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| **Abstract:** | This document describes the WatIF Health project as a use-case application for AI in primary health care for resource-constrained settings. It is submitted as one of the potential projects to be considered for the ITU-WHO exercise of developing a regulatory framework for AI in health. |

# 1 Introduction

The WatIF Health project will demonstrate a use-case application for AI in primary health care for resource constrained settings that is based on an existing application.

It is submitted as one of the potential projects to be considered for the ITU-WHO exercise of developing a regulatory framework for AI in health.

The purpose of this submission is to subject the project to a peer review and benchmarking process that will assess its fitness for purpose and performance level of its AI algorithms regarding:

* Explainability
* Interpretability
* Reproducibility
* Ability to deal with outliers and
* Amenability to human oversight.

The WatIF chronic disease management platform **(**WatIF AI Health Portal) is a multi-platform, plug and play application that is easy to deploy. Its easy deployment is also designed to interface well with existing paper based primary healthcare work flow

*The WatIF Health Portal was from 2016 for scalability at scale in South Africa using 50 private clinics that are owned by nurses across six provinces.*

Designed as a health workforce multiplier that utilizes the exponential power of AI to implement effective task-shifting at primary healthcare level, by incorporating community health workers into mainstream clinical work to do repetitive work previously carried out by nurses, such as measuring blood pressure, weight and height etc. Nurses arethen up-skilled to perform work previously reserved for doctors, and doctors are positioned to support more than one clinic in real-time from a remote location.

It utilizes AI to generate tertiary level clinical knowledge on Non-Communicable Diseases (NCDs), HIV/AIDS and TB to close the knowledge gap-commonly encountered between tertiary and primary health care institutions in low- and middle-income countries (LMICs).

It also utilizes AI to process old or current electronic health record (EHR) datasets derived mostly from laboratory test results, medicine prescription records, patient demographics and other clinical information that can now be transformed into comprehensive text based, clinical output statements that includemeaningful-use, disease and patient-specific clinical decision support outputs.

The WatIF health portal innovation is HL7 and DHIS2 compatible for inter-operability and real-time data sharing with existing government district health information systems.

The WatIF chronic disease management platform is based on a predefined medical knowledge system that was developed using human coding technology to mimic AI without machine learning capabilities, now in the second phase of development into a fully-fledged AI platform with machine learning capabilities.

WatIF innovation will demonstrate how the use of AI in primary health care can contribute to a high value intangible ROI, measured by the value that is attached to the benefit associated with reducing human suffering, protecting the poor and vulnerable from catastrophic health expenditure, as well as the impact that can be attributed to mitigating the effects of premature death and disability from NCDs, There is also the inherent value that comes with contributing to the strengthening of public health systems in LMIC.

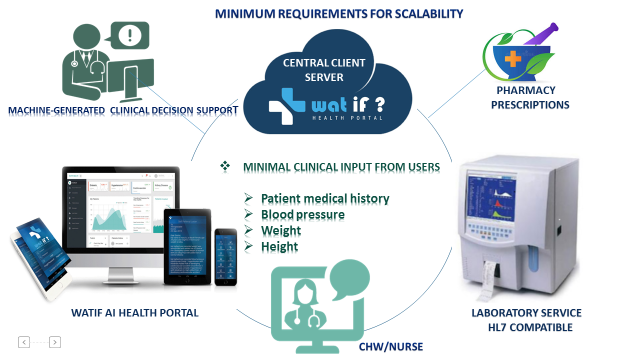


Figure – WatIF connecting different players for meeting minimum requirements

## 2 Overview

Closing the clinical knowledge Gap

The platform utilizes the exponential power of AI as an extraordinary health workforce multiplier to implement primary healthcare task-shifting and to close~~s~~ the NCD, HIV/AIDS clinical knowledge gap between tertiary and primary health care institutions in low to middle income countries (LMIC).

Incorporating Best Practice

The system is capable of generating tertiary level clinical knowledge from given datasets, transfer such derivative clinical knowledge back to primary health care workers, and present it in aneasy to comprehend, actionable medical knowledge in keeping with current best practice.

Automating Data Sets

The Watif HealthPortal utilizes an AI-driven methodology to processes old or current electronic health record (HER) datasets, derived mostly from laboratory test results, medicine prescription records, patient demographics and other clinical datasets-sometimes with very minimal direct input from nurses and doctors- to automate the integrated chronic disease management processes.

