M5 Portfolio Assignment: Artificial Intelligence-Based Diagnostic Function in the Digital or Virtual Health App for

Specialized Graduate Certificate in Health Informatics

Concentration: Digital Health

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Briefly introduce the AI-based diagnostic function

A panoptic ophthalmoscope attachment will be added to the iCare HOME2 for digital fundus photography. The device will snap pictures of the patient's fundus that are 5 times larger than a standard ophthalmoscope and require no dilation drops (Braganca et al, 2022). Fundus images will be transmitted to the iCare PATIENT2 smart phone app, the iCare CLINIC cloud, and the desktop iCare EXPORT (iCare, 2023). **AI diagnostic functions in the apps will do the following:**

- A Data-efficient image Transformer (DeiT) deep learning model analyzes the images and predicts retinal nerve fiber layer (RNFL) thickness, optic disc and cup to disc measurements along with "attention maps" to show visual features used in the final predictions (Fan et al, 2023). This will also classify the current stage of glaucoma.
- A Clinical Decision Support (CDS) algorithm within the iCare apps, driven by deep learning, can be used by the eye care provider to forecast disease progression and likelihood for future surgery based on the patient's IOP, fundus imaging, and medical history (Shivanajaiah et al, 2023).

Summarize anticipated benefits and risks of the AI-based diagnostic function

Benefits

- Elevated IOP is an "independent risk factor for glaucoma" but does not confirm the diagnosis of glaucoma (Isernhagen et al. 2021). Evaluating fundus imaging in parallel is paramount to diagnosis and monitoring progression as there can be multiple systemic causes of elevated IOP, ocular disc changes and RNFL thickness (Ishii et al, 2021).
- Fundus measures are prone to variable reproducibility and poor interrater reliability. Ophthalmologists under diagnose glaucoma in patients with small optic discs and over diagnose in patients with large optic cups (Thompson et al, 2020).
- The DeiT transformer uses "self-attention" to learn and predict an entire image and is capable of near accurate predictions on unseen data. It can predict fundus measures and identify pathology just as well as a human if not better (Fan et al, 2023). Just as in Radiology, this can serve as a "copilot" to making accurate diagnosis.

- The CDS algorithm is capable of processing structured and unstructured data to isolate features and patterns in the patient's medical history correlated with IOP and fundus measurements which can give the provider an accurate assessment of the patient's prognosis and treatment plan (Shivanajaiah et al, 2023).

Risks

- Deep Learning models are subject to biased training data, poor interpretability, data sparsity, model drift, and inability to generalize on unseen data (Doyen et al, 2022).
- CDS algorithms could be subject to false positive and poor predictions if there is missing data, overfitting, or anomalies in the data (Ishii et al, 2023).

List any AI features that require regulatory oversight and compliance

- The DeiT algorithm to predict glaucoma via fundus images is subject to FDA 510(k) clearance. It is equivalent in functionality to *iHealthScreen's iPredict Eye Screening System*, an AI screening tool for predicting age-related macular degeneration using a fundus camera (Healio, 2023).
- The CDS algorithm is subject to FDA regulation for SaMD (software as a medical device) as it *"utilizes an algorithm (logic, set of rules, or model) that operates on data input (digitized content) to produce an output that is intended for medical purposes* (FDA, 2017)."
- The FDA "Algorithm Change Protocol" applies including data management, re-training, performance evaluation, and updates must be clearly defined (FDA, 2021).

Recommend when AI tool is appropriate vs. inappropriate for target healthcare population

Appropriate: Patients who have "Normal Tension Glaucoma" (NTG), an average IOP of less than 21 mmHg will never spike an IOP, but will have severe optic disc changes, a higher optic cup to disc ratio, and is present in 50-70% of patients who are eventually diagnosed with primary open angle glaucoma (Barsegian, 2022). NTG is most prevalent in American Indians, Alaskan Natives, and Japanese Americans (Mansberger, 2006). Ironically, NTG is common in patients who have "wide diurnal IOP fluctuations and nocturnal IOP spikes" which are the main reasons for using home tonometry (Solish et al, 2022). Patients with vascular disease, diabetes, stroke and hypertension are systemic causes of NTG (Solish et al, 2022). African Americans are known to have larger optic nerves making it difficult to diagnose glaucoma, and Hispanics are more likely to have poor optic nerve blood flow, with both populations also being more susceptible to diabetes which is a leading cause of glaucoma (Ou, 2021). These physiological, structural and vulnerable racial disparities are appropriate cases for the AI driven tools to confirm a glaucoma diagnosis, predict level of disease, identify structural fundus changes an eye care provider may not be able to identify, and correlate IOP with optic nerve degeneration.

Inappropriate: Caucasian primary open angle glaucoma patients with consistent diurnal IOP spikes will be less likely to have structural optic nerve issues, thus use of these AI tools is not necessary (Ou, 2021). Additionally, patients who have emergent IOP spikes with either a history or concern for acute angle closure glaucoma are not candidates for these tools as their condition requires urgent intervention (Yang et al, 2019).

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