

Ethical Considerations while using Clinical Decision Support System (VisualDx) in Botswana





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Introduction

Healthcare undergoing transformation...

- Industry looking to implement new technology-based solutions and processes
- Inadequate health human resources in primary healthcare
 - A low doctor to patient ratio (3.8/10,000) and shortage of medical specialists
 - 2 full time Dermatologists under the Ministry of Health and 3 contract specialists from Cuba.
- Waiting times for appointments can be six or more months.
- Fatigue, Cognitive and Cultural biases
 - Technological balancer could reduce, if not eradicate, the effects of such biases.

Artificial Intelligence

- Al promising in healthcare.
- Private sector leads in AI Innovations.
- Universities environment for Testing, 'Proof of Concept', Capacity building, Sustainable Uptake of AI.
- "Set of technologies allowing machines to simulate human intelligence." -Wang et al.
 - Machine Learning basic level learning
 - Deep Learning complex structures and learning models
- Quality Data is Essential for AI applications.

Benefits

- Automation of tasks requiring human intervention.
- Addressing critical shortages in skilled medical personnel.
- Improved access to services in remote areas.
- Empowerment of healthcare professionals.
- More value out of the available data.
- Machines can never replace healthcare workers..





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Our mission is to improve healthcare decisions worldwide.







86,981,681 Images Viewed in 2019

3,654,244 Clinical Inquiries in 2019



UB-VisualDx Collaboration in Botswana

Research and Proof of Concept project **To Assess the Feasibility of a Mobile Clinical Decision Support System in Botswana**.

Implementation of clinical decision support software for healthcare providers in Botswana. Key objectives include:

- 1. Assessing the feasibility of VisualDx usage in patient care settings in Botswana.
- 2. Gathering feedback on the current product and identify improvements that can be made to better support health care providers in the region.

Research Permit Applications – Ethical Considerations



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21 December 2020

REPUBLIC OF BOTSWANA MINISTRY OF HEALTH AND WELLNESS

REFERENCE NO: HPDME: 13/18/1

Health Research and Development Division

Kagiso Ndlovu University of Botswana Private Bag 0022 Gaborone Botswana

Dear Kagiso Ndlovu

PERMIT: <u>IMPLEMENTATION AND PILOT EVALUATION OF A MOBILE</u> <u>CLINICAL DECISION SUPPORT TOOL IN BOTSWANA</u>

Your application for a research permit for the above stated research protocol refers. We note that your proposal has been reviewed and approved by University of Botswana Review Board.

Permission is therefore granted to conduct the above mentioned study. This approval is valid for a period of 1 year effective 21 December 2020.

5th July 2022

Ref No: UBR/RES/IRB/BIO/223

Permanent Secretary Ministry of Health and Wellness Private Bag 0038 Gaborone, Botswana

Study Title: "Implementation of a Mobile Diagnostic Support Tool in Botswana

Researcher (s): Mr. Kagiso Ndlovu

Review Type: Expedited Review by UB Institutional Review Board Committee

APPROVAL DATE	: 5 th July, 2022
EXPIRATION DATE	: 4th July, 2023

This certifies that continuing review request for the above protocol was reviewed and approved for a period of one year.

IThe study is still ongoing

VisualDx AI Feature (DermExpertTM)



Ethical Considerations: Informed Consent

Ethics approval by the University of Botswana IRB (UB: UBR/RES/IRB/BIO/223) and the Botswana Ministry of Health (MOH: HPDME: 13/18/1) through 2023.

Study participants gave consent prior to use of VisualDx.

Consent was given to engage further as new knowledge was discovered on the disease.



Ethical Considerations: Safety and Transparency

- Peer reviewed and expert validated content.
- GDPR & HIPAA compliant.
- Continuous sensitization to upskill users for safe use.
- Non-prescriptive AI Model.
- Teams formed across sites for knowledge exchange and 2nd opinion.



VisualDx Top-3 Accuracies over time (picture used with permission from: Miguel Dominguez, VisualDx)

Ethical Considerations: Algorithmic fairness and biases or discrimination

Dedicated DL model trained with > 80 mil images.

Image variations with different ethnicities (dark vs light skins).

Federated Learning.

AI model not prescriptive.

Ethical Considerations: Data privacy

Adherence to data protection standards - HIPAA & GDPR compliance.

Images not stored on the device.

Discarding of patient images immediately after analysis.

Collection of de-identified and generalized demographic information about the patient .

CONCLUSION

- VisualDx was well received despite the Health systems' infrastructure not being quite ready!
- Health system are unique in technology and care processes : algorithms may not work everywhere.
- Lack of quality data A significant barrier!
- Government just beginning to grapple with its regulatory role establishment of "good machine learning practices," oversight of how algorithms behave in real-world scenarios.
- Methods for rooting out bias and adhering to ethical practices.
- Regulating algorithms a challenge, given how quickly the technology evolves.