to the ambulance scenario as it does not need any travel. However, due to the operational risk, we so far have not demonstrated or tested the 5G-enabled remote surgery yet.

2.3 5G-enabled smart monitoring



Figure 5 – Demonstration of the 5G-enabled smart monitoring in FAHZZU.

The 5G-enabled smart ward and 5G-enabled in-home monitoring are two typical application scenarios of our 5G-enabled smart monitoring implementations. Similar to the 5G-enabled remote diagnosis and treatment, 5G-enabled smart ward and 5G-enabled in-home monitoring greatly rely on URLLC and eMBB characteristics. The in-home monitoring also requires massive Internet of things (IoT) devices connected to the Internet in order to continuously monitor the vital signs.

As depicted in Figure 5, in the 5G-enabled smart ward, we connect ward equipment such as the body vital sign monitoring sensors, intravenous injector, to a 5G wireless network. The patient's vital signs and venous transfusion can be remotely monitored and controlled. Whenever the transfusion is about to finish, the transfusion monitoring system can inform the nurse station via 5G networks to withdraw the needles. In contrast, patients and their escorts need to watch closely the transfusion speed, and call the nurse by pressing the emergency button if needed.

Secondly, doctors and nurses in ward rounds can share the patient's information with each other, and also share with the doctor's office. Real-time information can also be transferred to the security office in case of encountering a medical dispute. Security offices can immediately respond to these disputes and record the videos as evidence if needed.

3. CHALLENGING ISSUES

We have introduced the potential solutions and our implementations of the 5G-enabled health systems in the previous section. In the sequel, we will discuss challenging issues that are faced on implementing 5G-enabled health systems. Currently, eMBB and mMTC can be easily accomplished by emerging 5G NR technologies. However, it is still difficult to realize the URLLC requirements, especially the less than 1 ms latency. In this regard, we might need some trade-off strategies between the latency and reliability. Moral ethics is another challenging issue for implementing 5G-enabled health systems.

3.1 Trade-off between ultra-reliable and low latency

According to Shannon theory, the system achievable capacity can be given as

$$C = \log(1 + \text{SINR}) = \log(1 + \frac{P_t}{P_i + \sigma^2}), \qquad (1)$$

where SINR is the signal to interference plus noise ratio (SINR). As claimed by its definition, it is the allocated power for transmission (P_t) divided by the channel interference power (P_i) and channel noise power σ^2 . With achievable capacity in hand, system achievable transmission speed R will be R = BC, where B denotes the allocated carrier bandwidth. From these two equations, it is quite straightforward that more transmission power and wider bandwidth will yield high achievable transmission speed. Moreover, we can employ some new radio technologies and architectures to achieve faster transmission speeds and connect more devices.

However, story will be different when talking about URLLC. In prior wireless evolution, most of our attention has been on the transmission speed and network capacity enhancement, less attention has been paid to the latency and reliability (successive packet rate delivery (SPRD) [10]). This is because that the 10 ms magnitude latency and $1 - 10^{-2}$ reliability are not challenging technical issues (e.g., the channel coding and re-transmission can achieve $1 - 10^{-2}$ SPRD). However, when it comes to less than 1 ms latency and 1 - $[10^{-9}, 10^{-5}]$ reliability, things become difficult. Albeit the less than 10 ms and $1 - 10^{-2}$ are almost enough for the majority of wireless communications, but not in remote surgery. In addition, less latency and higher reliability always the mean the better performance and less operational risk.

In reality, it is a dilemma to achieve the ultra-reliable connections and low latency communications. For example, hybrid automatic repeat request (HARQ) re-transmissions is a good choice for higher reliability, but it will cause higher latency performance [10]. Most of the existing works on low latency divide the information into short packets, which will generate network jams because of the large volume of short packets. In addition, the short packet strategy is incapable of VR/AR streaming media information transmission. This is because AR/VR streaming media information transmission requires intensive computing and a large packet transmission strategy. Recently transmission without guarantee emerges as a hot topic in terms of low latency [11]. However, since there is no transmission guarantee, transmission reliability will be reduced. In this case, for the URLLC requirements, some trade-off strategies might be more reasonable choices [12].

Besides, URLLC solely for the wireless access part might be easy, yet it will be difficult from the whole network perspective. Redesigning the network architecture is required in this regard. For the upper layer technologies, mobile edge computing can offload the network load to edge server, reduce the distance from the subscriber to the vendor and provide edge computing ability for signal processing at the edge side. It thus can greatly enhance latency performance [12]. Network slicing is emerging as a promising technology for the new network architecture design and URLLC requirements. It can create some delegate network slicing services for specific applications. In network slicing studies, substantial works are still needed, for instance, the routing algorithm, labeling method, file division and cache strategy, orchestration of various network slicing pieces.

3.2 Ethics of 5G-enabled health systems

The ethics of 5G-enabled health systems is another challenging issue on its implementation. As we know, a remote surgery robot has contributed to the greater precision in surgical procedures. Thanks to 5G, we can reconstruct the three-dimensional view and transmit these high-definition streaming media [13]. Remote body vital sign monitoring sensors can be used for the in-home health monitoring, diagnosis and treatment and rescue ambulance. It can save rescue time, travel costs, and reduce the number of outpatients.

However, ICT-assisted health systems propose some new challenging issues to the legal and ethical fields. In literature, the relationship between robots and humans has been long argued even after Isaac Asimov's "Three Laws of Robotics". One of the widely discussed problems is the conflict of interactions between human verdict and robot command. For example, when faced with a potential traffic accident, should the automatically drive ambulance hit the pedestrian or avoid it even through it might cause some serious injury to its passengers? ICT-assisted health systems also raise some pitfalls to the ethics, e.g., patient-doctor relationship erosion, threat to patient information privacy. If this and similar ethic dilemmas cannot be perfectly solved, we may not be able to largely and widely implement the ICT-assisted health systems. The rapidly and even accelerating technical advances on AI and bio-robot raise new moral dilemmas, e.g., when the robot is intelligent enough, shall we treat it (or him/she) as a human or just a robot?

4. FUTURE RESEARCH TRENDS OF THE 5G-ENABLED HEALTH SYSTEMS

We focus on the future research trends of 5G-enabled health systems in this section. Due to the author's background, we mainly talk about the 5G NR technologies and network architecture redesigning topics here.

4.1 5G new radio technology

As discussed before, eMBB, mMTC and URLLC are inevitable elements of the 5G-enabled health systems to transmit high-definition streaming media data, to connect more devices to monitor the vital signs, and to reduce the response time. In literature, massive multi-input multi-output (MIMO), non-orthogonal multiple access (NOMA) and full duplex (FD) are some emerging technologies to accomplish the eMBB, mMTC and URLLC requirements. For instance, in the work of [6], it is proved that with antenna numbers increasing, uncorrelated noise and fast fading effects have vanished. Increasing the antenna numbers also leads to less required transmitted power per bit, which yields better capacity and faster transmission rates per user. However, the merits of massive MIMO are greatly hampered by the pilot contamination. Novel precoding and beam-forming algorithms are good topics for future research on massive MIMO.

Asides from massive MIMO, NOMA is another emerging 5G technology. It utilizes the superposition



Figure 6 – System capacity comparison between HD-OMA, HD-NOMA, FD-OMA, and FD-NOMA.

and successive interference cancellation (SIC) for simultaneously encoding and decoding multiple user's information[7]. In NOMA studies, we generally assumed that SIC can perfectly eliminate the interference from other users within the same resource block that are with inferior channel conditions. This is an ideal assumption, which is almost impossible. Moreover, SIC is a time-consuming and of great complexity method, which might even be beyond the processing ability of current electronic devices. In future studies, some novel encoding methods besides SIC might be needed.

Compared to massive MIMO and NOMA, FD enables synchronous transmission and reception. FD offers even lower latency and better capacity performance [7]. The weakness of FD lies in the self-interference [14] generated by its own transmitter. In order to deal with this problem, we may employ interference cancellation devices at the receiver side. This is not a simple job because digital-domain cancellation can be successfully implemented only when up to its effective dynamic range of the analog-to-digital (ADC) (suppose the FD terminal uses a *B*-bit ADC, the range is about 6.02(ENOB - 2) dB [15]. Additionally, this cancellation implementation generally has multiple Due to the consumed processing time of stages. these multiple stages, latency is increased. In future, self-interference cancellation algorithms and some fast processing devices can be some good topics for the FD studies. Besides, combining these 5G NR technologies can further improve performance, which is another interesting topic for future studies.

We compare the capacity performance between half duplex-NOMA (HD-NOMA), FD-NOMA, HD-orthogonal multiple access (HD-OMA) and FD-OMA by considering the Relay channel model. According to previous work, the achievable system ergodic capacity of FD-NOMA can be given as [7].

$$C \approx \pi \log_2 e \sum_{i=1}^{M} \sum_{j=1}^{N} \sum_{k=1}^{n+1} \sum_{s=1}^{t+1} e^{\left(\frac{1}{\bar{\gamma}_{i,j}}\right)} \times a_k \sqrt{b_k} a_s e^{\left(-b_k b_s \frac{1}{\bar{\gamma}_{i,j}}\right)},$$
(2)

where M, N denote the transmitter number and receiver number, respectively. We denote $\alpha_{i,k}$ as the FD self-interference from transmitter i to receiver j. Moreover, $\bar{\gamma}_{i,j}$ can be given by $\bar{\gamma}_{i,j} = \frac{\rho\alpha_{i,j}}{\rho(\sum_{l=i+1}^{N}\alpha_{i,l}+\eta\alpha_{i,k})+1}$, with $\alpha_{i,j}, \rho, \eta, \alpha_{i,k}$ the NOMA power coefficient, signal to noise ratio (SNR), FD coefficient and its corresponding FD self-interference. With regard to a_k, b_k, a_s, b_s , we have $a_k = \frac{\theta_k - \theta_{k-1}}{\pi}, b_k = \frac{\cot \theta_{k-1} - \cot \theta_k}{\pi}, a_s = \frac{\theta_s - \theta_{s-1}}{\pi}, b_s = \frac{\cot \theta_{s-1} - \cot \theta_s}{\pi}$, and $0 \leq \theta_1 < ... \theta_s < ... \frac{\pi}{2}$. On the contrary, the half-duplex (HD) based NOMA capacity expression can be obtained while removing the FD self-interference part. In literature, capacity expressions for HD-OMA and FD-OMA have been investigated a lot, we omitted the derivations here.

In this comparison, we paired 3 users of the NOMA scheme with normalized channel noise. The allocated NOMA powers are [4, 2, 1]. We average the allocated power for the OMA scheme, i.e., the power allocation for OMA user is $\frac{4+2+1}{2} = 3.5$. The comparison results are given as in Fig. 6. We can find that combining the FD and NOMA always has better capacity performance compared to the half duplex (HD) and OMA schemes. However, due to self-interference, the merit of FD-NOMA is reduced.

4.2 Redesigning the networking architecture technologies

The current driving force of wireless evolution is from the data-centric with the aim to connect more devices and provide even faster transmission speeds for the devices. As we know, massive connected devices and their faster transmission speeds bring in traffic overload, especially to wireless networks such as base stations (BS). Nevertheless, users do not care about how and where the data comes from but only the quality of service (QoS) and quality of experience (QoE) of its service. In order to solve this problem while catering to the driving force's shift from data-centric to information-centric, the information-centric networking (ICN) and edge computing technologies receive increasing attention [16, 17, 18, 19].

In Fig. 7, we compare the network throughput between the edge computing-assisted ICN and conventional network TCP technologies while increasing the subscriber numbers with per subscriber's transmission rate 10 MBit/s. As depicted by this figure, with subscriber numbers growing, curves of edge computing-assisted ICN remain constant while the TCP-based network throughput is growing exponentially until reaching the system's limitation. This is because in an edge computing-assisted ICN scenario, we may always obtain the required content from the nearest caches without routing back to the remote server through the BS.

Edge computing-assisted ICN indeed has some drawbacks, one of which is sub-network congestion. It happens especially when a bunch of sub-network subscribers simultaneously request the same content. For future studies, effective routing and cache distribution strategies can be good topics. On the other hand, optimal content division and labeling strategies can be for future studies.



Figure 7 – System throughput comparison between ICN-assisted edge computing and conventional scheme.

4.3 VR/AR, medical image processing and the AI-based technologies

Currently, image label and detection are needed for the implementation of remote surgery and rescue. For example, in machine learning based image detection, we need to label the targets beforehand. We can unmistakenly detect the target after training with existing objectives. However, it is still hard for the AI to detect the unexperienced targets. The omitted target poses risks to the automatic ambulance and remote surgery. Similarly, for the medical image applications, we also need to label these disease symptoms, once some labels are omitted or mistakenly studied by the algorithm, it will result in misdiagnosis.

Apart from the labeling and detection method, ML algorithm's processing speed is slowed down by the large scale and even growing AR/VR-based three-dimensional data volume. This is mainly due to the limited ability of existing processing devices. In order to accelerate the processing speed, large scale deep learning (DL) high-rank matrix factorization (MF) algorithms and dedicated processors are needed in the future. Due to the large scale and even growing data, we also need

some strategies to balance the volume of engaged label parameters and the processing accuracy. To this end, a joint force from the off-the-shelf cooperative edge computing chips, dedicated image processing chips and state-of-the-art algorithms, are comprehensively needed.

5. CONCLUSION

In this work, the 5G-enabled health systems are introduced. By leveraging the 5G NR and AI-based technologies, we can greatly improve the medical service quality for the remote areas, and upgrade in-hospital medical services. The solutions and demonstrations of the 5G-enabled health systems are introduced. For future studies, some new 5G NR technologies, network architecture redesigned from being data-centric to information and user-centric, the image processing algorithms and specialized devices are needed for better implementation of the 5G-enabled health systems.

ACKNOWLEDGMENT

This work is supported by the Zhengzhou University Research Startup Foundation under grant:124-32210907 124-32211247; Natural and the Science and Technology Major Projects of China under Grants: 2017ZX03001001-004; the JSPS KAKENHI of Japan under Grant JP18K18044, the National Funding from the FCT-Fundação para a Ciência e a Tecnologia through the UID/EEA/500008/2019 Project; and by the Brazilian National Council for Research and Development (CNPq) via Grant No. 309335/2017-5.

REFERENCES

- D. Zhang, Z. Zhou, S. Mumtaz, J. Rodriguez, and T. Sato, "One integrated energy efficiency proposal for 5G IoT communications," *IEEE Internet of Things Journal*, vol. 3, no. 6, pp. 1346–1354, Dec. 2016.
- [2] Y. Fan, L. Yang, D. Zhang, G. Han, and D. Zhang, "An angle rotate-qam aided differential spatial modulation for 5G ubiquitous mobile networks (accept)," *Mobile Networks and Applications*, 2019.
- [3] J. J. P. C. Rodrigues, I. de la Torre, G. FernÄandez, and M. LÄşpez-Coronado, "Analysis of the security and privacy requirements of cloud-based electronic health records systems," *Journal of Medical Internet Research*, vol. 15, no. 8, p. e186, Aug. 2013.
- [4] Y. Xue and H. Liang, "Analysis of telemedicine diffusion: The case of china," *IEEE Transactions* on Information Technology in Biomedicine, vol. 11, no. 2, pp. 231–233, Mar. 2007.
- [5] S. Thelen, M. Czaplik, P. Meisen, D. Schilberg, and S. Jeschke, "Using off-the-shelf medical devices for biomedical signal monitoring in a telemedicine

system for emergency medical services," *IEEE Journal of Biomedical and Health Informatics*, vol. 19, no. 1, pp. 117–123, Jan. 2015.

- [6] T. L. Marzetta, "Noncooperative cellular wireless with unlimited numbers of base station antennas," *IEEE Transactions on Wireless Communications*, vol. 9, no. 11, pp. 3590–3600, Nov. 2010.
- [7] D. Zhang, Y. Liu, L. Dai, A. K. Bashir, A. Nallanathan, and B. Shim, "Performance analysis of FD-NOMA-based decentralized V2X systems," *IEEE Transactions on Communications*, vol. 67, no. 7, pp. 5024–5036, July 2019.
- [8] D. Zhang, Z. Zhou, S. Mumtaz, J. Rodriguez, and T. Sato, "One integrated energy efficiency proposal for 5G IoT communications," *IEEE Internet of Things Journal*, vol. 3, no. 6, pp. 1346–1354, Dec. 2016.
- [9] M. Mikhail, K. Mithani, and G. M.Ibrahim, "Presurgical and intraoperative augmented reality in neuro-oncologic surgery: Clinical experiences and limitations," vol. 128, pp. 268–276, Aug. 2019.
- [10] M. Bennis, M. Debbah, and H. V. Poor, "Ultrareliable and low-latency wireless communication: Tail, risk, and scale," *Proceedings* of the IEEE, vol. 106, no. 10, pp. 1834–1853, Oct. 2018.
- [11] S. Dogan, А. Tusha, and Η. Arslan, index modulation "Noma with for uplink urllc through grant-free access [online:] https://ieeexplore.ieee.org/document/8703780," IEEE Journal of Selected Topics in Signal Processing, 2019.
- [12] J. Liu and Q. Zhang, "Offloading schemes in mobile edge computing for ultra-reliable low latency communications," *IEEE Access*, vol. 6, pp. 12 825–12 837, Feb. 2018.
- [13] R. Siqueira-Batista, C. R. Souza, P. M. Mata, and S. L. Siqueira, "Robotic surgery: Bioethical aspects," *Brazilian archives of digestive surgery*, vol. 29, no. 4, pp. 287–290, Nov. 2016.
- [14] X. Yue, Y. Liu, S. Kang, A. Nallanathan, and Z. Ding, "Exploiting full/half-duplex user relaying in noma systems," *IEEE Transactions on Communications*, vol. 66, no. 2, pp. 560–575, Feb. 2018.
- [15] A. Sabharwal, P. Schniter, D. Guo, D. W. Bliss, S. Rangarajan, and R. Wichman, "In-band full-duplex wireless: Challenges and opportunities," *IEEE Journal on Selected Areas* in Communications, vol. 32, no. 9, pp. 1637–1652, Sep. 2014.

- [16] H. Harai, K. Fujikawa, V. P. Kafle, T. Miyazawa, M. Murata, M. Ohnishi, M. Ohta, and T. Umezawa, "Design guidelines for new generation network architecture," *IEICE transactions on communications*, vol. 93, no. 3, pp. 462–465, Mar. 2010.
- [17] V. P. Kafle, Y. Fukushima, and H. Harai, "Internet of things standardization in ITU and prospective networking technologies," *IEEE Communications Magazine*, vol. 54, no. 9, pp. 43–49, Sep. 2016.
- [18] A. Laghrissi, T. Taleb, and M. Bagaa, "Conformal mapping for optimal network slice planning based on canonical domains," *IEEE Journal on Selected Areas in Communications*, vol. 36, no. 3, pp. 519–528, Mar. 2018.
- [19] Z. Wen, D. Zhang, K. Yu, and T. Sato, "Information centric networking for disaster information sharing services," *IEICE Transactions* on Fundamentals of Electronics, Communications and Computer Sciences, vol. 98, no. 8, pp. 1610–1617, Aug. 2015.

COMMUNITY HEALTHCARE MESH NETWORK ENGINEERING IN WHITE SPACE FREQUENCIES

Hope Mauwa¹; Antoine Bagula²; Emmanuel Tuyishimire²; Tembisa Ngqondi¹

¹University of Mpumalanga, Mbombela, South Africa ²University of the Western Cape, Cape Town, South Africa

ABSTRACT

The transition from analog to digital television has availed new spectrum called white space, which can be used to boost the capacity of wireless networks on an opportunistic basis. One sector in which there is a need to use white space frequencies is the healthcare sector because of existent protocols which are using it and the white space frequency is not as crowded as Wi-Fi. However, design simulations of wireless communication networks in white space frequencies have revealed dense network topology because of better signal propagation and penetration properties of white space frequencies. *Consequently*, communication networks designed in white space frequencies will require topology reduction for better communication and routing. Therefore, this paper proposes a link-based topology reduction algorithm to reduce a dense mesh network topology designed in white space frequencies into a sparse mesh network topology. The paper also proposes a network optimization function to introduce a hierarchical backbone-based network topology from the sparse network topology for better scalability. Performance evaluation on the proposed designs show that the designs can guide network engineers to select the most relevant performance metrics during a network feasibility study in white space frequencies, aimed at guiding the implementation process.

Keywords - Hierarchical backbone network, mesh network, network topology reduction, sparse network, white space

1. INTRODUCTION

The multi-hop wireless mesh networks in Wi-Fi frequencies induce prohibitive costs for network carriers to deploy ubiquitous Wi-Fi, as revealed by many in-field trials [1]. White space frequencies provide a better and affordable option for deployment of multi-hop wireless mesh networks, which have a far greater transmission range and better penetration properties than the Wi-Fi frequencies. It is predicted that white space frequencies will address geographic disparities that exist between cities and remote and under-served areas in terms of broadband internet access. Once that is addressed, the realization of telehealth, which has the potential to improve healthcare in these areas [2, 3, 4], is easy.

However, designing communication networks such as mesh networks in white space frequencies that accesses the

spectrum on an opportunistic basis comes with its own challenges that may have never been met before by network planners and designers. The temporal and spatial variations of the white space is one of the challenges that makes the planning and designing of communication networks in white space frequencies a difficult task. Due to the temporal and spatial variations of the white space, it is difficult to find a common control channel that nodes can use to exchange necessary control information. Zhao et al., [5] found that it is easier to find a common control channel for neighboring nodes than finding a network-wide availability of a common vacant channel. Cognitive radio technology is expected to eliminate this challenge as it has the ability to sense the spectrum widely and reconfigure itself to transmit in some targeted spectrum [6]. Another challenge that makes the planning and designing of communication networks in white space frequencies difficult is the dense network topology revealed by design simulations of wireless communication networks in white space frequencies because of better signal propagation and penetration properties of white space frequencies. The dense network topology entails many nodes being in communication range of each other, which may result in too many network packet collisions in the network. This is a complex operation for the MAC protocol and too many paths to choose from for a routing protocol [7, 8]. Therefore, network design in white space frequencies will require network topology control to 1) to improve the energy efficiency and battery lifetime of the network and 2) to reduce packet collisions, protocol overhead, and interference by means of a better control over the network connections and redundancy without affecting important network performance such as connectivity and throughput.

This paper proposes a link-based topology reduction algorithm to reduce a dense mesh network topology network designed in white space frequencies into a sparse mesh network topology. The paper also proposes a network optimization function to introduce hierarchical backbone-based network topology from the sparse network topology for better scalability of the network. The designs have been proposed to guide network engineers when selecting the most relevant performance metrics to favour during a network feasibility study aimed at guiding the actual implementation process. To evaluate engineering efficiency achieved by the proposed designs, a performance evaluation was conducted on a simulated public safety mesh network design connecting police stations in Cape Town, South Africa and the results show the designs can guide network engineers to select the most relevant performance metrics during a network feasibility study aimed at guiding the implementation process.

The rest of the paper is structured as follows: section 2 introduces topology reduction and discusses the approaches used to achieve it; section 3 discusses the proposed network optimization function that is used to introduce hierarchical backbone network topology from sparse network topology; section 4 discusses the proposed link-based topology reduction algorithm for reducing dense mesh network topology to sparse mesh network topology; section 5 discusses the backbone network topology algorithm used to introduce hierarchical backbone network topology algorithm used to introduce hierarchical backbone network topology from sparse network topology; section 6 is a performance evaluation of the proposed designs; and section 7 concludes the paper.

2. TOPOLOGY REDUCTION AND APPROACHES

While algorithms discussed in this section are designed for application in physical networks, the designs proposed in this paper are for predesigning a network topology offline before it is replicated in reality. In general, topology control can be achieved through three main mechanisms: power control technique, power mode mechanism and hierarchical formation technique.

In power control technique the communication range of the wireless nodes is controlled by modifying the transmission power parameter of the nodes in the network. This way the network nodes are able to better manage their neighborhood size, interference level, power consumption and connectivity [9]. In power mode mechanism, the node activity is controlled by switching between active and sleep operation modes to dispense with redundant nodes and still achieve the desired connectivity [10]. The main idea of the algorithms using these first two mechanisms is to produce a connected topology by connecting each node with the smallest necessary set of neighbors and with the minimum transmission power possible [11]. These first two techniques are the main options for flat networks, where all nodes have essentially the same role [7, 13], i.e., in an homogeneous infrastructure.

Controlling the transmission power of the nodes or their activities only reduces the network topology to help save energy but the approach does not prevent the transmission of redundant information when several nodes are close to each other and may not simplify the network topology enough for scalability [11]. The hierarchical formation technique addresses the scalability problem. In hierarchical formation technique, a reduced subset of the nodes in the network is selected and given more responsibilities on behalf of a simplified and reduced functionality for the majority of the nodes [11]. This approach greatly simplifies the network topology and saves additional energy by assigning useful functions, such as information aggregation and filtering and routing and message forwarding to the reduced subset of nodes [11]. A hierarchical topology can be constructed by using either a backbone network or a cluster-based network. The main goal of the backbone-based techniques is to find a connected subset of nodes in a network that guarantee connectivity by allowing every other node in the network to reach at least one node on the backbone in a direct way [11]. A communication backbone can be created by selecting nodes that form a connected dominating set (CDS). From graph theory, a CDS of a graph is a connected subset in which all other nodes that do not belong to that subset have at least one adjacent neighbor inside the subset. Advantages of this CDS-based topology control are collisions control, protocol overhead control and energy consumption reduction, efficient network organization and scalability improvement [10].

3. NETWORK OPTIMIZATION FUNCTION

The network design consists of finding a network configuration expressed by the graph $\mathcal{G} = (\mathcal{N}, \mathcal{L})$, where \mathcal{N} is the set of nodes while \mathcal{L} is the set of links connecting the nodes with the objective of optimizing an objective function representing a penalty to be minimized or a profit/reward to be gained. In this paper, the network engineering profit function $P(\mathcal{G})$ is considered. It combines reliability and quality of service (QoS) features, which are based on three metric measures; node degree, link margin and Euclidean distance.

3.1 Network engineering design

The profit function $P(\mathcal{G})$ is expressed as follows:

$$P(\mathcal{G}) = \sum_{i \in \mathcal{N}} P(i) \tag{1}$$

$$P(i) = \alpha * nd_i + \beta * lm_i + \gamma * sp_i$$
(2)

where, α , β and γ are coefficients of proportionality used to express the preference for a given metric measure. A high value of one of the coefficients reveals a preference for the corresponding metric measure. The profit P(i) expresses the resultant preference of node $i \in N$ to be part of the backbone. The metric measures are explained below.

 Node degree: Nodes with a higher node degree lead to reduced network topology for the backbone network, which is preferred to nodes with a lower node degree. Therefore, preference is given to nodes with a higher node degree than nodes with a lower node degree. The node degree nd(i) of node i in a network graph with N number of nodes is calculated as:

$$nd(i) = \sum_{j=1}^{N} x_{ij} \tag{3}$$

where $x_{ij} = 1$ if there is a link between node *i* and node *j* and $x_{ij} = 0$ otherwise.

2. Link margin: Links with higher link margins are better for communication than links with lower link margins. Furthermore, nodes whose corresponding links have smaller differences in link margins are better for communication than nodes whose corresponding links have bigger differences in link margins. Therefore, to know which nodes are well connected, the link margin of each node is considered as the coefficient of variation corresponding to the link margins of all the links connected to that node. For a node *i*, the coefficient lm(i) of variation is calculated as follows:

$$lm(i) = \frac{Avg_{lm}(i,x)}{Std_{lm}(i,x)} \forall x : (i,x) \in \mathcal{L}$$
(4)

where $Avg_{lm}(i)$ and $Std_{lm}(i)$ is the mean and the standard deviation of the link margins of the links connected to the underlying node respectively. The numerator makes a node better if it is high and the denominator supports the idea that large differences in link margins of the links connected to node *i* make the node less efficient in communication.

3. Average shortest path: It is the average distance from a node *i* to all other nodes using the Dijkstra's shortest path algorithm [12] given by equation 5 and denoted by sp(i).

$$sp(i) = Avg_{sp}(i, x) \ \forall \ x : (i, x) \in \mathcal{L}$$
 (5)

The link lengths are considered to be the Euclidean distances separating the connected nodes. Nodes with lower average shortest paths are the more likely ones to be part of the backbone than nodes with higher average shortest paths.

4. SPARSE NETWORK TOPOLOGY DESIGN

The sparse network topology design consists of finding a network configuration that maximizes/minimizes a network optimization function (a reward to be maximized or a penalty to be minimized) subject to QoS constraints expressed in terms of expected throughput by setting a link margin threshold and reliability by setting a minimum requirement on the path multiplicity to enable alternative path routing when an active path fails. Mathematically formulated, it consists of finding a network configuration C_{opt} derived from the graph $\mathcal{G} = (\mathcal{N}, \mathcal{L})$ such that

$$\hat{\tau}_{opt}(C_{opt}) = \max_{C_n \in \mathcal{G}} \sum_{k \in \mathbb{N}[C_n]} P(k)$$
(6)

subject to

((6).1)
$$\tau_{lm}(x, y) > \tau_{lm} \quad \forall \quad x, y \in C_{opt}$$

((6).2) $k_{sp}(x, y) > \tau_{sp} \quad \forall \quad x, y \in C_{opt}$

where $\mathbb{N}(X)$ is the set of nodes in the configuration *X*. Note that constraints (6).1 and (6).2 express the QoS in terms of link margin and reliability respectively.

4.1 The K-shortest path algorithm

Finding disjoint paths may be difficult when a network contains a trap topology between a source and a destination node as revealed by Figure 1. The trap topology presented



Figure 1 – Trap network topology

in the figure has three different paths between node 9 and 0, which can be found by the K-shortest path algorithm [14] by repeating k sequences of shortest path finding followed by pruning the links of the found shortest path to find k disjoint paths between any source destination pair of the network. However, the myopic deployment of the K-shortest path algorithm may fail to find more than one disjoint paths between node 9 and 0 if path 9-8-6-3-1-0 is found first. We propose in this paper a topology-aware K-shortest path finding algorithm using a link weight/metric over-subscription model to mitigate the impact of the presence of a trap topology in a mesh network. The link weight over-subscription will lead to paths 9 - 7 - 6 - 3 - 1 - 0 and 9 - 8 - 6 - 4 - 2 - 0 being selected first before path 9 - 8 - 6 - 3 - 1 - 0. A high-level description of the proposed algorithm is as described by the two-steps *KSP_{coarse}* algorithm described below

KSP_{coarse} Algorithm:

Step 1. Link weight over-subscription. Adjust the link weights

For each link $\ell \in \mathcal{L}$, set $w(\ell) = w(\ell) + d_s(\ell) + d_d(\ell)$ where

- $w(\ell)$ is the weight on link ℓ
- *d_s(l)* is the node density of the source node on link *l*
- $d_d(\ell)$ is the node density of destination node on link ℓ .
- **Step 2. Disjoint paths computation.** For each source-destination pair (S, D)
 - *path finding:* Find a shortest path *p* between *S* and *D*
 - *network pruning:* Prune the links of p from the network topology T^{*}
 - stopping condition: If *T*^{*} is disconnected then Exit else set *K*(*S*, *D*)=*K*(*S*, *D*) + *p*

*KSP*_{loose} **Algorithm:** Note that pruning the network to discard selected links imposes a coarse constraint on the network topology. The *KSP*_{coarse} algorithm can be relaxed by pruning from the network topology \mathcal{T}^* only the links that do not meet a given criteria, such as links with lower margins or links with poor white space quality, such as links where there is no common white space channels between the source and destination of the links.

4.2 Sparse network topology design algorithm

A link-based topology reduction (LTR) algorithm (Algorithm 1) is designed to reduce a dense mesh network topology

into a sparse mesh network topology. The objective of the

Algorithm 1: LTR algorithm

1 1	1 mark all links in dense mesh network as non-visited;					
2 for each non-visited link of the network do						
3	select worst non-visited link of the network; // i.e.,					
	link with lowest link margin.					
4	artificially delete the link;					
5	run the K-shortest path to detect if the network is still					
	k-connected; // it is k-connected if you					
	can find k-disjoint shortest paths for					
	each source-destination pair of the					
	reduced network.					
6	if it is k-connected then					
7	remove the link permanently;					
8	else					
9	leave the link and mark it as visited;					
10 end						

algorithm is to improve i) quality of the links by retaining the links of high margin and pruning those of low margin and ii) maintain the reliability of the network at a predefined level. In order to design fault-tolerant networks, the algorithm uses the K-Shortest Path (K-SP) algorithm in [14] to compute K-shortest paths between source-destination pairs where K >1. Links that provide K-disjoint shortest paths from each node to the network sink are considered and included in the sparse network.

5. HIERARCHICAL BACKBONE NETWORK TOPOLOGY DESIGN

The backbone design consists of finding a network configuration that maximizes the reward function subject to similar QoS constraints as in the sparse network design but with the objective of partitioning the network into two sets: a dominating set, which form the backbone and a dominated set forming the edge of the network. Mathematically formulated, the design process consists of finding a network configuration C_{opt} derived from the graph $\mathcal{G} = (\mathcal{N}, \mathcal{L})$ such that \mathcal{N} is divided into a dominating set $\hat{\mathcal{N}}$ and a dominated set $\tilde{\mathcal{N}}$, and the design objective is achieved and its constraints are met.

$$\hat{\tau}_{opt}(C_{opt}) = \max_{C_n \in \mathcal{G}} \sum_{k \in \mathbb{N}[C_n]} P(k)$$
(7)

subject to

$$\begin{array}{l} ((7).1) \quad _{lm}(x,y) > \tau_{lm} \ \forall \ x,y \in C_{opt} \\ ((7).2) \quad k_{sp}(x,y) > \tau_{sp} \ \forall \ x,y \in C_{opt} \\ ((7).3) \quad \forall n \in C_{opt} : n \in \hat{\mathcal{N}} \lor \exists m \in \hat{\mathcal{N}} : (n,m) \in \mathcal{L} \\ ((7).4) \quad \hat{\mathcal{N}} \cup \tilde{\mathcal{N}} = \emptyset \land \hat{\mathcal{N}} \cap \tilde{\mathcal{N}} = \mathcal{N} \end{array}$$

where $\mathbb{N}(X)$ is the set of nodes in the configuration *X*. Note that constraints (7).1 and (7).2 express the QoS in terms of link margin and reliability respectively, while constraints (7).3 and (7).4 represent the topology control model in terms of backbone connectivity based on the K-dominated set model [17, 18, 19].

5.1 Backbone network design algorithm

The algorithm for creating a hierarchical backbone network topology is provided by Algorithm 2. It uses a graph coloring approach, where the nodes of the network are initially assigned a white color and thereafter, they are colored black or gray, depending on whether they have qualified for backbone or edge status. This algorithm returns a network configuration

Algorithm 2: Backbone formation				
1.	Initialisation. Assign a white colour and zero height to all nodes of the network, Select a node <i>n</i> from <i>White</i> whose profit/reward is highest, <i>Backbone</i> $\leftarrow \{n\}$, <i>Grey</i> \leftarrow all neighbours of <i>n</i> , <i>White</i> $\leftarrow N \setminus (\{n\} \cup Grey)$.			
2.	Select a node k from $Grey$ whose profit/reward is highest and height is lower. Include k into the <i>Backbone</i> , Assign a black colour to k and update its height, Remove k and its neighbours from <i>White</i> , Include the neighbours of k in <i>Grey</i> .			

3. Repeat Step 2 whenever *White* $\neq \emptyset$.

where the backbone nodes are colored into black and the edge nodes are colored into gray.

6. PERFORMANCE EVALUATION

We conducted different experiments to evaluate the performance of our designs. The network engineering process in Figure 2 is proposed and was followed to evaluate our designs. Building upon the elevation maps of an area where the network is to be designed, network planning software tool such as Radio Mobile [15] or SPLAT [16] is used to produce feasible links of the targeted mesh network. Using the network report generated from the network planning tool, the proposed topology reduction process is



Figure 2 – Network engineering process

applied to map the targeted dense mesh network into a sparse network. The final step of the network engineering process consists of deriving a hierarchical backbone-based topology as a topology that may be more scalable than the flat sparse network topology.

The public safety mesh network design connecting police stations in the city of Cape Town in South Africa depicted in Figure 3 was used. The network design was simulated in TV white space frequency using the Radio Mobile network planning tool [15]. 42 network nodes were considered in the simulation.

A Python code implementation of the LTR Algorithm 1 was run on the network reports generated by the Radio Mobile network planning tool [15] to map the dense mesh network into sparse network topology. First, the GPS coordinates of the nodes were transformed into 2-dimensional Cartesian coordinates, which were used to compute Euclidean distances separating the nodes before running the LTR algorithm. During the reduction process, links that provided two disjoint shortest paths from each node to the network sink were considered and included in the sparse network topology. The reduced network topology is shown in Figure 4.

6.1 Sparse network topology reliability using the link length

We evaluated the reliability of the computation by looking at the number of disjoint shortest paths computed by considering the sparse network topology with the link length as the routing metric. The algorithm described in section 4.1 was used to compute the disjoint paths for each node of the sparse topology. In the rest of this paper, we refer to the number of disjoint paths from a node to all the other nodes of the sparse network as the disjoint path multiplicity (DPM) for that node. We considered the following performance metrics:

1. The average number of disjoint shortest paths per node. We let each node be a sink and evaluated the standard deviation in the number of shortest to the sink from each node of the network.



Figure 3 – Public safety mesh network of police stations in Cape Town, South Africa



Figure 4 – Sparse network topology

- 2. The variation of number of shortest paths per node. We let each node to be a sink and evaluated the standard deviation in the number of shortest to the sink from each node of the network.
- 3. **The maximum number of shortest paths.** To determine the liability of nodes (to be sinks), we computed this metric, which shows the node to which other nodes can reach using more alternatives paths.

Figure 5 shows that node 0 is the most reliable since it has the highest average number of disjoint shortest paths and in this case, node 29 is less reliable. Figure 6 shows when node 29 is chosen to be the sink, the number of shortest paths from each node to it varies less. However, choosing node 0, the number of shortest paths from each node varies most. Figure 7 confirms that node 1 is the most reliable but reveals that when node 29 is the sink, the number of shortest paths from each node is minimum.



Figure 5 – Average DPM



Figure 6 – DPM Variance



Figure 7 – Maximum DPM

6.2 Hierarchical backbone topology design

A Python code implementation of Algorithm 2 was run on the network reports for the sparse network topologies to introduce hierarchical backbone network topologies. Using the coefficient parameters in Equation (1) set as $\alpha = \beta = \gamma =$ 10, the hierarchical backbone network topology produced is shown in Figure 8.

6.3 Impact of backbone design on network performance

Experiment 1: Using the link length. Table 1 shows the main characterization of the formed backbone network and the sparse network for the Cape Town Public Safety network. The average node degree and the coefficient of the link margin variation for the backbone are greater than that of the sparse network. This is because a node with the highest degree or coefficient of variation is likely to be chosen as a backbone node according to Algorithm 2. On the other hand, the table shows that the average shortest path for the backbone is smaller. This is because the nodes closest to many nodes in



Figure 8 – Hierarchical backbone network topology

the network are also likely to be chosen as backbone nodes according to Algorithm 2.

The table reveal the advantage of using a backbone model by showing links with better quality in terms of link margin and a higher node degree, representing the potential of finding alternative paths for the traffic when a link/node fails. However, this is balanced by the path multiplicity, which is 1 because all the edge nodes are directly connected to the cluster heads thus offering a single path for the edge nodes while a flat network has the potential of building 2 paths for the edge network.

6.4 Impact of the design parameters on the backbone size

In this subsection, we study the effect of parameters on the size of the backbone. In each case, two parameters were fixed as the third parameter was being varied from 0 to 100. Figure 9 shows how the size of the backbone changed by varying the node degree. The figure shows that the size of the backbone varied but generally decreased down to the convergent point (10 nodes) as the node degree increased.

Figure 10 shows how the link margin parameter affects the size of the backbone. Like the trend shown by Figure



Figure 9 – Impact of α on backbone size

Network performance	Reduced network	Backbone
Node degree	3.81	4.03
Coefficient of variation (link margin-(dBm))	2.83	3.86
Shortest distance (km)	12.88	12.31
Path multiplicity	2	1

 Table 1 – Backbone network topology vs sparse network topology

9, the network backbone decreased towards a convergence. However, the decrease is slower and hence the backbone size converges to a higher number of nodes.

Considering the effect of shortest distance between nodes, Figure 11 shows a different trend. The size of backbone increased in general until it converges to a maximum.

The conclusions drawn from the three graphs depicting impact of the design parameters on the backbone size are as follows: the backbone size is affected by change of each of the three parameters. These results also reveal that the node degree has a much higher positive influence on the backbone size, leading to smaller backbones, which can allow networks to scale while keeping the size of the backbone constant and smaller.



Figure 10 – Impact of β on backbone size



Figure 11 – Impact of λ on backbone size

7. CONCLUSION

In this paper, design challenges expected to be met when designing mesh networks using opportunistic access to the white space frequencies were explored and discussed. Dense network topology was highlighted as one of the design challenges that network planners and designers in white space frequencies will face and the paper focused on addressing this challenge. A link-based topology reduction algorithm has been developed to reduce a dense mesh network topology designed in white space frequencies into sparse mesh network topology and a network optimization function based on three metrics has been developed to introduce hierarchical backbone-based network topology from the sparse network topology. Performance evaluation on the designs were carried out and the results show that the designs can guide network engineers to select the most relevant performance metrics during a network feasibility study in white space frequencies, aimed at guiding the implementation process.

REFERENCES

- [1] P. Cui, Y. Dong, H. Liu, D. Rajan, E. Olinick, and J. Camp, "Whitemesh: Leveraging white spaces in wireless mesh networks," In 2016 14th International Symposium on Modeling and Optimization in Mobile, Ad Hoc, and Wireless Networks (WiOpt), pp. 1-7. IEEE, 2016.
- [2] L. Uscher-Pines, K. Bouskill, J. Sousa, M. Shen, and S.H. Fischer. Experiences of Medicaid Programs and Health Centers in Implementing Telehealth. RAND, 2019.
- [3] The App Association, "Tuning into Telehealth: How TV White Spaces Can Help Mississippi Tackle the Diabetes Epidemic," 2017. http://actonline.org/2017/ 07/20/tuning-into-telehealth-how-tv-white-spacescan-help-mississippi-tackle-the-diabetes-epidemic/.
- [4] A. Chavez, R. Littman-Quinn, K. Ndlovu, and C.L. Kovarik, "Using TV white space spectrum to practise telemedicine: A promising technology to enhance broadband internet connectivity within healthcare facilities in rural regions of developing countries," Journal of telemedicine and telecare 22, no. 4 (2016): 260-263.
- [5] J. Zhao, H. Zheng, and G. Yang, "Distributed coordination in dynamic spectrum allocation networks," In First IEEE International Symposium on New

Frontiers in Dynamic Spectrum Access Networks, 2005. DySPAN 2005., pp. 259-268. IEEE, 2005.

- [6] P.H. Pathak, and R. Dutta. Designing for network and service continuity in wireless mesh networks. Springer Science & Business Media, 2012.
- [7] H. Karl, and A. Willig. Protocols and architectures for wireless sensor networks. John Wiley & Sons, 2007.
- [8] F. Zhao, L.J. Guibas, and L. Guibas. Wireless sensor networks: an information processing approach. Morgan Kaufmann, 2004.
- [9] N. Li, J.C. Hou, and L. Sha. "Design and analysis of an MST-based topology control algorithm," IEEE Transactions on Wireless Communications 4, no. 3 (2005): 1195-1206.
- [10] A. Vázquez-Rodas, and L.J. de la Cruz Llopis, "Topology control for wireless mesh networks based on centrality metrics," In Proceedings of the 10th ACM symposium on Performance evaluation of wireless ad hoc, sensor, & ubiquitous networks, pp. 25-32. ACM, 2013.
- [11] P.M.W. Rojas. Topology control in wireless sensor networks. University of South Florida, 2010.
- [12] E.W. Dijkstra, "A note on two problems in connexion with graphs." Numerische mathematik 1, no. 1 (1959): 269-271.
- [13] K. Sohraby, D. Minoli, and T. Znati. Wireless sensor networks: technology, protocols, and applications. John Wiley & Sons, 2007.
- [14] A.B. Bagula, and A.E. Krzesinski, "Traffic engineering label switched paths in IP networks using a pre-planned flow optimization model," In MASCOTS 2001, Proceedings Ninth International Symposium on Modeling, Analysis and Simulation of Computer and Telecommunication Systems, pp. 70-77. IEEE, 2001.
- [15] R. Coudé. Radio Mobile RF propagation simulation software, 1998. http://radiomobile.pe1mew.nl/.
- [16] J. Magliacane. SPLAT! Because the world isn't flat!, 1997. ITUurlhttps://www.qsl.net/kd2bd/splat.html.
- [17] J. Yu, N. Wang, G. Wang, and D. Yu, "Connected dominating sets in wireless ad hoc and sensor networks? A comprehensive survey," Computer Communications 36, no. 2 (2013): 121-134.
- [18] F. Dai, and J. Wu, "On constructing k-connected k-dominating set in wireless ad hoc and sensor networks," Journal of parallel and distributed computing 66, no. 7 (2006): 947-958.
- [19] S. Kutten, and D. Peleg, "Fast distributed construction of smallk-dominating sets and applications," Journal of Algorithms 28, no. 1 (1998): 40-66.
EXPLORATION OF NON-INTRUSIVE OPTICAL INTERVENTION THERAPY BASED ON THE INDOOR SMART LIGHTING FACILITY

Jian Song¹, Xiaofei Wang¹, Hongming Zhang¹ and Changyong Pan¹

¹Tsinghua University, Beijing, P. R. China

ABSTRACT

Light, originally the natural light, is one of the important contributing factors to the creation of life on earth, the evolution of human beings and the development of civilization. With the emergence of electric light sources, more specifically the LED lighting lamps which are now being utilized all over the world, the concept of Internet of light (IoL) using the existing LED illumination network with the combination of ICT technologies was created. It has become popular recently and is now widely believed to have a long-lasting impact. IoL not only improves the lighting efficiency, indoor lighting comfort level and other valueadded services, but also provides the possibilities for regulating human physiological rhythm, especially for the alleviation of degenerative neurological diseases, even for the treatment and service of healthy lighting in a nonintrusive way. This paper first introduces the concept and the system structure of IoL, and then gives the preliminary results and considerations on how this integrated platform can be utilized to carry the life sciences research and potentially the future applications for the wellness of senior people. More work could be conducted and it would be quite necessary to take into consideration standardization from the perspectives of communication, Internet of things applications, and non-intrusive optical intervention therapy.

Keywords – Alzheimer's disease, human physiological rhythm, Internet of light, LED, non-intrusive optical intervention therapy

1. INTRODUCTION

The artificial light source is perhaps one of the most important inventions for human beings. Since it is not always possible to enjoy the natural light day and night, human beings started to explore artificial light sources, and the electric light source is an important outcome from this effort. Thomas Edison first invented the incandescent lamp, marketed on a large scale in 1879, which is taken as the first leap in the development of electric light source. In 1938, the birth of the fluorescent lamp (low pressure gas discharge lamp) made the electric light source achieve its second giant leap. Later, in 1993, the famous blue-light LED technology, invented by Dr. Suiji Nakamura, and successfully promoted to commercialization of the LED lighting source is considered as the third great leap in the history of the development of electric light sources. Current statistics show that 25% of the world's electricity was depleted by lighting before LED was used as a source replacement. With the full use of LED lamps, the electricity usage for lighting could eventually be reduced to 4%, which would clearly change the whole world profoundly. Dr. Suiji Nakamura and other colleagues won the Nobel Prize in physics in 2014 precisely because of this century's contribution. In future, with people spending more and more time indoors (according to EPA statistics: people have an averaged indoor time of 87%), approaching LED-based lighting networks will have a much greater impact on people's daily lives.

The Nobel Prize in Physiology or Medicine 2017 was awarded to Jeffrey C. Hall, Michael Rosbash and Michael W. Young for their discoveries of molecular mechanisms controlling the circadian rhythm [1]. They found that for higher organisms which are normally light-sensitive, the biological clock is a functional system consisting of photoreceptor neurons, endocrine systems and gene timing oscillations. This produces the rhythm of day and night replacement from the gene expression at microscopic level, cellular metabolism, and to the macroscopic level behavior description. This research has made neuroscientists start to pay close attention to the impact of visible light on living organisms.

In 2018, Edward S. Boyden and Li-Huei Tsai showed that optogenetically driving fast-spiking parvalbumin-positive (FS-PV)-interneurons at gamma (40 Hz) can reduce levels of amyloid- β (A β)1–40 and A β 1–42 isoforms [2].They designed a non-invasive 40 Hz light-flickering regime that successfully reduced levels of A β 1–40 and A β 1–42 in the visual cortex of pre-depositing mice and mitigated plaque load in aged, depositing mice to attenuate Alzheimer's-disease-associated pathology [3][4].

On the other hand, LED lamps based on semiconductor lighting are becoming more and more popular in the world due to their low cost, high luminous efficiency and long-life expectancy. Unlike the incandescent lamps or other light sources in the past, one can easily adjust the intensity and color temperature of LED lights to accommodate people's needs. Preliminary research results show that it could potentially provide a new type of non-intrusive treatment by changing the intensity and color temperature for the indoor lighting environment. At present, the problem of an aging society in most countries around the world becomes much more severe than ever before. Depression is a high-risk disease for the senior people, which seriously affects the physical and mental health, and eventually jeopardizes the quality of life [5]. Numerous studies have shown that light stimulation can effectively alleviate depression or other psychological disorders. Some literature has attempted to systematically analyze the research trends for the optical intervention therapy for senile depression under the indoor lighting environment, and to combine the current light environment status of retirement buildings with the visual, psychological and physiological characteristics of the senior people. Following this, key considerations of the healthy light environment of the nursing space against the depression of the seniors [6] [7], are given. As an effective treatment, the optimal dose of phototherapy treatment time, light intensity and duration of illumination need to be intelligently adjusted depending on the type of illness, the severity of the condition, and individual characteristics. Phototherapy has advantages that are easy to control and implement with negligible side effect when compared with traditional drug treatments. More importantly, phototherapy provides a compatible aid with the regular drugs for the treatment of mental illness, which can accelerate improvement and alleviate the symptoms.

It is anticipated that with the continuous development of LED lighting technologies, together with the ever-increasing in-depth research on the relationship between LED lighting and human health, the adjustment of the light intensity and color temperature of LEDs without being perceived by the human eyes will be able to effectively alleviate, treat, and may even cure certain aging diseases and improve life quality for human beings.

Based on the above investigation on lighting and rhythm, this paper proposes the system structure of IoL and seeks its feasibility of using visible light to treat Alzheimer's disease and possibly other diseases considering the latest progress of semiconductor LED illumination. The paper is organized as follows: After a brief survey on the recent developments in the related areas of illumination and especially in human science in section 1, the functional blocks and the major research areas for IoL are briefly illustrated in section 2. The experiment set-up on the mice and the preliminary impact analysis of the visible light on the cranial, rhythm, and memory-related brain regions (hippocampus) of the cranial nervous system and its intrinsic mechanisms are demonstrated in section 3, exploring the intrinsic mechanisms and mitigation impact of visible light on Alzheimer's disease. The significance of the results in this experimental data from mice and primary explanations are shown in section 4. And then the possibility of non-intrusive optical intervention therapy, further experiments and medical clinical practice and proposing IoL standards, such as binary phase shift keying (BPSK), quadrature phase shift keving (QPSK), and even orthogonal frequency division multiplexing (OFDM) which have been quite commonly used in the visible light communications systems, for example, Internet of Radio and Light in [8][9], are discussed in section 5.

2. SYSTEM DESCRIPTION

The strategic roadmap from 2015 to 2025 of the European Lighting Association is shown in Figure 1, indicating that the semiconductor lighting started with the environment protection purpose is currently in the stage of intelligent lighting, which is about to transit to human-oriented lighting, that is, smart lighting [10]. The goal is to achieve smart lighting that supports healthy lighting by 2025 and to provide people with a healthy and comfortable indoor living environment. However, during the current stage of intelligent lighting, the main goal is still to save energy. Considering that the intensity and color temperature of LED light sources can be easily controlled, ICT technology combined with sensors and the intelligent driver in the luminaire can be used to monitor and track environmental changes in real time.



Figure 1 - The strategic roadmap from 2015 to 2025 of the European Lighting Association [10]

Scenario switchovers for lighting control, intensity adjustment, color temperature changes and even the color control can be fully supported to achieve a variety of lighting functionalities. Smart lighting (human-centric lighting) is the advanced stage of lighting control. With the help of the Internet of things, cloud computing technology and data mining, it becomes possible to understand users' lighting preferences, deeply digging into the lighting needs of users, and automatically building up the comfortable and healthy lighting environment by intelligent lighting control. And this will be further enhanced with the support of artificial intelligence technologies such as big data and machine learning, together with the active sensing of the users' environment.

In this paper, we proposed the concept of the Internet of light (IoL), an intelligent lighting network for indoor applications, as a platform in hope that this IoL could provide the infrastructure to address the aforementioned diseases of

senior people. The research focus on IoL can be summarized as the three following issues:

First is theoretical analysis on the multidimensional joint sensing and intrinsic data extraction under the dense, indepth illumination coverage to support the construction of ubiquitous multifunctional light-borne-based sensor networks.

Second is investigation of a heterogeneous network structure and channel characteristics consist of wireless and wired communication (powerline communication, PLC) systems and corresponding resource coordination mechanisms for the reliable, burst mobile access under massive interconnection.

Third is modeling on the application scenarios for smart lighting and intelligent control so that intelligent lighting services can be provided accordingly by data-mining, extracting and analyzing user needs.

Figure 2 depicts the constitution of the smart lighting system with the most important functional blocks while Figure 3 describes the main technical challenges and research objectives for IoL.

In this system, each LED can serve as the sensing node after being integrated with sensors such as the hazard gas, occupancy and moving objects; the sensing data collected by the node will be sent to the operating center any by the wired system (i.e., PLC) or the wireless (using radio frequency, RF, signals) system or the combination of both for robust data delivery. Then the operating center will analyze those received data, make decisions on the operations to be taken, and send the control commands to each node eventually. For example, if the hazard gas is detected by one node or several neighboring nodes, the alarm signal will be sent immediately to the operating center, and then to the corresponding people or the agency while the ventilation system will start working automatically. With this arrangement, IoL can be established by combining the naturally combined illumination and power supply networks to provide information services in a very cost-effective way.



Figure 2 - The illustration of a smart lighting system.

To deal with the challenges presented by the design and optimization on IoL systems, the research should focus on (1) joint sensing and key data extraction to improve both the accuracy and coverage from a sensing perspective; (2) resource coordination and control mechanism of the heterogeneous network (wired and wireless) for reliable access under the burst mobile environment; and (3) intelligent light control for user-centric applications which potentially provide the possibility for non-intrusive optical intervention therapy.



Figure 3 - Schematic diagram of IoL with the focus on main technical challenges and research objectives

Other than the advantages of energy saving, as well as the low operation and maintenance costs of lighting equipment inside the building, defining and producing the specific work environment or atmospheres and supporting LED lamp interconnectivity for the value-added services based on intelligent lighting systems, IoL is expected to be handily adjusted for the circadian rhythm control of the human body and with the function of serving healthy lighting. Here, we name it as non-intrusive optical intervention therapy, which is different from the well-known photo dynamic treatment. It covers quite different applications, not only the visual health needs such as suitable brightness, no glare and no stroboscopic illumination, but also psychological and physical health for working place safety and working efficiency improvement, circadian rhythm regulation and disease rehabilitation. The natural light changes during one day showing that the high color temperature environment under moderate brightness can inhibit melatonin secretion, induce alertness and improve work efficiency while the low color temperature environment stimulates melatonin, promotes relaxation and sleep. It is believed for an environment with high color temperature but insufficient brightness, people feel gloomy and depressed. Through an intelligent lighting control system which mimics the daily changes of the natural light for the indoor environment, LED physiological lighting that meets people's health needs can be used to improve lighting comfort, adjust physiological rhythm, improve psychological mood and improve work efficiency as well, assist and treat diseases, etc.

Our ultimate goal is to create a visible lighting strategy with different frequencies, waveforms and duration to prevent, relieve and treat depression, mania, Alzheimer's disease, preferably either in the hospital or nursing home.

Unlike mice, detecting human electroencephalogram(EEG) signals relies on non-invasive devices, such as the open-source brain-computer interface (OpenSCI) system [11]. Both commercial software and open-source software can be used in the analysis of collected EEG signals for verification in conjunction with life sciences and medical professionals[12]. This software and the hardware provide non-invasive methods to sample the electrical activities of the body and brain of human beings. These methods are not as precise as the method applied to mice in the following sections but conform to medical ethics.

3. DESCRIPTION OF THE EXPERIMENT AND PRELIMINARY ANALYSIS OF THE DATA

The common practice is to use the animal to conduct the research work and confirm the effectiveness first, to avoid problems such as high uncertainty and inconsistency for direct application to human beings, and most importantly the ethical issues. As a concept study, we used 40 Hz scintillation frequency for this preliminary experiment in visible light irradiation on mice, motivated by the work from Tsai and et. al [2]. The advantage of the mouse experiment is that we can use the multichannel in-vivo recording to record and monitor the point activity of the neuron group directly inside the brain to obtain the local field potential (LFP) signal of a certain brain region (hippocampus). Compared with the signals acquired outside the skull, it has higher time and spatial accuracy. In our preliminary experiments, the field status signals of the hippocampus associated with learning and memory were collected. The multichannel in-vivo recording technology, OmniPlex Neural Data Acquisition, and experiments on mice with implanted electrodes for collecting LFP are shown in Figures 4 and 5.



Figure 4 - OmniPlex Neural Data Acquisition system



Figure 5 - Experiment mouse with implanted electrode in hippocampus

Two groups of mice were used in the experiments. Following a standard procedure, the mice were implanted with electrodes in the hippocampus of the brain. After surgery, the mice were allowed to recover for a week. After restoration, the OmniPlex Neural Data Acquisition system of Plexon was used to collect local field potential signals for 15 minutes as reference. Then, the modulated 40Hz flashing LED lamp was turned on to radiate the mice for 15 minutes, and the local field potential signal was collected at the same time. Data was analyzed using NeuroExplorer, which is widely used in the field of neuroscience [13].

As shown in Figure 6, the brain electric local field potential signal of the mouse exhibited a significant enhancement in the 20 Hz portion in the modulated visible light irradiation. The two subgraphs above show the comparison of power spectral density (PSD) analysis results of local field potential signals of mice in the two groups. The left side is the PSD during the radiation and the right is the PSD before the radiation. It can be clearly seen that the hippocampal area of mice in the radiation has obvious discharge and energy response at the frequency of 20Hz. The third subgraph shows the heatmap of the hippocampal region of mice with changes over time. The left side is the heatmap during the radiation and the right is the heatmap before the radiation. It can also easily display that the energy distribution of the hippocampal region of mice at the frequency of 20Hz has been significantly enhanced during the whole radiation period. Here, we have observed the results yet lots of work needs to be done to offer the explanation why.



Figure 6 - Results of local field potential signal analysis in the hippocampal area of mice

4. DISCUSSIONS

From this preliminary experiment, it is proved that the hippocampus of mice, in charge of learning and memory is responsive to visible light modulation. From one side, it suggests that in a realistic lighting environment, appropriate modulation methods could be utilized to help prevent, relieve and treat some human diseases associated with this function. On the other hand, certain measures should be taken to reduce the possible negative impact of lighting on human health if visible light communications with different signal waveforms are used in conjunction with illumination purposes for the indoor environment.

The experiment is to let normal mice and mice with Alzheimer's disease exposed to visible light with the similar lighting environment as that for the human brain to observe the behavior, rhythm and memory changes of those mice under an LED light source operating at different operating frequencies (mainly concerned about 20Hz ~ 50Hz), different color temperatures and different constellation and modulation methods. The EEG signals were obtained by electrodes mounted outside the mouse's skull, and the electrical signals of their specific brain regions were by in-vivo patch clamps and recorded other electrophysiological techniques. When recording the data, the correspondence between the behavioral model of the mouse and the acquired signals should be carefully aligned. Since the anatomy of the mouse brain region is quite clear, we focus on the visual cortex, the rhythm control brain region and the hippocampus which is responsible for memory. The mice with Alzheimer's disease will be observed by dissection after the experiment, and whether the symptoms were alleviated (i.e., whether the amyloid deposition in the brain has been significantly reduced).

After many repetitive and more accurate experiments on mice in the future, more experimental data of various visible light signal constellation and modulation formats commonly used in the visible light communications systems, light color temperature, lighting frequency, continuous irradiation time and other factors will be obtained for the comparative analysis and clear conclusions can be drawn with greater confidence. Based on this analysis, an experimental model can be eventually established and this will pave the way, or at least lay down the foundations, for future initial human trials.

5. CONCLUSION AND FUTURE WORK

This paper introduces the basic concept, system architecture and schematic diagram of the main functional modules of the IoL network based on the combination of lighting LED and ICT technology for indoor applications. With this infrastructure, the concept of the non-intrusive optical intervention therapy is proposed to support regulating the human physiological rhythm while maintaining its main illumination functionality. The related research plan has been designed and carried out through a mouse experiment to see the impact of the visible light irradiation on mice. The feasibility of this idea is conceptually proved from the preliminary experimental results which could bring a new paradigm of treatments for nursing homes. In the future, we will further explore the possibilities from the following aspects with the help of current medical research progress on degenerative diseases:

1 Treatment of Alzheimer's disease

Combining more experiments on mice with advanced intelligent analysis, and also considering the combining effect of other traditional therapy. People can gradually explore the possibilities of reducing or removing Alzheimer's disease symptoms by this non-intrusive treatment on human beings, especially for the elderly in nursing homes.

2 Regulation of depression

Designing and conducting the experiments on mice to confirm the effectiveness of alleviating depressive symptoms by adjusting the parameters such as color temperature and intensity. The experimental treatment for the elderly can then be carried out in nursing homes.

3 Explain how light and the nervous system interacts

Study on the neurological mechanism of different factors of visible light radiation (color temperature, frequency, modulation mode, radiation intensity). The significance of light in biological evolution is self-evident, yet its molecular mechanism is still quite unclear, especially the mechanism of the direct effect of the light on the nervous system. One can continue to carry out mouse experiments on this platform to accumulate more knowledge in this area. It is anticipated that successful implementation of this work into the human medical applications will open a new field for human recognition.

There is no doubt ICT technology could play a much more important role with the combination of the non-intrusive optical intervention therapy by introducing an adaptive feedback mechanism through artificial intelligence, machine learning and other methods. The therapeutic effect can be tracked and the treatment process and intensity can be flexibly adjusted to further enhance the effectiveness. Other than that, there might be another advantage by conducting this research. As visible light communication is considered as a promising technology for indoor applications, it is also necessary to evaluate the potential impact from the lowfrequency operation of LED in VLC application on human wellness. Therefore, it is quite important to consider and coordinate standardization efforts from the perspectives of communication, Internet of light application, and the nonintrusive optical intervention therapy.

6. ACKNOWLEDGEMENT

The authors would like to thank Dr. Wei Shi for her great help in arranging mouse experiments. This work was supported by the National Key Research and Development Program of China (2017YFB0403402) and also by the Natural Science Foundation of Guangdong Province (Grant No. 2015A030312006).

REFERENCES

- [1] Nobel prize website 2017: https://www.nobelprize.org/prizes/medicine/2017/pr ess-release/
- [2] HF Iaccarino, AC Singer, AJ Martorell, A Rudenko, F Gao, TZ Gillingham, H Mathys, J Seo, O Kritskiy, F Abdurrob, C Adaikkan, RG Canter, R Rueda, EN Brown, ES Boyden, LH Tsai, "Gamma frequency entrainment attenuates amyloid load and modifies microglia", Nature 540:230–235, December 8, 2016
- [3] Nir Grossman, David Bono, Nina Dedic, Suhasa B.Kodandaramaiah, Andrii Rudenko, Ho-JunSuk, Antonino M.Cassara, Esra Neufeld, Niels Kuster, Li-HueiTsai, AlvaroPascual-Leone, Edward S.Boyden, "Noninvasive Deep Brain Stimulation via Temporally Interfering Electric Fields", Cell 169, 1029–1041, June 1, 2017

- [4] Chinnakkaruppan Adaikkan, Steven J.Middleton, Asaf Marco, Ping-Chieh Pao, Hansruedi Mathys, David Nam-Woo Kim, FanGao, Jennie Z.Young, Ho-Jun Suk,Edward S.Boyden,Thomas J.McHugh, Li-HueiTsai, "Gamma Entrainment Binds Higher-Order Brain Regions and Offers Neuroprotection", Neuron 102, 929–943 June 5, 2019
- [5] World Health Organization: Group Interpersonal Therapy (IPT) for Depression, 2016: <u>https://www.who.int/mental_health/mhgap/interpers_onal_therapy/en/</u>
- [6] Cui Zhe, Hao Luoxi, Xu Junli, "A Study on the Emotional and Visual Influence of the CICU Luminous Environment on Patients and Nurses", Journal of Asian Architecture and Building Engineering, 2017
- [7] World Health Organization, Mental health of older adults. December 2017: <u>https://www.who.int/en/news-room/fact-</u> <u>sheets/detail/mental-health-of-older-adults</u>
- [8] ITU-R REPORTS Visible light for broadband communications: https://www.itu.int/pub/R-REP-SM.2422
- J. Cosmas, Y. Zhang and X. Zhang, "Internet of Radio-Light: 5G Broadband in Buildings," European Wireless 2017; 23th European Wireless Conference, Dresden, Germany, 2017, pp. 1-6.[10] Strategic Roadmap 2025 of the European Lighting Industry: <u>https://www.lightingeurope.org/images/160404-LightingEurope_Roadmap---final-version.pdf</u>
- [11] openbci website: https://openbci.com/
- [12] EEGLAB website: https://sccn.ucsd.edu/eeglab/index.php
- [13] neuroexplorer website: https://www.neuroexplorer.com/

ACCESS TECHNOLOGIES FOR MEDICAL IOT SYSTEMS

Junaid Ahmed Siddiquee

Ericsson, India

ABSTRACT

ICT technologies are evolving and advances in the technologies hold promise for applications in diverse domains such as healthcare. Along with the development of access technologies, rapid advances are also taking place in related areas, machine learning, artificial intelligence, cloud computing, and big data. Availing healthcare in the developing countries is costly, time-consuming and, for populations located in remote areas, it also means adding in the cost of travel to nearby towns and cities where expert healthcare facilities are normally available. Leveraging ICT technologies, IoT systems for healthcare can bring affordable and quality healthcare to the population through e-health and m-health applications. The role of ICT technologies is paramount to the success of IoT applications for healthcare. Two such ICT access standards are the 3GPP-based 5G technology and IEEE-based Wi-Fi 6. However, challenges exist in the ecosystem that inhibit the realization of the full potential of these technologies. Based on current and future requirements, the paper proposes a model incorporating key factors impacting an IoT communication system and comes up with a set of recommendations to harness the Internet of things for healthcare.

Keywords – 5G, Wi-Fi 6, e-health, healthcare, ICT, IoT, m-health

1. INTRODUCTION

Good health is one of the essential requirements for any human. This goes hand in hand with other aspects like food, security, privacy and liberty that an individual need to enable her to perform in whatever field to maximize her full potential. In developing countries, access to well-equipped and expert healthcare remains a huge challenge. Most modern facilities are available in the cities and urban centers. The rural population is often at the receiving end when they have to avail of medical care either in response to emergencies or in the normal treatment of ailments like heart disease, HIV, etc. Even lifestyle diseases like diabetes and hypertension are increasingly extending beyond urban areas. The lack of healthcare facilities can be due to many reasons. The resources of setting up such centers bring challenges both to the public and private sectors. The government, for instance, must make decisions of allotting resources to other pressing needs and rural health often does not get the required attention in budgetary allocations. To set up a wellequipped center in every town and village will call for investment not only in money terms but also in getting the trained medical and auxiliary staff to diagnose, treat and help in the rehabilitation process. To bridge the gap between the needs and the supply of adequate and affordable healthcare is where technology can play a major role. IoT-based ehealth and m-health applications have huge potential. A robust and flexible ICT system is the backbone for m-health and e-health applications to work.

2. DEFINITIONS

The World Health Organization (WHO) defines e-health as "the use of information and communication technologies (ICT) for health" [1]. The Global Observatory for e-health (GOe) defines m-health as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices" [2]. Several definitions of IoT abound in the literature. Recommendation ITU-T Y.2060 defines IoT as "A global infrastructure for the information society enabling advanced services by interconnecting (physical and virtual) things based on existing and evolving, interoperable information and communication technologies".

3. OBJECTIVE OF THIS PAPER

This exploratory paper tries to answer the following broad questions: a) What are the requirements on the access network to implement an effective healthcare IoT system? b) Identify the challenges that are encountered while implementing a solution to meet the needs of healthcare IoT. c). Propose a model for the IoT architecture with a focus on the communication layer.

4. DEVICES AND USERS

Devices: Medical devices can range from sensors and monitors used for a range of medical conditions. The device types vary depending on whether it is meant for basic treatment, diagnostic needs or monitoring. It can be expected that in a healthcare facility there may be a mix and match of devices from different OEMs. As technology improvements take place, the end devices can become more sophisticated including equipment for remote surgery and real-time sensors. Device types in healthcare can be mobile handsets, laptops/computers, screens, cameras, diagnostic tools, monitors and other advanced tools and equipment.

Applications: The users of the m-health applications can be: [3] a) health professionals (physicians, nurses, midwives, etc.); b) public including patients and healthy individuals; c) health institutions (hospitals, insurance companies, drug stores, etc.). These users would be interested in the various lines of preventive and general treatment. Information availed from the end points will be analyzed resulting in the future course of action or to bring about new insights. This will enable medical expertise at a central location to quickly diagnose and send expert advice.

5. ARCHITECTURE AND TECHNOLOGIES

There are several ways to visualize the layers making up the IoT architecture. Here we show three layers; the lowermost layer has the IoT end points: the devices, sensors and other equipment that will communicate through intervening layers to talk to the application (s). The middle layer is the one that provides the connectivity between the devices to the different modules and functions residing in the upper layer. This is the access layer or the connectivity layer. The upper layer is a conglomeration of many sublayers: the connectivity management, device management and functions as the operations, billing and revenue management. Data resides here.



Figure 1 – Layers in an IoT architecture

Several access technologies exist that are being used or can be used for IoT access. 3GPP-based standards like GSM, CDMA, WCDMA, HSPA and LTE are available. IoT requirements have led to the development of NB-IoT and CAT M1 within the 3GPP family of standards. Besides the 3GPP standards, IEEE-based Wi-Fi standards also cater to IoT needs. Proprietary standards like SIGFOX add to the milieu. A list of access technologies (non-exhaustive) is depicted in the table below.

 Table 1 – Access technologies for IoT (Compilation)

3GPP/ 3GPP2	2G- GSM, CDMA	3G- WCDMA, HSPA	4G- LTE/ LTE-M	NB- IOT	5G
Zigbee					
IEEE	802.11 (Wi- Fi)	802.15.6 (WBAN)			
LoRa					
SIGFOX					
Bluetooth	BLE	BR/EDR			
Weightless					

6. ACCESS REQUIREMENTS OF MEDICAL IOT SYSTEMS

e-health and m-health services can be availed remotely. For these services to be effective, the communication access systems that talk to the end devices and the upper layers, including the applications, need to fulfill certain criteria. We can categorize the deployment requirements for such access systems into two categories: current requirements and upcoming requirements. By current we define the access systems that are presently serving the IoT needs.

6.1 Current Access Fulfillment

- Limited mobility: Most medical end-user devices are static today. These can be monitors of various types, sensors, counters and scales. Mobility within the same room or building is what is available.
- Low to mid-bandwidth: Most of the applications connected to the medical devices do not require data guzzling pipes in gigabytes and terabytes. In most cases, kilobytes and at most megabytes suffice.
- Tight integration with the device/equipment: Open interfaces and protocols are not the norm. Devices and applications are tightly linked. It is not expected that an IOT device made by a medical equipment manufacturer will interwork with an application made by another OEM.
- Integration with local databases: Cloud-based databases and computing are an exception rather than the rule. While manufacturers and third-party application entities are veering to exploit the efficiencies provided by cloudbased systems, current deployments often exist within departments, entities and organizations with their own private data storage. Exposure to external databases is limited.
- Basic security: Since the devices, applications and databases are tightly integrated, security is taken as an inbuilt functionality.

6.2 Upcoming Access Requirements

With developments in medical science, treatment methods and procedures have also evolved. Advances in technology, end-user equipment and applications are taking place. Awareness in integrating different tools and techniques are leading to newer ways of treatment and use of data available through the various end points, human or otherwise. These developments place demands on technology to meet enduser expectations.

 Table 2 – Access requirements

Area	Description
Low latency [4]	Life-saving equipment sensors and actuators need to respond within the shortest possible time. This leads to the need for ultra-low latency support in the access technology to reduce the e2e latency from the device to the application. Latencies in the range of 1-5 millisecond would be desirable as newer use cases and applications come up.
Enhanced mobility	Access technologies need to be able to give mobility support to the end- user device. A patient with a heart monitor should be able to use his device from within the medical center precincts to his home which may be several kms away.
Better quality & reliability [4]	Unlike other applications, medical IoT devices and applications require high quality, from the device to the application. The quality of service in the network should be able to ensure prioritization of the services and availability. The reliability of the communication system will be an important and life-saving need.
Interoperability and open standards	For ease of use and integration between devices and applications, the access technologies need to be based on open standards and protocols. Device to Device communication (D2D), Device to Application (D2A), the protocols and standards in the access, data retrieval and storage and processing need not be restricted to any
Dooming surgest	proprietary standards. This will lead to better integration efficiencies.
Koaming support	is mobility across geographies,

	states and countries. Roaming would be desirable to ensure that the end user is not restricted to one service provider while using the medical device. Portable medical kits are today available and roaming support will enable flexibility to the end user while being on the move.
Bandwidth – low to high	Some devices need only a few Kbps to send and receive data while other devices may require higher bandwidth in the order of Mbps. A 4K video transmitting medical image may require 15 Mbps to 25 Mbps throughput [5]. With higher quality 8K videos, this can be pushed upwards to 85-100 Mbps [6]. With remote surgery and other such uses cases, the requirements of video, audio and real-time data would need enough bandwidth to generate quality outputs. This, in turn, would require the access technologies to support a range of bandwidths from a few Kbps to multiple Gbps.
Integration with large databases and applications [7]	As data consumption and usage in the medical sector increases, this data can come from a multitude of sources: <i>imaging</i> , <i>MRIs</i> , <i>EEG</i> and <i>ECG</i> , audio files, patient records and storage and the like. This results in the medical care industry becoming one of the key users of big data [8].
Integration with other technologies, ML and AI [7]	Increasing evidence of the use of ML and AI can be seen in the medical space, image scanning and interpretation applications, radiology images and assisted surgery. The use of AI and big data analysis with the computing power of cloud-based solutions call for close integration between and among these technologies with the available ones [9]. The access technologies should be able to seamlessly and transparently allow this integration.
Enhanced security and privacy [7] [10]	The privacy of the end user is an unalienable right. The system should be capable of thwarting security breaches which can be catastrophic. The robustness of the system to remain resilient and reliable calls for implementing

	solutions that focus on		
	vulnerabilities. configuration		
	assessments malware defenses as		
	well as activity and event		
	monitoring [11] Administrations		
	monitoring [11]. Administrations		
	have begun issuing cybersecurity		
	regulation guidelines for network-		
	connected medical devices [12] [13]		
	[14]. ICT access technologies will		
	need to be in sync with the overall		
	ICT deployment.		
	a. Massive IoT (mMTC) and		
Support for	Critical IoT (uRRLC)		
different end-user	b. IP and non-IP-based device		
IoT types	support		

7. CHALLENGES

There exist several challenges in implementing the requirements as mentioned in the above sections.

1. Interoperability between different standards: Medical user equipment will need to have newer access, like 5G enablement, in the coming times. Devices currently have Wi-Fi enablement and some devices may have access features like infrared or other proprietary technologies. To have interoperability, one access system needs to integrate with other systems. For instance, a Wi-Fi system at a higher level will need integration with, a 5G system. However, seamless handovers between an ongoing Wi-Fi data session with a 4G or 5G system does not work as well as a handover between a 4G to 4G node.

2. Investment in the introduction of new technologies and architectures to enable required functionalities like low latency, higher throughput and security.

3. Quality of end devices and overall cost of ownership:

a) Resiliency: from cyberattacks, equipment and network architecture to enable availability. Node architectures like CU-DU split in radio access nodes, CP-UP in core networks, network slices, container-based cloud applications will help in application recovery and resilience. Implementation of such changes is not expected to take place rapidly and will take time for full-scale deployment. b) End-to-end ownership: spanning from the devices, access systems, gateways, internet, applications and databases spread in the cloud. Service Level Agreements (SLAs) of the network, SLAs of the medical equipment will become relevant and needed. Currently, e2e SLAs for IoT systems spanning across multiple layers with different ownerships are nonexistent or evolving.

5. Security a) Network security: algorithms used for encryption and ciphering at the access layer, application layer and database layer with adequate protection for the control and traffic layers. b) User security: the end-to-end encryption from user to application. SIM-based authentication, user authentication and database access authentication exist and need to be ensured across multiple diverse systems. Can the network identify the right user and allow him or her to access the upper layers?

6. Privacy: How much of a user's medical records will be made available, to whom and when? Can somebody pry into a user's health records and cause harm? Can the network identify identity theft through appropriate mechanisms? In a mix and match of technologies this aspect needs to be given careful consideration.

7. Power requirements, availability: Medical devices need the power to operate and be functional. Besides the processing done by the device, the device also would need to be in regular contact with the access network to indicate that it is "alive" and can send and receive data. This will require the end device to consume power only when it is in transreceive mode and consume minimal or no energy at other times. The access network would need to have the required power-saving modes and features.

8. Regulations are evolving especially so in the new frontiers of technology. In many countries, the impact is yet to be studied and implemented. How much impact will it play in IoT architectures and deployment is yet to be seen.

9. e2e solution life cycle: The IoT ecosystem at the lowest layer starts from the medical device, moves through different layers of connectivity and management and reaches the application layer. Each layer has its hardware and software and ideally should not impact the changes in other layers. It will be of importance to ensure that dependencies are known to the stakeholders in the chain whenever any functionality of any end and intermediate layers bears an impact on other layers.

10. Standardization: Standardization organizations exist in the telecommunication and ICT domains, where these bodies work on enhancements in existing features and functionalities. There exist medical associations and trade organizations that define the ethics and ways of working for the medical fraternity. Research is ongoing in the medical field in newer and better ways of treatment and drugs. The challenge lies in ensuring that the various research and standard organizations and associations operating for the various layers are working in tandem. This is a tall order in today's world.

8. MODEL FOR IOT DEPLOYMENT

The paper puts forward a model for IoT keeping in view the requirements of the healthcare sector. Multiple factors contribute to a healthy ecosystem for enabling IoT for healthcare. The importance of each factor cannot be discounted as the diffusion of IoT hinges on each of the enabling factors.



Figure 2 – Impacting factors of an IoT deployment for medical healthcare

We define each of these factors in this paper as follows:

Security: the confidentiality, integrity and/or availability of data collected by, stored on, processed by, or transmitted to or from the IoT device [15].

Privacy: the ability for people to selectively share, to determine how information about them is collected, used and passed along [16].

Quality: this determines the accuracy and sensitivity of the data collection and transmission, quality of service, quality of data, quality of devices, communication equipment, methods and procedures.

Mobility: ability to take the IoT sensors, readers, equipment(s) from a stationary position to other areas and still be functional.

Interoperability: The diverse elements comprising IoT (devices, communication, services, applications, etc.) should seamlessly cooperate and communicate with each other to realize the full potential of the IoT ecosystem [17]. Ability to mix and match more than one OEM's equipment and applications for an overall solution.

Standards: established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context [18]. In this paper, we refer to standards from different bodies like 3GPP, IEEE and the like.

Certification: IoT devices certified under this scheme comply with specified requirements supported by the industry to protect the availability, authenticity, integrity and confidentiality of stored or transmitted or processed data or the related functions or services offered by, or accessible via IoT devices throughout their life cycle [19]. This covers aspects such as hardware, software, security, conformity, quality and safety across the different layers of the IoT architecture.

Multi-device support: Medical IoT systems have end user equipment from different manufacturers supporting different protocols and other technical requirements. Systems should be able to take in this disparate end-user equipment and transmit and receive data from them to upper layers.

Policy & regulation: policies, laws, rules and regulations, enforcement of the same by public institutions and governments.

Ease of integration: should be possible to integrate disparate IoT devices, communication systems based on different standard and manufacturers.

Flexibility of deployment: IoT architectures need to provide the mix and match of different deployment architectures,viz. private and public networks.

TCO: Total cost of ownership=Capex+ Opex for device and equipment over the solution life cycle.



Figure 3 – Enhanced model of an IoT healthcare system

The IoT architecture model has been primarily depicted as 3layer [20] [21] [22] and 4-layer [23] [24] [25] [26] in most IoT literature. This paper takes the 4-layer architecture and builds upon it to incorporate the essential elements impacting the IoT ecosystem, security, quality, privacy and policy and regulation. For an IoT-based system to operate all these elements play their role in this 4-layer architecture.

9. 5G AND WI-FI 6 STANDARDS FOR IOT SYSTEMS

Existing access technologies, NB-IoT, SiGFOX and LoRa are developed for massive IoT deployments where latency may not be as critical, where the power consumption of the end devices need to last long and data transmission does not require too much bandwidth. Access technologies need to support both types of requirements, mass deployment with low throughput and latency and IoT systems where larger bandwidth and latency become increasingly important. We discuss in these paper two standards for access systems, 5G and Wi-Fi 6. These two technologies hold promise to the use of applications for critical IoT which requires low latency and high bandwidths.

5G: 3rd Generation Partnership Project (3GPP) has been working on enhancing radio and core standards ever since the early generations of the mobile systems. Release 15 being the first set of 5G system specifications brings new radio standards (NR) along with enhancements to the

existing LTE radios. Architectural improvements like the separation of Control and User planes (CUPs) in the core layer and slicing where different user types can be allotted their own virtual network helps in improving the latency that is so critical in some use cases. These and further enhancements bring more impetus to the deployment of IoT systems, spectrum efficiency, higher bit rates, reduced latency, connection density (devices/square Km) and enhanced battery life of the devices [14] [15]. In further updates through releases, 3GPP through NB-IoT, LTE and 5G is set to meet the needs for both massive Machine-Type Communications (mMTC) for a large number of devices requiring low data and latency requirements to Ultra-Reliable and Low Latency Communications (URLLC) for the mission-critical type of IoT applications. 3GPP standards are primarily designed for the commercial spectrum bands for connecting IoT devices. Moreover, through solutions like LAA and LTE-U, LTE can also work in the unlicensed bands.



Figure 4 – Architecture of IoT with 5G as an access medium

Wi-Fi 6: As Wi-Fi standard evolution continues, the new version of Wi-Fi known as Wi-Fi 6 based on the 802.11ax technology is offering better functionalities and features compared to previous releases: faster speeds, increased throughput using Multi-User Multiple-Input, Multiple-Output (MU-MIMO) and better latency through uplink and downlink Orthogonal Frequency Division Multiple Access (OFDMA). These are intended to meet the needs of IoT devices in consumer and enterprise environments [16]. Other considerations to meet IoT needs are improved battery life in end devices and increased network capacity and bandwidth are available in the new specifications. Many end-user devices, tablets and mobile handsets have Wi-Fi capability as an inbuilt capability. Considering the market requirements, 3GPP has defined ways of integrating Wi-Fi systems to the LTE and 5G networks. Wi-Fi devices primarily work on the 2.4 GHz and 5 GHz unlicensed bands. However, Wi-Fi suffers from some inherent issues, roaming, scalability and bandwidth. This arises because Wi-Fi utilizes unlicensed spectrum which is limited and the problem of "tragedy of commons" may result in Wi-Fi systems being unable to ensure stringent OoS and demanding requirements of applications like remote surgery.



