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Uduak Obot Date

DIABETES RESEARCH & WELLNESS FOUNDATION GRANT PROPOSAL THESIS

By

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ABSTRACT

DIABETES RESEARCH & WELLNESS FOUNDATION GRANT PROPOSAL THESIS

By Uduak Obot

According to the Centers for Disease Control and Prevention, more than 100 million adults are living with diabetes or prediabetes in the U.S. alone. African Americans are twice as likely to be diagnosed with diabetes as non-Hispanic whites with a growing racial health disparity. Diabetic retinopathy can result in permanent vision loss directly affecting one's quality of life in advanced and untreated cases. This grant proposal thesis is intended to evaluate the benefits of a hybrid patient portal with health rewards in limiting the progression of advanced diabetic retinopathy among diabetic African Americans ages 45-64 in the Metro Atlanta area of Georgia. The primary aim is to evaluate the progression of diabetic retinopathy status based on portal use. The secondary aim is to evaluate participants' understanding of diabetic retinopathy as a result of diabetes and attitudes toward their healthcare based on portal feedback surveys. I hypothesize that the usage of a hybrid patient portal with health incentives will improve health outcomes for patients with diabetic retinopathy as well as enhance diabetes management.

DIABETES RESEARCH & WELLNESS FOUNDATION GRANT PROPOSAL THESIS

By

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Thesis Committee Chair: Juan S. Leon, PhD, MPH

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I would like to thank Dr. Juan Leon for the continued support, dedication, and expertise in completing the thesis. Many thanks to all those who reviewed my grant proposal.

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CHAPTER I. DIABETIC RETINOPATHY LITERATURE REVIEW

Diabetes Overall Significance

Diabetes is a chronic disease gradually affecting millions globally each year. Its prevalence is widespread, especially in upward trends in middle and low-income countries [1]. As a significant cause of vision loss, myocardial infarction, kidney damage, limb removal and stroke, diabetes is not a condition to be taken lightly. Being that 1.6 million deaths were a direct cause of diabetes; it is rather of high priority to address not only management but also risk factors for diabetes [1]. Diabetes affects many aspects of daily quality of life and can lead to diabetic retinopathy.

Diabetes Specific to the United States

According to the Centers for Disease Control and Prevention (CDC), more than 100 million adults are living with diabetes or prediabetes in the U.S. alone [2]. Research found that as of 2015, 30.3 million Americans have diabetes - accounting for 9.4 percent of the U.S. population [2]. Nearly triple these number of individuals are living with prediabetes [2]. Left untreated for five years, 84.1 million individuals with prediabetes are on the trajectory of becoming an additional 84.1 million individuals with Type II diabetes [2].

Diabetic Retinopathy

Diabetic retinopathy is pathology of the eye in which the integrity of the retina is damaged and altered [3, 26]. The inner surface of the back eye is lined by a sensory membrane known as the retina [3]. Its photoreceptor cells convert light to neurological

signals transported to visual centers of the brain, which are then converted into images and visual perception [3].

Due to its gradual nature, it is possible to have diabetic retinopathy for a prolonged period without noticing symptoms until substantial damage has occurred [4]. This commonly yields to the general public's assumption that since they have not already observed visual issues, comprehensive dilated eye exams are not necessary. However, this thinking can be quite detrimental in detecting issues in the early stage. Being that diabetic retinopathy is a result of diabetes, consequently, anyone with diabetes is at risk of developing diabetic retinopathy [5]. Poor regulation of blood glucose levels, blood pressure and cholesterol level as well as pregnancy are significant risk factors [6]. In addition, disease duration plays a major role in illness severity. This is due to the direct correlational relationship of severity to duration. The longer someone has diabetes the greater their risk of developing consequential retinopathy [7].

Diabetes and Its Regulation

With the unfavorable statistics previously mentioned, it is important to understand the specifics of diabetes. Those with the chronic disease live a life in which their body's natural insulin production is mismanaged and faltered. This occurrence is twofold, providing a distinction for Type I and Type II forms of the disease.

Juvenile-onset diabetes and insulin-dependent diabetes were once used to describe what we more commonly refer to as Type I diabetes [8, 9]. This type of diabetes occurs due to deficiencies in insulin production. This is usually due to an auto-immune response

destroying cells in the pancreas [9]. The pancreas houses the cells required to produce insulin [9]. Thus, the auto-immune response damages crucial biological pathways, which inevitably disrupts the production of necessary insulin [4]. Genetic predisposition, virus and environmental factors are believed to be the culprits in the development of type I diabetes [9].

The most common form of diabetes is Type II diabetes [10]. Type II diabetes occurs when the body' is unable to use the insulin it has produced [10]. Insulin resistance and abnormal insulin secretion are usually the culprits for the body being unable to utilize its insulin [4]. Globally, the accelerated rate of obesity and escalation of physical inactivity are driving forces of Type II diabetes in developed and developing nations [4]. Type II diabetes was previously referred to as adult-onset diabetes [4]. However, with the obesity epidemic, this distinction has become a misnomer [4]. Overweight and obese adults as well as children and teenagers are increasingly susceptible to this form of non-insulin dependent diabetes [5].

The discussion of insulin deficiency, mismanagement and the sort lead one to question, *what is the big fuss about insulin?* Insulin is a hormone created in the beta cells inside the pancreas [5]. It is the precursor to proinsulin, which is a combination of insulin and C-peptide prior to the biochemical separation of the two [5]. Insulin works to convert glucose from food consumption to energy for the body [5]. Moreover, it acts as glucose storage for future use whenever the body needs additional energy [5]. C-peptides play their own special role in treatment. They are used to measure the amount of insulin the body

produces, and thus are a tool for determining the amounts of insulin needed for prescription treatment [5].

Diabetic Retinopathy Mechanisms & Stages

The harmful changes to the retina are brought on by poor diabetic regulation and management. The resulting effects are observed by the swelling and leakage of blood vessels clustered at the rear of the eye [11]. These changes cause a distortion of vision [6]. When the body's insulin is unable to regulate amounts of sugar in the bloodstream due to an impairment, glucose levels may drastically increase or decrease [6]. In the case of the former, consistently high blood sugar levels in the bloodstream result in a blockage of the blood vessels responsible for nourishing the eyes [12]. Consequently, this blockage restricts blood flow to the eye which in turn restricts oxygen that is necessary to maintain the health and performance quality of the retina [12]. As a triggered response, the body naturally begins to make more blood vessels [12]. This process is known as neovascularization [12]. However, the proliferative effect of additional vessels made under stress causes for the production of weakened and lesser quality vessels [12]. These vessels are more likely to leak blood into the eye, further advancing damage to the retina [12].

The progression of diabetic retinopathy is grouped into four categories. The earliest stage of retinopathy is mild non-proliferative retinopathy. This stage is characterized by the development of microaneurysms [12]. These aneurysms display as minute specks that can be viewed during a dilated exam and on fundus photography of the retina. They are caused by balloon-like swelling in the vessels of the retina when they begin to leak blood as

mentioned previously [12]. The visible leakage of small blood vessel hemorrhages classify the initial stage of retinopathy [13].

