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Contact: Nina Linder
University of Helsinki
Finland
E-mail: nina.linder@helsinki.fi

Abstract: This document contains the "Call for topic group participation" for TG-POC, addressing members of the medical and artificial intelligence communities with a vested interest in point of care diagnostics: Become engaged in the topic group dedicated to establishing a standardized benchmarking procedure for AI in point-of-care diagnostics within the International Telecommunication Union (ITU)/World Health Organization (WHO) Focus Group on "Artificial Intelligence for Health" (FG- AI4H).

This version of the CfTGP is the same as seen in Meeting M (FGAI4H-M-029-A02), reproduced for easier reference as a Meeting N document.

ITU/WHO Focus Group on artificial intelligence for health (FG-AI4H)

Call for Topic Group Participation: AI for point-of-care diagnostics

The International Telecommunication Union (ITU)/World Health Organization (WHO) Focus Group on "Artificial Intelligence for Health" (FG-AI4H; https://itu.int/go/fgai4h) seeks engagement from members of the medical and artificial intelligence (AI) communities (including clinicians, technologists, entrepreneurs, potential benchmarking data providers, machine learning experts, software developers, researchers, regulators, policy-makers, companies/institutions, and field experts) with a vested interest in shaping the benchmarking process of AI for point-of-care diagnostics.

1 About FG-AI4H

Over the past decade, considerable resources have been allocated to exploring the use of AI for health, which has revealed an immense potential. Yet, due to the complexity of AI models, it is difficult to understand their strengths, weaknesses, and limitations. If the technology is poorly designed or the underlying training data is biased or incomplete, errors or problematic results can occur. AI technology can only be used with complete confidence if it has been quality controlled through a rigorous evaluation in a standardized way. Towards developing this standard assessment framework of AI for health, the ITU has established FG-AI4H in partnership with the WHO.

Thus far, FG-AI4H has established 24 topic groups. The topic groups are: use of AI in cardiovascular disease management, dermatology, diagnoses of bacterial infection and anti-microbial resistance, falls among the elderly, histopathology, malaria detection, maternal and child health, neurological disorders, ophthalmology, outbreak detection, psychiatry, radiology, snakebite and snake identification, symptom assessment, tuberculosis, volumetric chest computed tomography, dental diagnostics and digital dentistry, AI based detection of falsified medicine, primary and secondary diabetes prediction, endoscopy, musculoskeletal medicine, fertility and human reproduction, sanitation for public health, and AI for point-of-care diagnostics.

Each topic group agrees upon representative benchmarking tasks in a pragmatic, best-practice approach, which can later be scaled and expanded to similar tasks. Every benchmarking task should address a health problem of relevance (e.g., impacting a large and diverse part of the global population or challenging to treat) and for which AI technology would provide a tangible improvement relative to the current practice (e.g., better care, results, and/or cost/time effectiveness).

For a rigorous and sound evaluation, undisclosed test data sets must be available (or must be collected) for each task. All data must be of high quality and compliant with ethical and legal standards. In addition, the data must originate from a variety of sources so that it can be determined whether an AI algorithm can generalize across different conditions, locations, or settings (e.g., across different people, hospitals, and/or measurement devices). The format/properties of the data serving as input to the AI and of the output expected from the AI, as well as the benchmarking metrics are agreed upon and specified by the topic group.

Finally, the AI-to-be-evaluated will be benchmarked with the undisclosed test data on FG-AI4H computing infrastructure. Here, the AI will process single samples of the undisclosed test data set and predict output variables, which will be compared with the "ground truth." The results of the benchmarking will be provided to the AI developers and will appear on a (potentially anonymized) leaderboard.

2 Topic group: AI for point-of-care diagnostics

A topic group is a community of stakeholders from the medical and AI communities with a shared interest in a topic. The objectives of the topic groups are manifold:

1. to provide a forum for open communication among various stakeholders,
2. to agree upon the benchmarking tasks of this topic and scoring metrics,
3. to facilitate the collection of high-quality labelled test data from different sources,
4. to clarify the input and output format of the test data,
5. to define and set-up the technical benchmarking infrastructure, and
6. to coordinate the benchmarking process in collaboration with the Focus Group management and working groups.

The primary output of a topic group is one document that describes all aspects of how to perform the benchmarking for this topic. The document will be developed in a cooperative way by suggesting changes as input documents for the next FG-AI4H meeting that will then be discussed and integrated into an official output document of this meeting. The process will continue over several meetings until the topic description document is ready for performing the first benchmarking.

This topic group is dedicated to AI for point-of-care diagnostics.

The diagnostic system includes obtaining a sample, digitizing the sample with a mobile microscope scanner, image transfer over mobile networks, AI-analysis, and verification by remote expert and feed-back of results back to the point-of-care for decision support. This means a significant step towards a more equal and sustainable access to high-quality diagnostics especially in low- and middle-income countries

The method is applicable to any disease that currently is diagnosed by microscopy (e.g., cancer, malaria, and tropical neglected diseases) (1, 2, 3). The focus is on a low-and middle-income countries, but the method is equally applicable in mid to high-income countries.

The instruments include software that improves the quality of captured images and performs image compression for rapid and cost-effective data transfer and AI analysis. Deep learning has recently been successfully applied to medical image-based diagnostics.