Figure 5 – Architecture of IoT with WiFi6 as an access medium

10. DEPLOYMENT MODELS

There exist various options to avail access systems needed for IOT applications for medical usage. This can be depicted as given in Figure 6 below:



Figure 6 – Deployment models

Private networks: An enterprise may decide to build its private network for extending healthcare. For budget, criticality, and ease of design considerations, an enterprise may go along the route of not making any additional outlay in the procuring of spectrum by utilizing free to use spectrum in the ISM and/or 2.4 GHz and 5 GHz in most countries. Spectrum is expensive in many countries and if budget limitations are an important factor, the choice is clear. Alternately, an enterprise may procure the required spectrum to build a privately-owned LTE or 5G network. In this case, the enterprise will take full ownership of the design, deployment and maintenance of the access network. This will give reliability and QoS which may be critical in certain aspects of healthcare such as remote surgery.

Service providers: An enterprise can subscribe to an existing mobile or integrated service provider for IoT access requirements. This will help avoid the hassle of setting up and maintaining a private network. Service Level Agreements (SLAs) need to be agreed between the provider and the enterprise. The service provider can offer systems operating in the commercially allotted spectrum and unlicensed spectrum technologies or both. In some countries, a new breed of service providers catering exclusively to IoT users is also available.

11. WAY FORWARD

This paper posits some recommendations to leverage the potential of IoT in the ever-increasing domain of medical healthcare. However, to effectively harness the potential of technology, certain steps need to be taken in the overall ecosystem.

1. Build reference frameworks

This paper suggests that a reference model be formulated keeping in consideration the unique needs of the healthcare sector. A model is proposed in this paper. This will help each actor in the ecosystem to understand the requirements and work accordingly to bring in synergies. This aspect is significant in a fragmented environment where multiple OEMs and service providers are present.

2. Regulatory guidance

In the face of fast-moving developments in the use of technology in the healthcare industry, the regulation in any dispensation will need to be lightweight. This will help innovation. Regulation needs to come up with recommendations on individual privacy and security needs and protecting the end consumer of medical services. Areas like the development of technology, devices, the architecture of deploying the IoT systems, etc. are best left to the market. Besides institutional regulation, the role of self-regulation in this emerging field calls for high ethical standards from professional bodies, manufacturers, service providers and users.

3. Certification

A plethora of standard bodies, 3GPP, IEEE, Open stack, OpenFOG, IETF and OMA exist today. The future is increasingly heterogeneous and interoperability and interworking between different standards will be the need. Quality has to be the essence on which medical IoT systems would hinge on. An independent certification process that ensures the quality of the products and meet minimum standards like power consumption, interference to other systems, security aspects need to be followed. Regulation and certification are normally independent functions. The certification process may need to conform to the guidelines emanating from the regulation aide. Learnings from the certification process may, in turn, lead to changes in regulatory guidelines.

4. Demonstrate POC in real conditions

Healthcare conditions are unique in different countries. In the western world, facilities are remarkably different from the developing world. Proof of concepts and trial systems help enhance the knowledge of the application of technologies like IoT to real-world problems. Healthcare is an area that directly touches the user and success and confidence of IoT-based technologies will help in the acceptance of such solutions.

12. CONCLUSION

Affordable healthcare through m-health and e-health applications riding on ICT will play an important role in providing healthcare to remote and rural areas. This paper brings out the needs of IoT-based systems for medical applications and takes it forward to capture the probable needs for future systems. The challenges for the deployment of IoT systems to fulfill the needs of medical systems are analyzed and two technological standards, 5G and Wi-Fi 6 that hold promise for meeting the future needs of medical IoT systems, are analyzed. Deployment models for the access technologies are presented. However, significant changes are needed in the ecosystem and the paper suggests some actions to bring out the latent potential for the use and diffusion of IoT systems in the healthcare sector.

REFERENCES

- [1] "eHealth," WHO, [Online]. Available: https://www.who.int/ehealth/en/. [Accessed 1 July 2019].
- [2] WHO, "mHealth New horizons for health through mobile technologies," Global Observatory for eHealth series Volume 3, 2011.
- [3] ,. G. M. Mobin YASINIa, "Toward a use case based classification of mobile health applications," *Digital Healthcare Empowering Europeans R. Cornet et al.* (Eds.) © 2015 European Federation for Medical Informatics (EFMI)., pp. 175-179, 2015.
- [4] S. &. S. S. K. &. W. X. Bhandari, "Latency Minimization in Wireless IoT Using Prioritized Channel Access and Data Aggregation," 0.1109/GLOCOM.2017.8255038, 2017.
- [5] R. Pegoraro, "You're buying a 4K TV. How much Internet bandwidth do you need?," 2017. [Online]. Available: https://www.usatoday.com/story/tech/columnist/201 7/12/10/youre-buying-4-k-tv-how-much-internetbandwidth-do-you-need/933989001/.
- [6] A. Kishore, "Worried About Bandwidth for 4K? Here Comes 8K!," 2017. [Online]. Available: https://www.lightreading.com/video/4k-8kvideo/worried-about-bandwidth-for-4k-here-comes-8k!/d/d-id/737330.
- [7] A. P. L. D. N. & F. F. Noemi Scarpato, "E-health-IoT Universe: A Review," *International Journal on Advanced Science Engineering Information Technology*, vol. Vol.7 (2017), no. No 6, 2017.
- [8] D. V. Dimitrov, "Medical Internet of Things and Big Data in Healthcare," *Healthc Inform Res, doi:* 10.4258/hir.2016.22.3.156, 2016.
- [9] U. &. D. R. Kar, "Application of Artificial Intelligence in Healthcare: Past, Present and Future," *Arch Biomed Eng & Biotechnol.1(1):* 2018.ABEB.MS.ID.000503, 2018.

- [10] M. A. K. Sultan H. AlMotiri and M. A. AlGhamdi, "Mobile Health (m-health) System in the context of IoT," 2016 4th International Conference on Future Internet of Things and Cloud Workshops, DOI: 10.1109/W-FiCloud.2016.24, no. ;, 2016.
- [11] A. &. H. T. Chacko, "Security and Privacy Issues with IoT in Healthcare," *EAI Endorsed Transactions* on Pervasive Health and Technology. 4. 155079. 10.4108/eai.13-7-2018.155079., 2018.
- [12] F. O. f. I. Security, "Cyber Security Requirements for Network-Connected Medical Devices," 13 11 2018.
 [Online]. Available: https://www.allianz-fuercybersicherheit.de/ACS/DE/_/downloads/BSI-CS_132E.pdf; jsessionid=A73F550EB7FB2E04A98 6F9E477D6E8A5.1_cid360?__blob=publicationFile &v=5.
- [13] "Therapeautic Goods Administration, Department of Health, Australian Givernment," TGA, 19 July 2019.
 [Online]. Available: https://www.tga.gov.au/publication/medical-devicecyber-security-guidance-industry.
- [14] A. Mulero, "France Drafts Medical Device Cybersecurity Recommendations," 23 July 2019. [Online]. Available: https://www.raps.org/news-andarticles/news-articles/2019/7/france-drafts-medicaldevice-cybersecurity-recomme.
- [15] K. e. a. Boeckl, "Considerations for Managing Internet of Things (IoT) Cybersecurity and Privacy Risks," National Institute of Standards and Technology, June 2018.
- [16] G. &. K. E. Rosner, "Privacy and the Internet of Things : Emerging Frameworks For Policy and Design," Center For Long-Term CyberSecurity.
- [17] M. Noura and M. &. G. Atiquzzaman, "Interoperability in Internet of Things: Taxonomies and Open Challenges," *Mobile Networks and Applications*(2019) 24:796–809, 2018.
- [18] P. Hatto, "Standards and Standardization Handbook," Directorate-General for Research-European Commission, 2010.
- [19] R. Atoui, "Eurosmart IoT Device Certification Scheme".
- [20] M. Bilal, "A Review of Internet of Things Architecture, Technologies and Analysis Smartphone-based Attacks Against 3D printers". Department of Computer Science, Zhejiang

University Hangzhou, Chinahttps://arxiv.org/ftp/arxiv/papers/1708/1708.04560.p df.

- [21] B. Silva and K. &. H., "Internet of Things: A Comprehensive Review of Enabling Technologies, Architecture, and Challenges," *IETE Technical Review*, DOI: 10.1080/02564602.2016.1276416, 2017.
- [22] J. e. a. Lin, " A Survey on Internet of Things: Architecture, Enabling Technologies, Security and Privacy, and Applications," *IEEE Internet of Things Journal, vol. 4, no. 5, pp. 1125-1142, doi: 10.110*, Oct 2017.
- [23] Rashmi, "IoT (Internet of Things) Concept and Improved Layered Architecture," *JEDR*, *Volume 6, Issue 2, ISSN: 2321-9939,* 2018.
- [24] Recommendation ITU-T Y.2060 (2012), Overview of the Internet of things.
- [25] "Infrastructure, Internet Protocol Aspects And Next-Generation Networks- Overview Of The Internet Of Things".
- [26] D. Darwish, "Improved Layered Architecture for Internet of Things".- International Journal of Computing Academic Research (IJCAR) ISSN 2305-9184 Volume 4, Number 4 (August 2015), pp.214-223
 © MEACSE Publications http://www.meacse.org/ijcar.
- [27] ETSI, "Why do we need 5G?," [Online]. Available: https://www.etsi.org/technologies/5g.
- [28] 3. T. S. C. Balazs Bertenyi, "3GPP system standards heading into the 5G era," *Eurescom message, Spring issue 2014*, 2014.
- [29] "Wi-Fi Alliance® introduces Wi-Fi 6," 2018. [Online]. Available: https://www.wi-fi.org/newsevents/newsroom/wi-fi-alliance-introduces-wi-fi-6.
- [30] "What is LoRa®?," [Online]. Available: https://www.semtech.com/lora/what-is-lora.
- [31] "Sigfox Technology Overview," [Online]. Available: https://www.sigfox.com/en/sigfox-iot-technologyoverview.

SESSION 2

MEDICAL ICT

- S2.1 Module structure for foot prosthetic and interface standardization
- S2.2 Development of hearing technology with personalized safe listening features

MODULE STRUCTURE FOR FOOT PROSTHETIC AND INTERFACE STANDARDIZATION

Yoshitoshi Murata¹; Tomoki Yamato²

¹ Faculty of Software and Information Science, Iwate Prefectural University ²Solution Strategic Department, DOCOMO Technology, Inc.

ABSTRACT

Several million people around the world live with limb loss. Prosthetics are useful to improve their quality of life, and some powered prosthetics enable them to walk naturally. However, most are too expensive for most amputees to afford. We propose a module structure for a foot prosthetic and standardized interfaces between modules to lower the price of powered ones. The prosthetic is battery-powered and controlled by data from sensors built into the heel of a shoe for a healthy foot. Some modules can be applied to people with walking disabilities. Such standardization can lower the price of such modules, and many amputees and people with walking disabilities, such as hemiplegia, can easily afford them, which can help improve their quality of life.

Keywords – Amputee, foot prosthetic, gait assist, walking disability

1. INTRODUCTION

As the percentage of elderly people in the world's population is increasing [1], the number of functionally impaired people, such as those with cerebrovascular diseases, will also increase. People with such diseases often have walking disabilities, which increases their risk of falling and consequently injuring themselves [2]. One main cause of this is due to their inability to raise their heel and swing their toes up because of muscle weakness [3].

There are nearly 2 million people living with limb loss in the United States [4]. Maurice LeBlanc estimated the number of amputees was approximately 10 million in the world, with 30% comprising arm amputees [5]. Therefore, the number of leg amputees was 7 million. Leg amputees use foot prosthetics to improve their quality of life. However, low-priced foot prosthetics have rigid ankle parts and no power drive mechanism, which makes it difficult to raise the heel and swing the toes up. Therefore, most users need more power to move their foot. Powered foot prosthetics enable users to move their foot easily and walk more naturally. However, such prosthetics are too expensive for most amputees. One example is that in Japan it costs more than 2 million yen (\$18,000).

One of the main reasons why the cost of introducing existing powered prosthetics is too expensive may be that the prosthetic market is not open. A number of manufacturers provide them as an integrated device, and the components are not compatible between different manufacturers.

Introducing a module structure to prosthetics and standardizing the interface between modules will enable the price of powered prosthetics to be lower. In this paper, we propose a module structure for foot prosthetics with standardized components.

Our paper is outlined as follows. Existing power-assist prosthetic leg designs are introduced in section 2. The results of our research related to the gait of stroke patients are introduced in section 3. We developed a walking assist shoe that has a coil and leaf spring to easily raise the heel. Its structure and effect of raising the heel are introduced in section 4. Our proposed module structure for a foot prosthetic is introduced in section 5. The heel-up spring, which is one of the modules comprising the foot prosthetic, is derived from the results of the walking assist shoe introduced in section 4. We conclude in section 6.

2. EXISTING POWER-ASSIST FOOT PROSTHETIC

In this section, we introduce existing powered foot prosthetics. Ottobock in Germany and Ösuur in Iceland provide such prosthetics to consumers and the Biomechatronics Group, a research group within MIT Media Lab., has also developed some models.

Ottobock provides a power-assist foot prosthetic called "1B1 Meridium [6]." Its mechanism is shown in Figure 1. It adopts a hydraulic pressure mechanism, in which a hydraulic pressure cylinder pushes and pulls a lever on the toe plate, causing the instep to rise and fall, respectively.

Össur provides a power-assist foot prosthetic called "PROPRIO FOOT[®] [7]" shown in Figure 2. Due to a lack of relevant material on the product's operation, we assume from observations that an air cylinder positioned in the area of the Achilles' tendon raises and lowers the foot part.



Figure 1 – Mechanism of 1B1 Meridium, Ottobock



Figure 2 – PROPRIO FOOT[®], Össur



Figure 3 – Power-assist foot prosthetic developed by the Biomechatronics Group of MIT Media Laboratory

The Biomechatronics Group of MIT Media Lab. developed a powered foot prosthetic as shown in Figure 3 [8]. Its heel part (in-series spring) is pulled up and down by the ball screw driven by the motor through the timing belt.

This prosthetic, however, is not a commercial product. Prices of the PROPRIO FOOT[®] and 1B1 Meridium are not available to the public, but are assumed to be more than 2 million yen (\$18,000) in Japan, which is too expensive for most amputees.

The main purpose of our research is to provide a low price powered prosthetic foot based on a module structure concept and standardization interface between modules.

3. DIFFERENCES IN GAIT BETWEEN HEMIPLEGIA PATIENTS AND HEALTHY PEOPLE

We analyzed the walking gait cycles of unimpaired people and those with walking disabilities using a wearable device (WD) and a KINECT to detect warning signs of falls [3]. We experimentally measured the output data of an acceleration sensor and gyroscope sensor in a WD mounted on the front of a shoe to estimate the kicking power and change of angle between a foot and the floor.

Figures 5 and 6 show examples of changes in acceleration, angle velocity, and angle for an unimpaired participant and one with a walking disability, respectively. Data for two steps are plotted. Each flat period (roughly the center period)

in these figures represents when the entire shoe sole touched the floor. The maximum angle velocity at timing A indicates the kicking power when raising the heel, and the minimum angle at timing B indicates the angle to the floor at terminal swing.

The lower angle velocity at A in Figure 5 is about 420 deg./sec. On the other hand, the higher angle velocity at A in Figure 6 is about 250 deg./sec. Thus, the participant with a walking disability clearly has a weaker kicking power when raising their heel compared with that of the unimpaired participant, indicating a clear difference in terms of gait.

The higher angle at B in Figure 5 is about -18 deg. On the other hand, the lower angle at B in Figure 6 is about -8 deg. Thus, the participant with a walking disability expressed difficultly when raising their toe at the terminal swing phase.

Tables 1 and 2 list the averages and standard deviations (SDs) of measured data for angle velocity at timing A and angle at timing B. The angle velocity at timing A is clearly different between unimpaired participants and those with walking disabilities. There is a big difference between them in the angle at timing B; however, this value would have sometimes overlapped each other.





(a) WD: Sony SmartWatch 3

(b) WD mounted on foot





Figure 5 – Angle velocity, angle, and acceleration for unimpaired participant



Figure 6 – Angle velocity, angle, and acceleration for participant with walking disability

Table 1 – Angle velocity	at the	terminal	stance
--------------------------	--------	----------	--------

Participant	Average (deg./s)	SD (deg./s)
Unimpaired participant	509.36	18.91
Participant with walking disability	342.06	86.52

Table 2 – Angle at the terminal swing

Participant	Average (deg.)	SD (deg.)
Unimpaired Participant	-17.76	8.02
Participant with disability	-7.45	8.02

4. PROTOTYPE OF SHOE TO ASSIST PEOPLE WITH WALKING DISABILITIES

As described in section 3, people with walking disabilities, such as those who suffer from hemiplegia, clearly have a weaker kicking power when raising their heel and swing power when swinging their toe up. We have developed a shoe, shown in Figure 7, that assists people with walking disabilities. This shoe has a coil spring and leaf spring to enable a user to easily raise their heel. The spring force of the coil spring is 15 kg. The shoe has a roller to avoid the toe accidentally tripping.

We compare the kicking power (angle velocity) when the heel is raised between a normal shoe and our proposed assist shoe worn by a stroke patient. The data is shown in Figure 8. The kicking power with the assist shoe is lower and more stable than that with a normal shoe. We then measured a group of 8 students who were asked to walk as if they had a disability while wearing a normal shoe and the assist shoe. Measured data is shown in Figure 9. In every participant except one, their kicking power with the assist shoe was lower and more stable than that with the normal shoe. Authors also examined, and sensed that the shoe compensated to raise his foot slower with weaker power than the normal shoe and its compensation power was stable. Measured data in Figures 8 and 9 indicate the above senses.

We measured integrated electromyogram (iEMG) readings for two people with walking disabilities to confirm the effect of the assist shoe. We used the wireless EMG logger from Logical Product Corporation [9]. The wireless EMG sensors were attached to the gastrocnemius of the right leg as shown in Figure 10. The sampling rate was 500 Hz. Measured data is shown in Figure 11. The results for the assist shoe are lower than those with a normal shoe for both people. The compensation effect of the proposed assist shoe is also confirmed with the iEMG.



Figure 7 – Assist shoe prototype



Figure 8 – Kicking power when heel is raised with normal and proposed assist shoes for a stroke patient



Figure 9 – Kicking power when heel is raised with normal and proposed assist shoes



Figure 10 – EMG sensors placement



(2) I erson when wanning ersecurity #2

Figure 11 - iEMG data when heel was raised

It is clear that the proposed shoe compensates for muscle weakness. However, most evaluators including authors felt the timing to generate a spring reaction force is too early to walk smoothly; the timing at which the knee comes out in front of the ankle is best.

The solid-ankle cushion heel (SACH) has been provided to the foot prosthetic, and popularly used [10]. Most of them are made with rubber, and inserted as the heel part of the prosthetic foot. It assists foot prosthetic users to walk easily, not walking disabilities. Its compensation principle would be the same as the proposed shoe. Since SACHs are made with rubber, a period of compensation effect is limited. They have to be exchanged periodically. However, since metal springs are used in the proposed shoe, these would not need exchange.

The proposed shoe has a toe roller. However, as it is difficult to have a person with walking disabilities intentionally trip over an obstacle, we could not quantitatively evaluate it.

5. MODULE STRUCTURE AND ITS STANDARDIZATION

One main reason why existing powered prosthetics are so expensive is that the prosthetic market is not open in terms of standards. A few manufacturers provide prosthetics to replace a foot, leg and hip as an integrated device. These are selected and adopted to each patient accordingly. However, the components that comprise each prosthetic are not compatible with those of other manufacturers.

By introducing a module structure and standardized interfaces between module parts, third-party manufacturers could produce individual components, significantly reducing the overall price of prosthetics.

5.1 Module structure

From analyzing existing powered foot prosthetics, shown in Figures 1, 2 and 3, we propose a standardized foot prosthetic that comprises the following ten modules as shown in Figure 12:

- socket: connecting the leg to a prosthetic;
- ankle joint: connecting the socket to the foot with rotational connector;
- foot: the same as a typical foot on which a battery and control board are mounted:
- instep push/pull: enabling a foot to be raised and lowered;
- heel-up spring: absorbing shock when landing on a hard surface and raising the heel (optional);
- toe: triggers walking to start from a standing position, and connects to a hard surface when walking with wide strides (optional);
- battery: driving a single cylinder module and toe module;
- control board: controlling a single cylinder module and a toe module in accordance with signals from a central terminal;
- heel sensor: sensing the motion of a healthy foot;
- central terminal: sending signals to a control board to raise or lower a foot and toe (smartphone).

As described in section 4, a shoe with a built-in coil spring compensates for muscle weakness. However, we believe that this is insufficient to raise the foot module of a prosthetic in the same way as a person would raise a healthy foot. Therefore, we believe the instep push/pull is needed to raise or lower a foot module in addition to the heel-up spring. An ankle joint module is necessary to connect the leg socket to the foot module in the same way as an actual ankle joint.

In existing powered foot prosthetics, sensors have been incorporated into the prosthetic control board to raise or lower the foot part. However, there are differences between a foot prosthetic and a healthy foot in motion. A computer built into the prosthetic gradually compensates for such differences. The proposed foot prosthetic is based on the idea that both legs and feet move in essentially the same way, but the motion cycle of each leg and foot is offset by half a cycle. There are no such differences as the foot prosthetic moves synchronously with the healthy foot. However, a sensor that monitors the healthy foot is needed. From our existing research, we determined that monitoring the heel position of the healthy foot is best. This is why a sensor is built into the heel of the shoe.

The central terminal is required to control the instep push/pull module in collaboration with the control board. We believe the upper position of the foot module is ideal for mounting the battery and control board to the foot prosthetic.

We plan to use a single motor cylinder for the instep push/pull module. The module is attached to the front of the shin as shown in Figure 12. However, we plan to determine whether the module should be placed on the front of shin or on part of the Achilles' tendon on the basis of experimental results.

For the single motor cylinder, we used an Oriental Motor DR series with a 30-mm stroke, 2-kg carrying force, and a 100-mm/sec maximum stroke speed [11]. The heel-up spring has a motor-driven spring-release mechanism. However, we estimate that the release timing must be controlled by a sensor built into the heel-up spring, not one built into the heel of a shoe for a healthy foot.

We estimate the instep push/pull module and heel-up spring can be applied to people with walking disabilities. In particular, the heel-up spring is useful as it compensates for muscle weakness, as described in section 4. This means that the price of the heel-up spring can be lowered.



Figure 12 – Module structure foot prosthetic

5.2 Interface and standardization items

In the case of unpowered prosthetics, interfaces between modules are at the physical level, since there is no control information transferred between them. Physical level information, such as size, weight, connecting method, reliability, etc. must be defined in standardization. On the other hand, since a computer system controls several modules in a powered prosthetic, not only physical information but also data-level information must be standardized.

The following eight interfaces shown in Figure 12 do not have exchange information between modules, so their interface level is physical:

- INT-1: size, connection method, and reliability between socket and ankle joint;
- INT-2: size, connection method, and reliability between ankle joint and instep push/pull;
- INT-3: size, connection method, and reliability between ankle joint and foot;
- INT-4: size, connection method, and reliability between instep push/pull and foot;
- INT-5: size, connection method, and reliability between foot and toe;
- INT-6: size, connection method, and reliability between heel sensor and shoe;
- INT-7: DC/AC, voltage, and connector type between battery and instep push/pull;
- INT-8: DC/AC, voltage, and connector type between battery and toe.

On the other hand, the following four interfaces include datalevel information in addition to the physical level information;

- INT-9:

Physical level: connector type;

Data level: pulses from the control board to the instep. The control board changes the direction, speed and number of pulses to control the cylinder speed and stroke.

- INT-10:

Physical level: connector type;

Data level: pulses from the control board to a cylinder of the toe module. The control board changes the direction, speed and number of pulses to control the cylinder speed and stroke.

- INT-11:

Physical to session level: wireless connection (Bluetooth);

Application level: controls direction, speed and maximum angle of foot rotation.

- INT-12:

Physical to session level: wireless connection (Bluetooth);.

Application level: controls direction, speed and maximum angle of foot rotation.

6. CONCLUSION

There are several million people living with limb loss in the world. Powered leg and/or foot prosthetics enable amputees

to walk naturally. However, most of them are too expensive for most leg amputees to afford.

We determined through experimentation that people with walking disabilities, such as hemiplegia, clearly have a weaker kicking power when raising their heel and a weaker swing power when swinging their toes up than unimpaired people. Our proposed shoe design has springs in the heel that compensate for muscle weakness.

We proposed a module structure for a foot prosthetic derived from our research results and observations of existing powered foot prosthetics. We also proposed standardizing interfaces between modules, enabling third-party manufacturers to produce prosthetic components at lower costs.

The introduction of such modules and standardization can lower overall prices for prosthetics, enabling them to be more affordable for foot amputees and people with walking disabilities, which, as a result, will improve their quality of life.

7. ACKNOWLEDGEMENTS

Thanks to Mr. Takashi Ushizaki, Dr. Koya Sato for helping with this research. This work was supported by JSPS KAKENHI Grant Number 19K11326.

REFERENCES

- World Population Ageing: 1950-2050, Population Division, Department of Economic and Social Affairs, United Nations, <u>http://www.un.org/esa/population/publications/worl</u> <u>dageing 19502050/</u> [retrieved: September, 2019].
- [2] W. P. Berg, H. M. Alessio, E. M. Mills, and C. Tong, "Circumstances and consequences of falls in independent community-dwelling older adults", Age Ageing, Vol. 26, pp. 261–268, 1997.
- [3] Y. Murata, S. Yoshida, T. Niinuma, K. Yoshida, "Comparative Analysis of Walking Gait Cycle between Healthy People and Walking Disabilities to Prevent Tripping Using Wearable Device and KINECT," IARIA, International Journal on Advances in Life Sciences, vol 9 no 3 & 4, 2017.

- [4] K. Ziegler Graham, E. J. MacKenzie, P. L. Ephraim, T. G. Travison, R. Brookmeyer, "Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050," Archives of Physical Medicine and Rehabilitation 2008, vol. 89 IS. 3, pp.422 - 429, 2008.
- [5] Estimated of Amputee Population 11/09/2008, https://web.stanford.edu/class/engr110/2011/LeBlan c-03a.pdf, [retrieved: September 2019].
- [6] Ottobock, 1B1 Meridium, <u>https://professionals.ottobock.com.au/Products/Prost</u> <u>hetics/Prosthetics-Lower-Limb/Feet/1B1-</u> <u>Meridium/p/1B1</u>, [retrieved: September 2019].
- [7] Ossur, PROPRIO FOOT®, <u>https://www.ossur.com/prosthetic-</u> <u>solutions/products/dynamic-solutions/proprio-foot</u>, [retrieved: September 2019].
- [8] M. F. Eilenberg, H. Geyer, and H. Herr, "Control of a Powered Ankle–Foot Prosthesis Based on a Neuromuscular Model," IEEE, Transaction on Neural System and Rehabilitation Engineering, VOL. 18, NO. 2, pp. 164-173, 2010.
- [9] Wireless EMG logger, Logical Product Corporation, http://www.lp-d.co.jp/EMGSensor.html , [in Japanese, retrieved: September 2019].
- [10] A. Staros, "The SACH (Solid-Ankle Cushion-Heel)," Orthopedic & Prosthetic Appliance Journal, pp. 23-31, June-August 1957.
- [11] Single motor cylinder, DR series, Oriental Motor Ltd., <u>https://www.orientalmotor.co.jp/products/new/18061</u> <u>1341135dr/</u> [in Japanese, retrieved: September 2019].

DEVELOPMENT OF HEARING TECHNOLOGY WITH PERSONALIZED SAFE LISTENING FEATURES

Shayan Gupta^{1,2}; Xuan Xu²; Hongfu Liu²; Jacqueline Zhang²; Joshua N Bas²; Shawn K. Kelly²

¹Audition Technology, LLC., Pittsburgh, PA, USA ²Carnegie Mellon University, USA

ABSTRACT

Noise induced hearing loss (NIHL) is a growing public health concern in the US and globally due to the emergence of lifestyle preferences and environmental exposures to sound levels exceeding safe listening limits for extended periods of time. Issuance of the ITU guidelines for safe listening devices/systems (ITU-T H.870) leading to the 2019 WHO-ITU standard, along with existing US federal and military standards, provide a framework for developing an accessible tool for promoting safe listening. Our proposed Hearing Health app, is being developed for an aggregated assessment of a user's daily sound exposure, through the audio system and the environment (occupation and beyond) by integrating WHO-ITU and US safe listening standards, providing real-time alerts, user-centric recommendations and education that can be integrated into user lifestyles, representing a wide demographic including young adult, adult, civilian and military populations. The overall goal of the app will be to increase NIHL awareness and facilitate improvement of user's listening behaviors.

Keywords – App, NIHL, safe listening standards, usercentric, user listening behavior

1. INTRODUCTION

There is an increased global focus on improving hearing healthcare due to auditory and non-auditory adverse health outcomes resulting from noise induced hearing loss (NIHL) [1]. The US Center for Disease Control (CDC) estimates ~ 24% of US adults and WHO projects >1 billion young adults worldwide are at risk of NIHL due routine, prolonged exposures to loud noise [2,3]. The lack of awareness is apparent in the latest CDC estimates, which state that 40 million US adults (20-69 years old) have NIHL, 1 in 2 of whom *not* having noisy jobs, and 1 in 4 US adults who report excellent to good hearing already have hearing damage [4].

Standards have been proposed to promote safe listening. In the US, there are safe listening standards from National Institute for Deafness and Communication Disorders (NIDCD) [5], National Institute for Occupational Safety and Health (NIOSH) [6], and Occupational Safety and Health Administration (OSHA) [7] to limit occupational noise exposures. The NIOSH Sound Level Meter app measures environmental sound and provides information on hazardous levels [8]. The Department of Defense, Hearing Center of Excellence (DoD, HCE) along with the Army Research Lab (ARL) and Army Public Health Center (APHC) provide safe listening standards and education to mitigate NIHL risk in service personnel [9-11]. To address evolving young adult lifestyles, the ITU-T H.870 guideline and the WHO-ITU global standard for safe listening devices and systems regulate exposure to loud sounds through personal audio devices/systems [12, 13]. In addition, the hearWHO app was launched recently to serve as a hearing screening to check one's hearing status [14].

An unmet need is the aggregation of the various UN and US standards for real-time, cumulative assessment of daily noise exposure, because of daily activities and lifestyle choices, with features to facilitate the adoption of safe listening practices into one's lifestyle. We are proposing a 'Hearing Health App' (App) that integrates US and UN safe listening standards with features to match personal, occupational and lifestyle needs, as well as personal preferences to improve listening behaviors across a wide demographic.

2. METHODOLOGY

2.1 m-health app for hearing health

Mobile phones are ubiquitous devices that can have a longrange wireless communication with the Internet, as well as short-range wired or wireless communication with nearby objects. Therefore, mobile phones can send and receive information from the Internet, as well as from a nearby device with Bluetooth connectivity, such as a Bluetoothenabled hearing technology (personal sound amplification product, PSAP). The app can be downloaded and executed with currently available global mobile phone technology, potentially enabling global access to a hearing health tool.

The WHO defines mobile health (m-health), a subset of ehealth, as 'the use of mobile wireless technologies for health' and recognizes the value of digital technologies to contribute to advancing health aims of the Sustainable Development Goals [15]. Our selection of development of an app acknowledges the WHO m-health directive and is guided by the importance of the incorporation of user voice to promote access, engagement and hearing health decision making. An additional consideration for app development is the incorporation of the WHO recommended Principles of Digital Development [16] to further facilitate access and ease of use. Overall, the Hearing Health app could serve to provide a 'digital health intervention' for supporting hearing healthcare.

2.2 App functionalities

The functioning of the Hearing Health app is based on:

- daily sound exposures, as a summation of A-weighted sound pressure levels (SPL in dBA) over time, based on daily activities related to occupation, lifestyle and recreational choices;
- estimation of the user's cumulative daily exposure vs sound dosage from recommended US (occupational, military) and UN (WHO-ITU) safe listening standards;
- risk notifications about unsafe noise exposures;
- incorporation of user voice on engagement strategies;
- option for connection to a personal hearing device, e.g., PSAP, via Bluetooth.

App functionalities and user voice implementation were based on user feedback from a wide demographic.

2.3 Evaluation and incorporation of safe listening standards

Exposure type	Standard
Recreational (audio	WHO-ITU (H.870)
device)	Adults: 80 dBA for 40 hours a week
	Children: 75 dBA for 40 hours a week
Occupational	CDC, NIOSH Recommended Exposure Level (REL): 85 dBA over 8 hours daily
	OSHA Permissible Exposure Limit (PEL): 90 dBA over 9 hours daily
	NIDCD: ≤ 70 dBA is safe; > 85 dBA is damaging over time
Military	US ARL: SPL <i>shall not</i> exceed an 8- hour time weighted average of 85 dBA

Table 1 – US and UN safe listening standards [5-7, 9-13]

US APHC: Damage occurs at 85 dBA or more for continuous noise

DoD HCE: Limit exposure exceeding 80 - 85 dBA

The available US and UN safe listening standards can be segmented into three main categories: recreational, occupational, and military, as summarized in Table 1. The standards are reflective of anticipated noise exposures in daily life with associated standards for hearing safety.

Of the various standards, only the OSHA PEL and the WHO-ITU provide methodology for computing A-weighted sound pressure level exposures. The resultant exposure assessments can be used to address the noise limits recommended by the other agencies listed in Table 1. Also, OSHA recommends that when daily noise exposure is composed of at least two periods of different sound pressure levels, the combined effect should be considered, rather than the individual effect of each. The exposure calculations take this recommendation into account.

The Hearing Health app calculates the user's occupational environmental exposure compared to OSHA's PEL exposure using the following formula:

$$D = 100 * \left(\frac{C(1)}{T(1)} + \frac{C(2)}{T(2)} + \dots + \frac{C(n)}{T(n)}\right)$$
(1)

where C(n) indicates the total time of exposure at a specific noise level. D represents what percentage of the OSHA standard for daily noise exposure to which the user has already been exposed.

T(n) indicates the reference duration calculated by:

$$T(n) = \frac{8}{2^{(L-90)/5}}$$
(2)

where L is the A-weighted SPL of the exposure.

For users whose sound exposure is primarily through audio devices, the app calculates audio exposure via the WHO-ITU standard. The exposure is calculated by

$$\int_{t1}^{t2} (p_a(t))^2 \, dt \tag{3}$$

where $p_a(t)$ is the A-weighted SPL in Pa. This exposure is then compared to WHO's weekly dose of 1.6 pa²h for adults and 0.51 pa²h for sensitive users (i.e. children).

The remaining occupational and military standards described in Table 1 prescribe noise dosages over a set amount of time. Therefore, to address the standards specified for an 8-hour time period (CDC, Military), the cumulative exposures can be calculated using the OSHA formula. To compensate for the different exposure volume for the 8-hour period, the percent dosage calculation is multiplied by a factor f, where f is the ratio of OSHA's recommended 8-hour noise level (85 dBA) over the other standard's recommended 8-hour noise level.

2.4 Mitigation of discrepancies in measuring sound exposure

There are a few causes of discrepancy when measuring a user's sound exposure. One such cause is the difference in distance between the ear and microphone sampling environmental noise. Because sound attenuation is inversely proportional to the distance from the source, squared, the perceived sound at a point closer to the source of the sound can be substantially louder than the perceived sound at a point farther away. Another such cause is the type of microphone that is sampling. Different microphones have different sensitivities, meaning that different microphones can possibly register different sound pressure levels from the same sound signal. To mitigate these two causes of discrepancy, we propose using a microphone from a specific PSAP product because the distance between the PSAP microphone and the user's eardrum is decreased and because the software can be standardized to that specific PSAP microphone's sensitivity.

3. RESULTS

3.1 App overview

The Hearing Health app (Figure 1) is designed as a software tool to serve as a companion for personal hearing health that prompts a user to make informed decisions about personal listening behaviors based on personal listening trends. Throughout the day, the app monitors sound levels to estimate the user's sound exposure, while also presenting alerts and notifications to the user to indicate how the personal listening behavior compares to sound doses prescribed by safe listening standards. The app also provides personalized recommendations to limit or counteract unsafe noise exposure that is relatable to daily lifestyles.





The app samples environmental noise exposure using an external microphone or internal phone microphone and can sample audio sound exposure from the mobile phone's system audio player. The app leverages the mobile phone's short-range wireless connection to a PSAP consisting of digital signal processor (DSP) packaged with a Bluetooth Low Energy (LE) module to more accurately measure the environmental and streamed sound exposure from a closer distance to the user's eardrum (Figure 1). Following the Bluetooth LE protocol will allow the app to receive data points from the PSAP, subject to the particular DSP. For example, volume settings, battery level and ambient noise levels may be available data points the app can query. When possible, hardware tests of the PSAP device can be performed by ensuring that input and output voltages do not exceed those as listed in the DSP specification, as well as accessing test points from the Bluetooth LE module to program and debug the module. Note that the PSAP is indicated for users without hearing impairment.

Privacy and security measures to safeguard personal information include: (i) limiting data collection to that required specifically for app execution, (ii) implementing Health Insurance Portability and Accountability Act (HIPAA) and General Data Protection Regulation (GPDR), and (iii) using Amazon Web Services (AWS) for cloud security. To ensure data security, the app only collects amplitudes of the sound in decibels and stores them in dynamoDB using s3 provided by AWS, which highly emphasizes security and strictly meets US and international compliance requirements.

3.2 User voice assessment for app personalization

An initial assessment of user awareness of NIHL and preferences for app personalization features was conducted in several user segments to represent a wide demographic and is summarized below. The user segments included military and civilian, young adults (age 18-25 years) and adults (age >25 years), with or without perceived hearing impairment.

CIVILIAN, young adult, not aware of personal impairment:

- limited awareness of NIHL;
- general perception that NIHL is not a risk for them;
- prefer to use personal audio devices throughout the day, even during classes and face-to-face conversations;
- some would like to mitigate NIHL risk;
- app would be helpful; but need to integrate to daily life.

CIVILIAN, young adult, with hearing impairment, tinnitus:

- some awareness of NIHL;
- may or may not wear hearing aids or hearing protection devices as they are inconvenient or not effective;

- app could be helpful to assess and potentially mitigate risk;
- willing to make incremental lifestyle changes after NIHL awareness using hearWHO App .

CIVILIAN, adult, not aware of personal impairment:

- some awareness of NIHL;
- sound measurement accuracy and use of reliable standards important;
- app should provide continuum of assessment, alerts and meaningful recommendations throughout the day that can be readily incorporated into daily activities;
- privacy and security concerns need to be addressed.

CIVILIAN, adult, with hearing loss, tinnitus:

- strong concern about NIHL;
- reluctance to take action due to stigma;
- concerned about hearing aid amplification being used; could damage hearing further;
- want personalized and relatable feedback to integrate into daily life and potentially decrease further loss;
- receptive to using phone to measure sound exposure.

MILITARY, young adult, not aware of personal impairment:

- understand high risk of NIHL due to instructions from senior personnel;
- do not consistently use hearing protection devices as these prevent hearing normal conversation and impact completion of duties;
- only wear hearing protection devices when operating machinery; often still exposed to loud sounds, such as artillery;
- app could help to assess risk during off-duty hours or post-discharge; potentially help in preserving residual hearing.

In summary, there was varying awareness of NIHL and its consequences; however, it was encouraging that there was interest in personal hearing health and support for a tool that could be integrated into daily life.

3.3 App functionalities to implement safe listening standards and personalization

The Hearing Health app functionalities (Figure 2) were designed based on user feedback and the WHO-ITU toolkit [17] as presented in Figure 2.



Figure 2 – Hearing Health app functionalities

TRACK - *Real-time volume level and cumulative sound pressure exposure*: Real-time volume level is measured in dBAs, capturing the sound exposure the user is experiencing. This lets the user see the sound level of their current surroundings, meanwhile allowing the app to sample this exposure and make recommendations based on the sample.

Cumulative sound pressure exposure monitors the user's daily and weekly noise dosage based on adjustable user preferences. The user can leave the microphone on for continuous sampling throughout the day or turn the microphone on during different parts of their day where exposures are anticipated to be high, for example sampling their commute route or gym routine.

ALERT - *Risk of NIHL*: Risk alerts are in place for potentially unsafe exposure, calculated based on the US and UN standards as described previously, with a timer for the remaining amount of time left that is recommended for the user to continue listening at that exposure level. Additional notification options (e.g. set at fixed time intervals) are available based on user preference.

REPORT - *Personalized to user activities:* Daily and weekly exposure reports are based on calculations aligned with US and UN standards. Recommendations are made based on the app's analysis of the user's listening behaviors. These notifications would advise the user based on their sound exposure such as to lower phone volume, listen to music of a different genre, use hearing protection based on their environment, shorten exposure duration by suggesting breaks and alternative sound exposure options (guided by daily activities) if there are continuous exposures above safe listening.

EDUCATE - *NIHL awareness and preventative measures:* As the purpose of the app is to help users practice hearing wellness, relevant education and information on NIHL from medical, federal, military and regulatory sources will be provided. This material would cover the causes of hearing loss, who is at risk, and current standards that regulate noise exposure. Concerned users can learn more about various hearing healthcare topics relevant to their lifestyle, easily accessible options to check their hearing (e.g. hearWHO

app), considerations for selecting hearing protection based on their needs and preferences, and other recommended practices aimed at preventing hearing loss.

The main goal of the app is to encourage and facilitate healthy listening behaviors by creating a personalized sound exposure profile and with engagement tools personalized to the user. Based on the functionalities described above, there are three main approaches for user interface personalization: (i) active and customizable monitoring, (ii) awareness of personal exposure and (iii) feedback.

Personalized monitoring is accomplished selecting intervals at which noise exposure is sampled and logged into the cumulative exposure assessment. This flexibility allows for improving accuracy by recommending the user to increase the sampling rate, and accounts for efficiency by letting the user pick times of the day to sample based on daily habits. The user also has the flexibility of choosing the interval of alerts and recommendations. This enables the user to select timing when the information will be useful and likely to be acted upon.

Personalized real-time exposure monitoring overcomes the fact that a user cannot always perceive noise exposures that have the potential to impair hearing. For example, short-term loud volume levels (e.g., impact sounds) or long-term exposure to seemingly tolerated sound levels may not cause discomfort to otherwise alert the user of unsafe exposure. The app's functionality provides the user with a method of estimating personal exposure, through defined standards, which can then be used to assess the risk of such exposures. The user's estimated real-time noise exposure with effective visual and haptic cues indicate potentially damaging exposure levels. The cumulative noise exposure acts similarly to indicate the potential risk faced by the user based on the cumulative exposure duration.

Personalized feedback is derived from a comparison of trends in the user's real-time sound pressure level and cumulative sound pressure exposure to the user's desired sound exposure, as per the relevant standards. The generated feedback addresses outliers in the user's noise exposure with suggested recommendations to address the unsafe exposures. These feedback mechanisms are iterative, in that previous feedback is evaluated alongside changes in listening behavior to assess the usefulness of that feedback to the user. In the case that the previous feedback did not produce the desired change in listening behavior, feedback offering different solutions will be presented to the user.

3.4 Hearing Health app visual interfaces

The following interfaces display a sequence from login, user profile selection, personal sound exposure report, alerts with recommendation, education. As depicted in Figure 3, the app presents the highlights of the user's noise exposure in the Hearing History and the Listening Profile modules. The Hearing History module displays graphs of the user's measured noise exposure over the time period to which the user toggles (i.e. past hour, past day, past week). The listening profile keeps track of the qualitative aspects of the user's listening experience, such as what genre of music to which the user frequently listens and periods of the user's day where the noise exposure is heightened (i.e. an exercise class or a noisy commute).





Figure 3– Examples of Hearing Health app interfaces with personal sound exposure, time-based alert and education

3.5 Incorporation of principles of digital development

To enhance the value of the app, the nine principles of digital development are being implemented as follows:

Design with the user: User-centricity is highlighted in the personalization features described previously. An iterative process incorporating user feedback to further adapt personalization features is planned.

Understand the existing ecosystem: The app integrates WHO-ITU and US occupational and military standards. The app will be available for use with Android and iOS operating systems and will connect to a user's PSAP. Additional features addressing the FDA OTC Hearing Aid Rule (to be finalized by Aug 2020) is anticipated. Features and claims of the proposed app are in alignment with FDA's Patient Decision Support guidance [18] that is exempt from regulatory oversight.

Design for scale: Achieving greater outside communication is planned by the following activities: outreach to WHO (hosting World Hearing Day, attending 2019 UNICEF-WHO Exhibition on Assistive Technology), US Military (presentation at 2019 Military Health System Research Symposium), CDC and NIOSH. Small business funding applications to the Department of Defense, NIDCD, National Science Foundation are ongoing. Commercialization strategies that allow for distribution on larger scales include app distribution on AppStore and Google Play and participation in UN Global Marketplace. *Build for sustainability:* Effective and continued adoption of the app is being ensured by core features that can be readily integrated to a user's lifestyle with core app functionalities based on UN and US standards. These will be continuously updated based on the evolution of standards, as well as user needs.

Be data driven: The app utilizes personal sound exposure data to calculate cumulative and real-time exposures. Focus is on obtaining the highest possible level of accuracy in capturing sound exposures and associated computations to inform users. Personalization features such as customizable monitoring, personal exposure reports and feedback are anticipated to have a positive impact on user's listening behaviors.

Use open standards, open data, open source, and open innovation: The app implements public regulatory standards. The user can share data obtained by the app at his/her discretion.

Reuse and improve: Ongoing development of the app will include modular user recommendations and interfaces for specific user subsections (e.g. based on age, occupation).

Address privacy & security: All user data is taken with the user's consent, as per HIPAA guidelines. Only the user can export his/her data. Future plans are for alignment with EU GDPR. All data is stored in AWS to ensure security.

Be collaborative: The app development is a culmination of input from regulatory agencies (including the US Food and Drug Administration) and end users from various demographics.

4. CONCLUSIONS

To facilitate the integration of safe hearing standards to influence an individual's listening behaviors, we propose the Hearing Health app, available on both iOS and Android operating systems. The app can be paired to hearing technology hardware, including a PSAP, to track daily exposures to audio and environmental sounds, provide alerts based on WHO-ITU and US (federal and military) standards, and engage users by providing recommendations and education that can be integrated into their occupational needs, daily lifestyle and recreational activities. The app development is aligned with WHO principles of digital development and is envisioned to function as a companion tool to encourage safe listening behaviors.

The current proposal is focused on implementation of aggregated safe listening standards primarily for users with no perceived hearing impairment. An advancement of the app will be for users with hearing impairment with the objectives of evaluating appropriate standards for use with hearing aids and engagement strategies for effective use of

hearing aids, preservation of residual hearing and improvement of quality of life.

The app development has been influenced by the global need, priorities for systems and services for assistive products as announced by the UN Global Partnership for Assistive Technology [19]. For hearing aids, one of the five identified 'priority' products, the proposed *a*pp could serve as a tool to advance overall hearing healthcare while addressing needs for global awareness, access and user-centric innovation.

In the US, the National Academies of Science, Engineering and Medicine (NASEM) report on improving access and affordability for hearing healthcare identifies the need for innovative solutions for patient-centered care with a recommendation for a new category of over-the-counter hearing devices [20]. The report also recommends engaging a wider community by awareness, education and support. We envision the Hearing Health *app* to be a component of an OTC hearing aid system that would engage the user in better management of personal hearing health needs supporting effective use of the hearing aid.

Cumulatively, the experience from users with and without hearing impairment could be of significance for potential extensions of *Recommendation ITU-T* H.870 to other use cases.

REFERENCES

- J. Eichwald, F. Scinicariello, J.L. Teffer, and Y.I. Carroll. "Use of personal hearing protection devices at loud athletic or entertainment events among adults – United States, 2018. Morbidity and Mortality Weekly Report, vol. 67 no. 41, pp 1151-1155, 2018.
- [2] National Institute on Deafness and other Communication Disorders, 2017: https://www.nidcd.nih.gov/news/2017/us-adultsaged-20-69-years-show-signs-noise-inducedhearing-loss
- [3] World Health Organization, 2019: https://www.who.int/deafness/en/
- [4] Centers for Disease Control and Prevention, 2017: https://www.cdc.gov/vitalsigns/HearingLoss/
- [5] National Institute on Deafness and other Communication Disorders, 2019: https://www.noisyplanet.nidcd.nih.gov/kidspreteens/keep-listening-to-the-beat
- [6] NIOSH Occupational noise exposure, revised criteria, 1998: https://www.cdc.gov/niosh/docs/98-126/pdfs/98-126.pdf?id=10.26616/NIOSHPUB98126

 [7] OSHA standard 1910.95, Occupational noise exposure, accessed 2019: https://www.osha.gov/lawsregs/regulations/standardnumber/1910/1910.95

> Appendix A Noise exposure computation https://www.osha.gov/lawsregs/regulations/standardnumber/1910/1910.95App A

- [8] NIOSH Sound Level Meter App, 2019: https://www.cdc.gov/niosh/topics/noise/app.html
- [9] Department of Defense, Design criteria noise limits.
 2015: https://www.arl.army.mil/www/pages/343/MIL-STD-1474E-Final-15Apr2015.pdf
- U.S. Army Public Health Command. Hearing loss and noise. 2019: https://phc.amedd.army.mil/PHC%20Resource%20 Library/HEARING_LOSS_AND_NOISE.pdf
- [11] Department of Defense, Hearing Center of Excellence, accessed 2019: https://hearing.health.mil/Prevention/Preventing-Noise-Induced-Hearing-Loss/How-Loud-is-Too-Loud
- [12] ITU-T. H.870. Guidelines for safe listening devices/systems, 2018. https://www.itu.int/rec/T-REC-H.870-201808-I/en
- WHO-ITU Standard. Safe Listening Devices and Systems, 2019. https://apps.who.int/iris/bitstream/handle/10665/280 085/9789241515276-eng.pdf?ua=1
- [14] World Health Organization, hearWHO, 2019. https://www.who.int/deafness/hearWHO/en/
- [15] WHO guideline, Recommendations on digital interventions for health system strengthening, 2019: https://apps.who.int/iris/bitstream/handle/10665/311 941/9789241550505-eng.pdf?ua=1
- [16] Principles of digital development, accessed 2019: https://digitalprinciples.org/principles/
- [17] WHO-ITU toolkit for safe listening devices and systems, 2019: https://apps.who.int/iris/bitstream/handle/10665/280 086/9789241515283-eng.pdf?ua=1
- [18] FDA Draft Guidance. Clinical and Patient Decision Support Software, 2017: https://www.fda.gov/media/109618/download

- [19] ATScale, Global Partnership for Assistive Technology, 2019: https://static1.squarespace.com/static/5b3f6ff171069 9a7ebb64495/t/5ca3cfd3fa0d60051a9a7703/155423 9448526/ATscale_Strategy_Overview_February_20 19.pdf
- [20] Hearing health care for adults. Priorities for improving access and affordability, NASEM, 2016.

SESSION 3

MEDICAL IOT

- S3.1 Facilitating healthcare IoT standardization with open source: A case study on OCF and IoTivity
- S3.2 Empirical study of medical IoT for patients with intractable diseases at home

FACILITATING HEALTHCARE IOT STANDARDIZATION WITH OPEN SOURCE: A CASE STUDY ON OCF AND IOTIVITY

Hongki Cha¹, Younghwan Choi¹ and Kangchan Lee¹

¹Electronics and Telecommunications Research Institute (ETRI), Daejeon, Republic of Korea {cha8476, yhc, chan}@etri.re.kr

ABSTRACT

Healthcare Internet of things (IoT) opens up seamless opportunities by unleashing possibilities to implement better healthcare services. Increased interest in this led to active standardization in various standards development organizations (SDOs). However, the proliferation of different international healthcare standards has not brought about full deployment of healthcare IoT services and business opportunities in the healthcare domain. *Nevertheless, there have been some efforts to take advantage* of open-source projects as an enabler to facilitate better deployment of healthcare IoT standards. In this paper, the authors develop a case study of their efforts to standardize healthcare IoT with IoTivity, with the Open Connectivity Foundation (OCF). Then they discuss the benefits of IoTivity and how it has led to the enhancement of standardization efficiency and acceleration in healthcare IoT. The authors conclude by recommending ITU-T to continue their efforts to seek the roles of open-source implementation for faster adoption of not only healthcare IoT standards but also their overall Recommendations.

Keywords – healthcare, IoT, IoTivity, OCF, open source, standardization

1. INTRODUCTION

Digital health, an integral part of the "Fourth Industrial Revolution", revolutionizes the medical and healthcare domain, and in turn, helps us overcome the technical and socio-economic challenges we face around health. Leaping to the next level of connected healthcare services is only possible when taking advantage of the Internet of things (IoT), 5G and other emerging technologies. Such a globally connected healthcare ecosystem facilitates remote medical services which act as a bridge between medical practitioners and people who are especially in need.

Healthcare IoT opens up seamless opportunities by unleashing possibilities to better implement healthcare services to patients, physicians and hospitals. Patients with wirelessly connected devices can seamlessly track their health conditions and request emergency assistance from physicians and hospitals. Physicians can track or monitor patients' health conditions and respond to immediate medical conditions more proactively and predict conditions based on the data collected from IoT devices. Hospitals can keep track of medical devices embedded with geolocation sensors such as wheelchairs and oxygen pumps to better locate patients.

Taking into account that healthcare IoT has the potential to change people's lives and can deliver a significant impact on the medical domain, an increased interest in this has led to active standardization in various standards development organizations (SDOs). The Open Connectivity Foundation (OCF) defined several healthcare devices which can interoperate with other OCF smart home devices in the OCF ecosystem. IEEE specified the base architecture and device specializations for healthcare and medical devices, which were reflected in Continua guidelines of Personal Connected Health Alliance (PCHA). Health Level 7 International (HL7) provides a common data model framework named Fast Health Interoperable Resources (FHIR). IEC/TC 62 defines international standards for healthcare electrical systems and software.

However, the proliferation of different international healthcare standards has not brought about a wide deployment of healthcare IoT services and business opportunities. The fragmentation of standards hindered the access and usage of developed standards because implementing such standards did not always guarantee interconnectivity and compatibility between services and devices. In addition, it was difficult to assure that such healthcare devices can interoperate with other devices from different silos. Such concerns eventually isolated healthcare devices to communicate with other devices from other domains.

Nevertheless, there have been some efforts in taking advantage of open-source projects as an enabler to better deploy healthcare IoT standards. Most recent and remarkable efforts include the standardization activities in the Open Connectivity Foundation (OCF). The OCF sponsors an open-source project to provide reference implementations of the OCF specifications. IoTivity, an open-source project of the Linux Foundation, is sponsored by the OCF and aims to bring the open-source community together to accelerate the deployment of OCF specifications. The reference implementation of healthcare devices such as blood pressure monitors helps developers to install pre-written code very quickly and allows them to test and enhance the software.

In this paper, the authors develop a case study of their efforts to standardize healthcare IoT with IoTivity, with the OCF. First, the authors conduct a literature review on open-source innovation to provide a theoretical background to the case study. Second, the authors introduce the OCF, its policy called "3-pillar alignment" and IoTivity to illustrate what open-source implementation means to the OCF. Third, the authors discuss how they proposed new healthcare devices and data models and how they eventually published the first healthcare devices in the OCF. Finally, the authors discuss the benefits of taking advantage of IoTivity and how it led to the enhancement of standardization efficiency and acceleration in healthcare IoT.

2. RELATED WORKS

In this section, the authors review relevant literature and studies on open-source innovation to provide a theoretical background to this paper. A large volume of research on open-source innovation has found that such organizational principles and operational culture has attracted competent individuals and organizations. The authors mainly focus on existing findings, especially to understand why open-source innovation and projects attract people and organizations. The review helps us understand why the OCF has put a particular emphasis on taking advantage of open-source projects to provide reference implementations of OCF specifications since its establishment.

2.1 Motivations of open-source software contributors

Motivations of open-source software contributors have always been the leading interest for research on open-source innovation. These studies on open-source innovation claimed that the popularity growth of open-source products and platforms from various perspectives are: career concern [1], ego gratification incentive [2] that motivate programmers to participate in open-source projects, and organization and process of innovation [3]. These authors commonly stressed that the success of an open-source project is attributed to its modularity, fun challenges to pursue and credible leadership.

There also have been studies which summarized five characteristics that have led to the proliferation of multidisciplinary research with regard to open-source innovation. They include impact, transparency, theoretical tension, communal reflexivity and proximity [4]. It is noted that open-source licenses are designed to ensure the rights of future users against appropriation [5]. Nevertheless, there are significant advantages to open source whereby resources and contributors involved in innovation are widely distributed throughout the globe. However, other studies have stressed the drawbacks of open-source innovation such as free-riding [6], loss of productivity and motivation at work [7], and violation of license policy [8].

2.2 Governance, organization and the process of innovation in open-source software projects

Competitive dynamics enforced by open-source innovation in organizations, from the governance perspective, has led to more interest and resolutions to better adoption. It was found that the share of corporate contributions is much larger in large and growing projects [9], which implies that the contributions of companies are growing in volume.

Meanwhile, the operational efficiency potential and business agility of open-source adoption are expected to mitigate the difficulty of accepting new models for designing, developing, testing and deploying network solutions to the telecommunications industry [10]. In this sense, the 2016 World Telecommunication Standardization Assembly (WTSA-16) resolved that the Telecommunication Standardization Advisory Group (TSAG) pursue their work on the benefits and disadvantages of the implementation of open-source projects in relation to the work of the ITU Telecommunication Standardization Sector (ITU-T), as appropriate [11]. More general research on this subject was a review that authors provided a framework which classified six distinctly different ways in which organizations adopt open-source software [12].

Based on the common understanding of open-source innovation and why they attract individuals, the authors proceeded to discuss a specific case of the OCF on how they took advantage of open-source projects to develop healthcare standards.

3. INTRODUCTION TO OCF

In this section, the OCF, its unique policy called "3-pillar alignment" and its open-source project "IoTivity" are introduced to provide a basic understanding of the OCF.

3.1 OCF

Founded in 2014, the OCF comprises of over 400 member companies including Samsung Electronics, Intel, LG Electronics, and Qualcomm to provide an IoT framework that works in various vertical domains including smart home, healthcare, etc. [13] The OCF aims to provide interoperability among IoT devices not only in the OCF ecosystem but also outside OCF boundaries to support multiple verticals. Legacy vertical services are traditionally designed as silos where there are no universal ways to interwork between them. However, the OCF sets its goals to specify and provide a foundational middleware platform for heterogeneous vertical applications. They develop technical specifications to provide a foundational architecture, security, bridging and other requirements, which in turn allow devices, regardless of manufacturers, to communicate between themselves. Table 1 describes the list of OCF specifications and OCF healthcare devices that the authors proposed and

OCF specifications		
OCF Core Specification		
OCF Core Optional Specification		
OCF Bridging Specification		
OCF Resource Type Specification		
OCF Device Specification		
OCF Wi-Fi Easy Setup Specification		
OCF Device to Cloud Services Specification		
OCF Resource to AllJoyn Interface Mapping Specification		
OCF OneM2M Module Class Mapping Specification		
OCF Resource to Zigbee Cluster Mapping Specification]	
OCF Security Specification		
OCF Onboarding Tool Specification]	
OCF Cloud Security Specification		

Table 2 – OCF specification development proc

Process	Description
1	Identify use cases, scope, and requirements
2	Write draft specification
3	Develop open source code and test cases
4	Distribute draft specification for IPR review
5	Publish final specification

defined as part of the OCF Device Specification. The development of OCF healthcare devices are further elaborated in section 4.

The OCF offers RAND-Z as its intellectual property rights (IPR) to facilitate the deployment of OCF technology among members. Offering manufacturer-friendly IPR policies enables the growth of the market by attracting not only large enterprises but also start-ups. After a continuous merger with UPnP and AllSeen Alliance, the OCF has become one of the most significant industrial consortia for IoT standardization. Most recently in November 2018, the OCF announced that OCF 1.0 specifications have been ratified as international standards by ISO/IEC JTC 1 and approved as ISO/IEC 30118 (Parts 1-6) [14].

3.2 3-pillar alignment

Unlike any other industry groups or SDOs, the OCF has a unique policy when developing its specifications: the policy is titled the "3-pillar alignment", which mandates specification developers to provide not only specifications, but also a proof of passing the certification program provided by the OCF, and finally, an open-source reference implementation of the proposed specification. The ultimate goal of 3-pillar alignment is to ensure full interoperability between devices and compatibility to specifications.

The first pillar is the specifications which define baseline functionalities and vertical profiles for OCF devices as described above. The second pillar is the certification program to carry out conformance testing for interoperability

OCF healthcare devices	Releases
Blood pressure monitor	2.0.0
Glucose meter	2.0.0
Body scale	2.0.0
Body thermometer	2.0.0
Heart rate monitor	2.0.4
Pulse oximeter	2.0.4
Sleep monitor	2.0.4
Activity tracker	2.0.4
Continuous glucose meter	2.0.4
Cycling power meter	2.0.5
Cycling speed sensor	2.0.5
Cycling cadence sensor	2.0.5

and validation to OCF specifications. The OCF provides the conformance test tool (CTT) to authorized test laboratories (ATLs) and specification developers to validate devices. Specification developers must define new test cases to the CTT to test whether devices comply with the proposed specification or not. The OCF gives logos to the devices that pass the certification test. The final pillar is the open-source reference implementation of the OCF specifications. Specification developers have to provide a properly working open-source code to guarantee whether the proposed specification is valid or not. The CTT validates the reference implementation. A new specification is allowed to be published if all three pillars are satisfied.

3.3 **IoTivity**

 Table 1 – List of OCF specifications and OCF healthcare devices

IoTivity is an OCF-sponsored open-source project, which implements all mandatory features of the OCF specification along with some optional features [15]. It provides a reference implementation of OCF specifications to ensure interoperability between OCF devices and certification of OCF products. OCF members take advantage of IoTivity because publication of OCF specifications requires opensource implementation and certification. In this sense, IoTivity provides the fastest and the easiest way to develop not only standards but also products. IoTivity can be installed in many IoT devices, even in class 2 constrained devices [16] to minimize CPU load, traffic and bandwidth. IoTivity uses an Apache 2.0 license with its accompanying patent grant.

4. HEALTHCARE SPECIFICATION **DEVELOPMENT IN OCF USING IOTIVITY**

In this section, the authors carry out an in-depth analysis of their standardization efforts for the development of healthcare IoT devices for the OCF specification and how they engaged in open-source reference implementations. The authors primarily focus on the interaction with IoTivity and why using the open-source solution was crucial during the specification development. The authors explain how IoTivity offered a solution to meet the challenge of developing

 Table 3 – OpenAPI code snippet of blood pressure

```
"swagger": "2.0",
"info": {
 "title": "Blood Pressure",
},
"definitions": {
 "BloodPressure": {
  "properties": {
    "systolic": {
     "description": "Systolic blood pressure",
     "minimum": 0.0,
     "readOnly": true,
     "type": "number"
    }.
    "diastolic": {
     "description": "Diastolic blood pressure",
     "minimum": 0.0,
     "readOnly": true,
     "type": "number"
   },
  "type": "object",
  "required": [
    "systolic",
    "diastolic"
  1
 }
```

healthcare applications. Table 2 summarizes the specification development process in the OCF. The table provides an overall view of how the authors developed OCF specifications.

4.1 Identify use cases, scope and requirements

New specification development in the OCF starts with identifying use cases, scope and technical requirements. In this sense, the authors proposed the Healthcare Project to initiate standardization on healthcare IoT. The objective of the new group was to evaluate use cases, derive interoperability requirements and develop technical specifications for the healthcare vertical within the framework of the OCF.

The goal of the specification was to define OCF healthcare devices in healthcare, fitness and medical domains of the OCF ecosystem. Regardless of devices, the authors proposed a simplified operational scenario which involves OCF servers (e.g. body scale, glucose meter, etc.) and OCF clients (monitoring devices such as smartphones). Eventually, the collected data could be used for tracking users' fitness conditions or transferring them to medical institutes to receive remote services. The technical requirements for healthcare specifications were to provide additional healthcare device types and data models and, if deemed necessary, additional functional requirements to be added to the core specification [17].

The authors also emphasized that healthcare IoT devices could keep track of the people at risk of developing chronic disease and manage their ailments. These devices can weave into everyday lives, seamlessly collect activity metrics, and encourage maintaining healthy behaviors. Furthermore, the authors stressed that standardizing the healthcare ecosystem was the way forward to ensuring peer to peer independence, user's confidence and data, which eventually lead to actionable business insights. Since the healthcare industry is affected by many regulatory bodies, the new group intended to account for privacy, security and global regulatory bodies. The OCF approved the establishment of the Healthcare Project and the specification development was initiated.

4.2 Write draft specification

Defining a new OCF device is twofold: Specify the behavior and requirements of a new device, and design any necessary data models which need to support the new device. The authors leveraged the existing core functionalities including the protocol used for transmission [17], data modeling practices [18], and security [19] to ensure the OCF healthcare devices are interoperable with other OCF devices from different silos.

The authors designed each healthcare device as follows. The authors specified a minimal set of resources that shall be implemented by the device and an additional optional set of resources that may be exposed by the device. A blood pressure monitor, for example, must expose blood pressure information (systolic blood pressure, diastolic blood pressure, etc.) but may expose mean arterial pressure (MAP), pulse rate, units (mmHg or kPa), associated timestamp [20] and user identification. Defining mandatory and optional resources separately allowed minimizing payload transmitting between OCF devices.

Next, the authors defined healthcare data models based on the OpenAPI specification [21]. The OpenAPI specification is an open-source project which defines programming language-agnostic RESTful APIs. The specification is expressed by Swagger [22]. Table 3 is a snippet of authors' proposed data model for blood pressure. The data model is uploaded to OCF Github [23] and oneIoTa [24], which is the OCF's official web-based data model repository. The data model specifies how blood pressure data shall be exposed on the wire. For example, all systolic blood pressure communicated within the OCF must be a read-only floating number titled "systolic" whose minimum value is 0. The proposed data model was approved by OCF reviewers as final prior to open-source development because the opensource reference implementation had to comply with the predefined approved data model.

In addition, the authors defined an additional functionality and requirement to the core specification [17] to ensure better interoperability among OCF devices. In certain use cases, healthcare devices require that the information of multiple resources be only accessible as a group and individual access to this information of each resource by an
Table 4 – C++ Code snippet of blood pressure monitor

//
// Title: [IoTivity][Blood Pressure Monitor] Linked Resource Type: Blood Pressure
// Description: Defines "oic r blood pressure" and its behaviors
//
OCRepPayload* getBP1Payload(const char* uri)
{
OCRenPayload* navload = OCRenPayloadCreate():
if(Insuland)
n(:payload)
{
OIC_LOG(ERROR, TAG, PCF("Failed to allocate
Payload"));
return nullptr;
}
size t dimensions $[M\Delta X REP \Delta RR\Delta Y DEPTH] = \{0\}$
$SIZE_t unitensions[imm_references] = [0];$
dimension = [0] 1.
dimensions[0] = 1;
char * rtStr[] = {"oic.r.blood.pressure"};
OCRepPayloadSetStringArray(payload, "rt", (const char
**)rtStr, dimensions);
OCRepPayloadSetPropString(payload, "id",
"user example id").
OCPanPauloadSatPronInt(navload "systelic" ();
OCRept ayloadsett topint(payload, systolic, 0),
OCREPPayloadSelPropint(payload, diastone, 0);
OCRepPayloadSetPropString(payload, "units", "mmHg");
return payload;

OCF client is prohibited. For example, users need to be able to retrieve their blood sugar level and the time of measurement simultaneously from his or her glucose meter, in order to properly keep track of the daily glucose level fluctuation. In this sense, the authors named this additional feature as "atomic measurement" and defined its common properties, normative behavior, security considerations and other requirements. The proposal was also drafted but had to be discussed at a different group (Architecture Task Group) where the Core Specification [17] is developed.

4.3 Develop open-source code and test cases

While the authors were developing the specification for new healthcare devices and additional functional requirements, they had to simultaneously develop the open-source reference implementation of the proposed specification and test cases for the certification and CTT.

In the OCF, developers are free to choose any open-source code for reference implementations. Similarly, the authors had the freedom to choose from existing open-source projects which implement OCF specifications or could start from scratch. As introduced above, IoTivity has been an OCF-sponsored open-source project since the establishment of the OCF. The project was initiated and developed by architects of Intel and Samsung Electronics, and periodically published stable releases. Any developers can download, fork, commit and contribute to the existing project to file bugs and improve the code. The authors thus decided to take advantage of the existing architecture and APIs of IoTivity using C/C++ [25].

First of all, the authors wrote a C/C++ code which encapsulates the requirements and functionalities of the proposed additional functional requirement (atomic measurements), which had the potential to affect the core specification [17]. There existed two ways to develop: first was to modify the core code of IoTivity by adding new APIs to the IoTivity library [25] with regard to the new functional requirement, and second was to build an application which runs on top of the existing core IoTivity code but not adding new APIs to the IoTivity library. The authors chose the latter because building a separate application would save much more time.

In this sense, the authors developed a proof of concept (PoC) of blood pressure monitor reflecting the atomic measurements requirements and uploaded to GitHub for peer review [26]. Table 4 is a C/C++ code snippet which describes the payload transferred from the blood pressure monitor. The payload had to comply with not only the schema in Table 3 but also the atomic measurement requirements that the authors proposed. Thus, several APIs defined in IoTivity C SDK [27] and IoTivity C++ SDK [28] were used to describe the payload. For example, OCRepPayloadCreate() function was used to create а new payload and OCRepPayloadSetPropInt() was used to set an integer property to that payload. Meanwhile, the way to encapsulate the overall payload and send them on the wire required certain routines of combining functions and triggering error messages. Taking advantage of the existing SDK allowed the authors to easily duplicate, test and eventually improve the deliverables in the future.

Finally, the authors proposed new healthcare device definitions and asked for a pull request by adding lines of device and resource definitions in JSON format to the OCF's GitHub repository where the OCF manages all device, resource and enumeration definitions [29]. In the repository, there is a folder where the information of the device specification in a machine-readable format is stored. This repository intends to provide the information in a machine-readable format for CTT, which in turn, ensures the latest information of OCF devices for certification program. The pull request was eventually merged as final.

Concurrently, the authors had to develop test cases while developing the code. Test cases in the OCF aim to verify if the written code well complies with the specification. All mandatory requirements of OCF specifications must have corresponding test cases which ensure compatibility and interoperability of OCF devices. The test cases should be able to run in all OCF devices regardless of manufacturers and platforms. The approach here for authors was also twofold: the test cases for mandatory resources of each healthcare device and the test cases for atomic measurement. The authors developed all necessary test cases, and the test cases were incorporated into the CTT. The CTT was eventually ready for Plugfest, which is an official OCF interoperability and compatibility certification event for OCF members to test their device against the CTT and the OCF devices of other companies.

Figure 1 – Healthcare PoC at CES 2018



4.4 Distribute draft specification for IPR review

When all three pillars, including the specification, the test cases for certification, and the open-source reference implementation, were considered stable enough by OCF members, the draft specifications including the new healthcare devices and data models were put through IPR review. In general, the OCF posts new draft specifications for 60-day member IPR review when the test cases and opensource code are also ready for distribution. The comments are subsequently submitted to the OCF and are reviewed by the relevant members if deemed necessary. If any OCF members intend to exclude necessary claims from the OCF's IPR policy, they must provide a complete, appropriate and timely written notice of such intent to the OCF, no later than the IPR review deadline. Since sufficient discussion was made during the specification development and data models, the authors received no additional comments with regard to the new healthcare devices and data models.

4.5 Publish final specification

After the IPR review, the OCF published the new healthcare devices and data models as part of OCF 2.0.0 Specification in June 2018 [30]. Publication of new OCF specifications implies full support of certification and open-source reference implementation. In addition to the first four published healthcare devices, the authors defined five additional healthcare devices, which in turn, were published as part of OCF 2.0.4 Specification in July 2019.

5. DISCUSSION

In this section, the authors discuss the benefits of taking advantage of IoTivity and how it has led to the enhancement of standardization efficiency and acceleration in healthcare IoT.

5.1 Enhancement of standardization efficiency

The main benefits of using IoTivity as an enabler was to improve the development efficiency of the reference implementation of the OCF healthcare specification. Typically, sharing the same open-source project allows developers to share best practices among peers while using the code. These peer IoTivity developers may contribute to the IoTivity project hoping for better promotion [1], or perhaps pursuing self-satisfaction [2]. Regardless of their motivations, such reference implementations lowered the boundaries of OCF specifications, and it was clear that IoTivity led to better organizational innovation [3] because the authors fully benefited from the existing code provided by IoTivity and its contributors. The authors were able to spend dramatically less resource compared to what the authors might have spent when developing from scratch. The authors found that it is especially useful in the healthcare domain because developers can put more efforts on privacy, security and other regulatory aspects, which is considered much stricter than those in the smart home domain.

The authors stress that reference implementations using open source enhances standardization efficiency. There is a considerable population of companies, start-ups and hobbyists who are low on resources but interested in developing applications and products based on the published standards. An open-source community discloses extensive opportunities for those who need help from external experts around the world. Requesting a public review by other experts can decrease debugging time. Also, it accelerates better exposure and deployment of emerging technology standards. It must also be noted that free-riding [6] by other stakeholders could discourage development. However, it is highly recommended to use appropriate open-source licenses to protect ownership and track history of code change [5].

5.2 Acceleration in healthcare IoT

Developing reference implementation using IoTivity opened the potential and accelerated the healthcare IoT best practices of IoT application developers. Reference implementation eventually allowed manufacturers of other domains to connect healthcare devices to their devices. When the authors developed their PoC, the IoTivity code was also used and developed by other OCF members who were smart home device vendors. Thanks to the same code base, which acted as the same foundational software architecture, the IoT devices from different domains were able to be tested with less challenge.

The active corporate participation and contribution to IoTivity lured more member companies into joining IoTivity. While contributions were growing in volume [9], the OCF was able to exhibit the devices of its members at CES 2018. The devices were developed with IoTivity. At CES 2018, The authors presented their healthcare PoC, including blood pressure monitors, body thermometers, body scales and other healthcare devices. The devices were able to connect and interoperate with other smart home devices. Figure 1 displays a user's health information, which was measured using healthcare devices developed by the authors, to another OCF member's refrigerator. The exhibition at CES 2018 provided the viewers with insight on how the future of healthcare IoT would look like upon its realization.

6. CONCLUSION

In this paper, the authors discussed the standardization of healthcare IoT at the OCF while focusing on IoTivity as its

enabler for the reference implementation. First, a literature review on open-source innovation was carried out to provide a theoretical background to this paper. Second, the OCF, "3pillar alignment" and IoTivity were introduced to offer a contextual background to this paper. Third, a case study on the authors' efforts to specification development for healthcare devices in the OCF using IoTivity was illustrated. Finally, the benefits of taking advantage of IoTivity and the implications for better enabling healthcare IoT standardization were discussed.

6.1 **Prospective future works**

IoTivity was discussed as a best practice for a reference implementation of OCF specifications, as well as an enabler of facilitating the healthcare IoT. To harmonize with other SDOs outside the OCF, however, ensuring interoperability between different healthcare standards groups using a universal healthcare bridge could be a next step forward. The OCF has already defined an OCF bridging specification to specify a high-level framework to translate between OCF devices and other ecosystems [31].

However, work on developing a specific healthcare interface mapping standard is not yet initiated. For example, HL7 FHIR specifies over 100 data formats and elements, APIs to exchange electronic health records (EHR) in the medical domain [32]. Similar to IoTivity, there exists an open-source project called HL7 Application Programming Interface (HAPI) to provide reference implementations of HL7 FHIR [33]. In this sense, connecting the OCF and HL7, by developing an interface mapping standard could surely bring synergy not only to the OCF and HL7 but also to future healthcare IoT ecosystems. Such prospective work could be accompanied by IoTivity and other possible open-source activities for developers to understand the collaborating standard more rapidly.

6.2 Proposed efforts to ITU-T

International standards organizations are recognizing the importance of open-source innovation. The WTSA-16 instructed all applicable and relevant Study Groups of the ITU-T, to consider output from TSAG on open source mentioned in section 2, within available financial resources, to study the benefits of using open source to develop reference implementations of ITU-T Recommendations [11]. Likewise, JTC 1 recently reconstituted the Advisory Group on Open Source Software (ISO/IEC JTC 1/AG 3) to assess JTC 1's current and potential requirements and opportunities with regard to open-source software [34]. The ISO/IEC JTC 1/AG 3 also seeks to identify areas where open-source software can be used to initiate or accelerate standardization projects and work programs within JTC 1 scope.

ITU-T requires industry's adoption and exposure of their Recommendations. One possible way to facilitate the adoption and exposure of their Recommendations is granting incentives when standards developers provide reference implementations of Recommendations. For example, inside the ITU-T's template for A.1 justification for a new work item (NWI) proposal [35], a new line asking for plans for reference implementations of Recommendations could be added. By the time of completion of the Recommendation, the draft Recommendation could be evaluated and consented based on the reference implementation, which complies with the proposed Recommendation.

From the technological perspective, developing reference implementations would require Recommendation developers to take advantage of existing open-source projects to save time and resource. During code development, developers would seek guidance for external experts, which will in turn, produce more mature deliverables. From the marketing perspective, active participation in open-source projects would result in better promotion and exposure of ITU-T Recommendations.

Taking into account some best practices in the industry including IoTivity, the authors strongly recommend that ITU-T, within their core mandates, continue their efforts to seek the roles of open-source implementation for faster and equal adoption of not only healthcare IoT but also their overall Recommendations. Such efforts could lead to the active participation of developers who can provide codes immediately applicable to production and deployment, which helps companies who are especially in need of standardization development resources. Such practice could adoption eventually facilitate wider of ITU-T Recommendations.

7. ACKNOWLEDGEMENT

This work was supported by the Institute for Information & communications Technology Promotion (IITP) grant funded by the Korea government (MSIT) (No. 2019-0-00137, Standards Development of Platform and Networking Interworking for IoT Interoperability).

REFERENCES

- J. Lerner and J. Tirole, "Some Simple Economics of Open Source," *J. Ind. Econ.*, vol. 50, no. 2, pp. 197–234, Mar. 2003.
- J. Lerner and J. Tirole, "The Economics of Technology Sharing: Open Source and Beyond," J. Econ. Perspect., vol. 19, no. 2, pp. 99–120, 2005.
- [3] G. Von Krogh and E. Von Hippel, "The Promise of Research on Open Source Software," *Manage. Sci.*, vol. 52, no. 7, pp. 975–983, 2006.
- [4] G. Von Krogh and S. Spaeth, "The open source software phenomenon: Characteristics that promote research," *J. Strateg. Inf. Syst.*, vol. 16, pp. 236– 253, 2007.

- [5] G. Von Krogh and E. Von Hippel, "Special issue on open source software development," *Res. Policy*, vol. 32, pp. 1149–1157, 2003.
- [6] C. Y. Baldwin and K. B. Clark, "The Architecture of Participation: Does Code Architecture Mitigate Free Riding in the Open Source Development Model?," *Manage. Sci.*, vol. 52, no. 7, pp. 1116– 1127, 2006.
- [7] C. Melian and M. Mähring, "Lost and Gained in Translation: Adoption of Open Source Software Development at Hewlett-Packard," in *International Federation for Information Processing 2008*, pp. 93–104, 2008.
- [8] M. Henley and R. Kemp, "Open Source Software: An introduction," *Comput. law Secur. Rep.*, vol. 24, pp. 77–85, 2008.
- [9] J. Lerner, P. A. Pathak, and J. Tirole, "The Dynamics of Open-Source Contributors," *Am. Econ. Rev.*, vol. 96, no. 2, pp. 114–118, 2006.
- [10] S. A. Wright and D. Druta, "Open source and standards: The role of open source in the dialogue between research and standardization," in 2014 IEEE Globecom Workshops (GC Wkshps), pp. 650– 655. 2014.
- [11] Proceedings of WTSA-16: https://ituk2019.page.link/nM9x
- [12] Ø. Hauge, C. Ayala, and R. Conradi, "Adoption of open source software in software-intensive organizations - A systematic literature review," *Inf. Softw. Technol.*, vol. 52, no. 7491, pp. 1133–1154, 2010.
- [13] Open Connectivity Foundation (OCF): https://ituk2019.page.link/sReo
- [14] OCF official announcement of ratification of International Standards: <u>https://ituk2019.page.link/4xSE</u>
- [15] IoTivity: https://ituk2019.page.link/KPM8
- [16] RFC 7228 Terminology for Constrained-Node Networks: https://ituk2019.page.link/EBMe
- [17] ISO/IEC 30118-1:2018 Information technology --Open Connectivity Foundation (OCF) Specification -- Part 1: Core specification: <u>https://ituk2019.page.link/oySD</u>

- [18] ISO/IEC 30118-4:2018 Information technology --Open Connectivity Foundation (OCF) Specification -- Part 4: Resource type specification: <u>https://ituk2019.page.link/ey3j</u>
- [19] ISO/IEC 30118-2:2018 Information technology --Open Connectivity Foundation (OCF) Specification -- Part 2: Security specification: <u>https://ituk2019.page.link/B8Ro</u>
- [20] RFC 3339 Date and Time on the Internet: Timestamps: <u>https://ituk2019.page.link/uUB8</u>
- [21] OpenAPI Specification: https://ituk2019.page.link/2m6g
- [22] Swagger: https://ituk2019.page.link/8h2g
- [23] Blood pressure definition in OpenAPI (GitHub): https://ituk2019.page.link/g8n6
- [24] Blood pressure definition in OpenAPI (oneIoTa): https://ituk2019.page.link/DLNP
- [25] Official repository of IoTivity: https://ituk2019.page.link/3cXL
- [26] Reference implementation of blood pressure monitor: <u>https://ituk2019.page.link/tega</u>
- [27] IoTivity C SDK: https://ituk2019.page.link/wHgA
- [28] IoTivity C++ SDK: https://ituk2019.page.link/pWaL
- [29] Information of the OCF device specification in machine readable format: <u>https://ituk2019.page.link/cx9A</u>
- [30] OCF The OCF Healthcare Project: Improving health outcomes through IoT data: <u>https://ituk2019.page.link/9i2F</u>
- [31] ISO/IEC 30118-3:2018 Information technology --Open Connectivity Foundation (OCF) Specification -- Part 3: Bridging specification: <u>https://ituk2019.page.link/U3E6</u>
- [32] HL7 FHIR: https://ituk2019.page.link/1nmD
- [33] HAPI FHIR: https://ituk2019.page.link/bjy4

- [34] ISO/IEC JTC 1 Information technology: https://ituk2019.page.link/NW44
- [35] ITU-T Templates: https://ituk2019.page.link/xcWS

EMPIRICAL STUDY OF MEDICAL IOT FOR PATIENTS WITH INTRACTABLE DISEASES AT HOME

Kentaro Yoshikawa^{1,2}; Masaomi Takizawa³; Akinori Nakamura¹ and Masahiro Kuroda⁴

¹Shinshu University School of Medicine, Japan ²Nagano Prefectural Kiso Hospital, Japan ³Central Corridor Communications 21, Japan⁴Goleta Networks Co. Ltd <u>yoshikaw@shinshu-u.ac.jp; takizawa@ccc21.co.jp; anakamu@shinshu-u.ac.jp; marshkamakura@yc5.so-net.ne.jp</u>

ABSTRACT

Telemedicine for chronic disease management is extending to the home through the use of medical devices and ICT technologies. Patients with intractable diseases, such as lateral sclerosis (ALS) and lethal amyotrophic neurodegenerative diseases, have been returning to their homes rather than remaining hospitalized. Reliable alarms for condition changes of patients and burden reduction of their families are taking root as foundations of telemedicine for patients with intractable diseases. This paper discusses reliable alarm delivery and expected medical IoT features for those patients. A patient's family has difficulty in setting optimal parameters of life-support medical devices following patient condition changes. Also, caregivers and patients' families expect reliable alarms and false alarm reduction from tele-alarm systems used at home. We need to provide both anxiety relief for patients' families and patient safety by reliably monitoring the patients. We designed and implemented an alarm delivery system for patients with intractable diseases, and here we propose a prototype falsealarm reduction mechanism for highly-controlled medical device systems including an artificial ventilator. We investigated alarms of a patient for one year, cooperating with the patient's family. We need both hardware standard interfaces and consistent alarm functions between artificial ventilators. We conclude with our further work for patients with different types of intractable diseases and for standardization of medical IoT networks integrating falsealarm reduction systems.