The mild stage of retinopathy is followed by moderate non-proliferative retinopathy, which is characterized by swelling of the retina and, in some cases, blood vessel blockage [12]. As blood and fluid accumulate in the retina, diabetic macular edema (DME) become a serious concern due to the effects of swelling [37]. Being that the macula is an area of the retina in which vision is its sharpest, swelling in this particular region can lead to vision loss [12].

Severe non-proliferative retinopathy marks the stage in which a significantly elevated number of blood vessels, meant to nourish the eye, become blocked [12]. The body responds to this stressor by signaling the retina to neovascularize, as mentioned previously – grow new blood vessels of a weakened and lesser quality than healthy blood vessels [12].

Proliferative diabetic retinopathy (PDR), in which blood vessels neovascularize through the retina, causing fluid to fill the eye, accounts for the final stage [12]. The blood vessels created are much more fragile and prone to leak. The attenuated blood vessels bleed into the layers of the retina and the vitreous fluid above [13]. When this happens, the next danger is the opportunity for a retinal detachment [12]. This occurs when the retina pulls away from the underlying tissue of the eye - detaching itself from the backing of the

eye [12]. People with retinal detachments may experience spotty vision, bright flashes of light, or severe vision loss [12].

It has been established that diabetes complications accompany a host of systemic ailments. With a general understanding of the stages of diabetic retinopathy, it is also important to note associated risks with the possible development of ocular conditions such as cataracts and glaucoma [13].

Unless of a congenital or abnormally manifestation, cataract development is concomitant [6]. The gradual clouding of the eye's lens is a normal component of the aging process [6]. However, adults with diabetes are up to five times as likely to develop cataracts at an earlier age due to the consequences of diabetic mismanagement [14].

Glaucoma is term describing various diseases that damage the optic nerve of the eye [15]. The bundle of nerve fibers that compose the optic nerve connect to the brain in order for visual signals to be converted to sight and vision perception [6]. Elevated eye pressure is common in most types of glaucoma. In adults, diabetes nearly doubles the risk of glaucoma [6]. This is due in part to the element of neovascularization of diabetic retinopathy. The growth of these vessels extending to the iris of the eye increases intraocular eye pressure and clogs the drainage system of the eye which is vital in regulating eye pressure [4].

Diabetic Retinopathy Diagnostic Testing

When diagnosing diabetic retinopathy, a dilated eye exam is the best method. [4].

Dilated exams are recommended once a year. During this exam, cycloplegic medicated drops are given to the patient to dilate their pupils. Pupil dilation allows for a better view of the back of the eye, where the retina is located, for physician observation [13]. Eye care physicians inspect this area for swelling in the retina that threatens vision known as diabetic macular edema [6]. Physicians also examine evidence of retinal ischemia, which is poor retina blood vessel circulation, as well as irregular promote neovascularization [4].

If any areas of concern are found, ancillary testing is required to further support physician observations. Optical coherence tomography (OCT) are common ophthalmic tests performed on diabetic patients [11, 28]. These tests provide high-level, detailed anatomical images of the retina [11]. By doing so, practitioners are able to gage retina thickness which is important in determining if fluid has collected in the tissues of the retina [11]. Fundus photography, photos of the retina, may be performed to identify and monitor diabetic retinopathy [11]. Fundus photos along with OCTs assist in follow-up visits to track eye health and the progression of illness. To evaluate vessel circulation and proliferation, fluorescein angiography may be necessary [11]. This requires trained staff to inject a dye into the patient's arm [11]. As the dye circulates, photos are consistently taken to document vessel circulation or lack thereof [11].

Previous Studies

With the rise of diabetes and the advancement of technology, patient portals have emerged as a means to help manage disease treatment and healthcare practices. In line with the transition to electronic health records, patient portals have also been growing in

popularity throughout the years. Patient portals act as a secure tool for patients to access personal health information via an online website [17]. Satisfaction of care has been observed in patient populations using patient portals [17]. Studies have found patient portals to also reduce medical error and further engage patients [17] Nonetheless, it does not go without saying that certain technological drawbacks persist. Some patients have poor accessibility to computers, difficulty logging into portal systems, apprehensions concerning their privacy, visual or motor disablements, and so forth [17]. Despite this, a study with participants averaging 57.1 years in age with Type II diabetes found patient portal use with physician secure messaging to produce favorable outcomes [17]. With a heavy emphasis on secure messaging, it was found that these outcomes aided in access to care, enhanced the quality of office visit and were associated with patient satisfaction and clinical outcomes [17]. Other studies reflected the same feedback. For example, a similar diabetic qualitative study conducted in Ontario, Canada revealed increased engagement and access to information for patients using chronic disease management portals [18]. They predicted to have even more usability ease and reduced attrition with portal adjustments [18].

Moreover, a Massachusetts study at Beth Israel Deacon Medical Center sought to investigate the role of clinic notes in assisting patients with self-care by enhancing communication and education when electronic access is simplified [19]. Using a web-based survey and four-point Likert scale, the study found that majority of its participants with and without diabetes documented a favorable impact from portal usage [19]. Implications from this study encouraged physician and patient participation in patient portals [19]. The

patient portals provided a platform for increased daily attention to health management as well as increased levels of patient activation and engagement for diabetics and those with other chronic diseases [19].

A Vancouver based study looked to investigate if improved glycemic control correlated with web-based patient portal accessibility [20]. With the study's BCDiabetes patient portal, users were found to have more favorable glycated hemoglobin (A1C) measurements such that A1C results were more likely to be stable or even lower than their last visits [20]. The study noted significant improvement of diabetes management in cases where patients are given medical information and education [20]. In addition, improved results were associated with increased self-care capacities, duration of education, and diabetes knowledge [20]. Access to the portal was free of charge with the assumption that patients who were able to provide email addresses possessed internet competency to navigate the portal without training [20]. Even with this assumption, a telephone helpline was provided to aid in patient overview of their journals and laboratory data [20]. It also included general educational materials and a messaging system that allowed for questions to be answered by the diabetologist [20]. Conclusively, the Vancouver study found that the results supported the theory that patient portal access improved A1C outcomes - patients with access to utilize the portal were more likely to achieve target A1C than patients who did not have access [20].

To a different tune from conventional patient portals, Go365 is a recent program created by Humana that has been implemented in employee work settings to improve

employee output [21]. The program uses smart phone technology applications and wearable tracking devices to record and measure employee health data including but not limited to daily steps, workouts, other physical activity, sleep quality, dietary intake, weight loss, mental health, tobacco smoking addiction cessation programming, chronic disease risk factor calculators, and so forth [21]. Positive interactions, accomplishing targets, and health- related recordkeeping within the application are incentivized by a points reward system allotting for an encouraging and wide selection of useful prizes [21].

