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mHealth: A Utilization Review by Feature Classification for Sustained Use

BY Elaine Dunn

A doctoral project submitted to the faculty of the Medical University of South Carolina in partial fulfillment of the requirements for the degree Doctor of Health Administration in the College of Health Professions

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mHEALTH: A UTILIZATION REVIEW BY FEATURE CLASSIFICATION FOR SUSTAINED USE

BY

Elaine Dunn

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Table of Contents

Ackno	owledgements	iii.
List o	f Figures	vi.
List o	f Tables	vii
	act	vii
I.	INTRODUCTION.	1
	Background and Need	
	Problem Statement	
	Research Question	
	Population	
	Assumptions	
II.	REVIEW OF THE LITERATURE.	17
	Review Process	
	Diabetes Impact	
	Diabetes Self-Management.	
	mHealth – Status of the Research	
	mHealth – Implications for Effective Design	
	Delone and McLean Framework.	
	Summary	
III.	METHODS.	35
	Introduction	
	Research Design	
	Classification Framework	
	Data Set Description.	
	Data Analysis	
	Limitations	
IV.	RESULTS	47
	Review of Methods	
	General User and Utilization Statistics	
	Information versus System Utilization	
V.	DISCUSSION	58
	Discussion of Results	
	Conclusions and Implications	

	Summary	
VI.	REFERENCES.	67
VII.	APPENDICES	79

List of Figures

Figure 1.	Delone and McLean Information System Success Model
Figure 2.	Total uses over time
Figure 3.	Aggregate utilization by age group
Figure 4.	Framework category utilization over time
Figure 5.	Gender utilization over time
Figure 6.	Age group utilization over time

List of Tables

Table 1. Classification schema

Table 2. Final feature classification schema

Abstract of Doctoral Project Report Presented to the

Executive Doctoral Program in Health Administration & Leadership Medical University of South Carolina

In Partial Fulfillment of the Requirements for the

Degree of Doctor of Health Administration

mHEALTH: A UTILIZATION REVIEW BY FEATURE CLASSIFICATION FOR

SUSTAINED USE

ByElaine Dunn

Chairperson: Dr. Dusti Annan-Coultas

Committee:

Dr. Mrunal Shah, Dr. James Zoller

mHealth is a fast growing segment for healthcare. However, there has been little research

into the specific elements of mHealth that can drive continued use for optimization of the

potential benefits.

The purpose of this case study was to use the Delone and McLean Information System

Model as a framework for classification of mHealth functionality and then to review the

utilization of those categories over a six month period of time.

A sample of 137 pediatric diabetics was reviewed. The activation rate was high at 94.9%

indicating an interest in using mHealth. There was higher utilization of system features in the

group of users with 60.3% of total uses being related to a system feature. There also were

specific use patterns between gender with male patients consisting of 66.2% of the overall uses.

Future applications should focus on system features and customization by gender to support

sustained use.

viii.

Introduction

Background and Need

This section will provide an overview of the need for enhanced engagement and education for patients with chronic diseases, specifically diabetes mellitus, to improve self-management measures. Self-management is defined as the tasks undertaken directly by a patient in the day-to-day management of symptoms relating to a chronic illness (Lorig & Holman, 2003). Information will also be provided regarding the prevalence and effect of diabetes mellitus on patients and health systems. A literature review indicates there is significant potential in using mobile technology to collect data and provide education, coaching, and feedback to improve education and self-management of chronic diseases, such as diabetes. A general overview of mHealth and the proposed program goals will be discussed. Finally, findings related to the documented benefits and current deficits of mHealth for care management will be presented. *Diabetes Scope*

Diabetes mellitus is a disorder in which glucose (blood sugar) levels are abnormally high because of an inability to produce and regulate insulin, a hormone released from the pancreas that controls the amount of glucose in the blood. Diabetics experience many serious, long-term complications including neuropathy, circulatory disorders, and renal insufficiency (Beers, 2003). The primary test to monitor diabetes treatment is the amount of hemoglobin A1C (HbA1c) in the blood. HbA1c is an indication of the amount of glucose available in the bloodstream. A diabetic that is considered well controlled would exhibit an HbA1c ranging from 2.5% to 5.9% (Pagana & Pagana, 2005).

The general population of diabetics is massive. Nearly 29.1 million or 9.3% of the U.S. population have diabetes. This is in addition to an estimated 8.1 million people that may be

undiagnosed. Diabetes is the seventh leading cause of death in the United States (CDC, 2014). The prevalence of diabetes is expected to increase an estimated 67% by the year 2030 (Adepoju, 2014).