Keywords – Artificial ventilator, crying wolf, false alarm, intractable disease, medical IoT, telemedicine

1. INTRODUCTION

The number of patients with intractable diseases is increasing worldwide. The increasing number of ventilatordependent patients is exceeding the capabilities of hospitals and health organizations, shifting the burden of chronic care to patients' families. The need to reduce the burden on caregivers and to increase safety has accelerated the development of remote monitoring for home ventilator assistance [1], even though there are still legal issues associated with remote patient care. In cases of monitoring those patients remotely, critical events are false positive alarms and floods of similar alarms generated by highlycontrolled medical devices. These events cause alarm fatigue not only in professional caregivers but also in families. There have been trials reducing the number of these events in hospitals intensive care units (ICUs), but the need for home care means that we also need to deal with intractable-disease patients at home. There are investigations and discussions on alarms at ICU in hospitals [2-3]. Along with the trend to extend the use of highly-controlled medical devices, such as an artificial ventilator, to the patient's home, we need to tackle technical issues on alarms and also the management of the devices.

Medical devices have been developed for hospital use and have proprietary functions to output alarm sounds and to provide nurse calls via a wired interface [4]. When these devices are used at home, users need to carefully integrate and operate them in their home network. A user needs to know the detailed meanings of functions in sophisticated devices provided by manufacturers and to understand the meaning of the data. In hospitals, medical doctors and engineering staff take care of these issues, whereas at home it is difficult for them to be taken care of by the patient's family. There are two ways to develop standard interfaces and procedures reducing the burden that artificial ventilators impose upon medical doctors, visiting nurses and patient families. One is to integrate any artificial ventilator following a standard operating interface and the other is to provide consistent alarm functions between ventilators.

In this paper, we first introduce a tele-alarm system and explain real alarm-related issues. We explain issues that must be dealt with when managing a highly controlled medical device, such as an artificial ventilator, at home. We then describe and discuss an approach to integrate various ventilators manufactured by different companies expecting standard operating interfaces. We propose a software framework to integrate with a home IoT network and describe our implementation of an alarm delivery system for patients with intractable diseases and of a prototype falsealarm reduction system having an interface to connect various highly-controlled medical devices including an artificial ventilator. When consistent alarm functions are defined, they can be designed in various false-alarm reduction systems. We investigated alarms of a patient for one year in cooperation with the patient's family and discussed false alarm reductions that are required especially for home use. We raise issues and conclude with our further work for patients with different types of intractable diseases and for standardization of alarms and their treatment in medical IoT networks integrating false-alarm reduction systems.

2. BACKGROUND AND RELATED WORKS

2.1 Tele-alarm experimental system

The use of life supporting devices, such as an artificial ventilator, at home is increasing rapidly. Accompanying this use, emergency situations, such as accidents, are often reported. It is required to equip networked alarms along with the device uses at home. Artificial ventilators are used in medical facilities under the management of caregivers, but even there, it is better to have network functions to deal with emergency situations. It is also important to have patient data monitored by multiple caregivers who can respond quickly to a change of a patient's condition.

We have implemented a tele-alarm system in Figure 1 with a patient care team consisting of medical doctors, nurses, medical engineering staff, and so on to quickly respond to alarms.



Figure 1 - Tele-alarm system

The system supports multiple patients at home and multiple caregivers and reduces the load of each caregiver, but we found differences in the meanings of alarms among artificial ventilators, and some devices do not have the interface needed to deliver alarms remotely.

2.2 Proprietary alarm delivery function

Along with the number of uses, severe sequelae or death cases are increasing because medical staff do not always notice alarm events immediately.

Most artificial ventilators have a nurse-call switch which is implemented as a means to inform caregivers of an urgent situation caused by delayed notice of an alarm sound. Most ventilators are equipped with an emergency call connector, and each model is connected to a gateway server by a connector.

There are two types of connecters to plug in a gateway, one using a cable with 3 core wires for detection of cable disconnection and the other using 2 core wires. The left figure and photo in Figure 2 show the normally closed (NC) type connection of an HT70Plus ventilator using a 3-core wire cable, whereas the right figure and photos show the normally open (NO) type connection of a Vivo50 ventilator using a 2-core wire cable. Each ventilator uses either type of connections.



Figure 2 - Alarm transmission via nurse-call connector

The NC method is safer than the NO method because the NC can detect a hardware failure, such as a cable disconnect. The NC method is preferable for a connection between a ventilator and a gateway that transfers alarm data to an outside network. The need for such a connection is evident, but the interface to raise an alarm is not standardized yet.



Figure 3 - Experimental scheme of vital signs and alarm delivery

It is important to determine the emergency condition of a patient from the alarm category and vital signs data at the same time when an alarm is raised. We used five off-theshelf artificial ventilators. The experimental transmission of vital signs data and alarms is shown in Figure 3. We have implemented the delivery of physiological data and alarm signals by the following three methods depending on available interfaces. The first type uses a USB or UART interface to send data and alarm signals to a gateway (HT-70plus manufactured by COVIDIEN Co., Ltd.-USA, Vivo 50 manufactured by BREAS Co., Ltd, Sweden). The second type has only a nurse call. We converted the nurse call signal to an alarm signal at a gateway and transmitted it to the Internet (Monnal T50 manufactured by the IMI, France and Trilogy 100 manufactured by Philips, Netherlands). The third type uses a LAN port to integrate physiological data and alarm signals and to send to a server. At the same time, the notification message is delivered to caregivers according to the alarm level [5] (Figure 4).



Figure 4 - Ventilators (left) and experimental ventilator using LAN (right) in test

In addition to the connection interface, we acknowledged differences in the alarm-call signal tone, the alarm action procedure, the alarm signal duration and flexibility in the alarm signal setting between them. These differences prevent home use. We need to standardize the device hardware interface to provide safer alarming and the software interface to translate alarm events into common meanings between medical devices used for the same medical purposes.

2.3 Medical IoT system at home

A Medical IoT system for a patient with intractable diseases at home is expected to provide easy-to-use interfaces to the caregivers. In the system, a highly-controlled medical device sends not only vital data but also information which is used to set optimal parameters of the device depending on condition changes of the patient. The parameter changes should be done by a medical doctor, but at home it may be difficult to work on them in a timely manner.



Figure 5 - Medical IoT model and roles

In future medical IoT system, once consistent alarm functions are standardized between medical devices used for the same purposes, information and instructions may go directly to a medical device associated with the patient through a caregiver such as a medical doctor and the patient family member shown in Figure 5 [6]. The caregiver analyzes data and information and sends instructions for the device to the patient family member.

3. RELIABLE ALARM DELIVERY AND OPTIMAL OPERATION

Reliability and efficiency are important for intractabledisease patients in the hospital and at home. Alarms are used to indicate when physiologic parameters monitored in critically ill patients are abnormal. In typical cases, multiple alarms are raised but are not specific to patient treatments. They have a negative impact on the quality of patient care. Caregivers of patients need minimal and specific alarms relevant to their patients' conditions.

There are discussions on advantages of IoT devices in medical use. A medical IoT application can change the operating conditions of an artificial ventilator according to the instruction of a medical doctor referencing data received from various medical devices. At home, a family member is close to his or her patient and can provide quick actions anywhere in the house when a home network is provided. The family member may be in another room in the house and an alarm is transferred from network connecting medical devices to a home device in another home IoT network.

3.1 System configuration

An alarm delivery system consists of two components. LANenabled components are made up of highly-controlled medical devices, such as a pulse oximeter and artificial ventilator, and a gateway in which an alarm platform manages data and alarms including nurse call signals. The alarm platform collects sensor data, alarm data and emergency alerts, and it transfers this information to a smart alarm IoT platform in a cloud. Alarms are transferred to the home network IoT platform in the cloud and delivered to the home network located in the same house that the LANenabled system is in. Each medical device generates an alarm event when conditions change, and those events come to the gateway. The alarm and related information are analyzed and the results are delivered to a person close to the patient or to a remote person in the home IoT platform.



Figure 6 - Alarm delivery system configuration

3.2 Alarm analysis

We have implemented an alarm delivery system integrating an artificial ventilator and pulse oximeter with cooperation of the family of a pediatric patient with intractable disease under the study approval at the ethics committee in Kiso Hospital, Nagano, Japan. The patient was attached to an artificial ventilator and pulse oximeter at night. In order to reduce false alarms, we collected and analyzed alarm data from medical devices for one year from 1 June 2018 to 31 May 2019.

The total number of measured days was 327 days in the case of the artificial ventilator and 269 days for the pulse oximeter. The existence of unmeasured days are caused by the patient's social hospitalization to make caregivers rest and the disconnection of cables between medical devices and the gateway.

For each alarm code, we summed up the number of times for occurrence, frequency in a day and average duration. The alarms on the pulse oximeter accounted for 90% of *motion*, and the frequency exceeded 1200 times per day as shown in Table 1. The alarm means the patient's body movement and clinical emergency is low. We understood that the *motion* should be reduced to prevent alarm fatigue of caregivers.

Five alarms (*pulse_search*, *sensor_off*, *loss_of_pulse*, *loss_of_pulse_with_motion*, *no_sensor*) associate with a connection between sensors and a patient, and clinical emergency of these alarms are also low in short time. The frequency of these alarms is 9.8% in the pulse oximeter. Three alarms (*spo2_lo*, *pulse_rate_lo*, *pulse_rate_high*) associate with vital signs of a patient, and clinical emergency of these alarms are high. The frequency of these alarms is 0.6% in the pulse oximeter.

In ventilator alarms, *peak_press_insp_lo* (*peak air way pressure on inspiration is lower than the setting*) is the most

frequent, as shown in Table 1. The alarm is mainly caused by an intentional and temporal removal of the respiration circuit by a caregiver for suction of sputum or change of the patient's body position. An accidental removal may also be a possible reason. The second most frequent alarm is *peak_press_hi* (*peak air way pressure is higher than the setting*). This alarm is mainly caused by obstruction of the air way by sputum or secretion. These alarms are clinically important to prevent artificial ventilator associated accidents.

Table 1 - Frequency and duration of alarms

	-		Frequency		D	Juration	[sec]		Elapsed
Alarm Code	Count	%	[/day]	Min	25%	Median	75%	Max	time
Pulse Oximeter									
motion	139811	90	1260	2	2	2	4	114	
pulse_search	5259	3.4	47.41	2	2	2	6	94	
sensor_off	3662	2.4	33.01	2	2	4	6	148	
loss_of_pulse	3603	2.3	32.48	2	2	2	4	66	
loss_of_pulse_with_motion	2071	1.3	18.67	2	2	4	6	98	110 days
spo2_lo	662	0.43	5.968	2	2	6	8	70	22:10:45
pulse_rate_lo	246	0.16	2.218	2	2	4	8	94	
pulse_rate_hi	4	0.026	0.03606	4	6	8	31	92	
no_sensor	1	0.00064	0.009015	8	8	8	8	8	
Subtotal	155319	100	1400	2	2	2	4	148	
Artificial Ventilator									
peak press insp lo	13304	89	94.26	1	3	4	6	214	
peak press hi	1075	7.2	7.616	1	2	3	4	11	
insp time over 2	361	2.4	2.577	1	2	2	3	4	141 days
others	173	1.2	1.226	1	1	1	1	2	3:21:28
Subtotal	14913	100	105.7	1	3	4	5	214	
Total	170232		1506	1	2	2	5	214	

3.3 False alarm reduction

We found differences in alarm-related functions between artificial ventilators provided by different manufacturers. To manage medical devices appropriately, we need to understand alarms of each device behavior, as there looks like there are no standard specifications to handle from clinical viewpoints [7-8].

Our alarm delivery system analyzes alarm information, such as alarm signals and vital signs data, and provides the information and data to the most appropriate caregivers. The escalation service depending on the type of alarms and their time duration may be needed to provide better and the most suitable treatment for a patient.

The system deals with the following situations: An alarm condition happens, but it lasts a very short time, less than 2 seconds. The system should be smart enough not to raise a false alarm. The system also takes care of alarm timing. For example, when an alarm condition lasts for a short time, the system may not raise an alarm immediately; instead it raises an alarm when the condition lasts beyond a threshold number of seconds.

We propose a prototype false-alarm reduction method using the duration of pulse oximeter and artificial ventilator alarm conditions. Alarm priority is determined by the alarm duration, and there are different threshold durations for different kinds of alarm. If the alarm duration exceeds an escalated threshold, the alarm managing state is escalated from alarm-priority Low (L) to alarm-priority Middle (M) or from M to alarm-priority High (H). The alarm priority and escalation method are referred to IEC 60601-1-8 [9]. Figure 7 shows the relationship between three alarm priorities and the medical treatments. When an escalation occurs, alarm priority changes from a lower level to a higher level, as specified in Table 2.



Figure 7 - Decision of alarm priority and medical treatment assuming alarm-priority "Middle"

Table 2 - Alarm priority and time duration for notification

Alarm Cada	In	itial Alarm	Esc	alated Alarm
Alarm Code	Priority	Duration [sec]	Priority	Duration [sec
Pulse Oximeter				
motion	-	-	-	-
pulse_search	L	> 6	M	> 12
sensor_off	L	> 6	М	> 12
loss_of_pulse	L	> 4	M	> 8
loss_of_pulse_with_motion	L	> 6	M	> 12
spo2_lo	M	> 8	н	> 16
pulse_rate_lo	M	> 8	н	> 16
pulse_rate_hi	M	> 31	н	> 62
no_sensor	L	> 8	M	> 16
Artificial Ventilator				
peak_press_insp_lo	M	> 6	н	> 12
peak_press_hi	M	> 4	Н	> 8
insp time over 2	M	> 3	н	> 6

The motion alarm is removed 100%, because it appears very frequently with very low clinical emergency. When other alarms continue over the third quartile (75%) of duration of the alarm code on Table 1, the system notifies caregivers as an initial alarm priority. The alarm time, then, lasts over two times that of the duration; alarm priority is escalated to upper alarm priority. Alarms associated with the connection between sensors and a patient (pulse_search, sensor_off, loss_of_pulse, loss_of_pulse_with_motion, no_sensor) start from low emergency. Alarms associated with the physiological status of a patient (spo2_lo, pulse_rate_lo, *pulse_rate_high*) start from middle priority. Three alarms (*peak_press_insp_lo, peak_press_hi, insp_time_over_2*) associated with patient respiration in the artificial ventilator start from middle priority. Other alarms in the artificial ventilator were omitted, because they are inner status information of the artificial ventilator and the clinical meanings of the events are unclear from a clinical viewpoint. They are also of very short duration and low frequency. The false alarm reduction rate of this method is estimated to be 95.5%, as shown in Table 3.

In the current environment, all highly managed medical devices raise alarms when unusual conditions are detected, even if the conditions are due to regular suction use. Lots of alarms are raised and it may be difficult to find real alarms among them. Caregivers, therefore, sometimes disable alarm functions.

Table 3 - Expected a	larm reduction	effect
----------------------	----------------	--------

Alexand Orde	a .		Expected Alar	m Reduction
Alarm Code	Count	Reduction Rate [%] -	Count	Rate [%]
Pulse Oximeter				
motion	139811	100	139811	
pulse_search	5259	75	3944	
sensor_off	3662	75	2747	
loss_of_pulse	3603	75	2702	
loss_of_pulse_with_motion	2071	75	1553	
spo2_lo	662	75	498	
pulse_rate_lo	246	75	185	
pulse_rate_hi	4	75	3.0	
no_sensor	1	75	0.75	
Subtotal	155319		151442	97.5
Artificial Ventilator				
peak_press_insp_lo	13304	75	9978	
peak_press_hi	1075	75	806	
insp_time_over_2	361	75	271	
Subtotal	14913		11055	74.1
Total	170232		162497	95.5

4. CONCLUSION AND FUTURE WORKS

We designed and implemented an alarm delivery system for patients with intractable diseases that can be integrated with home networks used for medical IoT networks. We proposed a prototype false-alarm reduction mechanism for highlycontrolled medical device systems including an artificial ventilator. We investigated alarms for one year in cooperation with a patient's family. We focused on alarm duration of alarm codes and decided initial and escalated alarm priorities with trigger duration to notify caregivers from a clinical viewpoint. We are currently working on the next step of alarm optimization in systems having various highly-controlled medical devices and on operational optimization taking advantage of medical IoT network features.

After that we need to tackle standardization of alarms and the treatments that are suitable for home use. The alarms are raised depending on medical devices manufactured by different companies. To use them at home, we need to establish medical treatments following standard meanings for the same category of medical devices. There are standards, such as IEEE 11073-10404[10] which is device specialization of a pulse oximeter on IEEE 11073-20601[11]. But it defines low-level specifications to connect to networks and is not aimed at alarm management. There is still no device specialization of artificial ventilators on IEEE 11073-20601. IHE (Integrating the Healthcare Enterprise) PCD (patient care device) ACM (alarm communication model) profile based on HL7 [12] is directed for mainly hospital use, and seems to lack perspective of false alarm reduction. IEC 80001-2-5 [13] is application guidance of risk management on distributed alarm systems for IT-networks incorporating medical devices.

We expect standards in both hardware interfaces and consistent alarm meanings used for patients with artificial ventilators and their caregivers at homes to reduce false alarms and prevent missing alarms.

5. ACKNOWLEDGMENTS

This work was funded by the "Development of a smart-alarm system for improving the safety of ventilator-equipped child patients at home" R&D project of the fiscal year 2017/2020 in the Strategic Information and Communications R&D Promotion Programme (SCOPE) #172104101, Ministry of Internal Affairs and Communications, Japan.

REFERENCES

- Nicolino Ambrosino, Michele Vitacca et al.,"Telemonitoring of ventilator-dependent patients: a European Respiratory Society Statement", European Respiratory Journal 2016 48: 648-663.
- [2] Ryota Inokuchi, Hajime Sato et al., "The proportion of clinically relevant alarms decreases as patient clinical severity decreases in intensive care units: a pilot study", BMJ Open, 3(9), [e003354], bmjopen-2013-003354, 2013.
- [3] Xiwei Xu, Liming Zhu et al., "Crying Wolf and Meaning It: Reducing False Alarms in Monitoring of Sporadic Operations through POD-Monitor", DOI: 10.1109/COUFLESS.2015.18, 2015.
- [4] Clinical Alarm Management Compendium, AAMI Foundation, Nov. 2015.
- [5] Kentaro Yoshikawa, Masaomi Takizawa and Akinori Nakamura, "Alarm transmission system of artificial respirator currently used", JJTTA pp98-101, 2016 (In Japanese).
- [6] Masahiro Kuroda and Michiko Fukahori, "Affordable M2M enabled e-health using standard ban technology", IEEE Healthcare Innovation Conference 2014, pp276-279, 2014.

- [7] Muñoz-Bonet JI, López-Prats JL, Flor-Macián EM, Cantavella T, Bonet L, Domínguez A, and Brines J, "Usefulness of telemedicine for home ventilatordependent children.", Journal of Telemedicine and Telecare 0(0) 1-9, 2018.
- [8] Muñoz-Bonet JI, López-Prats JL, Flor-Macián EM, Cantavella T, Bonet L, Domínguez A, and Brines J, "Medical complications in a telemedicine home care programme for paediatric ventilated patients.", Journal of Telemedicine and Telecare 0(0) 1-12, 2019.
- [9] <u>https://www.iso.org/standard/41986.html</u>.
- [10] <u>https://www.iso.org/standard/54572.html</u>.
- [11] <u>https://standards.ieee.org/content/ieee-</u> standards/en/standard/11073-20601-2019.html .
- [12] <u>http://www.hl7.org/</u>.
- [13] <u>https://www.iso.org/standard/63718.html</u>.

SESSION 4

DIGITAL HEALTH STRATEGIES

- S4.1 **Invited paper** Towards international standards for the evaluation of artificial intelligence for health
- S4.2 Redesigning a basic laboratory information system for the global south
- S4.3 #RingingTheAlarm: Chronic "Pilotitis" stunts digital health in Nepal
- S4.4 Designing national health stack for public health: Role of ICT-based knowledge management system

TOWARDS INTERNATIONAL STANDARDS FOR THE EVALUATION OF ARTIFICIAL INTELLIGENCE FOR HEALTH

Markus A. Wenzel¹, Thomas Wiegand^{1,2}

¹Fraunhofer Heinrich Hertz Institute, Berlin, Germany ²Technische Universität Berlin, Berlin, Germany

ABSTRACT

Healthcare can benefit considerably from advanced information processing technologies, in particular from machine learning (ML) and artificial intelligence (AI). However, the health domain only hesitantly adopts these powerful but complex innovations so far, because any technical fault can affect people's health, privacy, and consequently their entire lives. In this paper, we substantiate that international standards are required for thoroughly validating AI solutions for health, by benchmarking their performance. These standards might ultimately create wellfounded trust in those AI solutions that have provided conclusive evidence to be accurate, effective and reliable. We give reasons that standardized benchmarking of AI solutions for health is a necessary complement of established assessment procedures. In particular, we demonstrate that it is beneficial to tackle this topic on a global scale and summarize the achievements of the first year of the ITU/WHO focus group on "AI for Health" that has tasked itself to work towards creating these evaluation standards.

Keywords – Artificial intelligence, benchmarking, evidence, ITU-T, machine learning, medicine, standards, validation, World Health Organization

1. HEALTH AI

Advanced information technologies from machine learning (ML) and artificial intelligence (AI) have been attracting much interest in the health domain lately. The recent global strategy on digital health of the World Health Organization (WHO) mentions AI as technology that has "the potential to enhance health significantly" [1]. Regulatory bodies, in particular the U. S. Food and Drug Administration, are beginning to permit AI-based medical devices [2, 3], and start the discussion on the regulation of continuously learning ML/AI-based medical software [4]. Renowned medical and scientific journals are dedicating special issues

and journal branches to digital health with a focus on ML and AI [cf. 5, 6, 7], and the English National Health Service has created several guiding documents on AI in healthcare [8, 9, 10].

The capacity of ML and AI for applications in healthcare is founded upon the increasing availability of digital health data, which can be used to train and to apply advanced models, on increasingly powerful computing infrastructure, potentially accessible from around the globe via the Internet. Available data include, e.g. radiology or microscope images, free text, sensor time series, lab measurements, and other information stored in electronic health records. These data enable ML and AI algorithms to learn to perform a wide range of recognition, early-detection, classification, prediction, image-segmentation and image-reconstruction tasks that only humans had been able to perform previously and that can now be automated very fast and at large scale with computers.

Medical image analysis is a large field of application for ML methods [11, 12, 13]. For instance, ML models can recognize lung nodules from radiology images [14], detect malaria from microscope images of blood samples [15], or classify skin cancer based on dermoscopy images [16]. The models can process electronic health records in order to categorize patients, make clinical decisions, predict patient trajectories [17] or forecast the outcome [18], e.g. in the intensive care unit [19, 20]. From the electrocardiogram, algorithms can detect myocardial infarction and heart arrhythmia [21, 22]. In addition, AI methods not rooted in ML can contribute to healthcare: Knowledge-based expert systems can ask systematic questions about symptoms and advise on how to proceed, e.g. recommend visiting a hospital immediately [23]. Access via the Internet is a considerable driver for health AI technology because it makes novel types of health delivery possible, as well as innovative business models, in particular via mobile applications that can give expert advice to virtually everyone, everywhere, e.g. based on text input, camera or even cellphone-based, deep-learning-enhanced microscopy [24].

In contrast to the growing interest and impressive advancements, the healthcare sector has only hesitantly adopted these powerful innovations in practice so far, because any technical fault can affect people's health, privacy, and lives [25]. Providing conclusive evidence about the performance, reliability and limits of the ML/AI models is required for harnessing the benefits of trustworthy solutions, while avoiding the risks of inadequate implementations. Due to the high complexity of the ML/AI models and the addressed health tasks, it is not trivial to demonstrate conclusively whether particular а implementation solves a task adequately and reliably under realistic conditions. For safe usage, it is of paramount importance that future international standards can give clear recommendations about how to validate the models. These standards are expected to promote interoperability and dismantle trade barriers too. Moreover, the development of these standards is in line with the Sustainable Development Goals (SDG) of the United Nations (UN), in particular with "SDG 3: Ensure healthy lives and promote wellbeing for all at all ages" [26].

2. INTERNATIONAL STANDARDIZATION ACTIVITIES RELATED TO AI

Several standardization bodies have begun addressing the subject area of AI over the past two years. The International Telecommunication Union (ITU) and the WHO are two specialized agencies of the UN authorized for creating global standards. ITU establishes standards ("Recommendations") for information and communication technologies, which include ML and AI. WHO considers the "development of global guidelines ensuring the appropriate use of evidence" as a "core function" [27], e.g. "recommendations on the diagnosis and treatment of malaria" [28]. Standards setting organizations are aware that the multidisciplinary field of health AI requires cooperation. Therefore, ITU and WHO have joined forces and have created a focus group on "AI for Health" in July 2018 [29]. The group has begun working towards establishing a rigorous evaluation process for AI solutions for health that a global community of experts-from health, ML, AI, regulation, ethics, industry and academia supports, which comprises an important first step towards international standards for AI in health. A dedicated section below presents this joint global standardization activity in more detail. The authors are members of the focus group.

The International Organization for Standardization (ISO) subcommittee ISO/IEC JTC 1/SC 42 "Artificial intelligence" [31] has been developing a framework for AI systems using ML (ISO/IEC WD 23053), addressing AI concepts and terminology (ISO/IEC WD 22989) and AI risk management (ISO/IEC AWI 23894). Furthermore, ISO is working on robustness (ISO/IEC NP TR 24029-1), trustworthiness (ISO/IEC PDTR 24028), bias (ISO/IEC NP TR 24027) and use cases (ISO/IEC NP TR 24030) in AI. While these documents address AI in more general terms, the use cases include healthcare applications too. Again, standard setting organizations are beginning to cooperate: ISO/IEC JTC 1/SC 42 "AI" and the ITU/WHO focus group have recently

exchanged liaison statements, in view of common use cases addressed.

The Institute of Electrical and Electronics Engineers (IEEE) has established an "Artificial Intelligence Medical Device Working Group" that has started working on two projects for new IEEE standards in 2018. "P2802" is a "Standard for the Performance and Safety Evaluation of Artificial Intelligence Based Medical Device: Terminology" and "P2801" is about the "Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence" [30].

The U. S. Consumer Technology Association (CTA) started a working group on "Artificial Intelligence in Health Care (R13 WG1)" in April 2019, with the participation of AT&T, Google, IBM, Philips, Samsung, and other companies [32]. This initiative has "launched a new standards effort addressing The Use of Artificial Intelligence in Health Care: Trustworthiness". Moreover, CTA has released a "White Paper on Use Cases in Artificial Intelligence" in December 2018, which includes use cases in healthcare [33].

The U.S. National Institute of Standards and Technology (NIST) was directed by the President in February 2019 with Executive Order 13859 to "issue a plan for Federal engagement in the development of technical standards and related tools in support of reliable, robust, and trustworthy systems that use AI technologies" [34]. NIST submitted the plan in August 2019 and recommends to "commit to deeper, consistent, long-term engagement in AI standards development activities (...) to speed the pace of reliable, robust, and trustworthy AI technology development". The plan advises to "promote focused research to advance (...) understanding of how aspects of trustworthiness can be practically incorporated within standards and standardsrelated tools". In particular, the plan recommends to "spur benchmarking efforts to assess the reliability, robustness, and trustworthiness of AI systems" and to "ensure that these benchmarks are widely available, result in best practices, and improve AI evaluations and methods for verification and validation" [35, 36].

In China, "a joint effort by more than 30 academic and industry organizations overseen by the Chinese Electronics Standards Institute" published an "Artificial Intelligence Standardization White Paper" in January 2018 [37, 38]. "Clinical medical imaging diagnosis" is mentioned as one of ten "real-world AI commercial application cases" according to a review available in English [39].

The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) "launched a new Focus Group on Artificial Intelligence" in April 2019 [40] as a "starting point to support the identification of specific European Standardization needs". Additionally, the EU High-Level Expert Group on AI published "Ethics Guidelines for Trustworthy Artificial Intelligence" in April 2019 with "technical robustness and safety" as one of seven key requirements for trustworthy AI [41]. In Germany, the Deutsches Institut für Normung (DIN) began drafting an "AI roadmap" in May 2019 "to create a framework for action for standardization" [42]. DIN has also founded an interdisciplinary AI Working Committee [43] and is working on two DIN SPECs related to AI [44, 45].

Large companies lead the field in the area of AI and have started joint activities on safe AI, which potentially can establish de-facto standards fast. The "Partnership on Artificial Intelligence to Benefit People and Society" is led by representatives from large technology firms and several other member organizations, also from academia and civil society. The first goal of this initiative is "to develop and share best-practice methods and approaches in the research, development, testing, and fielding of AI technologies". This includes addressing "the trustworthiness, reliability, containment, safety, and robustness of the technology". They are particularly interested in "safety-critical application areas" and mention healthcare as an example [46].

The "OpenAI" research center, which is well known in the ML/AI research community and backed by large investors, has recently published a policy paper on "the role of cooperation in responsible AI development", "across organizational and national borders", discussing "joint research into the formal verification of AI systems' capabilities and other aspects of AI safety". In particular, they mention "various applied 'AI for good' projects whose results might have wide ranging and largely positive applications (e.g. in domains like [...] health); coordinating on the use of particular benchmarks; joint creation and sharing of datasets that aid in safety research". Moreover, they raise the question of the role of "standardization bodies in resolving collective action problems between companies", in particular internationally [47]. OpenAI claims, "AI companies can work to develop industry norms and standards that ensure systems are developed and released only if they are safe, and can agree to invest resources in safety during development and meet appropriate standards prior to release". They "anticipate that identifying similar mechanisms to improve cooperation on AI safety between states and with other non-industry actors will be of increasing importance in the years to come" [48].

3. VALIDATING DIGITAL HEALTH TECHNOLOGIES

Previous work can provide orientation for future international standards for the validation of novel ML/AIbased health technologies. Physicians, regulators, scientists and engineers have long-ranging experience in dealing with complex safety-critical health interventions and technologies that require careful validation checks prior to usage. These technologies include, for instance, clinical interventions, surgical procedures, pharmaceutics, medical devices and software. Randomized controlled clinical trials, peer-review of scientific literature and standard tests in accredited testing laboratories are examples of well-established methods for assessing these interventions, substances or devices. Typically, AI serves as a *multivariable prediction model* that maps multidimensional input variables to one or multidimensional output variables, e.g. pictures to disease classification codes. Accordingly, the TRIPOD statement for the "transparent reporting of a multivariable prediction model for individual prognosis or diagnosis" can serve as a landmark for AI methods too. These guidelines have been published by the EQUATOR Network, an organization aiming to enhance the quality and transparency of health research [49, 50, 51]. Cf. [52] for a discussion about how the TRIPOD statement relates to AI.

ML/AI models are implemented as pieces of software and hence belong to digital technologies in almost all cases (in principle, they can be analogue hardware, too [53]). The International Medical Device Regulators Forum has outlined principles for the clinical evaluation of *software* as a medical device in a draft from 2017 [54]. Three main topics structure this clinical evaluation process: (a) Assuring that there is a "valid clinical association" between the software output and the "targeted clinical condition". (b) Correct processing of the "input data to generate accurate, reliable, and precise output data". (c) Achieving the "intended purpose in your target population in the context of clinical care" using the software output data. The English National Institute for Health and Care Excellence (NICE) has published an standards framework for digital health "evidence technologies" in March 2019 [55]. This document "describes standards for the evidence (...) of effectiveness relevant to the intended use(s) of the technology". Moreover, the document states that the framework is applicable to digital health technologies "that incorporate artificial intelligence using fixed algorithms", excluding adaptive AI algorithms.

4. ML/AI PERFORMANCE EVALUATION

The ML/AI models are expected to return meaningful results that are accurate, plausible and reliable, when processing completely novel data points that the model has never seen before, during the actual usage in the "real world". Out-ofsample tests make it possible to assess this capability to some degree, if the tests are conducted appropriately. These tests can be largely conducted *in silico*, at least as a first step, without posing the potential hazards of clinical trials, by confronting the model with previously recorded test samples, and by comparing the model output with the "ground truth" for the respective task. This characteristic allows conducting systematic tests at large scale (e.g. using databases with thousands of MRT images), replicable and fast (e.g. in the case of software updates, or adaptive algorithms).

The machine learning community evaluates the performance of ML/AI models usually as follows: First, the model is tested out-of-sample, but in-house, by splitting the available data in a training and a test set, often in a cross-validation scheme. The trained model computes labels or other output variables from the input data of the test set, which are statistically compared with the "true" labels or annotations (the comparison is summarized in a score). Then, method and in-house test results are reported in a scientific paper that is reviewed by peers for publication in a journal or conference proceeding. Occasional open-source releases of the software code can allow the reviewers and other peers to reproduce the results, in principle. Yet, the model performance is evaluated in-house only in many cases, e.g. because the code/model is not published or because of legal or other barriers to share the test data. Therefore, it remains unclear if the evaluation was conducted properly, if common pitfalls were avoided [cf. 56] such as leakage between test and training data, or if the test data set was (un)intentionally curated, which can all result in overestimating the model performance and in spurious results. Performance reports of different models can often not be compared, because of individual data preprocessing and filtering. This problem is even more severe for commercial AI developers that typically refrain from publishing details of their methods or the code [57].

For a range of tasks, human experts are required to label or annotate the test data. In fact, experts can disagree, which leads to questions related to the so called "ground truth" or "gold standard". How many experts of which level of expertise [57] need to be asked? Crucially, in-house test data are often very similar to the training data, e.g. when originating from the same measurement device, due to practical reasons (cost, time, access and legal hurdles). Therefore, the capacity of the AI to generalize to potentially different, previously unseen data is often unclear, e.g. to data from other laboratories, hospitals, regions or countries [cf. 58].

Researchers from the medical and machine learning communities are aware of these open questions and problems. The medical journal "The Lancet - Digital Health" sets a good example and requires "independent validation for all AI studies that screen, treat, or diagnose disease" [59]. Machine learning scientists urge towards reproducibility and replicability by organizing challenges (also known as competitions), where an independent, neutral arbiter evaluates the AI on a separate test data set [e.g. 60]. These challenges are conducted at scientific conferences (e.g. NeurIPS, MICCAI, CVPR, SPIE, etc.) and on Internet platforms (e.g. Kaggle, Alcrowd, EvalAI, DREAM Challenges, Grand Challenge etc.). Challenge design is not trivial and research shows that many design decisions can have a large impact on the benchmarking outcome [61]. Aspects beyond mere performance have not been addressed sufficiently so far, including the benchmarking of robustness [62], and of uncertainty [63], which is important for the practical application in healthcare. Moreover, further indepth discussions with domain experts, e.g. physicians, are required, in order to find out if the used evaluation metrics are actually relevant with meaningful (clinical) endpoints [64].

5. ITU/WHO FOCUS GROUP ON AI FOR HEALTH

While there is considerable experience and previous work to build upon, generally accepted, impartial standards for health ML/AI evaluation are still missing. Standardization bodies have merely started to address health ML/AI technologies (cf. section 2). Principles for prediction models, software and digital health technologies can provide some overall orientation (section 3), but can only serve as a starting point, and need to be transferred to the characteristics of the novel technologies. State-of-the-art procedures for ML/AI performance evaluation are a sound foundation, but the limits discussed in section 4 need to be addressed.

The mission of the ITU/WHO focus group on "AI for Health" is to undertake crucial steps towards evaluation standards that are applicable on a global scale, an approach that offers substantial potential for synergies. A large number of national regulatory institutions, public health institutes, physicians, patients, developers, health insurances, licensees, hospitals and other decision-makers around the globe can profit from a common, standardized benchmarking framework for health ML/AI. Standards live on being sustained by a broad *community*. Therefore, the focus group is creating an ecosystem of diverse stakeholders from industry, academia, regulation, and policy with a common, substantial interest in health ML/AI benchmarking. ITU and WHO officials monitor and document the overall process. Since its foundation in July 2018, the focus group has been organizing a series of free workshops with subsequent multiday meetings in Europe, North America, Asia, Africa and India (and South America in January 2020) every two or three months for engaging the regional communities. Participation in the focus group is encouraged by attending the events on site or via the Internet remotely. In addition, further virtual collaboration allows for carrying forward work in between meetings. These online participation possibilities and the generous support from a charitable foundation, with travel grants for priority regions, foster the global participation, considering time and resource constraints.

The structure of FG-AI4H is shown below, Figure 1. Two types of sub-groups are generating the main deliverables: working groups (WGs) and topic groups (TGs).



Figure 1 – Structure of FG-AI4H

WGs consider matters such as data and AI solution handling, assessment methods, health requirements, operations, and regulatory considerations. Many of these matters are crosscutting subjects that affect a specific aspect of an AI for health application. The deliverables of the WGs are planned to be a number of documents that cover topics including:

- AI ethical considerations,
- AI legal consideration,
- AI software life-cycle,
- reference data annotation specification,
- training and test data specification,
- AI training process specification,
- AI test process specification,
- AI test metric specification, and
- AI post-market adaptation and surveillance specification.

An overview of the technical output of the WGs is given in Figure 2.



Figure 2 – Overview of the technical output of the WGs

The WG *data and AI solution assessment methods* reviews the topic description documents (see below), in collaboration with independent *experts* with substantial records of accomplishment in the respective health topic, with proficient knowledge in ML/AI, and with transversal competences from areas such as ethics and statistics. During a repeated review cycle, the working group and the experts check that the topic description documents are accurate, complete, sound, understandable and objective, and give according feedback for improvement to the respective topic group and the entire focus group. The WG is in charge of providing a number of technical deliverables, given above.

The working group *data and AI solution handling* takes charge for a range of tasks related to conducting the tests, which requires bringing the test data and the to-be-tested AI solutions together. Relevant aspects include, e.g. transfer agreements, secure data and solution transfer, data checks, IT infrastructure, access rights, traceability, IT security, test implementation and report generation.

The working group for *regulatory considerations* is involved in the entire process, with representatives of FDA (USA), CMDE/ NMPA (China), CDSCO (India), EMA (Europe) and BfArM (Germany) so far. In close collaboration with the WHO, the working group facilitates subsequent steps (e.g. AI testing process specification, clinical evaluation, certification etc.) towards deployment of the health AI solution in practice.

The *topic groups*, TGs, take charge of specific health domains with corresponding ML/AI tasks. They are providing the connection of the WGs with actual health

topics and the specific problems involved with a number of AI for health tasks and data modalities. At present, the topic groups address AI-based cardiovascular disease risk prediction, dermatology, histopathology, outbreak detection, ophthalmology, radiotherapy, symptom assessment, tuberculosis prognostics/diagnostics and several further domains. In each topic group, different stakeholders, including competing companies, with a common interest in the topic are working together. "Calls for topic group participation" are published on the website (https://www.itu.int/go/fgai4h), introduce the respective topic group and invite participation. The creation of many other topic groups in response to the open "call for proposals: use cases, benchmarking, and data" is expected. Selection criteria include the prospect for a widespread and, ideally, global impact, a clear concept described in sufficient detail, and preliminary evidence for feasibility.

Every topic group defines its scope, the specific ML/AI tasks and the evaluation procedures with corresponding test data and metrics in a *topic description document* in full detail. Statistical metrics for assessing the model performance are, e.g. precision, specificity, F1 score and area under curve, but can be multiple or combined metrics too [61]. In particular, it should be assured that the (e.g. clinical) endpoints are meaningful in practice. Further criteria should be considered, e.g. robustness to noise and to other variations in the input data [62], or to manipulations [65]. Humans prefer transparent decision-making: Can the model adequately quantify the uncertainty [63] and plausibly explain the decision [66, 67]? These criteria beyond mere performance should also be considered.

The topic description document must capture a range of aspects related to the test data, because they determine largely if the evaluation procedure is appropriate and meaningful. The procedure can return conclusive results if, and only if, the test data are realistic, i.e. close to the actual application, of representative coverage, and of traceable provenance from different sources. Data acquisition must be transparently documented in full detail [cf. 68], including annotation guidelines, for reproducibility, replicability, and scalability. All ethical and legal questions related to the acquisition, storage and processing of health data must be taken into careful consideration. Bias must be controlled and documented clearly. The document shall specify quality and quantity criteria for the test data, including corresponding references. The annotation needs to be conducted by experts with a defined level of expertise, with potentially several independent annotations per sample (if applicable). Technical matters, e.g. data formats [cf. 69, 70] and data management [71], need to be specified. A reference model can potentially be defined (e.g. "average human performance for this task", "best in class"). Limiting factors for data availability should be referred to, such as finances or time. The plan detailed in the topic description document must be implemented in practice. The test data must be provided or acquired, and measures for quality assurance taken. The evaluation routine must be implemented, and the code published together with at least a few example data with

references (e.g. annotated images) to enable the developers carrying out a trial run of their code.

For a clean and fair evaluation, a trusted third party should receive the trained model, as independent arbiter, and conduct the tests on data that have never been published before. This cautious procedure prevents unfair conduct, e.g. tuning the model for optimal performance on this particular test set ("overfitting"), without actually being able to generalize well to real-world data, which can be expected in practice. Therefore, widely available, public data sets cannot be used for the evaluation and the entire test data set must remain secret, i.e. neither labeled nor unlabeled test data should be made available. The model performance should be evaluated in a closed computing environment without Internet access. Otherwise, test data could be leaked, against the rules, and the model be tweaked on the test data. Besides, leaderboard probing and other potential pitfalls known from ML challenges must be kept in mind [72, 73]. The trusted third party is responsible to protect both test data and ML/AI model. The test data have to remain secret for subsequent meaningful testing and the AI models may contain businessrelevant trade secrets of the developer.

In this spirit, focus group members have conducted a first proof-of-concept benchmark for digital pathology, where an ML/AI model can provide diagnostic support by quantifying tumor infiltrating lymphocytes in breast cancer, from whole slide histopathology images, which is relevant for prognosis and therapy selection [cf. 74, 75]. The topic group had defined the evaluation task and procedure, and had acquired and annotated test data. The developer had trained a model on own training data to predict the annotations that a pathologist would give from the images. A focus group member as arbiter provided the computing infrastructure according to specifications of the developer (here a desktop computer with a certain graphics processing unit, operating system, package manager, and ML framework installed) and granted the developer access via the Internet to install the prediction routine. Few annotated example data enabled the developer to test the prediction routine. After disconnecting the computer from the Internet, the arbiter uploaded undisclosed test data, directly received from the topic group, on the machine, and executed the prediction routine, which processed the data and predicted the annotations. Finally, scores (true positive rate and true negative rate) were computed by comparison with the reference annotations, and reported back to the topic group and the developer. Naturally, this manual procedure can be automatized and scaled, e.g. with one of the ML challenge frameworks mentioned in section 4, potentially installed on a server on ITU or UN premises.

Interaction with further health institutions will be strengthened, potentially, e.g., with the International Association of National Public Health Institutes, the InterAcademy Partnership and the World Health Summit. Further information about the scope and general process of the focus group can be found in a commentary in *The Lancet* [29] and a white paper on the website, where also the full documentation of all previous meetings is published.

6. OUTLOOK

In summary, the ITU/WHO focus group on "AI for Health" has taken the first exploratory steps towards international health ML/AI evaluation standards. For the future, we expect that a wide spectrum of health ML/AI topics will be addressed and that insights from the evaluation will be brought back to research and development. The evaluation procedure will be continuously refined in a repeated cycle, considering further quality criteria beyond mere performance, and including high quality test data with increasing geographic coverage. For the years to come, we also anticipate further deepening of cooperation on ML/AI between standard setting organizations. While the standardization activities on ML/AI differ in their thematic scope and particular objective (see section 2), they can profit from collaboration, because different application areas of ML/AI often share problems and data modalities. For instance, assuring robust automatic image interpretation can be relevant for a range of safety-critical application domains, and is not limited to healthcare. At the same time, a generic approach is often not possible, because the cross-sectional ML/AI technologies require cooperation with the respective domain experts. A good example for this multidisciplinary cooperation is the joint focus group of ITU and WHO, which brings together expertise from information technology and health standardization bodies. In particular, this initiative shows that global collaboration can leverage synergy effects, since many relevant issues are common across the world.

REFERENCES

- [1] World Health Organization (2019) Global Strategy on Digital Health 2020-2024. Retrieved from <u>https://www.who.int/DHStrategy</u>
- [2] U.S. Food and Drug Administration (2018). FDA News Release. Retrieved from https://www.fda.gov/news-events/pressannouncements/fda-permits-marketing-artificialintelligence-based-device-detect-certain-diabetesrelated-eye
- [3] Mesko, B. (2019). FDA Approvals For Smart Algorithms In Medicine In One Giant Infographic. *The Medical Futurist*. Retrieved from <u>https://medicalfuturist.com/fda-approvals-for-algorithms-in-medicine</u>
- U. S. Food and Drug Administration (2019). Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback. Retrieved from <u>https://www.regulations.gov/document?D=FDA-2019-N-1185-0001</u>

- [5] Editorial (2019). Medicine in the digital age. *Nature Medicine*, **25**, 1. <u>https://doi.org/10.1038/s41591-018-0322-1</u>
- [6] Editorial (2019) Machine Learning in Medicine. Nature Materials 18, 407. https://doi.org/10.1038/s41563-019-0360-1
- [7] Editorial (2019). A digital (r)evolution: introducing The Lancet Digital Health. *The Lancet Digital Health*, 1(1). <u>https://doi.org/10.1016/S2589-</u> 7500(19)30010-X
- [8] Trendall, S. (2019). NHSX to create policy guide for use of AI in healthcare. *Public Technology*. Retrieved from <u>https://www.publictechnology.net/articles/news/nhs</u> <u>x-create-policy-guide-use-ai-healthcare</u>
- [9] Dunbar, K. (2019). New guidance for AI in screening. *Public Health England Screening Blog.* Retrieved from <u>https://phescreening.blog.gov.uk/2019/03/14/new-guidance-for-ai-in-screening</u>
- [10] UK Department of Health and Social Care (2019). New code of conduct for artificial intelligence (AI) systems used by the NHS. GOV. UK. Retrieved from <u>https://www.gov.uk/government/news/new-code-ofconduct-for-artificial-intelligence-ai-systems-usedby-the-nhs</u>
- [11] Litjens, G., Kooi, T., Bejnordi, B. E., Setio, A., Ciompi, F., Ghafoorian, M., ... & Sánchez, C. I. (2017). A survey on deep learning in medical image analysis. *Medical image analysis*, 42, 60-88. <u>https://doi.org/10.1016/j.media.2017.07.005</u>
- Shen, D., Wu, G., & Suk, H. I. (2017). Deep learning in medical image analysis. *Annual review of biomedical engineering*, 19, 221-248. <u>https://doi.org/10.1146/annurev-bioeng-071516-044442</u>
- [13] Esteva, A., Robicquet, A., Ramsundar, B., Kuleshov, V., DePristo, M., Chou, K., Cui, C., Corrado, G., Thrun, S. & Dean, J. (2019). A guide to deep learning in healthcare. *Nature medicine*, 25(1), 24. <u>https://doi.org/10.1038/s41591-018-0316-z</u>
- [14] Setio, A. A. A., Traverso, A., De Bel, T., Berens, M. S., van den Bogaard, C., Cerello, P., ... & van der Gugten, R. (2017). Validation, comparison, and combination of algorithms for automatic detection of pulmonary nodules in computed tomography images: the LUNA16 challenge. *Medical image analysis*, 42, 1-13. https://doi.org/10.1016/j.media.2017.06.015

- [15] Park, H. S., Rinehart, M. T., Walzer, K. A., Chi, J. T. A., & Wax, A. (2016). Automated detection of P. falciparum using machine learning algorithms with quantitative phase images of unstained cells. *PloS one*, **11**(9), e0163045. <u>https://doi.org/10.1371/journal.pone.0163045</u>
- [16] Esteva, A., Kuprel, B., Novoa, R. A., Ko, J., Swetter, S. M., Blau, H. M., & Thrun, S. (2017). Dermatologist-level classification of skin cancer with deep neural networks. *Nature*, 542(7639), 115. <u>https://doi.org/10.1038/nature21056</u>
- [17] Ching, T., Himmelstein, D. S., Beaulieu-Jones, B. K., Kalinin, A. A., Do, B. T., Way, G. P., ... & Xie, W. (2018). Opportunities and obstacles for deep learning in biology and medicine. *Journal of The Royal Society Interface*, **15**(141), 20170387. <u>https://doi.org/10.1098/rsif.2017.0387</u>
- [18] Norgeot, B., Glicksberg, B. S., Trupin, L., Lituiev, D., Gianfrancesco, M., Oskotsky, B., ... & Butte, A. J. (2019). Assessment of a deep learning model based on electronic health record data to forecast clinical outcomes in patients with rheumatoid arthritis. *JAMA network open*, 2(3), e190606e190606. https://doi.org/10.1001/jamanetworkopen.2019.0606
- [19] Meiring, C., Dixit, A., Harris, S., MacCallum, N. S., Brealey, D. A., Watkinson, P. J., ... & Singer, M. (2018). Optimal intensive care outcome prediction over time using machine learning. *PloS one*, **13**(11), e0206862. https://doi.org/10.1371/journal.pone.0206862
- [20] Nemati, S., Holder, A., Razmi, F., Stanley, M. D., Clifford, G. D., & Buchman, T. G. (2018). An Interpretable Machine Learning Model for Accurate Prediction of Sepsis in the ICU. *Critical care medicine*, 46(4), 547-553. https://dx.doi.org/10.1097/CCM.00000000002936
- [21] Strodthoff, N., & Strodthoff, C. (2019). Detecting and interpreting myocardial infarction using fully convolutional neural networks. *Physiological measurement*, 40(1). <u>https://doi.org/10.1088/1361-6579/aaf34d</u>
- [22] Hannun, A. Y., Rajpurkar, P., Haghpanahi, M., Tison, G. H., Bourn, C., Turakhia, M. P., & Ng, A. Y. (2019). Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network. *Nature medicine*, 25(1), 65. <u>https://doi.org/10.1038/s41591-018-0268-</u><u>3</u>

- [23] Semigran, H. L., Linder, J. A., Gidengil, C., & Mehrotra, A. (2015). Evaluation of symptom checkers for self diagnosis and triage: audit study. *BMJ*, 351, h3480. <u>https://doi.org/10.1136/bmj.h3480</u>
- [24] Rivenson, Y., Ceylan Koydemir, H., Wang, H., Wei, Z., Ren, Z., Günaydın, H., ... & Ozcan, A. (2018). Deep learning enhanced mobile-phone microscopy. *Acs Photonics*, 5(6), 2354-2364. <u>https://doi.org/10.1021/acsphotonics.8b00146</u>
- [25] He, J., Baxter, S. L., Xu, J., Xu, J., Zhou, X., & Zhang, K. (2019). The practical implementation of artificial intelligence technologies in medicine. *Nature medicine*, 25(1), 30. <u>https://doi.org/10.1038/s41591-018-0307-0</u>
- [26] United Nations (2015). United Nations Sustainable Development Goals. Retrieved from <u>https://www.un.org/sustainabledevelopment/sustainable-development-goals/</u>
- [27] World Health Organization. WHO guidelines approved by the Guidelines Review Committee. Retrieved from https://www.who.int/publications/guidelines/
- [28] World Health Organization. (2015). Guidelines for the treatment of malaria. World Health Organization. Retrieved from <u>https://www.who.int/malaria/publications/atoz/9789</u> 241549127/en/
- [29] Wiegand, T., Krishnamurthy, R., Kuglitsch, M., Lee, N., Pujari, S., Salathé, M., Wenzel, M. & Xu, S. (2019). WHO and ITU establish benchmarking process for artificial intelligence in health. *The Lancet*, **394**(10192), 9-11. <u>https://doi.org/10.1016/S0140-6736(19)30762-7</u>
- [30] IEEE Artificial Intelligence Medical Device Working Group (EMB/Stds Com/AIMDWG). Retrieved from <u>https://sagroups.ieee.org/aimdwg/</u>
- [31] ISO/IEC JTC 1/SC 42 Artificial intelligence. Retrieved from https://www.iso.org/committee/6794475.html
- [32] Consumer Technology Association (2019). CTA Brings Together Tech Giants, Trade Associations to Improve Efficiencies in AI and Health Care. CTA Press Releases. Retrieved from <u>https://www.cta.tech/News/Press-</u> <u>Releases/2019/April/CTA-Brings-Together-Tech-Giants,-Trade-Association.aspx</u>
- [33] Consumer Technology Association (2018). CTA Releases White Paper on Use Cases in Artificial Intelligence. CTA Standards News. Retrieved from https://standards.cta.tech/kwspub/home/

- [34] Trump, D. J. (2019). Executive Order on Maintaining American Leadership in Artificial Intelligence. Retrieved from <u>https://www.whitehouse.gov/presidential-</u> <u>actions/executive-order-maintaining-americanleadership-artificial-intelligence/</u>
- U. S. National Institute of Standards and Technology (2019a). U.S. Leadership in AI: A Plan for Federal Engagement in Developing Technical Standards and Related Tools. Prepared in response to Executive Order 13859. Retrieved from <u>https://www.nist.gov/sites/default/files/documents/2</u> 019/08/10/ai standards fedengagement plan 9aug2 019.pdf
- [36] U. S. National Institute of Standards and Technology (2019b). Plan Outlines Priorities for Federal Agency Engagement in AI Standards Development. Retrieved from <u>https://www.nist.gov/newsevents/news/2019/08/plan-outlines-prioritiesfederal-agency-engagement-ai-standardsdevelopment</u>
- [37] Ding, J. and Triolo, P. (2018). Translation: Excerpts from China's 'White Paper on Artificial Intelligence Standardization'. New America DigiChina Blog. Retrieved from <u>https://www.newamerica.org/cybersecurity-</u> <u>initiative/digichina/blog/translation-excerpts-chinas-</u> <u>white-paper-artificial-intelligence-standardization/</u>
- [38] China Electronics Standards Institute (2018). Artificial Intelligence Standardization White Paper. Retrieved from www.cesi.ac.cn/images/editor/20180118/201801180 90346205.pdf
- [39] Han, M. (2018). China Aims to Get the Jump on AI Standardization. Synced. Retrieved from <u>https://syncedreview.com/2018/01/25/china-aims-to-get-the-jump-on-ai-standardization/</u>
- [40] Briard, I. (2019). CEN and CENELEC launched a new Focus Group on Artificial Intelligence. CEN CENELEC News. Retrieved from <u>https://www.cencenelec.eu/news/articles/Pages/AR-2019-001.aspx</u>
- [41] Independent High-Level Expert Group On Artificial Intelligence Set Up By The European Commission (2019). Ethics Guidelines For Trustworthy AI. European Commission Digital Single Market News. Retrieved from <u>https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai</u>

- [42] DIN Deutsches Institut f
 ür Normung e. V. (2019a). DIN to develop AI standardization roadmap. DIN Press Releases. Retrieved from <u>https://www.din.de/en/din-and-our-partners/press/press-releases/din-to-develop-ai-standardization-roadmap-330542</u>
- [43] DIN Deutsches Institut für Normung e. V. (2018). Interdisciplinary DIN Working Committee "Artificial Intelligence". Retrieved from <u>https://www.din.de/en/innovation-and-research/artificial-intelligence/ai-working-committee</u>
- [44] DIN Deutsches Institut für Normung e. V. (2019). DIN SPEC 92001-1:2019-04 Artificial Intelligence -Life Cycle Processes and Quality Requirements -Part 1: Quality Meta Model. <u>https://dx.doi.org/10.31030/3050203</u>
- [45] DIN Deutsches Institut für Normung e. V. (2019). DIN SPECs on Artificial Intelligence. Retrieved from <u>https://www.din.de/en/innovation-andresearch/artificial-intelligence/ai-din-spec</u>
- [46] Partnership on AI to Benefit People and Society (2019). Retrieved from <u>https://www.partnershiponai.org/</u>
- [47] Askell, A., Brundage, M., & Hadfield, G. (2019). The Role of Cooperation in Responsible AI Development. arXiv preprint. <u>https://arxiv.org/abs/1907.04534</u>
- [48] Askell, A., Brundage, M., & Clark, J. (2019). Why Responsible AI Development Needs Cooperation on Safety. *OpenAI Blog*. Retrieved from <u>https://openai.com/blog/cooperation-on-safety/</u>
- [49] Collins, G. S., Reitsma, J. B., Altman, D. G., & Moons, K. G. (2015). Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD): the TRIPOD statement. *BMC medicine*, 13(1), 1. https://doi.org/10.1186/s12916-014-0241-z
- [50] Moons, K. G., Altman, D. G., Reitsma, J. B., Ioannidis, J. P., Macaskill, P., Steyerberg, E. W., ... & Collins, G. S. (2015). Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD): explanation and elaboration. *Annals of internal medicine*, **162**(1), W1-W73. <u>https://doi.org/10.7326/M14-0698</u>
- [51] Heus, P., Damen, J. A., Pajouheshnia, R., Scholten, R. J., Reitsma, J. B., Collins, G. S., ... & Hooft, L. (2019). Uniformity in measuring adherence to reporting guidelines: the example of TRIPOD for assessing completeness of reporting of prediction model studies. *BMJ open*, 9(4), e025611. https://doi.org/10.1136/bmjopen-2018-025611

- [52] Collins, G. S., & Moons, K. G. (2019). Reporting of artificial intelligence prediction models. *The Lancet*, **393**(10181), 1577-1579. https://doi.org/10.1016/S0140-6736(19)30037-6
- [53] Khoram, E., Chen, A., Liu, D., Ying, L., Wang, Q., Yuan, M., & Yu, Z. (2019). Nanophotonic media for artificial neural inference. *Photonics Research*, 7(8), 823-827. <u>https://doi.org/10.1364/PRJ.7.000823</u>
- [54] International Medical Device Regulators Forum (2017). Software as a Medical Device (SaMD): Clinical Evaluation. Retrieved from <u>http://www.imdrf.org/docs/imdrf/final/technical/imd</u> <u>rf-tech-170921-samd-n41-clinical-evaluation_1.pdf</u>
- [55] The English National Institute for Health and Care Excellence (2019). Evidence Standards Framework for Digital Health Technologies. Retrieved from https://www.nice.org.uk/Media/Default/About/whatwe-do/our-programmes/evidence-standardsframework/digital-evidence-standardsframework.pdf
- [56] Lemm, S., Blankertz, B., Dickhaus, T., & Müller, K. R. (2011). Introduction to machine learning for brain imaging. *Neuroimage*, 56(2), 387-399. <u>https://doi.org/10.1016/j.neuroimage.2010.11.004</u>
- [57] Jacobs, C., & van Ginneken, B. (2019). Google's lung cancer AI: a promising tool that needs further validation. *Nature Reviews Clinical Oncology*, 1. <u>https://doi.org/10.1038/s41571-019-0248-7</u>
- [58] Couzin-Frankel, J. (2019). Medicine contends with how to use artificial intelligence. *Science*, 364(6446), 1119-1120. <u>https://doi.org/10.1126/science.364.6446.1119</u>
- [59] Editorial (July 2019). Walking the tightrope of artificial intelligence guidelines in clinical practice. *The Lancet Digital Health*, 1(3), Pe100. <u>https://doi.org/10.1016/S2589-7500(19)30063-9</u>
- [60] Saez-Rodriguez, J., Costello, J. C., Friend, S. H., Kellen, M. R., Mangravite, L., Meyer, P., ... & Stolovitzky, G. (2016). Crowdsourcing biomedical research: leveraging communities as innovation engines. *Nature Reviews Genetics*, **17**(8), 470. <u>https://doi.org/10.1038/nrg.2016.69</u>
- [61] Maier-Hein, L., Eisenmann, M., Reinke, A., Onogur, S., Stankovic, M., Scholz, P., ... & Feldmann, C. (2018). Why rankings of biomedical image analysis competitions should be interpreted with care. *Nature communications*, 9(1), 5217. https://doi.org/10.1038/s41467-018-07619-7
- [62] Michaelis, C., Mitzkus, B., Geirhos, R., Rusak, E., Bringmann, O., Ecker, A. S., ... & Brendel, W.

(2019). Benchmarking Robustness in Object Detection: Autonomous Driving when Winter is Coming. *arXiv preprint*. https://arxiv.org/abs/1907.07484

- [63] Filos, A., Farquhar, S., Gomez, A. N., Rudner, T. G. J., Kenton, Z., Smith, L., Alizadeh, M., de Kroon, A. & Gal, Y (2019). Benchmarking Bayesian Deep Learning with Diabetic Retinopathy Diagnosis. *Preprint*. Retrieved from http://www.cs.ox.ac.uk/people/angelos.filos/publicat_ions/diabetic_retinopathy_diagnosis.pdf
- [64] Parikh, R. B., Obermeyer, Z., & Navathe, A. S. (2019). Regulation of predictive analytics in medicine. *Science*, 363(6429), 810-812. https://doi.org/10.1126/science.aaw0029
- [65] Finlayson, S. G., Bowers, J. D., Ito, J., Zittrain, J. L., Beam, A. L., & Kohane, I. S. (2019). Adversarial attacks on medical machine learning. *Science*, **363**(6433), 1287-1289. <u>https://doi.org/10.1126/science.aaw4399</u>
- [66] Lapuschkin, S., Wäldchen, S., Binder, A., Montavon, G., Samek, W., & Müller, K. R. (2019). Unmasking Clever Hans predictors and assessing what machines really learn. *Nature communications*, 10(1), 1096. <u>https://doi.org/10.1038/s41467-019-08987-4</u>
- [67] Voosen, P. (2017). The AI detectives. Science, 357(6346), pp. 22-27. https://doi.org/10.1126/science.357.6346.22
- [68] Gebru, T., Morgenstern, J., Vecchione, B., Vaughan, J. W., Wallach, H., Daumeé III, H., & Crawford, K. (2018). Datasheets for datasets. arXiv preprint. <u>https://arxiv.org/abs/1803.09010</u>
- [69] Mildenberger, P., Eichelberg, M., & Martin, E. (2002). Introduction to the DICOM standard. *European radiology*, **12**(4), 920-927. <u>https://doi.org/10.1007/s003300101100</u>

- [70] Bender, D., & Sartipi, K. (2013). HL7 FHIR: An Agile and RESTful approach to healthcare information exchange. In *Proceedings of the 26th IEEE international symposium on computer-based medical systems* (pp. 326-331). IEEE. <u>https://doi.org/10.1109/CBMS.2013.6627810</u>
- [71] Wilkinson, M. D., Dumontier, M., Aalbersberg, I. J., Appleton, G., Axton, M., Baak, A., ... & Bouwman, J. (2016). The FAIR Guiding Principles for scientific data management and stewardship. *Scientific data*, 3. <u>https://doi.org/10.1038/sdata.2016.18</u>
- [72] Blum, A., & Hardt, M. (2015). The ladder: A reliable leaderboard for machine learning competitions. arXiv preprint. <u>https://arxiv.org/abs/1502.04585</u>
- [73] Anderson-Cook, C. M., Myers, K. L., Lu, L., Fugate, M. L., Quinlan, K. R., & Pawley, N. (2019). How to Host a Data Competition: Statistical Advice for Design and Analysis of a Data Competition. *arXiv preprint*. <u>https://arxiv.org/abs/1901.05356</u>
- Binder, A., Bockmayr, M., Hägele, M., Wienert, S., Heim, D., Hellweg, K., ... & Treue, D. (2018). Towards computational fluorescence microscopy: Machine learning-based integrated prediction of morphological and molecular tumor profiles. *arXiv preprint*. <u>https://arxiv.org/abs/1805.11178</u>
- [75] Klauschen, F., Müller, K. R., Binder, A., Bockmayr, M., Hägele, M., Seegerer, P., ... & Michiels, S. (2018, October). Scoring of tumor-infiltrating lymphocytes: From visual estimation to machine learning. In *Seminars in cancer biology* (Vol. 52, pp. 151-157). Academic Press. https://doi.org/10.1016/j.semcancer.2018.07.001

REDESIGNING A BASIC LABORATORY INFORMATION SYSTEM FOR THE GLOBAL SOUTH

Jung Wook Park¹; Aditi Shah¹; Rosa I. Arriaga¹; Santosh Vempala¹

¹Georgia Institute of Technology

ABSTRACT

Laboratory information systems (LIS) optimize information storage and processing for clinics and hospitals. In the recent past, developers of LIS for the global south have worked under the assumption that computing environments will be very limited. However, the computing resources in the area have been rapidly enriched. This has also changed the expectations that users have about the LIS interface and functionality. In this paper, we provide a case study of C4G BLIS that has been in operation for nearly a decade in seven African countries. In two studies that included 51 participants from three African countries, we redesigned the LIS to better suit the changing technical landscape and user needs and evaluated the new design. The study procedure, usability metrics and lessons learned from our evaluation provide a model that other researchers can use. The findings provide empirical insights that can benefit designers and developers of LIS in the global south. The results also highlight the need for adding usability specifications for international standard organizations.

Keywords - ICT4D, C4G BLIS, Laboratory Information System, User Interface, Usability Standard, Global South

1. INTRODUCTION

In the past, computing resources available to hospitals in the global south were very limited. As an illustration, the largest teaching and research hospital, University College Hospital, in Nigeria managed medical records through a paper-based system for more than a million patients in 2008 [1]. In recent times, however, there has been a proliferation of computing technologies through investments coming from internal as well as global sources [2]. The access to information and communication technologies has grown up rapidly across hospitals in Africa; mobile phone-based health applications are becoming available, and country-wide health information systems are also becoming digitized [2].

As computing environments in the hospitals are advancing, medical staff such as doctors, nurses, and lab technicians are exploring newer avenues to leverage technology for more efficient treatment and diagnosis for patients [3]. Health care professionals are adopting the use of smartphones or tablets with an aim to transform many tasks of their clinical practice [4]. For example, the use of laboratory information system (LIS) on portable devices like smartphones can make accessing of patient clinical records a significantly smoother experience and thus foster better decision making eventually leading to better service to the patients [4].

Users in the global south aspire to embrace mobile devices in clinical settings [5]. Considering that most of the available open source LIS are web applications, we might assume that they can be easily accessed using any web-browser across different types of platforms and devices. One might consider that since most devices come with a pre-installed web browser, there should be no additional effort required by the end-user to access a LIS on their preferred device. This, however, is not always the case.

Not having appropriate interfaces that are suited for a given task is not just an inconvenience, but in fact it makes medical professionals less efficient and less productive. Past studies have found that varying screen sizes and different interaction mechanisms require substantially different approaches for accessing information [6, 7]. For example, participants using a small screen (640 x 480) had to put twice the search effort as compared to those with a large screen (1074 x 768) [6].

In this paper, we provide a case study of the redesign of an open source LIS to meet the emerging demands of the LIS communities. C4G BLIS has been operating in seven African countries for almost a decade [8]. During this time, there have been great strides in the growth of technical infrastructures of the region it serves. We provide the details of a user study comparing task execution times between devices with large and small screen dimensions. Actual users of the latest version of C4G BLIS in three African countries participated in this user study. The findings helped us identify areas of the system requiring redesign to improve their usability. We then validate the impact of these redesign attempts and present the results.

2. BACKGROUND

LIS have become a common patients' data management tool in many countries, and there are more than ten open source software programs (e.g., Open-LIMS, Baobab LIMS, Bika LIMS, ERPNext Healthcare, eLabFTW, and GNU LIMS) in this category in 2019. LIS is specialized to support a variety of needs, from DNA/RNA processing information to human biobanking and more. It also has a variety of features. Bika LIMS, for example, provides a responsive user interface with features for reporting, inventory managing, and cataloging [9]. Occhiolino (also known as GNU LIMS) provides an interface which allows a user to interconnect lab equipment automatically and features reporting, auditing, and managing workflows. These systems are constantly needing to adapt their interface layout and elements to the demands of the user. For example, GNU LIMS is currently unable to respond to the users working environment, including accommodating the changing sizes of the screens [10].

In general, these systems are developed to address the traceability of samples, tests, and other patient information in resource-constrained areas. Traditionally, these systems have been designed to be used on a low-performance computer, a small-size monitor, and old-version software at limited network speed. However, the infrastructure for information and communication technology has been rapidly improving for the last decade. For example, 167 million of 1 billion people in Africa have access to the Internet, and connectivity is on the sharp rise [11]. Almost all the open source LIS programs cannot keep up with the growth of infrastructure and computing environments in the global south.

The technological changes in the global south are exemplified in a recent study conducted in Africa. Adedeji et al. surveyed 206 nurses in Nigeria to investigate current and preferred documentation methods and tools for the use of electronic health records in a hospital [5]. Although 94% of the nurses in the survey managed patient records using paper-based processes, 80% wanted to change to electronic methods. Forty-two% of the nurses surveyed preferred to use mobile devices such as iPad, Tablet PC, or Android Phones, while desktop computers were the least preferred devices in this survey. This is interesting in light of the fact that more of them used computers compared to mobile phones or tablets, 79.6%, 35.4%, and 14%, respectively.

3. C4G BLIS

In this section, we present the overview of C4G BLIS and analyze the problems of the current interface of the system. Then, we propose a more advanced interface to resolve the problems.

3.1 Overview

C4G BLIS is an open-source web-based system to track patients, specimens and laboratory results. It has been developed and managed by the Georgia Institute of Technology, the Centers for Disease Control and Prevention (CDC) in the United States, and Ministries of Health of several countries in Africa since 2011 [12]. Unlike other laboratory information systems, C4G BLIS was designed to address the challenges of resource-constrained settings such as computing infrastructure, variability in lab practices, and difficulty of record-keeping. The system provides three key features: 1) Robustness - To guarantee the stable operation under limited access of the Internet, it does not rely on online-based libraries for any of its operation. It only requires a simple network router, which can locally interconnect computers in a hospital. 2) Fully configurable and



Figure 1 – The registration page of C4G BLIS

Single Specimen Results	Batch Results
Patient Name Contains abdul Lab Section ALL	Test Type Select one +
Search	From 27 - 11 - 2017 (dd) (mm) (yyyy)
Verify Results	To 📑 24-08-2018
Test Type Select one Search	Search

Figure 2 – One of the issues of the current interface - inconsistent layouts of the query builder

customizable workflow - Lab administrators can determine their preferred workflows with configurable user interfaces. It means that the system does not require additional training for new users by adopting their work procedures. and 3) **Flexible database** - This feature allows to add and modify data fields as labs evolve. For example, as the specimen types and results may vary widely across laboratories and change over time, even within the same lab, the system can handle the diversity and transition smoothly. Despite many advantages of the system, there were also some problems with its user interface.

3.2 Problems of the Current Interface

In this section, we highlight problems within two core modules of the system - search and registration. Figure 1 shows the user interface for a registration function. By selecting one of the search fields (e.g., Patient Name and Patient ID) and entering keywords, a user can retrieve patients' information. The problem of this page is that the size of the actionable components is not responsive to its working environment. For example, the system cannot adjust the size of the drop-down list for a small-size smartphone. Similarly, the tiny *Search* button in the current interface will also be difficult to touch or press in the same environment.

In the Reports page of C4G BLIS, a user can generate various reports by filtering on specimen type, test type, period, and so on. As shown in Figure 2, similar search options and buttons are inconsistently located across the sub-pages of Reports. It means that the user needs to remember all the different locations of the same or similar components in each page to perform the same task; otherwise, the user should skim over each page for every trial. Consequently, this interface is likely to result in a high cognitive load or low task performance. We

Name			Abdul Juarez								
Gender			F					Register Nev	Specimen		
Age 77 Years		77 Years		Print Patient Report							
Date of	te of Birth 15-02-1941					Print Patient	Barcode				
								Billing Repor			
Test His	story ÷	Lab Receipt Date	÷	Status	•		¢		•	\$	
'est Hi e Type Semen	story ¢	Lab Receipt Date	¢	Status Results Pending	¢	Details	÷	Report	Delete	Print Barcode	
'est Hi: Type Semen Semen	story ÷	Lab Receipt Date 07-05-2010 07-05-2010	¢	Status Results Pending Results Pending	¢	Details Details	¢	Report Report	Delete Delete	Print Barcode Print Barcode	
Test His Type Semen Semen Plasma	story ¢	Lab Receipt Date 07-05-2010 07-05-2010 30-11-2009	¢	Status Results Pending Results Pending Completed	¢	Details Details Details	÷	Report Report Report	Delete Delete Delete	Print Barcode Print Barcode Print Barcode	
' est Hi : Type Semen Semen Plasma Plasma	story ¢	Lab Receipt Date 07-05-2010 07-05-2010 30-11-2009 30-11-2009	*	Status Results Pending Results Pending Completed Completed	¢	Details Details Details Details	¢	Report Report Report Report	Delete Delete Delete Delete	Print Barcode Print Barcode Print Barcode Print Barcode Print Barcode	

Figure 3 – The issue of the interface - no distinction between regular and critical operations

		search rieus	Conditio	15	Input	
Serotogy	Ŧ	Patient Name	* Contai	ns *	Search tor	Search
n Results						
Test Type	From (dd/mn	n/yyyy)	To (dd/m	n/yyyy)		
						Search
AFB	 dd/mm/yy 		ad/mn			
AFB	• dd/mm/yy		od/mn			

Figure 4 – The proposed interface of the Results.

can resolve this issue by placing the same components in the same positions across all the pages. Another problem with the current interface is that there are no visual clues to inform the users of critical task execution (see Figure 3). The users should be cautious while performing important tasks such as deleting a user or a test result. For such an issue, modern user interfaces tend to highlight the buttons related to crucial tasks with noticeable colors or shapes.

3.3 Design Proposals

In order to resolve the interface problems noted in the previous section, we redesigned the user interface with the focus on visibility, efficiency, consistency, and adaptability of the system. Figure 4 shows the consistent style and location of the search options and button in different pages of the new user interface. The size of actionable components is also increased. The left side of Figure 5 presents the Registration page of the new user interface. There is a clear visual distinction among all the different function blocks: Search, Tips, and Results. In the Search block, we kept the same style and layout of search options and button like other pages. In the Result block, we distinguished the data and buttons by providing a visual clue, a rounded rectangle, and highlighted critical actions (e.g., Delete) with a red color. Most importantly, the proposed interface is responsive, which means it can adjust its layout and elements to the user's screen setting. The right side of Figure 5 shows the same registration page accessed from a smartphone. The three blocks are vertically re-arranged, and the components of each block are also re-configured (i.e., their size and position are different). We implemented the proposed interface using Tabler dashboard toolkit [13].

4. USABILITY STUDY DESIGN

In this section, we describe the procedures and details of our user study. Overall, our user study is divided into two parts: 1) The evaluation of the existing user interface and 2) The newly proposed interface. We focus on two core functions of the system - search and registration in this study.

4.1 Participants

For the first part of the user study, we recruited 30 participants from Ghana, Cameroon, and Nigeria through system administrators of C4G BLIS in each country. For the second part, we recruited 21 participants from the three countries through the same method. To be eligible to participate in both parts of the study, participants were required to have a prior experience of using C4G BLIS. Personal information such as age, education, and gender were not collected in accordance with the research guidelines of the Institutional Review Board of Georgia Tech. The system administrators and participants were not compensated for their participation. Part 1 took 17 weeks to complete and Part 2 took 7 weeks.

4.2 Data Collection Tool

For both parts of the user study, we used the same data collection tool, HotJar, which is an advanced logging and analysis system that reveals the online behavior of users [14]. Particularly, the visitor recording feature allows us to eliminate guesswork by recording of users' actions while using C4G BLIS. By observing the participants' clicks, taps, and mouse movements, we could identify usability issues and compute the execution time of given tasks. Figure 6 presents a captured image of the HotJar system interface.

4.3 System Setup

To protect personally identifiable information of real patients in the participating labs, we decided not to run the evaluation on the systems in use; instead we set up the latest version of C4G BLIS in a Google Cloud server with dummy data set and dummy login credentials. Since the access of the Internet and the supply of electric power are sometimes unreliable, regional administrators were asked to check whether they could access the system before participating in the study.

4.4 User Study Procedure

Since the research team is based in the US, and the target users are based in Africa, we were not able to visit the laboratories where the user studies were conducted. Thus, we trained the system administrators in the target countries through conference calls and documents shared over e-mails. Later, the instructed administrators conducted the user study on-site. The training process for the administrators took about one hour per person. As shown in Table 1, our user

	Registration
Registration This pages allow us to register new patients or lookup existing patients based on name, patient ID Patient Look-up	I. Please search a patient by entering his/her name, ID, number or barcode. I. Please search a patient by entering his/her name, ID, number or barcode. I. If you cannot find him/her in the list, you can add him/her by clicking the button below.
Search Fields Conditions Input Patient Name Contains	Search patient by entering his/her This pages allow us to register new patients or lookup existing patients based on name, patient ID or number. Search or barcode. Patient Look-up 2. If you cannot find him/her in the list, you can add Search Fields
Results	him/her by conditions clicking the button below.
- 17593 Carlson Limited Female Register Specimen V	Update Delete Search for Search
- 03443 Abdul Lawson Female Register Specimen V	Update Delete
- 08940 Abra King Female Register Specimen V	Vpdate Delete PATIENT ID NAME GENDER - 17593 Carlson Limited Female Resist

Figure 5 – The proposed interface of the registration page: The user interface on a desktop (Left) and a smartphone (Right).



Figure 6 – The interface of HotJar, the data collection tool used in our user study. (Left) The red-line indicates the moving trajectory of the mouse cursor. The color dots on the bottom side illustrate events such as clicking, typing, and so on. (Right) The list shows the actions performed sequentially.

study contains two interfaces, two devices, and three jobs. In this study, laptop and desktop were not distinguished and considered as "Desktop". First, we attempted to examine the usability of the current interface of C4G BLIS. Among many factors (e.g., learnability, efficiency, memorability, and errors) used to test the usability, we chose the efficiency; the time a user takes to complete a task (The rationale for this being the fact that the primary objective of the system is to manage patient data as quickly as possible [15]).

In the training sessions with the regional administrators, we ensured that they randomize the order of desktop and smartphone studies for each participant. After a regional administrator explained the goal and details of the user study to a participant, he/she was asked to perform three tasks - 1) Find a patient with a given dummy name and view the

patient's information, 2) Find a patient with a given dummy ID number and view the patient's information, and 3) Register a new patient with a given dummy name and other details like gender, age, date of birth, and date of registration. For the second part of the user study, to evaluate the usability of the proposed interface, we followed the same structure used in the first part.

4.5 Data Collection

For the desktop environment, we were able to collect 20 and 11 datapoints in Study 1 and 2, respectively. For a smartphone setting, we gathered five and four datapoints in Study 1 and 2, respectively. For both studies in Cameroon, participants used a two-in-one computer, which is both a laptop and a tablet combined in one lightweight, portable device. After finishing the user studies in a laptop setting, they flipped its screen, switched to the tablet mode, and conducted another part of the study.

We excluded some datapoints for a number of reasons. First, the datapoints from the tablet setting were removed because we did not provide precise guidelines for that environment. We also excluded the log data for people that did not follow directions. For example, we asked a participant to find a patient on the registration page. However, he or she moved to the search page and found the patient. In this case, the two menus were different for the two pages. In Nigeria, participants were not allowed to access patient data on the smartphone. Thus, they decided not to participate in the study with the smartphone setting. Due to the tablet issue in Cameroon and the security policy issue in Nigeria, we were able to capture fewer datapoints on smartphones compared to desktops.

		User Study					
	Study 1 - Current Interface		Study 2 - Propo	sed Interface			
Device	Desktop	Smartphone	Desktop	Smartphone			
Task 1	F	inding an existing patier	nt using a given name				
Task 2	Finding an existing patient using a given patient ID number						
Task 3	Registering a new patie	nt using a given name a	and additional information	(e.g., name, age)			

 Table 1 – The structure of the user study

5. DATA ANALYSES AND RESULTS

5.1 Data Analysis

The three tasks presented in Table 1 contain the same or similar actions such as clicking the search button and moving the cursor to the view button in the result block. For the sake of data analysis, we categorized the tasks into seven actions as follows:

- Action 1: Open the Registration page and select the text input box in the search bar.
- Action 2: Open the Registration page and select the Patient ID in the option of the search field.
- Action 3: Enter the given patient name and click the search button
- Action 4: Enter the given patient identification number and click the search button
- Action 5: After checking the search result, click the profile view button
- Action 6: After checking the search result, click the new patient button
- Action 7: Fill out the patient information and submit the form.

As a quantitative metric for each action, we measured its execution time, the difference between the start and end time, and excluded the loading time such as the delay from clicking the search button to retrieving the inquiry data.

5.2 Results

Participants in our study used various devices and software as follows: Devices (Desktop, Laptop, 2-in-1 Laptop, Smartphone), Operating Systems (Windows, MacOS, Android, iOS), and Browsers (Firefox, Chrome, Edge, Safari). Their screen resolution ranged from 320x432 to 1600x786.

Table 2 describes the average execution time of each action, and the whisker plots in Figure 7 presents the minimum, first quartile, median, third quartile, and maximum values of task execution time in seconds. In order to determine how much the proposed interface has improved, we adopt one of the the usability metrics proposed by Jakob Nielsen [16]. Since adding up the task times may be misleading if the given tasks are unevenly performed, Nielsen recommended to compute the scores of improvement for each of the tasks and take the geometric mean of these scores later. For example, the relative score of the proposed interface for Action 1 in the desktop setting can be computed as ((2.5 - 1.7)/1.7 * 100) + 100 = 147% (improvement of 47%). The percentages of improvement of each action are presented in Table 2. The geometric means of the desktop and smartphone environments are 132% and 134%, respectively. In other words, it indicates that the proposed interface was perceived as having 32% and 34% higher usability in the desktop and smartphone settings, respectively than the current one. Nielsen suggested to utilize a user satisfaction score to formulate an overall conclusion if the target website is about entertainment or rarely used. However, we did not normalize the usability results with users' subjective satisfaction as C4G BLIS is informative and frequently used in hospitals.

6. **DISCUSSION**

6.1 Design

In this study, we compared the usability of desktop versus smartphone interfaces for C4G BLIS. This study was carried out at three different sites with actual users. We were able to recruit local system administrators to carry out the user studies. We then collected the log data for three tasks that were based on dummy data sets. We found improvements of up to 32% usability for desktop and up to 34% for smartphone settings for all three tasks. Although our results are promising, we found some areas where we could improve.

First, the system should allow end-users to customize more configurations. For instance, we can consider the location of the tips block (See Figure 5). Since the system is designed for medical professionals, the usage tips might not be useful after several sessions of using the system. Thus, we need to provide an option to let the user hide the tips block. This preference can be stored in the cache so that we can keep it hidden. By doing so, the user can view more search results on the same screen without scrolling. Secondly, we can streamline other



Table 2 – The average execution time for each action in seconds and the percentage of improvement



Figure 7 - Comparison of Task Execution Time. C: Current Interface, P: Proposed Interface

tasks. The actionable items in the rows of the result table need to be effectively reorganized. As shown in the bottom-right of Figure 5, the user has to swipe right to access the view, update, and delete buttons in the result table, which are the essential functions of the page. Overall, we recommend that designers and developers of LIS should carefully consider their specific target users, goals, and workflows. One way to do so is to consult with end-users and system administrators before designing the user interface.

6.2 Computing Environments

As of May 2019, the most widely used browser in Africa is Chrome for Android (35.09% in the market share), and the latest Chrome (Version 74.0) is also broadly adopted (17.65%) [17]. In sharp contrast, there was one dominant operating condition when C4G BLIS was designed in 2011 -Windows (81%), About 1024x768 screen resolution (51%), and Internet Explorer (15%) or Opera (11%) browsers. This fact suggests that the user interfaces designed for the global south should be revisited so that they are stable, adaptive, and responsive to their heterogeneous operating environments.

6.3 Needs in the Near Future

A system administrator in Cameroon reported that 75% of the participants preferred working with tablets if the screen was large enough, and 25% of them were approved the use of smartphones to access the laboratory data. We also found similar needs in Section 2; 42% of nurses in Nigeria preferred to use mobile devices such as iPad, Tablet PC, or Android Phones. Future studies should collect qualitative data to see where these preferences are coming from – aspirational desires (i.e., preference for a modern device) or needs (better portability throughout the clinic).

6.4 Interface Standard and Usability

Medical data exchange standards have been considered as a central issue of hospital information systems, thus many researchers and organizations have attempted to develop efficient, inter-operable standards and protocols such as Health Level Seven (HL7), Clinical Document Architecture (CDA) and Continuity of Care Document (CCD), and Systematized Nomenclature of Medicine (SNOMED). Several studies found that adopting such a standard could simplify communication interfaces and improve the quality of patient care [18, 19]. Another critical issue of the clinical information systems is the difficulty of use, which is one of the dissatisfaction factors expressed by healthcare professionals [20]. Specifically, the complex interfaces and the lack of intuitiveness causes usability problems. However, this issue has not been treated as necessary as the data exchange standards [21].