Diabetic Retinopathy in African Americans

As mentioned before, diabetes prevalence is constantly increasing but so are portals and other interventions to help manage the disease. It also begs to question where the burden of the disease lies and what populations are most at risk. In the context of the United States, African Americans are 60% more likely to be diagnosed with diabetes as non-Hispanic whites and twice as likely to die from the condition [22]. In addition, this racial health disparity is continuously expanding [22]. The state of Georgia is ranked the fourth highest population of African Americans in the United States at 32%population by race [23]. The state of Georgia also exceeds national averages of those with diabetes [24]. Therefore, targeted interventions are of the essence for those who suffer from diabetes, and it is directly related to complication, diabetic retinopathy, as well as those who are at risk of developing diabetes.

CHAPTER II. METHODOLOGY

A review of the types of funding agencies that typically address your topic (or similar topics).

Diabetes research is typically funded by national federal and non-federal research organizations such as Lions Club International, American Diabetes Association and the National Institute of Health's National Institute of Diabetes and Digestive and Kidney Disease. I selected the Diabetes Research and Wellness Foundation grant because of their primary focus on diabetes and history of contributing to diabetes research.

A summary of the grant announcement (RFA, RFP) that the proposal is a response to (a copy of the full announcement should be included in the appendix)

The Diabetes Research & Wellness Foundation (DRWF) sought after diabetes research relating to cause, prevention and treatment of the disease and its complications. The grant offers $50,000 per year for up to 2 years. (see *Appendix*)

The grant review process

How/when did the reviewers get the proposal to review?

- Reviewers received the proposal and reviewer questionnaire on March 20, 2020 in PDF format via email.

How much time did they have to review it?

- Reviewers had four weeks to review the grant.

What instructions and review criteria were provided to reviewers?

- Reviewers were asked to provide constructive feedback in response to reading the proposal via a questionnaire form that was emailed to them. The questionnaire included fields for the reviewers to list critiques and areas of improvement. (see *Appendix*)

Were reviews shared among reviewers or provided individually?

- Reviews were provided individually

How was the information returned to the student, analyzed and interpreted?

- External review forms were completed and sent back to the student. Some reviewers included additional documents of grammatical revisions.

A description of the grant proposal reviewers and their expertise.

- **Chidinma Ogojiaku**: MPH candidate currently working for the Georgia Health Policy where she daily contributes to grant proposals. She holds a bachelor's degree in medicine, health and society with a concentration in health behaviors and science from Vanderbilt University. In addition, she has experience working in ophthalmic clinical practice. She is a trusted colleague
- **Sarah Blanton**: Program Manager for Alcohol, Tobacco, and Other Drugs in the University of Cincinnati Student Wellness Center. She also has her MPH with

concentrations in health promotion and education. She is also a trusted colleague.
- **Ezimma Nnyagu**: PharmD and MPH candidate for class of 2020 at the University of Georgia Athens. She is also a trusted colleague.

Protection of Human Subjects:
Human subjects' involvement, characteristics, and design.

The study involves diabetic African Americans ages 45-64 in the metropolitan Atlanta area. The selection process for recruitment aims for a total of 64 participants evenly distributed from four Sandy Springs study sites. Due to the study involving an intervention to observe its impact, a randomized controlled trial (RCT) was most compatible with this effort. RCTs allow for the experimentation of observing study groups with and without intervention - access to the portal in this case.

The sample size was calculated using OpenEpi software for randomized controlled trials [36]. A two-sided confidence was level set to 95% with a power of 80%. The ratio of sample size of unexposed to exposed was set as a 1:1. The percentage of unexposed participants was defined as the control group receiving annual reminders. The control group is under the applied assumptions that they have a status of moderate non-proliferative diabetic retinopathy or a subsequent stage of the disease with an intensified morbidity magnitude. Furthermore, the control group is also under the applied assumption that they do not change their lifestyle to improve diabetes management. The percent exposed is defined as the intervention group of participants using the patient portal with controlled diabetic retinopathy as a result of improved diabetic management.

Human subjects' materials collected.

Research instruments used throughout the recruitment process and intervention period will include survey and questionnaires as follows:

- Pre-Enrollment Questionnaire: Questionnaire designed to determine if a patient meets participant selection criteria for study.
- Guided Pre-Survey: Survey to be completed after patient's enrollment into study. Survey is to be taken in a participant group setting with staff guidance for navigating website software. This survey will establish baseline knowledge and awareness of diabetic retinopathy and diabetes management and condition-related complications. Staff will also be able to answer participants' questions and concerns during this time.
- Medical Correspondence Follow-Up Survey: Survey to be completed following examination with vision and medical physicians. Here, a vision physician refers to an optometrist or ophthalmologist. Medical physician refers to a physician that the patient receives direct diabetic treatment which can be a primary care and/or an endocrinologist. This survey will evaluate a patient's understanding of visit results, care and treatment.

- Post-Survey: Survey disseminated during the 14-month mark. Survey will access patient's diabetic retinopathy knowledge for comparison to the initial pre-survey.
- Office Visit: Office visits will be conducted externally via established ophthalmic practices within the scope of health network primary care referrals to practices within Sandy Springs, GA. During office visits, participants will undergo comprehensive dilated examinations, routine follow-up OCT, Visual Acuities (VA's), and fundus photography testing, and additional treatment as determined by the ophthalmologist. Office visit examination and testing records will be uploaded directly to the portal at the conclusion of each visit.

Proposal project researchers/ analysts will be the only individuals with access to the information collected for this study. This will be strictly enforced to secure participant data.

Recruitment and informing subjects of study or program

From the four study sites (health networks), participants will be selected based on diagnosis status of diabetes mellitus I and II and their primary care provider's recommendation of hybrid patient portal to patient. After primary care consultation, the appointment practice staff member will provide the patient with additional information about the hybrid portal and submit the patient's demographic information to the hybrid portal recruiter. Selected participants will be recruited from the Sandy Springs' diabetic population of those recommended to the program to reflect the demographics of Metro Atlanta. This will take place at the four major healthcare networks in Sandy Springs, Georgia: Emory at Saint Joseph's Primary Care, Piedmont Physicians of Sandy Springs, North Atlanta Primary Care and Laureate Medical Group.

During the guided pre-survey (*see* Human subject materials collected), participants will be asked permission authorizing the access and review of their personal health records as it relates to the study. Consent will be documented through electronic signatures with digital keypads to be handled by the study staff responsible for coordinating the large group meeting.

Potential risks to human subjects.

I anticipate risks surrounding patient confidentiality as we are working directly with electronic records examinations and personal data. To reduce this risk, only study staff involved with data extraction and analysis will have access to participant records. Accessing the records will require password security with permission only granted to the data staff.