It is estimated that by 2030 nearly 366 million people will have diabetes (Quinn, Clough, Minor, Lender, Okafor, & Gruber-Baldini, 2008). The cost associated with the treatment of diabetes is a significant burden on the health care system. Total direct and indirect costs expended in the treatment and management of diabetes is estimated at \$245 billion (CDC, 2014). As providers' time becomes more finite, the ability to manage chronic diseases via traditional methods such as office visits will become increasingly difficult prompting the need for innovative techniques to provide patient education in a time and cost efficient manner.

Healthcare systems struggle to effectively manage even the current population of diabetics. As with many chronic diseases, diabetes control is largely dependent on self-management (Faridi, Liberti, Shuval, Northrup, Ali, & Katz, 2008). However, health systems are failing to effectively treat diabetes because of an inability to ensure patient compliance with care plans and to provide adequate education. Only 63% of diabetics meet the guidelines for controlled HcA1c and only 7% are considered to have controlled glycemic, lipid, and blood pressure goals (Quinn, Minor, et al., 2008).

Population Health Management as a Driver for Patient Engagement

The near pervasive prevalence of diabetes in the U.S. is a perfect example of what is driving the need for population health management in this country. Population health management is the systematic approach to ensuring all patients receive appropriate care (Matthews & Hodach, 2012). This is a very different approach to care than care management tactics that are commonly used in health systems today. Population health approach strives to

manage the wellness of an entire population by being proactive on interventions and engaging patients in their own care. The current medical model has three characteristics:

- Care is disease based with focus on treating specific diseases after a diagnosis has been made.
- Care is focused on treating one patient at a time.
- Providers are reimbursed based on volume of care provided.

In contrast, the future model of health care will be focused on preventing disease, promoting health, and providing health services to a population of patients and will be driven by outcomes rather than volume (Stephan, 2011). This is a fundamental change in how healthcare is delivered and managed in this country and the impact of this shift will be felt first in those patient groups with chronic diseases.

Patient engagement is critical to the success of population health management. This is particularly important in patients with chronic diseases, as that population constitutes 75% of healthcare costs. These patients are often tasked with managing their own conditions, which will require more focused education to create knowledgeable health consumers equipped to manage certain aspects of their own care plan. Focused education not only contributes to informed consumers; it also has a clinical impact. Research has shown that self-management education has a positive effect on clinical outcomes (El-Gayar, Timsina, & Nawar, 2013). To manage both the health needs and cost of treating this group of patients, health systems will be required to automate through information technology the routine tasks of population health management such as monitoring and performing outreach and education (Matthews & Hodach, 2012).

mHealth Introduction and Program Goals

One tactic for improving education and self-management measures for diabetic patients is to leverage mobile technology. mHealth is the use of mobile communication devices, such as cellular telephones and wireless tablets, for health services management and information delivery (Klonoff, 2013). Health interventions that can be facilitated via mobile technology include (de la Vega & Miro, 2014):

- Provider communication regarding health and appointment reminders in the form of push notifications or text messaging.
- Documentation of disease management tactics.
- Remote monitoring of biometric measures and behaviors.
- Delivery of health education.

The aim of mHealth in the context of patient engagement is to assist patients to make decisions for themselves in real time while minimizing the need for direct contact with their healthcare provider (Klonoff, 2013). The use of mobile technology to achieve improvement in patient adherence with healthy lifestyle choices has three specific goals.

First, the use of mobile technology can leverage a device with which the patient is already familiar and use that medium to provide patient education. Providing patient education has tangible results for improving self-management in diabetics. Mazzuca et al. (1986) completed a study that showed patient education resulted in clinically and statistically significant improvement in self-care skills and compliance behaviors in a diabetic population. A reduction in key biometric measures such as blood glucose, body weight, and blood pressure were noticed in the group receiving education as well. Using mobile technology to provide health education

allows providers to use a system that is widely accepted by patients thus mitigating content usability and delivery concerns.

Second, mobile technology provides the ability to remind patients of key care management concepts that are presented by their healthcare team, but may need reiterated at a later date for the patient and the circle of care. Using mHealth to provide care management content also facilitates a feeling of service for patients as reinforcement, feedback, and guidance is provided in an on-demand format. This not only is beneficial for the patient, but also saves provider contract time. The U.S. healthcare system is facing a significant shortage of providers. The shortage is estimated to reach over 51,000 physicians by the year 2025 (Heisler, 2013). Strategies that mitigate the need for direct provider contact are extremely valuable to health systems that are forced to balance the need for continuity of care and cost.