In the evaluation report of Electrical Medical Record (EMR), Belden et al. said that "Usability is one of the major factors possibly the most important factor - hindering widespread adoption of EMRs. Usability has a strong, often direct relationship with clinical productivity, error rate, user fatigue and user satisfaction ... [22]." Although there have been some efforts to resolve the usability issues such as the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009 and an incentive program by the U.S. Centers for Medicare & Medicaid Services, the improvement of the usability has still been slow [21]. As shown in our study, we were able to improve the usability by up to 34% by applying a responsive, simple, open-source website framework to the existing LIS. It should not be a challenging task in terms of cost and development effort. We highly encourage that international standards organizations dealing with health informatics should pay attention to the usability standards for laboratory information systems as they include diverse devices, platforms, and browsers, as important as they did for medical record interoperability.

Since the International Organization for Standardization (ISO) proposed the definition of usability (ISO 9241-11) and its metrics (ISO/IEC 9126-4), a few usability models and evaluation techniques have been studied in the hospital information system domain [23, 24]. Among them, a prime example would be the empirical guideline for safety-related usability of EHR (NISTIR 7804-1) proposed by the National Institute of Standards and Technology (NIST) [25]. The guidelines described three critical implications -1) Consistently present patient identification in a reserved area to prevent wrong-patient errors, 2) Provide visual cues to minimize the risk of entering information and writing orders in the wrong patient's chart, and 3) Support efficient and easy identification of incorrect items in lists of grouped information by presenting clear, well-organized evidence. Similar to the standardization efforts in NIST, more practical and applicable standards are needed for safer and effective hospital information systems.

7. LIMITATIONS

We were in the US, and our target users were in Africa. We opted to use log data for the analyses, which meant that we were not able to observe participants' behavior in person while they completed the tasks. Thus, it was challenging to understand unexpected behaviors such as inactive mouse cursors and random delays in typing. While we did our best to train the administrators, we cannot guarantee that all the coordinators kept their eyes on the participants during the entire user study. In this study, we only focused on the task execution time, but future studies should evaluate task success rate, error rate, and user satisfaction since these are also important usability measures.

8. CONCLUSION

In this paper, we have examined the usability issues of an existing LIS and proposed a new, responsive user interface to resolve them. We were interested in the extent to which the proposed interface could improve usability in heterogeneous environments. Results indicated an average improvement of about 30% across various metrics. Based on the results, we highlighted the current status of computing environments and user needs in the near future. Additionally, we discussed several factors which can improve the quality of laboratory information systems and recommend adding usability specifications to international standards.

REFERENCES

- I. E. Asangansi, O. O. Adejoro, O. Farriab, and O. Makinde, "Computer use among doctors in africa:survey of trainees in a nigerian teaching hospital," *Journal of Health Informatics in Developing Countries*, vol. 2, no. 1, pp. 10–13, 2008.
- [2] M. Shekar and K. Otto, "Information and communication technologies for health in africa," The World Bank Group, Tech. Rep., 01 2014. [Online]. Available: http://documents.worldbank.org/curated/en/ 553151468009030957/ICTs-for-health-in-Africa
- [3] C. L. Ventola, "Mobile devices and apps for health care professionals: uses and benefits," *P T*, vol. 39, no. 5, pp. 356–364, May 2014, 24883008[pmid].
 [Online]. Available: https://www.ncbi.nlm.nih.gov/pubmed/24883008
- [4] S. Wallace, M. Clark, and J. White, "it's on my iphone': attitudes to the use of mobile computing devices in medical education, a mixed-methods study," *BMJ Open*, vol. 2, no. 4, 2012. [Online]. Available: https://bmjopen.bmj.com/content/2/4/e001099
- [5] P. Adedeji, O. Irinoye, R. Ikono, and A. Komolafe, "Factors influencing the use of electronic health records among nurses in a teaching hospital in nigeria," *Journal of Health Informatics in Developing Countries*, vol. 12, no. 2, pp. 1–20, 2018. [Online]. Available: http://www.jhidc.org/index.php/jhidc/article/view/174
- [6] M. Jones, G. Marsden, N. Mohd-Nasir, K. Boone, and G. Buchanan, "Improving web interaction on small displays," in *Proceedings of the Eighth International Conference on World Wide Web*, ser. WWW '99. New York, NY, USA: Elsevier North-Holland, Inc., 1999, pp. 1129–1137. [Online]. Available: http://dl.acm.org/citation.cfm?id=313234.313014

- [7] V. Roto and A. Oulasvirta, "Need for non-visual feedback with long response times in mobile hci," in Special Interest Tracks and Posters of the 14th International Conference on World Wide Web, ser. WWW '05. New York, NY, USA: ACM, 2005, pp. 775–781. [Online]. Available: http://doi.acm.org/10.1145/1062745.1062747
- [8] Georgia Institute of Technology, "C4G Basic Laboratory Information System." [Online]. Available: http://blis.cc.gatech.edu/
- [9] BIKA Lab Systems, "Bika lims, open source laboratory information management system." [Online]. Available: https://www.bikalims.org
- [10] GNU Solidario, "Occhiolino, gnu laboratory information management system." [Online]. Available: http://lims.gnu.org
- [11] Internet Society, "History of the internet in africa." [Online]. Available: https://www.internetsociety.org/ internet/history-of-the-internet-in-africa/
- [12] S. Vempala, N. Chopra, A. Rajagopal, J. Nkengasong, and S. Akuro, "C4g blis: Health care delivery via iterative collaborative design in resource-constrained settings," in *Proceedings of the Eighth International Conference on Information and Communication Technologies and Development*. New York, NY, USA: Association for Computing Machinery, 2016. [Online]. Available: https://doi.org/10.1145/2909609.2909657
- [13] Codecalm.net, "Tabler ui kit." [Online]. Available: https://github.com/tabler/tabler
- [14] Hotjar, "Hotjar: Visitor recording platform." [Online]. Available: https://www.hotjar.com/
- [15] J. Nielsen, "Usability metrics: Tracking interface improvements," *IEEE Software*, vol. 13, no. 6, pp. 12–13, Nov. 1996. [Online]. Available: http: //dl.acm.org/citation.cfm?id=624616.625647
- [16] Nielsen Norman Group, "Usability metrics," Nielsen Norman Group, Jan. 2001. [Online]. Available: https://www.nngroup.com/articles/usability-metrics/
- [17] StatCounter, "Browser version market share africa," StatCounter Global Stats, Jun. 2019. [Online]. Available: http://gs.statcounter.com/browser-versionmarket-share/all/africa
- [18] C.-H. Lin, I.-C. Lin, J.-S. Roan, and J.-S. Yeh, "Critical factors influencing hospitals' adoption of hl7 version 2 standards: An empirical investigation," *Journal of Medical Systems*, vol. 36, no. 3, pp. 1183–1192, Jun 2012. [Online]. Available: https://doi.org/10.1007/s10916-010-9580-2
- [19] O. Lupse, M. Vida, L. Stoicu Tivadar, and V. Stoicu Tivadar, "Using hl7 cda and ccd standards

to improve communication between healthcare information systems," in 2011 IEEE 9th International Symposium on Intelligent Systems and Informatics, Sep. 2011, pp. 453–457.

- [20] ASC Communications, "Survey: Providers investing heavily in ehrs, but dissatisfied with purchase," *Becker's Hospital Review*, Jun 2014. [Online]. Available: https://www.beckershospitalreview.com/healthcareinformation-technology/survey-providers-investingheavily-in-ehrs-but-dissatisfied-with-purchase.html
- [21] P. Sengstack and C. Boicey, *Mastering informatics: a healthcare handbook for success*. Sigma Theta Tau International, Honor Society of Nursing, 2015.
- [22] J. L. Belden, R. Grayson, and J. Barnes, "Defining and testing emr usability: Principles and proposed methods of emr usability evaluation and rating," *HIMSS EHR Usability Task Force*, pp. 1–38, Jun. 2009. [Online]. Available: https://www.himss.org/file/ 1268216/download?token=L4oSWWi1
- [23] "Ergonomics of human-system interaction Part 11: Usability: Definitions and concepts, ISO 9241-11:2018," International Organization for Standardization, Geneva, CH, Standard, 2018.
- [24] "Software engineering Product quality Part 4: Quality in use metrics, ISO/IEC TR 9126-4:2004," International Organization for Standardization, Geneva, CH, Standard, 2004.
- [25] Svetlana Z. Lowry, Mala Ramaiah, Emily S. Patterson, Sandra S. Prettyman, Debora Simmons, David Brick, Latkany A. Paul, Michael C. Gibbons, Sheryl L. Taylor, "(NISTIR 7804-1)Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records: Empirically Based Use Cases for Validating Safety-Enhanced Usability and Guidelines for Standardization," *NIST Interagency/Internal Report*, pp. 1–44, 2015. [Online]. Available: https: //doi.org/10.6028/NIST.IR.7804-1

#RINGINGTHEALARM: CHRONIC "PILOTITIS" STUNTS DIGITAL HEALTH IN NEPAL

Ichhya Pant¹; Anubhuti Poudyal²

¹George Washington University School of Public Health ²George Washington University School of Medicine and Health Sciences

ABSTRACT

Nepal Health Sector Strategy (NHSS) 2015-2020 aspires to leverage digital health to improve health outcomes for Nepalese citizens. At present, there is a paucity in evidence on digital health projects that have been implemented in Nepal. This study aims to map past and extant digital health projects using Arksey and O'Malley's scoping design framework and assess projects using the World Health Organization (WHO) building blocks of a health systems framework. Our findings shed light on the current actors in the digital health space, the spectrum of health services offered, along with opportunities and challenges to move beyond "pilotitis". In total, 20 digital health solutions were identified through our review that were implemented between 1993 to 2017. The momentum for digital health projects in Nepal is sporadic but continuous. Overall, digital health solutions in Nepal are limited in scope, focus areas, target audiences and sustainability potential. At the national level, implementation of digital health projects is frayed, issue and organization-centric, and primarily driven by donor or non-governmental organizations. Engaging the private sector, especially telecommunications companies, is an underutilized strategy to move beyond "pilotitis". Existing pioneers in the space must engage in strategic collaborative partnerships with the private sector or incentivize independent commercial health technology ventures.

Keywords – Digital health, ICTs, Nepal, pilotitis

1. INTRODUCTION

The health system in Nepal is fraught with systemic challenges due to factors such as the country's status as an economically least developed country, inaccessible mountainous terrains and sociological and topographical diversity. Economic and demographic transitions, migration and unplanned urbanization adversely influence the health of the population as well [1,2]. A decade-long civil conflict and political turmoil has also contributed to worsening mental health outcomes, disruption of service delivery in impacted areas, and a compromised health policy and governance system [3,4,5]. Despite these setbacks and challenges, Nepal has made significant progress in reducing under-five

mortality by 73%, infant mortality by 67%, and maternal mortality by 76% over the course of a few decades after the Millennium Development Goals (MDGs) declaration in 1990 [2]. In parallel, advances in mobile (138.59%) and Internet market penetration (67.23%) have facilitated an uptake of electronic health (e-health) and mobile health (m-health) tools and solutions within the health sector [6,7].

Globally, there is great enthusiasm for the potential of digital health solutions to radically improve population health outcomes especially in low-resource settings [8]. Studies have, however, recognized challenges in integrating mhealth interventions into existing healthcare systems [9,10]. These challenges range from regulatory to technological and user-specific [10]. Competing health priorities, underdeveloped infrastructure, lack of knowledge among country or regional e-health policy makers concerning the potential applications of m-health and its recognition as an approach to health-related issues are some of the key barriers to digital health uptake and institutional adoption [11]. However, insufficient evidence remains the primary reason for the inability of governments to establish the effectiveness of digital health efforts in improving access or affordability of preventative, curative or rehabilitative services [11,12,13] and Nepal is no different. There is a paucity of documentation and evidence related to digital health solutions implemented in Nepal to date.

To bridge this gap in documentation and evidence, this study aims to scope digital health solutions implemented in Nepal.

2. METHODS

The study uses a scoping design to obtain information on digital health initiatives in Nepal. Research activities were conducted between June 2017 to September 2018. The George Washington University Institutional Review Board and Nepal Health Research Council (NHRC) approved this study. Scoping review is a method of synthesizing knowledge on studies when: it is difficult to employ a narrow review question; synthesizing information from studies that have used a wide variety of data collection and analysis techniques; there is a scarcity of prior synthesis on the topic; or a quality control mechanism of the reviewed sources will not be conducted [12,14,15]. This study replicated a scoping

review conducted in Bangladesh utilizing Arksey and O'Malley's framework to map digital health initiatives due to scarcity of prior synthesis on the topic [12,14,15]. It is a method that is used widely in scoping reviews because it maintains a rigorous process for transparency, replicability and reliability of study findings. The study was designed to answer the following research questions: 1) who are the subsisting digital health actors in Nepal, and 2) what spectrum of services are being covered through digital health initiatives?

Our study first identified grey literature on digital health initiatives, then assessed them according to the WHO Health Systems Framework [16]. Relevant literature was identified using two sets of keywords: one for journal articles and the other for grey literature. For journal articles, the keywords were adopted from prior systematic reviews on digital health solutions as shown in Table 1 [17]. For additional sources, a Google search using specific keywords was conducted. For newspaper articles, the NewsBank database was utilized. The initial search yielded 316 articles on Google scholar, 72 articles on PubMed, and 274 articles via NewsBank. A screening tool was developed to ensure selected documents focused on digital health solutions in Nepal and provided details on the organization or project associated with its implementation. After the screening process, a total of 31 documents dating from 2005 to 2017 were selected for charting. Types of documents selected are journal articles, newspaper articles, websites, presentations slides, conference briefings, organizational reports and blog posts. Selected documents were systematically charted by three research assistants followed by ongoing quality assurance audits by the lead authors to ensure uniformity and rigor in the charting process. The charting was done under the following themes addressing the WHO health system building blocks, organizational profile, program overview, financial profile, human resource, services, monitoring and evaluation framework, sustainability plan, and future direction. Once the charting process was completed, the research team analyzed the charted information looking for common traits and themes under each charting category [16].

 Table 1 – Digital health solutions search keywords

Database/Search engine	Keywords
PubMed	mHealth, mobile phone, phone, SMS, text message, mobile device, telemedicine, cell phone, mobile health, mobile applications, cell phones
Google	mobile health, mHealth, electronic health, eHealth, mobile phones and health, Nepal, technology
Google scholar	mHealth, mobile phone, SMS, text messages, mobile devices, telemedicine, cell phone, mobile health, cell phones, mobile applications

3. RESULTS

In total, 20 digital health solutions were identified through our review that were implemented between 1993 to 2017. In 1993, an integrated health management information system (HMIS) was introduced in Nepal by the government marking the first e-health effort in the country [18]. A decade later the private sector initiated the first telemedicine system (HealthNet Nepal) which was a collaborative telehealth effort between Om Hospital Research Center and the Apollo Hospital in India [18,19]. This was followed by a three-city telemedicine program by a social enterprise in 2006 [19,20]. Next, a formal government led telehealth program with a budget of approximately Rs. 20 million (NPR) was established offering telehealth services to 25 districts [19,21]. Specialized telehealth programs were also established, primarily in the non-governmental sector, to provide healthcare for epilepsy diagnosis, treatment of severe wasp stings or dermatological consultations [22,23,24]. Beyond telehealth programs, collaborative projects between the Government of Nepal (GoN) and development partners have been established over time [24,25,27,28]. These efforts have entailed bolstering population-health surveillance efforts with the migration of HMIS to the District Health Information System (DHIS)-2 platform, expansion of HMIS e-reporting from facilities, Smart Health Nepal initiative, and projects exploring the feasibility of mobile data collection from frontline workers in remote areas [18].

Table 2 – Digital health solutions in Nepal (1993-2016)

Status	Name	Launch Year
	I/NGOs (11, 55%)	
*	Nepal Wireless Telemedicine Program	2006
\checkmark	Dhulikhel Hospital Telemedicine Program	2011
*	USAID Health for Life	2013
*	Nick Simon Institute Celemedicine Program	2013
\checkmark	Golden Community eHealth Nepal Program	2015
\checkmark	Possible Health CHW Mobile Reporting Trial	2015
\checkmark	Medicine Du Monde Telecom Sans Frontiere Surveillance Project	2015
\checkmark	Maiti Nepal mHealth Capacity Building Projects	2015
\checkmark	Dhulikhel Hospital Epilepsy Diagnosis Application	2016
\checkmark	One Heart Worldwide Maternal Health mHealth Project	2016
(?)	CHEST Project by CHEST Nepal	2017
	Public (6, 30%)	
*	HMIS	1993
*	Hello Health, Rural Telemedicine Program	2010
\checkmark	RCM-MP	2015
*	m4ASRH	2015
*	DHIS-2	2016

(?)	Smart Health Nepal	2017
Private (3, 15%)		
×	HealthNet Nepal Telemedicine Program	2004
*	Health at Home Nepal	2007
	Safe SIM	2015

*Ongoing $\sqrt{\text{Completed} \times \text{Discontinued}}$ (?) Unknown

Table 2 identifies the 20 projects, affiliated organizations, implementation launch year and their current implementation status. More projects had been completed (45%) compared to ongoing (40%) ones based on our review. At least one identified program, the earliest telemedicine program offered in Nepal (HealthNet Nepal) has been discontinued citing financial viability as their primary barrier [26]. To understand these initiatives in greater depth, we have categorized them per WHO health system building blocks [16].

3.1 Health service delivery

Telehealth programs are the most prevalent form of service delivery format for digital health solutions implemented in Nepal. Focus areas for digital health solutions ranged from health surveillance, adolescent, sexual, and reproductive health, detection of disease outbreaks, maternal and child health, and mental health issues [25,26,35,36]. Services provided by digital health solutions focused on bolstering health information systems, increasing access and utilization of health services, increasing access to health information, providing health education and generating health awareness, developing referral mechanisms, providing specialized healthcare via telemedicine, and improving technical capacity among health professionals and frontline workers [27,28,29,30].

3.2 Health information

Health information systems developed for population health surveillance, data collection and management, and patient monitoring and support are the major focus areas for digital health solutions implemented in Nepal. According to a country profile on HMIS capacity developed by Measure Evaluation, the existence of a national health information system (HIS) policy is unknown [31]. Currently, there is an HIS strategic plan and a national HIS coordinating body was established in the past, but their current activities are also unknown [31]. In 2016, the Nepalese MoH transitioned from HMIS to DHIS-2. The DHIS-2 serves as a subnational level electronic system for aggregating routine facility or community service data. Its roll-out is in an early phase, starting at the national level followed by the district level then extending to health posts and primary care facilities in a few districts. Remote locations, underdeveloped information communication technology (ICT) infrastructure, difficult terrain, digital data and technological literacy, and a lack of data standards and interoperability have challenged the implementation of health information systems [32,38]. However, substantial time savings in data collection and entry have helped mitigate these challenges. The increase in convenience by being able to analyze and visualize data, monitor data collection and management in real time, and more importantly improve data quality, have been well received by impacted teams and stakeholders. The ability to make informed decisions will soon be available at multiple levels of the health system in Nepal due to these efforts. Ultimately, these efforts, if sustained, will strengthen health sector governance and improve the availability and quality of health service delivery [32]. However, doing so will require forethought and development of data strategies with feedback loops into implementation strategic plans. Our review did not find any mention of either of these activities happening in Nepal to date.

3.3 Health workforce

Frontline workers were the target audience for over half of the identified projects (55%) especially female community health volunteers (FCHVs) [24,28,33-37]. Mid-level medical personnel and health staff at remote locations were also other beneficiaries of digital health initiatives in Nepal [19,23,29,38,39,42]. Scarcity of a readily available and skilled in digital health workforce trained implementation result in projects relying on internal training to sensitize project staff in the use of technological solutions [18,28]. Our review did not find existing academic digital health programs in Nepal. Significant issues at the workforce level cited by the initiatives reviewed in our study were poor coordination between ground level and higher-level staff and educational, digital and data illiteracy within the workforce. Readiness to utilize developed solutions was assessed infrequently.

3.4 Technology

Telecommunication-based digital health solutions were most prevalent. These solutions ranged from smart-phone applications for patient monitoring, care or diagnosis, data collection via a simple SMS-based reporting, telemedicine [21] or population-health surveillance via health information systems [38]. Challenges that hindered technological implementation were weak mobile networks [40], slow Internet service [27], unreliable power [27,40], technical difficulties such as unanticipated system errors and reliance on undeveloped ICT infrastructure [28].

3.5 Leadership and governance

There are a few notable policy and strategic frameworks in Nepal that speak towards the utility and uptake of digital health solutions. In 2014, the Nepal Health Sector Strategy (NHSS) 2015-2020 was published by the Government of Nepal [41]. It functions as Nepal's guide to graduate from "Least Developed Country" to "Middle Income Developing Country" by 2022. Additionally, it articulates the nation's commitment towards achieving universal health coverage (UHC) by placing health at the center of the overall socioeconomic development efforts. Per the NHSS, the GoN in collaboration with its development partners, aspires to leverage novel technologies to address health challenges in the country. Recognizing that health is a critical indicator of economic advancement, NHSS stipulates ICT such as digital health tools as essential in improving access and quality of health services delivery [43]. Nepal's eHealth Strategy was published in 2017 which documents the vision of using ehealth to facilitate the delivery of accountable, equitable and high-quality health service delivery [18,37].

Evidence supports the notion that investments made to bolster ICT infrastructure result in tangible improvements in economic growth and achievement of human development milestones especially for developing countries [39,44]. However, mirroring the economic divide between developed, developing and least developed nations is the digital divide defined as the difference between the uptake and utilization of ICT in the daily lives of citizens [45]. Reflecting this digital divide, Nepal ranks 165th in the e-government development index [38,46]. The ICT policy environment in Nepal does not meet modern demands mired by endemic corruption, political instability and civil conflict [6,47]. A detailed strategic framework has been put forward to improve access to quality healthcare using ICT and modern technologies in the latest update to the national ICT policy. This will be achieved through an increased investment in ICT-based healthcare systems with a special emphasis on telemedicine programs. These systems and networks will be developed and implemented through a collaborative approach involving public, private and civil society actors. Regulatory frameworks will be developed to guide and govern health information and ensure security measures curtail any privacy and ethical concerns [48,49]. So far, three policies have been established that address digital health efforts in Nepal: Nepal E-governance Interoperability Framework. Electronic Transaction Act and Telecommunication Policy [18]. The Nepalese Ministry of Health (MoH) has identified the formulation and institutionalization of a national e-health steering committee planning. and task force to govern strategic institutionalization of an e-health unit at the MoH, procurement of resources and technical assistance, development of prioritized e-health plans. This is reflected in annual work plans and budgets, development of legal provisions such as a Health Information Act to address data use, privacy and confidentiality issues, and development of monitoring and evaluation frameworks embedded into NHSS as prerequisites to achieving the goals set forth in the national eHealth strategy of 2017.

3.6 Financing and sustainability

More than half of the 20 initiatives were implemented by international or national-level non-profit organizations (I/NGOs) such as RTI International, USAID, GIZ, Possible Health, Nick Simon's Institute, and One Heart Worldwide (Table 2). This contrasts the findings of Ahmed et al. [12] in Bangladesh where the private sector leads the development and implementation of digital health solutions. In Nepal, the private sector is the least prolific in this space (15%). Digital health solutions in Nepal appear to be mainly donor (55%) and government driven (30%). Our findings, however, are in alignment with the results of a global e-health survey conducted by the WHO which note that financial management in e-health and m-health is largely fulfilled by donors [50]. Among the identified projects, 85% were conducted in multi-sectoral collaborative partnership between donors, non-governmental organizations, or the GoN. Some of these actors collaborated directly with the GoN at the national level. Other collaborations were with the regional or local governing bodies. Direct financial assistance from the government was not apparent in our review aside from the allocated funding for the Hello Health telemedicine program. Financial stability was an important indicator of the sustainability of identified projects. Irregular funding has been noted as a significant hindrance to the effective implementation of projects [27]. Assessing economic feasibility was also a rarity among identified initiatives despite most projects indicating monitoring and evaluation frameworks at the project level. One identified project ended their feasibility trial without plans for scaling up despite improvement in project indicators after performing an economic evaluation which determined the program was not worth the financial and human costs incurred by their organization [28].

Very few projects discussed the potential of sustainability. Identified projects were primarily feasibility trials in earlyphases (85%) conducted in rural areas (65%). Since most of these projects were short-term, the results ended with no plans to continue the initiative after the end of the funding period. The GoN was identified as the appropriate lead actor in taking ownership of the space and assessing the effectiveness of digital health solutions in Nepal then working towards scaling them up through integration and institutionalization with national-level systems [27]. Leadership turnover, especially when multiple partners were involved, was identified as a contributing factor for the failure of digital health solutions [23,28,40].

4. DISCUSSION

Due to a recent constitutional mandate, Nepal is currently in the process of transitioning to a federal state. Local municipal governing bodies will soon fully assume the responsibility of health-sector planning, budgeting and oversight of health service delivery. In parallel, the country's commitment to UHC and its quest to develop high-quality health systems to meet Sustainable Health Development Goals (SDGs) by 2025 place Nepal at an opportune juncture to map out its strategic course of action within the health sector. This is an apt time to assess where digital health solutions fit within the current health system and how they can be leveraged in impactful ways. The implementation timeline and trajectory represented by our review indicate that the momentum for digital health solutions has been sporadic but continuous in Nepal. Its evolution is still in nascent stages thus presenting opportunities to influence it with evidence-based and data-driven strategies. In the past 25 years, there has been an absence of diversity in the application, utilization and uptake of digital health solutions in Nepal demonstrated by the limited scope, focus areas,
target audiences, sustainability potential and proliferation in certain sectors only.

Much like the overall course of the health system evolution in Nepal [51], digital health solutions are frayed, issue and organization-centric, and primarily driven by donor or nongovernmental organizations. Most solutions have focused on telemedicine to enhance gaps in healthcare access in rural areas with frontline workers heavily burdened with multiple e-health or m-health tools and solutions for different programs or organizations. There are missed opportunities to increase service delivery beyond providing basic or specialized healthcare in rural areas and addressing health challenges related to maternal and child health or sexual and reproductive health. The rise of non-communicable diseases, unplanned urbanization and demographic transition to a higher number of elderly populations juxtaposed with a continuing flow of migrant youth working abroad warrant the exploration of digital health solutions beyond its current limited scope and application [1,2,27,52,53,54]. Informal consultations with key informants have shed light on the fact that digital health solutions are being implemented in Nepal in these areas through informal channels on an as-needed basis and are yet to be documented or formalized due to regulatory, financial/compensation or resource gaps. Our team is currently analyzing findings of key informant interviews with stakeholders on the ground to share our review findings, attain insights regarding facilitators and barriers, and explore the utilization and potential of digital health solutions in Nepal beyond what has been found through this review.

From a leadership and governance perspective, progress has been made to set the stage for digital health solutions to be implemented in Nepal by establishing a few strategic frameworks and policies in place. However, integration and institutionalization of digital health solutions are still not at the forefront of these policy agendas. While a national health ID, data standardization, and interoperability frameworks are critical key ingredients in this space [38], so too is gathering knowledge and evidence on the implementation and effectiveness of digital health solutions at a national level. It is also important to understand and tailor digital health solutions and frameworks according to the needs of the target audience so that the output is user-centric [6,59]. Furthermore, there is a critical need to address technical, cultural and knowledge barriers among stakeholders such as lack of data and digital literacy, fear of technology, and a shared understanding of the definition and application of digital health solutions respectively among stakeholders, decision-makers, and policy makers. Equally critical is the need for the GoN to mitigate the vast digital divide in Nepal [38]. A national-level monitoring and evaluation of innovative digital health solutions is needed to identify costeffective solutions that can be scaled up and integrated to the overall health system framework. Assuring sustainability of effective solutions will require thought leadership, strategic oversight, resource allocation, transparency by the GoN, and a baseline level of understanding of the potential of digital health solutions among stakeholders. Developing local workforce capacity and enriching academic programs to meet increasing demands for digital health expertise is another area that requires investment and sustained commitment by stakeholders. Engaging the private sector, especially telecommunication companies, is an underutilized strategy to address current barriers related to implementation, technical, financial and sustainability challenges [12]. Existing pioneers in this space (GoN and I/NGOs) must engage in strategic planning on how to increase collaborative partnerships with the private sector or incentivize independent commercial ventures [55].

5. STRENGTHS AND LIMITATIONS

Our scoping study was successful in retrieving information regarding 20 digital health solutions implemented via formal channels in Nepal to date. To the best of our knowledge, this is the first paper to capture national level digital health efforts implemented in Nepal and analyze the space utilizing two rigorous evidence-based frameworks [15,16]. Informal consultations with experts suggest the potential of additional digital health solutions implemented via both formal and informal channels that were not captured in our study since they are not publicly accessible via the Internet or published in academic journals. There is currently an effort on our part to analyze findings from key informant interviews to bridge this documentation gap. Evaluating the effectiveness of identified solutions was not feasible with the limited resources available to achieve the scope of this study. This line of investigation is a fruitful avenue for future studies to explore and research.

6. CONCLUSION

Due to its current sociopolitical and ICT climate, Nepal is well-positioned to take a holistic multilevel systems perspective accounting for the WHO building blocks in charting the course of digital health solutions in Nepal. In doing so, we echo the recommendation of Ahmed et al. [12] to adopt the guidelines and toolkits established by the Rockefeller Foundation, WHO, and International Telecommunication Union (ITU) in addition to conducting a national-level assessment exploring the application of digital health solutions along with an evaluation of all solutions developed to date [12,56,57,58]. Additionally, we recommend the adoption of the Principles of Digital Development developed in consultation with multiple development and health organizations and foundations [59], the recently released guidelines for digital interventions for health systems strengthening by the World Health organization [60], while taking a whole-of-government investment approach [61].

Taking a regional and global perspective on our findings, China, India and Uganda serve as exemplary cases. With the proliferation of the digital era, digital health interventions have been prolific in middle and low-income countries. However, they remain stuck in "pilotitis" without the ability to scale [62]. Frustrated by this phenomenon, the government of Uganda issued a moratorium on digital health interventions in 2012 [63]. In contrast, the adoption of digital health solutions sparked into existence in China when combating SARS in late 2002. In both countries, however, there has been substantial challenges related to buy-in from stakeholders to adopt digital innovations. The reasons cited mirror our findings. In the same vein, the Indian MoH published a National Digital Health blueprint for public comment and review in 2019 to address this endemic issue of fragmentation and "pilotitis" within the digital health space [64]. To counter the documented stunting of digital health interventions nationally, regionally and globally, we wholeheartedly agree with Huang and colleagues that the key to moving beyond digital health "pilotitis" is in considering the governmental, social, political and historical contexts so that the attitudes, perceptions and needs of stakeholders are accounted for just as much as the design and development of digital health solutions [61,62].

REFERENCES

- Y. Subedi, P. Simkhada, E.R.V. Teijlingen. "Where is Nepal in the Demographic Transition in the Wider Context of the Nutrition Transition?", Open Journal of Social Sciences, vol 04(05), pp 155-166, 2016.
- [2] WHO Nepal. Health System in Nepal: Challenges and Strategic Options, 2007.
- [3] N.P. Luitel, M.J.D. Jordans, A. Adhikari, A., N. Upadhaya, C. Hanlon, C. Lund, and I.H. Komproe. "Mental health care in Nepal: current situation and challenges for development of a district mental health care plan". Conflict Health; vol 9, pp 3, 2015.
- [4] Nepal Ministry of Health and Population. National Mental Health Policy. Kathmandu: Ministry of Health and Population; 1997.
- S. Singh. "Impact of long-term political conflict on population health in Nepal". Can Med Assoc J, 171(12), pp 1499–502. doi: 10.1503/cmaj.1040777, 2004.
- [6] A. Sharma, Y.S. Kim. "Information Communication Technology Development in Nepal". JRSD, pp 101-141, 2018.
- [7] Nepal Telecommunications Authority. MIS Report, vol 177(129), 2019: <u>https://nta.gov.np/wpcontent/uploads/MIS-2076-Shrawan.pdf</u>
- [8] J.G. Kahn, J.S. Yang, & J.S. "Mobile" health needs and opportunities in developing countries. Health Affairs, vol 29, pp 252 – 258, 2010.
- [9] V. P. Gurupur, Wan T.H. "Challenges in implementing mHealth interventions: a technical perspective". mHealth, 3, 32. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC558</u> <u>3043/</u>

- [10] L. Wallist. "Integrating mHealth at point of care in low- and middle-income settings: the system perspective." Global Health Action. 10(3). <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC564</u> <u>5717/</u>
- [11] WHO Department of Health Statistics and Information of the Innovation, Information, Evidence, and Research Cluster in collaboration with WHO technical programmes and regional offices: World Health Statistics 2011. France: World Health Organization, 2011.
- [12] T. Ahmed., H. Lucas, A.S. Khan, R. Islan, A. Bhuiya, M. Iqbal. "eHealth and mHealth initiatives in Bangladesh: A scoping study". BMC Health Services Research, vol 14, pp 260, 2014.
- [13] A. Chib, M.H. Velthoven, C. Joseph. "mHealth Adoption in Low-Resource Environments: A Review of the Use of Mobile Healthcare in Developing Countries". Journal of Health Communication, vol 20(1), pp 4-34, 2015.
- J. O'Flaherty, C. Phillips. "The use of flipped classrooms in higher education: A scoping review." The Internet and Higher Education, vol 25, pp 85-95.
- [15] H. Arksey, L. O'Malley. "Scoping studies: towards a methodological framework". International Journal of Social Research Methodology: Theory & Practice. 2005, vol 8(1), pp 19-32, 2005.
- [16] WHO Department of Health Statistics and Information of the Innovation, Information, Evidence, and Research Cluster. Monitoring the Building Blocks of Health Systems: A Handbook of Indicators and their Measurement Strategies, Geneva, Switzerland, 2010: <u>http://www.who.int/healthinfo/systems/WHO_MBH</u> <u>SS_2010_full_web.pdf</u>
- [17] D. Colaci, S. Chaudhri, A. Vasan. "mHealth interventions in low-income countries to address maternal health: A systematic review". Ann Glob Health, vol 82(5), pp 922-935, 2016.
- [18] Nepal Ministry of Health. "eHealth initiatives in Nepal", 2017: <u>http://nhsp.org.np/wp-</u> content/uploads/2017/08/eHealth-Initiatives.pdf
- P.R. Lama. "Scope and challenges of Telemedicine in Nepal: A look towards future. A case study at Om Hospital and research Centre Kathmandu, Nepal.", 2010: <u>http://nrl.northumbria.ac.uk/11374/1/lama.tshering</u> <u>phd.pdf</u>

- [20] M. Pun, R. Shields, Paudel R., P. Mucci. Nepal Wireless Networking Project: Case Study and Evaluation Report, 2006.
- [21] B. Bhandari, B. "Telemedicine: Healthcare in Times of High Technology". My Republica, 2010: <u>http://archives.myrepublica.com/portal/index.php?ac</u> <u>tion=news_details&news_id=1636</u>
- [22] V. Patterson, M. Singh, H. Rajbhandari, S. Vishnubhatla. "Validation of a phone app for epilepsy diagnosis in India and Nepal". Elsevier, 30:46-49, 2015.
- [23] J. Morrison, N.R. Shrestha, B. Hayes, & M. Zimmerman. "Mobile phone support for rural health workers in Nepal through 'celemedicine'". Journal of Nepal Medical Association, vol 52(191), 2013.
- [24] United Nations Population Fund Nepal. Harnessing Mobile Technology to Improve ASRH Knowledge in Nepal, 2014: <u>https://nepal.unfpa.org/en/news/harnessing-mobiletechnology-improve-asrh-knowledge-nepal</u>
- [25] USAID. Reaching Pregnant Women in Marginalized Communities to Increase Utilization of Maternal, New Born, and Family Planning Services. Health for Life: Technical Brief, RTI International, Kathmandu, Nepal, 2016: <u>https://www.rti.org/sites/default/files/mobile_trackin g_technical_brief_final.pdf</u>
- [26] A. Dhakal, A. "Telemedicine and Consultation in Nepal (Unpublished bachelor's thesis)". Turku University of Applied Sciences, Turku, Finland, 2017.
- [27] R. Bhatta. "Telemedicine and eHealth in Nepal." Journal of Nepal Public Health Association, vol 6(1), pp 41-46.
- [28] D.J. Meyers, M. Filkins, A.H. Bangura, R. Sharma, A. Baruwal, S. Pande & D. Maru. "Management challenges in mHealth: failures of a mobile community health worker surveillance programme in rural Nepal". BMJ Innovations, 2017.Nepal", 2015: <u>http://ictpost.com/telemental-health-supporteclinics-in-nepal/</u>
- [29] A.K. Jha & S. Karki. "Reaching the Unreached: Integrated Approach at Grass Root Population by Tele-Health". C.H.E.S.T. Nepal, 2017: <u>http://smgebooks.com/telemedicine/chapters/TELM</u> <u>ED-17-06.pdf</u>
- [30] Inmarsat. "Inmarsat enables emergency mHealth in Nepal", 2015: <u>https://www.inmarsat.com/news/inmarsat-enables-</u> <u>emergency-mhealth-in-nepal/</u>

- [31] Measure Evaluation. Nepal: HIS Indicators, 2018: https://www.measureevaluation.org/hisstrengthening-resource-center/country-profiles/nepal
- [32] K. Birdsall. "Bringing the power of digital data to rural Nepal. Healthy Developments". Federal Ministry of Economic Cooperation and Development (BMZ), 2018: <u>https://health.bmz.de/events/In_focus/bringing_pow_er_digital_data_rural_nepal/index.html</u>.
- [33] Ekantipur. "Ministry of health pilots mHealth, eHealth services". Kathmandu Post, 2017: <u>http://kathmandupost.ekantipur.com/news/2017-07-04/ministry-of-health-pilots-mhealth-ehealth-services.html</u>.
- [34] Johns Hopkins. "mHealth internships build lasting partnerships to help prevent human trafficking in Nepal", n.d.: <u>https://www.jhsph.edu/departments/internationalhealth/news/student-internships-nepal.html</u>
- [35] One Heart World-Wide. "Maternal health in Nepal", 2016: <u>https://give.onedayswages.org/campaign/maternal-</u> <u>health-in-nepal-or-one-heart-worldwide/c104911</u>
- [36] One Heart World-Wide. One heart world-wide quarterly report, 2016: https://static1.squarespace.com/static/5700f29260b5 e92eb865e179/t/591b31b329687f883309ae10/14949 54456275/OHW+2016+Annual+Report.pdf
- [37] S.M. Van Buren. "Evaluating the viability of a mobile-device-based intervention to improve maternal health in Achham, Nepal", 2013: <u>https://bir.brandeis.edu/bitstream/handle/10192/2503</u> <u>1/VanBurenThesis2013.pdf?sequence=3&isAllowed</u> =y
- [38] P. Rana. Two exciting new government open data initiatives presented at Kathmandu Open Data Day 2017: <u>http://archive.opennepal.net/blog/twoexciting-new-government-open-data-initiativespresented-kathmandu-open-data-day-2017</u>.
- [39] S. Thapa. "Empowering Health Workers in Nepal with mHealth", 2016: <u>https://www.linkedin.com/pulse/empowering-health-</u> workers-nepal-mhealth-samita-thapa
- [40] A. Harsha, D.S. Maru, E. Okada, P. Acharya, R. Sharma, S. Bhatta, S. Dahal, T. Yangdol. "Pilot and evaluation of the feasibility of SafeSIM-a mobile technology platform for maternal health care coordination in Nepal", 2015: <u>http://medicmobile.org/assets/downloads/Safe-SIMpreliminary-evaluation_findings-07.2015.pdf</u>.

- [41] Nepal Ministry of Health and Population. "National Health Sector Strategy 2015-2020.", 2015: <u>http://www.nationalplanningcycles.org/sites/default/</u><u>files/planning_cycle_repository/nepal/nhss-english-book-final-4-21-2016.pdf</u>
- [42] ICT Post. "Telemental health support eClinics in Nepal", 2015: <u>http://ictpost.com/telemental-health-support-eclinics-in-nepal/</u>.
- [43] S. Lange & S. Vollmer. "The effect of economic development on population health: a review of the empirical evidence". British Medical Bulletin, vol 121(1), pp 47-60, 2017.
- [44] M. Kuppusanmy. & S. Santhapparay. "Investment in Information and Communication Technologies (ICT) and its Payoff in Malaysia". Perspectives on Global Development and Technology, vol 4(2), pp 147-16, 2005.
- [45] International Telecommunications Union. ICT facts and figures, 2015: <u>https://www.itu.int/en/ITU-</u> <u>D/Statistics/Documents/facts/ICTFactsFigures2015.</u> <u>pdf</u>
- [46] United Nations. United National E-Government Survey 2014. New York: United Nations: <u>https://publicadministration.un.org/egovkb/en-us/Reports/UN-E-Government-Survey-2014</u>
- [47] R. Shields. "Information access and communications policy in Nepal". Telecommunications policy, vol 33 (3-4), pp 207-214, 2009.
- [48] S. Sigdel. (2017). "eHealth in Nepal, Policies and Strategies: a quick overview", 2017: <u>https://medium.com/hisn-health-informatics-society-of-nepal/e-health-in-nepal-policies-and-strategies-a-quick-overview-by-mr-giriraj-subedi-5874d2e22d19</u>
- [49] K. Regmi. "Mainstreaming mHealth in Nepal: Highlights of a One-Day Workshop", 2016: <u>https://webcache.googleusercontent.com/search?q=c</u> <u>ache:CPUZ-PE-</u> <u>MPMJ:https://www.herd.org.np/blogs/118+&cd=3&</u> <u>hl=en&ct=clnk&gl=us</u>
- [50] M. Kay, J. Santos, M. Takane. "WHO Global Observatory for eHealth: mHealth new horizons for health through mobile technologies", vol 3, 2011.
- [51] J. Sharma, A. Aryal, G.K. Thapa. "Envisioning a high-quality health system in Nepal: if not now, when?" The Lancet Global Health, vol 6(11), pp 1146-1148, 2018.

- [52] M.J. Allsop. "The State of mHealth development and use by palliative care services in sub-Saharan Africa: a systematic review of the literature". BMJ Supportive and Palliative Care, vol 8(2), pp 155-153, 2015.
- [53] M. Staeheli, R.H. Aseltine, E. Schilling, D. Anderson & B. Gould. "Using mHealth technologies to improve the identification of behavioral health in urban primary care settings". SAGE Open Med, 5:2050312117712656, 2017.
- [54] L.T.H. Vu, N.T.K. Nguyen, H.T.D. Tran, N. Muhajarine. "mHealth information for migrants: an eHealth intervention for internal migrants in Vietnam". Reproductive Health, 13:55, 2016.
- [55] K4Health. "The mHealth Planning Guide: Key Considerations for Integrating Mobile Technology into Health Programs". K4Health, 2014: <u>https://www.k4health.org/toolkits/mhealth-planningguide</u>
- [56] Al-Shorbaji, N. "The World Health Assembly Resolutions on eHealth: eHealth in Support of Universal Health Coverage". Methods Inf Med, vol 52, pp 463-466, 2013.
- [57] The Rockefeller Foundation. "From Silos to Systems: An Overview of eHealth's Transformative Power". In Rockefeller Foundation Report. Making the eHealth Connection: Global Partnerships, Local Solutions, Bellagio Conference Series. New York, 2010.
- [58] World Health Organization & International Telecommunications Union. National eHealth strategy Toolkit, 2012. Geneva.
- [59] USAID & DIAL. "Principles for Digital Development", 2017: https://digitalprinciples.org/principles/
- [60] World Health Organization. "Recommendation on digital interventions for health system strengthening". Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO, 2019.
- [61] ITU & DIAL. "SDG Digital Investment Framework: A whole-of-government approach to investing in digital technologies to achieve the SDGs", 2019.
- [62] F. Huang, S. Blaschke, & H. Lucas. Beyond pilotitis: taking digital health interventions to the national level in China and Uganda. Globalization and Health, vol 13, pp 49, 2017.

- [63] D. McCann. "A Ugandan mHealth moratorium is a good thing", 2012: <u>https://ictworks.org/2012/02/22/ugandan-mhealth-moratorium-good-thing/</u>
- [64] Ministry of Health & Family Welfare Government of India. "National Digital Health Blueprint", 2019.

DESIGNING NATIONAL HEALTH STACK FOR PUBLIC HEALTH: ROLE OF ICT-BASED KNOWLEDGE MANAGEMENT SYSTEM

Dr. Charru Malhotra¹; Vinod Kotwal²; Aniket Basu³

¹Indian Institute of Public Administration, New Delhi ²Department of Telecommunication, Government of India ³Indian Institute of Public Administration, New Delhi

ABSTRACT

Public health (PH), as a domain, requires astute amalgamation of the workings of different disciplines, because its eventual aim is to 'prevent' and not just 'cure' the health concerns of the entire community/population under consideration. Public health goals can be achieved more meaningfully by the application of information communication technology (ICT) that helps in overcoming the bottlenecks of brick-and-mortar healthcare models. Online consultations, cloud-based health management solutions, smart service-supported diagnoses are some such examples. The present study attempts to explore the design and implementation of ICT-based holistic knowledge management systems (KMS) to address public health concerns at the national level. At any point in time, different management information systems (MIS) are being used by various public authorities that directly or indirectly impact PH. However, the data being generated by these MIS is "stove piped" into standalone, heterogeneous databases. Non-standardized data formats, incompatible IT systems, an aggravated sense of ownership by the agency that collects the data are some of the factors that further worsen the problem. To overcome these issues, based on the study of best practices and literature review, the review paper proposes a conceptual model, referred to as national health stack (NHS). NHS is a multilayered KMS designed to support evidence-based decisions of public health and would pave the way towards "Good Health and well being" (UN SDG 3) for All.

Keywords – Application program interface (API), digital service standard, emerging technologies (AI, IoT, ML, blockchain, wearable/immersive technologies), knowledge management systems (KMS), national health stack (NHS), public health (PH), quality of life (QoL)

1. INTRODUCTION

"Attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector..."

Declaration of Alma Ata, 1978

The Alma Ata declaration of the World Health Conference (1978) reflects the ideals of social justice and equality taking at its point of departure that health is a fundamental human right. The declaration can be accepted as a major milestone in delineation of public health wherein it had unequivocally underpinned adoption of a multidisciplinary approach to achieve the milestone of 'Health for All'.

The United Nations (UN) Sustainable Development Goals (SDGs) are meant to be achieved by the year 2030. Out of the 17 SDGs, SDG 1 (No poverty), SDG 2 (Zero hunger), SDG 3 (Good health & well-being), SDG 6 (Clean water & sanitation) and SDG 10 (Reduced inequalities) are closely linked to human health. However, of particular relevance is SDG 3 that aims to ensure healthy lives and promote wellbeing for all at all ages. Amongst other goals, SDG 3 focuses on reduction in maternal mortality rate (MMR), reduction of non-communicable diseases through prevention and treatment, achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all, etc [1]. Also, understanding the linkages of health with other factors, SDG 3 aims to substantially reduce the number of deaths and illnesses from hazardous chemicals, air, water and soil pollution and contamination by the year 2030. There is emphasis on research and development (R&D), capacity building for early warning, risk reduction and management of national and global health risks.

Public health (PH) by definition is "the science and art of preventing disease, prolonging life and promoting human health through organized efforts and informed choices of society, organizations, public and private, communities and individuals" [2]. It is therefore understood to be the science of protecting the safety and improving the health of communities including mental health through prevention and treatment of diseases with the aim of improving the quality of life (OoL). PH is an interdisciplinary field that takes inputs from epidemiologists, microbiologists, technologists, food veterinarians, environmental and occupational health experts, community health experts, behavioral health specialists, health economists, biostatisticians, public policy experts, etc. [3].

Stack can be understood as a set of APIs and systems that allow various stakeholders including governments, businesses, developers, etc. to utilize this digital infrastructure towards achievement of common goals. Creation of a stack on any vertical at a national level would enable paperless, cashless and presence-less secure access to the system. Such a holistic approach fosters innovation in service delivery.

In the present scenario, the data that is needed to build "One Public Healthcare System" is available in standalone systems, only some of which are connected. The most notable attribute of PH is that it aims to widen the health system goals from the one that is narrowly focused on curing diseases in hospitals by health professionals, to a system that is focused on keeping populations/communities healthy by providing advance information to stakeholders. Therefore, for improving the PH scenario in a developing country like India, an integrated knowledge management system (KMS) that could interconnect the standalone, existing healthcare applications/other related applications into a holistic integrated national health stack (stack is a data structure used to store a collection of objects) by employing information communication technologies (ICTs) will go a long way in achieving PH goals.

The aim of the present study is to propose a conceptual design and an actionable implementation strategy for building a KMS, referred to as a national health stack (NHS). Introduction of the paper establishes the 'multidisciplinary' and 'preventive' nature of PH. This is followed by a 'Review of Literature', section 2, on core subject areas viz. ICT and KMS implementation in the health domain of various countries, with special reference to emerging technologies, PH and best practices related to the subject under consideration. Section 3 examines the national health scenario of India with special reference to its policies on information systems pertaining to ICT implementation in health, the current status and future vision. Once both the theoretical propositions as well as the ground reality of the Indian health ecosystem have been elucidated, the paper moves on to state the goal, objectives and design of the proposed conceptual model, section 4: Proposed Conceptual Model of NHS. The implementation strategy is described in the subsequent section, section 5: Implementation of the Proposed Model), followed by 'Issues and Opportunities' in section 6, and 'Conclusion' insection 7.

2. REVIEW OF LITERATURE

2.1 Application of ICT in health sector

Rapid proliferation of ICTs has catalyzed its application in the health domain since the 1990s by implementation of mobile collaboration technologies, hospital management systems, online patient information systems, and so on [4].Several related challenges including, but not limited to, infrastructure concerns that are more often sighted in developing countries like India, did not deter researchers from examining the merits of employing ICTs in these countries for shaping its healthcare services to be more inclusive [5].

At present, emerging technologies such as Internet of things (IoT), artificial intelligence (AI) and others are being employed to design disruptive health innovations so that quality healthcare may be accessible to a larger population. Literature is replete with application of wireless technology almost two decades ago in the area of telemedicine in select countries of Europe including Athens (Greece), Cyprus, Italy and Sweden [6] and the use of artificial intelligence and artificial neural networks (ANNs) for maintaining and analyzing electronic health records (EHRs) by University of California and University of Chicago for a period ranging from the year 2009 till 2016 [7]. Even in developing countries, drones are assisting in providing medicines and medical aid in difficult and inaccessible areas of India [8]. The wearable devices are being popularly used to provide remote and continuous monitoring of each heartbeat, moment-to-moment blood pressure, oxygen concentration in blood, body temperature, level of glucose, human activities and emotions [9]. IoT-based solutions have the potential to reduce the required time for remote health provision and increase the quality of care by reducing costs with enriched user experience. Similarly, robotics process automation (RPA)-based bots can 'advise' primary care patients; machine learning (ML)-based systems can help to identify diseases early that indeed constitutes an important step towards preventive healthcare [10]. The National Health Service (NHS), UK is planning to extensively harness the potential of AI to make 30 million outpatient visits unnecessary so that the resources saved can be used for frontline care [11].

However, apart from these various ways in which the advances in communication technology, computing, storage, analytics etc. are helping in achieving the health goals, ICT can also play a more fundamental role. ICT can be used to link the different sources of data, collate the information available, provide tools for analysis and make it available to the stakeholders for predictive analysis. Knowledge management (KM) of this data pertaining to different aspects of healthcare would help to provide deeper insights into the various aspects of organizational learning and community wellbeing, as indicated subsequently.

2.2 Applying principles of knowledge management (KM) in public health

Knowledge management (KM) refers to a multidisciplinary process of creating, sharing, using and managing the information from different systems for achieving organizational objectives. ICT can provide knowledge discovery through integrated data mining of health data that is provided by heterogeneous sources. With special reference to developing countries, Blaya*et al.*, (2010) assert health solutions that emanate from well-designed ICT-based KMS in resource-poor environments have a tangible impact on the quality of health care [12]. However, the experience validates that the data that is needed in the first place for the knowledge management system to work is either not available or recorded and stored in isolation. Addressing the various issues in the public health sector, amongst other factors, include the need for more collaborative inter-sectoral engagement, 'buy-in' from the political authorities and decision makers etc. To resolve these concerns, Thailand, in the 1990s, had adopted a paradigm called "Triangle that Moves the Mountain" [13]. 'The Mountain' means a big and complicated problem, usually unmovable. 'The Triangle' consists of: creation of relevant knowledge through research, social movement or social learning, and political involvement. The three components of the triangle have to work together in tandem to achieve the goals of resolving the health issues. This has resulted in the near elimination of the uninsured with its universal health coverage, elevated almost a million Thai citizens from poverty while strengthening the capacity of knowledge generation and management [14]. This approach can form a remarkable basis for evolving a structure and systematic approach for building a KM system for any vertical including health. Some instances of best application of knowledge management using ICT in public health with varying degrees of implementation have been observed in a number of countries, notably Canada, Germany, New Zealand, South Korea and the U.S.A [14].

3. A CASE STUDY FROM INDIA: HMIS AND OTHER SYSTEMS HAVING LINKAGES WITH PUBLIC HEALTH

India is a country with a vast requirement for a stable public healthcare system due to its complex health needs of over a billion people with diverse social, economic, geographical and cultural context. Despite its rapid economic growth, it has been ranked 143rdin a list of 188 countries in the 'Health Related SDG' index that aims to assess each country's performance across 33 indicators in a global burden of disease (GBD) study [15]. Also, according to another GBD study published in the medical journal The Lancet, India has finished 154th among 195 countries on the healthcare index, which is based on death rates for 32 diseases that can be avoided or effectively treated with proper medical care [16]. These rankings are a cue enough for revamping existing approaches towards public healthcare systems. Before the study moves ahead to propose a KMS conceptual model to address these public health concerns, it might be more prudent to first enumerate strides that the country has made in this direction.

At present, a number of health management systems (HMS) by the public sector are operational in the country that can be categorized as follows.

a. Performance reporting portal including the Health Management Information System (HMIS), National Health Portal (<u>https://www.nhp.gov.in/</u>) andState Health Programportals

b. Disease surveillance portal including Integrated Disease Surveillance Programme, National Vector Borne

Disease Control Programme (NVBDCP) &National Tuberculosis Control Programme (<u>https://nikshay.in/</u>)

c. Electronic Medical Records (EMRs) including the Mother Child Tracking System and Reproductive Child Health Register

d. Clinical decision support system (CDSS):radiodiagnostics and laboratories

e. Computerized physician order entry:secondary and tertiary care private institutions

f. Online registry system for patients' appointments:e-hospitals (ehospital.gov.in)

g. Applications based on electronic health records: PM JAY, national health insurance (https://www.pmjay.gov.in/)

The most popular of these initiatives is the HMIS, which is an online portal that provides information on the human health indicators in the country. It is a tool that provides a framework for gathering the raw data from primary care health institutions upwards at state level from primary health centers (PHCs) onwards. This data is then compiled at block level, district level and finally at the state HQ level before feeding into the national level database. Data aggregation units are at block and district level. The flow of data is upwards as well as downwards. HMIS also compiles data from the National Family Health Survey (NFHS), the District Level Household Survey (DLHS), and the Office of the Registrar General and Census Commissioner, among other sources [17]. The information generated from this analysis is then used for taking actions that help in improving health outcomes. The Online Registry System (ORS) for patients is a framework that links various hospitals across the country for the Aadhaar-based (biometric digital identity) online registration and appointment system, where the counter-based outpatient department (OPD) registration and appointment system through HMIS has been digitized. At the end of June 2019, 230 hospitals across the country are using ORS [18].

The Integrated Disease Surveillance Programme (IDSP) was launched in 2004 by the National Centre for Disease Control (NCDC), India. The program continues under National Health Mission with the objective to strengthen/maintain the decentralized laboratory-based information technology (IT)enabled disease surveillance system for epidemic-prone diseases to monitor disease trends and to detect and respond to outbreaks in early rising phase through trained rapid response teams (RRTs). Under the program, surveillance units have been established in all districts of the country and it collects data on disease outbreaks for the country as a whole, excluding non-communicable diseases.

Similarly, there are other systems being maintained by different government institutions that are collecting data, which have implications on PH but are not connected to the HMIS. A case in point is the All India Network Project on Pesticide Residues (AINPPR). The laboratories under the network collect the samples from the nearby Agriculture Produce Marketing Corporation (APMC) markets and analyze for the possible residues of the pesticide and since

2007-08 and till about 2016 about more than 1 lakh samples of various food commodities have been analyzed [19]. Foodborne diseases (FBDs) not only directly impact human health but also impede socioeconomic development by straining healthcare systems and harming national economies, tourism and trade [20]. Thus, information on pesticide residues in food, as well as food-borne diseases, should be integrated with the HMIS. Similarly, information on air pollution, waterpollution, soil pollution etc. being collected by various government authorities (pollution control boards) that has direct or indirect impact on human health should also be available to PH authorities. However, data being collected by these various authorities is "stove piped" into standalone databases that are not accessible within and across government agencies. Non-standardized data collection, varied data formats, incompatible data IT systems, a sense of ownership by the group that collects the data are the factors that further worsen the problem [21].

To surmount these issues, India has also renewed its focus on the implementation of the proposed 'National Digital Health Blueprint', the precursor of which can be traced back to NITI Aayog's vision document in 2018 laying out the strategy and approach for a national health stack [22]. In "India's Trillion-Dollar Digital Opportunity" (pp 122), a report by the Ministry of Electronics and Information Technology, Government of India (GoI) [23], there are examples of actions that are required for improving PH. The need to build an integrated health information platform to create and provide access to electronic health records (EHR) for every Indian has been highlighted, which would be using open APIs. Emphasizing the need of public private partnerships (PPP) in the health domain, suggests the development of the PPP model for setting up digital infrastructure and training for health workers in primary health centers and other medical care facilities. The report also highlights the need of finalization and implementation of the 'Digital Information Security in Healthcare' Act (DISHA Act) to provide a framework for the sharing of health information digitally. The need to frame policy to mandate EHR adoption was also highlighted. To catalyze implementation of these health aspirations of the nation, the Satyanarayana Committee (2018-19), setup by Government of India, has been recently tasked with the purpose of suggesting a National Digital Health Blueprint so that continuum of care could be provided to the citizens.

Thus, it is the right time to design and implement an integrated, comprehensive and effective ICT-based system with real-time linkages not only between various public health authorities but also other authorities that impact public health. This can be achieved by adopting a holistic knowledge management system, as proposed below.

4. PROPOSED CONCEPTUAL MODEL OF NHS: ICT-BASED KMS FOR PUBLIC HEALTH

As already stated in section 1, PH is a multidisciplinary field that requires data/information from multiple sources (disease surveillance, health systems, food testing as well as

laboratories working in the research area of pesticides/contaminants/toxicology/pollution, nutrition and total diet studies/surveys, etc.). It is therefore of paramount importance that countries like India implement an integrated national health stack (NHS) built on the principles of knowledge management systems (KMS) connecting all the relevant sources. The proposed conceptual model (Figure 1) henceforth referred to as the national health stack (NHS) is a multilayered and multi-stakeholder model. The main objectives of NHS (Figure1) would be to:

- 1. facilitate inter-sectoral involvement and collaboration of various stakeholders including government authorities and citizens (Figure 1: referred to as 'Block1 Data Providers');
- 2. develop an integrated KM platform using appropriate technologies (Figure 1, referred to as 'Block2 KM Platform');
- evolve policies, regulations and health standards, based on the (public) health predictions made by the related decision making/decision support bodies of the country (Figure 1, referred to as 'Block3 Decision makers and R&D');
- 4. spread social learning; NHS to also serve as a tool for spreading awareness on the creation and usage of this unified approach (Figure 1, Block3).

The aforementioned four layers (S. No. 1-4) form the basic design structure of the proposed NHS. However, depending on the implementation context of the respective countries, more layers can be added to the NHS. Irrespective of the number of layers or building blocks in each of these layers, the underlying system design principle weaving all of them remains the same. This principle is that all data/information flows emanating to/from each of these blocks/layers of NHS have strong bidirectional feedback loops (Figure 1). Only then the proposed NHS would be able to serve as a common repository data for multiple of agencies/authorities/stakeholders. The multisectoral data would be collated, analyzed using advanced ICT techniques and presented as a 'visualization layer', pictorial, userfriendly information presented to the decision makers for strategic planning. Collecting data from different authorities will require inter-sectoral cooperation, interoperability and adequate digital standards and 'openness' (to share). Such a national level KMS will essentially consist of the technology layer viz.hardware (servers for storage of data, routers for communication, etc.), software (database for storage of information, interfaces, etc.), Connectivity (telecom/data connectivity and related protocols for connecting the various databases and exchange of information) and the application layer that would adequately employ a decision support system to run data analytics, open APIs etc. (Figure 1, Block2). The output of these analyses will then be shared with the related stakeholders (Figure 1, Block3) such as government, regulatory bodies, at various levels for policy making, setting standards, regulation making, prospective planning and building synergies with government plans in an integrated manner. This synergy can be assured only when adequate adherence is done to international health standards

such as health level seven (HL7) clinical document architecture (CDA), and Integrating the Healthcare Enterprise (IHE), Cross-enterprise Document Sharing-b (XDS.b) profile to build a nationwide secure NHS. The strategic information emanating from Block3 information can also be shared for research purposes with research institutions, academics etc. for providing solutions to various problems, as well as for supporting social learning activities including spreading awareness and conduct of sensitization drives.

5. IMPLEMENTATION OF THE PROPOSED MODEL

The implementation of the proposed ICT-based KMS for creating a national health stack (NHS) will follow a structured, multi-stakeholder, multi-collaborative approach (Figure 1). Some of the suggested steps for creating its various components could be delineated as below:

STEP 1: Identifying the goal and objectives to be achieved by national public health policy and various KPIs across identified dimensions

The first and foremost step for designing an NHS is to identify the goals, objectives, mission and vision related to the public health strategies of a country, which are articulated in the national health policy (NHP). Taking a cue from NHP, the designers of NHS could strive to:

- Identify and define various building blocks of the national health ecosystem including varied health/other information systems, datasets, system constraints, stakeholders, etc.
- Define ICT benchmarks in terms of key performance indicators (KPIs) across dimensions that impact PH and may include 'health management', 'food-safety', 'water and sanitation', 'nutrition', 'pollution control' and 'disaster management'. This would help in assessing the ground situation and then explore digital standards to be adopted to make the building blocks interoperable and 'open'.
- Provide an institutional, regulatory, policy framework required to implement these building blocks.

This helps in envisioning the "AS-IS" to a "TO-BE" scenario. After this step, the process of data collection and data aggregation would commence, using the proposed blueprint.

STEP 2: Mapping of various stakeholders, data sources related to public health and linking them

The next step focuses on data collection, mapping of various stakeholders who can potentially provide information pertaining to the health of citizens, identifying channels through which this data can be shared/transferred to the NHS, making an operational strategy for the data sharing through these channels (amount of data to be shared, frequency of sharing, format and conversion to the necessary format if required, etc.) and then ensuring this sharing happens while adhering to KPIs across identified dimensions and Figure 1, Block1).

In order to create a robust operational execution strategy for communication between Block1 and Block2 (Figure 1), the journey of the patient from even before the time their exposure might happen to contract a particular disease (the stage at which prevention is possible) till the time they have been completely healed, including diagnosis, treatment, recovery and follow-up, needs to be thoroughly studied and mapped with touchpoints of data collection about their health.





For example, at the diagnosis and treatment stage, the data is entered by the patient into the public health record (PHR) and by the hospitals into the electronic medical record (EMR) in the national health portal. This data from the health records (PHR and EHR/EMR) is an important source of information from the health management dimension and shall feed into the national health stack (NHS) in real time. Similarly, data pertaining to all the treatment received and diagnostics made from any hospital or clinic in the country would constitute an important source for the NHS. This would require public-private partnerships to ensure seamless flow and sharing among the consented parties while taking into account patient data sharing and privacy laws. On the prevention and research side, the stack would also receive data from R&D repositories on health and nutrition of India like the Indian Council of Medical Research (ICMR); national research institutions like the National Institute of Nutrition (NIN); National Centre for Disease Control (NCDC) implementing the disease surveillance programs of the government; radio and diagnostic systems, laboratories; and various government departments that have linkages with human health including academia. To enable forecasting for prevention of diseases, effective linkages established between food control agencies and the public health systems including epidemiologists and microbiologists can provide information on food-borne diseases, which may be linked to food monitoring data and lead to appropriate risk-based policies. This information includes annual incidence trends, identification of susceptible population groups, identification of hazards, identification and tracking of causes of diseases and the development of early warning systems for disease outbreaks. Therefore, IDSP, HMIS, AINPPR and similar other data emerging from various sources will have to be collected and analyzed centrally by the knowledge management system (KMS). Once this data mapping and feeding mechanism is strategized, implemented and executed over an extended period of time, the NHS shall act as a centralized health record repository for all citizens.

Once the sources of data are identified by mapping the patient journey, the next step would be to focus on the data formats/databases, and then connecting them. The need for uniform standards to make multiple EMR systems compatible and the information interoperable is paramount as it will tie up isolated pools of data. A consortium can be setup consisting of representatives from various consenting data-sharing stakeholders to identify and list the various current formats being used, come up with short-term interoperability solutions and envisage long-term data sharing standards on common agreed formats. Effective change management would play a pivotal role in aiding the stakeholders to adopt the new agreed formats to process and share the data being collected at their end. The costs involved in the change can be managed in a way that is offset by the overall commercial gains incurred due to the implementation of the NHS. In terms of channel usage, high speed communication technology is proposed to facilitate data collection, analysis and reduce reaction time as well as enable effective sharing. This digitized data will then be stored in a central place like a cloud. It will be accessed remotely by all stakeholders. Also, standards of data security need to be strengthened with the use of blockchain technology so as to protect this data from cyber threats.

This is the most critical step towards building the KMS as it strives to bring together "stove piped" data and needs substantial investment of resources not only in terms of funds but also manpower. Here, buy-in from the decision-making authorities is important as it will drive the project.

STEP 3: Applying data analytics

Through data collection from a variety of sources, the knowledge management platform will be a treasure trove of big data. With the help of artificial intelligence tools, big data analytics as well as information systems like GIS, this data can be analyzed to extract important insights needed for answering relevant questions like reasons for a disease outbreak, areas involved, etc. as well as mapping and predicting outbreaks, triggering response mechanisms and taking preventive action. However, there may be a need to democratize this data in a way so as to make it available for use of machine learning (ML) and AI.

Decision support algorithms employing quantitative data superimposed on qualitative understanding of local contexts would help to undertake risk assessments of public health domains. Predictive modeling would help to improve estimates and thereby allow quantification of health risks and also find applications for assessing prevention strategies in risk management. The processed data from the stack can be made available to various stakeholders through open application programming interfaces (APIs).

STEP 4: Use of NHS information for evidence-based decision making, forecasting, planning and research by different stakeholders

The insights generated based on the analysis of data can provide not only straightforward information that is useful to the health functionaries directly but also enable crossfunctional collaboration between various stakeholders (Figure 1, Block 3).

For example, information on the immunization status in a particular area can help the health officer to plan resource allocation of both staff and material for those areas that are lagging in immunization coverage. On the other hand, cases of nicotine toxicity in tobacco harvesters or cases of silicosis from mining may require collaboration with research institutions that can provide technological solutions like suitable nylon gloves for tobacco farmers or well-designed masks for the miners.

STEP 5: Social learning: awareness, sensitization and training

The implementation of a project with an all-encompassing vision would be meaningful only if stakeholders' capabilities are augmented at all levels ranging from the top till the 'bottom of the pyramid'. Political leaders and policy makers at the highest level must be encouraged to stay aligned to the successful culmination of the 'Health for All' goal. Awareness is equally critical amongst patients whose public health data and the related socioeconomic indicators are the mainstay of the system. In addition, health data may also be crowdsourced from citizens, therefore the citizens need to be sensitized about the 'principle of consent' with regard to their health data and personal health records (PHR). Equally relevant is capacity building drive for every constituent. As an example, the capabilities of the grass-root level public health worker, who is expected to input the information at

the PHC level to the highest level of political leaders and policy makers, all need to be trained according to the functions they perform.

6. ISSUES AND OPPORTUNITIES OF THE PROPOSED MODEL

Though ICT-based national KMS has a disruptive potential to mainstream preventive public health care, there are substantial technical, legal and socioeconomic challenges that remain to be addressed. Some of the most critical issues involved are standardization of the collection methodology, collection of data, its verification and the identification of KPIs across various dimensions. In addition, issues like interoperability between various databases need to be resolved [24]. Adoption of DSS would permit consistent dataexchange, robust measurement processes and also lead to the creation of healthy feedback loops [25]. Similarly, enabling infrastructure that includes robust telecom connectivity, particularly last-mile, in the context of developing countries is very important.

Data protection, data privacy, confidentiality and data are other important issues. The security security ramifications of personal health data misuse are several and cannot be ignored; therefore, the regulatory framework of the country must be stringent. In fact, national/international consortia and global data communities must ensure that there are adequate rights/instruments and related institutions to redress grievances if citizens' personal sensitive (health) data is misused anywhere, without their consent. Learning from the German example, the citizens must be empowered to decide, to hide or block any entry in the health record. This can be achieved through awareness and sensitization. ITU-T Focus Group on Artificial Intelligence 4 Health (FGAI4H) can also work on the identification of KPIs, collection methodology and regulatory/policy aspects arising from the generation of health data and its usage.

In terms of opportunities in this domain, wearable sensors and implantable medical devices (to monitor and transmit health recorded data) will feature prominently in the future of wireless telemedicine systems. There are already many examples of wearable/implantable medical devices (e.g., cochlear implants, cardiac defibrillators/pacemakers, insulin pumps). In the future, interfacing these wireless sensing devices with 5G will present unprecedented opportunities of crowdsourcing EHR directly into NHS by the patient herself. Further, the tactile Internet, an ultra-responsive and ultrareliable network connectivity, that is envisioned to transmit touch and actuation in real time, will pave the way for realtime interactive systems being used directly by the citizens who would be able to access the NHS by employing agile APIs [26]. The health sector is experiencing technological advancements which are enhancing the government's ability in providing a quality health care in an affordable and accessible manner.

The unique contributions of this KM model include clear identification of service portfolios to meet health goals and

related indicators, as well as their targets. It also provides a federated structure of detailing out interrelated services, their process flows and the process rules governing these services. Another differential aspect of this model is clear segregation of the service model and ICT layer which defines this health stack as technology-agnostic and relevant at all times. However, the study is still theoretical rumination by the authors and needs to be implemented as a proof of concept before being deemed as a visionary concept.

7. CONCLUSION

Establishment of NHS for public healthcare delivery is a novel approach to tackle healthcare disparity. New models of data-driven interpretation, forecasting and decision making facilitated by an ICT-driven KMS can go a long way in establishing evidence-based health systems. The most notable attribute of such a KMS would be to enable the transformation of the health system from one that is narrowly focused on curing diseases in hospitals by health professionals to a more holistic integrated KMS focused on examining other aspects that impact human health, like food safety, environmental pollution etc. However, optimal utilization of ICT-based KMS in healthcare delivery systems requires overcoming barriers at multiple levels including standardization of KPIs, databases, processes, technology and policy/regulatory levels. This entails that right from the outset of its design phase, a synergetic cooperation must be assured amongst all the disciplines related to public health. Such а synchronized multistakeholder and multidisciplinary collaboration shall provide an increased level of citizens' confidence in public healthcare systems, which in turn can go a long way to improve the quality of life (QoL) and achieve "Good Health and well being" for all.

REFERENCES

- UN SDG 3: United Nations Sustainable Development Goals Good Health and Well-being. (n.d.). Retrieved from <u>http://in.one.un.org/page/</u> sustainable-development-goals/sdg-3-2
- [2] Winslow, Charles-Edward, Amory (1920). "The Untilled Field of Public Health". *Modern Medicine*. 2: 183–191.
- [3] Van Teijlingen, E. R., Regmi, P. R., Adhikary, P., Aryal, N., &Simkhada, P. (2019). Interdisciplinary Research in Public Health: Not quite straightforward. *Health Prospect*, *18*(1), 4-7.
- Zain Abbas, Nadeem Mahmood and Aqil S M Burney. Article: Information and Communication Technology in Healthcare Management Systems: Prospects for Developing Countries. International Journal of Computer Applications 4(2):27–32, July 2010. Foundation of Computer Science.
- [5] Jarosławski, S., Saberwal, G., 2014. In eHealth in India today, the nature of work, the challenges and the finances: an interview-based study. BMC Med. Inform. Decis. Mak. 14, 1. <u>https://doi.org/10.1186/1472-6947-14-1</u>

- [6] Pavlopoulos, S., Kyriacou, E., Berler, A., Dembeyiotis, S., &Koutsouris, D. (1998). A novel emergency telemedicine system based on wireless communication technology-AMBULANCE. *IEEE Transactions on Information Technology in Biomedicine*, 2(4), 261-267.
- [7] Rajkomar, A., Oren, E., Chen, K., Dai, A. M., Hajaj, N., Hardt, M., ... & Sundberg, P. (2018). Scalable and accurate deep learning with electronic health records. *NPJ Digital Medicine*, 1(1), 18.
- [8] Subhan, I., Ghazi, S. S., & Nabi, S. (2019). Use of drones (unmanned aerial vehicles) for supporting emergency medical services in India. *Apollo Medicine*, 16(1), 61.
- [9] Adhikary, T., Jana, A. D., Chakrabarty, A., & Jana, S. K. (2019, January). The Internet of Things (IoT) Augmentation in Healthcare: An Application Analytics. In *International Conference on Intelligent Computing and Communication Technologies* (pp. 576-583). Springer, Singapore.
- [10] Davenport, T. H., &Ronanki, R. (2018). Artificial intelligence for the real world. *Harvard business review*, 96(1), 108-116.
- [11] (n.d.). Retrieved Spring, 2019, from https://www.england.nhs.uk/2019/06/nhs-aims-tobe-a-world-leader-in-ai-and-machine-learningwithin-5-years/
- [12] Blaya, J.A., Fraser, H.S.F., Holt, B., e2010. E-Health Technologies Show Promise In Developing Countries. Health Aff. (Millwood) 29, 244–251. <u>https://doi.org/10.1377/hlthaff.2009.0894</u>
- [13] Wasi, P (2000). "Triangle that moves the mountain" and Health System Reform Movement in Thailand". Human Resources for Health Development Journal (HRDJ) Vol. 4 No. 2 May-August 2000
- [14] Srivastava, S. K. (2016). Adoption of electronic health records: a roadmap for India. *Healthcare informatics research*, *22*(4), 261-269.
- [15] Lim, S. S., Allen, K., Bhutta, Z. A., Dandona, L., Forouzanfar, M. H., Fullman, N., ... &Kinfu, Y. (2016). Measuring the health-related Sustainable Development Goals in 188 countries: a baseline analysis from the Global Burden of Disease Study 2015. *The Lancet*, 388(10053), 1813-1850.
- [16] Barber, R.M. et al, 2017. Healthcare Access and Quality Index based on mortality from causes amenable to personal health care in 195 countries and territories, 1990–2015: a novel analysis from the Global Burden of Disease Study 2015. The Lancet 390, 231–266. <u>https://doi.org/ 10.1016/S0140- 6736(17)30818-8</u>
- [17] India Health Management Information System (HMIS). (n.d.). Retrieved from <u>http://ghdx.healthdata.org/series/india-health-management-information-system-hmis</u>

- [18] (n.d.). Retrieved July 13, 2019, from https://ors.gov.in/index.html
- [19] D. (n.d.). Monitoring of Pesticide Residues at National Level. Retrieved from <u>http://agricoop.nic.in/sites/default/files/MPRNL</u> <u>Guidelines 0.pdf</u>
- [20] Food safety. (2019, June 04). Retrieved from http://www.who.int/mediacentre/factsheets/fs399/en
- [21] Taylor, M.R., and M.B. Batz. 2008. Harnessing knowledge to ensure Food Safety: Opportunities to Improve the Nation's Food Safety Information Infrastructure. Gainesville, FL: Food Safety Research Consortium
- [22] NitiAyog, GoI (n.d.). National Health Stack-Strategy and Approach. Retrieved June, https://niti.gov.in/writereaddata/files/document_ publication/NHS-Strategy-and-Approach-Document - for-consultation.pdf
- [23] GoI (n.d.). India's Trillion-Dollar Digital Opportunity. Retrieved from <u>https://meity.gov.in/writereaddata/files/india_trillion</u> <u>-dollar_digital_opportunity.pdf</u>
- [24] Mathur, P., Srivastava, S., Lalch, A., ani, Mehta, J.L., 2017. Evolving Role of Telemedicine in Health Care Delivery in India. Prim. Healthc. Open Access 7, 1–6. https://doi.org/10.4172/2167-1079.1000260
- [25] J. Satyanaraya& Charru Malhotra. (2018). Universalization and Replication:-Towards a consistent service experience- The role of a Digital Service Standard (DSS) in Citizen Centric Governance. In, DARPG and NASSCOM Publication, 'Technology for Accelerating Development', Government of India: New Delhi. URL:https://community.nasscom.in/docs/DOC-1696.
- [26] Mittal, M. & Charru Malhotra (2017). e-Health Initiatives in India - An Analysis from the Technological Problem. Indian Institute of Public Administration. Unpublished.

SESSION 5

SMART TECHNOLOGIES FOR CAREGIVERS

- S5.1 Elderly health monitoring system with fall detection using multi-feature based person tracking
- S5.2 A healthcare cost calculator for older patients over the first year after renal transplantation
- S5.3 Automatic plan generating system for geriatric care based on mapping similarity and global optimization

ELDERLY HEALTH MONITORING SYSTEM WITH FALL DETECTION USING MULTI-FEATURE BASED PERSON TRACKING

Dhananjay Kumar¹, Aswin Kumar Ravikumar¹, Vivekanandan Dharmalingam¹, Ved P. Kafle²

¹Department of Information Technology, Anna University, MIT Campus, Chennai, India ² National Institute of Information and Communications Technology, Nukui-Kitamachi, Koganei, Tokyo, Japan

ABSTRACT

The need for personalized surveillance systems for elderly health care has risen drastically. However, recent methods involving the usage of wearable devices for activity monitoring offer limited solutions. To address this issue, we have proposed a system that incorporates a vision-based deep learning solution for elderly surveillance. This system primarily consists of a novel multi-feature-based person tracker (MFPT), supported by an efficient vision-based person fall detector (VPFD). The MFPT encompasses a combination of appearance and motion similarity in order to perform effective target association for object tracking. The similarity computations are carried out through Siamese convolutional neural networks (CNNs) and long-short term memory (LSTM). The VPFD employs histogram-of-orientedgradients (HoGs) for feature extraction, followed by the LSTM network for fall classification. The cloud-based storage and retrieval of objects is employed allowing the two models to work in a distributed manner. The proposed system meets the objectives of ITU Focus Group on AI for Health (FG-AI4H) under the category, "falls among the elderly". The system also complies with ITU-T F.743.1 standard, and it has been evaluated over benchmarked object tracking and fall detection datasets. The evaluation results show that our system achieves the tracking precision of 94.67% and the accuracy of 98.01% in fall detection, making it practical for health care system use. The HoG feature-based LSTM model is a promising item to be standardized in ITU for fall detection in elderly healthcare management under the requirements and service description provided by ITU-T F.743.1.

Keywords – CNN, fall detection, HoG, LSTM, object tracking

1. INTRODUCTION

According to the United Nations (UN) report on ageing world population [1], the population of elderly people will rise to 2 billion by the year 2050. The guidelines for Integrated Care for Older People (ICOPE) [2] released by the World Health Organization (WHO) clearly indicates that accidental fall is one of the common reasons for the decline in the health of the elderly. The surveillance system for effectively monitoring the elderly's health can be achieved by either a sensor or vision-based system, or a combination of both. The sensor-oriented surveillance systems generally utilize accelerometer and GPS sensors to locate the person [3]. Although, these sensors provide highly accurate realworld coordinates, there exists a possibility of sensors being misplaced, not worn by the user, or worn by the wrong user, thus restricting the tracking ability of the system. Although other alternative methods employing devices like thermal sensors have been proposed to work, they work only within a short range [4-5]. On the whole, sensor-based tracking techniques heavily rely on the assumption that users continuously wear the devices. In general, sensor-based fall identification involves the use of triaxial accelerometer sensor [6] which records real-world 3D coordinates. The continuous analysis of coordinate information also poses difficulty in differentiating between daily activities such as sleeping, sitting and standing, implying the need of more sophisticated and accurate systems based on artificial intelligence techniques such as deep learning. Vision-based fall detection using optical flow and convolutional neural networks (CNNs) [7] can be used to extract temporal features needed for improving system performance. However, existing customized techniques such as curvelets [8] do not extract deep features for human representation to detect falls.

Visual object tracking can be categorized into two broad categories namely detection-based tracking and detectionfree tracking. The detection-based tracking consists of three main components: moving object detection, object classification and localization, and object tracking [9]. The moving object detection component identifies the salient objects that are present in the current frame using bounding boxes. Object classification is carried out in identifying the detected objects and segregating into specific classes, while the tracking is performed for target association in subsequent frames. On the other hand, detection-free tracking does not involve recognition of different objects, rather it utilizes motion features in order to locate moving objects. Typical detection-free tracking involves the usage of optical flow, background subtraction in order to eliminate static objects in each frame. Tracking based on background subtraction in video usually requires manual intervention to identify scenespecific objects [10]. An optical flow-based tracking algorithm also requires additional support from appearance modelling in order to produce accurate results. Optical flow along with blob analysis yields better traffic surveillance systems [11]. However, these algorithms are only capable of tracking generic objects rather than specific objects, which may lead to a reduction in the efficiency of the system.

Detection-based tracking algorithms first identify the target object to be tracked and then find the object in each frame of the video. Unique object identification can be achieved with the help of salient features the object possesses. Many methods have exploited the object appearance as an important feature to represent it in a numerical way. The appearance features such as histogram of oriented gradients, scale invariant feature transform and local Binary Pattern have significantly improved the overall accuracy of object detection and tracking.

Some of the difficulties of existing feature extraction methods have been overcome by CNN in more complex object segmentation-cum-detection processes [12-13]. Further extension of the generalized object detection using CNN [14] allows specific object tracking to be performed with high precision. The usage of Long Short-Term Memory (LSTM) helps in inferring deeper features from time-series data, thus posing it as a potential technique to be coupled with CNN for multiple object tracking. Siamese CNN helps in finding similarities in consecutive frames, due to its identical sub-network components [15].

The ITU-T Focus Group on Artificial Intelligence for Health (FG-AI4H) has considered "Falls among the elderly" [16] as one of the key areas that needs to be addressed for better healthcare. Although curvelet coefficient-based fall detection techniques [7] have translation and scaling invariant properties, detection accuracy suffers in complex background and moving objects. A machine learning-based approach [8] can handle complex scenarios of detection, but training a CNN-based generic network is not only inefficient, but also difficult to achieve a higher accuracy of fall detection in real-time environments.

To address the above limitations, we propose a system that utilizes machine-learning techniques to improve its performance accuracy. The major contribution of this work is twofold: a person tracker that considers both appearance and motion features for target association, and a fall detector that considers the sequence of person orientations. Our models are designed to leverage deep-learning techniques while complying with the criteria set by the ITU FG-AI4H. Both the models have been developed as per Recommendation ITU-T F.743.1 - "Requirements for intelligent visual surveillance". In our system, target recognition and association are achieved with the combination of CNN and LSTM to uniquely distinguish persons from other objects. The core of the system is HoG for feature extraction which is an LSTM based model for fall detection, a promising candidate for standardization in ITU.

The remainder of the paper is organized as follows. Section 2 provides a background overview and section 3 describes the proposed system. The implementation detail for performance evaluation and experimental results are presented in section 4, while section 5 concludes the paper.

2. BACKGROUND

2.1 HOG Feature Descriptor

HoG-based feature extraction [17] uses edge orientations for object detection. It operates on grayscale image and its workflow is as follows: Initially gradient computation is carried out for each pixel in the image, by placing a mask on the image with a pixel as its center and performing elementwise multiplication. The orientations of these gradients are further found out and a histogram of orientations is created for each block. This is then subjected to both local and global normalization to finally produce the required feature descriptor.