As the study does have a focus on patient awareness and understanding of diabetic retinopathy, diabetes and their treatment, additional potential risks are information overload and misinterpretation. To reduce this, intentional effort will be placed in information output with focus on clear, concise, and culturally appropriate delivery in

laymen terms. Educational material will also be geared towards multiple learning styles such providing visual and audio guides. As participants may suffer visual impairments, options to enlarge texts along with auditory material, previously mentioned, will be provided. In an effort to reduce feelings of overstimulation, study staff plan an educational rollout that best distributes information in abridged yet effective sizes that are easy for participants manage in their regular routines.

Benefits of the program to human subjects and society

Increased patient autonomy, awareness and surveillance are necessary to preserve vision, prevent additional vision loss and reduce risks of associated diabetes complications. The introduction and usage of an incentivized patient portal provides an ideal platform for people with diabetes and other chronic diseases to better manage their conditions. Incentives will mirror those offered by the Go365 program in which recording health progress and meeting targets gain participants portal based congratulatory rewards and points that can be used towards health-driven merchandise such as step counters and bicycles. Bettered health management behaviors and components of the app have the potential to improve biometric measurements, which influence diabetic retinopathy and thus diabetes. Active usage of the app can serve as a model that is easily adaptable to management of other comorbidities and chronic diseases. In addition, increased medical awareness and transparency provides potential in bridging the gaps between physician and patient.

At the conclusion of the study, personal results will be shared with each participant as well as additional study materials. This includes all data collected using the Research Instruments from the Pre-Enrollment Questionnaire to the Post-Survey and all office visits.

CHAPTER III: INCORPORATION OF REVIEWER COMMENTS

Reviewer 1 comments:

Comment 1: The Design section of the methodology should include more information while still being an overview. The PI does not mention how she plans on accessing the data of these medical clinics. There should be mention of a drafted and distributed Data Sharing Agreement with clinics. The PI should have included why Sandy Springs was selected as the site location while the proposal mentioned metro Atlanta several times.

Response to comment 1:

- Based on formatting with Methodology as the overarching header, I chose to keep the Design formatting the same as it suffices as an overview while further details are mentioned according to subtitle sectioning from pages 4-8. Thank you for the feedback.
- The Ophthalmic Examination Data Collection section discusses the use of a cloud system to access patient information in depth. Please refer to pages 30-31 for further information.
- I added participating physician consent to data sharing agreement in the final paragraph of this section.
- Sandy Springs was selected based on the knowledge that patients from all parts of Atlanta and its surrounding locations are often referred to one of the several ophthalmic specialty clinics there. In the Study Sites section, I added "Sandy Spring was selected as the focal study location based on firsthand clinical knowledge of patient demography being representative of the metropolitan Atlanta area. This is directly observed by physician specialty availability, external physician referral patterns and insurance network coverages of which I have 3 years of field experience coordinating."

Reviewer 2 comments:

Comment 1: No comment provided.

Response to comment 1: N/A

Reviewer 3 comments:

Comment 1: The submission possessed an adequate level of relevance to the DRWF mission.

Response to comment 1: Thank you for your feedback.

Comment 2: Content is appropriate. PI should work to improve flow, grammar and overall readability of the document.

Response to comment 2: Revised per previous reviewers' grammatical revisions.

DRWF GRANT PROPOSAL Uduak Obot

Comment 3: Diabetes is one of the fastest growing chronic diseases and is projected to be the leading cause of morbidity and mortality by 2030. Additionally, black/African American population is disproportionately affected by this disease. The PI considers both ideas and notes these in the goal statement and throughout the document.

Response to comment 3: I thanked the reviewer.

Thank you message to reviewers:

Thank you for reviewing my thesis. I greatly appreciate your time and effort in offering thorough feedback and revisions.

-All the Best,

Uduak Obot

CHAPTER IV: DIABETES RESEARCH & WELLNESS FOUNDATION GRANT PROPOSAL

ABSTRACT

According to the Centers for Disease Control and Prevention, more than 100 million adults are living with diabetes or prediabetes in the U.S. alone [2]. Africans Americans are twice as likely to be diagnosed with diabetes as non-Hispanic whites [22]. This is a racial health disparity that continues to expand [22]. Diabetic retinopathy can result in permanent vision loss directly affecting one's quality of life in advanced and untreated cases [25]. This study is intended to evaluate the benefits of a hybrid patient portal with health rewards in limiting the progression of advanced diabetic retinopathy among diabetic African Americans ages 45-64 in the metropolitan Atlanta area of Georgia. The primary aim of this proposal is to evaluate the progression of diabetic retinopathy status based on portal use. The secondary aim of this proposal is to evaluate participants' understanding of diabetic retinopathy as a result of diabetes and attitudes toward their healthcare based on portal feedback surveys. I hypothesize that the usage of a hybrid patient portal with health incentives will improve health outcomes for patients with diabetic retinopathy as well as enhance diabetes management.

SPECIFIC AIMS

Goal Statement

The goal for this study is to evaluate the benefits of a hybrid patient portal with health rewards in limiting the progression of advanced diabetic retinopathy among diabetic African Americans aged 45-64 in the metropolitan Atlanta area. Advanced diabetic retinopathy will be defined as cases in which disease status is classified as a moderate non-proliferative diabetic retinopathy or a more exacerbated stage such as severe non-proliferative or proliferative diabetic retinopathy. Progression will refer to any exacerbation of ophthalmic health indicators as it relates to diabetic retinopathy. Those indicators include increased or detrimental presence of lipids and debris buildup, macular edema, and vessel leakage or hemorrhage in the retina.

Hypothesis

I hypothesize that if patients use the hybrid patient portal, that both centrally organizes their medical health management as well as provides healthy habit incentives, their health status, as it relates to diabetic retinopathy, will remain controlled and well – managed. Thus, use of the hybrid patient portal will reduce further damage to the retina.

Medical health management, as stated previously, refers to patient's adhering and keeping track of ophthalmic and diabetes-related medical examinations as well as other aspects of health care details, such as medical practices contact information and logistics, insurance policies, and other particulars of healthcare.

Research Rationale

My rationale for this study is based on studies confirming an increase in patient satisfaction and health outcomes (such as A1C levels) due to boosted patient engagement and activation as a result of using patient portals [19, 20]

Aims

Primary: To evaluate the progression of diabetic retinopathy status based on portal use.
Secondary: To evaluate participants' understanding of diabetic retinopathy as a result of diabetes and attitudes toward their healthcare based on portal feedback surveys.

SIGNIFICANCE

Existing Background Information

In the United States, over 100 million people are diabetic or prediabetic with rates of disease burden steadily increasing [2]. African Americans are twice as likely to be diagnosed with diabetes as non-Hispanic. [22]. Georgia is ranked fourth amongst the highest population of African Americans in the United States [23]. The state of Georgia also exceeds the national averages of those with diabetes [24].

