Ethics of AI in global health research

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Case study
Feasibility, acceptance and ethical considerations of a mobile clinical decision support system in Botswana

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Brief description of the research project

Globally, the healthcare industry is undergoing transformation to mitigate the rising costs of healthcare provision and shortages of medical experts. The industry is looking to implement new technology solutions and processes. In Botswana, these efforts are coordinated by the Ministry of Health (MOH) with guidance from the National eHealth Strategy (2020-2024). The MOH acknowledges shortage of health human resources, most significantly in primary healthcare[1]. Moreover, healthcare workers in remote areas have limited training and insufficient reference materials to support diagnosis and management of diseases in dermatology and other subspecialties. Over the years, this has resulted in unnecessary patient referrals and increased burden on the few dermatologists in the country. In order to contribute to addressing this challenge, the University of Botswana collaborated on a research study with an international private organization (VisualDx), to assess feasibility and acceptance of a mobile clinical decision support system in Botswana.

VisualDx is an artificial intelligence (AI) driven mobile clinical decision support system with documented benefits. Previous studies have demonstrated that implementation of AI systems is commonly associated with challenges such as algorithm bias, privacy, and the protection of all beneficiaries. Prior to implementation of VisualDx in Botswana, ethical review processes at both the University of Botswana and the MOH Research Unit were followed.

Overall, study participants' responses indicated acceptance of the VisualDx platform. The ability to access information quickly without internet connection is crucial in resource constrained environments such as in Botswana. User confidence on the VisualDx platform was likely increased by, 1) prior approval by Institutional Review Boards, 2) the informed consent option prior to participation, 3) adherence to data protection standards such as the Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR), 4) collection of de-identified and generalized demographic information about the patient and 5) discarding of patient images immediately after analysis. In order to inform future adoption strategies for VisualDx in Botswana, it is important to evaluate how the platform aligns with standard ethical considerations. Findings could inform policy decisions towards adoption of AI systems in Botswana and similar developing countries.

Background

Botswana is a low-middle-income-country (LMIC) situated in southern Africa, and sharing borders with South Africa, Namibia, Zimbabwe and Zambia. The majority of Batswana live in urban villages (villages surrounding urban areas; 43%), followed by rural villages (36%), and then cities and towns (21%)[2]. The Ministry of Health (MOH) in Botswana is mandated with the oversight and delivery of healthcare services and has recently launched a National eHealth Strategy which recognizes eHealth (the cost-effective use of ICT's for health) as a means of improving healthcare provision and delivery[3]. The number of dermatology specialists in Botswana's public health sector has varied from none to most recently 2 full time MOH employees and three contract specialists from Cuba. However, the demand for dermatology care continues to be much higher than can be provided by the current specialists resulting in six or more months of waiting times for

appointments[4]. This shortage of dermatology specialists in Botswana necessitates efficient use of the limited resources and continuous empowerment of those commonly engaged in the management of prevalent skin conditions[5]. It further suggests a critical need for a clinical decision support system (CDSS) to ameliorate current challenges.

Although CDSS offer some documented benefits, it is essential to consider ethical issues arising in their use. Botswana has an established research governance and oversight system for research involving human subjects that has existed since 1980. There exists a mandatory requirement for a research permit before commencement of any research in Botswana. There are established country-wide Institutional Review Boards (IRBs) at academic and institutional levels as well as Community Advisory Boards (CABs) mostly linked to IRBs.

In 2020, the University of Botswana (UB) collaborated with VisualDx on a research study funded by the Bill & Melinda Gates Foundation (grant number INV003773) to assess the feasibility of VisualDx usage in patient care settings in Botswana and also gather feedback to inform further improvements of the platform. Prior to VisualDx implementation in Botswana, research ethical clearance was sought through UB and MOH. A total of 20 dermatology clinics in Botswana participated and these were nominated by the Gaborone District Health Management Team (DHMT). The DHMT is a local authority under MOHW tasked with overlooking management and staffing of primary care clinics. Two VisualDx employees supported the research project by attending weekly update meetings and also supporting virtual user training. No feature modifications were introduced on the VisualDx platform prior to implementation in Botswana and product intellectual property rights remained with VisualDx.

The recently launched Botswana national eHealth Strategy (2020-2024) notes potential value of emerging technologies, including utilizing mobile devices and IoT (subsection 2.2.3) as is the value of “Sensors to populate digital devices with data” (subsection 2.2.3). It however lacks guidance towards ethical considerations while using AI in healthcare research studies. This shortcoming must be addressed. This study aims to assess the extent to which VisualDx conformed to ethical practices while implemented in Botswana.

Brief history of VisualDx

VisualDx has over 20 years of experience in supporting healthcare providers with their clinical decision making. It employs over 70 full-time team members all dedicated to maintaining accurate, up to date content with user friendly functionality. The platform has become a standard professional resource at more than 2,300+ universities, hospitals, and clinical sites globally. It combines expert knowledge, problem-oriented search, the world’s best curated medical image library, and technology to support differential diagnosis, treatment recommendations, and patient education. VisualDx is available on the web, native iOS and Android applications and most recently includes off-line capability on Android devices.

VisualDx has the potential to contribute to increased provider confidence and a reduction in diagnostic errors in primary care settings[6, 7]. The platform combines machine learning algorithms and vision science with a structured clinical knowledge base to allow non-specialist healthcare providers to capture patient-specific findings, build custom differentials, and view images and treatment recommendations. The DermExpert™ feature in VisualDx uses a Convolutional Neural Network (CNN) to estimate diagnosis and lesion categories from an input image. CNNs are data-driven models that require a large dataset of labeled pairs to train and validate[8].