2.2 CNN Based Feature Extraction

CNN [12] utilizes kernels for automatic deep feature extraction, classification or detection. The CNN model commonly consists of two important segments: automatic feature extraction and dimensionality reduction. Feature extraction is achieved with the help of convolutional layers. A convolutional layer consists of different kernels which learn different features, through backpropagation. The stacking of different convolutional layers allows learning of deeper features. Dimensionality reduction is achieved with the help of pooling layers and dense layers. A combination of all these layers allows the construction of a CNN model that can be utilized to solve different domain problems.

2.3 Long Short-Term Memory Network

A long short-term memory (LSTM) network [18] is a recurrent neural network that performs well for time-series based analysis in extracting temporal features. The LSTM network is made of stacks of cells in order to represent the sequential data better. An LSTM cell consists of an input gate, an output gate, and a forget gate. The input gate allows new information to enter into the cell, while the forget gate helps in remembering only the important information regarding the input data in achieving higher performance. The LSTM cell incorporates a sigmoid activation function to restrict the information flow within it and *tanh* function in order to remember relevant features.

3. PROPOSED SYSTEM

The architecture of the proposed system, as shown in Figure 1, consists of three components: client, server and cloud service. The overall workflow in the proposed system is as follows. A client, typically a hospital room or elderly home, is configured to stream videos, to the receiver (medical center/care takers) over HTTP using ITU-T H.264 encoding. The frame processing and video analysis are carried out on the server end where both MFPD and VPFD models are executed to track persons and detect occurrences of human falls. The detected person's location and image is stored in the cloud along with the fall occurrence status. An alert is generated at the concerned client end, either a hospital or a



Figure 1 – The architecture of the proposed model

family member, to provide location information of the persons who has fallen.

3.1 Key Frame Selection

In the server end, key frame selection has been carried out to improve the overall processing speed of the system without degrading its performance. This is achieved by comparing the previous processed frame and incoming frame using the structural similarity index (SSIM), which is calculated by Equation 1.

$$f(x,y) = \frac{(2\mu_X\mu_y + c_1)(2\sigma_{xy} + c_2)}{(\mu_x^2 + \mu_y^2 + c_1)(\sigma_x^2 + \sigma_y^2 + c_2)} \quad (1)$$

Where μ_x , σ_x^2 are the mean and variance of pixels in image x respectively and μ_y and σ_y^2 are the mean and variance of pixels in image y, respectively.

The SSIM index value is subjected to a custom threshold to process only dissimilar images by the system. Similar images are simply skipped for faster video processing.

3.2 Person Detection

The decoded frames from the preprocessing stage are given to the object detector to accurately classify and localize different objects present in each frame. This is achieved with the help of the CNN-based YOLO model [19]. The given frame is fed as input to the YOLO model, which divides it into segments and finds objects in each segment, along with their bounding box coordinates and confidence score. The confidence score has been used as a threshold to eliminate false positive detections. The YOLO model trained on the COCO dataset [20] has the ability to detect many different object classes. The output of the model is then filtered to contain bounding box values of class 'person' only.

3.3 Target Association

Target association is the process of mapping the existing objects with newly detected objects from the current frame. After preprocessing and person detection stages, one of two possibilities are tested, either any of the previously moving persons could have moved to the new position or a new person could have started moving. Using this fact, tracking can be carried out for all persons, who enter and exit the scene in the video. This architecture performs tracking of the detected persons from the CNN using two distinct features, namely the visual feature and motion feature. The visual feature denotes the image similarity that helps find whether the currently found person matches with the appearance of one of the existing persons. The motion feature denotes the possibility of the existing person moving from his/her previous location to the location of the currently detected object. Visual and motion features are obtained using Siamese CNN and LSTM respectively. The utilization of dual features allows the handling of sudden entry and exit of persons in the given video.

3.4 Image Similarity

Siamese CNN, shown in Figure 2, is a neural network model that operates on a pair of images and produces a score denoting the appearance similarity between the two images. Bounding box coordinates obtained in the previous step have been used to extract the person's image from the frame. The previously stored person's images are then compared with the extracted image. The feature extraction layers in this CNN network are made the same for both images, thus making it vertically symmetrical. The resultant features of both images are merged by finding the element-wise squared difference. It is then fed into fully-connected layers for dimensionality reduction and finally to obtain the similarity score.



Figure 2 - Image similarity using Siamese CNN

A custom threshold is employed, where scores greater than a threshold value are considered similar and vice versa (Algorithm 1).

Algorithm 1: Image similarity
Input: P_{prev} – Previously detected persons
P_{curr} – Currently detected persons
Output: <i>S</i> – appearance similarity matrix <i>Model</i> _{app} = Trained Siamese CNN model $M = \text{count} (P_{curr})$ $N = \text{count} (P_{prev})$ S = Null matrix of dimensions M*N for $i = \{0, 1,, M-1\}$ $img_{curr} = P_{curr} [i].img$ for $j = \{0, 1,, N-1\}$ $img_{prev} = P_{prev} [j].img$ $input = (img_{curr}, img_{prev})$ $score = Model_{app} (input)$ if score > threshold: S[i][j] = score end if end for end for
return S

3.5 Motion Similarity

Motion prediction has been used in the proposed system in order to associate objects based on their recent movements. This has been implemented using LSTM on the basis of the previous 12 center coordinates of stored persons. This vector is fed as input to the Motion LSTM model which performs temporal processing and predicts the new center for each stored person. This center indicates the next possible position

Algorithm 2: Motion similarity		
Input: <i>P</i> _{prev} – Previously detected person		
P_{curr} – Currently detected person		
Output: <i>S</i> – motion similarity matrix <i>Model</i> _{motion} = Trained motion LSTM model $M = \text{count} (P_{curr})$ $N = \text{count} (P_{prev})$ S = Null matrix of dimensions M*N for $i = \{0, 1,, M-1\}$ <i>center</i> _{curr} = <i>P</i> _{curr} [<i>i</i>].center for $j = \{0, 1,, N-1\}$ <i>center</i> <u>seq</u> _{prev} = <i>P</i> _{prev} [<i>j</i>].center [$\{1, 2, 12\}$] <i>center</i> <u>pred</u> = Model _{motion} () <i>dist</i> = Euclid_Dist (center _{curr} , center _{pred}) <i>score</i> = 1/ <i>dist</i> if <i>score</i> > <i>threshold</i> :		
S[t][t] = score end if		
end for		
return S		

of the person. The predicted centers are compared with the centers of the currently detected persons via Euclidean distance and inverse of this value is considered as the overall motion score (Algorithm 2).

3.6 Object Mapping

The mapping of previous to current persons is achieved by finding the best candidate for each currently detected person from the appearance and motion similarity matrices. A map data structure helps in store the detected persons in each video frame efficiently. The map stores information in distinct key-value pairs. A unique ID is assigned for every person appearing at any part of the video. Each person detected in the frame is stored in the map data structure with an ID as the key and the bounding box coordinates, frame number in which he/she was detected and the previous center list as value. During the retrieval of the person for target association, only the candidates which have a frame number less than the current frame number are considered, in order to avoid mismatching. The best candidate for the current person is selected by choosing the person with the highest appearance similarity and with a motion similarity greater than a specific threshold. The best candidate values are updated to match the current target. If no such match is found for the target, then the target is newly added into the map data structure. This data structure is stored in the cloud and both MFPD and VPFD access the data. This reduces the overall workload and allows multiple computers to run tasks in parallel improving the processing speed. The map data structure is made persistent in order to last till the end of the video instead of removing the objects that have temporarily exited, which helps in handling short-term occlusions. Also, this persistent data structure allows persons to be tracked through different cameras in the surveillance system.

3.7 Fall Detection

The VPFD model constitutes two important phases: feature extraction using HoG and sequence analysis using LSTM. For each frame, the image is converted to grayscale and resized to a dimension of 640 x 480 in order to maintain the same dimension of the resultant feature vector during the training and testing phase. The HoG feature vector is then computed from the reshaped image and passed on to the LSTM model. For each frame, the HoG features of the previous three frames, including the current frame are considered as input to the LSTM model. Temporal sequence of feature vectors is taken into account to eliminate false detection, thus improving the capability of differentiating falls and actions of daily-living. The model output indicates the occurrence of a fall. In order to map the fall with the detected person, angles of previous center coordinates are calculated as shown in Equation 2. The midpoint of the lower boundary line of the image is taken as the reference plane for angle computation as shown in Figure 3.



Figure 3 – Angle between two centers of same person

Vector-based notation is utilized to represent both OA and OB vectors respectively, as given in following equations.

$$OA = (x1 - x0)i + (y1 - y0)j$$
(2)

$$OB = (x^2 - x^0)i + (y^2 - y^0)j$$
(3)

The angle between vectors OA and OB can be obtained by finding the cosine inverse of the dot product of two vectors as:

$$\cos \alpha = \frac{OA \cdot OB}{|OA||OB|} \tag{4}$$

The person with an angle greater than the specific threshold

```
Algorithm 3: Fall Detection
     _____
Input: curr – current frame index
       seq – sequence of frames
       P_{curr} – Currently detected persons
Output: FP – Fallen person
Model fall = Trained HoG-LSTM model
N = count (P_{curr})
T = time window
max angle = 0
FP = None
      data = empty array
      for j = \{0, 1, \dots, T-1\}
           feature = HoG(seq[i-j])
           data.append(feature)
      end for
      val = Model_{fall}(data)
      if val > threshold
         for k = \{1, 2, \dots, N\}
         angle = find_avg_angle (P_{curr}[k].center, T)
             if max_angle < angle
                max_angle = angle
                        FP = k
             end if
            end for
      end if
return FP
```

is determined as the fallen person (Algorithm 3). The possibility of multiple persons falling at the same time can also be taken into consideration in this approach. The threshold value helps in eliminating false fall detection instances.

4. IMPLEMENTATION AND RESULTS

The proposed system has been implemented and tested on the Intel i5 processor CPU and Nvidia GeForce 940MX GPU over standard datasets. The MFPT model is trained on the Object Tracking Benchmark (OTB - 100) dataset and Multiple Object Tracking (MOT) dataset. The UR Fall dataset [21] is utilized to train the VPFD model. The proposed system has been implemented using the Python programming language. FFMPEG has been utilized for video encoding and decoding purposes. The image preprocessing techniques are executed with the help of OpenCV library. The Keras library in Python was used to create both the CNN and LSTM deep-learning models. The overall performance of the proposed system is shown in Figure 4, where a red boundary indicates that a person is falling.



Figure 4 – System applied on UR Fall dataset

4.1 Siamese CNN Implementation

The Siamese CNN has been trained on a custom dataset generated from OTB and MOT datasets. This custom dataset is created by extracting the images of all the persons present in all the videos of the dataset using ground truth information. Similar and non-similar pairs of images are generated from the custom dataset by pairing images of the same object and pairing images of different objects respectively. The training parameters of this network are shown in Table 1. The network is trained such that similar pair inputs produce a score closer to 1 and dissimilar pair inputs produce a score closer to 0.

Table 1 – Siamese CNN parameters

S. No.	Parameter	Value
1	Learning Rate	0.001
2	Optimizer	Adam
3	Total epoch	5
4	Train image split	70%
5	Test image split	30%
6	No. of convolutional layers	9
	used	
7	No. of Pooling layers used	4
8	No. of Dense layers used	2
9	Threshold for image similarity	0.5

The trained model is then subjected to network pruning in order to increase the processing speed of the model. The overall training and validation phase of the model, shown in Table 2, indicates the maximum accuracy attained after 5 epochs.

Table 2 – Validation phase of Siamese CNN

Epoch	Loss	Accuracy (%)
1	0.3879	82.22
2	0.2716	86.39
3	0.2014	87.82
4	0.1862	91.78
5	0.1713	92.07

4.2 LSTM Implementation

A custom dataset containing the center coordinates of objects from OTB and MOT datasets has been utilized for the overall training of the motion-LSTM model. From the dataset, random sequences of length 12 are extracted as inputs to the model and centers of each sequence are considered as the actual outputs. The model is then trained with this data sequence using the parameters shown in Table 3.

The training phase results in Figure 5 show the model convergence with respect to the input data after 350 epochs. The slight increase of loss during the 150th epoch indicates that the model slightly falls in the local minimum rather than attaining global minimum. The use of Adam optimizer helps to regularize the parameters during this stage and allows to further decrease the overall loss value of the network.

Table 3 – Motion LSTM parameters

S. No.	Parameter	Value
1	Learning Rate	0.001
2	Optimizer	Adam
3	Total epoch	350
4	Train split	80%
5	Test split	20%
6	No. of LSTM units used	25
7	Euclidean distance threshold for motion similarity	10



Figure 5 – Validation phase of LSTM

4.3 MFPT Results

The performance of MFPT has been analyzed using the following two metrics: precision and multiple object tracking accuracy (MOTA). Precision is the measure of detecting objects with appropriate bounding boxes. This is calculated by finding the Manhattan distance between the predicted bounding box center and actual bounding box center. If the distance is less than the threshold then it indicates correct object detection. The average precision of the tracker for all the person videos in the OTB 100 dataset is shown in Figure 6. The percentage of average precision at threshold value of 20 is 94.67%.



Figure 6 – Average precision in OTB 100 data set

MOTA, denotes how well the tracker is able to map the person to a unique ID from the entrance till the exit of the object from the video. This metric is calculated with the help of four parameters, namely the number of correct detections, number of misses, number of wrong detections and number of ID switches. The correct detections denote the assignment of correct IDs to corresponding persons. Misses denote the count of persons that the tracker did not detect. Wrong detections signify the action of the tracker to make false person detections and the ID switches denote the number of times the object's ID has been changed. The overall MOT accuracy is calculated using Equation 5.

$$MOTA = 1 - (M + WD + ID_{switch}) / (Obj_{qt})$$
(5)

Where *M* denotes person misses, *WD* denotes wrong person detections, ID_{switch} represents ID switches and Obj_{gt} denotes total persons in the entire video.

The accuracy for the MOT dataset along with the four mentioned parameters is listed in Table 4. This table also shows the performance comparison of three different sub components. The results show that the combination of appearance and motion similarity yields higher accuracy.

Method	Correct Detects	Miss	Wrong Detects	ID switch	МОТА
CNN + LSTM	78.23%	12.2%	3.3%	7.5%	76.6%
CNN	77.1%	15.4%	7.01%	7.5%	70.1%
LSTM	78.96%	14%	8.1%	7.1%	70.8%

Table 4 – MOTA results

4.4 VPFD Results

The UR Fall dataset has been utilized for the training and validation phase of the VPFD model. The fall dataset consists of 30 Fall event videos and 40 normal videos containing daily life activities. The ground truth specifies whether fall has occurred in each and every frame of the

videos. Every frame in the dataset video is resized to 640 x 480 in order to maintain uniformity in feature dimension. After applying HoG, the training sequences for LSTM are generated by considering three consecutive frames and their feature vectors. The output for this sequence is majority voting of the ground truth values for each frame. These sequences are passed as training input to the LSTM model initialized with parameters as shown in Table 5.

The validation phase of the fall detector in Table 6, indicates that the VPFD model has learnt to differentiate between fall and non-fall sequences with high accuracy.

The accuracy comparison of various methods in Table 7 show that better feature extraction and effective time series representation can improve the overall performance of the fall detector.

Table 5 – Fall LSTM parameters

S. No.	Parameter	Value
1	Learning Rate	0.001
2	Optimizer	Adam
3	Total epoch	6
4	Train split	80%
5	Test split	20%
6	No. of LSTM units used	64

Table 6 – Validation phase of VPFD

Epoch	Loss	Accuracy %
1	0.2937	87.42
2	0.1401	93.45
3	0.1051	96.52
4	0.0874	97.68
5	0.1211	95.20
6	0.0553	98.01

Table 7 – Comparison of methods based on accuracy

S. No.	Method	Accuracy %
1	Curvelets + HMM [7]	96.88
2	Optical Flow + CNN [8]	95.00
3	HoG + LSTM (Proposed)	98.01

Although fall detection methods based on curvelets and HMM [7] produce higher accuracy than the optical flow technique with CNN [8], the proposed technique employing HoG features in LSTM achieves significantly higher accuracy due to an enhanced learning technique.

5. CONCLUSION

The proposed system is based on the combination of two models: MFPT and VPFD to monitor an elderly person's health related activities and report any falls detected through

video surveillance. The system is designed to work within a confined location such as hospitals, indoor rooms and public places. The system has been tested on two different datasets of MOT and UR Fall and evaluated the performance of both models. The MFPT model's precision and accuracy denote the fact that multiple feature-based models help in achieving higher efficiency. The proposed system achieved 94.67% precision in tracking and 98.01% accuracy in elderly fall detection. The usage of LSTM model in both the models has aided in representing time-series data effectively. The proposed system for elderly healthcare in homes and hospitals can be standardized in ITU-T Study Group 16, which is the parent group of Focus Group on Artificial Intelligence for Health (FG-AI4H). The proposed work can be extended to detect different activities apart from fall detection, and recognize and report in the cases of anomalies. The fall detection module consisting of a HoG feature-based LSTM training network is the standardization item.

REFERENCES

- World Population Aging Report, United Nations 2017, <u>https://www.un.org/en/development/desa/population</u>/publications/pdf/ageing/WPA2017_Highlights.pdf
- [2] WHO Guidelines on Integrated Care for Older People: https://www.who.int/ageing/publications/guidelinesicope/en/
- [3] S. Van der Spek, J. Van Schaick, P. De Bois, and R. De Haan, "Sensing human activity: GPS tracking," Sensors vol. 9 no. 4, pp. 3033-3055, 2009.
- S. K. Opoku, "An indoor tracking system based on bluetooth technology," arXiv preprint arXiv 1209.3053, 2012. <u>https://arxiv.org/ftp/arxiv/papers/1209/1209.3053.pd</u> <u>f</u>
- [5] M. Shankar, J. B. Burchett, Q. Hao, B. D. Guenther, and D. J. Brady, "Human-tracking systems using pyroelectric infrared detectors," Optical Engineering, vol 45, no. 10, 2006.
- [6] F. Wu, H. Zhao, Y. Zhao, and H. Zhong, "Development of a wearable-sensor-based fall detection system," International Journal of Telemedicine and Applications, Vol 2015 Article ID 576364, 2015
- [7] N. Zerrouki, and A. Houacine, "Combined curvelets and hidden Markov models for human fall detection", Multimedia Tools and Applications vol 77 no. 5 pp. 6405-6424, 2018.

- [8] A. Núñez-Marcos, G. Azkune, and I. Arganda-Carreras, "Vision-based fall detection with convolutional neural networks", Wireless Communications and Mobile computing, Volume 2017, Article ID 9474806, 2017.
- [9] H. S. Parekh, D. G. Thakore, and U. K. Jaliya, "A survey on object detection and tracking methods, " International Journal of Innovative Research in Computer and Communication Engineering vol 2, no. 2 pp. 2970-2979, 2014.
- [10] A. Aggarwal, S. Biswas, S. Singh, S. Sural, and A. K. Majumdar, "Object tracking using background subtraction and motion estimation in MPEG videos," Asian Conference on Computer Vision, Springer, pp. 121-130, 2006.
- [11] S. Aslani, and H. M. Nasab, "Optical flow based moving object detection and tracking for traffic surveillance," International Journal of Electrical, Electronics, Communication, Energy Science and Engineering" vol. 7, no. 9 pp. 789-793, 2013.
- [12] Y. LeCun, L. Bottou, Y. Bengio, and P. Haffner, "Gradient-based learning applied to document recognition," Proceedings of the IEEE, vol. 86, no. 11, pp. 2278-2324, 1998.
- [13] R. Girshick, J. Donahue, T. Darrell, and J. Malik, "Rich feature hierarchies for accurate object detection and semantic segmentation," IEEE conference on Computer Vision and Pattern Recognition, pp. 580-587, 2014.
- [14] D. Held, S. Thrun, and S. Savarese, "Learning to track at 100 fps with deep regression networks," European Conference on Computer Vision, pp. 749-765., 2016.
- [15] X. Liu, Y. Zhou, J. Zhao, R. Yao, B. Liu and Y. Zheng, "Siamese Convolutional Neural Networks for Remote Sensing Scene Classification," IEEE Geoscience and Remote Sensing Letters. vol. 16, no. 8, pp. 1200-1204, Aug. 2019.
- [16] ITU focus group on "Artificial Intelligence for Health" <u>https://www.itu.int/en/ITU-</u> <u>T/focusgroups/ai4h/Pages/default.aspx</u>
- [17] N. Dalal, and B. Triggs, "Histograms of oriented gradients for human detection," IEEE Conference on Computer Vision & Pattern Recognition (CVPR'05), vol. 1, pp. 886-893. IEEE Computer Society, 2005.
- [18] S. Hochreiter, and J. Schmidhuber, "Long short-term memory," Neural Computation vol. 9, no. 8 pp. 1735-1780, 1997.

- [19] J. Redmon, S. Divvala, R. Girshick, and A. Farhadi, "You only look once: Unified, real-time object detection," Procs. of the IEEE Conferece on Computer Vision and Pattern Recognition, pp. 779-788. 2016.
- [20] T. Lin, M. Maire, S. Belongie, J. Hays, P. Perona, D. Ramanan, P. Dollár, and C. L. Zitnick, "Microsoft coco: Common objects in context," European Conference on Computer Vision, pp. 740-755, 2014.
- [21] B. Kwolek, and M. Kepski, "Human fall detection on embedded platform using depth maps and wireless accelerometer," Computer Methods and Programs in Biomedicine vol. 117, no. 3 pp. 489-501, 2014.

A HEALTHCARE COST CALCULATOR FOR OLDER PATIENTS OVER THE FIRST YEAR AFTER RENAL TRANSPLANTATION

Rui Fu¹; Nicholas Mitsakakis¹; Peter C. Coyte¹

¹Institute of Health Policy, Management and Evaluation, University of Toronto, Canada

ABSTRACT

Forecasting tools that accurately predict posttransplantation healthcare use of older end-stage renal disease (ESRD) patients are needed at the time of transplantation in order to ensure smooth care delivery in the post-transplant period. We addressed this need by developing a machine-learning-based calculator that predicts the cost of healthcare for older recipients of a deceased-donor kidney over the first year following transplantation. Regression tree and regularized linear regression methods, including ridge regression, lasso regression and elastic net regression were explored on all cases of deceased-donor renal transplants performed for patients aged over 60 in Ontario, Canada between March 31, 2002 and April 31, 2013 (N=1328), The optimal model (lasso) identified age, membership of one of 14 regionalized Local Health Integration Networks, blood type, sensitization, having diabetes as the primary case of ESRD, total healthcare costs in the 12-month pre-workup period and the 6-month workup period to be inputs to the cost calculator. This cost calculator, in conjunction with clinical outcome information, will aid health system planning and performance to ensure better management of recipients of scarce kidneys.

Keywords –healthcare costs, health economics, machine learning, renal transplant

1. INTRODUCTION

End-stage renal disease (ESRD) is the terminal stage of chronic kidney disease [1]. At this stage, patients have lost at least 85% of renal function and require immediate initiation of renal replacement therapy, whether by lifelong dialysis or renal transplantation, to sustain life [1]. Compared with dialysis, transplantation is preferred for most patients since it improves health outcomes in the long run at substantially lower costs [2], [3]. However, unless patients can identify a medically compatible living donor at the time of diagnosis, they must wait for a kidney from a deceased donor, a scarce healthcare resource. Average waiting time in the US and Canada has exceeded five and four years, respectively, in recent years [4], [5]. Meanwhile, transplantation has extremely high upfront costs to the healthcare system, which may not pay off until decades after transplantation, especially for older recipients [6], [7].

Multiple clinical decision aids have been developed to help inform patients, families and the health system about possible outcomes once patients have received a transplant. Patzer et al. [8] from Atlanta, Georgia, US have developed *iChoose Kidney* (http://ichoosekidney.emory.edu/), a risk calculator that provides individualized one and three-year mortality estimates for dialysis or transplantation. The calculator is based on conventional multivariate logistic regression models applied to large person-level records extracted from the US Renal Disease System (USRDS) and has been validated outside of the US (in Ontario, Canada [9]) with acceptable performance.

For patients undergoing transplantation, surprisingly, little effort has been made to understand their imminent use of healthcare services after transplantation, especially during the first post-transplant year, a high-risk period marked by elevated rates of hospitalization and intensive use of care [7]. This is an urgent gap in healthcare planning since renal transplant recipients, especially those aged over 60, require care planning immediately after surgery to ensure optimal outcomes. Hence, predictive tools are required to foresee their use of healthcare after transplantation using information available at the time of transplant.

Recent years have witnessed exponential growth of machinelearning applications in healthcare [10]–[13], including studies of organ transplantation [10], [12], [13]. Haddad et al. [10] used machine-learning methods to predict the total hospital cost of liver transplant recipients at one-year after transplant, and found comorbidities to be the most significant drivers of high cost. However, their study is limited by the hospital setting and short observational window (from 2011 to 2012). Furthermore, their use of the Charlson Comorbidity Index and van Walraven Score, both ordinal measures of comorbidities, impeded their ability to unveil potential associations between the use of healthcare and specific types of comorbid conditions. Additionally, the optimal model estimated in their study (Support Vector Machine with linear kernel) does not directly identify a set of cost predictors.

In the present study, we used machine-learning methods to develop a calculator that predicts the healthcare costs of deceased-donor renal transplant recipients aged over 60 during the first year after transplant using patient-level characteristics known at the time of transplantation. To the best of our knowledge, this is the first investigation that uses machine-learning methods to predict patient-level healthcare costs following renal transplantation.

2. MATERIAL AND VARIABLES

2.1 Patient population

We used all cases of kidney-only transplantation from a deceased donor performed in Ontario, Canada between March 31, 2002 and April 1, 2013. Recipients aged over 60 were followed until death or to April 1, 2016 (N=1425). We excluded the small number of patients who died within one year after transplant (N=70, 4.9%) in order to have our final model generalize to the more homogeneous group of transplant recipients who survived for at least a year. We further excluded patients with missing data on healthcare use (N=27, 1.9%), most of whom were transplanted during the earliest year of our study period, 2002 (N=19 of the 27 patients with unknown healthcare use). These exclusions resulted in a total of 1328 transplant recipients in the cohort.

2.2 Data sources

We used a multicenter, population-based dataset derived by the Institute for Clinical Evaluative Sciences (ICES) in Toronto, Ontario, Canada. Person-level records submitted by all (six) transplantation centers in Ontario to the Canadian Organ Replacement Registry (CORR), a national database that tracks end-stage organ failure patients, were linked to various health service utilization and administrative databases using a validated unique patient identifier [14].

2.3 Outcome

We focused on total healthcare costs of transplant recipients during the first year after transplantation. In Ontario, Canada, renal transplantation is covered for all residents by universal public health insurance. Costs were calculated at the patient level across healthcare sectors using a validated, microcosting, algorithm [15]. We reported costs in Canadian Dollars (CAD) that were adjusted to 2019 (April) values using the monthly Consumer Price Index [16], where \$1.00 CAD = \$0.75 USD [17].

2.4 Predictors

We considered a similar set of patient-level predictors as those examined by Patzer et al. [8] and Tan et al. [9] in their respective *iChoose Kidney* models. Five categories of patient attributes were collected at transplantation that we have listed below.

2.4.1 Demographics

We included patient sex (female or male), age (61-70, 71-80, or 81+) and race (Caucasian, African American, Asian or Pacific Islanders, or others).

2.4.2 Socioeconomic status

We included each patient's membership of one of 14 regionally based Local Health Integration Networks (LHINs), which govern and coordinate health and social services in Ontario, Canada [18].

2.4.3 Comorbidities

We considered each patient's status of the 11 Collapsed Aggregated Disease Groups (CADG) as defined in Johns Hopkins' Adjusted Clinical Group (ACG® [19]) case-mix system, a well-validated method of categorizing comorbidities [20]. We excluded CADG 12 (pregnancy) since no patients in our cohort were pregnant at the time of transplantation. **CADGs** were established using administrative records, including diagnostic codes in the format of the International Statistical Classification of Disease and Related Health Problems, 10th version, Canada (ICD-10-CA), from the Discharge Abstract Database (DAD), a database that includes acute care inpatient hospitalization; physician billing codes from the Ontario Health Insurance Plan (OHIP); and records from the National Ambulatory Care Reporting System (NACRS). ICD-10-CA codes were first assigned to one of the 32 Aggregated Diagnosis Groups (ADG) based on five clinical dimensions, including the duration of the condition, severity, diagnostic certainty, etiology and involvement of special care. ADGs were then collapsed into 12 CADGs based on the likelihood that the condition would persist or recur, severity and the type of healthcare services required [19].

2.4.4 Clinical characteristics

We included sensitization indicated by level of peak panel reactive antibodies (PRA) of 0% (not sensitized) or > 0% (sensitized), primary cause of ESRD (glomerulonephritis / autoimmune, diabetes, renal vascular, cystic / genetic, or others), and blood type (O, A, B, or AB).

2.4.5 Transplant information

We considered dialysis vintage (pre-emptive transplant or transplantation without initiating dialysis, or transplant following dialysis duration of <6 months, 6-12 months or > 12 months) and graft number (first graft or re-graft).

2.4.6 Pre-transplant healthcare use

For each patient, we calculated the total healthcare costs for during a 6-month workup period before transplant and for the 12-month period before the start of workup (i.e., pre-workup). Costs were measured in 2019 (April) CAD.

There were missing values found in our dataset for race (N=98, 7.4%), sensitization (N=237, 17.8%) and primary cause of ESRD (N=296, 22.3%). In our primary regression analysis, we imputed Caucasian for those with missing race, not sensitized (peak PRA = 0%) for those with missing sensitization, and glomerulonephritis / autoimmune for

patients with missing primary cause of ESRD. We addressed the two variables with significantly missing values (peak PRA and primary cause of ESRD) using multiple imputation methods in sensitivity analysis (see Sensitivity Analysis). Reference-based characteristics were male; age 71-80; Caucasian; from LHIN A; comorbidity-free; not sensitized (peak PRA = 0%); ESRD caused by glomerulonephritis / autoimmune; blood type A; and having received a first graft pre-emptively.

3. DATA ANALYSIS

We first summarized patient characteristics at baseline (transplantation). Continuous variables were represented by means and standard deviations (SD), as well as by medians and inter-quantile ranges (IQR). Categorical variables were summarized by counts and percentages.

Similar to the methods employed by Haddad et al. [10], we included patients transplanted between 2012 and 2014 in the testing set (N=294, 22.1%) while the remainder were in the training set (N=1034, 77.9%), achieving a size ratio (testing: training) of roughly 2:8 [21]. This ratio is reflective of idea practice in machine learning whereby earlier data is used to construct models and more recent data (in our case, 2012-2014) used to validate such models [10]. The optimal model was selected by ten-fold cross-validation (CV) on the testing set based on the averaged test root mean square error (RMSE) and \mathbb{R}^2 value [22]. Since we had both categorical (e.g. age groups) and continuous (i.e., pre-transplant healthcare use) variables as candidate predictors, they were standardized prior to model training and testing. Following Haddad et al., we log-transformed healthcare costs incurred during preworkup, workup, and the first post-transplant year in model training and testing. Results were then exponentiated to aid interpretation [10].

3.1 Regularized linear regression

The goal of our analysis is to estimate a regression equation on the natural log of total healthcare costs over the first posttransplant year:

$$E(y) = w_0 + \sum_{j=1}^p (w_j x_j)$$

where y is the log of one-year heathcare costs, w_0 the intercept of the equation (i.e., mean log cost for patients with reference-level characteristics), and w_j the weight associated with predictor x_j . Conventional ordinary least square (OLS) methods search for estimates of w_j that minimize a loss function that is equal to the total sum of square errors:

$$l_0 = \sum_{i=1}^{N} \left(y_i - \sum_{j=1}^{p} (w_0 + w_j x_{ij}) \right)^2$$

To overcome potential model overfitting due to multicollinearity among candidate predictors (e.g. having

blood type AB and shorter dialysis durations [23]), we applied three regularized linear regression methods.

3.1.1 Ridge regression

Ridge regression aims to minimize the sum of the original loss function l_0 and a regularized term, known as the L2 Norm [24] that we described below. As the parameter λ increases, w_j is shrunk towards 0. Optimal λ is determined by ten-fold CV within the training set such that the averaged test RMSE is minimized.

$$\|\boldsymbol{w}\|_2 = \lambda \sum_{j=1}^p (w_j)^2$$

3.1.2 Lasso regression

Lasso or least absolute shrinkage and selection operator [25] searches for estimates of w_j that minimize the sun of the original loss function l_0 and the L₁ Norm that we presented below. Compared with ridge regression, lasso forces the weights of some predictors to be zero to achieve a sparse model. Similar with ridge regression, the optimal λ value is selected by ten-fold CV such that the averaged test RMSE is minimized within the training set.

$$\|\boldsymbol{w}\|_1 = \lambda \sum_{j=1}^p |w_j|$$

3.1.3 Elastic net regression

Elastic net regression is a compromise between ridge regression and lasso regression in a sense that it excludes irrelevant predictors but keeps both of the correlated predictors [26]. Mathematically, the regularized term of elastic net regression, $\|\boldsymbol{w}\|_e$, is a linear combination of the L₁ Norm ($\|\boldsymbol{w}\|_1$ of lasso) and the L₂ Norm ($\|\boldsymbol{w}\|_2$ of ridge), where α is between 0 and 1. The optimal α and λ are selected by ten-fold CV.

$$\|\boldsymbol{w}\|_{e} = \frac{1-\alpha}{2} \|\boldsymbol{w}\|_{1} + \alpha \|\boldsymbol{w}\|_{2}$$

3.2 Regression tree

The regression tree partitions the feature space recursively to create a tree-like structure [27]. At each split in the tree a node is created to ensure maximum homogeneity of the data being partitioned to the two regions. To train a full tree, we selected features and the corresponding thresholds at each node such that the squared loss function is minimized:

$$\sum_{x_i \in R_1} (y_i - \hat{y}x_i)^2 + \sum_{x_i \in R_2} (y_i - \hat{y}x_i)^2$$

where R_1 and R_2 denote the two regions separated by the node. To avoid overfitting, tree pruning was performed on the full tree for a parsimonious tree (T) such that the following loss function is minimized:

$$\sum_{m=1}^{|T|} \sum_{x_i \in R_m} (y_i - \hat{y}x_i)^2 + \alpha |T|$$

The size of the final tree, |T|, is penalized by the complexity parameter α which is determined using ten-fold CV in the training set to minimize the averaged RMSE.

3.3 Sensitivity analysis

We conducted analysis to examine the impact of missing values on the primary results. Multiple imputation using Markov-chain Monte Carlo (MCMC) methods, assuming missing at random [28], was conducted to address patients with missing peak PRA (N=237, 17.8%) and primary cause of ESRD (N=296, 22.3%), respectively. We repeated the imputation procedure ten times [28] and performed the regression analysis on each of the ten newly imputed dataset. Analyses were performed using R (version 3.5.1).

4. **RESULTS**

4.1 Baseline characteristics

There are 1328 older deceased-donor renal transplant recipients who survived for at least a year after transplant (Table 1). The majority of these patients received a transplant when aged 61-70 (N=1081, 81.4%), more than three-quarters (N=999, 75.2%) are Caucasian, and over half are male (N=894, 67.3%). Distribution of older transplant recipients amongst the 14 LHINs is imbalanced. Notably, one LHIN (LHIN A) is responsible for performing 14.3% (N=190) of all transplantations while another one (LHIN F) accounts for less than one-per cent (N=8, 0.6%).

Table 1 - Characteristics of older transplant recipients at
the time of transplantation (N=1328)

Characteristics	Total (N=1328)
Sex (female)	434 (32.7%)
Age	
61-70	1081 (81.4%)
71-80	244 (18.4%)
81+	3 (0.2%)
Race	
Caucasian	999 (75.2%)
Asian or Pacific islander	189 (14.2%)
African American	94 (7.1%)
Others	46 (3.5%)
Membership of LHIN (censored)	
А	190 (14.3%)
В	160 (12.5%)
С	58 (4.4%)
D	42 (3.2%)
E	50 (3.8%)
F	8 (0.6%)
G	106 (8.0%)
Н	63 (4.7%)

Ι	177 (13.3%)
J	82 (6.2%)
K	68 (5.1%)
L	86 (6.5%)
М	104 (7.8%)
Ν	134 (10.1%)
Comorbidities	
CADG 1: Acute minor	906 (68.2%)
CADG 2: Acute major	1220 (91.9%)
CADG 3: Likely to recur	809 (60.9%)
CADG 4: Asthma	75 (5.6%)
CADG 5: Chronic medical, unstable	1310 (98.6%)
CADG 6: Chronic medical, stable	873 (65.7%)
CADG 7: Chronic specialty, stable	51 (3.8%)
CADG 8: Eye/dental	218 (16.4%)
CADG 9: Chronic specialty, unstable	185 (13.9%)
CADG 10: Psychosocial	228 (17.2%)
CADG 11: Preventive / administrative	614 (46.2%)
Sensitized (peak PRA $> 0\%$)	548 (41.3%)
Primary cause of ESRD	
Glomerulonephritis / autoimmune	696 (52.4%)
Diabetes	246 (18.5%)
Renal vascular	158 (11.9%)
Cystic / genetic	136 (10.2%)
Others	92 (6 9%)
Blood type	
0	539 (40.6%)
Δ	541 (40 7%)
B	167 (12.6%)
AB	81 (6 1%)
Graft number (first graft)	1261 (95.0%)
Dialysis vintage	1201 ()3.070)
Pre-emptive transplant	10 (0.8%)
< 6 months	10(0.8%)
< 0 months	72(5.4%)
> 12 months	12(3.4%)
Transplant year	1100 (07.570)
	55 (4.1%)
2002	55(4.1%)
2003	57 (4.3%)
2004	37 (4.3%) 80 (6.0%)
2005	06(0.0%)
2000	90(7.2%)
2007	110(0.7%) 124(0.2%)
2008	124(9.5%)
2009	144(10.8%)
2010	148(11.1%)
2011	150 (11.5%)
2012	145 (10.9%)
2013	149 (11.2%)
Costs during transplant workup (CAD)	45460 . 01051
Mean \pm SD	45460 ± 31271
Median (IQR)	48971 (55185)
Costs during pre-workup year (CAD)	
Mean ± SD	75608 ± 71855
Median (IQR)	70550 (101154)

Older transplant recipients in our cohort had a range of comorbidities at the time of transplantation. Less than half of them are sensitized (N=548, 41.3%). The most prevalent cause of ESRD is glomerulonephritis/ autoimmune (N=696, 52.4%), followed by diabetes (N=246, 18.5%). Most patients underwent a first-time renal transplantation (N=1261, 95.0%). Over forty-per cent of patients have blood type O (N=539, 40.6%) and A (N=541, 40.7%), respectively. Most transplantations were performed in 2011 (N=150, 11.3%). There are ten (0.8%) pre-emptive transplantations, and the majority of the remaining patients were transplanted after maintaining on dialysis for over 12 months (N=1186, 89.3%). Before receiving a transplant, total healthcare costs averaged \$45460 CAD (SD, \$31271) over the six-month workup period and \$75608 CAD (SD, \$71855) during the preworkup year.

Table 2 summarizes the total healthcare costs over the first post-transplant year, stratified by age at transplant. Average costs for all patients are \$72723 CAD (SD, \$63256) with median costs at \$56819 CAD (IQR, \$45568). Costs range greatly across patients from a low of \$517 CAD to a high of \$720917 CAD at year one post-transplant.

 Table 2 – Health system costs over the first year after transplantation stratified by age at transplant

Costs	Total	61-70	71-80	81+
Mean ± SD	72723 ± 63256	70623 ± 61736	81942 ± 69162	79659 ± 52161
Median (IQR)	56819	55288	65891	50498
	(45568)	(45547)	(45682)	(42134)
Min, Max	517,	517,	5082,	48600,
	720917	720917	628354	139879

4.2 Model training

4.2.1 Regularized linear regression

Figure 1 shows the shrinkage of regression coefficients against the log of λ in ridge regression. The optimal λ value that minimized test RMSE for ridge regression is 0.07796363.



Figure 1 – Plot showing the shrinkage of coefficients in ridge regression

Figure 2 shows the shrinkage of coefficients in lasso regression. The optimal λ value that minimized test RMSE for lasso regression is 0.0317323. Unlike ridge regression, lasso forces the coefficients of some predictors to be zero. Three predictors appeared to have the strongest impact, including the log of workup cost (*logwork*), the log of preworkup cost (*logpre*), and transplanted at ages 81+(*age81*+).



Figure 2 – Plot showing the shrinkage of coefficients in lasso regression

The optimal λ value that minimized test RMSE for elastic net regression is 0.01024383. Summary of regression results of the three models is presented in Table 3. Predictors that were deemed non-significant were denoted by "NS".

Variables	Ridge	Lasso	Elastic net
Female	0.0420	NS	0.0198
Age 81+	-0.531	-0.299	-0.350
Age 61-70	-0.129	-0.0574	-1.717
Asian	-0.0399	NS	-0.0156
African American	0.0567	NS	0.0259
Other races	0.136	NS	0.101
LHIN B	0.00909	NS	NS
LHIN C	0.0493	NS	NS
LHIN D	0.0993	NS	0.0320
LHIN E	0.0514	NS	NS
LHIN F	-0.183	NS	-0.0850
LHIN G	0.00247	NS	NS
LHIN H	0.0607	NS	0.00906
LHIN I	0.0769	NS	0.0347
LHIN J	0.130	0.00242	0.0833
LHIN K	-0.0996	-0.0317	-0.0962
LHIN L	0.0557	NS	NS
LHIN M	-0.0393	NS	-0.0178
LHIN N	-0.0233	NS	-0.0143
CADG 1	0.0110	NS	NS
CADG 2	-0.0424	NS	-0.0176
CADG 3	0.0259	NS	0.0169
CADG 4	-0.00101	NS	NS
CADG 5	-0.208	NS	-0.146
CADG 6	-0.00439	NS	NS
CADG 7	-0.0432	NS	0.0000955
CADG 8	0.0322	NS	0.0151
CADG 9	0.0344	NS	0.00798
CADG 10	-0.00708	NS	NS
CADG 11	-0.0310	NS	-0.0171
Peak PRA > 0%	0.0862	0.0501	0.0870
ESRD: Diabetes	0.0833	0.00617	0.0600
ESRD: Renal vascular	0.0645	NS	0.0367
ESRD: Cystic/genetic	-0.0737	NS	-0.0485
ESRD: Others	0.0346	NS	0.00333
Blood type B	-0.0895	-0.0155	-0.0713
Blood type AB	0.0870	NS	0.0473
Blood type O	0.0122	NS	NS
Re-graft	0.0926	NS	0.0610
Dialysis < 6 months	0.0912	NS	0.00205
Dialysis 6-12 months	0.0224	NS	NS
Dialysis > 12 months	-0.0377	NS	-0.00224
Log of workup cost	0.333	0.382	0.393
Log of pre-workup cost	0.139	0.0887	0.0983
Intercept	6.248	6.037	6.010

 Table 3 – Coefficients of predictors estimated by the three regularized linear regression models (N=1034)

The lasso model identified nine predictors of the log of posttransplant costs at year one. Membership of LHIN J, sensitized (peak PRA > 0%), having diabetes as the primary cause of ESRD, higher pre-workup and workup costs were found to heighten the cost. Notably, compared with unsensitized patients, sensitized patients were expected to incur 5.0% higher costs during the first year after transplant. Furthermore, for a one-percent cost increase during the sixmonth workup period and the one-year pre-workup period, post-transplant costs at year one are expected to increase by 0.38% and 0.09%, respectively. The lasso model also identified age 61-70, age 81+, membership of LHIN K, and blood type B as predictors of lower costs at year one. Compared with patients who received a transplant at ages 71-80, younger recipients aged 61-70 and older recipients beyond 80 years of age were found to cost 5.7% and nearly 30% (29.9%) less at year one, respectively. Furthermore, patients with blood type B were found to incur 1.6% less costs compared to type A patients during the first posttransplant year.

The elastic net regression model concluded a total of 33 significant predictors of one-year costs, including all of the nine predictors identified by the lasso regression.

4.2.2 Regression tree

Figure 3 shows the regression tree model trained by patients who underwent transplantation between 2002 and 2011. The log of pre-workup (logpre) and workup (logwork) costs were identified as the only two predictors of the mean log of costs during the first year after transplantation (logtarget). The regression rules used are as follows: (1) patients who incurred at least \$10938 during workup (logwork ≥ 9.3 , i.e., having logged workup costs of at least 9.3) were expected to cost an average of \$59874 during the first post-transplant year (logtarget = 11); (2) patients who incurred less than \$10938 during workup (logwork < 9.3) but at least \$4024 during pre-workup (logpre >= 8.3, i.e., having logged preworkup costs of at least 8.3) were expected to cost an average of \$22026 over the first post-transplant year (*logtarget* = 10); (3) patients who incurred less than \$10938 during workup (logwork < 9.3) and less than \$4024 during pre-workup (log pre < 8.3) were expected to cost an average of \$2981 over the first year post-transplant (*logtarget* = 8).



Figure 3 – Regression tree

4.3 Model validation

We validated the four models using ten-fold CV on transplant recipients during the years 2012 and 2013 (N=294, 22.1%). Results are summarized in Table 4. Ridge regression, lasso regression, elastic net regression and regression tree achieved an averaged test RMSE of 0.618, 0.604, 0.610 and 0.630, respectively, while reaching averaged test R^2 values of 0.255, 0.258, 0.251 and 0.0101. Hence, we concluded lasso regression to have the best performance.

Models	RMSE	R ²
Ridge regression	0.618	0.255
Lasso regression	0.604	0.258
Elastic net regression	0.610	0.251
Regression tree	0.630	0.0101

Table 4 – Testing results of the four models (N=294)

4.4 Sensitivity analysis

We iterated the multiple imputation methods ten times to impute values for patients with missing peak PRA (N=237, 17.8%) and primary cause of ESRD (N=296, 22.3%). Training and testing procedures were repeated for each newly imputed dataset. The lasso regression model had the best performance in each iteration, with an averaged test RMSE of 0.611 (SD, 0.144) and R² of 0.257 (SD, 0.100) over the ten iterations. The same set of eight predictors were identified, with the weights of having diabetes as the primary cause of ESRD and sensitized (peak PRA > 0%) being enlarged. Specifically, the estimated coefficient of diabetes increased from 0.00617 in the original analysis to an averaged 0.0125 (SD, 0.0123) over the ten iterations. Meanwhile, the estimated coefficient of sensitized also rose from 0.0501 to 0.0823 (SD, 0.032).

5. **DISCUSSION**

In the present study, we used machine-learning methods to develop a cost calculator for deceased-donor renal transplant recipients aged above 60 over the first post-transplant year. The final calculator was based on a lasso linear regression model and required the following inputs to be collected at the time of transplantation: age, membership of one of 14 regionalized LHINs, blood type, sensitization, having diabetes as the primary cause of ESRD, and healthcare costs during the six-month transplant workup and during the year before workup. This cost calculator minimized test RMSE at 0.604 while achieving an acceptable test R^2 of 0.258. The results are robust to missing values found in our dataset.

Our study has demonstrated that basic machine-learning methods, including regularized linear regression and regression tree, are promising tools for predicting healthcare costs. It is important to note that in our model we found previous healthcare expenditures to be one of the most important drivers of upcoming expenditures. This consistent pattern of healthcare use needs to be addressed in future cost calculators for older adults with chronic diseases. A further implication of this finding points to the importance of continuously monitoring an individual's spending on healthcare. In this way, our calculator serves as a simple prototype for a more advanced algorithm that is capable of continuous cost prediction.

There are limitations associated with our study. First, unlike Patzer et al. and Haddad et al., we did not consider patient ethnicity (i.e., Hispanic or non-Hispanic) in our regression analysis. However, as Tan et al. pointed out, less than 0.5% of Canadians identify as Hispanic [9]. Second, we did not have access to donor-level information, including donor age and cause of death, as well as facility-level factors, including hospital bed size and type of admission. This may explain the relatively low test R^2 (0.258) achieved by our model. Future investigators with a more comprehensive tracking of patients may provide additional insights on predictors of post-transplant costs. Third, accuracy of our primary analysis is limited by variables with significantly missing values, especially peak PRA (N=237, 17.8%) and primary cause of ESRD (N=296, 22.3%). However, through extensive sensitivity analysis based on multiple imputation methods we were able to rule out such potential bias caused by these missing values.

Our study has some key strengths. First, use of a linked administrative dataset has enabled us to have comprehensive tracking of older renal transplant recipients from the year before transplant workup to death. Second, we used CADGs to characterize comorbidities at the time of transplantation, which enabled us to arrive at conclusions that are specific to disease type. Third, we were able to construct person-level healthcare costs across healthcare sectors, which gave us transplant recipients' precise use of healthcare, both before and after transplantation. Fourth, through our use of machine-learning techniques, we were able to identify predictors of post-transplant healthcare use while overcoming potential overfitting due to multicollinearity, a common threat to conventional multivariate regression analysis.

6. ACKNOWLEDGEMENT

This study was supported by the Institute for Clinical Evaluative Sciences (ICES), which is funded by an annual grant from the Ontario Ministry of Health and Long-Term Care (MOHLTC). The opinions, results and conclusions reported in this paper are those of the authors and are independent from the funding sources. No endorsement by ICES or the Ontario MOHLTC is intended or should be inferred.

REFERENCES

 National Kidney Foundation, "K/DOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification," *American Journal of Kidney Diseases*, vol. 39, no. 2 Suppl 1, pp. 1-266, 2002.

- [2] A. Laupacis et al., "A study of the quality of life and cost-utility of renal transplant," *Kidney International*, vol. 50, no. 1, pp. 235–242, 1996.
- [3] R. A. Wolfe et al., "Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant," *New England Journal of Medicine*, vol. 341, no. 23, pp. 1725–1730, 1999.
- [4] American Kidney Fund, "Waiting for a kidney transplant," [Online]. Available: <u>http://www.kidneyfund.org/kidney-disease/kidney-failure/treatment-of-kidney-failure/kidney-transplant/transplant-waitlist/</u>
- [5] Trillium Gift of Life network, "Trillium Gift of Life Network annual report 2017/18," Available: <u>https://www.giftoflife.on.ca/resources/pdf/TGLN_A</u><u>nnual Report 17 18 EN WA F.pdf</u>.
- [6] J. F. Whiting et al., "Economic cost of expanded criteria donors in cadaveric renal transplantation: analysis of Medicare payments," *Transplantation*, vol. 70, no. 5, pp. 755–760, 2000.
- S. V. Jassal et al., "Kidney transplantation in the elderly: a decision analysis," *Journal of the American Society of Nephrology*, vol. 14, no. 1, pp. 187–196, 2003.
- [8] R. Patzer et al., "iChoose Kidney: a clinical decision aid for kidney transplantation versus dialysis treatment," *Transplantation*, vol. 100, no. 3, pp. 630–639, 2016.
- [9] V. S. Tan et al., "Predicting 3-year survival in patients receiving maintenance dialysis: an external validation of iChoose Kidney in Ontario, Canada," *Canadian Journal of Kidney Health and Disease*, vol. 5, pp. 1–11, 2018.
- [10] L. B. de P. Haddad, L. R. B. C. Mendes, L. Ducatti, V. Rocha-Santos, W. Andraus, and L. A. C. D'Albuquerque, "Machine learning in the prediction of costs for liver transplantation," *Quality in Primary Care*, vol. 25, no. 5, 2017.
- [11] I. Kononenko, "Machine learning for medical diagnosis: history, state of the art and perspective," *Artificial Intelligence in Medicine*, vol. 23, pp. 89– 109, 2001.
- [12] E. Mark, D. Goldsman, B. Gurbaxani, P. Keskinocak, J. Sokol, "Using machine learning and an ensemble of methods to predict kidney transplant survival," *PLoS ONE*, vol. 14, no. 1, 2019.

- [13] K. D. Yoo et al., "A machine learning approach using survival statistics to predict graft survival in kidney transplant recipients: a multicentre cohort study," *Scientific Reports*, vol. 7, no. 1, p. 8904, 2017.
- [14] Canadian Institute for Health Information, "Canadian Organ Replacement Register Metadata (CORR)," [Online]. Available: <u>https://www.cihi.ca/en/canadian-organ-replacement-register-metadata-corr</u>
- [15] W. P. Wodchis, K. Bushmeneva, M. Nikitovic, and I. McKillop, "Guidelines on person-level costing using administrative databases in Ontario," *Health* System Performance Research Network Working Paper Series, vol.1, 2013. Available: <u>http://www.hsprn.ca/uploads/files/Guidelines_on_Pe</u> rsonLevel_Costing_May_2013.pdf.
- [16] Statistics Canada, "Table 18-10-0005-01 Consumer Price Index, annual average, not seasonally adjusted,"[Online]. Available: <u>https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1810000501.</u>
- [17] Bank of Canada. "Monthly exchange rates," [Online]. Available: <u>https://www.bankofcanada.ca/rates/exchange/monthl</u> <u>y-exchange-rates/</u>
- [18] Local Health Integration Network. "Local Health Integration Network (LHIN)," [Online]. Available: <u>http://www.lhins.on.ca/</u>
- [19] The Johns Hopkins University, "The Johns Hopkins ACG® System Excerpt from Version 11.0 Technical Reference Guide, " 2015. [Online]. Available: <u>https://www.healthpartners.com/ucm/groups/public/</u> <u>@hp/@public/documents/documents/cntrb_035024.</u> <u>pdf</u>
- [20] P. C. Austin, C. van Walraven, W. P. Wodchis, A. Newman, and G. M. Anderson, "Using the Johns Hopkins Aggregated Diagnosis Groups (ADGs) to predict mortality in a general adult population cohort in Ontario, Canada," *Medical Care*, vol. 49, no. 10, pp. 932–939, 2011.
- [21] M. Gen and R. Cheng, *Genetic Algorithms and Engineering Optimization*. New York: Wiley, 1999.
- [22] C. M. Bishop, *Pattern recognition and machine learning*. New York: Springer, 2006.

- [23] R. Fu, S. J. Kim, C. de Oliveria, P. C. Coyte, "An instrumental variable approach confirms that the duration of pretransplant dialysis has a negative impact on the survival of kidney transplant recipients and quantifies the risk," *Kidney International*, vol. 96, no. 2, pp. 450-459, 2019.
- [24] A.E. Hoerl and R. W. Kennard, "Ridge regression: biased estimation for nonorthogonal problems," *Technometrics*, vol. 12, no. 1, pp. 55-67, 1970.
- [25] R. Tibshirani, "Regression shrinkage and selection via the Lasso," *Journal of the Royal Statistical Society. Series B (Methodological)*, vol. 58, no. 1, pp. 267-288, 1996.
- [26] H. Zou and T. Hastie, "Regularization and variable selection via the elastic net," *Journal of the Royal Statistical Society. Series B (Methodological)*, vol.67, no. 2, pp. 301-320, 2005.
- [27] L. Breiman, J. Friedman, C. J. Stone, R. A. Olshen, *Classification and Regression Trees*, 1st ed. Chapman and Hall/CRC, 1984.
- [28] J. Sterne et al., "Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls," *BMJ*, vol. 338, p. b2393, 2009.
AUTOMATIC PLAN GENERATING SYSTEM FOR GERIATRIC CARE BASED ON MAPPING SIMILARITY AND GLOBAL OPTIMIZATION

Fei Ma¹; Chengliang Wang²; Zhuo Zeng³

^{1,2,3}Chongqing University, China

ABSTRACT

The smart home is an effective means of providing geriatric care to increase the ability of the elderly to live independently and ensure their health in daily life. However, the smart home is not widely used because it is arduous to obtain a sensing devices selection plan. In this paper, the accuracy of service selection and cost savings assumes enormous importance. Therefore, we propose an automatically plan generating system for the elderly based on semantic similarity, intuitionistic fuzzy theory, and global optimization algorithm, aiming at searching for an optimized plan. Experiment results indicate that our approach can satisfy care demands and provide an optimized plan of sensing devices selection.

Keywords - Care demand, geriatric care, selection plan, smart home, smart service

1. INTRODUCTION

Due to low birth rates and low mortality rates and the extension of life expectancy, the aging of population has been accelerating quickly and severely. An epidemiological study estimates that 11% of the world's population is over 60 years old, but that figure is expected to rise to 22% by 2050[1]. Accompanied by the substantial growth in the size of the elderly population during the last several decades, the growing prevalence of geriatric diseases associated with aging increases the burden on the health care systems. More importantly, geriatric diseases have a powerful negative impact on perceived mental and physical functioning in geriatric patients. It also increases life-threatening risks of the elderly[2], for example, heart disease and stroke account for more than 40% of all deaths among persons aged 65-74 and almost 60% of those aged 85 years[3]. Therefore, geriatric care plays an important role in maintaining good health and increasing the life quality of the elderly.

Recently, with remarkable advancements in machine learning and artificial intelligence, the smart home emerges into the public consciousness, because of its convenience and precision in health care[4][5][6]. Smart homes could not only monitor the daily living of the elderly and assist living in patients, but also evaluate the emotions of inhabitant and warn of dangers[7][8][9]. However, the smart home is not widely used in the field of geriatric care, because of two main reasons: (1) the challenge of extracting required smart services for elderly with high precision, based on user demands; 2) the huge complexity and high costs of smart home design, especially the difficulty in designing a sensing devices selection plan (SDSP). Traditionally, in order to implement a user-oriented smart home for geriatric care, designers firstly collaborate with elderly and geriatric experts to extract digital care demands based on natural language care needs. Then, designers choose corresponding services to achieve care demands of the elderly based on their own comprehension, and select sensing devices to develop a SDSP by manually comparing the performance of sensing devices. Therefore, the traditional method limits the promotion and use of the smart home in the field of geriatric care, including the following shortcomings and obstacles.

- Informal description: Since geriatric diagnosis and smart services are deposited in the literature database without classification and arrangement, it increases the burden of designers to extract care demands of geriatric diseases and select smart services.
- Costly and casual design pattern: Due to the difficulty of manually extracting elderly demands, the elderly must pay expensive labor costs. Besides, it is casual and arbitrary for designers to select services, since the elderly do not understand the principles of smart services.
- Non-optimized plan: As it is arduous for designers to quantify the performance of sensing devices and to compare their performance manually, the traditional SDSP is not optimized, and may result in surplus or inadequate sensing devices for implementing services.

In order to promote the use of the smart home in the field of geriatric care, we have designed an Automatic Plan Generating System (APGS) that automatically generates the optimized SDSP. The contributions of this paper are given below.

- UDSD architecture: We proposed a UDSD (user demand service device) architecture, which uses key labels instead of natural language descriptions to formalize user information, care demands, smart services, and sensing devices, including the user layer, demand layer, service layer and device layer.
- Smart-desire mapping method: Due to the high cost and casual selection of traditional design method, we designed a Smart-desire mapping method (SDMM) to automatically extract atomic care demands based on expert knowledge and mapping smart services by calculating semantic similarity and QoS similarity.

 Self-repairing artificial fish swarm algorithm: Owing to the stronger optimization ability and faster convergence speed, we proposed the self-repairing artificial fish swarm algorithm(SAFSA) to search for an optimized SDSP by limiting artificial fish moving near the constraint boundary by self-repairing behavior.

The rest of this paper is organized as follows: we briefly review the past research on the in-home health-care system in the smart home, and intelligent optimization algorithms in section 2. We propose the framework of the APGS in section 3. The Smart-desire mapping method is described in section 4 and self-repairing artificial fish swarm algorithm is presented in section 5. We perform a series of experiments to verify the scientificity and validity of SDSP in section 6. The conclusion and future work are discussed in section 7.

2. RELATED WORKS

Recently, owing to the development and advancement of the Internet of things and digital health, research in the smart home becomes increasingly important. A smart home, in which artificial intelligence techniques control home settings, collects data by sensors when residents perform their normal daily routines. Since sensors can collect data in a naturalistic way without modifying an individual's behavior, the smart home provides a new way for automated health care. The survey in [10] showed that all participants had positive attitudes towards the technology of the smart home and were willing to accept the installation of sensing devices in their homes. Afterwards, more researchers were committed to providing health care services for users of various ages. Portet et al. [11] showed that inexpensive smart home technologies could be used for the purpose of self-monitoring of safety, health and functional statuses in existing homes, and are urgently required. Nehmer et al. [12] used the smart home to provide a better assistant system in health monitoring and to improve the quality of life of elderly and disabled people. Skubic et al. [13] provided passive sensor networks to capture patterns representing physical and cognitive health conditions in an aging in place elderly-care facility. Additionally, Mario et al. [14] proposed a software architecture that modeled the functionalities of a smart home platform to deploy sensitive services into the digital home for health care.

However, due to the high costs and untrusted design, the smart home failed to make headway in the field of health care. In order to reduce the costs and to systematize the design of SDSP, we first formalize elderly care demands and smart services in a fixed data structure based on medical diagnosis and recent research in the smart home, such as activity recognition, health change detection, falling detection and so on [15]. Since the expert knowledge system with a large amount of knowledge provided a method of simulating the decision process of human experts [16], the expert knowledge learned in geriatric diagnosis was adopted to decompose user demands into atomic demands. Thereafter, we extracted smart services based on functional similarity and QoS similarity between atomic demands and smart services. As the selection of sensing devices is regarded as a

multi-objective knapsack problem, a global optimization algorithm is urgently needed to search for an optimized SDSP, which promotes the accuracy of smart services and reduces the cost of sensing devices. For a multi-objective knapsack problem, people have put forward valuable methods, mainly divided into two types: (1) heuristic algorithms, such as greedy algorithm, dynamic programming algorithm, simulated annealing algorithm and so on; (2) swarm intelligent optimization algorithm: genetic algorithm [17], particle swarm optimization algorithm [18], ant colony algorithm [19] and so on. Because of the low efficiency and slow convergence rate for large-scale problems, heuristic algorithms are replaced by swarm intelligent optimization algorithm. However, classical intelligent optimization algorithms will usually plunge into local optimization and are sensitive to the initial parameters. For example, the artificial fish swarm may plunge into local optimization if the visual of artificial fish is too small; additionally, changes of crossover and mutation probabilities of genetic algorithm will result in different genetic speeds. Therefore, in order to generate the optimized SDSP for geriatric care, we present a self-repairing artificial fish swarm algorithm, which introduce self-repairing behavior to limit artificial fish searching for an optimized solution near the constraint boundary.

3. THE FRAMEWORK OF AUTOMATIC PLAN GENERATING SYSTEM

As shown in Figure 1, we formalize user care demands and expert knowledge into digital description based on expert diagnosis, medical literature, and clinical diagnosis. Additionally, smart services for geriatric care are extracted from recent researches. In this framework, *Automatic Plan Generating* is the key module including two submodules: (1) Smart-desire module is proposed to extract required smart services for geriatric care by decomposing care demands into atomic demands, calculating functional similarity and non-functional similarity between atomic demands and smart service; (2) Global optimization module, in which the SAFSA is proposed to search for the optimized solution of SDSP for geriatric care based on cost evaluation and performance evaluation.



Figure 1 – The framework of APGS

More narrowly, user demands are decomposed into atomic care demands automatically by traveling expert knowledge

forest. Then, we extract atomic care demands according to their slot values. Additionally, an expert knowledge forest is built by expert knowledge trees which integrate expert knowledge and care demands for every geriatric disease. Thereafter, it is a requisite to obtain smart services for providing geriatric care for the elderly by the smart home, based on mapping similarity consisting of functional similarity and non-functional similarity between atomic demands and smart services. In order to make the selection of sensing devices unambiguous, we convert the problem of selecting suitable sensing devices to realize selected smart services into a multi-objective knapsack problem of searching for the optimized solution. In this paper, SAFSA is selected to search for the optimized solution, which could be replaced by other optimization algorithms. Finally, we decode the optimized artificial fish to recommend the user-oriented SDSP for the target elderly, including types, commodity selections, quantities and installation positions of sensing devices.

4. THE SMART-DESIRE MAPPING METHOD

4.1 The UDSD architecture for data formalization

As the informal descriptions of user demands and smart services limit the efficiency of automatically generating optimized SDSP, we proposed a UDSD architecture to formalize elderly information, care demands, smart services and sensing devices, and which consisted of a user layer, demand layer, service layer and device layer, as shown in Figure 2.

- User layer: The concept of the user layer is used to sort and formalize key information of diseases description, natural language care needs, and other living requirements of elderly.
- Demand layer: After we extract expert knowledge in expert diagnosis, medical literature and clinical diagnosis of geriatric diseases, the demand layer fuses user demands and expert knowledge. Specifically, care demands are divided into composite care demands and atomic care demands.
- Service layer: It is proposed to formalize technologies and services in recent research into smart services with a fixed format, including name, label, description, quality of service and input requirement.
- Device layer: This layer formalizes digital descriptions of sensing devices, including price, precision, measuring range and so on, which are important in analyzing the ability and performance of sensing devices.

4.1.1 Demand layer

Generally, care demands are extracted in expert diagnosis of geriatric diseases, which represents the real care needs of elderly for 24-hour geriatric care in the smart home, including diet care, sport care, daily care, danger warning



Figure 2 – The system workflow in UDSD model

and so on. As shown in Definition 1, the care demand contains *ID*, *Label*, *Description*, *Children* and *Quality Requirement(QR)*, where *ID* the unique identifier of one care demand, *Label* are keywords of functional description, *Description* expresses user demand in natural language, and *QR* expresses quality constraints of required service. Moreover, *Children* contains the *ID* of its sub-demands, if this care demand is a composited demand. Generally, *QR* consists of some non-functional attributes, including price, response time, availability, reliability and so on. In this paper, the non-functional attribute *QR* with accuracy, response_time, smart_level, availability and reliability.

Definition 1 Every care demand in this paper contains ID, Label, Description, Children and Quality Requirement.

 $De = \{ID, Label, Description, Children, QR\}$

4.1.2 Service Layer

In order to obtain the suitable smart services for geriatric care automatically, we need to formalize smart services into digital description in the service layer, including *ID*, *Label*, *Description* and *Quality of Service(QoS)*. Therefore, smart services in this paper are formalized with three modules.

- 1. Definition: The definition of the smart service indicates the functional description for geriatric care, including *ID*, *Label*, *Description*.
- 2. *QoS*: This represents the non-functional parameters of the smart service, including accuracy, response-time, smart-level, availability and reliability.
- 3. Input requirements: It is proposed to summarize the hardware requirements of the smart service.

4.1.3 Expert knowledge forest

Knowledge excavation is the mining of potential patterns and behaviors by highly automated analysis of legacy data to help people make the right decisions. The expression of expert knowledge directly affects the efficiency of knowledge reasoning and the ability to acquire new knowledge. However, due to the complex care demands of various geriatric diseases, the traditional knowledge expression methods are not suitable for care demands decomposition, such as logical representation, semantic network, rule-based system and so on. Therefore, we designed the *expert knowledge forest* to combine care demands and expert knowledge based on the decision tree structure and the frame knowledge expression. In the *expert knowledge forest*, every frame consists of five expert knowledge components: (1) name, a unique name that can be any constant; (2) slot, a combination of expert knowledge and care demand; (3) slot value, the attribute value, which can be 0 or 1; (4) relation, the knowledge associations between frames; (5) slot constraints, related constraints contributed to the corresponding slot value.

4.2 Smart-desire model

Due to the limitations of family space and expenditure, designers need to extract suitable smart services to provide geriatric care for the elderly in the smart home. In this paper, we proposed a Smart-desire model to extract smart services based on *expert knowledge forest* and mapping similarity. As shown in Definition 2, S_{desire} is the output of SDMM, and P_{UED} is proposed to decompose care demands(D) by traveling *expert knowledge forest* (E) based on user information(U). Additionally, in the Smart-desire model, *SS* is a set of all smart services in the service layer, and $\varphi(x^*, y^*)$ is the mapping method in SDMM.

Definition 2 *Smart-Desire* is presented to obtain S_{desire} based on user information and expert knowledge.

$$Smart_Desire = \{SS, P_{UED}, \varphi(x^*, y^*), S_{desire}\}.$$

$$S_{desire} = \varphi(P_{UED}, SS) = \sum S_i.$$

4.3 Mapping similarity calculation method

4.3.1 Functional similarity calculation

In the Definition module of the smart service, the *Label* and *Description* describe the function of this service with phrases, sentences, or concepts. In order to weight the importance of words in the *Description* of smart services and care demands, we employ the famous term frequency-inverse document frequency (TF-IDF) method. After calculating the TF-IDF values of words in *Description* of smart service s_j , we obtain the vector X and vector Y by ranking these words according to TF-IDF values, as shown in Equation (1) and Equation (2).

$$X = (x_1, x_2, ..., x_n) \tag{1}$$

$$Y = (y_1, y_2, ..., y_m)$$
(2)

Then, we propose the fuzzy similarity matrix S_{XY} between vector X and vector Y, in which $x_i y_j$ represents the semantic

similarity between keyword x_i and y_j .

$$S_{XY} = \begin{pmatrix} x_1y_1 & x_1y_2 & \cdots & x_1y_m \\ x_2y_1 & x_2y_2 & \cdots & x_2y_m \\ \vdots & \vdots & \ddots & \vdots \\ x_ny_1 & x_ny_2 & \cdots & x_ny_m \end{pmatrix}$$
(3)

According to [20], the semantic similarity between keywords x_i and y_j is calculated based on path length, depth and local density as shown in Equation (4), where *l* represents the path length and *h* represent the path depth. Simultaneously, α is a constant and β is a smoothing factor where $\beta > 0$. In this paper, we set $\alpha = 0.2$ and $\beta = 0.6$ to generate optimal semantic similarity, as details are shown in [20].

$$s(x_i, y_j) = e^{-\alpha l} \cdot \frac{e^{\beta h} - e^{-\beta h}}{e^{\beta h} + e^{-\beta h}}$$
(4)

In order to normalize the fuzzy similarity matrix, we compress it into one dimension by taking the maximum value for each row of the matrix, and average these maximum values by Equation (5). However, $s_sem(X,Y)$ only represents the average semantic similarity between the vector B and every word in A. Thus, we use Equation (6) to calculate the semantic similarity between vector *X* and vector *Y*.

$$s_sem(X,Y) = \frac{1}{n} \times \sum_{i=1}^{n} \max(x_i y_j); j \in [1,m]$$
 (5)

$$s_sem(|X,Y|) = \frac{(s_sem(X,Y) + s_sem(Y,X))}{2} \quad (6)$$

Therefore, the functional similarity between care demand *c* and smart service *s* is calculated by Equation (7), where φ_1 and φ_2 are weight coefficients of service name and service description, with $\varphi_1+\varphi_2=1$.

$$f_sim(|c,s|) = \varphi_1 \times s_sem(|c_Description, s_Description|)$$

$$\varphi_2 \times s_sem(|c_Label, s_Label|)$$

(7)

4.3.2 Non-functional similarity calculation

Since the QR of user demands are difficult to accurately represent with a number, we propose a scoring set to standardize these parameters, as shown in Equation (8).

score \in {Excellent, Good, Medium, Poor, Very Poor} (8)

Although the scoring set can express the level of QR parameters, it cannot be directly used for calculation. Therefore, the intuitionistic fuzzy theory is used to quantify these QR parameters. In this paper, since the scoring set is defined as 5 levels, the intermediate value is defined as 0.5, and the remaining distribute symmetrically. According to the fuzzy number of the scoring set in Table 1, we use Equation (9) to convert the QR to a numeric value, where μ_{QR} represents the membership degree, v_{QR} represents the non-membership degree and ρ_{QR} is uncertainty degree.

Table 1 – The fuzzy number of scoring set

Laval	Intuitionistic Fuzzy Numbers
Level	$[\mu_{QR}, \nu_{QR} - \rho_{QR}]$
Excellent	$[0.9, 0.1 - \rho_{QR}]$
Good	$[0.7, 0.3 - \rho_{QR}]$
Medium	$[0.5, 0.5 - \rho_{QR}]$
Poor	$[0.3, 0.7 - \rho_{QR}]$
Very Poor	$[0.1, 0.9 - \rho_{QR}]$

$$q_{QR} = \mu_{QR} - \nu_{QR} \times \rho_{QR} \tag{9}$$

In order to compare performance of smart services, the QoS values need to be normalized. In this paper, Equation (10) in [21] is adopted to normalize positive QoS attributes of smart services, and Equation (11) is used for negative attributes.

$$q_{ij} = \begin{cases} \frac{q_{ij} - q_j^{\min}}{q_j^{\max} - q_j^{\min}} & if \ q_j^{\max} - q_j^{\min} \neq 0\\ 1 & if \ q_j^{\max} - q_j^{\min} = 0 \end{cases}$$
(10)

$$q_{ij} = \begin{cases} \frac{q_j^{\max} - q_{ij}}{q_j^{\max} - q_j^{\min}} & if \ q_j^{\max} - q_j^{\min} \neq 0\\ 1 & if \ q_j^{\max} - q_j^{\min} = 0 \end{cases}$$
(11)

Then, the cosine similarity is used to calculate the non-functional similarity between care demand c_i and smart service s_j , as shown in Equation (12), where Q' represents the normalized QR and Q is the normalized QoS.

may

$$q_sim(c_i, s_j) = \frac{Q \cdot Q'}{||Q|| \times ||Q'||} = \frac{\sum_{k=1}^{5} q'_k \times q_k}{\sqrt{\sum_{k=1}^{5} q'_k^2} \times \sqrt{\sum_{k=1}^{5} q_k^2}} \quad (12)$$

Finally, the mapping similarity between atomic care demand c_i and smart service s_j is calculated by Equation (13), based on functional similarity and non-functional similarity, where γ_1 and γ_2 are the weight coefficients with $\gamma_1 + \gamma_2 = 1$.

$$m_sim(c_i, s_j) = \gamma_1 \times s_sim(c_i, s_j) + \gamma_2 \times q_sim(c_i, s_j) \quad (13)$$

5. GLOBAL OPTIMIZATION ALGORITHM

5.1 Transformation of sensing devices selection

In order to improve service performance and reduce the cost of sensing devices, we first need to count the requirement of sensing devices for geriatric care. Suppose that there are Atypes of sensing devices and B commodities for each type of sensing devices. The problem of selecting sensing devices can be converted into a multi-objective knapsack problem, if we can calculate the unknown data in Table 2. Then, we establish a global optimization selection model to maximize the total performance and to minimize the total cost of sensing devices, as shown in Equation (14). Therefore, this problem is a NP-complete problem like the knapsack problem.

Table 2 – Unknown data for global optimization

Symbol Meaning Symbol Meaning				
Unknown	М	Quantity	V	Performance Values
Data	W	Weight	L	Installation Location

$$Y_{1} = Min \left\{ \sum_{i=1}^{A} \left(\sum_{j=1}^{B} p_{ij} * x_{ij} \right) * m_{i} \right\}$$

$$Y_{2} = Max \left\{ \sum_{i=1}^{A} \left(\sum_{j=1}^{B} v_{ij} * x_{ij} \right) * w_{i} \right\}$$

$$S.t. \left\{ \begin{array}{l} \sum_{i=1}^{A} \left(\sum_{j=1}^{B} p_{ij} * x_{ij} \right) * m_{i} \leq Max_\text{Cost}, \quad (14) \\ \sum_{j=1}^{B} x_{ij} = 1, i = 1, 2, ..., A \\ x_{ij} = \begin{cases} 1, sensing \ device \ x_{ij} \ is \ selected \\ 0, sensing \ device \ x_{ij} \ is \ not \ selected \end{cases} \right\}$$

5.2 Unknown data acquisition

As opposed to web services and cloud services, the cost of smart services depends on the price of sensing devices. However, two different services may require the same sensing device. For example, the *Activity Monitoring* service requires the acceleration data and the *Falling Detection* service requires the same data. Therefore, we need to reduce repeatable sensing devices of selected services.

Definition 3 As a sensing device in smart service work in a specific position, we formalize every required sensing device with its type and position, as $d_i = \{type, position\}$.

In Definition 3, *type* represents the type of the sensing device and *position* is the installation position. Therefore, we count the quantity of every type of sensing device with two rules:

- 1. If d_i and d_j from different services in S_{desire} have the same d_type and $d_position$, we suppose that one sensing device is enough for both smart services. Thus, the quantity of this type of sensing devices is unchanged, while the weight is increased by one.
- 2. If d_i and d_j from different services in S_{desire} have the same d_type but different $d_positions$, only one sensing device is not enough. Hence, the quantity and weight of this type of sensing devices are both increased by one, and two installation locations are added into the *L*.

In this paper, we adopt Formula (15) to evaluate the performance of sensing devices, where ω is the compensation coefficient and ξ is the general error. Additionally, y is the service life of sensing devices, r is the measuring range and \bar{r} is the average measuring range. η ($\eta \in (0, 1)$) indicates the effect of sensing devices in smart services.

$$R = \eta \frac{\omega y}{\xi} \sqrt{\frac{r}{\bar{r}}}$$
(15)

5.3 Self-repairing artificial fish swarm algorithm

Artificial fish swarm algorithm is a new bionic and swarm intelligence algorithm to search for an optimized solution by modeling four daily behavior including preying, swarming, following and random behavior. Since only one commodity in each type of sensing device could be selected, we proposed the representation scheme of artificial fish to compress the solution space and reduce the search region, as shown in Equation (16). More specifically, the value of x_i shows that the x_i th commodity for *i*th type of sensing devices is selected.

$$X_f = \{x_1, x_2, x_3, \dots, x_i, \dots, x_m\}$$
 (16)

Definition 4 The artificial fish X_f is located near the constraint boundary of the problem, if X_f is a feasible solution and it would become infeasible when we find a commodity k in type i and assign k to x_i , where $i \in \{1,2,3...A\}$, $k \in \{1,2,3...B\}$ and the **Performance/Price** of kth commodity is bigger than x_i 's in type i sensing devices.

The research [22] proves that an optimized solution and constraint boundary of the knapsack problem are usually symbiotic. Thus, we proposed a self-repairing strategy to repair artificial fish return to the constraint boundary. For any infeasible solution X_f , there are two self-repairing strategies, where **Operation** (1) on x_i with the least value of *Performance/Price* and **Operation** (2) on x_i with the biggest value of *Price*:

Operation (1): Replacing x_i with k, if *Performance/Price* of kth commodity is biggest in the same type of sensing devices whose *Price* is less than the *Price* of x_i , where $i \in \{1, 2, 3...A\}$ and $k \in \{1, 2, 3...B\}$.

Operation (2): Replacing x_i with k, as the *Price* of kth commodity is least in the same type of sensing devices whose *Performance/Price* is bigger than x_i , where $i \in \{1, 2, 3...A\}$ and $k \in \{1, 2, 3...B\}$.

Proof 1 If the infeasible artificial fish X_f becomes a feasible solution after the last **Operation** (1), we can conclude that the Price of kth sensing device is less than x_i . Assume that the artificial fish X_f is not near the constraint boundary. According to Definition 4, there is a sensing device whose Performance/Price is bigger than k and Price is less than x_i . However, due to the description of **Operation** (1), the value of Value/Price of k is biggest in the candidate sensing devices whose Price is less than Price of x_i . Therefore, the assumption is not true and X_f is near the constraint boundary after **Operation** (1) of self-repairing behavior.

As the above Proof 1 reveals, the artificial fish X_f become feasible solution after **Operation** (1). Additionally, **Operation** (2) can be similarly proved with the same method. Therefore, we properly invoke self-repairing behavior to search for the optimal solution, when the artificial fish X_f become infeasible after four basic behaviors.

Since two objective functions of the multi-objective knapsack problem have opposite targets, we make a conversion for the objective functions Y_1 , as shown in Equation (17):

$$Y_{1} = Max \left\{ \sum_{i=0}^{A} \left(\sum_{j=0}^{B} \frac{1}{p_{ij}} * x_{ij} \right) * m_{i} \right\}$$
(17)

Compared to the Ideal point method and Hierarchical method, we choose the Linear-weighting method that uses λ_1 and λ_2 as weights of two objective functions based on the elderly desires. As shown in Equation (18), λ_1 and λ_2 are adjusted based on the inclination of the elderly, while $\lambda_1 + \lambda_2 = 1$. Also, w_1 and w_2 are the weighting factors of the objective functions Y_1 and Y_2 . Finally, $Max\{Y_1\}$ is the optimal value of Y_1 and $Max\{Y_2\}$ is the optimal value of Y_2 under the same constraints.

$$Y = Max\{\lambda_1 w_1 Y_1 + \lambda_2 w_2 Y_2\}$$
(18)

$$v_1 = \frac{1}{Max\{Y_1\}}$$
(19)

$$w_2 = \frac{1}{Max\{Y_2\}}$$
(20)

6. EXPERIMENTS AND RESULTS ANALYSIS

И

In order to verify the accuracy and validity of the proposed APGS, we formalized 40 care demands and 200 smart services for geriatric care, including hypertension, heart diseases and diabetes. Firstly, we need to verify the scientificity and validity of selected services for geriatric care in experiment 1; then, the global optimization capability and convergence rate of SAFSA should be verified in experiment 2; finally, we built the evaluation indicator system of SDSP to verify the scientificity and validity of SDSP of the smart home, based on evaluations of smart home researchers.

In the first experiment, we listed care demands for geriatric experts to select needed care demands for 100 sample elderly, suffering from hypertension, diabetes and heart diseases. Weight parameters in SDMM are set as: $\varphi_1 = \varphi_2 = 0.5$, $\gamma_1 = 0.7$ and $\gamma_2 = 0.3$. Then, we recommended smart services, whose mapping similarity are bigger than 0.8, for geriatric experts to manually select suitable smart services to meet care demands. Ultimately, we use Precision $(\frac{C \cap D}{C})$, Recall $(\frac{C \cap D}{D})$ and F1 $(\frac{2*Precision*Recall}{Precision+Recall})$ to verify the validity of selected services, where *C* is the service set calculated by proposed SDMM and *D* is the service set selected by experts.

We compared the performance of mapping similarity method (MS), keyword mapping method (KM) and variable precision rough set method (VPRS). As shown in Figure-3(a), the precision is more than 94.4%, which indicates that selected smart services can excellently cover care demands of the sample elderly. Compared to KM and VPRS methods, our approach has higher accuracy and coverage, since precision, recall and F1 of the proposed MS are almost the biggest. The similar function and description between smart services are important reasons causing 4.5% of the mismatch. In Figure-3(b), the performance of MS for elderly suffering from diabetes is better than hypertension and heart diseases. In particular, the performance of MS for a single geriatric disease is usually better than two or more geriatric diseases.



Figure 3 - (a)The results of MS, KM and VPRS; (b) the results of SM for different geriatrics.

In order to verify the global optimization capability and convergence rate of SAFSA, we randomly generated Performance of sensing devices in [0,50] and generated Price in [0,100]. Supposing that there are 20×20 sensing devices, we make experiments under *Visual=*30, *Step=*10, *Try_Number=*50, δ =35 and $\lambda_1=\lambda_2=0.5$. As optimal and worst solutions of SAFSA are all better than AFSA, PSO and GA in Figure-4(a), we concluded that SAFSA has a better global optimization capability. As shown in Figure-4(b), since cycle times of SAFSA for generating the global optimal solution is less than AFSA, the convergence rate of SAFSA is better than AFSA because of the self-repairing behavior. Finally, average cycle times of GA and PSO are similar to SAFSA, because they are easier to fall into local optimum.



Figure 4-(a) The optimal values of optimization algorithms; (b) The cycle times for obtaining the optimal solutions.

Finally, we built an evaluation indicator system of SDSP to verify the scientificity and validity of SDSP of the smart home, based on evaluations of smart home researchers, as shown in Table 3. Then, we presented 20 SDSP to conduct surveys of 20 smart home researchers. As shown in Figure 5, the average score is bigger than '9' of the three secondary indexes of smart services and showed that SDSP has better accuracy, faster response times and higher intelligence levels. However, more than half of researchers gave a '4-6' score to 'Energy Consumption', mainly because the energy consumption was not taken into account to evaluate the performance of sensing devices.

Table 3 – The evaluation is	ndicator system	ı of SDSP
------------------------------------	-----------------	-----------

Primary Index	Secondary Index	Scores
Sansing Davicas	Energy Consumption(EC)	1-10
Sensing Devices	Utilization Rate(UR)	1-10
Smart	Accuracy(Acc)	1-10
Services	Response Speed(RS)	1-10
	Intelligence Level(IL)	1-10
Installation		
& Deployment	Accuracy Rate(AR)	1-10

Summarily, we implemented a prototype system to extract the



Figure 5 – The results of SDSP evaluation.

smart services set S_{desire} and to generate an optimized SDSP of the smart home, including types, quantities and positions of sensing devices, as shown in Figure 6. In future work, energy consumption and the layout of the family should be taken into account to reduce the waste of energy resource and to guide the deployment of sensing devices. Therefore, the work of this paper will help the development and promotion of the smart home in the field of geriatric care.