Finally, mobile technology allows the provider an opportunity to distribute health education content over which it has control. As consumerism in healthcare increases due to healthcare reform and patients are driven to be more knowledgeable in their health needs, healthcare providers will have to deliver educational content in a user friendly, on-demand format. As healthcare evolves into a consumer driven industry and patients seek more health information, providers will have to ensure that accurate and evidence-based information is readily available to reduce the need for patients to seek this information from other less credible sources. Segal (1998) confirms this by stating that consumer empowerment through health education that is focused on increasing the involvement of patients in healthcare decisions is a central requirement for healthcare reform. Mobile technology offers a cost-efficient manner to accomplish this task.

The program goals addressed above create the core value proposition for mHealth applications. It is important that providers and users of mobile health applications understand these goals and use them as the foundation for a mHealth program.

mHealth Benefit and Limitation Summary

mHealth is a relatively new field in healthcare, but there is sufficient evidence to support further development and implementation of this technology. A high level summary of relevant studies that support that explains the promise and current limitations of mHealth is presented below.

A literature review conducted by Krishna, Boren, and Balas (2009) showed that cell phones could be used in disease management to improve a wide range of outcomes including medication compliance, biological outcomes such as HbA1c, and measures of self-management. There is widespread use of mobile technology in patients that crosses socioeconomic status, gender, and age that makes it a good tool to provide care management programs (Quinn, Minor et al., 2008). Blake (2008) lists many contributions that mobile technology can make to patient care. These include:

- Personalized messages to patients based on their results
- Efficient data collection
- Continuity of care through improved patient to provider communication
- Access to expertise for patients outside of the service area
- Electronic tracking of dementia patients
- Distance monitoring of glucose
- Assistance with self-management of chronic diseases

Many studies about the effectiveness of mobile technology on patient outcomes were completed via a randomized control trial. These studies primarily focused on the use of mobile technology to transmit blood glucose levels and in turn provide remote coaching based on those results, with the ultimate goal of demonstrating a decrease in biometric measures. Of those studies reviewed on this topic, most demonstrated a decrease in the intervention group in important diabetic physiological measures by using mobile technology for reporting home blood glucose levels and providing subsequent feedback and coaching. For example, Yoon and Kim (2008) demonstrated that text messaging and subsequent feedback was linked to a reduction in HbA1c in the intervention group over the control group. In addition to evaluating the link between HbA1c and mobile phone interventions, investigators have also evaluated the effect on healthy behaviors. Glasgow et al. (2011) also evaluated the effect on exercise, eating habits, and medication adherence with the intervention of a self-management website and found a positive correlation.

Similar to the research above, Faridi et al. (2008) conducted a randomized control trial of diabetic patients that provided real time feedback via text messages in response to uploaded biometric measures over a three-month period. At the end of the trial, the intervention group showed improved self-management scores and a slight improvement in HbA1c trending.

In addition to studying mobile technology intervention on biometric outcomes, there has been additional promise demonstrated in using that same technology to improve the qualitative measures of self-management and patient satisfaction. The National Institute of Health conducted a trial to assess not just biological measures but also the variable of self-efficacy in the review of self-management tactics provided via mobile technology. This is an important study because it showed the potential of mobile technology to improve not just the quantitative

outcome of HbA1c but also to positively impact patient's behaviors to a statistically significant degree using mobile education content (Faridi, et al. 2008). Quinn et al. (2008) demonstrated a correlation between providing virtual coaching via mobile phones and a reduction in HbA1c. This study also went further to show that the intervention group reported an improvement in treatment decisions related to diet, medication, and exercise. Furthermore, a substantial increase in patient satisfaction, from 41.7% to 91% was noted. Given the increased focus on patient satisfaction and the impact to the Medicare payment under new value-based reimbursement systems, this result represents a great opportunity for health systems. The studies discussed above support that mHealth interventions can positively impact measures of self-management and can improve adherence to disease management plans (Faridi et al., 2008).

As healthcare moves towards the era of population health management, it will be vital to reach the entire constituency of patients. This presents a difficult task given the geographical and socioeconomic range of patients to be served. There is promise in using mobile technology in this area as well. Maglaveras, Chouvarda, Koutkias, Meletiadis, Haris, and Balas (2002) demonstrated that there is a great potential to leverage mobile technology in regional health networks to provide access to those that are unable to come to the main service hub.

Before significant investment is made in this technology, it is important to know if patients and the circle of care will utilize it. In a survey of parents with diabetic children, 50% stated they would use a mobile-based service for education and communication with providers. The study went further to state that the use of mobile phone technology could assist with the parent's perceived lack of access to the provider (Pena, Watson, Kvedar, & Grant, 2009). This research helps to confirm mHealth benefits include improved patient satisfaction and reduced need for direct provider contact.

