M9 Portfolio Assignment: Final Portfolio Proposal Packet for

Specialized Graduate Certificate in Health Informatics

Concentration: Digital Health

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Introduction to digital/virtual health technology

The iCare HOME2 is a novel hand-held rebound tonometer manufactured by the company “iCare” used for diagnosis and remote monitoring of intraocular pressure measurements (IOP) in patients with acute and chronic glaucoma (iCare, 2023). With the recent increase in “Teleglaucoma” utilization by Ophthalmology providers, this device has become a vital piece of the telehealth toolbox for treating patients with glaucoma (Ertel et al, 2021). The iCare HOME2 is more user friendly and practical than standard non-contact tonometer’s used in an eyecare providers office that can cost anywhere from $5,000 to $22,000, as well as the “gold standard” Goldmann applanation tonometer or the Perkins applanation tonometer. These methods all require the presence of an eyecare provider, use of topical anesthesia, and the patient must sit upright (Kratz et al, 2023). The iCare HOME2 requires no anesthesia, and the patient can obtain their IOP measurements sitting, standing or supine (iCare, 2023). Furthermore, the iCare HOME2 offers a comprehensive suite of mobile, cloud and desktop applications that enable real-time data collection, transmission, storage and analysis by the patient and provider allowing providers to actively monitor the patient’s IOP changes and deliver precision care (Kratz et al, 2023).

Explains the intended disease, population, and setting for use

Glaucoma is the #1 cause of irreversible blindness in the world and #2 cause of blindness in the United States (Lee et al, 2016). The pathophysiology of glaucoma is a slowing or blockage of the natural flow of aqueous humor fluid in the anterior chamber of the eye. This leads to a buildup of the IOP within the anterior chamber that causes progressive optic neuropathy

leading to gradual degeneration and denervation of retinal ganglion cells and nerve fibers within the optic nerve (Harasymowycz et al, 2016).

Glaucoma is a complicated eye disease for many reasons. The two most common presentations are "Primary open-angle glaucoma" and "Angle-Closure glaucoma." Primary open angle is most common as every 9 in 10 patients with glaucoma present with this type (National Eye Institute, 2021). While primary open angle is most common, it is the most difficult to diagnose due to slow underlying often undetectable changes leading to this often being called “silent blindness" and up to 50% of patients will go undiagnosed until later stages of disease (Arora et al, 2015). Angle-Closure glaucoma, while less common, is considered an ophthalmic emergency due to rapid spikes in the IOP (Lee et al, 2016).

IOP measurement is the most common method to confirm a diagnosis of glaucoma. However, it is well known IOPs have "diurnal variations" with a high percentage of patients presenting with normal IOP measurements during daytime clinic hours of 8am-5pm but IOP spikes that mostly occur overnight or in the early morning (Arora et al, 2015). If a patient only sees an eyecare provider every few months or even once a year, they may never present with an IOP spike during their visit and may never be diagnosed with glaucoma until later stages of the disease. Furthermore, providers used to admit patients to the hospital and wake them every few hours or even keep them for prolonged hours during clinic time to check more frequent IOP measures, but this has been shown to be a waste of time and money and not extremely sensitive (Wirostko, 2023).

Specific racial and cultural populations are known to have a predilection for glaucoma.

Primary open angle glaucoma has a higher prevalence in African Americans (5.6%) and Hispanics (4.7%) than in non-Hispanic whites (1.7%), and Asians are more likely to present with angle-closure glaucoma (Delavar et al, 2022). "Normal Tension Glaucoma" (NTG) is a form of glaucoma not mentioned above. NTG patients have an IOP average of less than the normal threshold of 21 mmHg and will never spike an IOP but will have severe underlying optical changes and 50-70% of patients who end up with primary open angle glaucoma can have NTG (Barsegian, 2022). NTG shows a racial dominance in American Indian, Alaskan Native and Japanese Americans (Mansberger, 2006).