Smart-Desire Syste	en l			Ч.
Sleep Quality:	Good	Bed .		
Daily Living:	🗌 Regular	🖉 Irregular		
ther Requirements				
			Extract	
intelligent Services:	Medicine_F	eminding_Care		^
	Sports Real	inding_Care		
	Eating_Rea	inding_Care		~
	1.0.00000000000000000000000000000000000		Generate	
Deploying Plan:	Devices: 1 Devices: 5 Stove. Devices: F Devices: F	nfrared_Sensor, ID: 5, Number: 20, Pos witch_Sensor, ID: 3, Number: 3, Positi eminding_Devices, ID: 3, Number: 2, Po ressure Sensor, ID: 6, Number: 9, Posi	ition: Indoor. on: Medical_Kit, sition: Medical_ tion: Red. Posit	Pc ^
	Dining_Des Devices: A	k. ccerelation_Sensor, ID: 8, Number: 3, 3	Position: Wrist,	Pc
	Devices: 7 Position:	emperature_Sensor, ID: 1, Number: 3, P Wash Room.	osition: Stove,	Pos
	Devices: H Devices: S Devices: W	lood_Pressure_Meter, ID: 5, Number: 1, mart_Veighting_Machine, ID: 2, Number: eighting_Battle, ID: 9, Number: 1, Pos	Position: Indoo 1, Position: In ition: Salt_Batt	r. doc le.
	Devices: H Devices: H	umidity_Sensor, ID: 6, Number: 1, Posi umidifier, ID: 7, Number: 1, Position:	tion: Indoor. Living_Room.	
	Devices: A	ir_Conditioning, ID: 10, Number: 2, Po	sition: Living_R	000

Figure 6 – The prototype system of APGS.

7. CONCLUSIONS AND FUTURE WORK

Due to the complexity and waste of resources in traditional SDSP design, the smart home is not widely used in health care. In order to promote the role of the smart home in the field of health care, we proposed an APGS to generate the SDSP for the smart home automatically and efficiently based on the Smart-desire mapping method and Self-repairing artificial fish swarm algorithm. Ultimately, experiments of elderly suffering from hypertension, diabetes and heart diseases verified the scientificity and validity of SDSP. Our work provides a novel approach to designing a user-oriented smart home efficiently and automatically, which could reduce the labor costs and make the design pattern more transparent and reliable. Furthermore, an accurate SDSP is very helpful for promoting the use of the smart home in geriatric care. In future work, many standards in the field of geriatric care and smart services will be considered to standardize the design of the smart home, since the standards can not only help the elderly understand smart services, but also provide an aid for the application and promotion of our method. Then, a new method of assigning intelligence to sensing devices by software-defining intelligence is necessary to improve the coding efficiency in smart home design. We will commit to providing user-oriented geriatric care for the elderly in the smart home to greatly improve the quality of life of the elderly in our future work.

REFERENCES

- [1] Christopher B Newgard and Norman E Sharpless. Coming of age: molecular drivers of aging and therapeutic opportunities. *The Journal of clinical investigation*, 123(3):946–950, 2013.
- [2] Sharon R Kaufman. Old age, disease, and the discourse on risk: geriatric assessment in us health care. *Medical Anthropology Quarterly*, 8(4):430–447, 1994.
- [3] Igor Akushevich, Julia Kravchenko, Svetlana Ukraintseva, Konstantin Arbeev, and Anatoliy I Yashin. Age patterns of incidence of geriatric disease in the us elderly population: Medicare-based analysis. *Journal of the American Geriatrics Society*, 60(2):323–327, 2012.
- [4] Jan Vanus, Jana Belesova, Radek Martinek, Jan Nedoma, Marcel Fajkus, Petr Bilik, and Jan Zidek. Monitoring of the daily living activities in smart home care. *Human-centric Computing and Information Sciences*, 7(1):30, 2017.
- [5] Frank G Miskelly. Assistive technology in elderly care. *Age and ageing*, 30(6):455–458, 2001.
- [6] Ahmad Alaiad and Lina Zhou. Patients' adoption of wsn-based smart home healthcare systems: An integrated model of facilitators and barriers. *IEEE Transactions on Professional Communication*, 60(1):4–23, 2017.
- [7] Diane J Cook, Maureen Schmitter-Edgecombe, and Prafulla Dawadi. Analyzing activity behavior and movement in a naturalistic environment using smart home techniques. *IEEE journal of biomedical and health informatics*, 19(6):1882–1892, 2015.
- [8] Boyuan Sun, Qiang Ma, Shanfeng Zhang, Kebin Liu, and Yunhao Liu. iself: Towards cold-start emotion labeling using transfer learning with smartphones. ACM Transactions on Sensor Networks (TOSN), 2017.
- [9] Jens Lundström, Eric Järpe, and Antanas Verikas. Detecting and exploring deviating behaviour of smart home residents. *Expert Systems with Applications*, 55:429–440, 2016.
- [10] George Demiris, Marilyn J Rantz, Myra A Aud, Karen D Marek, Harry W Tyrer, Marjorie Skubic, and Ali A Hussam. Older adults' attitudes towards and perceptions of 'smart home'technologies: a pilot study. *Medical informatics and the Internet in medicine*, 29(2), 2004.
- [11] François Portet, Michel Vacher, Caroline Golanski, Camille Roux, and Brigitte Meillon. Design and evaluation of a smart home voice interface for the elderly: acceptability and objection aspects. *Personal and Ubiquitous Computing*, 17(1):127–144, 2013.

- [12] Jürgen Nehmer, Martin Becker, Arthur Karshmer, and Rosemarie Lamm. Living assistance systems: an ambient intelligence approach. In *Proceedings of the* 28th international conference on Software engineering, pages 43–50. ACM, 2006.
- [13] Marjorie Skubic, Gregory Alexander, Mihail Popescu, Marilyn Rantz, and James Keller. A smart home application to eldercare: Current status and lessons learned. *Technology and Health Care*, 17(3), 2009.
- [14] Mario Vega-Barbas, Iván Pau, María Martín-Ruiz, and Fernando Seoane. Adaptive software architecture based on confident hci for the deployment of sensitive services in smart homes. *Sensors*, 15(4):7294–7322, 2015.
- [15] Moeness G Amin, Yimin D Zhang, Fauzia Ahmad, and KC Dominic Ho. Radar signal processing for elderly fall detection: The future for in-home monitoring. *IEEE Signal Processing Magazine*, 33(2):71–80, 2016.
- [16] Xuewei Wang, Haibin Qu, Ping Liu, and Yiyu Cheng. A self-learning expert system for diagnosis in traditional chinese medicine. *Expert systems with applications*, 26(4):557–566, 2004.
- [17] Paul C Chu and John E Beasley. A genetic algorithm for the multidimensional knapsack problem. *Journal of heuristics*, 4(1):63–86, 1998.
- [18] Jagdish Chand Bansal and Kusum Deep. A modified binary particle swarm optimization for knapsack problems. *Applied Mathematics and Computation*, 218(22):11042–11061, 2012.
- [19] Min Kong, Peng Tian, and Yucheng Kao. A new ant colony optimization algorithm for the multidimensional knapsack problem. *Computers & Operations Research*, 35(8):2672–2683, 2008.
- [20] Yuhua Li, Zuhair A Bandar, and David McLean. An approach for measuring semantic similarity between words using multiple information sources. *IEEE Transactions on knowledge and data engineering*, 15(4):871–882, 2003.
- [21] Liangzhao Zeng, Boualem Benatallah, Anne HH Ngu, Marlon Dumas, Jayant Kalagnanam, and Henry Chang. Qos-aware middleware for web services composition. *IEEE Transactions on software engineering*, 30(5):311–327, 2004.
- [22] Qing Liu, Tomohiro Odaka, Jousuke Kuroiwa, Haruhiko Shirai, and Hisakazu Ogura. A new artificial fish swarm algorithm for the multiple knapsack problem. *IEICE TRANSACTIONS on Information and Systems*, 97(3):455–468, 2014.

SESSION 6

DATA AND ARTIFICIAL INTELLIGENCE ERA

- S6.1 **Invited paper** Preparing for the AI era under the digital health framework
- S6.2 Operationalizing data justice in health informatics

PREPARING FOR THE AI ERA UNDER THE DIGITAL HEALTH FRAMEWORK

Shan Xu¹; Chunxia Hu¹; Dong Min¹

¹China Academy of Information and Communication Technology (CAICT), China

ABSTRACT

Information and communication technology (ICT) for health has shown great potential to improve healthcare efficiency. especially artificial intelligence (AI). To better understand the influence of ICT technology on health, a framework of the digital health industry has been proposed in this paper. Factors from the health industry and the ICT part are extracted to study the interaction between two groups of component factors. Health factors include service and management; and ICT factors include sensors, networks, data resources, platforms, applications and solutions. The interaction between ICT and health can be traced through the development history, from the stage of institutional informationization to regional informationization, and finally to service intelligentization. Following such a developmental roadmap, AI was chosen as one of the most powerful technologies to study the penetration effect and key development trends from the perspectives of data, computing power and algorithms. The health industry will be much improved or redefined in the coming AI era. To better understand the strengths, weaknesses and limitations of AI for health, exogenous factors are discussed at the end of the preparations on collaboration mechanism; paper; standardization and regulation have been proposed for the sustainable development of digital health in the AI era.

Keywords – Artificial intelligence, digital health, framework, information and communication technology, interaction

1. INTRODUCTION

Health, as defined by the World Health Organization (WHO), is "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."[1][2]. After decades of development, the demand and supply of the health industry have quietly changed. Complying with the industrial development requirements, information and communication technology (ICT) was introduced as a new technology which has great potential to improve healthcare efficiency, thus the digital health era has begun. Among those ICT technologies, artificial intelligence (AI) is regarded as the most powerful one with an unpredictable developing rate. To understand the strengths, weaknesses and limitations of AI for health has become more and more necessary.

1.1 Health industry changes

The developing requirement for the health industry has changed over the decades in terms of demand and supply. The gap between supply and demand is now increasingly growing, waiting for new technological productivity to fill this gap. From the demand side, an aging population is poised to become one of the most significant social transformations in the twenty-first century, with implications for nearly all sectors of society. According to data from World Population Prospects: the 2019 Revision [3], by 2050, one in six people in the world will be over age 65 (16%), up from one in 11 in 2019 (9%). This is especially directly reflected in changes of the population's disease spectrum. Take China for example, the prevalence of chronic diseases in the population over 65 years old is 539.9‰ [4], which is much higher than for the entire population. For the future, chronic diseases, such as cardiovascular and cerebrovascular diseases, cancer, diabetes, chronic respiratory diseases, etc. will become the biggest threat to public health. However, the growth of supply resources lags much behind demand [6], the situation is particularly serious for imaging, pathology and general practitioners. For example, the growth rate of medical imaging data in China is about 30% per year, while the annual growth rate of radiologists is only 4.1%, the gap of pathologists is estimated to be 100 000[6][7], and it is not only limited to radiology. Training doctors takes a long time, which means that the gap cannot be solved in the short term.

1.2 ICT penetration into health

The good news is that the arrival of the fourth industrial revolution has brought us ICT technology, which has enormous potential to help overcome this socioeconomic challenge. Digital health refers to the use of ICT to help address the health problems and challenges faced by people under treatment [8]. Technologies such the fifth generation (5G) communications, machine-to-machine (M2M) communications, cloud computing, Internet of things (IoT), big data, AI and machine learning(ML) etc. [9] will inevitably penetrate theinto health industry and lead to new improvements in digital health services, from medical device manufacturing to healthcare delivery, from medical research

to institution management, finally leading to an increased life expectancy and a greatly enhanced quality of life. The specific interaction from ICT to health industry will be illustrated in section 2.2 and later.

1.3 AI for health

Of all ICT technologies, AI is one of the most significant trends. Many countries deploy their national strategy on AI in response to any forthcoming impact and seize the opportunity for development, as is shown in Table 1. Most of the national plans defined the priority areas in AI, and a basic consensus has been reached on the priority development of the digital health field. Under the guidance of these national strategies, considerable resources will be allocated to exploring the use of AI for health. Yet, due to the complexity of AI models, cautious consideration needs to be taken in relation to data handling rules, interoperability standards and evaluation methodologies, etc. to make a good preparation for the future development of AI for health.

Table 1 - National AI strategy deployment

Country	Policy	Release
	Preparing for the Future of Artificial Intelligence	2016.10
	The National Artificial Intelligence Research and Development Strategic Plan	2016.10
US	Artificial Intelligence, Automation and the Economy	2016.12
US	Artificial Intelligence and National Security	2018.07
	Executive Order on Maintaining American Leadership in Artificial Intelligence	2019.02
	The National Artificial Intelligence Research and Development Strategic Plan:2019 Update	2019.06
EU	Artificial Intelligence for Europe	2018.04
	Declaration of Cooperation on Artificial Intelligence	2018.04
	European Coordinated Plan on Artificial Intelligence	2019.2
UK	Artificial intelligence: opportunities and implications for the future of decision making	201611
	Growing the Artificial Intelligence Industry in UK	2017.10
	AI in the UK_ ready, willing and able?	2018.04
	Industrial Strategy: Artificial Intelligence Sector Deal	2018.04
China	A new generation of artificial intelligence development planning	2017.07
Iopop	Next generation artificial intelligence promotion strategy	2016.7
Japan	Artificial intelligence technology strategy	2018.6

2. INDUSTRIAL FRAMEWORK

To see the essence of digital health development for various applications and use cases, an overarching vision is necessary to judge the current situation and predict the future. But currently much of the academic research in this area is limited to relatively narrow topics such as experiment improvement, so far there is no consensus on the overall view of the digital health industry. Therefore, this paper tries to propose an industrial framework to follow the penetration of ICT in health, and study the corresponding effects from the penetration. The framework will be expanded from the traditional health industry to digital health, and the specific discussion on AI for health will be in section 4.

2.1 Health industrial framework

The traditional health industry consists of two parts: healthcare service and management of staff and equipment. Figure 1 shows the framework when considering single healthcare institutions. Both the services and management activities can be reflected in a certain kind of record in the healthcare institution.

- Service: refers to a series of healthcare options provided to patients; although there are different understandings of the workflow [10] [11], the common process always includes doctor reservation, check-in & triage, payment/ pre-pay, symptom check, image inspection, laboratory test, medical treatment, monitor & recover, etc.
- Management: refers to the effective control of staff and equipment inside the institution. Staff usually includes general practitioners, specialists and nurses, etc.; equipment includes device used in imaging, testing, surgery and monitoring, etc. [12].



Figure 1 – Health industrial framework in single institution

2.2 Digital health framework

Regarding digital health, some factors are extracted from the ICT side to discuss their corresponding effect on the above health industrial framework. Figure 2 shows the framework of digital health and the ICT factors are listed on the right side.

Sensors: enable real-time collection of information at anytime and anywhere. It can be customized to different scenarios and requirements, such as various wearable devices.

- Network: ensures effective transmission of information collected by sensors. 5G is an innovation on networks, combined with upper factors, giving birth to new applications such as telemedicine.
- Data resource: refers to how the data transmitted by networks is effectively integrated and further processed. Data center construction is an example.
- Platforms: integrate various component and computing capabilities to achieve integration and modularity. For example, cloud computing provides the foundation support for the upper applications of digital health.
- Applications: promote the service in specific scenarios and meet specific needs. AI and ML are examples closely integrated into the service process to provide a comprehensive service.
- Solutions: provide an overall service including technical support, consulting, design, operation, etc.





3. ICT INTEGRATION STAGE

To verify the rationality of the framework, penetration between ICT and the health industry can be tracked from the very beginning of digital health development. The history is usually defined as three stages, corresponding to the informationization of institution, region and service. In the future, the combination of big data, and the massively parallel computing and AI may create a revolutionary way for evidence-based and personalized treatment.

3.1 Institutional informationization

The first stage is informationization within one institution, marked by the hospital information system (HIS) and management information system (MIS). The digitization within one institution is the most important feature at this stage, including the digitization of healthcare processes (HIS as an example) and management improvement (MIS as an example). Figure 3 shows the penetration of influencing factors on the previous digital health framework, and the specific interaction is marked in blue. Among those ICT factors, data resource and software development were the leading ones. These information systems are software contributed to the digitization of data, and they started to be applied in 1960s, when the United States began research on HIS in military hospitals, and then Japan and some European countries followed and promoted HIS in the late 1970s [13]. Additionally, data played an invisible key role in the process. In particular, the replacement of paper electronic data is a huge innovation for the traditional industry. Electronic information is more efficiently processed, analyzed and calculated than paper records, with an improvement in efficiency, as well as a reduction in the operational costs [14]. However, there is still limited improvement when only considering the simple point of institution; the full value of informationization is still waiting to be amplified.



Figure 3 – Interaction between ICT and health at Stage 1

3.2 Regional informationization

The second stage is regional informationization, mostly driven by the requirements of electronic record rating and network interconnection. Different information systems developed at the first stage, such as HIS, HRP, EMR, PACS, RIS, NIS, LIS, etc., are still scattered information islands in one hospital. Much improvement could be made to their integration, Figure 4 shows the process. Other healthcare institutions were added as similar blocks in the bottom, and community network and electronic data resources played significant roles at this stage. They were carriers and channels for communication between different institutions. In the late 1980s, the United States used the Community Health Information Network (CHINS) [15, 16] to explore regional informationization. Followed by 2004, former US President George W. Bush proposed to establish a national electronic record system within 10 years. Canada established the Infoway organization in 2000 and invested hundreds of millions in citizen electronic health systems. The British government signed a total of 6 billion pounds with top information companies to establish a long-term nationwide health information network. The Korean government then also set up a committee, specializing in the research and development of electronic health records (EHR), to promote the sharing of health data nationwide [17]. Unlike the previous stage, regional informationization is a huge project with many stakeholders involved, with a large investment and low construction success rate. Even in the United States, the construction success rate is only one third [18-22]. The construction experiences need to be shared and serve for future development.



Figure 4 – Interaction between ICT and health at Stage 2

3.3 Service intelligentization

The third stage is service intelligentization. In the previous stage, the digitization of health records laid a good foundation of data sharing and intelligent services for a wider range [23]. Figure 5 shows the interaction in blue. Data, computing platforms and personalized applications are the main factors to promote service intelligentization. Data is not limited to the digitization of records, but also refers to emerging big data technology, such as IBM Watson built on big data analysis. Computing platforms are to support the process of 'massive' EHR and mining the hidden values. With the increasing volume and complexity of patient information, the expectations for rapid and accurate diagnosis and treatment also rises. AI/ML has great potential to assist physicians with reference diagnosis and personalized treatment. An evidence-based medical decision-making system was established with the help of a large number of cancer clinical knowledge, molecular and genomic data and cancer case history information [24]. DeepMind also stepped into the AI for health field and announced its first major health project in 2016: a collaboration with the Royal Free London NHS Foundation Trust, to assist in the management of acute kidney injury [25]. Not only diagnosis and treatment are penetrated, intelligent applications can be integrated in every part of the service chain, and the corresponding application comes into being, which will be illustrated in section 4.3.



Figure 5 – Interaction between ICT and health at Stage 3

4. KEY TRENDS IN AI ERA

Following the development track, AI is seen as one of the most prominent technologies in the intelligent stage, as is also reflected by the national strategy documents of countries. The following sections will extract the interaction of AI on digital health separately from the intelligence stage and discuss the key trends from the perspective of the main component factors of AI. They are data, computing power and algorithms which can correspond to the data, platform and application of the ICT part in the previous framework.

4.1 Comprehensive description of health data

Large amounts of data are the foundation of intelligent services. In order to more fully describe the state of human health, two dimensions of expansion are undertaken, horizontally and vertically.

Horizontal expansion refers to the full coverage of a life cycle. With the keen perception of sensors and strong analytical ability of AI, it could ideally cover the whole process of user life, continuously monitoring and comprehensively analyzing various data indicators, including physiological data (such as blood pressure, pulse), environmental data (such as air that is breathed in), behavior data (such as exercising or diet), etc. IBM Watson and Microsoft Azure have built a population health platform based on "AI+Cloud", providing an overview analysis of various impact factors on personal health. Potential stakeholders including wearables companies, medical institutions, HIS developers and health insurance, etc. can all benefit from this model. From "treat diseases" to "prevent diseases", it will to some extent alleviate the gap between supply and demand, mentioned in section 1.

Vertical expansion refers to the deep description of life. Measurement technology is continuously evolving, from the individual level, anatomical level, human tissue, metabolism, to protein, genetic aspects. Precision medicine was proposed with the rapid advancement of genome sequencing technology and the cross-application of big data technology. The United States initially invested \$215 million in the Precision Medicine Initiative, China has planned to invest US\$9 billion and mentioned precision medicine in the "13th Five-Year Plan"; Australia launched the Zero Childhood Cancer Program in 2016 with an investment of A\$20 million; the French genome medical treatment 2025 was also launched with an investment of 670 million euros. As the granularity of health data descriptions deepens. AI is able to establish an interpretation bridge between genetic information and clinical characterization, and ultimately achieve personalized and precise treatment.

4.2 Customized computing abilities for scenarios

With rapid increases in the amount and complexity of health data, higher requirements are proposed for the platform. Two ways for improvement are: processors and architecture. Processors are major computing units in AI for health systems. Performance could be evaluated by the metrics of calculation speed, data bandwidth and power consumption per unit of time. Processors used in AI usually include central processing unit (CPU), graphics processing unit (GPU), field-programmable gate array (FPGA), application specific integrated circuit (ASIC) and system-on-a-chip (SoC) accelerators, etc. The Google Brain was once based on the CPU, but the general calculators have limited abilities for floating point calculations, and was unable to meet deep learning requirements, especially in model training. Though GPU is currently the primary choice due to its highbandwidth caches and strong parallel computing power, customized chips have more potential than these generalpurpose chips. FPGA is very flexible to achieve a high degree of customization, and ASIC even has a better performance, with a computing speed of over 5-10 times faster than FPGA. High R&D costs and production cycles are two main obstacles for customized processors. A scale effect may reduce the cost in the long term. Tractica forecasts that the market for deep learning chipsets will increase from \$1.6 billion in 2017 to \$66.3 billion by 2025, and ASIC market will be the largest by 2025 [26].

Network architecture is also customized to support AI services. Continuous health condition monitoring and complex health management scenarios require flexible computing abilities. Architecture with a combination of cloud and edge computing will be increasingly suitable for growing health needs. Cloud-computing solutions offer a pay-per-use model that provides on-demand access to computing resources. The cloud platform for deep learning can be customized on TensorFlow, Caffe, MXNet, Torch, etc., and provides developers with common models to reduce R&D costs. Algorithm training, assessment, visualization tools and API services are also available for customization. Because of the convenience and low-cost operation, AI training tasks are gradually deployed on the cloud instead of the device. Meanwhile, edge computing developed on the devices is designed to be adaptive to application scenarios. It is a blue sea with diverse forms and low competitiveness. IoT or wearables such as intelligent watches, headphones and wristbands, and mobile phones are currently major drivers of the edge market. AI inference tasks are increasingly deployed on devices to support the diversified scenarios and needs.

4.3 Closely integrated algorithm with health process

With large databases, high-performance computing, AI algorithms could strongly support and achieve personalized medicine. The close combination between AI algorithms and traditional health processes is the key to success. As is shown in Figure 1, the framework of the health industry consists of service and management. The integration can also be seen from these two perspectives.

Service process usually includes reservation, check-in & triage, payment/ pre-pay, symptom check, image inspection,

laboratory test, medical treatment, monitor & recovery. The mainstream applications of AI are listed as below.

- \triangleright AI Virtual assistant: Logistics such as online reservation, intelligence triage, payment and repairment monitoring could be effectively completed by AI virtual assistants. Information input could be in various formats, such as audio, pictures, EHR scan and questions answering. By speech/image recognition and natural language processing technology, it could understand the patient's description of symptoms, automatically provides intelligent consultation, triage suggestions and payment assistance. An intelligent voice product "Yun Medical Sound" has been applied in more than 40 hospitals in China, with a voice transcription accuracy rate of over 97%. Additionally, these kinds of products' functions can also be expanded to service rating, doctor matching, in-hospital navigation, medical insurance reimbursement, prediagnosis data collection, post-diagnosis follow-up, reexamination reminder, health knowledge teaching, etc. The application forms of the virtual assistant are very flexible and adaptive to certain scenarios, including APP, websites and embedded programs, etc.
- \triangleright Medical imaging aided diagnosis: The core steps in health service, such as symptom check and image inspection are currently penetrated with AI in the form of medical imaging aided diagnosis. Based on computer vision and pattern recognition technology, AI could achieve image classification and retrieval, 3D reconstruction, image segmentation, feature extraction, lesion identification, target area delineation and automatic annotation, etc. Various application scenarios include fundus screening [27], breast pathology diagnosis [28], X-ray reading, brain CT segmentation, bone injury identification, bone age analysis, organ delineation, dermatological auxiliary diagnosis, etc. Some research even shows a better performance and efficiency than that provided by humans [29].
- \triangleright Clinical decision support system (CDSS): Key steps such as laboratory test judgement and medical treatment are integrated with CDSS. Traditional CDSS builds on a top-down approach, with expertise and rules based on expert systems to simulate the clinical decision-making process. AI based CDSS, without the reliance on predefined rules, could ensure the timeliness of evidence updates. Advanced natural language processing, cognitive computing, automatic reasoning and deep learning, etc. are used. AI-based CDSS could greatly take full advantage of digital medical data accumulated on a large scale in clinical work in recent years, and overcome the weakness of inefficiency in knowledge construction and limited information coverage for traditional decision making, thus eventually accelerating industry development.

The management process in the health industrial framework is divided into two parts: equipment and staff. The corresponding applications of AI are also listed as below.

- \triangleright Staff and institution management: Personnel in health institutions usually includes physicians of various specialties, nurses, technicians specializing in specific equipment, administrative financial clerks and other support personnel. Intelligent institution management application could either refer to specific problems like scheduling the nurse personnel, performance appraisal, workload distribution, task assignment, patient feedback collection and analysis, etc. [12]. Besides, auxiliary talent training is another direction for AI to improve staff management. Royal Philips' annual health survey shows that in Singapore, about 37% of medical professionals can use artificial intelligence to support administrative tasks, only 28 % of them have the digital literacy to use it for diagnosis. Auxiliary talent training could be a customized education and collaboration platform. InferScholar Center released in March 2019 [30] is equipped with advanced models and visualization tools for the clinical research. Ali Health is trying to break down various clinical case data into a three-dimensional "virtual patient" in the physician training system of Ali ET Medical Brain [31].
- Equipment and drug operation: Health institutions \triangleright frequently and continuously use large equipment to measure patients' health data. Intelligently detecting the operation of the equipment with IoT sensors and AI analysis could avoid emergencies such as equipment failures. Moreover, drug development could also be supported by AI. New drug development requires an averaged investment of 2.87 billion US dollars [32]. Only 5 out of the 5 000 can be used in animal experiments on average, and finally only 1 of them can enter the clinical trial stage [33]. AI could help with including target screening, drug mining and drug optimization to improve development efficiency. Computer simulation calculates the ability of small molecules to the drug target, increasing the screening speed and success rate, and eventually reducing the development cycles and overall costs.

5. CORRESPONDING PREPARATION

With the increasing penetration of AI into health processes, and considerable resources allocated to exploring the use of AI for health, the era of AI for health is coming. 9.5 billion dollars of venture investment is reported in global digital health in 2018, which is an increase of more than 30% over the previous year; and the corporate finance provided to digital health companies totaled \$13 billion, which is a 58% increase from \$8.2 billion in 2017 [34]. Yet, due to the complexity of AI models, it is difficult to fully understand their strengths, weaknesses and limitations. The corresponding preparation is necessary, requiring serious consideration.

These preparation factors sit alongside the health direct workflow in healthcare institutions; thus, they can be defined as exogenous factors that play an external effect on the health industry. Figure 6 shows the complete framework of digital health with the consideration of exogenous factors including collaboration mechanisms, standardization and regulation, etc.



Figure 6 – Effects from exogenous factors

5.1 Collaboration mechanism

The collaboration mechanism refers to the way that related stakeholders collaborate and contribute together. AI for health is an interdisciplinary integration and innovation between the ICT and the health industry. Expertise from the health and AI community are of great importance to promote this cross-domain task. The mechanism can be considered in three aspects listed below.

- Top-level design: National or overview strategy of AI for health industrial plan can act as a guidance to gather more industrial power. This top-level design may include goal definition, demand analysis, strategic direction, priorities, timeline and role division. Many AI strategies were deployed, but not AI for health. This kind of top-level design will give an overarching view of the industry development and help form an industry consensus to integrate scattered opportunities and create a common blueprint.
- Information exchange: AI for health provides end-toend service, which give higher requirements on product development. Effective ways for information exchange can help gather more news from different roles in the production chain. Competition provides early incentives to prototype in the early stages; industry alliance is another flexible way to extensively gather industrial forces and seek cooperation opportunities in mature stages.
- Financing: To improve the health level of mankind is a huge project that needs strong support including

financing. It includes major R&D project budget support, profit distribution and national health insurance management, etc. Especially with the progress of aging, how to effectively reduce the cost of medical insurance has become a common problem that needs to be solved in various countries.

5.2 Standardization

Under the overview control of the collaboration mechanism, standardization could technically act as an accelerator for integration innovation. Consideration on standardization could be prepared as the following part.

- Data format and interface: Much previous efforts have been made to meet the demand of medical system interconnection and compatibility. Personal health device standards (ISO / IEEE 11073) and Digital Imaging and Communications in Medicine (DICOM) are known as addressing the interoperability. Though AI for health focuses more on the application layer, updates on data formats and interfaces should also be considered to meet the development requirement.
- \triangleright Data quality: It refers to the standardization of content requirement input to AI algorithms, and it is a new demand due to new technology of AI. Medical images used by AI may contain undesirable artefacts (e.g. background noise), lack focus, exhibit uneven illumination or under/overexposure, etc. [35]. Moreover, the quality of the annotation for AI training is also critical. To form a unified understanding and workflow on annotation among different groups of clinicians is a difficult but necessary task. Several public datasets are released for research, including Kaggle, ImageNet, Messidor database [36-40], but for long-term development and scaled application, standardization on data content and annotation are very necessary requirements for sustainable development.

5.3 Regulation

With collaboration mechanism acting as a macro-control, standardization as a technical accelerator, regulation is to define the bottom line of the industry and maintain its legality. The International Medical Device Regulators Forum (IMDRF) was established to discuss the common problems in international medical device regulation, with representatives from regulatory authorities in Australia, Brazil, Canada, China, European Union, Japan and the United States, as well as WHO [41]. From their working group setting, main concerns on regulation can be divided into reliability, security and ethics parts.

Reliability: The performance of AI algorithms can be evaluated in the metrics of accuracy, precision, ROC, F-measures, interpretability, robustness, generalization, etc. In the face of such an emerging technology, how to evaluate AI/ML-based software as a medical device (SaMD) is a problem that all national regulatory agencies need to answer. Recently, the International Telecommunication Union (ITU) established an ITU/WHO Focus Group on artificial intelligence for health (FG-AI4H), which works in partnership with WHO to especially establish a standardized assessment framework for the evaluation of AI-based methods for health, diagnosis, triage or treatment decisions [42]

- Security: It includes the concerns of data security, network security and product security. Data security refers to data ownership, data handling policy and privacy protection during usage. Network security refers to cybersecurity, avoiding products being attacked by illegal cyberattacks. Product security refers to the safe use of the product. Currently with the rapid development of AI for health application, most of the applications investigated could not provide relevant evidence or peer-reviewed research to support their products. According to a study published in Nature Digital Medicine, only two of the 73 applications in their survey provided evidence of research [43].
- Ethics: Ethics are important to consider especially for the health field. Major countries and international organizations have established AI ethics institutions focusing on the discussion of ethical guidelines and standards. In June 2019 the US Food and Drug Administration released a discussion paper of proposed 'Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)' and also requested feedback including on ethical aspects [44].

6. CONCLUSION

In this work, we choose the perspective of interaction of ICT on the health industry. An industrial framework of the digital health industry was proposed to better understand the interaction between component factors from the health and ICT sides. We extracted and reconstructed different component factors to expand the framework from the traditional health industry to digital health. The traditional health industrial framework is divided into service and management parts, and ICT factors are listed as sensors, networks, data resources, platforms, applications and solutions. This paper also tracks the interaction through the development history of the digital health industry, from informationization institutional to regional informationization, and finally to service intelligentization. Following such a developmental roadmap, AI was chosen as one of the most powerful technologies to discuss the key trends from data, computing power and algorithms. Service and management processes in the health industry were observed on the effects of ICT penetration. In the end, exogenous factors such as a collaboration mechanism, standardization and regulation were proposed and discussed to better prepare for supporting the sustainable development of digital health in the AI era.

7. ACKNOWLEDGEMENT

I would like to thank Mr Yuntao WANG, Ms Weimin ZHANG from CAICT for the data and cases from first-hand industrial research, and Mr Tao WANG for reading a first version of this editorial. In addition, many thanks to Dr Gauden GALEA and Ms Mengji CHEN from WHO for providing many valuable suggestions during the writing process.

REFERENCES

- [1] World Health Organization Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19–22 June 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. In Grad, Frank P. (2002). "The Preamble of the Constitution of the World Health Organization". Bulletin of the World Health Organization. 80 (12): 982.
- [2] World Health Organization. (2006). Constitution of the World Health Organization – Basic Documents, Forty-fifth edition, Supplement, October 2006.
- [3] United Nations: World Population Prospects 2019: Highlights: <u>https://population.un.org/wpp/Publications/Files/WP</u> <u>P2019 Highlights.pdf</u>
- [4] World Bank East Asia and Pacific Regional Report: https://openknowledge.worldbank.org/bitstream/han dle/10986/23133/32945.pdf?sequence=4&isAllowed =y
- [5] World Health Organization, World Health Statistics 2018: <u>https://apps.who.int/iris/bitstream/handle/10665/272</u> 596/9789241565585-eng.pdf?ua=1
- [6] Annual Report on Healthy City Construction in China (2018), ISBN: 978-7-5201-3936-6
- [7] 2018-2024 Artificial Intelligence + Medical Imaging Industry Market Research and Investment Prospect: https://www.chyxx.com/research/201710/578114.ht ml
- [8] Bhavnani, Sanjeev P.; Narula, Jagat; Sengupta, Partho P. (7 May 2016). "Mobile technology and the digitization of healthcare". European Heart Journal. 37 (18): 1428–38. doi:10.1093/eurheartj/ehv770. PMC 4914890. PMID 26873093.
- [9] Svetlana Sicular, Kenneth Brant, Hype Cycle for Artificial Intelligence, 2018[J], Gartner.

- [10] Quaglini, S., Stefanelli, M., Lanzola, G., Caporusso, V., Panzarasa, S.: Flexible guideline-based patient careflow systems. Artificial Intelligence in Medicine 22(1), 65–80 (2001)
- [11] Reijers H.A., Russell N., van der Geer S., Krekels G.A.M. (2010) Workflow for Healthcare: A Methodology for Realizing Flexible Medical Treatment Processes. In: Rinderle-Ma S., Sadiq S., Leymann F. (eds) Business Process Management Workshops. BPM 2009. Lecture Notes in Business Information Processing, vol 43. Springer, Berlin, Heidelberg
- [12] Pyropoulos C D. AI planning and scheduling in the medical hospital environment[J]. Artificial Intelligence in Medicine, 2000, 20(2):101-111.
- K Lynas. Canada Health Infoway properly managing federal taxpayer dollars: Auditor General[J]. Canadian Pharmacists Journal, 2010, 143(1):9.
- [14] Morris, A.H. (2000). Developing and implementing computerized protocols for standardization of clinical decisions. Annals of Internal Medicine, 132, 373–83.
- Qian W, Jie W, Yao D etal. Ontology-Based design and information sharing for medical information[C]. In: IEEE Int Conf on Software Engineering and Service Sciences. Piscataway, NJ, USA: IEEE, 2010, 663-666.
- [16] Kilic O, Dogac A, Eichelberg M. Providing interoperability of eHealth communities through Peer-to-Peer networks[J]. IEEE Transactions on Information Technology in Biomedicine, 2010, 14(3): 846-853.
- [17] Edwards, Michael. Lippeveld, Theo. Decision support systems for improving the analytic capacity of decentralized routine health information systems in developing countries. Proceedings of the Hawaii Internadonal Conference on Sciences[J]. v 37, 2004, P 2375-2383.
- [18] Gajanayake R, Iannella R, Sahama T. Sharing with care: an information accountability perspective[J]. IEEE Internet Computing, 2011, 15(4): 31-38.
- [19] Tiina,Suominen,Tarjal, Asikainen, Paula. The outcomes of regional healthcam information systems in health care-A review of the research literature International Journal of Medical Informafics[J]. V 78, nil, 2009(9), P 757-771.
- [20] Stolyar, Anna. Lober, William B. Drozd, Daniel R. A patient-centered health record in a demonstration regional health information network Conference Proceedings* 1st Transdisciplinary Conference on

Distributed Diagnosis and Home Healthcare [J]. D2H2 2006, 2006, P 160-163.

- [21] Haux,. Health information systems-Past, present, future. International Journal of Medical Informatics[J]. V 75,n 3-4 SPEC. ISS. March / April 2006,P 268-281.
- [22] Winter Alfred. Brig Birgitl. Funkat Gert. 3LGM2-Modeling to support management of health information systems. International Journal of Medical Informatics [J]. V 76, n2*3, February / March 2007, P145-150.
- [23] Centers for Medicare & Medicaid Services (CMS), and Office of the National Coordinator for Health Information Technology (ONC), HHS. Medicare and Medicaid programs; modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and other changes to EHR Incentive Program; and health information technology: revision to the certified EHR technology definition and EHR certification changes related to standards. Final rule[J]. Federal Register, 2014, 79(171):52909-33.
- [24] Doyle-Lindrud, Susan, DNP, AOCNP, DCC. Watson Will See You Now: A Supercomputer to Help Clinicians Make Informed Treatment Decisions. Clinical Journal of Oncology Nursing; Pittsburgh Vol. 19, Iss. 1, (Feb 2015): 31-32.
- [25] Julia Powles, Hal Hodson. Google DeepMind and healthcare in an age of algorithms, Health and Technology, 2017, Volume 7, Number 4, Page 351
- [26] Deep Learning Chipsets, CPUs, GPUs, FPGAs, ASICs, SoC Accelerators, and Other Chipsets for Training and Inference Applications: Global Market Analysis and Forecasts: <u>https://www.tractica.com/research/deep-learningchipsets/</u>
- [27] Mookiah MRK, Acharya UR, Chua CK, Lim CM, Ng EYK, Laude A. Computer-aided diagnosis of diabetic retinopathy: a review. Comput Biol Med. 2013;43(12):2136-2155.
- [28] Elmore JG, Longton GM, Carney PA, et al. Diagnostic Concordance Among Pathologists Interpreting Breast Biopsy Specimens. JAMA. 2015;313(11):1122–1132. doi:10.1001/jama.2015.1405
- [29] Gulshan V, Peng L, Coram M, et al. Development and Validation of a Deep Learning Algorithm for Detection of Diabetic Retinopathy in Retinal Fundus Photographs. JAMA. 2016;316(22):2402–2410. doi:10.1001/jama.2016.17216

- [30] InferScholar Center. https://www.infervision.com/en/solution
- [31] Ali ET Medical Brain. https://www.alibabacloud.com/et/medical
- [32] Joseph A. DiMasi, Henry G. Grabowski, Ronald W. Hansen (2016). "Innovation in the pharmaceutical industry: New estimates of R&D costs". Journal of Health Economics.
- [33] California Biomedical Research Association. "New Drug Development Process" <u>https://cabiomed.org/wp-content/uploads/2018/02/FS-DrugDevelop.pdf</u>
- [34] Mercom Capital Group report, https://www.fiercehealthcare.com/tech/venturefunding-for-digital-health-reached-9-5b-2018
- [35] A. Galdran, T. Araújo, A. Mendonça, A. Campilho. Retinal Image Quality Assessment by Mean-Subtracted Contrast-Normalized Coefficients, in: European Congress on Computational Methods in Applied Sciences and Engineering Springer 2017 pp. 844–853.
- [36] Kaggle diabetic retinopathy competition forum. https://www.kaggle.com/c/diabeticretinopathy-detection/forums/t/15605/humanperformance-on-the-competition-data-set . Accessed June 30, 2016.
- [37] Kaggle Diabetic Retinopathy Detection competition. https://www.kaggle.com/c/diabeticretinopathy-detection . Accessed June 30, 2016.
- [38] Krizhevsky A, Sutskever I, Hinton GE. ImageNet classification with deep convolutional neural networks. Adv Neural Inf Processing Syst. 2012:1097-1105.
- [39] Russakovsky O, Deng J, Su H, et al. ImageNet large scale visual recognition challenge. Int J Comput Vis. 2015;115(3):211-252.
- [40] Decencière E, Etienne D, Xiwei Z, et al. Feedback on a publicly distributed image database: the Messidor database. Image Anal Stereol. 2014;33(3):231-234. doi:10.5566/ias.1155
- [41] The International Medical Device Regulators Forum (IMDRF): <u>http://www.imdrf.org</u>
- [42] Wiegand Thomas, Krishnamurthy Ramesh, Kuglitsch Monique, et al. (2019). WHO and ITU establish benchmarking process for artificial intelligence in health. The Lancet. 394. 10.1016/S0140-6736(19)30762-7.

- [43] Digital mental health tools won't see clinical adoption without validation, industry players say. <u>https://www.mobihealthnews.com/content/digitalmental-health-tools-wont-see-clinical-adoptionwithout-validation-industry-players</u>
- [44] US Food and Drug Administration, proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML) -Based software as Medical Device (SaMD): https://www.fda.gov/media/122535/download

OPERATIONALIZING DATA JUSTICE IN HEALTH INFORMATICS

Mamello Thinyane

United Nations University Institute on Computing and Society, Macau SAR, China

ABSTRACT

There is a growing awareness of the need and increasing demands for technology to embed, be sensitive to, be informed by, and to be a conduit of societal values and ethical principles. Besides the normative frameworks, such as the Human Rights principles, being used to inform technology developments, numerous stakeholders are also developing ethical guidelines and principles to inform their technology solutions across various domains, particularly around the use of frontier technologies such as artificial intelligence, machine learning, Internet of things, robotics and big data. Digital health is one of the domains where the convergence of technology and health stands to have a significant impact on advancing sustainable development imperatives, specifically around health and wellbeing (i.e. SDG3). As far as digital health is concerned, what values and ethical principles should inform solutions in this domain, and more significantly, how should these be translated and embedded into specific technology solutions? This paper explores the notion of data justice in the context of health informatics and outlines the key considerations for data collection, processing, use, sharing and exchange towards health outcomes and impact. Further, the paper explores the operationalization of Mortier et al.'s Human-Data Interaction principles of legibility, agency and negotiability through a health informatics system architecture.

Keywords – data justice, human-data interaction, personal health informatics

1. INTRODUCTION

The fourth industrial revolution (4IR) is set to transform society in many fundamentally deep and broad ways. Unlike the previous industrial revolutions, the impact of the 4IR stands to be unprecedented due to the velocity, scope and system impacts of the technological developments [1]. Some of the ensuing and anticipated technological developments are set to have fundamental and existential impacts on our lives, for example, the societal evolution towards the infosphere [2], human augmentation through biotechnology, and the pervasiveness of robotics, autonomous computing and artificial intelligence (AI). The potential of the 4IR, like other technological developments before, to contribute to advancing sustainable development imperatives is broadly recognized, e.g. supporting innovation, improving efficiencies and enhancing livelihoods. However, the challenges and risks presented by these technological developments are also increasingly being recognized and understood: growing inequality, new forms of marginalization and exclusion, digital waste, disruptions and decimation of norms.

This potential of the 4IR to have adverse developmental impacts is giving motivation and impetus to global efforts towards ensuring that the outcomes of the use of technology in society are consistent with our values, goals and desired futures. These efforts are advancing at many levels (e.g. organization, national, global) and from various fronts (e.g. legal, technological, educational, standards). For example, legal stipulations such as the General Data Protection Regulation (GDPR), the Health Insurance Portability and Accountability Act (HIPAA), and the Protection of Personal Information Act (POPIA) are in place to protect and guide the use of data. Ethics frameworks such as Ethical OS, Data Ethics Framework, and Asilomar AI principles, are being formulated to inform technology solutions and use. At the standards level, examples include the ISO/IEC 29100:2011 "Information technology, security techniques, privacy framework" standard on privacy protection of personally identifiable information (PII), as well as the work from the International Telecommunication Union (ITU) Focus Group on Data Processing and Management (FG-DPM) within Working Group 3 on "Data sharing, interoperability and blockchain" as well as Working Group 4 on "Security, privacy and trust including Governance". At the global level, normative frameworks such as the Human Rights principles, provide high-level guidelines that could be operationalized in the development of technology solutions across various domains. One such domain that is being transformed by the recent information and communication technology developments is health. Digital health is not only improving health service delivery, it is also introducing new technologies and solutions towards universal health coverage and global health and wellbeing goals [3].

This research explores the use of data within the digital health domain, highlighting the pathways from data to health outcomes and impacts, the key challenges and risks associated with the use of personal health data, as well as an overview of data justice principles and their application in digital health. The discussions in this paper are supported and augmented with the findings from a survey that was undertaken in pursuit of two lines of inquiry, firstly, to understand individuals' use of personal health informatics, in particular, their motivations for data collection and monitoring, as well as their current practice around health monitoring; secondly, to understand the attitudes and values around data sharing and social sense-making. The survey consisted of 14 questions on demographics, personal health informatics practice, sustainable development goals, data sharing, and an open-ended question on the current practice (i.e. framed as "What information and data do you use in your everyday life that you find relevant for your wellbeing?"). The 981 respondents in the survey, the majority of whom are from North America, were recruited via virtual snowballing, social media channels and a research panel via an online survey platform.

The paper is structured as follows: the next section provides a broad overview of digital health, paying attention to health informatics and the value proposition of data for health. This is followed by an introduction of the notion of data justice and its relevance to the digital health domain in general, but also to health informatics specifically. Various formulations of data justice are discussed, after which is distilled a list of requirements to inform technology designs. This is followed by a proposal of a health informatics architecture that is informed by the data justice principles. Lastly, the merits of this architecture are discussed, juxtaposed to other related technologies.

2. DIGITAL HEALTH AND HEALTH INFORMATICS

Digital health, the confluence of information and communication technologies (ICTs) and health, has opened up numerous opportunities to both enhance the delivery of existing health interventions and introduce new technologydriven health interventions [3]. Digital health includes telehealth, tele-consultants, tele-coaching, social networking, and online communities, online access to records, as well as independent self-monitoring apps. In recognizing the potential of technology and innovation to enhance health services, the seventy-first World Health Assembly underscored the need to "ensure that digital health solutions complement and enhance existing health service delivery models, strengthen integrated, people-centered health services and contribute to improved health, and health equity, including gender equality, and addressing the lack of evidence on the impact of digital health" [3].

One of the core elements within digital health is health informatics, comprising the technologies for the management of electronic health records, medical data, health indicators and personal health data. Traditionally, the bulk of health data collection and processing was undertaken by health service providers, with individuals as the primary sources of health data, as well as the primary beneficiaries of the health outcomes associated with the use of the data. This data, which represents one of the key resources for the business operation of health providers, typically exists in the form of electronic health records. However, with the growing ubiquity of health technology tools, individuals are increasingly also participating in the collection and management of their health data. In the context of personal health informatics, individuals are collecting data for selfmanagement of their health, including to inform behavior change and track progress on specific health goals.

2.1 Personal health informatics

Li et al. [4] formally define personal health informatics simply as a class of applications "that help people collect and reflect on personal information." The field has gained increasing popularity due to several developments, including the rise of quantified-self movement [5], the availability of affordable self-tracking technology, and the proliferating phenomenon of datafication of individuals and societies [6]. The promise of the self-tracking devices to offer individuals a non-subjective and unambiguous assessment of their physical wellbeing and the state of their bodies has been part of society for over a century; the weigh scales have played a predominant role in this regard [7]. Beyond the development of new technologies used for personal health informatics, the 21st century self-tracking landscape has also introduced new considerations, including the commoditization of personal data, new value dimensions associated with aggregate data, and the wide sharing of data beyond the individuals who the data is about [7], [8]. Therefore, while personal informatics fundamentally regards the use of own data by individuals for their benefits, the contemporary reality is that personal data and its use exists within a broad, multifaceted ecosystem.



Figure 1 - Motivation and uses of personal informatics

The use of data towards the achievement of health outcomes has traditionally been premised on the argument that more and better data leads to better health choices and decisions, and that the increasing availability of health information on the Internet would lead to the emergence of 'informed patients' [9] and 'digitally engaged patients' [10]. The transtheoretical model (TTM) of behavior change [11], which has been the predominant model for the psychology of intentional behavior change, has also informed the formulation of personal health informatics models such as the stage-based model of personal informatics [4] and the lived informatics model of personal informatics [12]. In our research, we have identified, through the thematic coding of the open-ended survey question, the predominant pathways to impact as well as the motivations and current practice of the participants with regards to personal informatics. Figure 1 highlights the main "motivation and use" themes with their corresponding coding reference frequencies.

Table 1 - Motivations and styles of personal informatics

Motivation & use / Tracking style	Directive	Documentary	Diagnostic	Rewards	Fetishised
Awareness and monitoring		Х			
Benefit for others					
Compare and reflect			Х		
Curiosity and information					
Dealing with an ailment	Х		Х		
Informing action	Х				
Maintaining health and		Х			
wellbeing					
Reach new goals and improve	Х				

The motivations and uses of personal health informatics identified in our research correspond to three of five of Rooksby *et al.* [13] style styles of personal information tracking. These observations support the position that as individuals engage in the collection and use of personal health data, through various impact pathways and a combination of personal conversion factors [14], they are empowered to pursue and achieved desired health outcomes. This empowerment narrative of personal health informatics has informed many digital health programs and projects around the world. It has, however, been criticized and shown to present an overly simplified techno-utopian perspective that fails to consider the nuanced complexities of personal health informatics.

Firstly, while the importance of the informational and technology resources cannot be denied, the empowerment narrative fails to recognize the varying agency as well as the endowments of conversion factors, such as underlying data and digital illiteracies, as well as general illiteracy, for different individuals and population groups [14]. In an empirical research investigating "informational practices" of 32 mid-life women on the use of hormone replace therapy (HRT) for relief of menopausal symptoms, Henwood *et al.* [9] found that there was a strong reluctance on the part of the participants to take on the implied responsibilities of data management; they observed problems with the information literacy of the participants; and there were also challenges associated with information-sharing in medical encounters with health professionals.

Secondly, the proliferation of personal health informatics technologies that track and monitor our everyday functioning has the potential to unleash Orwellian techno-dystopia of panoptic surveillance assemblages that extend paternalistic social control by the strong and the powerful [15], [16].

Beyond the risks of social control, this has the potential to open up individuals to the risks of exploitation through surveillance capitalism and commoditization of personal data, as has been demonstrated, for example, in the cases of 23andMe, Facebook, and Cambridge Analytica [17]–[19].

Thirdly, the empowerment narrative echoes the technological determinism sentiments, which are not universally valid and consistent. In our survey results, on the investigation of the participants' use of personal health informatics towards health outcomes and the attitudes towards data sharing, we coded 18 references that expressed both a strong resistance and refusal to use and / or to share personal health data. For example: "I don't use information or data. I take mv medicines and vitamins, and see mv doctor often" (GIS 806); "How I feel, do not use data" (GIS 504), "Mindfulness of my moods and stress level; awareness that I am the major actor in my life, but that I can't control anything outside myself' (GIS 379), where the participants emphasized the reliance on self-awareness as opposed to on technology devices and data; "Actually none because everything changes and everyone has their viewpoint to make you believe what they are telling is true" (GIS 596), expressing the lack of trust in the system stakeholders.

Health informatics tools and technologies are employed to empower patients to achieve better health and to improve health service delivery by health service providers. The impact pathways from these digital resources to specific health outcomes are non-trivial and need to be critically understood, taking into consideration the situations of the different actants, the contextual factors, as well as the overall digital health ecosystem.

2.2 Health data ecosystem

Individuals are the primary unit of attention within the health domain, as far as being the main beneficiaries of the targeted health outcomes. They, however, exist as one of the actants within a complex ecosystem consisting of a variety of stakeholders, including health service providers, health industry stakeholders, public sector entities, households, and communities, as well as other civil society stakeholders. The use of data towards the achievement of health outcomes, therefore, permeates this complex ecosystem and needs to be considered when taking into consideration the interactions with and the data exchanges between the different stakeholders.

Firstly, in the context of the sustainable development data ecosystem or that of future data-driven societies, sharing of personal data needs to be considered not only with individuals' personal social circles but also with other stakeholders within the wider data ecosystem. For example, the role of citizen-generate data to support the monitoring of progress towards the sustainable development goals, through direct contributions to the indicators or via proxy indicators, has been recognized and well highlighted in the literature. Secondly, while deriving relevant insights from health informatics primarily ensues through the individual's engagement with their data, research has found that individuals also engage in sharing of their data with others for sense-making purposes [20]–[22]. Thus, the collection and use of data by individuals also comprise the social dimension.

Thirdly, personal health data also gets shared to support external pursuits such as biomedical research, where data on health profiles, cohort data, as well as physical activity data can support projects such as the Global Alliance for Genomics and Health [23]. The sharing of data in this context can be motivated from the perspective of the Universal Declaration of Human Rights, which recognizes the "right of everyone to share in scientific advancement and its benefits" [23]. Thus sharing of data can be towards these goals, which are associated with citizen science, as well as increased participation and engagement in advancing scientific research [24].

In all these cases of external sharing of personal health data, there is, however, the persistent risk of "Googlization of health research," which is associated with the increasing data-driven encroachment and involvement of the major technology companies within the health and biomedical sectors [17]. The potential benefits of the application of these technological developments on issues of health and wellbeing are immense; they include major improvements in disease diagnosis, improving access to services through telehealth solutions and advancing the developmental aspirations of achieving universal health coverage. The challenges, however, are equally immense and are associated not only with adverse health outcomes but also with negative sociocultural and economic consequences. These challenges are related to issues of bias, privacy [25], informed consent, context transgressions [26], health data commoditization, new power asymmetries and discriminations [27], data valorization and benefit-sharing, and the importation of digital capitalism practices into the health realm [17].

3. DATA JUSTICE IN HEALTH INFORMATICS

Numerous definitions of "data justice" have been advanced in the literature, which fundamentally recognize the social justice dynamics and impacts of the use of data in society. Taylor [27] defines data justice as the "fairness in the way people are made visible, represented and treated as a result of the production of digital data." In her formulation of data justice she decomposes the concept to three notions of (in)visibility - associated with access to representation, and informational privacy; (dis)engagement with technology, which is linked to sharing in data benefits as well as autonomy in data choices; and to antidiscrimination, which is linked with the ability to challenge bias and preventing discrimination. Heeks and Renken [28] define data justice simply as "the primary ethical standard by which datarelated resources, processes and structures are evaluated." They, however, expand this to formulate three notions of instrumental, procedural and distributive rights-based data justice. As noted by Taylor [27], the ends of various data justice formulations is to achieve both specific outcomes and also specific configurations of the associated data assemblages towards the achievement of those outcomes: in the case of Johnson's [29] framework, the end goal is embedding anti-discrimination principles and features in the design of database systems; for Heeks and Renken [28], the focus is on data distribution in a way that achieves fair access, participation and representation; and lastly Dencik *et al.* [30] are interested in the means of limiting data collection and distribution in contexts of surveillance capitalism.

In the work of Mortier et al. [31], in which they formalize the notion of human-data interaction (HDI), they explicate the interaction between humans and data systems in a way that places "the human at the center of the flows of data, and providing mechanisms for citizens to interact with these systems and data explicitly". While the formulation of HDI is not explicitly from a social justice nor ethics perspective, it gives recognition to the fact that the underlying issues in HDI sit at the intersection of "the various disciplines including computer science, statistics, sociology, psychology, and behavioral economics" [31]. Further, it gives recognition to the fact that human-data interaction happens in the context of complex data ecosystems, which are constitutive of the global data-driven society. In this complex interaction of different stakeholders with different capabilities, interests and agendas, there is an ongoing contestation for the voices of humans and human-centric perspectives not to be marginalized and excluded. Some of the powerful and key actants within the health informatics ecosystem include health-service providers, the health industry, as well as the non-human technology-related actants, as has been highlighted by Sharon [17] regarding the influence of the technology companies in the health data research. Further highlighting the complexity, Morley and Floridi [16] offer a poignant critique of the techno-utopian formulation of mHealth technologies as empowering devices and warn against the risk of medical paternalism. Privileging the position of the humans within the health informatics ecosystem, as has been done in the HDI framework, allows for the critical investigation of issues towards an explicit goal of enhancing the substantive freedoms of individuals to achieve their desired health outcomes and enhancing their health capabilities [32].

In this paper, the HDI framework has been adopted to frame the discussion of the outworking of data justice in health informatics systems. The paper expands on the imperatives of *legibility*, *agency* and *negotiability* to identify specific considerations and non-functional requirements to inform the design of health informatics systems.

3.1 Legibility

Legibility is summarily defined as "being able to be understood by people they concern, as a precursor to exercising their agency" [31]. This is defined with regards to the data, as far as individuals understanding what data has been collected, how it is being used, by whom, and when it

is being used; but legibility is also defined with regards to the algorithms that process the data, towards ensuring that algorithms are understood and that the various forms of algorithm opacity are reasonably mitigated [33]. While at a simple level the "concerned" people could be understood to refer to the people who the data is about, in reality, the people who are impacted by collected health data, which Loi [34] terms as digital phenotypes, and the nature of the impact are very diverse. In the case of health informatics, there are the identified individuals who the data is about; there are individuals who collect the data and who are involved in the creation and shaping of the digital phenotypes, and there are also people who are impacted by generalizations that emanate from health informatics [34]. In this paper, the notion of "ownership" of data is used in the first sense, which regards health informatics as the self-extension of and as being constitutive of the individual who the data is about.

From the analysis of Mortier *et al.*'s [31] description and discussion of "legibility," supported by the investigations undertaken in this research, the following health informatics systems requirements and considerations are formulated:

- 1. Accounting and auditing: to keep track of and enable an inspectable audit of the use of personal health data. Further, to allow for the auditing of the associated algorithms.
- 2. Feedback and notifications: to inform the owners of the collection and use of their data.
- 3. Relevant insights: to provide actionable insights that facilitate the subsequent use of the data.

3.2 Agency

Agency is defined in terms of enhancing "the capacity for the humans to act in these data systems" [31]. Enhancing individuals' agency does not presuppose their intention to participate and to be engaged in the active management of their data, as observed in Henwood *et al.*'s [9] research, where participants showed reluctance to take on the responsibility of managing their data. It rather has implications on the technology affordances that enhance the ability of individuals to act on and with their data meaningfully. The requirements that emanate from the undertaken analysis include:

- 1. Permissions and access control: the ability of individuals to permit and restrict certain types of use of their data by different stakeholders.
- 2. Consent and withdrawal: to enable individuals to consent to data collection and also to withdraw and exercise the right to be forgotten.
- 3. Revocation of data: beyond the ability to withdraw from data collection, individuals should have the ability to have previously recorded data revoked and deleted.

3.3 Negotiability

Negotiability is defined in terms of "active and engaged interaction with data as contexts change." This makes recognition of the fact that not only do situations and contexts change, but also do individuals' desires, attitudes and preferences. The use of personal health data is tightly coupled to and contingent on the context; individuals need to retain the legibility and agency in different contexts. This further decomposes into the following considerations:

- 1. (Perpetual) Control: the continued ownership and control of personal health data and digital phenotypes, the digital traces that have value towards specific health outcomes, in perpetuity [34].
- 2. Data provenance: with the changing contexts and the evolution of data, it is vital to maintain the genealogy of personal health data.



Data sharing clustering

Figure 2 – Data-sharing stakeholder clusters

- 3. Contextual integrity: in the research undertaken in this project, an investigation into the willingness of participants to share their personal health data with specific stakeholders within the data ecosystem (i.e. question framed as "To what extent would you be happy to share your personal health information with the following individuals / organizations?") illustrates the significance of contextual integrity as far as personal health data is concerned [26]. A correlation (i.e. Spearman correlation) and clustering (i.e. agglomerative hierarchical clustering with complete linkages method using Euclidian distance between the scores) analysis of the responses highlights three distinct contexts within which the participants would share their data: with their doctors, with their families and friends, with external organizations and stakeholders (see Figure 2). Each of these contexts represents specific requirements and preferences regarding data use.
- 4. Anonymization, delinking, and data commons: the ability to anonymize and delink data, and to facilitate the ability of individuals to share their data broadly within the data ecosystem, e.g. to support scientific research by contributing to data commons.

4. PRELIMINARY ARCHITECTURE PROPOSAL

The architecture proposed in this paper is framed for a very specific digital health scenario, specific requirements and specific context. The scenario is that of sharing personal health information data (e.g. health indicators collected on personal monitoring devices, historical health records and digital phenotypes [34]) with a health service provider, and ensuring legibility, agency and negotiability in the interaction between the individual and their data. A subset of the requirements detailed in the previous section can be met and implemented with standard techniques and solutions. For example, some of the requirements around data privacy can be handled using information security techniques, such as public cryptography systems [35], as has been the practice for say HIPAA compliance and, more recently, GDPR compliance. However, there are specific requirements associated with the HDI imperatives, specifically negotiability, that give motivation for the architecture proposed in this paper. In particular, the architecture addresses the requirement for enhancing the control that owners of data retain over their data once the data is shared, and ensuring that the dynamic contextual constraints are enforced on the subsequent use of the data.

The proposed architecture, Personal Health Information eXchange (PHIX), is based on the multi-agent systems (MAS) paradigm. As a candidate implementation of this architecture, the JADE multi-agent system platform is considered [36]. JADE is a framework to develop agent applications in compliance with the Foundation for Intelligent Physical Agents (FIPA) specification for interoperable multi-agent systems. FIPA aims at providing a reference model for the implementation of highly interoperable complex agent systems. The specification defines a minimum set of key agents that are necessary for the operation of MAS platforms; these include the Agent Management System (AMS) - which provides for the management and control of other agents on the platform; the Agent Communication Channel (ACC) – which provides the communication mechanism between agents on the platform; as well the Directory Facilitator (DF) which provides a yellow page services for the agent platform. Besides providing the basic features that are specified in the FIPA specification, JADE provides a JAVA-based distributed agent platform, with transport mechanisms for inter-agent communication, automatic registration of agents with the AMS, a GUI for the management of the agent platform, a library of FIPA interaction protocols, as well functionality for monitoring the interactions between the agents [36].

PHIX consists of the core MAS platform, distributed agent containers hosted by the health service providers, and the *DataAgent*, which encapsulates personal health data, as well as the functionality associated with the use of the data. The key element of this architecture is the *DataAgent* which functions as a mobile virtual data double that allows for individuals' health data to be secure packaged, using relevant knowledge representation standards and ontologies (e.g. triple-based RDF or RDFS); allows for the data along with the functionality (e.g. access control, auditing, context integrity checks) to use the data to be shared with the health service providers; this is achieved through the cloning and migration of the *DataAgent* from the PHIX main container to the service provider containers, and provides inter-agent communication and synchronization between the associated *DataAgents*. The data owner has control of his community of *DataAgents* with the ability to gain visibility of where his data has been shared, to understand the specific utilization of their data and to control the use of specific *DataAgents*, for example, updating permissions and access control, revoking and killing shared agents.



Figure 3 - Health informatics architecture proposal

Within this architecture, as per the defined scenario, service discovery is primarily handled via the use of the DF through which the health service providers publish their details. Individuals who need to share their data (i.e. via cloning and migration) would similarly employ the DF to query the data for the relevant health providers. The key feature of this architecture is to bundle personal health data along with the functionality to manage its use in various contexts into the *DataAgent*, which is under the control of the data owner. By exploiting the agent mobility and migration feature of MAS, sharing of data is not associated with relinquishing control over the data, the *DataAgent* enforces the contextual constraints, as well as the dynamic access controls decided by the data owner.

5. DISCUSSION

While the PHIX architecture fundamentally explores and illustrates the operationalization of ethical principles and values, such as the HDI imperatives, in technology solutions, it also proposes a technical solution for the specific challenge associated with enhancing access control to and contextual integrity of personal health data. Some of the solutions that have been proposed for this challenge include MeD-lights, a system that uses the traffic light metaphor (i.e. red, yellow, green) to indicate and label the sensitivity levels of personal health data [37]. The MeD-lights system provides a mechanism for an intuitive specification of the privacy and confidentiality requirements associated with personal health data. In this solution, the challenge of forfeiting control, at a technology level, once data is shared, is not addressed.

Mortier et al. [31] have proposed the concept of a databox, initially conceived as a distributed system for the federation of personal health data, providing APIs to access data held in the personal databoxes, and fundamentally moving the code and processing to data, such that only results of the requested computation are communicated to third parties, without releasing personal data. The design of the databox is informed by the requirements for it to be a trusted platform, to provide for data management, enabled controlled access, and to enable incentives for all parties. While the databox in this solution has some similarities to the functionality of the DataAgent, the primary difference is that the databox provides a federated repository to various data sources and accepts code requests for execution on the personal data. The DataAgent provides data sharing through agent mobility, which is coupled with the functionality to manage the use of the data within the specific context.

The PHIX architecture is consistent with both the digital phenotype perspective [34], as well as the notion of a digital/virtual 'data double' that is endowed with both data and functionality. Invariably, the proposed architecture is framed to deal with a very specific narrowly defined scenario (i.e. sharing of personal health informatics data with a health service provider) that neglects some of the challenges experienced in personal health informatics, such as Ndimensional attribute of data associated with the social and communal ownership of data.

6. CONCLUSION

The use of technology and data in and by society needs to be on terms that are consistent with the values and the ethical standards of a society. As far as digital health and health informatics are concerned, the data justice principles encapsulated in frameworks such as the HDI, stand to provide guidelines that can inform the development and implementation of digital health technology solutions. Operationalizing such ethical principles and value frameworks is non-trivial and requires that the principles are translated and decomposed into specific constitutive system requirements. This paper has explored and presented an investigation of data justice in health informatics and has suggested the operationalization of the HDI negotiability requirements of (perpetual) control and contextual integrity through a MAS-based PHIX architecture that encapsulates individuals' data in a dynamic, mobile, virtual 'data double' DataAgent component.

REFERENCES

- [1] K. Schwab, "The Fourth Industrial Revolution: what it means, how to respond," *Foreign Affairs*, Dec. 2015.
- [2] L. Floridi, *The 4th revolution : how the infosphere is reshaping human reality*. Oxford University Press, 2014.
- [3] World Health Organization, "Resolution WHA71.7," *Resolut. deliberations eHealth*, no. May, 2018.
- [4] I. Li, A. Dey, and J. Forlizzi, "A stage-based model of personal informatics systems," in *Proceedings of the 28th international conference on Human factors in computing systems - CHI '10*, 2010, p. 557.
- [5] A. Marcengo and A. Rapp, "Visualization of human behavior data: the quantified self," *Innov. approaches data Vis. Vis. Anal.*, vol. 1, pp. 236--265, 2014.
- [6] J.E. Mai, "Big data privacy: The datafication of personal information," *Inf. Soc.*, vol. 32, no. 3, pp. 192–199, May 2016.
- K. Crawford, J. Lingel, and T. Karppi, "Our metrics, ourselves: A hundred years of self-tracking from the weight scale to the wrist wearable device," *Eur. J. Cult. Stud.*, vol. 18, no. 4–5, pp. 479--496, 2015.
- [8] D. Boyd and K. Crawford, "Critical Questions for Big Data," *Information, Commun. Soc.*, vol. 15, no. 5, pp. 662–679, Jun. 2012.
- [9] F. Henwood, S. Wyatt, A. Hart, and J. Smith, "Ignorance is bliss sometimes': Constraints on the emergence of the 'informed patient' in the changing landscapes of health information," *Sociol. Heal. Illn.*, vol. 25, no. 6, pp. 589–607, 2003.
- [10] D. Lupton, "The digitally engaged patient: Selfmonitoring and self-care in the digital health era," *Soc. Theory Heal.*, vol. 11, no. 3, pp. 256–270, Aug. 2013.
- [11] J. O. Prochaska and W. F. Velicer, "The Transtheoretical Model of Health Behavior Change," Am. J. Heal. Promot., vol. 12, no. 1, pp. 38–48, Sep. 1997.
- D. A. Epstein, A. Ping, J. Fogarty, and S. A. Munson, "A lived informatics model of personal informatics," in *Proceedings of the 2015 ACM International Joint Conference on Pervasive and Ubiquitous Computing - UbiComp '15*, 2015, pp. 731–742.

- [13] J. Rooksby *et al.*, "Personal tracking as lived informatics," in *Proceedings of the 32nd annual ACM conference on Human factors in computing systems - CHI '14*, 2014, pp. 1163–1172.
- [14] S. Nambiar, "Capabilities, conversion factors and institutions," *Prog. Dev. Stud.*, vol. 13, no. 3, pp. 221–230, Jul. 2013.
- K. D. Haggerty, Richard V. Ericson, "The surveillant assemblage," *Br. J. Sociol.*, vol. 51, no. 4, pp. 605–622, 2000.
- [16] J. Morley and L. Floridi, "The Limits of Empowerment: How to Reframe the Role of mHealth Tools in the Healthcare Ecosystem," *Sci. Eng. Ethics*, no. 0123456789, 2019.
- T. Sharon, "When digital health meets digital capitalism, how many common goods are at stake?" *Big Data Soc.*, vol. 5, no. 2, p. 205395171881903, 2018.
- [18] S. Sterckx, J. Cockbain, H. Howard, I. Huys, and P. Borry, "Trust is not something you can reclaim easily': patenting in the field of direct-to-consumer genetic testing," *Genet. Med.*, vol. 15, no. 5, pp. 382–387, May 2013.
- [19] S. Zuboff, "Big other: Surveillance Capitalism and the Prospects of an Information Civilization," J. Inf. Technol., vol. 30, no. 1, pp. 75–89, Mar. 2015.
- [20] A. Puussaar, A. Clear, and P. Wright, "Better together: Reciprocal sharing and social sensemaking of data," in *Workshop on "Quantified Data and Social Relationships" - CHI2017*, 2017.
- [21] R. Fleck and D. Harrison, "Shared PI: Sharing personal data to support reflection and behaviour change," in Workshop on" Beyond Personal Informatics: Designing for Experiences of Data"-CHI2015, 2015.
- [22] S. Stals, M. Smyth, and O. Mival, "Sharing and exploring Quantified-Self Data on In-Place experiences and emotions," in ACM CHI 2017 -Quantified Data and Social Relationships, 2017.
- [23] B. M. Knoppers and A. M. Thorogood, "Ethics and Big Data in health," *Curr. Opin. Syst. Biol.*, vol. 4, pp. 53–57, Aug. 2017.
- [24] J. P. Woolley *et al.*, "Citizen science or scientific citizenship? Disentangling the uses of public engagement rhetoric in national research initiatives," *BMC Med. Ethics*, vol. 17, no. 1, p. 33, Dec. 2016.

- [25] B. Jacobs and J. Popma, "Medical research, Big Data and the need for privacy by design," *Big Data Soc.*, vol. 6, no. 1, p. 205395171882435, 2019.
- [26] H. F. Nissenbaum, *Privacy in context : technology,* policy, and the integrity of social life. Stanford Law Books, 2010.
- [27] L. Taylor, "What is data justice? The case for connecting digital rights and freedoms globally," *Big Data Soc.*, vol. 4, no. 2, p. 205395171773633, Dec. 2017.
- [28] R. Heeks and J. Renken, "Data justice for development," *Inf. Dev.*, vol. 34, no. 1, pp. 90–102, Jan. 2018.
- [29] J. Johnson, "The question of information justice," *Commun. ACM*, vol. 59, no. 3, pp. 27–29, 2016.
- [30] L. Dencik, A. Hintz, and J. Cable, "Towards data justice? The ambiguity of anti-surveillance resistance in political activism," *Big Data Soc.*, vol. 3, no. 2, p. 205395171667967, Dec. 2016.
- [31] R. Mortier, H. Haddadi, T. Henderson, D. McAuley, and J. Crowcroft, "Human-Data Interaction: The Human Face of the Data-Driven Society," SSRN Electron. J., Oct. 2014.
- J. P. Ruger, "Toward a Theory of a Right to Health: Capability and Incompletely Theorized Agreements.," *Yale J. law Humanit.*, vol. 18, no. 2, p. 3, 2006.
- [33] J. Burrell, "How the machine 'thinks': Understanding opacity in machine learning algorithms," *Big Data Soc.*, vol. 3, no. 1, p. 205395171562251, Jan. 2016.
- [34] M. Loi, "The Digital Phenotype: a Philosophical and Ethical Exploration," *Philos. Technol.*, vol. 32, no. 1, pp. 155–171, Mar. 2019.
- [35] H. S. Gardiyawasam Pussewalage and V. A. Oleshchuk, "Privacy preserving mechanisms for enforcing security and privacy requirements in Ehealth solutions," *Int. J. Inf. Manage.*, vol. 36, no. 6, pp. 1161–1173, 2016.
- [36] F. Bellifemine, A. Poggi, and G. Rimassa, "JADE A FIPA-compliant Agent Framework," Fourth Int. Conf. Pract. Appl. Intell. Agents Multi-Agent Technol. (PAAM 1999), pp. 97–108, 1999.
- [37] E. K. Adams, M. Intwala, and A. Kapadia,
 "{MeD}-Lights: A Usable Metaphor for Patient Controlled Access to Electronic Health Records," in *Proceedings of the 1st {ACM} International Health Informatics Symposium*, 2010.

SESSION 7

SAFETY AND SECURITY IN HEALTHCARE

- S7.1 Thought-based authenticated key exchange
- S7.2 Cyber-safety in healthcare IoT

THOUGHT-BASED AUTHENTICATED KEY EXCHANGE

Phillip H. Griffin

Griffin Information Security

ABSTRACT

Identity authentication techniques based on passwordauthenticated key exchange (PAKE) protocols rely on weak secrets shared between users and host systems. In PAKE, a symmetric key is derived from the shared secret, used to mutually authenticate communicating parties, and then used to establish a secure channel for subsequent communications. A common source of PAKE weak secrets are password and passphrase strings. Though easily recalled by a user, these inputs typically require keyboard entry, limiting their utility in achieving universal access. This paper describes authentication techniques based on weak secrets derived from knowledge extracted from biometric sensors and brain-actuated control systems. The derived secrets are converted into a format suitable for use by a PAKE protocol. When combined with other authentication factors, PAKE protocols can be extended to provide strong, two-factor identity authentication that is easy to use by persons living in assistive environments.

Keywords – assistive environments, authentication, biometrics, key exchange, security

1. INTRODUCTION

In 2017, the World Health Organization (WHO) reported that more than "one billion people worldwide - about 15% of the world's population" are persons with some form of disability [1]. Earlier United Nations (UN) and WHO reports predicted a tripling of the number of "people aged 65 or older" in 2010 "to 1.5 billion in 2050, 16 % of the entire world population" [2]. As the numbers of elderly and disabled people continue to grow, more of them are striving to retain their autonomy and remain in their homes. As the cost of healthcare continues to rise, governments have struggled to find ways of providing care to these vulnerable populations.

Ambient assisted living (AAL) aims to achieve the UN Sustainable Development Goal (SDG) of ensuring healthy lives and promoting the wellbeing of all people, regardless of their age, location or income. At its core, AAL relies on the use of information and communications technology (ICT) innovation, networks and standards to deliver services that increase "the life quality of patients" and "their relatives" [2]. ICT and "specifically mHealth solutions" provide new opportunities to bring access to healthcare and AAL services "to people in remote areas" and to make "universal access to health care for all a reality – across the globe" [3]. With over "95% of the world population" being "covered by mobile networks" as of December 2018 and over "7 billion mobile subscriptions in the world" [3], ICT is poised to connect patients to the "social services, health workers, and care agencies" that can help them overcome their healthcare challenges [2].

Though there have been notable improvements in achieving SDG outcomes, there is still much more work to be done. ICT promises to play an increasingly important roll in this work, as it is the "technology with the greatest impact in promoting the inclusion of persons with disabilities" [4], and it has the ability to eliminate isolation of the elderly by "connecting them to the world around them" [5]. With the growing availability of smart phones, wireless and mobile computing, ICT can deliver a new age, "not only of information sharing in general, but of the proliferation of web-based services" and mobile access that can help bring health and wellbeing to both "disabled and non-disabled communities alike" [4].

It is especially important to remediate security risk for those people requiring assistive living services, and for those who depend on telemedicine. The delivery of ICT "services provided through cloud and web-based systems over unsecured public networks exposes this vulnerable population to increased security risk" [5]. Authentication and secure communications are crucial security controls for those who must rely on telemedicine, which uses "telecommunications to, remotely, provide medical information and services" and to reliably "transfer medical information and services from one place to another" [6].

Providing vulnerable populations and their caregivers who rely on these systems with security assurance begins with reliable mutual authentication that is accessible by everyone. A user-centric approach guided by the design goals of universal access can help to ensure that inclusive outcomes are achieved. Providing data confidentiality and secure communications solutions that combat man-in-the-middle and phishing attacks is also critical. These goals can be met by extending the capabilities and scope of an existing protocol used for secure authentication, Recommendation ITU-T X.1035.

2. PAKE PROTOCOL STANDARDIZATION

Password-authenticated key exchange (PAKE) protocols have been defined internationally in Recommendation ITU-T X.1035 [7] and ISO/IEC 11770-4 [8]. PAKE is a "cryptographic protocol that allows two parties who share knowledge of a password to mutually authenticate each other and establish a shared key, without explicitly revealing the password in the process" [9]. PAKE protects users from phishing and man-in-the-middle attacks, so that users can authenticate with an easily recalled password that is never exposed to an attacker.

PAKE protocols achieve mutual authentication without requiring that users possess digital certificates. By not requiring certificates, the cost and operational complexity of providing mutual authentication solutions can be reduced compared to solutions that rely on a public key infrastructure (PKI). By design, PAKE protocols never expose "the user password to a server impersonation or eavesdropping attack" [5] during a user authentication attempt.

This characteristic of PAKE "prevents off-line dictionary attacks, a common password authentication problem." [9]. The user's password is input to a Diffie-Hellman key exchange process to derive a symmetric key. This derived key is used as the basis for ensuring the confidentiality of communications between a user and a server during operation of a PAKE protocol.

The operation of a PAKE protocol, as depicted in Figure 1, begins with the user providing a password to a browser or user agent. The password must be preregistered, a value known to the server, so that the user and server can derive the same cryptographic key. The user can assert an identity claim by presenting an account name to the server in the clear, along with their authentication-attempt message encrypted using their password-derived key.



Figure 1 – PAKE-based web authentication (Source: Web 2.0 Security & Privacy (W2SP) 2009)

This encrypted message contains a user challenge to the server. If the server a user intends to access receives the encrypted message, the stored password for the user account can be located, the key needed to decrypt the message can be derived, the message can be decrypted, and the server can respond to the user challenge. If an attacker receives the encrypted message, they will not possess the user password needed to derive the key, and they will not be able to decrypt the user message and respond to the user challenge. In this case, the protocol will end without the user credentials being exposed to the attacker.

When the client authentication-attempt message in a PAKE protocol is augmented with a user's biometric sample, the PAKE protocol can be extended to provide both mutual authentication, and two-factor user identity authentication. The biometric sample included by the user in their authentication-attempt message enjoys the same protection against phishing and man-in-the-middle attacks afforded by PAKE. The user still benefits from mutual authentication, gaining assurance that the intended server has been accessed instead of an attacker's server.

3. BIOMETRIC EXTENDED PAKE PROTOCOL

Biometric authenticated key exchange (BAKE) is an extension of the PAKE protocol that provides strong, two-factor user identity authentication [10]. BAKE extends PAKE by including a user biometric sample, a *something-you-are* authenticator, in the PAKE authentication-attempt message sent by a user to a server [10]. A claimed user identity (i.e., an account name) is sent to the server in the clear. Transfer of the user biometric sample is protected by encryption under the symmetric key derived from a PAKE user password, a *something-you-know* authenticator.

ICT innovations have led to increased availability and sophistication of "inexpensive mobile computing devices" that incorporate "wide varieties of biometric sensors" [5]. "Face, voice, gesture and touch biometric sensors are becoming commonplace" [5]. This makes it practical for system designers to offer users greater choice that serves more users. Designers "no longer need to settle on just one biometric technology for authentication" [5]. The ubiquity of sensor-rich ICT devices presents opportunities "to create designs that provide secure authentication and access to web-based services to a greater number of elderly and disabled users" [5]. ICT innovation is an important enabler of universal access.

For some biometric technology types, operation of a BAKE protocol can require two user inputs, one input for each authentication factor. The user may be required to enter their password through a keyboard or touch screen, then to provide a biometric sample using a separate sensor device. Requiring two user input actions can make two-factor authentication solutions less convenient and more challenging for some users.

However, biometric sensor data provides a rich source of user authentication information. For some biometric technology types, data containing two authentication factors can be collected from a biometric sensor with a single user input. As one example, a microphone can collect a user voice sample that contains speaker recognition data, from which a biometric sample can be matched against a previously stored biometric reference. Using this same voice sample, a speech recognition tool can extract user knowledge, a spoken password that can be used to operate PAKE.

Figure 2 describes the steps required to operate a BAKE protocol. These steps illustrate that BAKE operations differ little from those of PAKE. These differences are in the collection of a user biometric sample, inclusion of the sample in the authentication-attempt message, and in the matching of the biometric sample by the server required by BAKE.



Figure 2 – Biometric authenticated key exchange

This similarity between the protocols makes it possible for BAKE to be gradually and unobtrusively introduced into an existing PAKE environment to enhance user security. If a PAKE protocol is presented with a biometric sample it does not expect or know how to use, processing of that component of a user authentication-attempt message can be ignored. The PAKE protocol can still achieve mutual authentication, thwart phishing and man-in-the-middle attacks, achieve single-factor user authentication, and establish a secure channel between communicating parties.

The PAKE protocol and its BAKE extension still face hurdles for establishing interoperable vendor solutions. First, there is presently no standardized, agreed format for messages used to exchange information between the user and server. Second, there is no standardized way to indicate which of all of the standard PAKE variants [7, 8] are being used in an encrypted message. Third, there is no standardized means of representing the schema of the payload that becomes the encrypted content of the user authentication-attempt and server response messages used by PAKE.

However, these information exchange message formats and payloads are defined for standardization, they can be wrapped for protection in a value of the cryptographic message syntax (CMS) type NamedKeyEncryptedData. This CMS type, specified in Recommendation ITU-T X.894 [11], can transfer encrypted content of any type or format using any symmetric encryption algorithm and a named key. When this CMS type is used with BAKE or PAKE, this key name can be set to the user account associated with the password known to the user and server.

4. BRAIN-ACTUATED AUTHENTICATION

Data sources other than biometric sensors can be mined for Researchers have user knowledge. shown that "noninvasively recorded electric brain activity can be used to voluntarily control switches and communication channels" [12]. Using brain accentuated techniques can allow "near-totally paralyzed subjects the ability to communicate" using "brain-actuated control" (BAC) devices [12]. Electroencephalogram (EEG) data collected from a human brain through a scalp sensor array can be filtered to reduce noise, and then further decomposed into discrete, independent components.

EEG data can be fed into a brain computer interface (BCI) to "enhance a user's ability to interact with the environment via a computer and through the use of only thought" [13]. BAC techniques allow the use of "brain signals to make decisions, control objects and communicate with the world using brain integration with peripheral devices and systems" [14]. Recent research that coupled an augmented-reality (AR) video streaming device to a BCI has shown that people can be trained "to modulate their sensorimotor rhythms to control an AR Drone navigating a 3D physical space" [13]. Through the use of a BCI, individuals living in assistive environments could gain access to healthcare information and telemedicine services "using telepresence robotics"[13].