It transforms this data into comprehensive text based, meaningful-use, clinical decision support statements that are disease and patient-specific, for use by care givers. This approach eliminates variability of care while influencing standardization of clinical outcomes, irrespective of the user’s level of prior clinical knowledge.

Electronic Health Records

In this project best practice clinical guidelines, recommendations and care pathways are entirely machine driven. For instance; when a patient visits a clinic, all that the health care worker has to do is open a system-generated, detailed patient electronic health record that is presented as a single integrated view of the his/her health status with a risk profile that comes with predetermined outcome based clinical care pathways.

Disease Management Process

The entire disease management process is activated and overseen by AI, including scheduling of appointments for disease-specific laboratory tests, consultations and clinical procedures. The portal utilizes system generated SMS reminders as a patient recall system, while trackingpatients/health care provider compliance with recommended international or country-specific best practice guidelines, treatment protocols and care pathways. It is also capable of flagging any anomalies and or deviations from such recommended best practice.

Real time support in multiple locations.

Multiple clinics are supported in real-time by one doctor/specialist from a remote location. Nurses are able to request a real-time, virtual/remote consultation with a doctor/specialist by sharing entire patient electronic health records, including medical images, prescriptions and laboratory test results. The doctor/specialist is also able to write clinical observations and recommendations on this single, longitudinal, life-long, shared electronic health record.

# 3 Impact

## 3.1 Problem Statement

Africa’s greatest inability to deal with the current burden of disease caused by NCDs, HIV/AIDS and TB among others, is not so much the poor socioeconomic conditions and lack of resources as it is in her inability to:

* Offer the little that there is, in increased simultaneous coverage.
* Offer it across multiple interventions and across different segments.
* Offer it to the population in a way that caters for all, particularly the poor and most vulnerable groups.

Many of Africa’s health care systems are hopelessly outdated, not structured to manage and cope with the current mortality and morbidity shift towards chronic diseases. As they were designed to deal with communicable diseases and acute conditions, they are inherently ill-positioned to deal with the recent emergence of lifelong or long-term conditions such as diabetes, hypertension, cardiovascular diseases, HIV/AIDS and TB.

These new epidemics require not just the rethinking of services, but also a reorientation of aspects of primary health care to rise to the challenge of integrated approach to the management of NCDs and other chronic conditions, using a labour-pool and resource-sharing approach that is in line with the dictates of Sustainable Development Goals and Universal Health Coverage (UHC). The increase in demand for expanded access to equitable, integrated, people-centred health services, reaffirms the urgency for such a need.

In response, society is now increasingly turning to ICT to deliver the little it has in a transparent and equitable manner, across different segments of population groups, to deal with endemic systemic problems peculiar to resource-constrained societies, such as:

* The global shortage of a health work-force that seem to worsen with each passing year.
* The inability to cascade outcome-based, tried and tested tertiary level clinical medical knowledge to primary health care workers, present it in a manner that speaks to NCDs, HIV/AIDS and TB in a UHC environment
* Weaknesses in health systems that are fast becoming ineffective in the face of NCDs and other chronic Diseases

## 3.2 Potential Impact of the project

### 3.2.1 Contributing to a Global Health Work-force for LMIC

The world will be short of 12.9 million health-care workers by 2035; today, that figure stands at 7.2 million. A WHO report released on 11th November 2013 warns that the findings - if not addressed now- will have serious implications for the health of billions of people across all regions of the world. Increasing demands are also being put on the sector from a growing world population with increasing risks of developing non-communicable diseases

“Sub-Saharan Africa, with about 11% of the world’s population bears over 24% of the global disease burden, is home to only 3% of the global health workforce, and spends less than 1% of the world’s financial resources on health” (Anyangwe and Mtonga, 2007).

The WatIF application is designed as a health workforce multiplier to address this very problem by increasing efficiency through task-shifting. It incorporates community health care workers into mainstream clinical work-with minimal clinical training required-they are tasked to carry out standardized, repetitive clinical work previously carried out by nurses, such as recording vital signs using digital blood pressure machine, glucose meter and weighing scales.