Additionally, the social determinants of health play a significant role in glaucoma patients. Eyecare specialists are mostly located in major metropolitan areas thus rural patients have limited access to care often due to long distances to travel and lack of access to transportation (Wang et al, 2022). A good example of this? The University of Colorado Anschutz Eye Clinic is the only Academic Medical Center within a 500-mile radius in the Rocky Mountains and patients may travel up to 500 miles or more for care (CU Anschutz, 2023). Urban patients who may live near major academic medical centers with eyecare specialists such as in Philadelphia are known to have low household incomes and are more likely to lack transportation and insurance to obtain care (Andoh et al, 2023). Other social issues contribute to glaucoma such as medication costs, chronic conditions such as diabetes, and age older than 65 (Allison et al, 2020). The need to reach these patients with lack of access to care either due to geographic disposition, socioeconomic factors, or other chronic disease states that limit the patient’s ability to travel frequently to see an eyecare specialist warrants use of the iCare HOME2 as a remote monitoring device for teleglaucoma. In addition, the ability to monitor

patient's adherence to glaucoma medications, adjust medication dosages to target IOP levels, diagnose "silent" disease that is undetectable during normal clinic hours, and monitor post operative patients are all primary examples of the importance of this technology (Liu et al, 2020).

Describes the device and/or software that comprise the technology

The iCare HOME2 is a handheld tonometer that fits easily in the palm of the user's hand. The device received FDA 510(k) clearance in January 2022 and is classified as a Class II medical device (FDANEWS, 2022). FDA 510(k) clearance was granted because the iCare HOME2 received "pre-market notification" demonstrating the device has similar safety, functionality and efficacy to devices already on the market such as the iCare HOME which was the original version of the iCare HOME2 (Le, 2021).What is unique about the newer iCare HOME2 design, is that it utilizes prompts to notify the patient if their eye is correctly positioned. A user will see a green rim if positioned correctly and red if incorrect. In addition, there are prompts on the display screen that give a countdown to when the device will take an IOP measurement, as well as display the IOP measure so the user can see it (iCare, 2023).

There is a comprehensive suite of digital applications supporting the iCare HOME2 tonometer. The iCare PATIENT2 is a mobile application available on both Android and iOS operating systems via their respective app stores. The iCare EXPORT is a desktop application that can be installed on any desktop computer. The iCare CLINIC is a cloud-based application that has dual functionality to store patient data as well as allowing eyecare providers the ability to visualize IOP results and use a suite of tools for data visualization to compare the patient's

IOP measurements over specific periods of time. Lastly, there is the iCare CLOUD which only functions as cloud storage for the patient's personal use. Usually, the iCare CLOUD is only used if the patient's eyecare provider does not utilize the iCare CLINIC (iCare CLOUD, 2023).

Data is transmitted in real-time from the iCare HOME2 via Bluetooth frequency to the iCare PATIENT2 mobile app, the iCare EXPORT, the iCare CLINIC, and the iCare CLOUD. In addition, data can be uploaded to all the applications via USB cable (iCare, 2023).

States the nature of data captured and whether the data are used to create AI algorithms

Data captured by the iCare HOME2 tonometer and its digital applications starts with each individual patient's intraocular pressure readings. IOP measures are transmitted to all digital applications. However, this is not the only data that is captured. There is individually identifiable health information linked to each patient and each data point. This information includes but is not limited to name, demographics, IP address, and geographic IDs (HHS.gov, 2022).

In addition, there is hidden language in the mobile app store privacy policy that states every patient's data will be captured, stored, and shared with "nonaffiliated service providers" and "regulatory authorities" (icare-world, 2021). Every patient's personal health information, data, as well as message exchanges on their system with the patient's providers are stored on the company's computer systems and servers and will be shared with unnamed third parties (icare-world, 2021).

While the data is not being used directly to train any AI algorithms, it should be noted this information is sensitive and subject to HIPAA rules (HHS.gov, 2023). We need to provide

each patient and provider using this device and its suite of digital applications with a privacy statement to consent to their data being stored and utilized by third parties. In addition, we should work to implement the standard OAuth multi-factor authentication for each user so the patient and provider consent to the data being captured, stored, and transmitted (Sayeed, 2021).