There are known limitations to using mobile technology what will need to be investigated further. One limitation of mobile technology for patient education is the access to that technology, particularly in low-income populations. However, Demartini, Beck, Klein, and Kahn (2013) studied an urban pediatric population with a 92% Medicaid payer mix and found that 71% of the studied population had a smart phone and 70% indicated that they would use mobile technology to access digital healthcare information. Wu and Shah (2007) established through a questionnaire that diabetic patients in safety net populations expressed interest in mobile phone strategies for education. Furthermore, it has been shown that mobile phone use is frequent in homes with lower education and socioeconomic status (Mulvaney, Anders, Smith, Pittel, & Johnson, 2012). This is promising as these patients can be difficult to reach with conventional education and management strategies.

Another barrier includes overcoming technology knowledge base deficits for some of the patient population (Faridi et al., 2008). There will be populations of patients that may not have the technical skills to effectively use a mobile application. Appropriate design of the application with specific focus on usability could help mitigate the knowledge deficit and improve patient comfort level with the technology.

Long-term engagement in mobile health applications is also a concern and is necessary to achieve the full potential of mHealth. Ongoing application usage is directly associated with improved attitudes on diabetes self-management. However, patients will not use an application as an integral part of their care plan if it is not easy to use and a natural complement to their daily self-management tasks. Research is needed for the creation of a user-centered and sociotechnical design to realize the full potential of mHealth for diabetics (El-Gayar, Timsina, & Nawar, 2013).

There is clear support that mHealth, when properly designed and implemented, can drive improvement in key diabetes metrics such as HbA1c by collecting data and providing directives on how to manage blood glucose levels. mHealth interventions can also improve scores of self-management by providing guidance on eating behaviors, exercise, and medication adherence. Finally, as part of a patient engagement strategy, mHealth can provide on-demand support that assists with improving patient satisfaction while reducing the need for direct provider contact. However, to realize these benefits on a broader scale, further research is needed in what design attributes will improve adoption and sustained use of this technology.

Problem Statement

The literature review suggests that mHealth can positively impact clinical outcomes by directly influencing biometric measures and self-management skills. These benefits are recognized only when a mHealth intervention employs intelligent design principles that address technology knowledge deficits and encourage long-term use.

The pace of mHealth research has not kept up with technological advances. While there are studies that point to the promise of mobile health applications as discussed above, questions still remain about what encourages patients to use the application more or less (Glasgow, Phillips & Sanchez, 2013). Specifically, there are few studies that specifically describe what features of mobile applications increase effectiveness of the application. Chomutare, Fernandez, Luque, Arsand, and Hartvigsen (2011) completed a review of commercially available mobile applications and compared available features with evidence-based guidelines for diabetes self-management. The most common features currently available are insulin recording; data export, diet recording, and weight management tools. When reviewing clinical guidelines for diabetes treatment and recommended self-management tactics, significant emphasis is placed on

education and feedback. However, none of the 137 applications surveyed provided this functionality. A more recent review of commercially available applications showed that only 18% contain self-management education (El-Gayar, et al. 2013). Comparison of these two studies shows that in two years, while there has been a significant increase in the number of applications, there is still a lack of education content available. Adding additional content alone will not improve the effectiveness of an application, though. The form in which that content is delivered is critical to the overall usability of the application as the average person still lacks the skills to identify and interpret meaningful health information (Chomutare, et al., 2011).

Many mHealth interventions studied are focused on text messages and real time feedback. Spring et al. (2012) demonstrated that mobile coaching via text messages paired with financial incentives was able to positively modify behavior regarding diet and exercise. While text messaging and push notifications are effective tactics, there are other interventions that can be provided via mobile technology that may be just as effective and less costly and resource intensive. The application features that facilitate these interventions will need to be evaluated for effectiveness. For example, Bell, Fonda, Walker, Schmidt, and Vigersky (2012) found that patients that used a mobile application with videos for self-care support showed an improvement in HbA1c compared to those patients who received only traditional care and educational measures. Other interventions that could provide benefit include interactive algorithms that direct patients on how to address blood glucose levels and real time guidance on making healthy behavior choices.

While research indicates that certain features such as text messaging are linked to favorable clinical outcomes, there is little evidence available about the specific application design needed to create an effective program. Design limitations can mitigate the benefit

received from mHealth interventions. For example, when using push notifications, patients reported that the messages, when delivered poorly, can be intrusive thus reducing the effectiveness of the intervention (Wangberg, Arsand, & Andersson, 2006). Design elements are critical to the application's success because technical difficulty can significantly impact the study results by discouraging patients to use the application (Istepanian, et al., 2009).