Nurses are up-skilled to perform work previously reserved for doctors, while doctors are positioned to support more than one clinic in real-time, from a remote location with the ability to share entire patient electronic health records including medical images, laboratory test results and prescriptions.

### 3.2.2 Mitigating the Impact of Burden of Disease

According to the most recent WHO estimates Non-communicable diseases (NCDs) kill 41 million people each year, equivalent to 71% of all deaths globally. Each year, 15 million people die from a NCD between the ages of 30 and 69 years; over 85% of these "premature" deaths occur in low- and middle-income countries. Cardiovascular diseases account for most NCD deaths, or 17.9 million people annually, followed by cancers (9.0 million), respiratory diseases (3.9million), and diabetes (1.6 million). These 4 groups of diseases account for over 80% of all premature NCD deaths.

The cumulative economic losses due to NCDs under a “business as usual” scenario in low- and middle-income countries from 2011-2025 are estimated at US$ 7 trillion. WHO estimates the cost of reducing the global NCD burden including diabetes as US$ 11.2 billion a year.

High rates of death and disability, particularly in LMIC are a reflection of inadequate investment in cost-effective NCD interventions. In LMIC it is the poorest people that bear the brunt of the highest exposure to risk factors leading to NCDs, and are at risk of dying prematurely from them because of inadequate health care services

# South Africans are dying a very slow death from Non-communicable diseases with more than 75% of Females over 35yrs being overweight or obese. (Chronic Diseases Initiative in Africa (CDIA) June 2013)

# 78% of South Africans over the age of 50 years are suffering from hypertension, the highest ever blood pressure reported by a national representative survey for people over 50 years for any country. (The Lancet April 2014)

# NCDs mainly stroke, heart attack, diabetes, hypertension and chronic respiratory diseases are responsible for43% of deaths in South Africa (Stats S.A 2017)

# In South Africa Diabetes has become the second highest killer behind TB and continues to rise (Stats S.A 2018)

HIV/AIDS and TB care is also delivered as a horizontal services with a dedicated budget unlinked to NCD acre despite overwhelming scientific evidence of a high prevalence of co-occurrences in the same individual

*At present, the main focus of health care services for NCDs in many countries including LMIC is hospital-cantered. America for instance, is now estimated to be spending 75% of its health-care dollar on NCDs**(American Center for Disease Control 2013)**The European Union countries are also spending between 70% to 80% of their health-care EURO on Chronic Diseases (Nessa Childers, European Parliament 2013)*

At this rate LMICs will struggle to achieve and maintain a similar level of spending as is the case in high-income countries, even with the best access to affordable generic medicines, because of budgetary constraints and a health work-force and skills shortages.

Yet AI technology could not have come at a more opportune moment in time than now for LMIC, because it is with assistance from AI, LMIC will be able to offer overarching solutions such as the WatIF Health Portal to innovatee for an integrated approach to NCDs,HIV/AIDS care, and will for the first time be in a position to present doctors with a digital panoramic view of the window through which death and disability walks into the lives of people afflicted by NCDs, long before it occurs.

Health care workers will now be in a position to determine who among a given population of patients is at risk of developing diabetes or hypertension, and who among NCD sufferers is at risk of developing cardiovascular accident, coronary atherosclerotic vascular disease, or chronic progressive renal disease, and to what degree, and be able to delineate the risk factors that drive such eventuality .This will contribute a great deal to the capacity of LMIC to respond to NCDs and other chronic diseases at a systemic level.

The WatIF platform is designed to strengthen public health systems by delivering a new primary health care model that is fit for purpose, positioned to reduce the number of complications, hospital admissions and premature death from NCDs. This model can be delivered at a fraction of the current cost of an American and/or European NCD care model, because LMIC have the advantage of starting from a greenfield environment that is unconstrained by system legacy considerations common to established markets.

# 4 Current State of the Art Projects

There are not many good examples of the state of the art AI projects that are all encompassing, with an integrated approach to clinical or public health, particularly in primary health care, WatIF Health Portal is one such example. Many of the current AI projects in health are designed to answer aspect of health care in a vertical approach, such as AI for bio-metric identification of individuals, AI for interpretation of radiological images, AI for interpretation of retinal images and for skin diseases.