The benchmarking task is a continuation of a previously developed deep learning based algorithm that will be used for detection of premalignant lesions in the digitized Pap smears (1). The algorithm has been trained > 16,000 manually annotated regions from 350 cervical samples, including areas of both normal cervical cellular morphology and various degrees of atypia as previously described (1). The AI-algorithm was validated on 390 different patient samples. Access to the trained model is possible remotely to analyze samples directly at the POC on a cloud-based platform via upload over mobile or landline networks. In the first phase, the AI results are reviewed and verified by a pathologist.

In preparation of effective implementation and sustainable scaling up of this novel diagnostic tool, we anticipate implementation challenges at various levels. At the end user level - availability of technical capacity and readiness to accurately use the technology; at health facility level - institutional readiness to incorporate the technology and availability of necessary institutional infrastructures that will facilitate the integration of the tool in a routine POC workflow; and at national level - presence of policy frameworks necessary to address ethical challenges that are anticipated when it comes to use of AI. We will identify and clearly describe the problems that will potentially prevent effective implementation of the tool. We will design and test implementation strategies that provide solutions to the identified problems and how to address these when using the diagnostic tool for diseases other than cervical cancer. The approach will be mixed methods (qualitative and quantitative) involving all key stakeholder in this project. The implementation research outcomes will include acceptability, adoption, appropriateness, and feasibility of using AI and mobile microscopy for cancer and infectious disease diagnostics in resource-limited settings.

Significance

The AI-based digital methods will enable accurate, efficient, and accessible diagnostics, partly by automation and partly by a decreased need for expertise at the point-of-care, and thereby contribute to the Sustainable Development Goals (SDGs) of the United Nations to ensure health and well-being for all. Improved prevention also indirectly has significance for the SDGs related to poverty, gender equality and quality education through prevention of unnecessary morbidity and mortality in relatively young women.

The patients. The methods will improve case management by providing access to diagnostics in areas where access to high quality microscopy services previously has been limited or resulted in delays in time to diagnosis.

The health care system and professionals. The methods enable remote consultation and thus directly addresses the need for task shifting and a more efficient use of available experts.

The scientific community. Within the project high-quality digitized medical images will be created, which will support research on medical diagnostics and applied AI.

The medical and technical educational system. The project will give teachers and students access to state-of-the art instruments for sample digitization, enable the establishment of digital sample archives for educational purposes, as well as build capacity for development of AI algorithms for a wide variety of diagnostic purposes.

Disease surveillance, epidemiology, and public health. The system will aid the assessment of the disease burden and epidemiology, which is essential to guide adequate disease control policies.

1. Holmström O, Linder N, Kaingu H, Mbuuko N, Mbete J, Kinyua F, Törnquist S, Muinde M, Krogerus L, Lundin M, Diwan V, Lundin J. Point-of-Care Digital Cytology With Artificial Intelligence for Cervical Cancer Screening in a Resource-Limited Setting. JAMA network open. 2021;4(3):e211740-e.

2. Holmström O, Linder N, Ngasala B, Mårtensson A, Linder E, Lundin M, Moilanen H, Suutala A, Diwan V, Lundin J. Point-of-care mobile digital microscopy and deep learning for the detection of soil-transmitted helminths and Schistosoma haematobium. Global Health Action. 2017;10(sup3):1337325.

3. Holmström O, Stenman S, Suutala A, Moilanen H, Kücükel H, Ngasala B, Mårtensson A, Mhamilawa L, Aydin-Schmidt B, Lundin M, Diwan V, Linder N, Lundin J. A novel deep learning-based point-of-care diagnostic method for detecting Plasmodium falciparum with fluorescence digital microscopy. PLOS ONE. 2020;15(11):e0242355.

More details about the activities of the topic group can be found in the documents on the FG-AI4H website and on the TG-POC collaboration site [https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-POC.aspx]. These can be accessed with a free ITU account (cf. “Get involved”).

Current members of the topic group on AI for point-of-care diagnostics include:

Nina Linder, MD, PhD is an Associate Professor at the Institute for Molecular Medicine-FIMM, University of Helsinki, Finland as well as the Department of Women's and Children's Health, International Maternal and Child Health at Uppsala University, Sweden. She is an expert in molecular medicine and medical artificial intelligence and diagnostics.

Johan Lundin, MD, PhD, is a Professor of Medical Technology at Karolinska Institute (KI), Sweden and a Research Director at the Institute for Molecular Medicine Finland-FIMM at the University of Helsinki, Finland. The research group of Lundin and Linder has earned international reputation within the field of digital diagnostics and applied AI. Areas of expertise include applied medical artificial intelligence, biomedical informatics, information technologies, prognostic modeling, and cancer biomarkers.

The topic group would benefit from further expertise of the medical and AI communities and from additional data, i.e., expertise that would be interested in implementing diagnostic tasks that rely on image-based diagnostics and hold clinical challenges that could be approached by the system that is described within the TG- AI for point-of-care diagnostics.

3 Get involved

To join this topic group, please send an e-mail to the focus group secretariat (tsbfgai4h@itu.int) and the topic driver (nina.linder@helsinki.fi). Please use a descriptive e-mail subject (e.g., "Participation topic group AI for point-of-care diagnostics"), briefly introduce yourself and your organization, concisely describe your relevant experience and expertise, and explain your interest in the topic group.

Participation in FG-AI4H is free of charge and open to all. To attend the workshops and meetings, please visit the Focus Group website (https://itu.int/go/fgai4h), where you can also find the whitepaper, get access to the documentation, and sign up to the mailing list.