The growing rate of diabetes directly renders millions of people vulnerable to the reversible and irreversible impacts of diabetic retinopathy and its consequential impacts on health status as well as daily quality of life [24]. Diabetic retinopathy is a pathology of the eye in which the integrity of the retina is damaged [25]. The inner surface of the back eye is lined by a sensory membrane known as the retina [3]. Its photoreceptor cells convert light to neurological signals transported to visual centers of the brain, which are then converted into images and visual perception [3]. The resulting altered state of the retina correlates to visual impairment and is indicative of inadequate diabetes management [26]. Visual impairment describes hazy and blurred vision to complete vision loss in worst case conditions. Thus, I observe a need to address the issue of diabetic retinopathy due to diabetes in the African American community in Georgia, specifically, those receiving care in the metropolitan area.

Current Status of Related Research

In line with the transition to electronic health records, patient portals have also been growing in popularity throughout the years. Patient portals act as secure tool for patients to access personal health information via an online website [17]. Overall, portal usage of has shown correlation with care satisfaction, and there has been discussion that these systems may better limit medical mistakes and engage patients [29].

However, it does not go without saying that certain technological drawbacks persist. Some patients lack access electronic devices essential for portal use, struggle maintaining log-in credentials, doubts about privacy, visual or physical restrictions, and so forth [16, 30, 31]. Nonetheless, a study with participants averaging 57.1 years in age with Type II diabetes found patient portal use with physician secure messaging to produce favorable outcomes in terms of patient satisfaction. With a heavy emphasis on secure messaging, it

was found that these outcomes aided in access to care, enhanced the quality of office visit and were associated with patient satisfaction and clinical outcomes [17].

Other studies centralized on patient perception reflected the same feedback. For example, a similar diabetic qualitative study conducted in Ontario, Canada revealed that patient engagement in their health care and access to information increased when chronic disease management portals were implemented [18]. Nonetheless, researchers saw the ongoing need to reduce attrition and enhance usability [18].

Moreover, a Massachusetts study at Beth Israel Deacon Medical Center sought to investigate the role of clinic notes in assisting patients with self-care by enhancing communication and education when electronic access is simplified [19]. Using a web-based survey and four-point Likert scale, the study found that majority of its participants with and without diabetes documented a favorable impact from portal usage [19]. Implications from this study encouraged physician and patient participation in portals. The patient portals provided a platform for increased daily attention to health management as well as increased levels of patient activation and engagement for diabetics and those with other chronic diseases [19].

Even though there are plentiful data concerning patient portal studies on perception, there are limited focus on patient outcomes. One of the scarce pools of patient outcome driven studies is a Vancouver based study, which looked to investigate if improved glycemic control correlated with web-based patient portal accessibility [20]. With the study's BCDiabetes patient portal, users were found to have more favorable glycated hemoglobin (A1C) measurements such that A1C results were more likely to be stable or even lower than their last visits [20]. The study noted significant improvement of diabetes management in cases where patients are given medical information and education [20]. In addition, improved results were associated with increased self-care capacities, duration of education, and diabetes knowledge [20]. Access to the portal was free of charge with the assumption that patients who were able to provide email addresses possessed internet competency to navigate the portal without training. Nevertheless, a telephone helpline was provided to aid in patient overview of their journal and laboratory data [20]. It also included general education materials and a messaging system that allowed for questions to be answer by the diabetologist [20]. Again, this emphasizes the need to address diabetic retinopathy as it pertains to the African American community affected in Georgia.

Implications

An anticipated implication of this grant is to reduce and halt diabetic retinopathy progression due to participant active engagement via a more closely monitored lifestyle choices encouraged by app usage. Achieving a controlled state of diabetic retinopathy is indicative of a positive correlation to improved overall diabetes management. Indicators of these achievements include but are not limited to healthier biometric measurements (A1C, glucose, cholesterol, etc.) that can be influenced by intervention in comparison to baseline measurements captured at the start of the study.

The app's promotion of physical exercise, dietary intake maintenance and medical

(appointment, medication intake, etc.) reminders coincide with decreased sedentary lifestyles, adherence to physician health recommendations, and improved overall health. As a whole, better health management behaviors and components of the apps can influence the management of other comorbidities and chronic disease. In addition, increased medical awareness and transparency holsters immense potential in bridging the gaps between physician and patient. Being that African American populations are heavily burdened by diabetes, the proposed grant will be of benefit to this community of individuals.

METHODS

Design

In this multi-site, intervention study, patients will be recruited to evaluate the health benefits of the diabetic retinopathy hybrid patient portal and health rewards program project.

Study Sites

Sandy Spring was selected as the focal study location based on firsthand clinical knowledge of patient demography being representative of the metropolitan Atlanta area. This is directly observed by physician specialty availability, external physician referral patterns and insurance network coverages of which I have 3 years of field experience coordinating.

Patients will be recruited from the following networks: Emory at Saint Joseph's Primary Care, Piedmont Physicians of Sandy Springs, Laureate Medical Group and North Atlanta Primary Care. Network yearly outpatient services signify the number of patients a network is able to handle. Thus, outpatient statistics show the participating network's ability to provide the sample size of necessary participants for the grant.

HEALTH NETWORK	LOCATION	OUTPATIENT SERVICES
Emory At Saint Joseph's Primary Care	Sandy Springs, GA	125,343[1]
Piedmont Physicians of Sandy Springs	Sandy Springs, GA	471,695[2]
North Atlanta Primary Care	Sandy Springs, GA	156,000[3]
Laureate Medical Group	Sandy Springs, GA	--[4]

1 (Georgia Department of Community Health, 2018) [33]
2 (Piedmont Healthcare, 2019) [34]
3 (North Atlanta Primary Care, 2019) [35]
4 Outpatient data not available. Assumption was applied that the median size of Laureate Medical Group is closely equivalent to the capacity and reach of similar networks in the area included in this study.

Study Sample

The selection process for recruitment will be continuously carried out until 8 patients are enrolled from each study site for the intervention group. The same will be done for the control group. Across the four study sites, including the intervention and control group, there will be a total of 64 participants recruited for the study.

The sample size was calculated using OpenEpi software for randomized controlled trials [36]. A two-sided confidence was level set to 95% with a power of 80%. The ratio of sample size of unexposed to exposed was set as a 1:1. The percentage of unexposed participants was defined as the control group receiving annual reminders. The control group is under the applied assumptions that they have a status of moderate non-proliferative diabetic retinopathy or a subsequent stage of the disease with an intensified morbidity magnitude. Furthermore, the control group is also under the applied assumption that they do not change their lifestyle to improve diabetes management. The percent exposed is defined as the intervention group of participants using the patient portal with controlled diabetic retinopathy as a result of improved diabetic management.

As hypothesized, it is expected that in the ideal case scenario, approximately more than 90% of participants in the intervention group exhibit controlled favorable outcomes. To detect a significant difference between intervention and control group participants, 8 intervention participants for the sample size will be required. Likewise, it is expected that approximately less than 10% of the control group will exhibit controlled favorable outcomes necessitating only 8 control participants.