Study participants

Healthcare workers supporting dermatology clinics and medical students participating in dermatology coursework or rotations at health facilities and universities across Botswana were sent an email and WhatsApp invitations to participate in the study through the eHealth Research Unit at the UB. Consent forms were also provided via email to confirm participation. A total of 28 participants enrolled from 20 sites (healthcare facilities and UB) in Botswana. Participants were based at 6 health districts (Greater Gaborone (21), Greater Palapye (1), Greater Phikwe (2), Greater Francistown (2), Maun (1) and Chobe (1)). All participants used personal smartphones or

tablet devices to download and install the VisualDx mobile application, with account credentials provided by VisualDx. They were offered mobile data vouchers to assist with the cost of data for the mobile application download and subsequent usage. Initial training of participants was conducted using the Zoom platform and later in-person training session at the UB eHealth Research Unit. Training sessions covered information technology skills, demonstrations of VisualDx application features and the practical application of VisualDx to common dermatologic and general medical conditions seen in Botswana. All training sessions were recorded and provided to participants who were unable to attend on the training day. Throughout the study duration, six case-based training sessions were provided to demonstrate the successful use of VisualDx to guide the clinical reasoning process. Participants used VisualDx at their own discretion throughout the study period. A WhatsApp group was created to offer a platform for sharing announcements and seeking support related to the research study.

Ethical issues and commentary on each issue

According to the World Health Organization (WHO), "Non nocere!" (do no harm) is the indispensable principle of the healthcare profession, meant to encourage healthcare practitioners to desist from actions that may result in causing more harm than good[9]. Consequently, in the age of digital health, the new definition of "do no harm" may include that AI driven digital health technologies should "do no harm". If properly implemented, AI in healthcare could uncover clinical best practices from electronic health records (EHRs) by analyzing clinical trends over time, thus assisting in the development of new clinical practice models of healthcare delivery such as precision medicine[10]. A recent study identified that in order "to fully achieve the potential of AI in healthcare, four major ethical issues must be addressed: (1) informed consent to use data, (2) safety and transparency, (3) algorithmic fairness and biases or discrimination, and (4) data privacy are all important factors to consider"[11]. Although the authors acknowledge that these recommendations are related to AI in healthcare, similar considerations can be applied to the use of AI in a research context. The following section outlines how the four ethical considerations were adhered to while using VisualDx in Botswana.

Informed consent to use data

All study participants gave informed consent prior to participation. In fact, the study protocol and consent form were approved by IRBs at the University of Botswana (UB: UBR/RES/IRB/BIO/223) and the Ministry of Health in Botswana (MOHW: HPDME: 13/18/1) prior to implementation.

Safety and transparency

To ensure safety, VisualDx uses peer-reviewed and experts' validated content. The platform is also complaint with the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA). In order to ensure correct and safe use, a series of training and sensitization sessions enabled continuous knowledge exchange. Study site teams allowed interactions among clinicians and specialists. While in use, the VisualDx AI model suggests possible diagnosis and treatment options, and is not prescriptive.

Algorithmic fairness and biases

VisualDx's DermExpert utilizes convolutional neural networks (CNN)[12], a popular deep learning architecture used for computer vision applications. In order to insure fairness and eliminate any biases, the CNN model was trained with over 80 million image variations with different ethnicities consisting of dark and light skins. The model was primarily tested on dark skin colors in Botswana, hence contributing towards the federated learning approach[13], thereby improving its fairness.

Data privacy

VisualDx collects only de-identified and generalized demographic information about the patient to provide a differential diagnosis. Even when using the 'DermExpert' AI tool, the image of the patient remains on the device at all times and is discarded immediately after the analysis is complete. This alleviates any data security concerns and allows the tool to conform to data protection standards such as the HIPAA and the GDPR[14,15].

Limitations and barriers to AI adoption

Despite the benefits that come with ethical use of AI in healthcare, more often health systems' infrastructure is not ready to support such innovations, especially in LMICs[16]. In Botswana, healthcare systems (across and within public and private sectors) are unique in technology adoption and care processes[17]. The private sector is ahead while the public sector is in the process of catching up on digital transformation. This hinders widespread adoption or use of AI algorithms. The lack of locally generated quality data to continuously train AI models is a significant barrier. In our research study, we used an AI model trained using external datasets hosted on VisualDx cloud servers. The regulatory role for AI systems in Botswana is still at an infancy stage, as well as the establishment of "good machine learning practices," and robust oversight mechanisms.

Conclusions and recommendations

VisualDx was a well-received amongst the study population in Botswana and has the potential to upskill and empower general practitioners to do more at the point of care. While the AI capabilities of VisualDx may not be able to completely replace clinical judgment, it can help clinicians make better decisions. The need for increased algorithmic transparency, privacy, and protection of all the beneficiaries is essential. Similar considerations are outlined in the Botswana Data Protection Act (DPA)[18] (Botswana Data Protection Act, 2018). In fact, efforts to utilize AI in Botswana should align with the DPA for guidance on security, privacy and confidentiality considerations. The national eHealth strategy should further guide ethical use of AI systems to support healthcare provision. VisualDx image security could be enhanced by disabling 'screen-capture' feature while using mobile devices.

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