* Livongo is a California based company operating an extensive non-AI, NCD program serving over 500 employer groups to empower those living with pre-diabetes, diabetes, hypertension and chronic conditions to live healthier lives. Their approach is to redesign chronic condition management and drive behaviour change through the combination of consumer health technology, personalized recommendations, and real-time support at the point of impact. Powered by advanced analytics, they create personalized experiences so their members receive the right information, tools, and support, at the right time with a knock-on effect of better financial and clinical outcomes for the patient, family, friends and medical professionals**.** https://www.livongo.com/
* [HealthRise](https://www.health-rise.org/) is a five-year, US $17 million community-based program that supports community-based demonstration projects designed to expand access to care and management of chronic NCDs, such as heart disease and diabetes, in India, Brazil, South Africa, and the United States. https://globalhealthleaders.org/partners/medtronic-philanthropy/
* Be He@lthy, Be Mobile **(**non-AI project)although not AI based this project harnesses the power and reach of mobile phones and space based technology to address the non-communicable disease (NCD) risk factors. The educational initiative deliver**s** disease prevention and management information directly to mobile phone users. And strengthens health systems by providing training to health workers.
* Non-health related state of the art AI projects
* Amazon e-commerce

# 5 Datasets

Datasets required for this project are:

* Laboratory and pathology test results
* Medicine prescription information
* De-identified clinical datasets
* Demographic data and
* Clinical guidelines, treatment protocols and care pathways

There are several international organizations that have well-structured repositories of high quality de-identified and un-linked datasets for laboratory test results, prescription medicines that are used for NCDs, HIV/AIDS and TB, as well as other patient clinical datasets. Organizations such as the *American College of Cardiology, American Diabetic Association, American Endocrine Society, The National Institute for Health and Care Excellence (NICE)**are the world’s best repositories of the most up to date, research based, peer reviewed clinical guidelines and care pathways.*

Clinical guidelines, care pathways medical laboratory test result, prescription medicines and clinical datasets such as NCD diagnosis and ICD10 codes used in this project, happen to be some of the oldest well documented, high quality, standardized and freely available medical datasets. They are also easily accessible in standardized high quality format even in LMIC environment.

# 6 Benchmarking

The project expects participants in the benchmarking process to submit benchmarking tools for ambulatory clinical test cases that are based on real or simulated, known and unknown or pre-determined clinical outcomes for the purposes of conducting the following bench marking exercise:

* Performance assessment against known clinical guidelines and standards of care.
* Evaluate consistency of the algorithms when subjected to a wider range of general datasets that are related to the same clinical guidelines and standard of care.
* *Subject the application to a benchmarking process that uses research based peer reviewed, approved clinical guidelines, treatment protocols and care pathways to validate the application’s clinical consistency against scientific rigor and ethical dictates.*
* Real-life situation or simulated clinical work-flow scenarios using randomized controlled crossover trials of human-computer interfaces, against performance by human clinicians that are unaided by computers.
* To subject the clinical decision supporting tools to independent assessment of their fitness for purpose as a health work-force multiplier and their appropriateness and fitness for purpose as a disseminator of tertiary level clinical knowledge to primary health care workers against clinical outcomes compared to human performance.
* *Subject the project to a benchmarking process that validates the application’s claim of value add, and fitness for purpose against known industry best practice*
* Use-case scenario challenges that are designed to highlight practical shortcomings and opportunities for improvement in the following area:
* Explainability
* Interpretability
* Reproducibility and
* Ability to deal with outliers in a consistent and predictable manner
* *Subject the application to a benchmarking process that tests its amenability to Human oversight a prerequisite for our philosophy on AI design for health.*

# 7 Organizational Information

The WatIF project is self-funded, designed and developed over a period of ten un-interrupted years by the same team of ICT engineers and doctors experienced in the management of NCD, HIV/AIDS and TB in resource constrained primary health care settings, and therefore, are very well acquainted with the complexities of Sub-Saharan health care challenge, and very keen to employ the resources of the ITU study to mitigate those challenges.

Our interest and passion for this area of health care is informed by the many years of practical experience and first hand exposure to the devastating impact of NCD, HIV/AIDS and TB on communities we serve. The observation of the many shortcomings on government lead programs, whose success depends on rapid adoption of enabling technology and ability and capacity to innovate for emerging global epidemics.