Larger EEG components that account for muscle or eye movements can be differentiated and grouped. Neural networks have been used in the past to classify these movements [14]. More recently, "artificial neural networks (ANNs)" have been used to "classify imaginary motions" of individuals [14]. This sorting process used to classify movements can be based on which scalp sensors detect them, and on their relative signal strength and timing following a stimulus event. These components allow the intentions of an individual to be distinguished from one another and used as the basis for selecting between control choice alternatives, i.e., choosing between left and right.

Thoughts of a subject imagining that they are moving an object can be filtered and modeled using neural networks to classify the "imaginary motions" performed by the individual [14]. These brain signals indicate the intent of a subject to perform some real act, such as moving their left hand or right foot, even when those body parts do not exist. The subject's intended motions can be executed using physical objects through BCI-activated controls. However, just before this activation occurs, these intentions are something the individual knows and can be considered user knowledge.

Knowledge-based cryptographic techniques such as PAKE combined with signals capable of "noninvasive brainactuated control of computerized screen displays or locomotive devices" could allow even "motor-limited and locked-in subjects" to securely authenticate their identities to an information system and to establish a secure channel for subsequent communications [12].

The key to making this approach to identity authentication and secure communication viable relies on the realization that human intentions manifested as electrical signals that emanate from the human brain can be used as *somethingyou-know* authentication factors. If a user's intentions can be treated as weak secrets that are represented in the form of character strings, they are in a format suitable for input to a PAKE protocol. At present there are no standardized techniques for mapping the results produced by a neural network model to the weak secrets needed to operate a PAKE protocol.

5. FUTURE STANDARDIZATION

5.1 Focus areas

ITU-T Study Group 17 (SG17) has developed a wide range of ICT standards. Their expertise spans many different areas of technology, including telebiometrics, cryptography, identity management, security architecture, modeling and formal definition languages for information exchange. This breadth of expertise makes it possible for SG17 to "bridge multiple domains, bringing them together in standards with a cross industry focus that benefit multiple communities" [15] and makes SG17 well suited to developing the crossdomain standards required to address the needs of elderly and disabled populations.

These populations often include underserved people that could benefit from remote services provided to AAL and other healthcare environments. To enhance the ability of these users to securely access remote resources, SG17 should revise its 2007 version of the ITU-T X.1035 PAKE protocol. Following revision, standardization efforts that leverage ITU-T X.1035 to create new PAKE-based mechanisms for identity authentication and access control should be undertaken. A core focus of this standardization effort should be on achieving the goals of universal access to enable more inclusive authentication solutions.

A first step in an ITU-T X.1035 revision should enable PAKE use with the secure information exchange messages approved recently in the ITU-T X.894 CMS Recommendation. This effort should define an information object identifier (OID) in ITU-T X.1035 that unambiguously identifies its processing requirements in an instance of communication. An ITU-T X.1035 OID will allow the ITU-T version of PAKE to be distinguished from the other standardized versions of PAKE defined in ISO/IEC 11770-4, which already assigns a unique OID value to each of its PAKE versions.

At present, information exchange in the ITU-T X.1035 protocol is defined only in prose. An ITU-T X.1035 revision should augment this prose with an ASN.1 schema defined in terms of ITU-T X.894 CMS type NamedKeyEncryptedData. This schema should associate a PAKE OID with this CMS type in a message. The NamedKeyEncryptedData type provides a standardized way for applications to encrypt content of any type or format with a cryptographic key that uses any encryption algorithm specified by a message sender.

This key can be identified using the keyName field of type NamedKeyEncryptedData. This field can be transferred unencrypted by a sender to indicate the name of their user account on a target server. The indicated account name can then be used by the server to identify that user's password. Type NamedKeyEncryptedData can be associated with an OID that identifies any PAKE protocol version as follows:

The account name indirectly identifies the user password on the server. The server uses this password to derive the key needed to decrypt the user message. If decryption succeeds, identity authentication of the user has also succeeded and the user challenge recovered.

The server can encrypt its response to the user's challenge with their shared symmetric key, and send the response to the user in another NamedKeyEncryptedData message. When the user receives a correct response from the server, mutual authentication is achieved, and a secure channel for subsequent communications is established.

An ASN.1 schema for the content encrypted for exchange between the user and server should be defined and standardized. At a minimum, the encrypted payload of NamedKeyEncryptedData must contain components for a user challenge and a server response. These components should be optional but constrained so that at least one component is present in an exchange. This would allow the client and the server to exchange the same schema payload during PAKE operation.

The encrypted payload schema should contain an optional component to support a BAKE extension to the PAKE protocol. This allows two-factor user authentication to be supported but not required. The payload schema should also include an optional extensibility mechanism for use by any implementation for any purpose. This mechanism should be defined as a series of one or more authenticated attributes, each uniquely identified by an OID. These attributes are protected in the encrypted payload and authenticated by PAKE processing.

5.2 Password-authenticated transport layer security

In their 2016 paper on password authentication in the transport layer security (TLS) protocol, Manulis, Stebila, Kiefer and Denham noted that password authentication is "perhaps the most prominent and human-friendly user authentication mechanism widely deployed on the Web" [16]. The authors described the many threats associated with user reliance for the protection of their credentials on secure server-authenticated TLS channels established using a public key infrastructure (PKI) [16]. They attribute these threats to PKI-related problems including that "security fully relies on a functional X.509" PKI that in practice may be flawed, and on "users correctly validating the server's X.509 certificate" without being phished by an attacker [16]. These assumptions about PKI implementations have been shown not to be unreliable.

The authors note that many PKI failures in TLS are due to the "problems with the trustworthiness of certification authorities (CAs), inadequate deployment of certificate revocation checking, ongoing threats from phishing attacks, and the poor ability of the users to understand and validate certificates" [16]. Rather than rely on the rare case where users possess the personal certificates needed to benefit from mutual authentication, the authors propose using PAKE as "part of the TLS handshake protocol" [16]. Following the execution of PAKE in the TLS handshake, "the key output by PAKE" would be used as "the TLS premaster secret" for deriving "further encryption keys according to the TLS specification" [16].

Though PAKE techniques have been standardized for years in Recommendation ITU-T X.1035 and in ISO/IEC, there has been no PAKE standard "agreed upon and implemented in existing web browser and server technologies" [16]. SG17 should standardize PAKE for use as an option in the TLS handshake. This would broaden the use of PAKE as a standalone authentication technique to its use in a protocol widely used to conduct online electronic commerce transactions and to provide secure communications between internet applications.

Adding PAKE to TLS would enable all users to benefit from "secure password authentication" in "any application that makes use of TLS", without requiring users to possess X.509 certificates [16]. ITU standardization of PAKE usage in the handshake would allow "standard TLS mechanisms for key derivation and secure record-layer communication" to continue being used [16]. An ITU-T standard for using PAKE in TLS would provide users the convenience and low cost of passwords and the security benefits of mutual authentication. By making PAKE available to users as a PKI alternative, the threats to users from phishing and manin-the-middle attacks that are known to plague TLS could be addressed.

5.3 Two-factor biometric authenticated key exchange

SG17 should create a new standard that provides a strong, two-factor identity authentication solution based on PAKE. The new standard should expand the current ITU-T X.1035 protocol processing to include a step for matching a user biometric sample to a reference template associated with their server account and password. For purposes of biometric matching, the user could be enrolled in a biometric system local to the server, or they could be enrolled in a separate system that provides a remote matching service. The later case could enable 'biometric portability', allowing a user to enroll one time in a biometric system, then subsequently to be matched from any device.

In current ITU-T X.1035 protocol processing, a user attempting authentication sends the server an encrypted message along with their account name. The server locates the password associated with the account and derives the key needed to decrypt the message and authenticate the user. When a biometric sample is included by the user in the encrypted authentication attempt, the server can use this biometric sample to further authenticate the user with a second authentication factor.

The confidentiality of the authentication-attempt message is provided using a symmetric key derived from the user password. The user can safely include their biometric sample in the encrypted message, since the PAKE protocol protects the confidentiality of their personally identifiable information (PII) from phishing and man-in-the-middle attack. Only the intended message recipient, the server that shares the user account password, can derive the key needed to decrypt the message and gain access to the user biometric sample.

When biometric matching is performed local to the server, at a minimum, the user biometric sample must be included in the encrypted user message. When more than one biometric technology type is supported, an identifier of the type of sample being presented for authentication must also be included. It is possible for a biometric matching system to support multiple technology types, so more than one sample and type may be presented by the user for authentication. The format and processing of these values should be standardized by SG17 to promote vendor interoperability.

Biometric matching may be performed on a system remote to the server authenticating the user. In this case, the encrypted user authentication-attempt must also identify the location of the remote matching service for each biometric type being presented for authentication. The unique biometric reference template identifier associated with the user enrolled in a biometric system, and the type of the biometric sample should also be included. A standardized schema for exchanging this information as an encrypted attribute should be standardized by SG17.

5.4 Brain-actuated control authenticated key exchange

The term 'telebiometrics' refers to the standardization of biometric devices used in the telecommunications domain. Recommendation ITU-T X.1081 specifies a telebiometric multimodal model based on both the "interaction between a human being and the environment", and on the "forms of measurement of the magnitude of physical interactions between a person and its environment" [17]. The model specifies measurements of these "physical interactions", and also recognizes "behavioral interactions" [17]. The multimodal model supports the measurement of the interactions between a person and a telebiometric device "in both directions" [17].

The telebiometric multimodal model provides a common framework for the specification of "security applications and safety aspects" [17] of telebiometrics. Though EEG data is not collected for the purpose of biometric matching, EEG data is similar to X.1081 telebiometric data collected "by a measurement instrument recording some biophenomenon". Both non-biometric EEG data and telebiometric data can be used to model interactions at a "layer where the human body meets electronic" devices [17].

Recommendation ITU-T X.1081 enables modeling of biometric authentication in terms of the interactions of a person with a biometric sensor. An important benefit of this standard is in its aiding in the design of authentication solutions that can preserve human "privacy and safety" by making these interactions "explicit and engineerable" [17]. However, there is no ITU authentication standard similar to Recommendation ITU-T X.1081 for using non-biometric devices that interact with people and telecommunication devices used to deliver healthcare.

As BAC devices become more integrated with mobile technologies for edge computing and part of the Internet of things (IoT), their users will gain greater access to in-home healthcare monitoring and other healthcare services delivered remotely. This connectivity gain will also make them more vulnerable to attack. The ITU-T X.1080.0 [18] telebiometric data protection Recommendation specifies use of the SignedData and EnvelopedData CMS types for authentication and data confidentiality, but does not allow PAKE or its extensions.

Both of these CMS types rely on the use of certificates supported by a PKI. Given an environment that involves a user's "brain signals to make decisions, control objects and communicate" [14], identity authentication is an important security control. The potential for risk inherent in systems that might provide feedback to the user makes mutual authentication an important consideration for both security and user safety. The CMS SignedData message does not provide mutual authentication, multifactor authentication of the user, or the convenience of password authentication. All of these capabilities can be provided by an extended PAKE.

CONCLUSION

In this paper, single and multifactor identity authentication techniques based on PAKE protocols were described. The ability to derive weak secrets from user knowledge extracted from biometric sensors and brain-actuated control systems was highlighted. The paper discussed how derived weak secrets could be converted into a format suitable for input to a PAKE protocol. The paper also illustrated how new standardization efforts to revise and extend PAKE could help achieve universal access to healthcare, telemedicine and other network services by users with diverse abilities, while enhancing the security of all users.

To achieve these aims, ITU should define a standardized ASN.1 schema for information exchange that supports all PAKE protocol versions and a BAKE extension. This schema should incorporate the NamedKeyEncryptedData cryptographic message defined in Recommendation ITU-T X.894. An extensible mechanism should be specified that makes possible the unambiguous identification of each PAKE protocol version.

This mechanism should use ASN.1 information object identifiers that can be associated with the ITU-T X.894 CMS type NamedKeyEncrptedData in a message. Standardization of a PAKE protocol message would enable the development of interoperable vendor solutions. These solutions would benefit users by lowering their cost of gaining secure access to network delivered health services, and enhancing their security through access that provides multifactor and mutual authentication.

ITU should standardize a common ASN.1 payload type for the content encrypted for exchange between users and servers during PAKE operations. An optional component of this ASN.1 type should allow a BAKE extension to be used to provide strong, multifactor user authentication. Another optional payload component should support a user proof-ofpossession authentication factor, a registered object known to the server.

An integer version component should be included to allow future changes to the payload to be detected by deployed implementations. Optional server challenge and response components should be defined as opaque strings to support any type of data in any format required by vendors. These optional components should be constrained so that at least one component is present in a message, so that the same payload type can be used by both communicating parties.

An optional authenticated attributes component should also be included. This payload component should be specified with ITU-T X.894 CMS type AuthAttributes to provide extensibility and to support the use of the schema in other standards, protocols and applications. An authenticated attribute should be defined to support biometric matching on a separate system. This attribute should allow a user to specify the location of a biometric service provider (BSP) that offers a remote matching service, the user biometric
type and sample, and the user-enrolled biometric reference template identifier at the BSP. This feature would provide user portability of their biometric credential across multiple devices with only a single user enrollment.

Recommendation ITU-T X.1080.0 provides an informal CMS specification for data protection based on IETF RFC 5652. SG17 should revise Recommendation ITU-T X.1080.0 to reference ITU-T X.894 CMS, whose syntax complies with the current ASN.1 standards. This change will allow ITU-T X.1080.0 adopters to eliminate the use of RFC 5652 syntax that is "based on X.208, the deprecated 1988 version of ASN.1 that was withdrawn as a standard in 2002" [15]. Adoption of ITU-T X.894 will allow any of the ASN.1 encoding rules to be used, removing the IETF one-rule restriction. ITU-T X.894-based ITU-T X.1080.0 implementations will also gain new options for telebiometric data protection, including field level tokenization and a SigncryptedData type that can be used to replace SignedData and EnvelopedData.

The TLS protocol is widely used and well suited for server to server mutual authentication, since both communicating parties are likely to possess digital certificates. However, when individuals must authenticate to a server using TLS, they must often rely on a password. The lack of users with certificates makes mutual authentication with TLS rare and successful phishing attacks on users likely.

ITU should standardize a profile of the TLS handshake protocol that ensures secure access for mobile device users. This profile should support mutual authentication based on user passwords protected by PAKE. An ITU standard for TLS should enable the use of PAKE extensions that provide multifactor user authentication with samples collected from the biometric sensors readily available on smart mobile devices. This new TLS standard would allow mobile users to enjoy the benefits of strong, two-factor user authentication and mutual authentication without the cost of digital certificates and the risk of being phished.

A revision of Recommendation ITU-T X.1081 should include consideration of non-biometric telemedicine devices. This revision could be achieved through a new normative annex or as a separate standard. ITU-T X.1081 security aspects could incorporate work being proposed in ITU-T X.tas, since, as this paper has shown, it is possible for a biometric sensor to also collect user knowledge for use as an authentication factor. The X.tas: Telebiometric authentication using speaker recognition standardization should especially consider the BAKE protocol extension to PAKE.

The X.tas work should be broadened to include other types of biometrics for which "knowledge extraction can mine *something-you-know* information from biometric sensor data" [10]. These biometric types could be used to support the operation of PAKE and its extensions. These types of biometrics include collected "user gestures as binary video images" that can "represent movements completely unrelated to any language" [10].

As described by Fong, Zhuang and Fister, these types include footsteps, "finger positions and hand posture" [19]. Some biometric technology types are considered to be 'weak' for general use. For a constrained population living in an in-home healthcare environment, who may have been authenticated on entry, these types may offer value for user identification and authentication, especially when telemedicine and telemonitoring services are assisted by robotics.

REFERENCES

- Astbrink, G., Shabbir, M., Giannoumis, G.A. (2018)
 1.3 Billion Reasons for Making Technology Accessible. Internet Governance Forum Workshop Session (WS) #45.
- [2] Calvaresi, D., Cesarini, D., Sernani, P., Marinoni, M., et al. (2017). Exploring the ambient assisted living domain: a systematic review. *Journal of Ambient Intelligence and Humanized Computing*, 8(2), 239-257.
- [3] ITU-D. (2019). mHealth for NCD BeHe@lthy BeMobile. ICT Applications.
- [4] ICT Consultation. (2013). The ICT opportunity for a disability-inclusive development framework.
- [5] Griffin, P. H. (2015). Security for ambient assisted living: Multi-factor authentication in the internet of things. In 2015 IEEE Globecom Workshops (GC Wkshps) (pp. 1-5). IEEE.
- [6] Hamdi, O., Chalouf, M. A., Ouattara, D., & Krief, F. (2014). eHealth: Survey on research projects, comparative study of telemonitoring architectures and main issues. *Journal of Network and Computer Applications*, 46, 100-112.
- [7] Recommendation ITU-T X.1035 Passwordauthenticated key (PAK) exchange protocol, 2007.
- [8] ISO/IEC 11770-4 Key Management Mechanisms Based on Weak Secrets, 2017.
- [9] Engler, J., Karlof, C., Shi, E., Song, D. (2009). Is it too late for PAKE? In Web 2.0 Security and Privacy (W2SP) 2009.
- [10] Griffin, P. H. (2015). Biometric knowledge extraction for multi-factor authentication and key exchange. Proceedings of the 2015 Complex Adaptive Systems Conference, Missouri Institute of Science and Technology, in San Jose, California.

- [11] Recommendation ITU-T X.894 Information technology - Generic applications of ASN.1: Cryptographic message syntax, 2018.
- [12] Makeig, S., Enghoff, S., Jung, T. P., & Sejnowski, T. J. (2000). A natural basis for efficient brain-actuated control. *IEEE Transactions on Rehabilitation Engineering*, 8(2), 208-211
- [13] LaFleur, K., Cassady, K., Doud, A., Shades, K., Rogin, E., & He, B. (2013). Quadcopter control in three-dimensional space using a noninvasive motor imagery-based brain–computer interface. *Journal of neural engineering*, 10(4), 046003.
- Bhattacharya, S. (2016). Optimization of Electroencephalograph-Based Classification for Imaginary Motion Brain Computer Interface Study.
- [15] Griffin, P. Telebiometric Information Security and Safety Management. Proceedings of the 5th ITU Kaleidoscope Conference: Building Sustainable Communities (ITU Kaleidoscope 2013).

- [16] Manulis, M., Stebila, D., Kiefer, F., & Denham, N. (2016). Secure modular password authentication for the web using channel bindings. *International Journal of Information Security*, 15(6), 597-620.
- [17] Recommendation ITU-T X.1081 The telebiometric multimodal model - A framework for the specification of security and safety aspects of telebiometrics, 2011.
- [18] Recommendation ITU-T X.1080.0 Telebiometrics -Access control for telebiometrics data protection, 2017.
- [19] Fong, S., Zhuang, Y., & Fister, I. (2013). A biometric authentication model using hand gesture images. *Biomedical engineering online*, 12(1), 111/.

CYBER-SAFETY IN HEALTHCARE IOT

Duncan Sparrell¹

¹sFractal Consulting, United States

ABSTRACT

Healthcare is becoming more connected. Risks to patient and public safety are increasing due to cybersecurity attacks. To best thwart cyberattacks, the Internet of health things (IoHT) must respond at machine speed. Cybersecurity standards being developed today will enable future IoHT systems to automatically adapt to cybersecurity threats in real time, based on a quantitative analysis of reasonable mitigations performing triage to economically optimize the overall healthcare outcome. This paper will discuss cybersecurity threats, risk, health impact, and how future IoHT cybersecurity systems will adapt to threats in real time.

Keywords – Cyber-safety, healthcare, Internet of things

1. INTRODUCTION

If "software is eating the world"[1], then the Internet of things (IoT) is blanketing the world. International Telecommunication Union (ITU), Recommendation ITU-T Y.2060 defines an IoT device as a "piece of equipment with the mandatory capabilities of communication and the optional capabilities of sensing, actuation, data capture, data storage and data processing." [2]. This paper defines the Internet of health things (IoHT) as all ITU-T Y.2060 IoT devices used in healthcare and ambient assisted living [3]. This definition is broader than implantable medical devices and includes: care, diagnostic, ambient-assisted and administrative devices, since they all could potentially affect patient health if exploited. "While advanced devices can offer safer, more convenient and timely health care delivery, a medical device connected to a communications network could have cybersecurity vulnerabilities that could be exploited resulting in patient harm." said Amy Abernethy, M.D., Ph.D., the United States (US) Food and Drug Administration (FDA) principal deputy commissioner [4].

IoHT is the merging of the information technology (IT) world with the operational technology (OT) world to bring about increased innovation, efficiency and quality of healthcare [5-11].

As IoT pervades the healthcare industry, cybersecurity in IoHT must evolve both to recognize new threats but also to recognize different consequences i.e. impact on patient health. This paper will discuss trends that when combined will make IoHT safer and demonstrate the important role cybersecurity standards will play as cybersecurity evolves from ancillary to safety critical. IAmTheCavalry.org was founded to focus on the intersection of computer security and public safety. "*IoT is where bits and bytes meet flesh and blood*" [12].

2. THREATS

Over 90% of healthcare institutions have been attacked [13]. The impact of failed security is increasing as well. At the RSA Conference USA in 2018, hackers "killed" (simulated) patients without the doctors even being aware the operating room (OR) had been hacked [14]. Marathons affect patient care due to the ambulance delays (due to rerouting around the marathon) resulting in a statistically significant increase in the 30-day mortality rates [15]. If people died due to a 4.5 minute average increase in the length of the ambulance ride, then it seems logical that people died in the massive hospital ransomware-caused outage in the UK [16] as well as other hospital attacks such as Hollywood Presbyterian where ambulances were rerouted to other hospitals in LA traffic [17] or similar events in other hospitals [18-22].

Attackers make use of automation, resulting in attacks occurring at the speed of light; yet defense occurs at the speed of lawyers. Obviously, lawyers need to be involved. Lawyers should be consulted a priori so they are not needed to be consulted during the attack. To do this requires anticipating the possible attacks and responses. "Think evilly but act ethically" [23].

IoHT designers must take into account attacks that will be part of a well-funded, well-staffed campaign to achieve a particular mission. The mission may be against the owner of the IoHT (e.g. the healthcare provider), the IoHT may be an attack vector against another entity (e.g. the healthcare client either as an individual, or as group such as military personnel).

Looking at real-world non-cyber failures and disasters gives great insights into what an attacker could do. As an example, there were 8 failures that led to the Deepwater Horizon / BP oil spill in the Gulf of Mexico [24]. Seven of the 8 problems were with actuators, sensors or decision algorithms, all failures that could also be caused by a cyberattack. Even the 8th cause, faulty cement, could be caused by a supply chain attack. The analysis does not have to be of mega-disasters. A similar analysis could be done of the typical failures in almost any manufacturing process, or to any medical simulation. This points out the need for domain-specific knowledge when assessing IoHT cybersecurity. This is not something that could be accomplished by the IT department or outside cybersecurity experts as it requires healthcare domain-specific knowledge.

3. RISK ANALYSIS

Cybersecurity spending for the period 2017-2021 is expected to total over 1 trillion dollars [25]. At the same time, the cost of cybercrime is projected to reach two trillion dollars by 2019 [26] despite the increased spending on cyber defense. Problems are exacerbated by the lack of trained security personnel [27,28].

The main purpose of cybersecurity is to reduce risk. However, most cybersecurity decisions today are made based on fear, uncertainly and doubt (FUD) [29]. Informed risk decisions should be made using mathematics, science and engineering. "*There are plenty of fields with massive risk, minimal data, and profoundly chaotic actors that are regularly modeled using traditional mathematical models*" [30]. Cybersecurity can learn from other fields such as the insurance industry where loss exceedance curves are used as a tool for catastrophe planning such as: river flooding, tornadoes, hurricane storm surges and droughts [31]. Similarly, loss exceedance curves are also used in oil and natural gas exploration [32].

Loss exceedance curves can be used in cybersecurity for mathematically modeling risk [30]. This approach incorporates decomposition, summation and validation over time. An example is shown in Figure 1. The curve is probabilistic and shows the likelihood of losses exceeding a certain amount. Note the x-axis is log scale and the entire chart is for a fixed time period, e.g. one year.



Figure 1– Loss Exceedance Curve

The real advantage comes from comparing two alternatives, as in Figure 2. The existing base case is shown in blue. The red alternative costs \$500k to implement and decreases the 50% loss by over \$4M. But note this particular alternative also increases the chance of a catastrophic loss by a factor of 10. Although this may seem counterintuitive, it is common

because the new technology itself becomes a low-probability, high-impact threat vector. A better alternative would be to increase the upfront costs to mitigate the catastrophic case with other controls and/or insurance.



Figure 2 – Comparing Loss Exceedance Curves

Loss exceedance curves can apply to casualty information. IoHT would need to incorporate both financial and casualty data to make informed risk decisions. Cybersecurity controls could potentially increase patient mortality in cases where the control impacts emergency access or constrained resources [33]. Quantitative studies optimize overall health outcomes by including both the positive impacts (e.g reduced mortality due to preventing attack) and negative impacts (e.g. increased mortality due to reduced emergency access) of cybersecurity controls.

Factor Analysis of Information Risk (FAIRTM) [34] is one methodology for conducting quantitative risk analysis and creating loss exceedance curves. Taxonomy and analysis standards have been developed for FAIRTM [35,36].

Duty of Care Risk Analysis (DoCRA) is a standard [37] developed to help organizations determine whether their safeguards appropriately protect others from harm while incurring a reasonable burden.

Chris Chronin, Chair of the DoCRA Council, recommends extending FAIRTM to explicitly balance the likelihood and impact of foreseeable threats against the burden of safeguards in such a way as to meet the legal definition of 'reasonable' from the judge's viewpoint in a case to determine liability [38].

4. AUTOMATION

The defense has not kept pace with the offense. Attackers can, on average, breach a system in seconds or minutes whereas it takes defenders weeks, months or even years to respond [39]. The attacker utilizes sophisticated, adaptive, automated tools and the defender reactively responds with manual, slow, uncoordinated tools and processes. The defense must automate to operate at the speed of the offense. Automation is a win/win, cheaper AND better.

Integrated Adaptive Cyber Defense (IACD) is a research effort jointly funded by the US Department of Homeland Security (DHS) and the US National Security Agency (NSA), in collaboration with The Johns Hopkins University Applied Physics Lab (JHU/APL) and industry. IACD seeks "to revolutionize cybersecurity ... through the universal automation and interoperability of cyber defenses" [40]. IACD is an effort to get humans from 'in the loop' to 'on the loop'. The focus is product agnostic interoperability by decoupling functions and standardizing interfaces. IACD seeks to create an adaptable, extensible ecosystem "to dramatically change the timeline and effectiveness of cyber defense via integration, automation, and information sharing." This can be accomplished by decoupling the functions and standardizing the interfaces between functions. IACD categorizes security functionality into:

- sensing: gathering all the data
- sense-making: correlating and analyzing data, transforming into information, knowledge and intelligence
- decision-making: deciding what to do
- acting: sending the actual commands.

Gap analysis of the IACD work has led to standards activities in sharing threat intelligence, sharing courses of action, and in a common command and control (C2) language.

One of the IACD objectives is the sharing of threat data among interested, trusted parties. DHS started an industry forum on threat sharing that evolved and moved into OASIS, a non-profit standards development organization. The OASIS Cyber Threat Intelligence (CTI) Technical Committee (TC) [41] created the Structured Threat Information Expression (STIXTM) [42] and the Trusted Automated Exchange of Intelligence Information (TAXIITM) specifications [43] to address the need to model, analyze and share cyberthreat intelligence. Figure 3 shows an example of STIXTM ontology.



Figure 3 – Example of STIXTM Ontology

Threat sharing has not been as effective as envisioned and has run into obstacles [44]. The initial STIXTM version 1 specification was not readily accepted by industry. Version 2 is now available with significant improvements addressing many of the industry concerns and is gaining broader adoption. In the US, the passage of the Cybersecurity Information Sharing Act [45] incentivized sharing by removing certain liabilities. Significant progress has been made in this area, particularly in certain industry groups working with their Information Sharing and Analysis Centers (ISACs).

To maximize the benefit of STIXTM involves not only sharing 'what happened' but also deciding 'what to do', called Courses of Action (CoAs). To effectively share CoAs, standards for both atomic actions and for a playbook including the decision points and the flow of the atomic actions are required.

Another IACD objective is the standardization of the command and control (C2) language for security technologies, the atomic actions in a CoA. For example, firewalls have existed for over 25 years yet the 'word' used to prevent a packet passing through the firewall could be: 'drop', 'deny', 'reject', 'block', 'blacklist', etc. depending on which implementation is used. This is compounded across many security technologies with new ones being continuously added. This poses several problems for the user community. It is hard to share CoAs when two organizations use different vendor products. The cost of retooling disincentivizes changing vendors or adding alternative vendor products. This was less of an issue when security technology was physical appliances. In today's cloud/IoT environment, switching vendors and/or adding new technologies should be quicker and easier.

The OASIS Open Command and Control (OpenC2) Technical Committee was founded to standardize machineto-machine command-and-control to enable cyber defense system interoperability at machine speed [46,47]. Just as automation has a fundamental impact on attacker economics, OpenC2 will have a fundamental impact on defender economics [48,49].

The OASIS Collaborative Automated Course of Action Operations (CACAO) for Cyber Security Technical Committee [50] develops standards for implementing CoAs including the decision points and playbooks mentioned earlier.

Figure 4 shows an automation flow including STIXTM, TAXIITM, OpenC2 and CACAO.



Figure 4 – Automation Flow

Efforts in this area are not confined to classic IT but also affect OT as cyber-physical systems disrupt many industries [51]. California Energy Systems for the 21st Century (CES-21) seeks to address the cybersecurity challenges of future energy systems in California [52]. The energy industry has increasing challenges as more energy generation moves to the edge (e.g. wind and solar power) while attacks increase both with IoT as a target and with IoT as a vector of attack [53,54]. CES-21 has developed a framework similar to IACD which utilizes the concept of a machine-to-machine (M2M) automated threat response (MMATR) which uses existing standards to the extent possible and identifies where new standards are needed. CES-21 has been active in STIXTM, TAXIITM, OpenC2 and CACAO.

JHU/APL did studies on their network comparing various automation scenarios with their current manual scenarios [55]. Figure 5 shows their findings. Computers scale better than humans, so more indicators were analyzed and efficiency was increased. The most significant finding was the attacks were stopped two orders of magnitude faster, resulting in significantly less damage.



Figure 5 – Automation Advantages

Phantom Cyber, a security orchestration vendor, published similar savings in combating phishing [56]. Their customer reduced phishing incident response costs by 98% and saved \$1.06M annually.

Zepko, a managed security service provider in the United Kingdom, used OpenC2 to increase the efficacy of their Security Operations Centre (SOC) by 25-30% [57].

The economic advantages to be gained by automation are better security at lower costs due to faster response times. In addition to lower costs, another advantage of vendor agnostic cybersecurity standards is removing 'vendor lock-in'. The commoditized interface [58] will force vendors to compete on price and functionality, and this should spur innovation as well. Several vendors recognize this and have made significant contributions [59]. Standards have been shown to spur innovation [60] by removing artificial barriers. In the case of the standards mentioned in this article, the intent is that standardizing the interface will allow innovators easier entry into the market due to the 'plug and play' standardization with existing customer ecosystems. Open source software projects are beginning to appear to support the community [61-69].

An area where healthcare has been in the lead is in the area of software transparency and using the Cybersecurity Bill of Materials (CBoM) for vulnerability analysis. A CBoM contains both a traditional hardware bill of materials and a Software Bill of Materials (SBoM). The US Federal Drug Administration (FDA) now includes CBoM as part of the pre-market guidance to medical device manufacturers [70] and the US National Telecommunications and Information Administration (NTIA) conducted a successful proof of concept (PoC) with multiple healthcare delivery organization and multiple medical device manufacturers [71].

5. CONCLUSIONS

Cybersecurity standards being developed today will enable future IoHT systems to automatically adapt to cybersecurity threats in real time, based on a quantitative analysis of reasonable mitigations performing triage to economically optimize the overall healthcare outcome. Quantitative risk analysis will use standards such as FAIRTM and DoCRA. Automation will be driven by standards such as SBoM, STIXTM, TAXIITM, OpenC2 and CACAO.

REFERENCES

- M. Andreessen, "Why Software Is Eating The World", The Wall Street Journal, August 20 2011. Available https://www.wsj.com/articles/SB1000142405311190 3480904576512250915629460.
- [2] International Telecommunication Union, *Recommendation ITU-T Y.2060, Overview of the Internet of things*, June, 2012. Available https://www.itu.int/rec/T-REC-Y.2060-201206-I.
- J. Rodrigues, D. Segundo, H. Junqueira, M.Sabino, R. Prince, J. Al-Muhtadi, V. De Albuquerque, "Enabling Technologies for the Internet of Health Things", Access IEEE, vol. 6, pp. 13129-13141, 2018.

- [4] USFDA, "FDA informs patients, providers and manufacturers about potential cybersecurity vulnerabilities for connected medical devices and health care networks that use certain communication software", USFDA News Release, 1-Oct-2019. Available https://www.fda.gov/newsevents/press-announcements/fda-informs-patientsproviders-and-manufacturers-about-potentialcybersecurity-vulnerabilities.
- [5] A. Martinez-Balleste, "Exploring IoT Industry Applications: Paving the Way for Future IoT Applications in Healthcare", IEEE. Available https://ieeexplore.ieee.org/servlet/opac?mdnumber= EW1485.
- [6] A. K. Alharam and W. El-madany, "Complexity of Cyber Security Architecture for IoT Healthcare Industry: A Comparative Study", 5th International Conference on Future Internet of Things and Cloud Workshops, 2017. Available https://ieeexplore.ieee.org/document/8113801.
- [7] H. Breivold and K. Sandstrom, "Internet of Things for Industrial Automation -- Challenges and Technical Solutions", 2015 IEEE International Conference on Data Science and Data Intensive Systems, Sydney, Australia, 2016, pp. 532-539.
- [8] L. Probst, et al., "Digital Transformation Scoreboard 2018", European Commission, Luxembourg 2018. Available: https://ec.europa.eu/growth/toolsdatabases/dem/monitor/sites/default/files/Digital%2 0Transformation%20Scoreboard%202018_0.pdf.
- [9] K. Pretz, "How the Industrial Internet of Things is Changing the Face of Manufacturing", The Institute, IEEE, Feb. 23, 2018. available: http://theinstitute.ieee.org/technology-topics/smarttechnology/how-the-industrial-internet-of-things-ischanging-the-face-of-manufacturing.
- [10] "Understanding the Industrial Internet of Things", Transmitter, IEEE, May 8, 2018. available: https://transmitter.ieee.org/understanding-industrialinternet-things/.
- [11] "Revolutionizing the IIoT Industry One Streetlight at a Time", Spectrum, IEEE. Available: https://spectrum.ieee.org/telecom/internet/revolutio nizing-the-iiot-industry-one-streetlight-at-a-time.
- [12] J. Corman, "Bits & Bytes Meet Flesh & Blood", presented at LASCON, Austin, TX, Oct 23, 2015.
- [13] E. Perakslis, "Cybersecurity in Healthcare", New England Journal of Medicine 371(5):395-7, July-2014.

- J. Corman, et al. "Hacking Healthcare Live", RSA Conference USA, San Francisco, April 25, 2018. Available: https://www.rsaconference.com/videos/livesimulation-a-medical-device-hack-and-patientcodes-rsac-2018.
- [15] A. Jenna, et al, "Delays in Emergency Care and Mortality during Major US Marathons", New England Journal of Medicine, Vol 376, 2017, pp. 1441-50. available: https://www.nejm.org/doi/pdf/10.1056/NEJMsa161 4073.
- [16] A. Morse, "Investigation: Wannacry cyber attack and the NHS", UK National Audit Office, April 25, 2018. Available: <u>https://www.nao.org.uk/wpcontent/uploads/2017/10/Investigation-WannaCrycyber-attack-and-the-NHS.pdf</u>.
- [17] K. Chinthapalli, "The hackers holding hospitals to ransom", BMJ 2017;357:j2214. Available <u>https://doi.org/10.1136/bmj.j2214</u>.
- [18] C. Sienko, "Ransomware Case Studies", Available https://resources.infosecinstitute.com/category/healt hcare-information-security/healthcare-attackstatistics-and-case-studies/ransomware-case-studieshollywood-presbyterian-and-the-ottawa-hospital/.
- [19] "Inside the New York hospital hackers took down for 6 weeks". 18-Aug-2917. Available https://www.cbsnews.com/news/cbsn-onassignment-hackers-targeting-medical-industryhospitals/.
- [20] B. Lovelace, L. Gurdis, "Hospital CEO forced to pay hackers in bitcoin now teaches others how to prepare for the worst". Available https://www.cnbc.com/amp/2018/04/06/hosptialceo-forced-to-pay-hackers-in-bitcoin-now-teachesothers.html.
- [21] C. O'Gara, "Would You Have Surgery in a Hacked Hospital?", 7-Oct-2019. Available https://www.secureworldexpo.com/industrynews/would-you-agree-to-surgery-in-a-hackedhospital.
- [22] L. Beers, "Multiple Victorian hospitals hacked in suspected ransomware attack". 1-Oct-2019. Available https://7news.com.au/news/health/multiplevictorian-hospitals-hacked-in-suspectedransomware-attack-c-481074.
- [23] D. Sparrell, "Let it be hacked," Code Beam SF 2018, San Francisco, USA, 15-17-March-2018, available: https://youtu.be/NYkwvVKlbU8.

- [24] J. Mullins, "The eight failures that caused the Gulf oil spill", New Scientist, Sep. 8, 2010 available: <u>https://www.newscientist.com/article/dn19425-theeight-failures-that-caused-the-gulf-oil-spill</u>.
- [25] S. Morgan, "2018 Cybersecurity Market Report", Cybersecurity Ventures, May 31, 2017,\. Available: https://cybersecurityventures.com/cybersecuritymarket-report/.
- [26] S. Morgan, "Cyber Crime Costs Projected to Reach \$2 Trillion by 2019", Forbes, Jan. 17, 2016. available: https://www.forbes.com/sites/stevemorgan/2016/01/ 17/cyber-crime-costs-projected-to-reach-2-trillionby-2019.
- [27] S. Morgan, "One Million Cybersecurity Job Openings in 2016", Forbes, Jan. 2, 2016. Available: <u>https://www.forbes.com/sites/stevemorgan/2016/01/</u>02/one-million-cybersecurity-job-openings-in-2016/.
- [28] P. Sawers, "Global cybersecurity workforce to be short 1.8 Million by 2022", Venture Beat, June 7, 2017. Available: <u>https://venturebeat.com/2017/06/07/globalcybersecurity-workforce-to-be-short-by-1-8million-personnel-by-2022-up-20-on-2015/</u>.
- [29] C. Bryant, "How to justify your IT Security Budget", 17-Oct-2016. Available <u>https://www.risklens.com/blog/how-to-justify-your-it-security-budget/</u>.
- [30] D. Hubbard and R. Seiersen, "How to Measure Anything in Cybersecurity Risk". Hoboken, NJ: Wiley, 2016.
- [31] C. Valasquez, et al., "Hybrid Loss Exceedance Curve (HLEC) for risk assessment", International Symposium on Computational Civil Engineering, Iasi, Romania, May, 2013. available: https://www.researchgate.net/profile/Alex_Barbat/p ublication/259609767_Hybrid_loss_exceedance_cu rve_HLEC_for_risk_assessment/links/0deec52ce53 c507de4000000/Hybrid-loss-exceedance-curve-HLEC-for-riskassessment.pdf?origin=publication_detail.
- [32] M. Nederlof (1994) "Comparing probabilistic predictions with outcomes in petroleum exploration prospect appraisal". Nonrenewable Resources, v.3, No.3, 1994, p.183-189.

- [33] G. Zheng, G.Zhang, W.Yang, C.Vali, R. Shankaran, M.Orgun, "From WannaCry to WannaDie: Security Trade-offs and design for implantable medical devices", IEEE, 17th International Symposium on Communications and Information Technologies, 25-27 Sept 2017. Available https://ieeexplore.ieee.org/document/8261228.
- [34] J. Freund, J. Jones, "*Measuring and Managing Information Risk: A FAIR Approach*", Butterworth-Heinemann, 2014. ISBN-13: 978-0124202313.
- [35] Open Group, "Risk Taxonomy (O-RT)", Open Group Technical Standards, Version 2.0, 18-Oct-2013. Available https://publications.opengroup.org/c13k.
- [36] Open Group, "*Risk Analysis (O-RA)*", Open Group Technical Standards, 18-Oct-2013. Available https://publications.opengroup.org/c13g.
- [37] DoCRA Council, "Duty of Care Risk Analysis Standard", Version 0.5, April, 2018. Available <u>https://docraprod.wpengine.com/wp-</u> <u>content/uploads/2018/04/Duty-of-Care-Risk-Analysis-Standard-v05.pdf</u>.
- 38] C. Cronin, "The Questions a Judge will ask you after a Data Breach", Borderless Cyber, Oct 2019. Available <u>https://us19.borderlesscyber.org/programschedule/program/108/plenary-session-keynote-thequestions-a-judge-will-ask-you-after-a-data-breach</u>.
- [39] Verizon, "2016 Data Breach Report", available: https://www.verizonenterprise.com/resources/report s/rp_DBIR_2016_Report_en_xg.pdf.
- [40] *"Integrated Adaptive Cyber Defense"* available: https://www.iacdautomate.org/learn/ .
- [41] *"OASIS Cyber Threat Intelligence (CTI) Technical Committee (TC)"*. Available: https://www.oasis-open.org/committees/tc_home.php?wg_abbrev=cti .
- [42] R. Piazza, J. Wunder, B. Jordan, "STIXTM Version 2.0", OASIS Committee Specification, 19 July 2017. Available <u>https://www.oasisopen.org/standards#stix2.0</u>.
- [43] J. Wunder, M. Davidson, B. Jordan, "TAXIITM Version 2.0", OASIS Committee Specification 01. Available http://docs.oasisopen.org/cti/taxii/v2.0/cs01/taxii-v2.0-cs01.html .

- [44] C. Douris, "Cyber Threat Data Sharing Needs Refinement", Lexington Institute white paper for Energy Industry, Aug 2017. Available: https://www.lexingtoninstitute.org/cyber-threatdata-sharing-needs-refinement/.
- [45] U.S. Senate. 114th Congress, (2015, Oct. 27). "The Cybersecurity Information Sharing Act". Available: https://www.congress.gov/bill/114thcongress/senate-bill/754.
- [46] T. Spring, "NSA-Backed OpenC2.org Aims to Defend Systems at Machine Speed", Threatpost, June 22, 2017. Available https://threatpost.com/nsabacked-openc2-org-aims-to-defend-systems-atmachine-speed/126454/.
- [47] J. Romano, D. Sparrell, "Open Command and Control (OpenC2) Language Specification Version 1.0", OASIS Committee Specification, 11-July-2019. Available <u>https://www.oasisopen.org/standards#oc2-ls-v1.0</u>.
- [48] D. Sparrell, "Defense at Machine Speed," Borderless Cyber USA Conference, New York, NY USA, June 21-22, 2017.
- [49] J. Hiner, "The four types of cybersecurity threats and a formula to fight them", June 22, 2017. Available: <u>https://www.techrepublic.com/article/the-4-types-of-cybersecurity-threats-and-a-formula-to-fight-them/</u>.
- [50] "OASIS Collaborative Automated Course of Action Operations (CACAO) for Cyber Security Technical Committee". Available https://www.oasisopen.org/committees/cacao/charter.php.
- [51] "The Cyber-Physical Systems Revolution" in IEEE Computing Edge, Vol. 4, No. 5, May, 2018, pp. 10-13. Available: https://www.computer.org/cms/computing-edge/cemay18-final.pdf.
- [52] R. Corrigan, "California Energy Systems for the 21st Century (CES-21)", presented at IACD Community Day, Laurel, Maryland, March 23, 2017. Available: https://drive.google.com/file/d/1NWtwUN4Uv2LFk TUdTfL5q-TfWATDgUMi/view .
- [53] J. Van Randwyk, et al., 'California Energy Systems for the 21st Centruy 2016 Annual Report", Lawrence Livermore National Laboratory, March 29, 2017. Available: <u>https://e-reportsext.llnl.gov/pdf/878504.pdf</u>.

- [54] C. Douris, "As Cyber Threats to the Electric Grid Rise, Utilities and Regulators Seek Solutions", Forbes, Jan 16, 2018. Available: https://www.forbes.com/sites/constancedouris/2018/ 01/16/as-cyber-threats-to-the-electric-grid-riseutilities-regulators-seek-solutions/#624559c1343e.
- [45] W. Peters, "IACD Overview and IACD Framework", IACD Community Day, Laurel, Maryland, 23-March-2017.
- [56] P. Royer, "Orchestration and Automation", OpenC2 Forum, 29-Sep-2016.
- [57] A. Bradbury, "OpenC2 and OrchID Using OpenC2 in a Managed Security Services Provider", OpenC2 Forum, 29-Sep-2016.
- [58] S. Yu, "*The Future of Orchestration*" Integrated Cyber, Laurel, Maryland, 1-2-May-2018.
- [59] "Symantec Integrate Cyber Defense Exchange", Symantec, 2019. Available https://www.symantec.com/content/dam/symantec/d ocs/data-sheets/integrated-cyber-defense-exchangeen.pdf.
- [60] M. Sherif, D. Sparrell, "Standards and innovation in telecommunications", Communications Magazine, IEEE Volume 30, Issue 7, Jul 1992 Page(s):22- 29.
- [61] J. Gurney, "*OpenC2 AWS Actuator*". Available: https://github.com/newcontext-oss/openc2-awsactuator .
- [62] W. Trost, "OpenC2 AWS Reference Implementation". Available: <u>https://github.com/att/openc2-aws</u>.
- [63] M. Stair, D. Hamilton, "*OpenC2 Lycan for Python*". Available: <u>https://github.com/oasis-open/openc2-lycan-python</u>.
- [64] E. Ortiz, "A Web Self Service Application for Generating OpenC2 Commands", available: https://github.com/netcoredor/openc2-cmdgen.
- [65] E. Ortiz, "GUI Tool for OpenC2 Command Generation", DefCon 26 Demolabs, Las Vegas, Nevada, 12-Aug-2018. Available: <u>https://www.defcon.org/html/defcon-26/dc-26demolabs.html</u>.
- [66] D. Sparrell, "OpenC2 API Simulator (OCAS)". Available: <u>https://github.com/oasis-open/openc2-ocas</u>.

- [67] D. Kemp, "JSON Abstract Data Notation (JADN)", Available: https://github.com/oasis-open/openc2jadn.
- [68] B. Essing, "OpenC2 Lycan for Java". Available: https://github.com/oasis-open/openc2-lycan-java.
- [69] D. Sparrell, "*OpenC2 Lycan for Beam*". Available: https://github.com/oasis-open/openc2-lycan-beam .
- USFDA, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". Available https://www.fda.gov/media/119933/download.
- [71] "Healthcare Proof of Concept", NTIA Software Component Transparency Working Group, 27-June-2019. Available https://www.ntia.doc.gov/files/ntia/publications/wor king_group_healthcare_proof_of_concept_-_2019-06-27_-_v1_002.pdf.

SESSION 8

DATA PROTECTION AND PRIVACY IN HEALTHCARE

- S8.1 Technical and legal challenges for healthcare blockchains cpf smart contracts
- S8.2 Design of a credible blockchain-based e-health records (CB-EHRs) platform
- S8.3 The GDPR transfer regime and modern technologies

TECHNICAL AND LEGAL CHALLENGES FOR HEALTHCARE BLOCKCHAINS AND SMART CONTRACTS

Steven A. Wright¹

¹Georgia State University

ABSTRACT

The paper considers the technical and legal challenges impacting recent proposals for healthcare applications of blockchain and smart contracts. Healthcare blockchain data and actors are rather different to cryptocurrency data and actors, resulting in a different emphasis on blockchain features. Technical issues with healthcare blockchain implementation and trust are considered, as well as a variety of potential legal issues. Conclusions and recommendations are proposed for open source and standardization efforts to reduce technical and legal risks for healthcare blockchains and smart contracts.

Keywords - blockchain, healthcare, legal, smart contract

1. INTRODUCTION

Blockchain's rise in popularity is usually traced from bitcoin though some antecedents exist [1]. Blockchains provide a distributed, peer-peer, linked data structure; a distributed ledger that can be used to maintain transaction order and consistency. A ledger is a book of accounts or transaction history that could be implemented in a number of ways. A blockchain can also be considered as a distributed database organized as a list of ordered, immutable blocks, where the entries in those blocks are not always transactions. The computing nodes (miners) of the blockchain sequence the blocks with timestamps and maintain integrity with each block containing a hash of the previous block. The blockchain structure maintains properties such as transparency, robustness, auditability and security [2]. While the initial bitcoin application was 'permissionless', recently applications have featured authorized use of the blockchain by trusted users. Beyond cryptocurrencies, blockchains have been proposed for applications in a number of different fields including financial, integrity verification, governance, Internet of things (IoT), health, education, privacy and security, business and industry [3]. The United Nations is also exploring options for blockchains [4]. Smart contracts

[5] are computerized transaction protocols executing contractual terms on top of the blockchain as code to minimize risk [6]. Digital Autonomous Organizations (DAOs) have been proposed as legal entities based on blockchains. Blockchain technology is evolving rapidly and some [7] refer to generations of blockchain, with Blockchain 1.0 associated with cryptocurrency, Blockchain 2.0 associated with smart contracts and Blockchain 3.0 including other application areas like health and IoT.

Blockchains are increasingly proposed as solutions in healthcare; however, technical and legal issues remain as risks for design and deployment of healthcare blockchains. One way to reduce risk and build trust in a software system is through the use of standards [8]. Though not specifically in the healthcare area, a number of standards development organizations have started work in the area of distributed ledger technologies including IEEE, ISO¹ ITU-T, W3C. Standards typically promote interoperability between complex systems. Open source software projects are also emerging that reduce risk as a complement to some traditional standardization activities [9]. Open source software can also increase the trust in a software system because the code is publicly available for inspection [10]. Open source implementations enable rapid evolution of technologies to adapt to uncertain and evolving requirements. A number of blockchain projects have open source code available and some² have initiatives focused on healthcare. Development of open source or standards takes time, but uncertainty around treatment of legal issues from accumulating legal precedent and evolution of laws and regulations in diverse jurisdictions may take longer.

The scope of healthcare blockchains is reviewed in section 2 to illustrate the variety of proposals and contrast these with cryptocurrency applications. Technical issues of particular relevance to healthcare blockchains are considered in section 3. A variety of general potential legal issues of healthcare blockchain operations are discussed in section 4. Conclusions and recommendations to reduce the technical

¹ ISO/TC 307 has a number of specifications under development including a Reference Architecture (ISO/CD 23257), Terminology (ISO/DIS 2739) and work on Smart Contract interactions (ISO/TR 23455).

² e.g. <u>https://www.hyperledger.org/resources/industries/healthcare</u>

and legal risks of healthcare blockchains are then presented in section 5.

2. HEALTHCARE BLOCKCHAINS

A variety of healthcare applications have been proposed [3],[11],[12],[13] including drug counterfeiting prevention³, clinical trials, public healthcare management, longitudinal healthcare records, automated health claims adjudication, online patient access, sharing patients' medical data, useroriented medical research, precision medicine and smart contracts to improve the credibility of medical research. Healthcare applications are being created; [14] identified nine different healthcare applications on Ethereum and two applications on Hyperledger. [15] points out that healthcare applications must balance patient care with information privacy, access, completeness and cost. The designers of healthcare information systems may have a number of different requirements associated with the systems they are designing, and the criteria for applying blockchain are not always clear [16]. Applications may be a good fit for blockchain according to [15] if: multiple stakeholders are contributing; more trust is required between parties than currently exists; an intermediary could be removed or omitted to increase trust or efficiency; there is a need for reliable tracking of activity and there is a need for data to be reliable over time. In their survey, [17] categorized healthcare blockchain application areas as clinical trials, biomedical databases, health records, medicines supply, medical insurance, wearables and embedded or mhealth, with the majority of papers on health records. [14] also noted electronic medical records as the most common area with an increasing numbers of papers. In their survey, [17] identified the following rationales for using blockchains in healthcare applications: access control, non-repudiation, data versioning, logging, data provenance, data auditing and data integrity. Access control, data integrity and logging were the most prevalent rationales. [14] identified the benefits of blockchains for healthcare applications as decentralization, improved data security and privacy, health data ownership, availability/robustness, transparency and trust, and data verifiability. The data stored in and the actors operating on a healthcare blockchain lead to some differences (c.f. cryptocurrencies) in required blockchain features.

2.1 Data in healthcare blockchains

Blockchains maintain timestamped and cryptographically signed blocks of transaction data. The data integrity mechanisms of the blockchain provide limitations in operational flexibility and governance. If the data structures and operations of the blockchain are truly immutable, then it cannot evolve to reflect the changing needs from its users and the commercial / legal environment. A blockchain is simply a distributed data structure that does not create value until it is applied in a particular economic context. In their survey, [17] categorized the health data referenced by the blockchain as financial, database queries, transaction records, ambient temperature, consent forms, clinical trial records, personal records, medical records, sensor data and/ or location data. Medical records, sensor data and personal records were the most frequently identified data categories. From 19 companies, [18] identified healthcare data being managed as electronic medical records, electronic health records, and personal health records. electronic medical records (EMRs) contain clinical data related to a specific patient stored by the responsible healthcare provider [19]. Personal health records (PHR), store data collected by patients monitoring their health conditions, using their smart phones or wearable devices [20]. Electronic health records (EHRs), for example, are designed to allow patient medical history to move with the patient or be made available to multiple healthcare providers [21]. [22] proposed a blockchain-based EHR as a mechanism to share data between PHRs and EHRs; but it did not resolve the trust and access control mechanisms required. The blockchain PHR feasibility study in [23] revealed some challenges due to the size of the data records (which impacted both the performance of the system and operational costs) as well as privacy aspects. A blockchain as a database of personalized records is likely structured significantly differently than a cryptocurrency blockchain (e.g. separate blockchains for personal records c.f. common blockchains for fungible currencies of commodities). The data lifecycle in the healthcare blockchain would depend on the use cases that are needed to support the healthcare actors.

2.2 Actors in healthcare blockchains

In considering the role of blockchain in a value chain, [24] identified the need to decide not just what valuable information to be captured in the blockchain, or what operations need to be performed by the blockchain, but also for whom the blockchain should be accruing this value. In EMR applications of blockchains, as an example, the value of the recorded data in the blockchain is not intrinsic; rather it comes from the association with a particular user e.g. a patient or a medical practitioner. As a result, the transactions adding data to the blockchain are most likely not anonymous transactions as in bitcoin; rather using the hash as an electronic signature to establish the provenance of the data. While medical actors may have need of the broader range of

³ The Drug Supply Chain Act (DSCSA) of 2013 requires the Food and Drug Administration (FDA) to develop standards and regulations for an interoperable electronic system to identify and trace medications. A number of pilot projects for this purpose have been developed using blockchain technologies (https://www.drstevenawright.com/pharmaceutical-supply-blockchains/).

blockchain applications such as those identified by [3], in this paper the focus is on application areas that are uniquely related to healthcare, rather than application areas like payments for services by bitcoin that may be broadly applicable across a number of industries. [25] identified the major stakeholders in digital health systems as patients, the public, healthcare professionals and health administrators; however, regulatory agencies and legal systems may also need to be able to operate on or interact with the healthcare blockchains. Provisions would also be needed for minors, access under a healthcare power of attorney, and in some cases access after death by heirs.

3. TECHNOLOGY ISSUES

Technology issues can be seen as risks impeding design and deployment of healthcare blockchains. Ethereum and Hyperledger were the most frequently mentioned blockchain implementation technologies, found by [17] but only 2% of the papers surveyed were reporting on implementations, so healthcare blockchains are still at the early stages of adoption. There is not one blockchain but a variety of implementations with different characteristics [26],[27] (even bitcoin has forked). Identified technology challenges to the development of healthcare blockchains include interoperability, security and privacy, scalability, speed and patient engagement [14]. Interoperability, scalability and speed are characteristics of the software implementation of healthcare applications on the blockchain. The degree of patient engagement can be significantly impacted by not just the implementation and trust issues, but also the usability of the system and the overall user experience with the healthcare blockchain. Security, privacy and trust issues reflect concerns about not just the implementation, but the processes for assuring the users can trust the blockchain and its associated software, as well as the organizational and legal context. [28] points out that health information technology in general needs to consider not just clinical information, but also sociotechnical concepts of value and trust concepts to be successful.

3.1 Implementation issues in healthcare blockchains

Healthcare blockchain applications, whether directly on the blockchain, or smart contracts or DAOs, are all software; and software bugs impact the functionality and quality of blockchain systems. [29] performed an empirical study of over one thousand bugs identified from 19 open source blockchain systems categorizing them and studying their resolution to determine that the frequency distributions of bug types share similar trends across the studied projects, implying that these would apply to healthcare blockchain applications also. They noted that security bugs took the longest median time to fix and that more than 35% of performance bugs took more than a year to fix. While not providing specific metrics, [30] identified dimensions for the quality of blockchain implementations as including security, privacy, throughput, size and bandwidth, performance, usability, data integrity and scalability. [31] surveyed the performance characteristics of six different blockchains against dimensions of time to achieve consistency, system availability, failure tolerance, scalability, latency, auditability, liveliness, denial of service resistance and system complexity. Standardized benchmarks and targets for healthcare blockchain performance have not yet been identified.

Software engineering has developed tools and methods to support the development and operation of software systems, but to date these are not optimized for blockchain systems. [32] identifies the features and implementation challenges of interoperability for healthcare blockchain applications and proposes foundational software patterns to help address them. [33] identifies blockchain oriented software engineering challenges as new professional roles, security and reliability, software architecture, modeling languages and metrics, and proposes new directions for blockchain oriented software engineering related to enhancement of testing and debugging for specific programming languages and the creation of software tools for smart contract languages. [34] echoes the call for further development of blockchain oriented software engineering best practices and design patterns.

3.2 Identity and trust issues in healthcare blockchains

Many of the benefits (e.g. improved data security and privacy, health data ownership, transparency and trust, data verifiability, non-repudiation, data provenance) sought from healthcare blockchains rely on some form of trust. To achieve their healthcare objectives, patients need to trust healthcare providers. Patients and healthcare professionals need to trust the validity of data used for diagnosis and treatment. Trust has been defined in many different ways by different researchers. [35] proposed an interdisciplinary model of trust involving components for disposition to trust, institution-based trust, trusting beliefs and trusting intentions. Since literally everyone is potentially a patient, and patients are actors in most healthcare blockchains, addressing all of those trust components may be necessary for the broad adoption of healthcare blockchains; not all of them, however, are directly solved by blockchains. Disposition to trust and institution-based trust lie more in the realm of psychological, sociological and economic concepts. Trusting beliefs and intentions may be more manageable for healthcare blockchains that are explicit about what actors can rely on and for what purposes in the healthcare blockchain use cases.

Because of the use of blockchain technology in the financial industry, and the associated loss risks, the security of blockchains and related smart contracts have received significant attention. In a survey on the security of blockchain systems [36] proposed a taxonomy of the targets of security attacks. For Blockchain 1.0 (cryptocurrency) blockchains the targets were the blockchain consensus mechanism, the public key encryption scheme, the cryptocurrency application criminal activity (e.g. money laundering ransomware), the transaction verification mechanism, and transaction design flaws that could lead to privacy leakage. For Blockchain 2.0 (smart contract) blockchains, the targets were the smart contract application (criminal smart contracts), program design flaws, program implementation flaws, smart contract virtual machine (e.g. Ethereum Virtual machine) design flaws. These same components would be risks for healthcare blockchains, though the incentives for exploitation would be different than for fungible commodities or currencies.

[31] analyzed six types of blockchains to identify the mechanisms that they used to implement traditional of information security principles confidentiality, information availability, integrity, non-repudiation, provenance, pseudonymity and selective disclosure, with confidentiality and selective disclosure being the least supported principles. Data security and privacy, however, have been identified as key objectives for healthcare blockchains, and the lack of support for these features would reduce trust in these systems. Confidentiality features can be built on top of the blockchain using smart contracts. [37] proposed a system for sharing medical records using permissioned blockchains for access control and smart contracts for monitoring and logging access violations but did not encrypt the underlying records for confidentiality. [38] proposed a mechanism for secure storage of medical records for use with blockchains. Most blockchains require some entity in the role of a "miner" to maintain the operation of the blockchain through consensus decisions for blockchain consistency, blockchain checkpointing, etc. but simple blockchains do not assure confidentiality of blockchains during mining operations. While basic blockchain functionality excels at assuring integrity, additional capabilities (different to cryptocurrencies) will likely be required to monitor and assure actors' requirements for confidentiality and selective access. Confidentiality and privacy considerations in healthcare use cases may require additional emerging crypto-technologies to enable patients' control of their data.

4. LEGAL ISSUES

Legal issues can be seen as risks impeding design and deployment of healthcare blockchains. Legal systems have geographic boundaries, but the distributed nature of blockchains can cross those boundaries. Participants in blockchains that cross the boundaries of different legal systems may be subject to foreign jurisdiction. Both the legal system and blockchains can promote trust or undermine it. [39] notes that blockchain can act as supplement, complement or substitute for the law. Where the existing trust architecture is generally functional, the blockchain application can act as an additional (supplementary) layer subject to established legal rules, e.g. by enhancing existing messaging or transaction systems with authenticated messages or transactions. Where the existing trust based on the legal system is insufficient or breaking down, then the distributed ledgers of the blockchain could complement and extend the existing trust architecture. As an example, if the data contained or referenced in the blockchain record is protected by some form of intellectual property a smart contract associated with the blockchain could provide an automated market for efficiently licensing such content. Where the blockchain acts as a substitute for the law, there is no backstop of traditional legal enforcement. This may be attractive in regions where there is no rule of law, or legal enforcement is weak. As an example of a substitute, the UN conducted a successful trial using blockchain to track food aid to refugees [40]. The challenge for such systems is the human actors interfacing with the blockchain system, and their incentives (or the lack of them) for participation.

4.1 Legal entities in healthcare blockchain architectures

The law covers relations among people and the things they own. At least since the industrial revolution, the law will consider human beings (or other legal persons) responsible for their machines' acts. While blockchains may be more secure than other approaches, courts can apply existing legal mechanisms to decide which parties bear the losses and responsibility for damages. Legal risks do not vanish if healthcare services are provided or supported through blockchains and smart contracts, etc. Whether DAOs could eventually rise to the status of a legally recognized person remains to be seen.

The actors that control the governance of the blockchain are not necessarily those using the blockchain. Disruptive evolution could strand users on an unsupported fork of the blockchain. The Ethereum and Hyperledger blockchain systems used in a number of healthcare blockchain applications are both open source projects that have some form of governance through the open source community; open source, however, is a gift economy which may be challenged to timely respond to some users' needs for evolution and support of the blockchain. Private blockchains whether organized for profit, or as non-profit consortiums can provide an entity to control the evolution of the private blockchain, but at the cost of centralizing the function on that entity (e.g. what happens if that entity fails?). Decred⁴ and Tezos⁵, in contrast, build in governance mechanisms for evolution of their blockchains.

A healthcare blockchain application could rise to the level of a smart contract; with autonomous (workflow) actions triggered by transactions as programmed in the terms of the smart contract running on the blockchain. A regular contract would identify the parties involved and their roles or actions required as part of the contract and similarly a smart contract defines the actors and roles associated with the contract. [41]. While the roles and responsibilities of actors in a smart contract can be changed at design time, they cannot be changed during operation. The entities designing the smart contract may not be the same as those creating instances of

^{4 &}lt;u>https://decred.org</u>.

⁵ <u>https://tezos.com</u>.

the smart contract; nor supporting the execution environment of that smart contract. The parties are identified with their blockchain accounts and transactions record obligations fulfilled under the smart contract. Smart contracts can replace error-prone human judgements with specific rulebased actions capturing best practices and by automating workflows eliminate the need for acknowledgements by healthcare professionals [42].

Perhaps inspired by Barlow's declaration of the independence of cyberspace [43], the decentralized, anonymous and autonomous nature of some early blockchain implementations lead to proponents of DAOs which purported to have the operating software of the blockchain be an independent legal entity. Other automated trading systems have made automated transactions on behalf of their account owners for some time, but here the software itself was purported to be the account owner. The law has a history of recognizing fictitious entities (e.g. corporations). Ownerless corporations have been proposed almost 30 years ago [44] and the enabling acts of several states would seem to permit zero-member LLCs [45] though such entities would raise a number of social and political concerns [46]. An early implementation of a DAO based on bitcoin did not fare well [47]. Despite efforts to transition governmental services to electronic form, from service of process to judgement enforcement a purely software entity would be difficult to interface with a human and paper-driven legal system.

Distributed ledger technologies could be considered by courts in several legal systems as joint ventures or partnerships between participants [48]. If a partnership were determined to exist, then joint and several liability would extend to all the partners. Joint and several liability means the plaintiffs can collect any damages award from any one of a group of partners. The extent of the partnership would be determined by the court given the facts and circumstances of the case.

4.2 Public law

Because blockchain technology is relatively new, there is not yet a lot of blockchain specific laws and regulation in place, and what there is has been driven by cryptocurrencies rather than healthcare blockchain applications. Blockchain related legislation is under consideration in a number of states⁶.Arizona explicitly recognized electronic signatures secured by blockchains as valid signatures and defined smart contracts secured through blockchains as valid electronic records. A.R.S §44-7061 defines a smart contract as: "an event-driven program, with state, that runs on a distributed, decentralized, shared and replicated ledger and that can take custody over and instruct transfer of assets on that ledger". Delaware enacted legislation (D.C. §8-224) enabling corporations to use distributed ledgers to maintain their share ownership registry. Vermont (12 V.S.A. § 1913) explicitly identified blockchain records as being admissible as evidence in court. Wyoming (§17-206) exempts open blockchain tokens from registration as securities in contrast with views from regulatory agencies like CFTC and SEC treating cryptocurrencies as securities or commodities. While healthcare data may not seem like a commodity or security, healthcare blockchain advocates may need to care whether emerging regulatory language is over-inclusive.

Much of the existing legal precedents are based on criminal behavior around blockchain 1.0 cryptocurrency/ fintech, but the data underlying healthcare blockchains is not a fungible financial asset. Market participants involved in distributed ledger systems like blockchain also must keep in mind conduct-related legislation implementing public policy including Antitrust, data protection, copyright, property and tax, but, in comparison with cryptocurrencies, these areas are not anticipated to be of particular concern for healthcare blockchains.

The recent European Union General Data Protection Regulation (GDPR) creates additional legal protections for personal information in general, and other jurisdictions may be considering similar regulations. Blockchains operated within the scope of those regulations may need additional design features to meet the GDPR requirements [49]. Beyond general data privacy regulation, healthcare blockchains and smart contracts would be impacted by healthcare specific regulations (e.g. HIPPA [50] which has obligations for data privacy in contrast with many blockchain implementations that rely on a publicly visible blockchain).

Consider a healthcare smart contract executing on a blockchain accepting data from an oracle reporting on a physiological condition through a smart phone, making some analysis of the data and reporting exceptional health conditions as an alarm to a healthcare professional. The definition of a medical device [51] is sufficiently broad that this healthcare smart contract could be considered a medical device and subject to medical device regulation. An error in such a smart contract medical device could create product liabilities.

4.3 Private law

Private law differs in different legal systems, but generally liabilities can arise through contracts, torts, partnerships or specific legislation. Tort claims are particularly important where there is no contractual liability. Joint tortfeasors are two or more individuals with joint and several liability in tort for the same injury to the same person or property. Whether healthcare smart contracts implemented on blockchain

⁶ http://www.ncsl.org/research/financial-services-and-commerce /the-fundamentals-of-risk-management-and-insurance-viewedthrough-the-lens-of-emerging-technology-webinar.aspx.

would be recognized as legitimate contracts would depend on the facts and circumstances in a particular jurisdiction, but it appears that some jurisdictions may recognize smart contracts as legally binding [52] [53]. Contract law typically recognizes a contract established through a variety of different mechanisms (implied agreements, click through licenses etc.), however currently, there is not a lot of specific legislation, regulation or legal precedent related to smart contracts. In the case of a private blockchain, there may be a number of ancillary documents that users of the blockchain may be required to agree to before using the service that can establish the legitimacy of the legal effect desired by the smart contract terms.

Smart contracts are good at setting forth, *ex ante*, the anticipated conditions and consequences and then ensuring the consequences occur upon fulfillment. Legal contracts are good at cleaning up the mess *ex post*, when, inevitably, things do not go according to plan [39]. Smart contracts, as proposed by Szabo, have no explicit linkage between the smart contract and any external legal contracts; Ricardian contracts explicitly link them [54]. Many smart contracts need to interface with the outside world for information and those external data sources are called oracles. Oracles can be humans though perhaps more typically some external entity makes its data feed available to the smart contract.

Smart contracts can include "self-help" enforcement mechanisms where breaches of the contractual terms can be identified, and remedies enforced, through execution of the smart contract [55]. The completeness of such approaches is one concern (e.g. did the parties identify all the possible ways in which the contract could be breached; can they agree on reasonable valuations for liquidation of the damages if the form of the breach is not foreseen). Another concern arises when the contract is impacted by external events not foreseen in the contract terms (e.g. a bankruptcy stay that impacts a blockchain transaction, frustration or force majeure). Courts may void contracts that exceed the limits of contract law, e.g. if the contract is unconscionable or violates some public policy. Smart contracts would not provide mechanisms to escape the limits of contract law. Blockchains have been hacked and forked which can impact the owners of assets administered by the blockchain. Smart contracts may be better positioned than the legal system to respond to such events assuming that they are foreseeable and detectable.

Smart contracts and oracles have been proposed as a mechanism for dispute resolution with courts or private actors interfaced with the smart contract [56]. More speculative and controversial approaches would be to use a computational mechanism for dispute resolution. The DAMN proposal [57] envisions a dispute resolution smart contract because arbitration is often easier to enforce internationally than local court decisions. Prediction markets have also been proposed for smart contract dispute resolution

(see e.g. [58] using the wisdom of the crowd rather than arbitrators, but ethical issues may limit the applicability of this approach in healthcare smart contract disputes. While legislation typically directs courts to respect private arbitration decisions, such legislation might need extensions to support dispute resolution by smart contracts.

5. CONCLUSIONS AND RECOMMENDATIONS

Emerging technologies often present a challenge or gap between technology advancements and the law. The gap creates uncertainty that limits commercial investments and adoption of the technologies. The gap can be closed from both sides, by designing technological solutions considering existing legal issues and/or by changing legal or regulatory regimes to consider aspects of the technology solutions. Open source and standards can help eliminate some barriers to wider deployment.

Many of the technological risks of blockchain implementations are not unique to healthcare use cases. Healthcare specific blockchain design patterns and performance benchmarks may eventually emerge through the open source communities as the healthcare use cases evolve. Evolution of blockchain capabilities and design patterns to support confidentiality and selective disclosure may be particularly helpful for healthcare applications. The blockchain work on zero knowledge proofs (e.g. zcash) and privacy preserving computation (e.g. [59]) seem promising directions.

While the evolution of public law and regulation will typically wait for action by deliberative bodies, private law related to contracts may be more amenable to innovative approaches from open source and standards. [39] identified safe harbors and sandboxes as well as modularization or standardized terms in smart contracts as legal initiatives to reduce risk in blockchain adoption. Healthcare is typically a regulated industry and the creation of safe harbors or sandboxes for healthcare blockchain applications would typically require actions by regulatory agencies. There are already examples of regulatory agencies such as the FDA experimenting with blockchain technology to build expertise [60].

Contracts are private law, and as lawyers build expertise in particular transactions, they typically reuse standard terms that experience has indicated as being enforceable to meet their objectives. Standardized forms may be used for particularly common transactions. Several consortia and commercial entities and standards bodies⁷ are working on standardized terms for smart contracts though these seem to be focused on commercial transaction terms rather than healthcare transactions and processes should facilitate the development of smart contracts could be designed to include dispute resolution

⁷ See e.g. OpenLaw, Clause.io, Agrello, ISO TC 307.

clauses, but standardized smart contract support for [12] confidentiality and selective disclosure (e.g. access logging) may be more tractable in the near term.

Reducing risks to design and deploy healthcare blockchains and smart contracts will require different approaches for the different types of risk. Interoperability risks can be reduced through the development of standardized data formats for the secure interchange of different types of health records. This [14] may not be the first risk to tackle though as it assumes there are existing systems that needs to interoperate. The security toolbox already provides a number of mechanisms to support [15] fine grained distinctions in authentication and authorization to support the privacy and security requirements of healthcare blockchains, though the specific use cases and role definitions may still be evolving. Reducing legal uncertainties may be a ^[16] longer process due to the timescales required to accumulate legal precedents or evolve laws and regulations through consensus mechanisms. Private law arrangements can provide [17] some protections while public laws evolve.

6. **REFERENCES**

- A. Narayanan, "Bitcoin's Academic Pedigree," Comm. of the ACM, vol. 60, no. 12, pp. 36-45, 2017.
- [2] K. Christidis, et. al. "Blockchains and smart contracts for the internet of things," *IEEE Access*, vol. 4, pp. 2292-2303, 2016.
- [3] F.Casino, "A systematic literature review of blockchainbased applications: Current status, classification and open issues," *Telematics and Informatics*, vol. 36, pp. 55-81, 2019.
- [4] UN, "Global Opportunity Explorer," 2019. <u>https://www.unglobalcompact.org/docs/publications/GOE</u> <u>2019 Insights.pdf</u>.
- [5] N. Szabo, "Smart Contracts", Virtual School, 1994
- [6] N. Szabo, "The idea of smart contracts", Nick Szabo's papers and concise tutorials Vol. 6, 1997
- [7] M. Swan, "Blockchain: Blueprint for a new economy", O'Reilly Media, Inc., 2015.
- [8] D. Osterwalder, "Trust Through Evaluation and Certification?," Soc. Science Comp. Rev., vol. 19, no. 1, pp. 32-46, 2001.
- [9] S.Wright, et., al., "Open source and standards: The role of open source in the dialogue between research and standardization." *IEEE Globecom Workshops 2014*.
- [10] Y. Ho, "Trust and distrust in open source software development.," J. of Comp. Inf. Sys., vol. 54, no. 1, pp. 84-93, 2013.
- [11] S. Angraal, et.al,"Blockchain technology: applications in health care." *Circulation: Cardiovascular quality and outcomes* 10.9 (2017): e003800.

T-T.Kuo, et .al."Blockchain distributed ledger technologies for biomedical and health care applications." *J. of the Am. Med. Informatics Assn.* 24.6 (2017): 1211-1220.

- [13] M. Mettler, "Blockchain technology in healthcare: The revolution starts here." *18th Int'l Conf. on e-Health Networking, App. and Serv. (Healthcom).* IEEE, 2016.
- 14] C.Agbo, et.al.,"Blockchain Technology in Healthcare: A Systematic Review," *Healthcare*, vol. 7, no. 56, 2019.
- 15] M. Englehardt, "Hitching healthcare to the chain: An introduction to blockchain technology in the healthcare sector.," *Tech. Innovation Mgmt Rev.*, vol. 7, no. 10, 2017.
- 16] S. Lo, "Evaluating Suitability of Applying Blockchain," in IEEE Int'l Conf. on Engg. of Complex Comp. Sys., 2017.
- 17] G.Drosatos, et. al., "Blockchain Applications in the Biomedical Domain: A Scoping Review", *Computational* and Structural Biotech. J., Vol 17, pp 229-240, 2019
- [18] D.Dimitrov, "Blockchain Applications for Healthcare Data Management," *Healthcare Information Res.*, vol. 25, no. 1, pp. 51-56, 2019.
- [19] M.Steward, "Electronic Medical Records," J. of Legal Medicine, vol. 26, no. 4, pp. 491-506, 2005.
- [20] P. Tang. et.al, "Personal Health Records: Definitions, Benefits, and Strategies for Overcoming Barriers to Adoption," J. of the American Medical Informatics Assoc., vol. 13, no. 2, pp. 121-126, 2006.
- [21] K. Hayrinena, et.al., Impacts of Electronic Health Records: A Review of the Research Literature,," *Int'l J. of Medical Informatics*, vol. 77, no. 5, pp. 291-304, 2008.
- [22] C.Esposito, et.al., "Blockchain: A Panacea for Healthcare Cloud-Based Data Security and Privacy?," *IEEE Cloud Computing*, vol. 5, no. 1, pp. 31-37, 2018.
- [23] Y. Park, et.al.,"Is Blockchain Technology Suitable for Managing Personal Health Records? Mixed-Methods Study to Test Feasibility," *J. Med. Internet Res.*, vol. 21, no. 2, pp. 1-8, 2019
- [24] T.Felin,et.al., "What problems will you solve with blockchain?," *MIT Sloan Mgmt Rev.*, Fall, pp. 32-38, 2018
- [25] A. Adjekum, et.al.,"Elements of Trust in Digital Health Systems: Scoping Review," J. Med. Internet Res., vol. 20, no. 12, 2018
- [26] M. Macdonald, M., et.al. "The blockchain: a comparison of platforms and their uses beyond bitcoin." COMS4507-Adv. Computer and Network Security(2017).
- [27] T-T. Kuo, et.al. "Comparison of blockchain platforms: a systematic review and healthcare examples." J. of the Am. Med. Informatics Assn. 26.5 (2019): 462-478.

- [28] M. Wong, et.al., "Socio-Technical Considerations for the Use of Blockchain Technology in Healthcare," *Studies in Health Tech. and Informatics*, vol. 247, pp. 636-640, 2018.
- [29] Z.Wan, et.al., "Bug characteristics in blockchain systems: A largescale empirical study," in *IEEE/ACM 14th Int'l Conf. on Mining Software Repositories (MSR)*, 2017.
- [30] B. Koteska, et.al., "Blockchain Implementation Quality Challenges: A Literature Review," in 6th Workshop on Software Quality, Analysis, Monitoring, Improvement, and Applications, 2017.
- [31] A. Anjum, et.al.,"Blockchain standards for compliance and trust.," *IEEE Cloud Computing*, vol. 4, no. 4, pp. 84-90, 2017.
- [32] P.Zhang, et.al.,"Applying Software Patterns to Address Interoperability in Blockchain-based Healthcare Apps," arXiv preprint arXiv:1706.03700, 2017.
- [33] S.Porru, et.al., "Blockchain-oriented Software Engineering: Challenges and New Directions," in *IEEE/ACM 39th Int'l Conf. on Software Engg.*, 2017
- [34] G. DeStefanis, "Smart contracts vulnerabilities: a call for blockchain software engineering?," in *IEEE Int'l* Workshop on Blockchain Oriented Software Engg., 2018.
- [35] D. McKnight, et.al.,"What is Trust? A Conceptual Analysis and an Interdisciplinary Model," in AMCIS 2000 Proc., 2000.
- [36] X.Li, et.al. "A Survey on the Security of Blockchain Systems," in *Future Gen. Computer Systems*, 2017.
- [37] Q.Xia, et.al., "MeDShare: Trust-Less Medical Data Sharing Among Cloud Service Providers via Blockchain," *IEEE Access*, vol. 5, pp. 14757-14767, 2017.
- [38] Y. Chen, et.al., "Blockchain-based medical records secure storage and medical service framework," J. of Medical Systems, vol. 43, no. 1, 2019.
- [39] K. Werbach, "Trust, but Verify: Why the Blockchain Needs the Law," *Berkeley Technology Law J.*, vol. 33, no. 2, pp. 487-550, 2018.
- [40] L. Cuen, "UN Using Blockchain Technology to Help Refugees, Fight World Hunger," *Int'l Bus. Times*, 4 May 2017.
- [41] I. Karamitsos, et.al., "Design of the Blockchain Smart Contract: A Use Case for Real Estate," *J. of Information Security*, vol. 9, pp. 177-190, 2018.
- [42] P.Cuccuru, "Beyond bitcoin: an early overview on smart contracts.," *Int'l J. of Law and Information Technology.*, vol. 25, pp. 179-195, 2017.
- [43] J. Barlow, "A Declaration of the Independence of Cyberspace," Electronic Frontier Foundation, [Online]. Available: <u>https://perma.cc/SF3L-Y7PX</u>.

- [44] K. Iwai, "Persons, Things and Corporations: The Corporate Personality Controversy and Comparative Corporate Governance," AM. J. COMP. L., vol. 49, pp. 583-600, 1999.
- [45] S.Bayern, "Of Bitcoins, Independently Wealthy Software, and the Zero-Member LLC," *Northwestern U. Law Rev.*, vol. 108, pp. 257-270, 2014.
- [46] L. Lopucki, "Algorithmic Entities," Washington U. Law Rev., vol. 95, no. 4, pp. 887-953, 2018.
- [47] Q. DuPont, "Experiments in Algorithmic Governance: A history and ethnography of 'The DAO,' a failed Decentralized Autonomous Organization.," in *Bitcoin and Beyond: Cryptocurrencies, Blockchains and Global Governance*, Routledge, 2017.
- [48] D. Zetsche, et.al. "The distributed liability of distributed ledgers: Legal risks of blockchain.," *U. Ill. L. Rev.*, 2018.
- [49] M.Beberich, et.al., "Blockchain Technology and GDPR-How to reconcile privacy and distributed ledgers.," *Eur. Data Prot. L. Rev.*, no. 2, p. 422, 2016
- [50] B.Fiedler, "Challenges of New Technology: Securing Medical Devices and Their Software for HIPPA Compliance.," in *Managing Medical Devices Within a Regulatory Framework*, Elsevier, 2017, pp. 315-329.
- [51] World Health Organization, "Medical device regulations: global overview and guiding principles," 2003.
- [52] K. Lauslahti, "Smart Contracts How will Blockchain Technology Affect Contractual Practices?," ETLA Reports No 68, 2017.
- [53] A. Savelyev, "Contract law 2.0: Smart'contracts as the beginning of the end of classic contract law," *Information & Communications Technology Law*, vol. 26, no. 2, pp. 116-134, 2017.
- [54] I. Grigg, "The Ricardian Contract," in *Proc. 1st IEEE* Workshop on Electronic Contracting, 2004.
- [55] M. Raskin, "The Law and Legality of Smart Contracts," *Georgetown Law and Tech. Rev.*, vol. 1, no. 2, pp. 305-341, 2017.
- [56] A. Wright, et.al., "Decentralized Blockchain Technology and the Rise of Lex Cryptographia," 2015. [Online]. Available: <u>https://perma.cc/3YUP-PNM4</u>.
- [57] P. Morgan, "Decentralized Arbitration and Mediation Network (DAMN)," 23 May 2016. [Online]. Available: <u>https://github.com/thirdkey-</u> solutions/damn/blob/master/proposal.asciidoc
- [58] A. Koulu, "Blockchains and Online Dispute Resolution: Smart Contracts as an Alternative to Enforcement," *SCRIPTed - A J. of Law, Tech. & Soc.*, vol. 13, no. 1, pp. 40-69, 2016.

- [59] A. Kosba, et al. "Hawk: The blockchain model of cryptography and privacy-preserving smart contracts." *Symp. on Security and Privacy*. IEEE, 2016.
- [60] J. Scott, "Booz Allen Hamilton Helps FDA Test Healthcare Blockchain Technology," Govcon Wire, 26 June 2018.

DESIGN OF A CREDIBLE BLOCKCHAIN-BASED E-HEALTH RECORDS (CB-EHRS) PLATFORM

Lingyu Xu¹; Antoine Bagula¹; Omowunmi Isafiade¹; Kun Ma¹; Tapiwa Chiwewe²

¹University of the Western Cape ²IBM Research Africa

ABSTRACT

With the rapid development of electronic health care, the era of medical big data has already emerged. However, in the global electronic health industry environment, one of the significant challenges is that the various medical institutions are independent of one another. Patients, doctors and medical researchers have significant barriers in accessing medical data. As an intervention strategy using blockchain principle, this paper explores the characteristics of blockchain which are applicable to the management of electronic health records (EHRs), and presents a credible blockchain-based electronic health records (CB-EHRs) management platform. A CB-EHRs platform is characterized by decentralization, data tamper-proof, collective maintenance mechanisms, security and credibility. This platform cannot only realize data sharing between medical institutions, but also ensures the privacy of users. This paper introduces the components of the CB-EHRs platform model and the implementation principle of its related functions. In addition, this paper also reviews and selects the delegated Byzantine Fault Tolerance (dBFT) consensus mechanism as a viable option for the CB-EHRs platform. Finally, by comparing with the Practical Byzantine Fault Tolerance (PBFT) consensus mechanism and our research, we highlight the potential advantages of our proposed *CB*-*EHRs* platform in the medical domain.