In response to the previous sample sizes being quite small given ideal percentage parameters and taking into account possible loss to follow-up, sensitivity was increased. In doing so, enrollment of participants was widened to detect a 40% risk difference between the favorable intervention outcome of 60 and control outcome of 18. Resulting sample sizes were rounded to the nearest the multiple of four for added convenience to recruitment at the four study sites.

Intervention Group

The intervention group will have access to the Diabetic Retinopathy Hybrid Patient Portal (DRHPP). This portal is twofold consisting of traditional portal elements that allow for secure physician to patient messaging, review of medical examination and testing records, and other information relating to medical practice logistics. The other component of the hybrid portal will mirror that of the Go365, an employee health rewards program implemented through Humana health insurance [21]. The
The second half of the portal provides health incentives for participants to keep track of their lifestyle habits, which has been seen to improve participants' health outcomes and awareness [21]. Health habits will include but are not limited to the tracking of daily steps and physical activity, logging dietary intake, recording glucose levels, and acknowledgement of medical appointment reminders. Participants will be allotted points for lifestyle habit activities displaying healthier decisions and biometric readings within or approaching optimal parameters. As participants accrue more points for healthy behaviors, they will have the option to redeem earned points for gift cards to local stores and lifestyle related merchandise such as step trackers, fitness equipment, etc. As such, the rewards component of the portal sets this program apart from traditional patient portals.

Control Group
The control group of enrolled participants will receive an annual reminder in the form of the requested communication type via automated phone call and/or postcard. This is the standard of care patients typically receive for annual vision specialist examinations [13].

Recruitment
From the four study sites (health networks), participants will be selected based on diagnosis status of diabetes mellitus I and II and their primary care provider's recommendation of hybrid patient portal to patient. After primary care consultation, the appointment practice staff member will provide the patient additional information about the hybrid portal and submit the patient's demographic information to the hybrid portal recruiter. Selected participants will be recruited from the Sandy Springs' diabetic population of those recommended to the program to reflect the demographics of Metro Atlanta. This will take place at the four major healthcare networks in Sandy Springs, Georgia as previously outlined (see *Study Sites)*.

Enrollment (first interaction of study staff with participants)
Those who agree to pre-enrollment in the study will be requested to complete a short questionnaire, which will be reviewed to ensure study eligibility. Selection criteria are contingent upon patients' stage of having moderate non-proliferative retinopathy advanced diabetic retinopathy. Those who meet selection requirements will be contacted to complete enrollment in the study. They will then be invited to a large group meeting to further introduce the hybrid patient portal and health rewards program (see *Introduction to Hybrid Patient Portal and Health Rewards Program Meeting*). If a patient cannot be reached, alternative patients will be selected using the same criteria.

Consent
During the large group meeting, participants will be asked permission authorizing the access and review of their personal health records as it relates to the study. Consent will be electronic signed with digital keypads to be handled by the study staff responsible for coordinating the large group meeting.

Research Instruments
Research instruments used throughout the recruitment process and intervention period will include survey and questionnaires as follows:

- Pre-Enrollment Questionnaire: Questionnaire designed to determine if a patient meets participant selection criteria for study.
- Guided Pre-Survey: Survey to be completed after patient's enrollment into study. Survey is to be taken in a participant group setting with staff guidance for navigating website software. This survey will establish baseline knowledge and awareness of diabetic retinopathy and diabetes management and condition-related complications. Staff will also be able to answer participants' questions and concerns during this time.

- Medical Correspondence Follow-Up Survey: Survey to be completed following examination with vision and medical physicians. Here, a vision physician refers to an optometrist or ophthalmologist. Medical physician refers to a physician that the patient receives direct diabetic treatment which can be a primary care and/or an endocrinologist. This survey will evaluate a patient's understanding of visit results, care and treatment.
- Post-Survey: Survey disseminated during the 14-month mark. Survey will assess patient's diabetic retinopathy knowledge for comparison to the initial pre-survey.
- Office Visit: Office visits will be conducted externally via established ophthalmic practices within the scope of health network primary care referrals to practices within Sandy Springs, GA. During office visits, participants will undergo comprehensive dilated examinations, routine follow-up OCT, Visual Acuities (VA's), and fundus photography testing, and additional treatment as determined by the ophthalmologist. Office visit examination and testing records will be uploaded directly to the portal at the conclusion of each visit.

Variables

Ophthalmic examination variables will be measured based on a scale of improved state (1), controlled state (0), or worsened state (-1). These will be captured during the office visit. Below are the ophthalmic examination variables and their significance.

- Visual Acuities (VA's): progression of diabetic retinopathy can result in decreased vision.
- Optical Coherence Topography (OCT): OCT testing is essential in measuring and identifying changes in macular thickness as a result of macular edema due to diabetic retinopathy.
- Fundus Photography: fundus photos capture images of the retina that are necessary in viewing changes in the retina and record keeping for examination comparisons of patient disease progression.

Patient survey feedback will be measured based on a five-Likert scale of strongly agree (+1), agree (+1), neither agree nor disagree (0), disagree (-1), strongly disagree (-1). These will be captured following the office visits via medical correspondence follow-up surveys. Patient survey feedback will involve questions related to the following healthcare factors:

- Patient's perceived understanding of treatment and diabetes management following examination.
- Patient's attitude towards provider and healthcare received.

Categorical variables will include age, gender, diabetes duration, HbA1C, diabetes type, tobacco use as well as presence of hypertension, elevated cholesterol and kidney disease based on previous studies of associated risk factors [27].

Data Analysis

Data analysis will be twofold to take into account examination assessment from routine visits and ancillary testing as well as feedback assessment from patient surveys. Analysis

will address the study aims (see *Aims)*. For Aim 1, for all patients, baseline VA's, OCT and fundus photography will be taken to track disease progression and repeated at every vision specialist visit. They will be graded based on ophthalmologist's observation of improved state (1), controlled state (0), or worsened state (-1) in comparison to patient's baseline and previous measurements. Specific to OCT measurements, changes within 11% will be classified as controlled and changes exceeding 11% will be classified as positive or negative progression [28]. The effect of the intervention (portal) on the outcome (progression), will be analyzed using a logistic regression model to calculate a relative risk for the outcome of interest in which successes are deemed as improved or controlled diabetic retinopathy, and fails deemed as a worsened state of diabetic retinopathy. With this model, the intervention group (hybrid patient portal use) will be compared to the control group, which only receives the standard of care – an annual reminder. Confounders will be adjusted accordingly (*see Variables).*

For Aim 2, secondary analysis will take into account participants' feedback on healthcare services received and understanding of diabetic retinopathy via patient surveys. Feedback questions are independent and will not be composited making for the use of a five-Likert type setting with Chi-square test analysis of participant response data from surveys.

STUDY TIMELINE

Overview

This study will take place over the span of the two years allotted for DRWF funding. Once recruited, participants will be followed for the fifteen months as data is collected from their ophthalmic medical visits and hybrid patient portal. Please see *Grant Proposal Time Table Figure* for an overview.