Evaluation strategies to ensure that the product is effective, efficient, and usable by the healthcare organization and target population

We will utilize the *"Evaluation Framework for Fit-For-Purpose Connected Sensor Technologies"* to evaluate this product (Coravos et al, 2020). The framework is specific for connected sensor technologies like the iCare HOME2. This evaluation tool has five dimensions which can validate the iCare HOME2's effectiveness, efficiency, and usability. The first dimension is “V3” as there are three sub dimensions within one, they are:

- **"Verification"** which evaluates the iCare HOME2's performance against standard IOP measurement criteria.
- **"Analytical Validation"** which assesses the iCare HOME2's ability to accurately detect physiological IOP measurements of the patient's eye.
- **"Clinical Validation"** which validates the iCare HOME2's function to obtain IOP measurements that are clinically relevant, meaning the IOP measurements are within a valid range for the device, the patient, and the condition it is diagnosing or monitoring which is glaucoma.

Before discussing the next few evaluation dimensions in this framework, we should pause to mention that the iCare HOME2 has been assessed for all 3 of these dimensions above

against the gold standard of care "Goldmann applanation tonometer" (GAT) in a recent head-to-head study. It was found that examining 135 eyes in 70 patients revealed the mean IOP for the standard GAT was 16.3 +/- 6.5 mmHg (range 3-56), and the mean IOP for the iCare HOME2 was 16.5 +/- 7.3 mmHg (range 3-55). Thus, the iCare HOME2 has been validated in terms of its functionality and ability to accurately detect a patient's IOP. However, it was also seen in this study that with higher IOPs the iCare HOME2 would overestimate the IOP, so this is a known problem to look out for (Kratz et al, 2023).

The next three dimensions we will use to evaluate the iCare HOME2 are:

- **“Security”** which will include assessment of the cybersecurity and security updates. We should also specifically assess Bluetooth security.
- **“Data rights and governance”** should be evaluated for the users right to their own data and how they can opt in or opt out of data sharing with third parties.
- **“Utility and Usability”** assessments will tell us how useful the product is for glaucoma patients. The utility specifically will tell us if the product has all the necessary features needed and the usability will tell us how "friendly" or intuitive these features are.

One thing that comes to mind with this device is the fact that patients with glaucoma may have partial or advanced blindness that the provider may or may not be aware of. I am not sure if this device is useful for patients with poor vision to be able to utilize on their own. There is a beeping sound that tells the patient when the IOP will be measured but some of the system prompts on the device screen may not be entirely visible (iCare, 2023).

- Economic feasibility will be evaluated. We will need to look at the big picture with regards to the cost to purchase the device currently around $3,000 vs. renting it which can vary by price vs. our clinic renting the device out to the patient free of charge (myeyes.net, 2023).
- The last evaluation technique I would recommend to assure the device and apps are usable is the ***"TURF" framework*** which stands for "task, user, representation, and function" (Zhang et al, 2011). The concept of TURF is that all users of the device/apps should find the tasks and steps to be intuitive and not need significant thought or effort. The task of using the device and for the patient and the provider to then evaluate the IOP results using the mobile app, the desktop app and the cloud apps should be intuitive. This will have to be evaluated before deployment in our clinic.

The value proposition to the organization related to costs and benefits (savings) to the healthcare organization and the target population

The centers for disease control reports the financial burden for vision loss in the United States is close to $134.2 billion with $98.7 billion related to support, nursing home care, and medical treatments (Rein et al, 2022). The cost of glaucoma is around $6.1 billion and is projected to double to $12 billion in 2032 and $17.3 billion by the year 2050 (Feldman et al, 2020). The average cost per patient for glaucoma treatments including but not limited to medications, office visits, surgery, and other interventions starts around $623 for "stage 0" and rapidly increases to more than $2500 per patient for end stage glaucoma (Varma et al, 2011). In addition, higher risk patients with specific racial backgrounds African American and Hispanics

are more likely to utilize the ED than routine outpatient follow up visits. These ED visits are also more likely to result in higher cost of care due to presenting at a later stage of disease with more interventions needed (Halawa et al, 2021).