Our organization is comprised of no less than twelve masters level ICT engineers, Epidemiologists, primary health care physicians qualified in NCD, HIV/AIDS and TB management with many years of field work experience in this area.

We have conducted a similar proof of concept in 2017 with the Eastern Cape provincial department of health in South Africa, where we successfully demonstrated the ability of the project’s methodology to multiply the health work force, up-skilling of nurses and established real-time support for multiple health care professionals by one doctor from a remote location. The ability to disseminate tertiary medical knowledge to primary health care workers, ease of adoption and scalability. The application was also tested for scale at scale, and is currently being used by fifty private primary health care nurses scattered around seven of the nine provinces in South Africa.

The WatIF Health Portal has received several international recognition, such as the Frost and Sullivan best South African technology award for NCD, The Global Mobile Award nomination for top five best contribution to SDG among others.

## 7.1 Co-Principal Investigator Roles:

* Dr. N.N Sipula is a Co-Principal Investigator responsible for directing implementation of EMR, AI and clinical interventions in the proposed use case. He is the Founder and CEO, responsible for the medical and clinical Systems Architect for AI software development at WatIF Health
* Jason Paul is a Co-Principal investigator who is an experienced masters level ICT engineer and the project manager and leader of the ICT team responsible for the AI design
* Dr. B. Muthambi (PHD) is a Co-Principal Investigator responsible for the design and conduct of the proposed use case study, and leading analyses & reporting of findings of the study. He is a Snr Scholar-in-Residence at the Institutes of Epidemiology & Public Health/IEPH, Inc. With more than 20 years’ experience as epidemiologist

## 7.2 Other Partners

1. Africare - A registered NGO specializing in the provision of HIV/AIDS services at community level, supports government programs
2. Unjani Clinics (Imperial Health Institute) Not for profit organization, for female nurse empowerment
3. Institutes of Epidemiology & Public Health/IEPH, Inc.
4. Ebenezer ICT solutions
5. Prelink Pty Ltd Laboratory systems integration
6. Health IQ2 Pty Ltd supplier of point of care devices
7. Active Care - Group of private clinics
8. The South African Department of Science and Technology (Innovation Section)

We also intend to add more partners and collaborators as and when the need arises, and at the appropriate time

# 8 Motivation for the submission

Despite advances in computing processing speed and capacity, relatively cheap digital storage, and a flood of available digital datasets, the current AI applications for health care have tended to be concentrated around high-tech projects that are funded by private enterprises seeking a high return on investment (ROI).

This has led to the concentration of resources on high-tech solutions that solvee first world health problems, as evidenced by substantive investments in R&D for Genomics, Robotics, and image analytics technology that promise a high ROI for investors.

The majority of these advancements offer limited, vertical clinical solutions that are not suitable for alleviating the current burden of disease experienced by LMIC.

Although LMIC are notorious for poor ROI on high-tech solutions-particularly in health- WatIF believes that in the current AI for health environment, there can be no lower hanging fruit than that which is presented by the use of AI innovation for primary health care, to address universal health coverage (UHC) and SDGs.and the UN Sustainable development goals of health care, education and poverty reduction by the deadline of 2030 will likely come up with good data that is helpful to not only Africa, but the rest of the under resourced countries like China, India and South America.

WatIF project will demonstrate how well thought through, low-tech innovation for primary health care can contribute to high value intangible ROI, measure base on the value attached to the benefit associated with reducing human suffering, protecting the poor and vulnerable from catastrophic health expenditure, as well as the impact associated with the prevention of premature death and disability from NCDs. There is also the inherent value that comes with contributing to the strengthening of public health systems in LMIC.

We feel the WatIF would be a perfect project to be evaluated as part of the ITU-WHO’s desire to develop a regulatory framework for AI in health. WatIF’s project could easily fit all parameters, and can be subjected to performance evaluation of its AI algorithms for Explainability, Interpretability, Reproducibility, its ability to deal with outliers and **its** amenability to human oversight, a factor most critical for acceptance as a tool to be trusted in health particularly in LMIC.

WatIF’s project looks forward to assisting in this endeavour, and feels passionate about Africans participating in solving Africa’s health problems and being part of the AI innovation movement at the appropriate level.

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