Study Set-Up

This process entails the logistical processes of organizing the staff members to launch the study. For two months, team members will be hired according to grant needs. Rapport will also be built with the primary care physicians and supporting staff of study sites outlined previously as well as the local ophthalmologists they refer participants to for the purposes of this study (see *Study Sites)*.

Participant Recruitment

Recruitment of study participants will be based on a primary care physician referral basis (see *Recruitment)*.

Intervention & Data Collection

Fifteen months of intervention data collection was determined based on several factors. Since diabetic patients are recommended to have an eye examination once a year and advised to visit their primary care or endocrinologist a minimum of three times a year, the fifteen-month time point allows for several months monitoring intervention outcomes (Prevent Blindness, 2019) Thus, the study period would allow for tracking the maintenance of lifestyle habits conducive or detrimental to diabetic retinopathy and diabetes management. Furthermore, stages of diabetic retinopathy that require anti-VEGF

treatments, such as intravitreal injections and lasers, fifteen months allows adequate time to observe participants' medical progress. The timeframe will also allow for health awareness, medical appointment adherence, and lifestyle changes in accordance with active hybrid patient portal usage has assisted in keeping patients on track to improved habits beneficial to condition management.

Introduction to Hybrid Patient Portal and Health Rewards Program Meeting
Patients will have baseline visual acuities (VA's), Optical Coherence Topography (OCT's) scans, fundus photography performed, and biometric readings collected at the large group meeting. A staff guided pre-survey will be administered at this time. [*see Research instruments*]

Ophthalmic Examination Data Collection:
Since the hybrid patient portal will actively store and record patient surveys, questionnaires, and uploaded physician electronic examination records, data will be taken directly from the portal to track uploads and, later, for analysis. In the case that patient examination records are not uploaded or forwarded to the hybrid patient portal within two weeks, reminders will be sent to the physician's assistant or responsible staff member until uploaded. Those in the control group will only receive an annual call and postcard reminder to visit vision specialist.

Ophthalmic practices using electronic medical record (EMR) systems possess electronic records of examination visits as well as testing records. In the case of Thomas Eye Group, a cloud service, Synergy, is used in combination with their EMR software in which test scans are uploaded directly to the electronic system. Uploading test results is simple in that it uses the same pathway needed for printing results. Instead of selecting to print, the option to save to company's cloud storage service is selected. Any company computer with designated login credentials can access testing results. All ophthalmic practices in this study will be required to have an EMR. Those that do not have a cloud will be temporarily allotted access to Synergy for uploading, which is usually completed by office technicians and assistants at the time of the test scans being captured. Therefore, a minimum - if not the same as a routine patient - time commitment is placed on the facilities' normal practices. With the longstanding tradition of study patients, additional compensation would be provided based on typical compensation for study patients.

Participating physicians have committed to collaborating on this grant and consenting to a data sharing agreement.

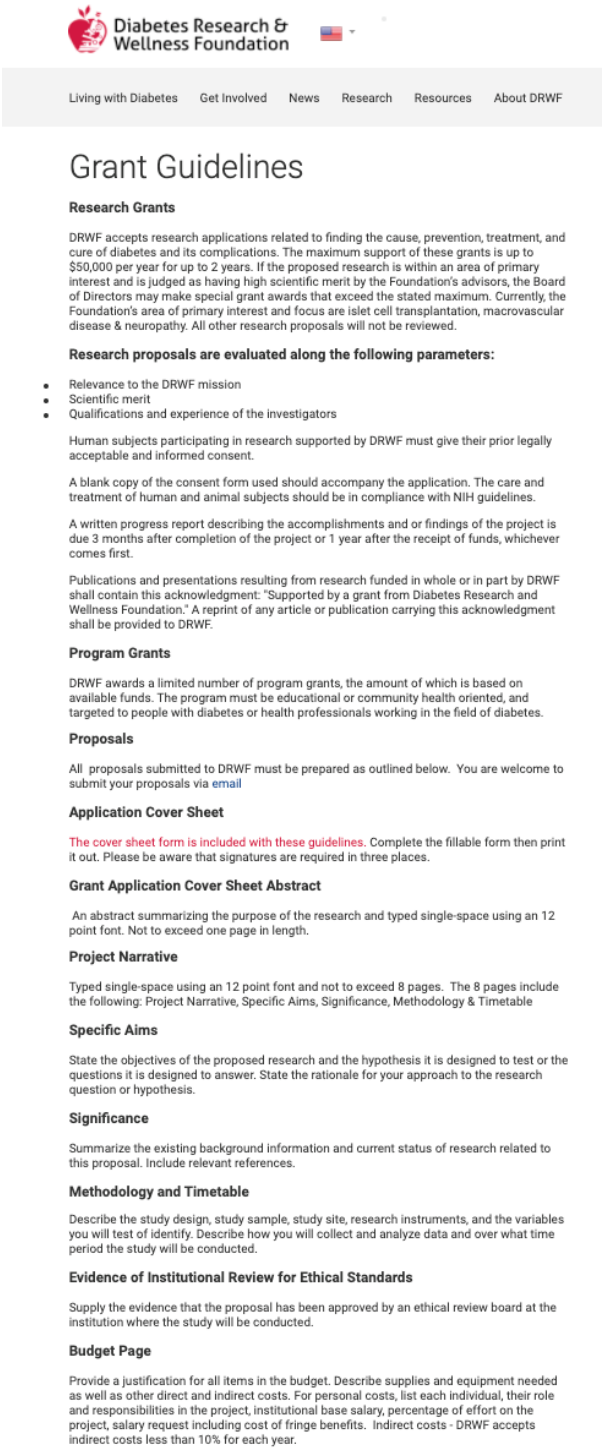
<u>Publication Submissions</u>
Results and findings from this proposal will be submitted to JAMA Ophthalmology, The American Journal of Ophthalmology, Diabetes Care, BMJ Open Diabetes Research & Care, Diabetes Spectrum, or The American Journal of Medicine.

<u>Conclusion</u>
Diabetes is a chronic disease gradually affecting millions globally each year. Its

prevalence is widespread with upward trends substantial increase [24]. As a significant cause of vision loss, myocardial infarction, kidney damage, heart attacks, stroke and limb removal, diabetes is not a condition to be taken lightly. Increased patient autonomy, awareness and surveillance are necessary to preserve vision, prevent additional vision loss and reduce risks of associated diabetes complications. The introduction and usage of an incentivized patient portal provides an ideal platform for people with diabetes and other chronic diseases to better manage their conditions. Bettered health management behaviors and components of the app have the potential to improve biometric measurements, which influence diabetic retinopathy and thus diabetes. Active usage of the app can serve as a model that is easily adaptable to management of other comorbidities and chronic diseases. In addition, increased medical awareness and transparency bolsters immense potential in bridging the gaps between physician and patient.