Value based care should be the result of any treatment considered. For glaucoma patients this means that to improve a patient's quality of life we want to improve their vision, reduce pain, and prevent them from going 100% blind. It is important to know that over 21 years, the mean cost of treatment for glaucoma is estimated to be $7,555, the mean return on investment (ROI) for prevention of end-stage glaucoma is $474,715, and the ROI rate is 23% annually and 6,284% for the full 21 year period (Brown et al, 2014). Using valued based metrics from landmark work done by Ophthalmologists, we know the quality adjusted life years (QALY) utility for early glaucoma is 0.97 and 0.5 for end stage glaucoma (Brown et al. 2014).

So, what does this mean for our organization and the target patient population? The annual ROI rate per QALY for early-stage glaucoma is 41.58%, the 21-year ROI rate is 5994%, with an annual treatment cost of $7,553.25 and a 21-year treatment cost of $7,781.44. The annual ROI rate per QALY for end stage glaucoma is 11.75%, the 21-year ROI rate is 3042%, annual treatment cost of $7,555, and 21-year treatment cost of $15,110.

While treating early glaucoma has a higher ROI, the ROI for treating end stage glaucoma is still significant as the patient gains quality of life by not going completely blind. This validates our use of the iCare HOME2 tonometer to diagnose and monitor glaucoma patients. If we can diagnose more patients with diurnal variations in their IOP with early disease, we can improve their overall quality of life as well as increase the ROI for the patient and our health system at

the same time. Furthermore, we know from recent studies that using remote tonometry via telehealth does result in an incremental cost effectiveness ratio (ICER) of $27,460 for each QALY gain per patient, and this extrapolates to preventing blindness in 24% of glaucoma patients over 30 years which is significant. This in turn reduces the number of emergent ED visits for specific high-risk populations (Hodge et al, 2015).

Planned strategies for implementing the digital/virtual technology that could lead to successful device adoption

A multi-pronged approach is needed for implementation to result in successful adoption. First, we need to identify the organizational resources including clinical departments, operational/IT, and administrative/executive leadership. It is prudent we identify internal champions within each of these resource departments and coordinate a cross-functional team approach (Liao et al, 2022). A successful governance strategy will also be needed so the administration is able to provide supportive oversight of the operational/IT and clinical coordination. Workflow assessments would be next, including a thorough mapping of all steps involved with the digital device and each team member's role. Also included is an analysis of the processes with development of "workarounds" in case planned workflows do not go as planned (Staras et al, 2021). Next up would be installation by the IT department which will require full coordination between the vendor, IT, and the department of Ophthalmology. Training and testing are the final important steps in the process with multiple stakeholders involved in the design and implementation of these steps (AHRQ, 2023).

While the implementation process is important, we need to plan for how to gain user adoption. To do this we need a solid change management process including gaining buy in from

all stakeholders and managing the change process in action through effective communication processes and empowering team players to take ownership of specific roles (Kho et al, 2020). Lastly, we need to plan for short term and long-term wins. This will involve making modifications as the implementation process goes on and utilizing debriefing processes throughout so the team can continue to learn what worked and what did not (AHRQ, 2023).

Finally, we will utilize key performance indicators (KPIs) to track the device effectiveness for patient care and in our organization. We will use clinical KPIs including patient prioritization, measuring clinical efficiencies, vision acuity metrics, and medication cost changes (Vitalnet, 2023). We will monitor Operational/IT KPIs including the accuracy of data being collected and transmitted by the device, the overhead cost, and the ultimate interoperability of the data from the iCare HOME2 suite of digital applications (Vitalnet, 2023). There will also be Administrative/Executive KPIs which will look at the overall impact of the device related to reducing ED visits and unnecessary healthcare system utilization, tracking number of telehealth visits using the device, and the return-on-investment short term vs. long term (Brown et al, 2014).