Keywords - Blockchain, CB-EHRs, data sharing, electronic health records, privacy protection

1. INTRODUCTION

In recent years, various electronic information technologies have penetrated daily human life, such as cloud computing, Internet of things and internet technologies. Hence, the era of globalized big data has emerged [1]. Furthermore, with the rapid development of medical and health services, a large amount of medical data is generated on a daily basis, which confirms a necessity for electronic health records (EHRs) technology. EHRs is an electronic version of a patients medical history. So far, most EHRs are managed by an EHRs platform belonging to an independent medical institution. Moreover, an EHRs platform also promotes data-driven decision support in healthcare, for example, through data mining [2, 3]. While the spread and use of EHRs across the globe have not been fully realized, EHRs is now becoming



Figure 1 – An assessment of the use of EHRs between 2012 and 2016 [5]

inevitable for most, if not all, medical practitioners [4]. In a EHRs study conducted in 2016 [5], researchers examined 15,285 physicians in 28 different departments. Figure 1 present an overview of the result of their study. The goal of the research was to know the extent to which the EHRs system is utilized, score of EHRs system, satisfaction levels, impacts on doctors' daily routines and doctor-patient communication. Overall, the acceptance and use of the EHRs system have dramatically changed since 2012 as seen in Figure 1. More than 91% respondents indicated that they are using EHRs, compared with a 74% rate observed in 2012. In addition, 2% of the respondents said that they are in the process of installing EHRs, and 3% plan to buy or use EHRs in the coming year. This means that almost every medical practitioner will use EHRs in the near future. Considering the outcome of this study, it is clear that the shift from a paper-based structure to electronic-based records is rapidly evolving. In the current age, only a few doctors can operate effectively and efficiently without EHRs.

While it is widely recognized that an EHRs platform is an inevitable technology platform in the medical domain, there are still a number of challenges that need to be tackled in this domain, in order to promote its use in the near future. Such challenges include, but are not limited to: (i) difficulty in data sharing; (ii) trust and (iii) privacy concerns. Hence, as a way of intervention and by leveraging the principles of blockchain technology, this paper presents a credible blockchain-based electronic health records (CB-EHRs) management platform. CB-EHRs platforms are

designed to promote EHRs' successful development and sustainability across the globe. This paper revisits the issue of healthcare management to describe the design of a credible blockchain-based e-health records (CB-EHRs) platform and its performance evaluation. The proposed platform can be used to secure transactions through anonymity and traceability of health data in cyber-healthcare systems, such as those proposed in [6-10].

The rest of the paper is structured as follows: section 2 presents related study on blockchain and a summary of challenges in the EHRs platform, highlighting the gaps and opportunities that have been identified in the current system. The key contribution of this paper is described in sections 3 and 4, detailing the components and related functions of the proposed CB-EHRs. Section 5 details the performance of the choice consensus algorithm. Finally, section 6 concludes the paper and presents a possible extension to the CB-EHRs platform.

2. BLOCKCHAIN-BASED RELATED WORK AND CHALLENGES OF EHRS PLATFORM

This section presents an expository detail on blockchain, the challenges of EHRs, and related research on blockchain-based EHRs. The section concludes by highlighting the contribution of CB-EHRs platform proposed in this paper.

2.1 Challenges of EHRs platform

The EHRs platform is widely recognized as an enabling platform, which promotes telemedicine in the current technology age [11]. However, despite its wide acceptance and use, there are some challenges that remain pertinent to the platform. Some of the known key challenges are:

- Difficulty in medical data sharing: In order to advance medical research and facilitate patients, researchers are committed to the sharing of medical data. At present, there are some trust issues among medical institutions around the world. Hence, the verification, synchronization and storage of medical data are hindered. When medical institutions and patients share data, they need to spend a lot of time and resources on identity and data validation. This makes medical data transmission is not secure and data can be tampered with. All of these challenges seriously hinder the development of medical big data and electronic healthcare systems.
- Information security and privacy protection concerns: Firstly, there is no complete scheme of medical privacy protection in the electronic medical industry [13]. Secondly, big data mining technology has potential risks of linkage attacks, which attempt to re-identify individuals in an anonymized data set by merging information from two or more datasets. Thirdly, the user does not fully participate in the access control policy of the electronic health record [14, 15]. However, more and more personal health information is now being

added to the Internet due to the growing popularity of EHRs, medical genetic sequencing and wearable medical devices. Therefore, the protection of user privacy and medical information security becomes more urgent and important.

2.2 Blockchain-based EHRs related research

In order to address the aforementioned problems, many researchers have proposed relevant solutions through strategy research, architectural frameworks and model designs [16-For example, in 2011 Sebastian Haas [16] et 18]. al. proposed a privacy protection system based on data services and patient service models. Yarmand et al. [17] in 2013 proposed a behavior-based access control for a distributed healthcare model to solve the user's privacy problem. Recently, with the development of blockchain technology, blockchain has not only been used in the financial industry, but has also been adopted as a protective mechanism in the medical domain. In 2016, Drew Ivan [18] proposed a blockchain approach to securely store patient medical records. While the above-mentioned models used blockchain technology to facilitate data sharing and privacy protection, the framework it adopted presents a large amount of network resource wastage or consumption. For users who need treatment, functionalities of these models are not complete and need to be improved. Hence, this research presents a credible blockchain-based electronic health records (CB-EHRs) management platform, which is characterized by decentralization, data tamper-proof, collective maintenance mechanisms, security and credibility. This platform cannot only realize the capabilities of medical data sharing, but also ensures the privacy of users.

3. BLOCKCHAIN TECHNOLOGY

3.1 The concept of blockchain

There are two basic definitions of blockchain [19, 20]. In a narrow sense, blockchain is a non-tampered and unforgeable distributed ledger that uses cryptographic correlation algorithms. It is a chained data structure that links data blocks together in time order [19]. Broadly speaking, blockchain technology refers to a new distributed infrastructure and computing paradigm which is built on a peer-to-peer network. It uses a chained data structure to validate and store data, a distributed node consensus algorithm to generate and update data, and a cryptography mechanism to protect data transmission and access security [20]. Alliance chain (adopted in this paper): In an alliance blockchain, the consensus process is controlled by preselected nodes. Only alliance members have permissions to read and write the blockchain [21]. This type of blockchain can be seen as "partially decentralized".

3.2 PKI and digital signature

The comprehensive technology required to provide public-key encryption and digital signature services is known

as a public-key infrastructure (PKI) [22]. The basic idea of applying PKI to the EHRs platform is to have the trusted user digitally sign documents certifying that a particular cryptographic key belongs to a particular user. The EHRs platform in the Internet brings convenience to users, but it also increases the possibility of privacy leaks. Using the PKI to generate a public key and identity identifier for him/her during the user registration process. Users are active and authenticated in the EHRs platform in this particular state. This approach not only ensures the user's legal identity but also protects the user's privacy. The purpose of PKI is to manage keys and certificates.

Digital signature, also known as public key digital signature [23], usually defines two corresponding operations, one for the signature (private key) and the other for the authentication (public key). The process of signing is as follows. First, the sender uses the hash algorithm to obtain a digital abstract, and the signature private key encrypts the digital abstract to obtain a digital signature. The original text and the digital signature will be sent to the recipient together. The receiver then verifies the signature by decrypting the digital signature with the sender's public key to obtain a digital abstract. The receiver will use the same hash algorithm to get a new digital abstract and compare the two abstracts. If the two match, the digitally-signed electronic file is successfully transmitted.

3.3 Consensus mechanism

Consensus refers to the process by which network nodes adhere to a common rule and achieves consistent results for certain problems through asynchronous interaction. The consensus mechanism in the blockchain is mainly used to make the network nodes agree on block generation and benefit distribution. The major difference between different blockchain networks comes from the difference in consensus mechanisms. Therefore, the characteristics and performance of different blockchain networks are also different, depending on the choice of consensus mechanism.

Currently, Proof of Work (PoW) is used in the bitcoin network [24]; Ethereum also uses PoW, and tend to gradually replace PoW with Proof of Stake (POS) [25]; Ripple uses Ripple Proof of Consensus Algorithm (RPCA) [26]; Fabric uses Practical Byzantine Fault Tolerance (PBFT) [27]; in addition, there are Delegated Proof of Stake (DPoS) [28] and Delegated Byzantine Fault Tolerance (dBFT) [29]. The CB-EHRs platform uses the dBFT consensus mechanism. This consensus mechanism was proposed by NEO [30], which is an open source blockchain project driven by the community. A comparison [31, 32] of the characteristics of several major consensus mechanisms is shown in Table 1.

3.4 Blockchain and CB-EHRs platform

• Openness: The blockchain system code is open source. The system's interface and data are also open to everyone [33]. Each node in the system is allowed to obtain the complete copy of the database. Based on this feature, the CB-EHRs platform enables medical data to be shared among medical institutions.

- Decentralization: The blockchain system is based on a peer-to-peer distributed network, this feature makes it not to rely on a centralized management agency. Therefore, the operation of the CB-EHRs platform is jointly accomplished and maintained by all medical institutions in the blockchain. If any medical institution node is lost or damaged, the system can still function effectively.
- Tamper-proof: The chained structure of the blockchain ensures the tamper resistance of the data in the blockchain system. If the information of a block is changed, the block header hash of the next block will also change. Therefore, if the attacking node wants to successfully change the transaction information, it only recalculates all subsequent blocks of the changed block and catches up with the progress of the legal blockchain in the network. In the current state of network technology development, such an attack is difficult to achieve [33]. Therefore, applying blockchain technology to the CB-EHRs platform makes EHRs data more secure.
- Anonymity: Transaction data on the blockchain is open and transparent. However, the owner's identity corresponding to the transaction is anonymous. The CB-EHRs platform can use blockchain encryption to hash user identity information. The resulting hash value is used as the unique identifier for the user, similar to the bitcoin's wallet address. The user's behavior on the CB-EHRs platform is associated with the hash value obtained earlier, rather than with the user identity information. This separation of user identity and user data protects patient privacy.

In what follows, we present the detail of the proposed CB-EHRs, its associated features and potential benefits.

4. DESIGN APPROACH OF CB-EHRS PLATFORM

This section provides a detailed explanation of related features and functioning of the proposed credible blockchain electronic health records (CB-EHRs) platform.

4.1 Platform architecture

The proposed architecture of the CB-EHRs platform is designed as a layered architecture. The entire platform is divided into three layers, which comprise: (i) the user interface layer, which is at the top; (ii) the business logic layer, which is in the middle; and (iii) the data access layer, positioned at the bottom of the framework. Figure 2 presents an overview of the CB-EHRs architectural framework and details of the architecture is presented hereafter.

4.1.1 User Interface layer

The user interface layer is used to display data and receive user's input information. It provides users with a graphic interface that can interoperate with the entire blockchain

Consensus Mechanism	PoW	PoS	DPoS	RPCA	PBFT	dBFT
Performance efficiency	Low	Low	High	High	High	High
Scenes	Public chain [21]	Public chain Alliance chain	Public chain Alliance chain	Public chain	Alliance chain	Alliance chain
Accounting nodes	All nodes	All nodes	Select All representative nodes		Static selection	Dynamic selection
Response	About	1	<1	<1	<1	<1
time	10 minutes	minute	minute	minute	minute	minute
Ideal state of Transaction Per Second (TPS)	7 TPS	300 TPS	500 TPS	>10 thousand TPS	1000 TPS	1000 TPS
Fault tolerance	50%	50%	50%	20%	33%	33%
Resource consumption	high	medium	low	low	low	low

 Table 1 – Summary of the characteristics of major consensus mechanisms



Figure 2 – The overall framework of the CB-EHRs platform

platform. The blockchain-based EHRs platform proposed in this paper can be used on mobile devices, PCs and smart wearable devices. On one hand, medical workers need to use PCs to fill out electronic health records, and users are able to access their own electronic health records. On the other hand, users can also use their mobile phones and smart wearable devices to share electronic health records with doctors at any time and place, when they need to conduct remote diagnosis. Hence this promotes ubiquitous access.

4.1.2 Business logic layer

The business logic layer is used to provide data conversion between actual users and the blockchain-based EHRs platform. It provides users with a unified data interface and unified data standards [34]. This layer includes three modules: (i) Basic Function Module, (ii) System Security Module and (iii) Other Functional Module.

Basic Function Module has four interfaces. The registration interface implements the registration function for new users. The record upload and record authorization interface provide users with services for uploading and signing their own medical records. The record query interface provides medical staff with a rich EHRs database that facilitates the research process for various diagnoses.

System Security Module includes four sub-modules. The addition of the access control facilitates system management. The module also controls user access. It can set up patients to access individual EHRs while doctors access all EHRs. There are many access control mechanisms that can be selected, such as role-based access control [35]. Hash encryption makes the data form a chain structure. The digital signature generates a key pair for the registered user. dBFT consensus acts on the P2P network and is responsible for running a set of nodes that implement the consensus mechanism. The dBFT consensus module works with these nodes to validate transactions and maintain distributed ledgers.

In Other Functional Module, Chatroom is added to the CB-EHRs platform to facilitate communication between the patient and the healthcare provider for remote diagnosis. Data statistics classifies data for medical researchers to facilitate medical research.

The business logic layer can encapsulate user data into virtual transactions and assets, then transfer these transactions and assets to nodes in the blockchain network. Through the interaction of these modules with the previously mentioned interfaces, data exchange between users and the blockchain database can be smoothly realized.

4.1.3 Data access layer

The data access layer contains a unique blockchain and a P2P network that maintains and validates the blockchain. The P2P network is used to maintain the operation of the CB-EHRs platform. It can receive transaction verification requests, generate blocks and vote on new blocks. The verification nodes in the network agree on the transaction sequence by running the dBFT consensus mechanism. The platform can then generate blocks and update the local blockchain database.

4.2 dBFT consensus mechanism in the platform

Unlike the current mainstream blockchain system, the CB-EHRs platform uses the dBFT consensus mechanism. dBFT is an improved Byzantine fault-tolerant protocol based on PBFT. The protocol first selects the accounting node in the network by voting, and after the process is simplified for the PBFT, the accounting nodes have a consensus [29]. This consensus mechanism simplifies the process and improves efficiency compared to PBFT, but retains all the excellent performance of PBFT.

The choice of consensus algorithm is motivated by the application scenario. Based on the analysis and comparison of Table 1, PoW and PoS are mainly applicable to the digital currency system. They all need to consume a certain amount of resources and are not suitable for commercial application services. DPoS is suitable for blockchain systems that rely on token operations, but has poor support for blockchain systems that operate without tokens. RPCA is currently only available in the currency or electronic asset clearing area and has poor support for other applications. PBFT and dBFT are widely available for commercial applications because they do not have an underlying token mechanism. However, on the one hand PBFT is currently unable to dynamically add nodes and cannot be applied to applications with large node sizes due to complex communication processes. On the other hand, the more nodes that join PBFT consensus, the quicker the performance drops, as the time complexity of the PBFT is $O(n^2)$ [27]. For this reason, NEO proposes an algorithm named dBFT, which combines the characteristics of dPoS. By voting on the blockchain, it decides the name list of consensus nodes for next round, namely authorizing a few nodes to reach consensus [30]. Therefore, combined with the business characteristics of EHRs application, this paper applies the core consensus process of dBFT to the construction of the EHRs platform, and realizes a special mechanism which is efficient and scalable.

4.3 Network structure

The network structure of the platform draws on the underlying core code of bitcoin technology, the P2P network [21]. According to the characteristics of the P2P network, we design a special electronic medical P2P network. In the special structure of the designed P2P network, each node in the network has the complete EHRs data replication. According to the rules of the alliance chain, the nodes in the blockchain network are composed of various medical institutions throughout the country. The user's device does not need to store a huge electronic health record. Each medical institution has equal status in the network, they have the same rights and need to assume the same obligations, as can be seen in the overview presented in Figure 3.

4.4 Platform workflow

While blockchain is essentially a decentralized distributed database, all its data exists in the form of transactions. If users want to store electronic health record data on the blockchain,



Figure 3 – Blockchain EHRs distributed in the network



Figure 4 – Process of user registration and identity information validation

the blockchain-based EHRs platform need to convert the actual operations into a one-off transaction and attach the user information to the storage of transaction at the same time.

4.4.1 User registration operation

A medical institution has a large number of new patients each year, and each patient needs an electronic medical record. On one hand, if medical institutions are required to collect patients' public key information, the workload will be heavy, and easy to make mistakes. If medical institutions are required to generate and distribute patient key pairs, the workload will also be enormous. On the other hand, if the key pair comes from a medical institution, the private key of the patient may be controlled by the medical institution. This situation also does not meet the actual requirements from the perspective of security.

In user registration operation, firstly, the user need to submit his or her personal information, then the EHRs platform will generate a set of key pairs that represent his or her identity and generate the hash value as the user's unique identifier. Figure 4 shows the process of user registration and identity information validation.

In our proposed blockchain-based EHRs platform, the



Figure 5 – Process of health record upload operation

medical institution represents an accounting node in the network. User's key pairs and unique identifier will be generated when a patient joins the CB-EHRs platform as a user. According to the setting of the CB-EHRs framework in this paper, a transaction is first initiated by the user, then the user transfers the virtual asset USER_INFO with his or her own identity information (public key and unique identifier) to the medical institution. In this way, the medical institution can obtain the user's public key and unique identifier to verify subsequent actions that may come from this user.

4.4.2 Health record upload operation

According to the characteristics of digital signature technology, each user in the platform is solely in charge of his or her private key. This means that each user participates in the platform and manages his or her own health records. Whether the user performs telemedicine or face-to-face consultation, the doctor needs to obtain the user's authorization (user private key encryption) before uploading the completed record to the database. In the CB-EHRs platform, unauthorized EHRs are separately stored in the data table. When an EHR is authorized by the user, the user node will encrypt the EHR with the private key. The data processed by the private key encryption is a transaction containing user identity information. It will be sent randomly to a medical facility node to start consensus. When medical institutions receive a transaction with user identity information, they need to decrypt the encrypted transaction with the user's public key. If the decrypted content can be successfully matched, the transaction content is encapsulated into a new block and added to the user's blockchain in the local database. The flow chart of the health record upload operation is shown in Figure 5.

4.5 Platform database

In the database of CB-EHRs, one blockchain contains records for all users. Each block is divided into two parts: a block header and a block body. Apart from the first block (Genesis



Figure 6 – Comparison result of 1000 transactions between dBFT and PBFT

block), which is generated when the platform creates the first medical record, the header part of each block includes previous hash, current hash, timestamp and nonce. The block body records a health record for a particular time. This structure is beneficial to researchers in tracking patients' chronic diseases and analyzing disease data.

5. TESTING AND EVALUATION

5.1 dBFT consensus test

Based on the realization of the dBFT consensus, the paper compared the consensus performance of dBFT and PBFT under the same network conditions. This paper uses Docker [36] virtualization technology to test the blockchain network. Before the test, the researchers built a test environment with four verification nodes in the Docker application based on the CB-EHRs platform structure. The communication, consensus, block generation and verification of the nodes in the block generation process are completed by the four verification nodes. The testing process is as follows: First, enabled dBFT in the EHRs alliance chain with four authentication nodes. Then send 1000 and 2000 transactions to the blockchain network node in turn. Finally, after the network has agreed, executed and finally generated the block, the transaction per second (TPS) of the network was calculated. Each of the above transactions was repeated 50 times to obtain a relatively stable processing capability of the network. In the same way, the PBFT consensus module was enabled in the EHRs alliance chain, and the transaction processing capability test was performed in the same way. After collecting the test data, this paper uses a line chart to compare and analyze the two sets of test results. As shown in Figure 6 and Figure 7.

According to the above experimental comparison, in addition to the large difference in the value of individual groups due to network fluctuations and transaction randomness, we can conclude that the transaction processing performance of dBFT is higher than PBFT in the two groups of experiments. This paper used the same test method to get more data in different networks which has a different number of the nodes. The average value of TPS in the above experimental data is obtained as a stable value of network consensus performance and grouped and summarized. The final result is shown in



Figure 7 – Comparison result of 2000 transactions between dBFT and PBFT

Table 2 - Performance comparison between dBFT and PBFT

Number of nodes	dBFT / TPS		PBFT / TPS		
	1000	2000	1000	2000	
4 Nodes	158.7006085	157.701429	145.9727725	145.7940789	
6 Nodes	149.0378482	148.5736732	138.0394872	137.2839271	
8 Nodes	133.3748567	131.4758392	121.7384793	121.1923744	

Table 2.

By analyzing figures 6 and 7, and Table 2, on the one hand, we conclude that the transaction processing efficiency of dBFT is about 9% higher than that of PBFT under the same network conditions. On the other hand, as the number of nodes increases, the performance of the two consensus mechanisms decreases significantly. However, the dBFT consensus used in this paper uses a representative mechanism to select relevant nodes. Therefore, even if there are more network nodes, dBFT will select a few nodes to participate in the consensus mechanism. In summary, the EHRs platform designed in this paper improves the performance of the consensus mechanism to a reasonable extent by using dBFT, which is consistent with the theoretical analysis results.

6. SUMMARY AND CONCLUSION

Blockchain technology is a new concept and theory which emerged from bitcoin applications using public chain. While various theoretical research on blockchain technology are still at their stage of exploratory and development, it is undeniable that blockchain will transform the global Internet infrastructure and has a promising prospect. This paper leverages blockchain technology in the electronic medical industry, and designs a credible electronic health records platform based on blockchain (CB-EHRs). Our proposed CB-EHRs platform is able to address some of the problems which are prevalent in the traditional electronic health records platform. It can help medical institutions transform their data centers and meet the needs of user privacy protection, safe storage and sharing of medical data. CB-EHRs also serves to promote telemedicine which is an inevitable requirement in the current technology age. It is important to note that while existing research attempts have proposed some ways to address some challenges faced in the EHRs platform, the framework they adopt results in a large amount of network resources wastage. As an intervention and an attempt to introduce and implement blockchain technology in electronic health records, this paper only considers some key technologies. This research is still at its stage of exploration and development in this domain of interest, hence a complete system development of the proposed CB-EHRs is still underway. The idea presented in this paper has paved the way for future implementation targets that will promote the utilization of EHRs across different domains, and even beyond health care.

REFERENCES

- Avgerou C. Discourses on ICT and development[J]. Information Technologies & International Development, 2010, 6(3): pp. 1-18.
- [2] Onashoga S., Sodiya A., Akinwale A.T., Falola O.E. Mining of Prevalent Ailments in a Health Database using Fp-Growth Algorithm. in International Journal of Data Engineering (IJDE). 2010, 2(2): 75-83.
- [3] Raghupathi W, Raghupathi V. Big data analytics in healthcare: promise and potential[J]. Health information science and systems, 2014, 2(1): 3.
- [4] Howe J L, Adams K T, Hettinger A Z, et al. Electronic health record usability issues and potential contribution to patient harm[J]. Jama, 2018, 319(12): 1276-1278.
- [5] Peckham C, Kane L, Rosensteel S. Medscape EHR Report 2016: physicians rate top EHRs[J]. Medscape. August, 2016, 25.
- [6] A. Bagula, M. Mandava and H. Bagula. A Framework for Supporting Healthcare in Rural and Isolated Areas in Elsevier Journal of Network and Communication Applications, 2018.
- [7] M. Mandava, C. Lubamba, A. Ismail, H. Bagula and A. Bagula, *Cyber- Healthcare for Public Healthcare in the Developing World*, in proceedings of the 2016 IEEE Symposium on Computers and Communication (ISCC), 27-30 June 2016, Messina-Italy, Pages 14-19, 2016.
- [8] A. Bagula, C. Lubamba, M. Mandava, H. Bagula, M. Zennaro and E. Pietrosemoli ", *Cloud Based Patient Prioritization as Service in Public Health Care*, in Proceedings of the ITU Kaleidoscope 2016, Bangkok, Thailand, 14-16 November, 2016.
- [9] M. Bagula, H. Bagula, M. Mandava, C. Kakoko and A Bagula, Cyber-healthcare Kiosks for Healthcare Support in Developing Countries, in proceedings of the Africomm 2018, Dakar-Senegal, November 29-30, 2018.
- [10] Claude Lubamba & A. Bagula, Cyber-Healthcare Cloud Computing Interoperability Using the HL7-CDA Standard in Proceedings of the ISCC 2017, Heraklion/Crete, Grece, 03-06 July 2017.

- [11] Dimitrov D V. Medical internet of things and big data in healthcare[J]. Healthcare informatics research, 2016, 22(3): 156-163.
- [12] Lo'ai A T, Mehmood R, Benkhlifa E, et al. Mobile cloud computing model and big data analysis for healthcare applications[J]. IEEE Access, 2016, 4: 6171-6180.
- [13] Chen M, Qian Y, Chen J, et al. Privacy protection and intrusion avoidance for cloudlet-based medical data sharing[J]. IEEE transactions on Cloud computing, 2016.
- [14] Reti S R, Feldman H J, Ross S E, et al. Improving personal health records for patient-centered care[J]. Journal of the American Medical Informatics Association, 2010, 17(2): 192-195.
- [15] Papoutsi C, Reed J E, Marston C, et al. Patient and public views about the security and privacy of Electronic Health Records (EHRs) in the UK: results from a mixed methods study[J]. BMC medical informatics and decision making, 2015, 15(1): 86.
- [16] Haas S, Wohlgemuth S, Echizen I, et al. Aspects of privacy for electronic health records[J]. International journal of medical informatics, 2011, 80(2): e26-e31.
- [17] Yarmand M H, Sartipi K, Down D G. Behavior-based access control for distributed healthcare systems[J]. Journal of Computer Security, 2013, 21(1): 1-39.
- [18] Ivan D. Moving toward a blockchain-based method for the secure storage of patient records[C]//ONC/NIST Use of Blockchain for Healthcare and Research Workshop. Gaithersburg, Maryland, United States: ONC/NIST. 2016.
- [19] Iansiti M, Lakhani K R. The truth about blockchain[J]. Harvard Business Review, 2017, 95(1): 118-127.
- [20] Crosby M, Pattanayak P, Verma S, et al. Blockchain technology: Beyond bitcoin[J]. Applied Innovation, 2016, 2(6-10): 71.
- [21] Casino F, Dasaklis T K, Patsakis C. A systematic literature review of blockchain-based applications: current status, classification and open issues[J]. Telematics and Informatics, 2018.
- [22] Vacca J R. Public key infrastructure: building trusted applications and Web services[M]. Auerbach Publications, 2004.
- [23] Kaur R, Kaur A. Digital signature[C]//2012 International Conference on Computing Sciences. IEEE, 2012: 295-301.
- [24] Gervais A, Karame G O, Wüst K, et al. On the security and performance of proof of work blockchains[C]//Proceedings of the 2016 ACM SIGSAC conference on computer and communications security. ACM, 2016: 3-16.

- [25] Bartoletti M, Lande S, Podda A S. A Proof-of-Stake protocol for consensus on Bitcoin subchains[C]//International Conference on Financial Cryptography and Data Security. Springer, Cham, 2017: 568-584.
- [26] Schwartz D, Youngs N, Britto A. The ripple protocol consensus algorithm[J]. Ripple Labs Inc White Paper, 2014, 5.
- [27] Castro M, Liskov B. Practical Byzantine fault tolerance[C]//OSDI. 1999, 99: 173-186.
- [28] ThePiachu's Bitcoin Blog. Thoughts on Delegated Proof of Stake and Bitshares[OL].2014. http://tpbit.blogspot. com/2014/08/thoughts-on-delegated-proof-of-stake. html
- [29] Crain T, Gramoli V, Larrea M, et al. DBFT: Efficient Leaderless Byzantine Consensus and its Application to Blockchains[C]//2018 IEEE 17th International Symposium on Network Computing and Applications (NCA). IEEE, 2018: 1-8.
- [30] NEO An Open Network For Smart Economy[OL].2014. https://neo.org/
- [31] Xia Q, Zhang F J, Zuo C. Review for consensus mechanism of cryptocurrency system[J]. Computer Systems & Applications, 2017.
- [32] Viriyasitavat W, Hoonsopon D. Blockchain characteristics and consensus in modern business processes[J]. Journal of Industrial Information Integration, 2019, 13: 32-39.
- [33] Tasca P, Tessone C J. Taxonomy of blockchain technologies. Principles of identification and classification[J]. arXiv preprint arXiv:1708.04872, 2017.
- [34] Gonzalez A. Unified application, user interface and data linking: U.S. Patent Application 10/796,422[P]. 2005-9-8.
- [35] Sandhu R S, Coyne E J, Feinstein H L, et al. Role-based access control models[J]. Computer, 1996, 29(2): 38-47.
- [36] Anderson C. Docker [software engineering][J]. IEEE Software, 2015, 32(3): 102-c3.

THE GDPR TRANSFER REGIME AND MODERN TECHNOLOGIES

Melania Tudorica; Trix Mulder

Rijksuniversiteit Groningen, the Netherlands

ABSTRACT

Health data comes within a person's most intimate sphere [1]. It is therefore considered to be sensitive data due to the great impact it could have on a person's life if this data were freely available. Unauthorized disclosure may lead to various forms of discrimination and violation of fundamental rights. Rapid modern technological developments bring enormous benefits to society. However, with this digitization, large amounts of health data are generated. This makes our health data vulnerable, especially when transferred across borders. The new EU General Data Protection Regulation (GDPR) legal framework provides for rights for users of modern technologies (data subjects) and obligations for companies (controllers and processors) with regard to the processing of personal data. Chapter V of the GDPR protects personal data that are transferred to third countries, outside the EU. The term 'transfer' itself, however, is not defined by the GDPR. This paper examines whether transfer within the meaning of the GDPR applies to health data processed by modern technologies and if the complexity of the GDPR legal framework as such sufficiently reflects reality and protects health data that moves across borders, in particular to jurisdictions outside the EU.

Keywords – Data protection, health data, transfer, transit

1. INTRODUCTION

In our rapidly evolving digital world, people use various modern technologies to track and measure their health and fitness. Modern technologies such as mobile applications and wearables (including watches, bracelets and smart fashion) are used to get into shape, keep fit, lose weight, reduce stress, manage mental health disorders, test and diagnose for specific diseases such as malaria, help with planning and ovulation tracking, etc. The family technologies enable people to monitor their own health and fitness by entering personal health data and using (pressure) sensing technologies which measure vital signs (such as heartrate) and track progress (such as counting steps) [2]. New health technologies are a key area of 21st century knowledge societies and economies, offering potential for growth and economic development [3]. It is one of the largest growing global markets. According to a recent article, there are more than 300 000 health related mobile device applications [4]. While the use of these technologies may bring benefits to society as they reduce the burden on doctors and empower people by putting them in control of their own health, in particular in low income and difficult to reach areas, the downside is that these technologies generate massive amounts of health data. Considering that health data comes within a person's most intimate sphere, it could have a great impact on a person's life if this data was freely available. Risks include discrimination and violation of fundamental rights.

There have been many reports over the past couple of years or so of data breaches and companies (routinely) sharing data. The 2018 Strava and Polar incidents immediately come to mind, but also Ovia (a pregnancy tracking app) sharing intimate information with employers and insurers [6], Facebook having access to sensitive information [7] and many more examples of health data being compromised by the use of modern technologies [8]. Our health data is particularly vulnerable if it is processed outside the protected sphere of a medical environment where health data is processed by professionals who are under the obligation of medical confidentiality. The health data that is processed by these modern technologies is, most of the time, processed by commercial companies who are generally unclear about their processing activities and with whom they share the collected data [9].

Legally a lot can be said about modern technologies, their use, privacy risks, infringements of rights, etc. This paper focusses specifically on transfer and modern technologies. Inherent to the nature of these technologies is that data is not bound by borders. Users of modern technologies may be located anywhere in the world and data may move across the globe while being processed by companies established anywhere in the world. One of the main challenges of the borderless nature of data processing is that it is difficult to track the data and as a consequence difficult to determine jurisdiction, which may lead to difficulties in data subjects exercising rights in cases of infringements.

Within the European Union (EU) data is protected by the General Data Protection Regulation (GDPR) [10]. The GDPR protects data, among other things, when it is transferred across borders. This research aims to answer how the GDPR transfer regime applies to data processing by modern technologies, if at all, and whether the GDPR legal framework as such offers sufficient protection. When using modern technologies, the data is collected by a device (such as a smartphone or wearable) by using applications developed by commercial companies. The applications

'send' the data to the servers of the company which owns the app and which then processes the data. What exactly happens technically behind the scenes is unclear. It is therefore unclear whether 'sending' data between the device and the server of a company can be seen as a transfer within the meaning of the GDPR and whether the GDPR transfer regime applies to processing by modern technologies.

This research argues that the complexity of the GDPR legal framework does not offer sufficient protection against processing by modern technologies. By taking a technical, behind the scenes perspective and looking at whether the (technical) process of 'sending' data from a user's device to the server of a company can be seen as a transfer within the meaning of the GDPR, we argue that this process is a mere transit of data where the device functions only as a tool for the companies to collect data [11]. In coming to this conclusion, this article first needs to establish what the legal basis for processing health data by modern technologies is. We then look at the technical process used by modern technologies and whether the GDPR transfer regime applies to this process in order to conclude whether the legal basis and the GDPR legal framework offer sufficient protection to processing by modern technologies.

2. LEGAL BASIS FOR PROCESSING HEALTH DATA BY MODERN TECHNOLOGIES

The GDPR provides rules for the protection of personal data and free movement of such data in order to protect the fundamental rights and freedoms of persons. It applies to the processing of personal data of data subjects who are in the EU, regardless of where the controller or processor are established [12]. This means that the GDPR applies to any company around the globe processing data of data subjects who are in the EU if the processing activities relate to offering goods or services to data subjects or monitoring the behavior of data subjects. As such, the GDPR aims at offering a similar level of protection for EU citizens regardless of where the data is being processed [13]. This is particularly important when health data is being processed by commercial companies who are not under any obligation of professional secrecy. In previous research we have established that many companies deny or at least do not mention the fact that they process health data while in fact they are [14].

While we use the more overarching term *health data*, Article 4 (15) of the General Data Protection Regulation (GDPR) refers to it as 'data concerning health' and defines it as:

Personal data related to the physical or mental health of a natural person, including the provision of healthcare services which reveal information about health status [15].

This is a very broad definition: any information which can reveal something about a person's (mental) health is considered to be health data. In the annex to its letter to the European Commission, the Article 29 Working Party (now the European Data Protection Board [16]) clarified the scope of the definition of data concerning health in relation to lifestyle and wellbeing apps and provides criteria to determine when data processed by such apps and devices is health data [17]. According to the Article 29 Working Party, personal data is health data when (1) the data is clearly medical data, (2) the data is raw sensor data that can be used in itself or in combination with other data to draw a conclusion about the actual health status or health risk of a person or (3) conclusions are drawn about a person's health status or health risk [18]. This means that, in general, data is health data when it is used or can be used to draw conclusions about a person's health. However, the Article 29 Working Party also acknowledges that in some cases the raw data itself is considered to be health data. It also acknowledges that presumably simple facts about individuals, such as IQ, wearing glasses or lenses, smoking and drinking habits, membership of patient support groups, etc. are considered to be health data. In our view, the mere fact that a person uses an app, for example to help quit smoking or to count calories already says a lot about a person. Whether or not true, the conclusion can be drawn that the person is a smoker or may be obese and that he or she may have health issues (such as lung or heart problems) because of this. The mere fact that a person uses a health app already can say a lot about their health, and even more so when the data is combined with other health information about a person. For example, an employer or insurer buying health data and combining it with the information already on record not only violates privacy but can also discriminate against their employee or the insured. This could lead to increases in insurance fees, rejection of insurance and perhaps even in unemployment. Data generated by modern technologies which can conclude something about a person's health in the broadest sense can therefore generally be seen as health data.

Health data has had a long history of being seen as a special category of data, also referred to as sensitive data, that requires additional protection. As such, Article 9 of the GDPR prohibits the processing of health data unless there is a legal basis to do so. If there is no legal basis for processing, the processing is considered to be unlawful. According to the GDPR, explicit consent given by the data subject is the legal basis for processing health data by modern technologies [20, 21]. The GDPR thus allows processing of personal health data by companies when a data subject explicitly consents. Consent of the data subject within the meaning of the GDPR means a clear affirmative act establishing at least the freely given, informed indication that the data subject agrees to the processing of his or her personal data [22]. Consent can also be given by electronic means, for example by ticking a box when visiting a website, choosing certain technical settings or any other statement or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing. Pre-ticked boxes or inactivity by the data subject do not constitute consent [23]. The request for consent has to be clear, concise, not unnecessarily

disruptive and needs to be presented in a clearly distinguishable form, meaning that it may not be buried within the fine print of a privacy policy or contract [24].

While at first sight it looks as if the GDPR offers sufficient protection against the processing of health data, the practical reality is quite different. Previous research has shown that companies offering health apps are by no means transparent about their processing activities and whom they share the data with [25]. While data subjects to some degree consent to data processing, some health apps do not even recognize the fact that they process health data, resulting in a lack of legal basis. As a result of this, risks of violation of rights and freedoms remain, as well as physical and practical challenges related to the use of modern technologies to process health data, such as jurisdiction and exercise of rights.

3. BEHIND THE SCENES OF MODERN TECHNOLOGIES

Processing personal data according to the GDPR includes 'collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction' of data [26]. This very broad definition means that basically any action performed on personal data is processing. The one word that is missing from the definition in *Article* 4 (2) GDPR is that processing also includes *disclosing the data by transmission* and *dissemination or otherwise making it available*. While it is interesting that transfer is not included in the definition for processing, disclosing and making data available can be seen as transfer of data.

Transfer has an important role in the GDPR. While the free flow of information has always been promoted by data protection legal frameworks, the major concern was that data protection legislation could be circumvented by moving processing operations to countries with no or less strict data protection laws [27]. European data protection legal frameworks have therefore always been cautious about transferring data to third countries who are not part of the legal regime. In order to prevent data from being transferred to 'data havens', the principle of equivalent protection was introduced, meaning that there should be no restrictions on transborder data flows to states with legal regimes which ensure data protection equivalent to data protection offered by the GDPR. Chapter V of the GDPR is dedicated to transfers of personal data to third countries or international organisations. Modern technologies process data electronically, making it easy to transfer data across the globe. The data can be sent from one actor to another or made accessible to more than one actor in a blink of an eye. Modern technologies thus impact the way that personal health data can be collected.

These modern technologies, such as mobile applications and wearables process large amounts of personal (health) data. The technologies make it possible to continuously monitor the user. Most people carry their mobile phone with them during the day and wearables made tracking even easier. A smart watch or smart glasses for example allow users to track their health and fitness with objects which are easy to carry. While making life and health easy for users, large amounts of health data become available to commercial companies who are by no means under any obligation of professional secrecy and what happens behind the scenes of these technologies is unknown to many. When unravelling what happens, behind the scenes, to the data we stumbled upon 2 major ways that the technologies function that are relevant for this article. Many health apps and wearables by default:

- 1. collect data via an app and store it on the device itself until the user actively choses to send the data to a cloud or server;
- 2. collect data via an app and store it on a (cloud) server. In this case the data exists outside of the app and is accessible to the developer, i.e. the device is used as a tool to collect data, the data can be seen separately from the app considering that it exists even if the app is deleted.

If we picture a user in the first situation and we take the example of an app that counts how many steps someone takes during the day, the app counts the steps and stores the data on the device itself by default. The data is stored on the device for as long as the user does not delete the data or chooses to store the data somewhere else, for example when the storage space of the device is full. In other words, the collected data remain on the user's device until the user actively decides to store the data elsewhere, outside of the app or wearable.

More importantly for this research is however the second situation, where data is collected by an app or wearable which does not intend to store it on the device. Instead, by default, the data is sent to and stored on the (cloud) server of the app company. Sending the data requires an active connection between the device and the (cloud) server. If this connection is unavailable, the data is most likely stored on the device until the connection is available.

There is a significant legal difference between the two situations. In the first situation the app is closely related to the data and therefore to the user, it is merely a means to an end. In the second situation, the purpose of the app or wearable is mainly to generate data. The device is not used for storage or not meant to be used for storage. As soon as an active connection is available, the data is sent to the designated (cloud) server. In this regard, we can make an analogy with streaming data. The user might have the app on their mobile phone or wearable, but the data exists separately, outside this app. For example, when watching a YouTube video, the app is solely used to stream the data available on the YouTube server. While health apps and wearables are more of a two-way-street considering that they can also generate data, the basic concept and comparison to YouTube streaming is the same.

Processing health data in a way where data is collected by an app or wearable and sent to a (cloud) server for (further) processing still leaves the question whether sending the data can be seen as a transfer within the meaning of the GDPR and is as such protected or whether the device functions merely as a tool for the companies to collect data where sending the data can be seen as a mere transit of data [28]. The concept of 'transfer' will therefore be discussed in the next paragraph.

4. THE NOTION OF TRANSFER

The GDPR aims at offering a similar level of data protection, regardless of where in the world data of data subjects who are in the EU is being processed. Therefore, Chapter V of the GDPR includes provisions on transfers of personal data to third countries. This section provides rules in order to ensure data protection equivalent to the GDPR, meaning that data may only be transferred to third countries outside the EU if the conditions of the GDPR are met. In short, this means that there needs to be: 1) an adequacy decision (such as the EU-U.S. Privacy Shield) or 2) appropriate safeguards or 3) that the data subject has given explicit consent for data processing in the third country. With emerging modern technologies, where data may be processed anywhere in the world, it is of the utmost importance to protect the data, in particular health data. In order to establish whether sending data, from the app or wearable onto the (cloud) server of a company for the purpose of being processed by that company, can be seen as a transfer within the meaning of the GDPR, it is important to establish what transfer exactly is in order to determine whether or not it falls under Chapter V GDPR and consequently whether or not health data in this regard is sufficiently protected. In literature transfer is described as to occur as a part of networked series of processes made to deliver a business result [29].

The GDPR is, however, unclear about what transfer is and does not provide a definition. What is clear is that it is a process where data moves between different actors. According to the European Data Protection Supervisor (EDPS) in its position paper on transfer to third countries and international organizations by EU institutions and bodies, the lack of a definition leads to the assumption that the term needs to be used in its natural meaning. As such transfer means that data 'moves' between different users. However, as the EDPS also concludes, this is not always straight forward. According to the Court of Justice of the European Union (CJEU) in the Lindqvist case, it is necessary to take account of both the technical nature of the operations carried out and of the purpose and structure of the provisions on transfer in EU legislation [30]. Taking into account the technical nature of processing operations, transfer, as such entails, among other things, the automatically or intentionally sending or accessing of *information.* Unfortunately, there is not a lot of case law in this regard to help further clarify the matter. If one of the factors determining what transfer is includes the technical nature by which it takes place, the question that arises is what technical circumstances can facilitate transfer. Council of Europe Convention 108 for the protection of individuals with regard to automatic processing of personal data [31] provides some insight in this regard.

Convention 108 includes a chapter on transborder data flows and determines that the provisions apply to the transfer across national borders by whatever medium [32]. It is aimed at the free flow of information, regardless of frontiers, taking into account the wide variety of factors determining the way in which data is transferred. These factors include: the mode of representation of the data, their storage medium, way of transport, interface, the circuit followed and the relations between the sender and recipient [33]. According to the explanatory memorandum the way of transport includes physical transport, mail, and circuitswitched or packet-switched telecommunications links. The interface, i.e. the point where two systems interact, can be, among other things, computer to terminal, computer to computer, and manual to computer. The circuit followed can be direct from the country of origin to the country of destination or via one or more countries of transit [34]. The explanatory report to the Modernized Convention provides some more clarity in determining that transborder data transfers occur when personal data is disclosed or made available to a *recipient* subject to the jurisdiction of another state or international organization. According to Article 2 (e) of the Convention a recipient is 'a natural or legal person, public authority, service, agency or any other body to whom data are disclosed or made available. The GDPR definition of recipient is almost the same, determining that recipient means a natural or legal person, public authority, agency or another body, to which the personal data are disclosed, whether a third party or not' [35]. The recipient thus receives the data or is given access to the data and can be a controller or a processor [36].

When it comes to moving data, there are two main ways to technically do this, namely by *exchanging* or *sharing* data. According to Doan et al. data exchange is the process of taking data that is structured within the source database system and transforming it into data structured under a target database system [37]. In other words, the data is transformed so that it becomes compatible with other systems which receive an accurate representation of the source data. Exchange thus allows data to be shared between systems and programs. The introductory report for updating Recommendation No. R (97) 5 defines exchange as the communication of information to (a) clearly *identified* recipient(s) by a known transmitter (such as secured e-mailing) [38]. When health data is exchanged, the data is sent from A to B using a transmitter. This can be an e-mail or other way of sending the data so that it can be read and used by B. Figure 1 below shows this process. In this case, A is the original controller of the health data and

B becomes the new controller of the data and will build on the received data for their own purpose.



Figure 1 – Exchange

Data sharing on the other hand is making data available to others through a variety of mechanisms [39]. According to the introductory report for updating Recommendation No. R (97) 5 sharing is making information accessible to third parties not necessarily identified at the time of the pooling and according to a principle of permissions (such as shared electronic medical records) [40]. Figure 2 below shows how, in a sharing system, various recipients (A – H) can access the data for the purpose processing it. A – H are not necessarily known at the time of pooling and need permission to access the data.



Figure 2 – Sharing

Both sharing and exchange of data are thus commanded by interoperable data processing systems and by common reference frameworks [40]. This allows health data to be moved or to be made accessible to a variety of actors. Considering that transfer can be automatically or intentionally sending information or making it accessible to a recipient by whatever medium, transfer can be both exchange and sharing of data. While exchange and sharing describe different ways of moving health data, both ways are a transfer of data. Taking the above-mentioned into account, the following conclusions can be drawn about transfer:

• Transfer does not have a legal meaning.

- Transfer has a natural meaning, i.e. data moves between users.
- Transfer may be the exchange or sharing of data.
- Data movement takes place by whatever medium.
- Data is disclosed or made available to a recipient.

5. TRANSFER OR TRANSIT?

When applying the notion of transfer to our case, where health data is being processed by commercial companies by modern technologies and the data is sent from the user's device to the (cloud) server of the company, sending this data can be seen as movement, even as an exchange of data between the user and the company, which takes place automatically and electronically. However, the GDPR applies to the processing of personal data of data subjects who are in the EU by a controller or processor regardless of whether the controller or processor is established in the EU. The actors in this case are the data subject who is the user of the app or wearable and the controller which is the company processing the data by modern technologies. The data subject does not determine the purpose and means and cannot be the controller of the data. Taking into account that the data exists separately from, i.e. outside the app, it is not the data subject who (actively) transfers the data to the company. The company as the controller cannot be both the controller of the data and the recipient to whom the data is disclosed. While sending the data may be seen as movement of data which can be a transfer of data, it remains difficult to classify processing by modern technologies as transfer of data. Consequentially, two questions arise. The first question is: if it is not a transfer of data, what is it then?

The Article 29 Working Party in its 2010 opinion on applicable law [41] mentions transit through EU territory, for example by way of telecommunication networks or postal services which ensure that communications are reached in third countries. While the context is slightly different, in our view the analogy can be made with modern technologies. When data is processed by modern technologies, the processing may take place anywhere in the world. For the data to reach the (cloud) server, a transit from the device to the server is necessary. Like an envelope containing data sent by post to a company outside the EU where it will undergo processing, a transit is required for the data to reach its destination. The data is simply being passed on and not being processed along the way [42]. In this case sending the data from the user's device to the (cloud) server of a company where it will undergo processing can be seen as a mere transit of data and cannot be classified as transfer within the meaning of the GDPR. The device on which the app is installed is a mere tool for companies to collect the data, which does not exist on the device, but on a (cloud) server owned by the company, which can be located anywhere in the world.

The second question is: if it is not transfer and the GDPR rules on transfer do not apply, is processing of health data by modern technologies sufficiently protected? Previous

research [43] has shown that there is a gap between the GDPR and practical reality. There is a general lack of transparency from commercial companies about their processing activities, their purposes for processing, the quantity of health data processed, the location of storage and recipients the data is shared with. In particular, the sharing of data is of a great concern as the data is collected and shared with actors who are by no means under any obligation of professional secrecy and who sell the data to the highest bidder which may lead to various forms of discrimination, violation of fundamental rights and difficulties with exercising rights in case of infringements. This is even more concerning considering that people generally do not inform themselves before giving away their data and/ or choose convenience over privacy. It is the responsibility of companies to protect their users' privacy; however, unfortunately they often fail to do so. Consent as a legal basis for processing health data by modern technologies is therefore not enough. As a result of this, the complexity of the GDPR legal framework does not offer sufficient protection for processing of health data by modern technologies.

6. CONCLUSION

The multitude of modern technologies that are available today process large amounts of health data. When processing data, controllers and processors need to abide by the GDPR, which requires that there needs to be a legal basis for processing. Commercial companies therefore need to request the users of their modern technologies for consent before being allowed to process health data. On many occasions, these companies collect data via an app and store it on a (cloud) server where it is being processed. The device is used as a tool to collect data and the data can be seen separately from the app considering that it exists outside of the app (even if the app is deleted) where it is accessible to the company. Taking into consideration that the data exists outside the app and that the data subject cannot be the controller of his or her own data, the transfer regime of the GDPR does not apply when the data is being sent from the device to the (cloud) server. This process is a mere transit of data.

Considering that the GDPR transfer regime does not apply, the question is whether consent as a legal basis is enough. While the GDPR applies to the processing of the data of data subjects who are in the EU, regardless of where the controller or processor is established, the reality remains that it is more difficult to track data processed by modern technologies, i.e. where it is stored and with whom is it shared, which may result in discrimination and violation of rights. There is a general lack in transparency from companies as regards to their processing operations. Furthermore, informing people via privacy policies of modern technologies does not offer sufficient protection considering that most people do not actually read them [45]. And even if they were to read them, they might not understand the meaning or the risks involved. As such, people do not know what they are consenting to. Therefore, combining the fact that commercial companies are generally not transparent enough about their processing activities with the fact that users generally do not know what they are consenting to, results in a weak legal basis. As a consequence, violations take place more frequently than we would wish.

As such, the complexity of the GDPR legal framework does not offer sufficient protection against data processing by modern technologies and commercial companies are not taking sufficient responsibility when processing health data. Perhaps the solution lies in prohibiting the use of health data in certain situations as suggested by Frank Pasquale [44]. A stricter approach, i.e. prohibiting the use of health data in certain situations, would at least be an incentive for companies not to violate the privacy of a person's most intimate sphere. This approach will require further research on how to limit processing health data by modern technologies. The situations where it might be limited or prohibited would have to be defined. It is, however, our opinion that we need another way of looking at health data processed by modern technologies that would be beneficial to all parties and still protects rights and freedoms.

REFERENCES

- [1] Council of Europe, Explanatory memorandum to Recommendation No. R (81) 1 of the Committee of Ministers to member states on regulations for automated medical data banks [1981], para. 6.
- B. Millington, 'Smartphone Apps and the Mobile Privatization of Health and Fitness', *Critical Studies in Media Communication*, v31 n5, December 2014, p. 479-493.
- [3] M. L. Flear et al., European Law and New Health Technologies, Oxford: University Press, 2013, p. 1.
- [4] Editorial, An app a day is only a framework away, Elsevier, The Lancet Digital Health, Volume 1, Issue 2, June 2019, Page e45, available at <u>https://www.sciencedirect.com/science/article/pii/S2</u> 589750019300317.
- [5] See for example: <u>https://www.theguardian.com/world/2018/jan/28/fitn</u> <u>ess-tracking-app-gives-away-location-of-secret-us-</u> <u>army-bases</u> and <u>https://decorrespondent.nl/8480/this-</u> <u>fitness-app-lets-anyone-find-names-and-addresses-</u> <u>for-thousands-of-soldiers-and-secret-</u> <u>agents/260810880-cc840165.</u>
- [6] See for example: https://www.washingtonpost.com/technology/2019/0 4/10/tracking-your-pregnancy-an-app-may-be-morepublic-than-youthink/?noredirect=on&utm_term=.7f91beb5e812.
- [7] See for example: <u>https://www.wsj.com/articles/you-give-apps-sensitive-personal-information-then-they-tell-facebook-11550851636?mod=e2tw_and_https://www.theguardian.com/technology/2017/may/01/facebook-advertising-data-insecure-teens>.</u>
- [8] See: <u>https://theoutline.com/post/7039/there-is-a-</u> reason-apps-make-it-so-fun-to-track-your-health.
- [9] T. Mulder, M. Tudorica, Privacy policies, crossborder health data and the GDPR, *Information & Communications Technology Law* (2019) 28,3.
- [10] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L 119/1.
- [11] See for example: The concept of 'transfer' of data under European data protection law – in the context of transborder data flows, Faculty of Law – University of Oslo, 01-12-2015, available at: <u>https://www.duo.uio.no/bitstream/handle/10852/497</u> 22/8026_The-concept-of-transfer-of-data-under-European-data-protection-law---In-the-context-oftransborder-dataflows.pdf?sequence=1&isAllowed=y.
- [12] Articles 2 and 3 GDPR.
- [13] N. Dasko, 'The General Data Protection Regulation (GDPR) – A Revolution Coming of European Data Protection Laws in 2018. What's New for Ordinary Citizens?', *Comparative Law Review*, p. 128, available at: http:h//tdtpx:./d/odix.o.drgo/i.100rg.g1/21707.152/7 C77L7R5./2C0L1R7.2.00156.
- [14] T. Mulder, M. Tudorica, Privacy policies, crossborder health data and the GDPR, *Information & Communications Technology Law* (2019) 28,3.
- [15] Article 4 (15) GDRP.
- [16] The EDPB is the independent European advisory body on data protection.

- [17] Article 29 Data Protection Working Party, Letter to Mr. Timmens and Annex – health data in apps and devices, 2015, available at: <u>https://ec.europa.eu/justice/article-</u>29/documentation/otherdocument/files/2015/20150205_letter_art29wp_ec_h ealth_data_after_plenary_en.pdf and <u>https://ec.europa.eu/justice/article-</u>29/documentation/otherdocument/files/2015/20150205_letter_art29wp_ec_h ealth_data_after_plenary_annex_en.pdf.
- [18] Article 29 Working Party (A29WP), Annex by letter – health data in apps and device, 2015 p. 5.
- [19] According to Article 5 (1, a) GDPR.
- [20] Article 9 (2,a) GDPR.
- [21] Article 6 (a) GDPR.
- [22] Article 4 (11) GDPR.
- [23] Recital 32 GDPR. See also L. Golba, 'Consent for Personal Data Processing in Digital Environment According to GDPR', Annuals of the Administration and Law, no. 17 (2), p. 253-265.
- [24] Article 7 (1) GDPR.
- [25] See for example: <u>https://www.theguardian.com/technology/appsblog/2013/sep/03/fitness-health-apps-sharing-data-insurance</u>; T. Mulder, 'Health Apps, their Privacy Policies and the GDPR', European Journal of Law and Technology, (10) 1 (2019).
- [26] Article 4 (2) GDPR.
- [27] Council of Europe, "Explanatory report to the Convention for the protection of individuals with regard to automatic processing of personal data" (ETS No 108), para. 9.
- [28] See for example: The concept of 'transfer' of data under European data protection law – in the context of transborder data flows, Faculty of Law – University of Oslo, 01-12-2015, available at: <u>https://www.duo.uio.no/bitstream/handle/10852/497</u> 22/8026 The-concept-of-transfer-of-data-under-European-data-protection-law---In-the-context-oftransborder-dataflows.pdf?sequence=1&isAllowed=y.
- [29] P.M. Schwartz, 'Managing Global Data Privacy' (2009) Privacy Projects, p. 4.

- Case C-101/01 Criminal proceedings against Bodil [30] Lindqvist [2015] ECLI:EU:C:2003:596. In the Lindqvist case one of the question was whether there was 'transfer of data' when personal data is loaded onto an Internet page which is stored on an Internet site on which the page can be consulted, thereby making the data accessible to anyone who connects to the Internet, including people in a third country. As regards the technical nature of the operations, the Court concluded that the Internet pages in question did not contain the technical means to send information automatically to people who did not intentionally seek access to those pages. Internet users would have to connect to the Internet and personally carry out the necessary actions to consult those pages. As such, the data was not directly transferred between the person uploading the information to the website and persons entering the website. The CJEU refers to the provisions on transfer in Chapter IV of Directive 95/46/EC, which has been replaced by Chapter V of the GDPR.
- [31] Convention for the protection of individuals with regard to automatic processing of personal data [1981] ETS No. 108.
- [32] Convention for the protection of individuals with regard to automatic processing of personal data [1981] ETS No. 108, Article 12.
- [33] Council of Europe, "Explanatory report to the Convention for the protection of individuals with regard to automatic processing of personal data" (ETS No 108), para. 62, 63.
- [34] Council of Europe, "Explanatory report to the Convention for the protection of individuals with regard to automatic processing of personal data" (ETS No 108), para. 63.
- [35] Article 4 (9) GDPR.
- [36] Council of Europe, "Explanatory report to the Protocol amending the Convention for the protection of individuals with regard to automatic processing of personal data" (ETS No 223), para. 23.
- [37] Doan, A., Halevy, A, Ives, Z., *Principles of data integration*, Elsevier: Morgan Kaufman, 2012, p. 276.
- [38] J. Bossi Malafosse et. al., Introductory report for updating recommendation R (97) 5 of the Council of Europe on the protection of medical data, 2015, T-PD(2015)07, available at: <u>https://rm.coe.int/introductory-report-for-updatingrecommendation-r-97-5-of-the-council-/168073510c</u>.

- [39] C. Cava et al., Bioinformatics clouds for highthroughput technologies, in: *Handbook of research* on cloud infrastructures for big data analytics, 2014, p. 489 – 507.
- [40] J. Bossi Malafosse et. al., Introductory report for updating recommendation R (97) 5 of the Council of Europe on the protection of medical data, 2015, T-PD (2015)07, available at <u>https://rm.coe.int/introductory-report-for-updatingrecommendation-r-97-5-of-the-council-/168073510c.</u>
- [41] Article 29 Data Protection Working Party, Opinion 8/2010 on applicable law, WP179, p. 23, available at: <u>https://ec.europa.eu/justice/article-29/documentation/opinionrecommendation/files/2010/wp179_en.pdf</u>.
- [42] The concept of 'transfer' of data under European data protection law – in the context of transborder data flows, Faculty of Law – University of Oslo, 01-12-2015, available at: https://www.duo.uio.no/bitstream/handle/10852/497 22/8026_The-concept-of-transfer-of-data-under-European-data-protection-law---In-the-context-oftransborder-dataflows.pdf?sequence=1&isAllowed=y.
- [43] T. Mulder, M. Tudorica, Privacy policies, crossborder health data and the GDPR, *Information & Communications Technology Law* (2019) 28,3.
- [44] F. Pasquale, 'Redescribing Health Privacy: the Importance of Information Policy' (2014) 103 HJHLP 127.
- [45] See for example: A M McDonald and L F Cranor, 'The Cost of Reading Privacy Policies' (2008) 4 A Journal of Law and Policy for the Information Society 543; F Schaub and os, 'Designing Effective Privacy Notices and Controls' (2017) 99 IEEE Internet Computing 70.

ABSTRACTS

Session 1: ICT infrastructure for healthcare ¹	
S1.1	5G-enabled health systems: Solutions, challenges and future research trends
	Di Zhang and Teng Zhang, Zhengzhou University, China; Yunkai Zhai, Zhengzhou University and National Engineering Laboratory for Internet Medical Systems and Applications, China; Joel J.P.C. Rodrigues, Federal University of Piauí, Brazil and Instituto de Telecomunicações, Portugal; Dalong Zhang, Zhengzhou University, China; Zheng Wen, Keping Yu and Takuro Sato, Waseda University, Japan
	In the literature, Information communication technology (ICT)-assisted health systems have been intensively discussed. However, it has seldom become a reality. This is mainly due to the current wireless technologies' limited transmission rate, few connected devices and high latency. On the contrary, the fifth generation (5G) wireless communications can connect more devices, provide faster transmission rates and a lower latency. In this article, we first introduce the 5G-enabled health systems and our specific implementation in the first affiliated hospital of Zhengzhou University (FAHZZU). Afterwards, the potential challenges and future research trends on demonstrating the 5G-enabled health systems are discussed.
S1.2	Community healthcare mesh network engineering in white space frequencies
	Hope Mauwa, University of Mpumalanga, South Africa; Antoine Bagula and Emmanuel Tuyishimire, University of the Western Cape, South Africa; and Tembisa Ngqondi, University of Mpumalanga, South Africa
	The transition from analog to digital television has availed new spectrum called white space, which can be used to boost the capacity of wireless networks on an opportunistic basis. One sector in which there is a need to use white space frequencies is the healthcare sector because of existent protocols which are using it and the white space frequency is not as crowded as Wi-Fi. However, design simulations of wireless communication networks in white space frequencies have revealed dense network topology because of better signal propagation and penetration properties of white space frequencies. Consequently, communication networks designed in white space frequencies will require topology reduction for better communication and routing. Therefore, this paper proposes a link-based topology reduction algorithm to reduce a dense mesh network topology designed in white space frequencies into a sparse mesh network topology. The paper also proposes a network optimization function to introduce a hierarchical backbone-based network topology from the sparse network topology for better scalability. Performance evaluation on the proposed designs show that the designs can guide network engineers to select the most relevant performance metrics during a network feasibility study in white space frequencies, aimed at guiding the implementation process.

¹ Papers marked with an "*" were nominated for the three best paper awards.

S1.3	Exploration of the non-intrusive optical intervention therapy based on the indoor smart lighting facility
	Jian Song, Xiaofei Wang, Hongming Zhang and Changyong Pan, Tsinghua University, China
	Light, originally the natural light, is one of the important contributing factors to the creation of life on earth, the evolution of human beings and the development of civilization. With the emergence of electric light sources, more specifically the LED lighting lamps which are now being utilized all over the world, the concept of Internet of light (IoL) using the existing LED illumination network with the combination of ICT technologies was created. It has become popular recently and is now widely believed to have a long-lasting impact. IoL not only improves the lighting efficiency, indoor lighting comfort level and other value-added services, but also provides the possibilities for regulating human physiological rhythm, especially for the alleviation of degenerative neurological diseases, even for the treatment and service of healthy lighting in a non-intrusive way. This paper first introduces the concept and the system structure of IoL, and then gives the preliminary results and considerations on how this integrated platform can be utilized to carry the life sciences research and potentially the future applications for the wellness of senior people. More work could be conducted and it would be quite necessary to take into consideration standardization from the perspectives of communication, Internet of things applications, and non-intrusive optical intervention therapy.
S1.4	Access technologies for medical IoT systems
	Junaid Ahmed Siddiquee, Ericsson, India
	ICT technologies are evolving and advances in the technologies hold promise for applications in diverse domains such as healthcare. Along with the development of access technologies, rapid advances are also taking place in related areas, machine learning, artificial intelligence, cloud computing, and big data. Availing healthcare in the developing countries is costly, time-consuming and, for populations located in remote areas, it also means adding in the cost of travel to nearby towns and cities where expert healthcare facilities are normally available. Leveraging ICT technologies, IoT systems for healthcare can bring affordable and quality healthcare to the population through e-health and m-health applications. The role of ICT technologies is paramount to the success of IoT applications for healthcare. Two such ICT access standards are the 3GPP-based 5G technology and IEEE-based Wi-Fi 6. However, challenges exist in the ecosystem that inhibit the realization of the full potential of these technologies. Based on current and future requirements, the paper proposes a model incorporating key factors impacting an IoT communication system and comes up with a set of recommendations to harness the Internet of things for healthcare.

Session 2: Medical ICT	
S2.1	Module structure for foot prosthetic and interface standardization*
	Yoshitoshi Murata, Iwate Prefectural University, Japan; and Tomoki Yamato, DOCOMO Technology, Inc., Japan
	Several million people around the world live with limb loss. Prosthetics are useful to improve their quality of life, and some powered prosthetics enable them to walk naturally. However, most are too expensive for most amputees to afford. We propose a module structure for a foot prosthetic and standardized interfaces between modules to lower the price of powered ones. The prosthetic is battery-powered and controlled by data from sensors built into the heel of a shoe for a healthy foot. Some modules can be applied to people with walking disabilities. Such standardization can lower the price of such modules, and many amputees and people with walking disabilities, such as hemiplegia, can easily afford them, which can help improve their quality of life.

S2.2	Development of hearing technology with personalized safe listening features
	Shayan Gupta, Carnegie Mellon University & Audition Technology, LLC, United States; Xuan Xu, Hongfu Liu, Jacqueline Zhang; Joshua N Bas and Shawn K. Kelly, Carnegie Mellon University, United States
	Noise induced hearing loss (NIHL) is a growing public health concern in the US and globally due to the emergence of lifestyle preferences and environmental exposures to sound levels exceeding safe listening limits for extended periods of time. Issuance of the ITU guidelines for safe listening devices/systems (ITU-T H.870) leading to the 2019 WHO-ITU standard, along with existing US federal and military standards, provide a framework for developing an accessible tool for promoting safe listening. Our proposed Hearing Health app, is being developed for an aggregated assessment of a user's daily sound exposure, through the audio system and the environment (occupation and beyond) by integrating WHO-ITU and US safe listening standards, providing real-time alerts, user-centric recommendations and education that can be integrated into user lifestyles, representing a wide demographic including young adult, adult, civilian and military populations. The overall goal of the app will be to increase NIHL awareness and facilitate improvement of user's listening behaviors.

Session 3	Session 3: Medical IoT	
S3.1	Facilitating healthcare IoT standardization with open source: A case study on OCF and IoTivity Hongki Cha, Younghwan Choi and Kangchan Lee, Electronics and Telecommunications Research Institute, Korea (Rep.of)	
	Healthcare Internet of things (IoT) opens up seamless opportunities by unleashing possibilities to implement better healthcare services. Increased interest in this led to active standardization in various standards development organizations (SDOs). However, the proliferation of different international healthcare standards has not brought about full deployment of healthcare IoT services and business opportunities in the healthcare domain. Nevertheless, there have been some efforts to take advantage of open-source projects as an enabler to facilitate better deployment of healthcare IoT standards. In this paper, the authors develop a case study of their efforts to standardize healthcare IoT with IoTivity, with the Open Connectivity Foundation (OCF). Then they discuss the benefits of IoTivity and how it has led to the enhancement of standardization efficiency and acceleration in healthcare IoT. The authors conclude by recommending ITU-T to continue their efforts to seek the roles of open-source implementation for faster adoption of not only healthcare IoT standards but also their overall Recommendations.	
\$3.2	Empirical study of medical IoT for patients with intractable diseases at home Kentaro Yoshikawa, Shinshu University and Nagano Prefectural Kiso Hospital, Japan; Masaomi Takizawa, Central Corridor Communications 21, Japan; Akinori Nakamura, Shinshu University, Japan; and Masahiro Kuroda, Goleta Networks Co., Ltd., Japan	
	Telemedicine for chronic disease management is extending to the home through the use of medical devices and ICT technologies. Patients with intractable diseases, such as amyotrophic lateral sclerosis (ALS) and lethal neurodegenerative diseases, have been returning to their homes rather than remaining hospitalized. Reliable alarms for condition changes of patients and burden reduction of their families are taking root as foundations of telemedicine for patients with intractable diseases. This paper discusses reliable alarm delivery and expected medical IoT features for those patients. A patient's family has difficulty in setting optimal parameters of life- support medical devices following patient condition changes. Also, caregivers and patients' families expect reliable alarms and false alarm reduction from tele-alarm systems used at home. We need to provide both anxiety relief for patients' families and patient safety by reliably monitoring the patients. We designed and implemented an alarm delivery system for patients with intractable diseases, and here we propose a prototype false-alarm reduction mechanism for highly-controlled medical device systems including an artificial ventilator. We investigated alarms of a patient for one year, cooperating with the patient's family. We need both hardware standard interfaces and consistent alarm functions between artificial ventilators. We conclude with our further work for patients with different types of intractable diseases and for standardization of medical IoT networks integrating false-alarm reduction systems.	

Session 4	Session 4: Digital health strategies	
S4.1	Invited paper - Towards international standards for the evaluation of artificial intelligence for health	
	Markus A. Wenzel, Fraunhofer Heinrich Hertz Institute, Germany; and Thomas Wiegand, Fraunhofer Heinrich Hertz Institute and Technische Universität Berlin, Germany	
	Healthcare can benefit considerably from advanced information processing technologies, in particular from machine learning (ML) and artificial intelligence (AI). However, the health domain only hesitantly adopts these powerful but complex innovations so far, because any technical fault can affect people's health, privacy, and consequently their entire lives. In this paper, we substantiate that international standards are required for thoroughly validating AI solutions for health, by benchmarking their performance. These standards might ultimately create well-founded trust in those AI solutions that have provided conclusive evidence to be accurate, effective and reliable. We give reasons that standardized benchmarking of AI solutions for health is a necessary complement of established assessment procedures. In particular, we demonstrate that it is beneficial to tackle this topic on a global scale and summarize the achievements of the first year of the ITU/WHO focus group on "AI for Health" that has tasked itself to work towards creating these evaluation standards.	
S4.2	Redesigning a basic laboratory information system for the global south*	
	Jung Wook Park, Aditi Shah, Rosa I. Arriaga and Santosh Vempala, Georgia Institute of Technology, United States	
	Laboratory information systems (LIS) optimize information storage and processing for clinics and hospitals. In the recent past, developers of LIS for the global south have worked under the assumption that computing environments will be very limited. However, the computing resources in the area have been rapidly enriched. This has also changed the expectations that users have about the LIS interface and functionality. In this paper, we provide a case study of C4C PLIS that has been in energy a decade in source A friend countries. In two	
	studies that included 51 participants from three African countries, we redesigned the LIS to better suit the changing technical landscape and user needs and evaluated the new design. The study procedure, usability metrics and lessons learned from our evaluation provide a model that other researchers can use. The findings provide empirical insights that can benefit designers and developers of LIS in the global south. The results also highlight the need for adding usability specifications for international standard organizations.	
S4.3	#RingingTheAlarm: Chronic "Pilotitis" stunts digital health in Nepal*	
	Ichhya Pant, George Washington University School of Public Health, United States; and Anubhuti Poudyal, George Washington University School of Medicine and Health Sciences, United States	
	Nepal Health Sector Strategy (NHSS) 2015-2020 aspires to leverage digital health to improve health outcomes for Nepalese citizens. At present, there is a paucity in evidence on digital health projects that have been implemented in Nepal. This study aims to map past and extant digital health projects using Arksey and O'Malley's scoping design framework and assess projects using the World Health Organization (WHO) building blocks of a health systems framework. Our findings shed light on the current actors in the digital health space, the spectrum of health services offered, along with opportunities and challenges to move beyond "pilotitis". In total, 20	
	digital health solutions were identified through our review that were implemented between 1993 to 2017. The momentum for digital health projects in Nepal is sporadic but continuous. Overall, digital health solutions in Nepal are limited in scope, focus areas, target audiences and sustainability potential. At the national level, implementation of digital health projects is frayed, issue and organization-centric, and primarily driven by donor or non-governmental organizations. Engaging the private sector, especially telecommunications companies, is an underutilized strategy to move beyond "pilotitis". Existing pioneers in the space must engage in strategic collaborative partnerships with the private sector or incentivize independent commercial health technology ventures	

S4.4	Designing national health stack for public health: Role of ICT-based knowledge management system
	Charru Malhotra, Indian Institute of Public Administration, India; Vinod Kotwal, Department of Telecommunication, India; and Aniket Basu, Indian Institute of Public Administration, India
	Public health (PH), as a domain, requires astute amalgamation of the workings of different disciplines, because its eventual aim is to 'prevent' and not just 'cure' the health concerns of the entire community/population under consideration. Public health goals can be achieved more meaningfully by the application of information communication technology (ICT) that helps in overcoming the bottlenecks of brick-and-mortar healthcare models. Online consultations, cloud-based health management solutions, smart service-supported diagnoses are some such examples. The present study attempts to explore the design and implementation of ICT-based holistic knowledge management systems (KMS) to address public health concerns at the national level. At any point in time, different management information systems (MIS) are being used by various public authorities that directly or indirectly impact PH. However, the data being generated by these MIS is "stove piped" into standalone, heterogeneous databases. Non-standardized data formats, incompatible IT systems, an aggravated sense of ownership by the agency that collects the data are some of the factors that further worsen the problem. To overcome these issues, based on the study of best practices and literature review, the review paper proposes a conceptual model, referred to as national health stack (NHS). NHS is a multilayered KMS designed to support evidence-based decisions of public health and would pave the way towards "Good Health and well being" (UN SDG 3) for All.

S5.1	Elderly health monitoring system with fall detection using multi-feature based person tracking*
	Dhananjay Kumar, Aswin Kumar Ravikumar and Vivekanandan Dharmalingham, Anna University, India; and Ved P. Kafle, National Institute of Information and Communications Technology, Japan
	The need for personalized surveillance systems for elderly health care has risen drastically. However, recent methods involving the usage of wearable devices for activity monitoring offer limited solutions. To address this issue, we have proposed a system that incorporates a vision- based deep learning solution for elderly surveillance. This system primarily consists of a novel multi-feature-based person tracker (MFPT), supported by an efficient vision-based person fall detector (VPFD). The MFPT encompasses a combination of appearance and motion similarity in order to perform effective target association for object tracking. The similarity computations are carried out through Siamese convolutional neural networks (CNNs) and long-short term memory (LSTM). The VPFD employs histogram-of-oriented-gradients (HoGs) for feature extraction, followed by the LSTM network for fall classification. The cloud-based storage and retrieval of objects is employed allowing the two models to work in a distributed manner. The proposed system meets the objectives of ITU Focus Group on AI for Health (FG-AI4H) under the category, "falls among the elderly". The system also complies with ITU-T F.743.1 standard, and it has been evaluated over benchmarked object tracking and fall detection datasets. The evaluation results show that our system achieves the tracking precision of 94.67% and the accuracy of 98.01% in fall detection, making it practical for health care system use. The HoG feature-based LSTM model is a promising item to be standardized in ITU for fall detection in elderly healthcare management under the requirements and service description provided by ITU T F.743.1.

S5.2	A healthcare cost calculator for older patients over the first year after renal transplantation
	Rui Fu, Nicholas Mitsakakis and Peter C. Coyte, University of Toronto, Canada
	Forecasting tools that accurately predict post-transplantation healthcare use of older end-stage renal disease (ESRD) patients are needed at the time of transplantation in order to ensure smooth care delivery in the post-transplant period. We addressed this need by developing a machine-learning-based calculator that predicts the cost of healthcare for older recipients of a deceased-donor kidney over the first year following transplantation. Regression tree and regularized linear regression methods, including ridge regression, lasso regression and elastic net regression were explored on all cases of deceased-donor renal transplants performed for patients aged over 60 in Ontario, Canada between March 31, 2002 and April 31, 2013 (N=1328), The optimal model (lasso) identified age, membership of one of 14 regionalized Local Health Integration Networks, blood type, sensitization, having diabetes as the primary case of ESRD, total healthcare costs in the 12-month pre-workup period and the 6-month workup period to be inputs to the cost calculator. This cost calculator, in conjunction with clinical outcome information, will aid health system planning and performance to ensure better management of recipients of scarce kidneys.
S5.3	Automatic plan generating system for geriatric care based on mapping similarity and global optimization
	Fei Ma, Chengliang Wang and Zhuo Zeng, Chongqing University, China
	The smart home is an effective means of providing geriatric care to increase the ability of the elderly to live independently and ensure their health in daily life. However, the smart home is not widely used because it is arduous to obtain a sensing devices selection plan. In this paper, the accuracy of service selection and cost savings assumes enormous importance. Therefore, we propose an automatically plan generating system for the elderly based on semantic similarity, intuitionistic fuzzy theory, and global optimization algorithm, aiming at searching for an optimized plan. Experiment results indicate that our approach can satisfy care demands and provide an optimized plan of sensing devices selection.

Session 6: Data and artificial intelligence era	
S6.1	Invited paper - Preparing for the AI era under the digital health framework
	Shan Xu, Chunxia Hu and Dong Min, China Academy of Information and Communication Technology (CAICT), China
	Information and communication technology (ICT) for health has shown great potential to improve healthcare efficiency, especially artificial intelligence (AI). To better understand the influence of ICT technology on health, a framework of the digital health industry has been proposed in this paper. Factors from the health industry and the ICT part are extracted to study the interaction between two groups of component factors. Health factors include service and management; and ICT factors include sensors, networks, data resources, platforms, applications and solutions. The interaction between ICT and health can be traced through the development history, from the stage of institutional informationization to regional informationization, and finally to service intelligentization. Following such a developmental roadmap, AI was chosen as one of the most powerful technologies to study the penetration effect and key development trends from the perspectives of data, computing power and algorithms. The health industry will be much improved or redefined in the coming AI era. To better understand the strengths, weaknesses and limitations of AI for health, exogenous factors are discussed at the end of the paper; preparations on collaboration mechanism; standardization and regulation have been proposed for the sustainable development of digital health in the AI era.

S6.2	Operationalizing data justice in health informatics*
	Mamello Thinyane, United Nations University, Macao SAR, China
	There is a growing awareness of the need and increasing demands for technology to embed, be sensitive to, be informed by, and to be a conduit of societal values and ethical principles. Besides the normative frameworks, such as the Human Rights principles, being used to inform technology developments, numerous stakeholders are also developing ethical guidelines and principles to inform their technology solutions across various domains, particularly around the use of frontier technologies such as artificial intelligence, machine learning, Internet of things, robotics and big data. Digital health is one of the domains where the convergence of technology and health stands to have a significant impact on advancing sustainable development imperatives, specifically around health and wellbeing (i.e. SDG3). As far as digital health is concerned, what values and ethical principles should inform solutions in this domain, and more significantly, how should these be translated and embedded into specific technology solutions? This paper explores the notion of data justice in the context of health informatics and outlines the key considerations for data collection, processing, use, sharing and exchange towards health outcomes and impact. Further, the paper explores the operationalization of Mortier et al.'s Human-Data Interaction principles of legibility, agency and negotiability through a health informatics system architecture.

٦

Session 7	Session 7: Safety and security in healthcare	
S7.1	Thought-based authenticated key exchange*	
	Phillip H. Griffin, Griffin Information Security, United States	
	Identity authentication techniques based on password-authenticated key exchange (PAKE) protocols rely on weak secrets shared between users and host systems. In PAKE, a symmetric key is derived from the shared secret, used to mutually authenticate communicating parties, and then used to establish a secure channel for subsequent communications. A common source of PAKE weak secrets are password and passphrase strings. Though easily recalled by a user, these inputs typically require keyboard entry, limiting their utility in achieving universal access. This paper describes authentication techniques based on weak secrets derived from knowledge extracted from biometric sensors and brain-actuated control systems. The derived secrets are converted into a format suitable for use by a PAKE protocol. When combined with other authentication factors, PAKE protocols can be extended to provide strong, two-factor identity authentication that is easy to use by persons living in assistive environments.	
S7.2	Cyber-safety in healthcare IoT Duncan Sparrell sFractal Consulting United States	
	Healthcare is becoming more connected. Risks to patient and public safety are increasing due to cybersecurity attacks. To best thwart cyberattacks, the Internet of health things (IoHT) must respond at machine speed. Cybersecurity standards being developed today will enable future IoHT systems to automatically adapt to cybersecurity threats in real time, based on a quantitative analysis of reasonable mitigations performing triage to economically optimize the overall healthcare outcome. This paper will discuss cybersecurity threats, risk, health impact, and how future IoHT cybersecurity systems will adapt to threats in real time.	

Session 8	: Data protection and privacy in healthcare
S8.1	Technical and legal challenges for healthcare blockchains and smart contracts
	Steven A. Wright, Georgia State University, United States
	The paper considers the technical and legal challenges impacting recent proposals for healthcare applications of blockchain and smart contracts. Healthcare blockchain data and actors are rather different to cryptocurrency data and actors, resulting in a different emphasis on blockchain features. Technical issues with healthcare blockchain implementation and trust are considered, as well as a variety of potential legal issues. Conclusions and recommendations are proposed for open source and standardization efforts to reduce technical and legal risks for healthcare blockchains and smart contracts.
S8.2	Design of a credible blockchain-based e-health records (CB-EHRs) platform
5012	Lingyu Xu, Antoine Bagula, Omowunmi Isafiade and Kun Ma, University of the Western Cape, South Africa; and Tapiwa Chiwewe, IBM Research Africa, South Africa
	With the rapid development of electronic health care, the era of medical big data has already emerged. However, in the global electronic health industry environment, one of the significant challenges is that the various medical institutions are independent of one another. Patients, doctors and medical researchers have significant barriers in accessing medical data. As an intervention strategy using blockchain principle, this paper explores the characteristics of blockchain which are applicable to the management of electronic health records (EHRs), and presents a credible blockchain-based electronic health records (CB-EHRs) management platform. A CB-EHRs platform is characterized by decentralization, data tamper-proof, collective maintenance mechanisms, security and credibility. This platform cannot only realize data sharing between medical institutions, but also ensures the privacy of users. This paper introduces the components of the CB-EHRs platformmodel and the implementation principle of its related functions. In addition, this paper also reviews and selects the delegated Byzantine Fault Tolerance (dBFT) consensus mechanism as a viable option for the CB-EHRs platform. Finally, by comparing with the Practical Byzantine Fault Tolerance (PBFT) consensus mechanism and our research, we highlight the potential advantages of our proposed CB-EHRs platform in the medical domain.
S8.3	The GDPR transfer regime and modern technologies Melania Tudorica and Trix Mulder, University of Groningen, The Netherlands
	Health data comes within a person's most intimate sphere. It is therefore considered to be sensitive data due to the great impact it could have on a person's life if this data were freely available. Unauthorized disclosure may lead to various forms of discrimination and violation of fundamental rights. Rapid modern technological developments bring enormous benefits to society. However, with this digitization, large amounts of health data are generated. This makes our health data vulnerable, especially when transferred across borders. The new EU General Data Protection Regulation (GDPR) legal framework provides for rights for users of modern technologies (data subjects) and obligations for companies (controllers and processors) with regard to the processing of personal data. Chapter V of the GDPR protects personal data that are transferred to third countries, outside the EU. The term 'transfer' itself, however, is not defined by the GDPR. This paper examines whether transfer within the meaning of the GDPR applies to health data processed by modern technologies and if the complexity of the GDPR legal framework as such sufficiently reflects reality and protects health data that moves across borders, in particular to jurisdictions outside the EU.

INDEX OF AUTHORS

Index of Authors

Arriaga,	Rosa I.				77
----------	---------	--	--	--	----

B agula, Antoine	9, 183
Bas, Joshua N.	39
Basu, Aniket	95

Cha, Hongki	49
Chiwewe, Tapiwa	
Choi, Younghwan	49
Coyte, Peter C	115

Dharmalingham, Vivekanandan......105

${f F}$ u, Rui	1	15

G riffin, Phillip H.	155
Gupta, Shayan	

H u, Chunxia	135
Isafiade, Omowunmi	

K afle, Ved P	105
Kelly, Shawn K.	
Kotwal, Vinod	95
Kumar, Dhananjay	105
Kuroda, Masahiro	59

Lee, Kangchan	49
Liu, Hongfu	

M a, Fei	125
Ma, Kun	183

Malhotra, Charru
Mauwa, Hope9
Min, Dong 135
Mitsakakis, Nicholas 115
Mulder, Trix 191
Murata, Yoshitoshi 33
Nakamura, Akinori 59
Ngqondi, Tembisa9
Pan. Changvong
Pant Ichhya 85
Park, Jung Wook
Poudval Anubhuti 85
1 oudya, 1 maonau
R avikumar Aswin Kumar 105
Dedrigues Icel I D C
Rodrigues, Joer J. P. C 1
a
Sato, Takuro 1
Shah, Aditi
Siddiquee, Junaid Ahmed 23
Song, Jian 17
Sparrell, Duncan 163
Takizawa, Masaomi 59
Thinvane, Mamello
Tudorica, Melania

Wright, Steven A

Xu, Lingyu	183	
Xu, Shan	135	
Xu, Xuan		

Yamato, Tomoki	33
Yoshikawa, Kentaro	59
Yu, Keping	1

Zeng, Zhuo	125
Zhai, Yunkai	1
Zhang, Dalong	1
Zhang, Di	1
Zhang, Hongming	17
Zhang, Jacqueline	
Zhang, Teng	1

International Telecommunication Union

Telecommunication Standardization Bureau Place des Nations CH-1211 Geneva 20 Switzerland



Published in Switzerland Geneva, 2019