APPENDIX

Grant Guideline
https://www.diabeteswellness.net/grant-guidelines



Diabetes Research & Wellness Foundation

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Grant Guidelines

Research Grants

DRWF accepts research applications related to finding the cause, prevention, treatment, and cure of diabetes and its complications. The maximum support of these grants is up to $50,000 per year for up to 2 years. If the proposed research is within an area of primary interest and is judged as having high scientific merit by the Foundation's advisors, the Board of Directors may make special grant awards that exceed the stated maximum. Currently, the Foundation's area of primary interest and focus are islet cell transplantation, macrovascular disease & neuropathy. All other research proposals will not be reviewed.

Research proposals are evaluated along the following parameters:

- Relevance to the DRWF mission
- Scientific merit
- Qualifications and experience of the investigators

Human subjects participating in research supported by DRWF must give their prior legally acceptable and informed consent.

A blank copy of the consent form used should accompany the application. The care and treatment of human and animal subjects should be in compliance with NIH guidelines.

A written progress report describing the accomplishments and or findings of the project is due 3 months after completion of the project or 1 year after the receipt of funds, whichever comes first.

Publications and presentations resulting from research funded in whole or in part by DRWF shall contain this acknowledgment: "Supported by a grant from Diabetes Research and Wellness Foundation." A reprint of any article or publication carrying this acknowledgment shall be provided to DRWF.

Program Grants

DRWF awards a limited number of program grants, the amount of which is based on available funds. The program must be educational or community health oriented, and targeted to people with diabetes or health professionals working in the field of diabetes.

Proposals

All proposals submitted to DRWF must be prepared as outlined below. You are welcome to submit your proposals via email

Application Cover Sheet

The cover sheet form is included with these guidelines. Complete the fillable form then print it out. Please be aware that signatures are required in three places.

Grant Application Cover Sheet Abstract

An abstract summarizing the purpose of the research and typed single-space using an 12 point font. Not to exceed one page in length.

Project Narrative

Typed single-space using an 12 point font and not to exceed 8 pages. The 8 pages include the following: Project Narrative, Specific Aims, Significance, Methodology & Timetable

Specific Aims

State the objectives of the proposed research and the hypothesis it is designed to test or the questions it is designed to answer. State the rationale for your approach to the research question or hypothesis.

Significance

Summarize the existing background information and current status of research related to this proposal. Include relevant references.

Methodology and Timetable

Describe the study design, study sample, study site, research instruments, and the variables you will test of identify. Describe how you will collect and analyze data and over what time period the study will be conducted.

Evidence of Institutional Review for Ethical Standards

Supply the evidence that the proposal has been approved by an ethical review board at the institution where the study will be conducted.

Budget Page

Provide a justification for all items in the budget. Describe supplies and equipment needed as well as other direct and indirect costs. For personal costs, list each individual, their role and responsibilities in the project, institutional base salary, percentage of effort on the project, salary request including cost of fringe benefits. Indirect costs - DRWF accepts indirect costs less than 10% for each year.

External Review Form

EXTERNAL REVIEWER

Grant proposal thesis – External Reviewer Feedback

Please use this template as a basis for providing feedback on the grant proposal you are reviewing to the student PI. Place an "x" in the shaded boxes and provide written feedback in the white boxes as they apply.

1. Please state your level of agreement/disagreement with the following statement: The proposal is relevant to the DRWF guidelines https://www.diabeteswellness.net/grant-guidelines

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree

- How could the submission have been more relevant to the DRWF mission?

2. Please state your level of agreement/disagreement with the following statement: The methodology is feasible and addresses the goal of the proposal.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree

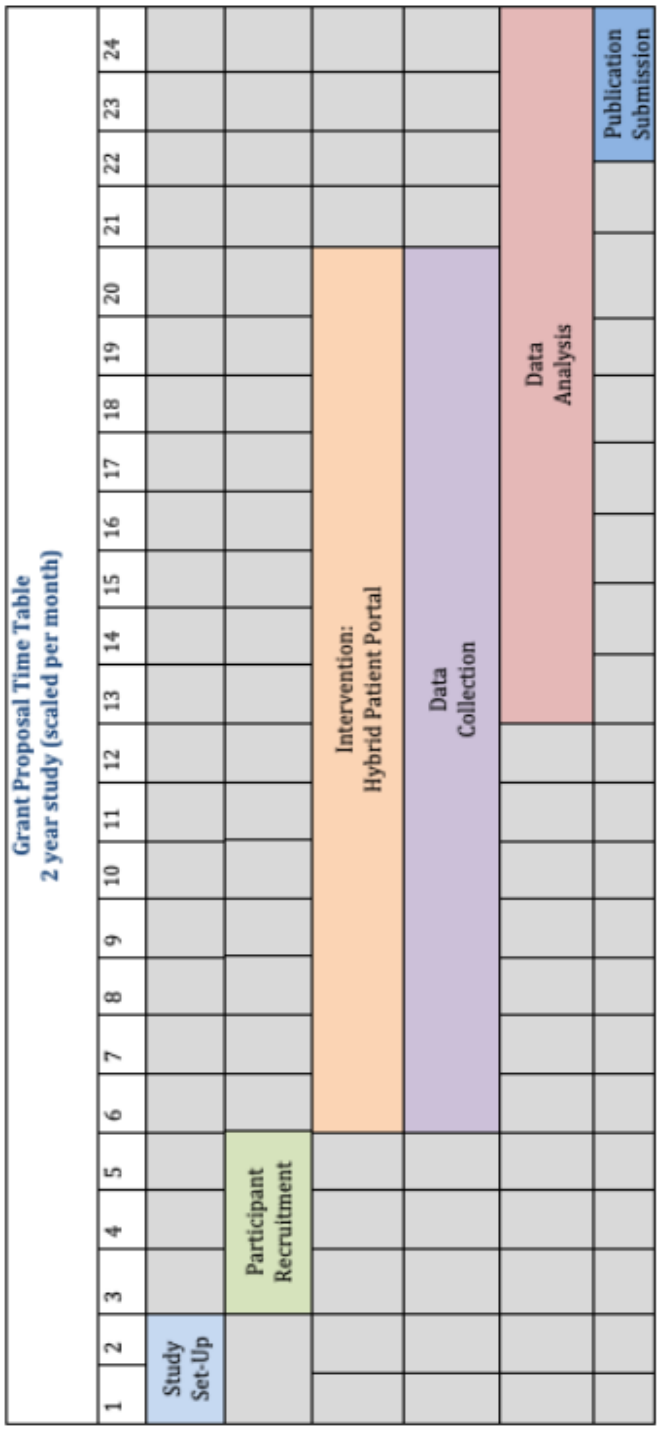
- What improvements could be made to the methodology of the proposal?

3. Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the proposal is necessary and has scientific merit.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree

- What would have improved the argument that the proposal is necessary and has merit?

Time Table


Grant Proposal Time Table
2 year study (scaled per month)
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Study Set-Up
Participant Recruitment
Intervention: Hybrid Patient Portal
Data Collection
Data Analysis
Publication Submission

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