Brief descriptions of maintaining the technology and ensuring strong security

The iCare HOME2 will require regular software updates that comply with the users' mobile phone operating systems for Android and iOS to prevent any bugs. All devices in the iCare suite have USB ports as a method of direct data transmission and this can be a concern for security due to ransomware, malware, and infected drives. Thus, to maintain best security

practices we should assure encryption of all data transmitted between devices, use antivirus tools, and conduct regular audits that include USB port security (Ekran, 2023).

Bluetooth technology is also used by all devices. The iCare digital health suite of apps supports "dual mode" which allows both classic Bluetooth and BLE modes of communication (Barua et al, 2022). To prevent short and long term vulnerabilities in the Bluetooth technology we need to make sure users do the following: do not keep devices in "always discoverable mode", implement security updates as soon as available, and do not use the "just works" pairing method, meaning users should use multi factor or another form of standard authentication (Barua et al, 2022).

The cloud devices (iCare CLINIC and iCare CLOUD) will present challenges with data security, network security, privacy, control, and risk of data breach (Mehrtak et al, 2021). We will need to implement data encryption methods at rest and in-transit, a standard multi factor authentication process or OAuth2, digital signatures, and firewalls (Mehrtak et al, 2021). If the data is going to be transmitted from these cloud devices via API to the patients electronic medical records, then we absolutely need to use the standard SMART on FHIR APIs that use OAuth2 authentication processes and continue to update, test and check on these to assure the strongest level of security practices (Mandel et al, 2016).

Provide a solid final summary and recommendation as to why a healthcare organization should utilize your chosen digital and virtual health technology.

The iCare HOME2 and its suite of digital applications should absolutely be adopted by our organization for remote diagnosis and monitoring of intraocular pressure in glaucoma patients. This device aligns with the CDC's "Vision Health Initiative" (VHI) to prevent blindness

which is a major concern in the United States and the world (CDC, 2023). Use of this device also aligns with the social determinants of health (SDOH) which plays a significant role in glaucoma. As mentioned earlier in this report, patients of lower socioeconomic status, lack of geographic access to eyecare specialists, lack of access to transportation, lack of insurance and specific racial/ethnic backgrounds such as African American or Hispanic are more likely to be diagnosed with glaucoma (Halawa et al, 2022). In addition, non-white patients with all the SDOH risk factors are more likely to utilize the ED rather than outpatient follow-up and are more likely to present at a later stage of disease due to poor compliance with medications and poor follow-up (Halawa et al, 2022).

Value Based Medicine was originally proposed by a group of Ophthalmologists in a 2004 publication (Brown et al, 2004). Since that time, the concept of Value Based Care has evolved to what is now the future of healthcare. Value Based Care is dependent upon improving the quality of life for glaucoma patients which means improving their vision, reducing pain, and preventing end stage vision loss (Brown et al, 2014). As we learned in this comprehensive portfolio report, annual and long-term treatment of glaucoma is cost effective and results in a significant return on investment for the patient, the provider and the healthcare system. Even treating end stage glaucoma for a period of 21 years results in a positive ROI. Using the iCare HOME2 to triage and monitor glaucoma patients to catch those with diurnal variations in IOP pressure never seen during a clinic visit, and monitor those that may be more inclined to progress to end stage disease, will reduce the number of clinic and ED visits, reduce the need for surgery, reduce overall medication costs, and allow eyecare specialists to provide precision treatments to improve patient's quality of life.

Despite the cost of this device averaging around $3,000, the overall ROI and low treatment costs are worth the QALYs gained per patient. We as a healthcare system need to find a way to finance this device for all glaucoma patients whether it means working with insurance companies to cover the cost or purchasing a set number of devices to loan to patients. Either way, the big picture here is to have a vision for delivering high quality care to glaucoma patients as this disease is not going away anytime soon.

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