In addition to the impact of design on technical ease, the design will further influence how often the application is used. Noh, et al. (2010) reviewed the effectiveness of web-based diabetes education on self-management and discovered there was a positive correlation between the frequency of application use and the improvement in HbA1c levels. Hanauer, Wentzell, Laffel, and Laffel (2009) also found that sustained use in a mobile technology program is challenging. Further research on design can assist with alleviating these issues and improving long-term effectiveness of the application.

As health systems begin to realize the potential of mHealth technology on diabetes management, specific functionality will need to be identified and included in application development to provide the needed return on investment in improved patient care and development costs. Education is a critical element of a mobile application as it is integral to self-management, which has a direct impact on prognosis. To be successful, the program must empower and motivate patients by developing problem solving and self-management skills (von Sengbusch, Muller-Godeffroy, Hager, Reintjes, Hirot, & Wagner, 2006).

A review of the current literature on the impact of mobile technology on chronic disease management, specifically on diabetes, shows that mHealth can be quite effective but challenges remain in adoption. More research is needed to assess functionality for providing mHealth content that is easy to use, effective for improving self-management, and engaging over time.

This research will address which features of mobile health applications best promote sustained use.

Research Question

The potential of diabetes mobile applications to improve patient outcomes has been established. There is a need to determine specific functionality requirements that will engage patients and caregivers to use a mobile phone application for self-management.

The primary research question is: What types of mHealth application functionality promote sustained use by pediatric diabetic patients? A case study research design will be used to answer this question. The case at the center of this research is a mHealth diabetes application recently developed and in use currently by diabetes patients. Sustained use for the purpose of this study will be defined as a time period of six months.

The application in review is the Nationwide Children's Diabetes Manager. The application is made to be used on smart phones and tablets. The core feature is the medical content dictionary that includes health education on the following topics:

- Overview of diabetes
- Monitoring blood sugar
- Insulin management
- Guidance on using insulin pumps and glucose monitoring equipment
- Protocols on how to handle insulin variances and prevent exacerbation

The application also allows for patients to create diabetes journals, take quizzes to test their diabetes self-management knowledge, and complete challenges to improve healthy behaviors. Application screen shots of key features are available in Appendix A.

The Nationwide Children's diabetes mobile application was selected for this study for two reasons. First, the application has a wide variety of functionality that allows for a utilization review of several different types of mHealth design attributes. Second, the researcher has access to all of the utilization statistics for the application directly through the developer.

The application functionality will be assessed by first classifying the features. The classifications will be validated by subject matter experts. Next, a review of utilization statistics of those specific application features will be completed. The goal is to inform optimal design of mobile health applications in the future.

This study is an important contribution to our understanding of the factors that may affect the adoption of mobile health applications through defining meaningful design attributes. This information will ultimately increase the acceptability of mobile applications and, in turn, contribute to improved management of diabetes across the affected population. The stakeholders for this study include healthcare providers, patients, and mHealth developers. Providers benefit because in order to realize the population health benefits and their return on investment, patients must use the application as an integral part of their care plan. Application developers will use this information to create an intervention that is marketable and provides meaningful outcomes as part of the technology's value proposition. Finally, patients could ultimately benefit as the era of consumer driven healthcare demands educated and self-sufficient health users. The ability to quickly and efficiently access health information using a technology they already possess will assist with this endeavor.

Population

The current mobile application design under review is aimed at improving selfmanagement for diabetic patients. The populations of diabetics studied for this research are patients under the age of 18 who have a known diagnosis of diabetes mellitus, receiving treatment at an urban children's hospital in central Ohio and who have access to a smart-phone.

The results have the potential to be applied to a significant number of patients. The CDC (2014) estimates that approximately 208,000 people under the age of 20 have diabetes. Nielson (2014) reports that 65% of the U.S. population owns a smart-phone. By applying this percentage to the diabetic population, it is inferred that nearly 1.8 million Americans that could potentially use a mHealth intervention.

With the near pervasive state of diabetes and pervasiveness of smart phone ownership, the use of mobile technology to effectively manage these patients will be critical to controlling associated healthcare costs and creating a healthier population.

Assumptions

To arrive at an outcome, certain assumptions are made in the course of this research.

Certain assumptions must be made about the availability of the application to the target population. First, it is assumed that all patients that meet these criteria are provided with an application access code to initiate use. This process is confirmed through the chair of the application development committee at the hospital where the application is in use. Second, it is assumed that all application functionality has been continuously available. This assumption was validated by reviewing indicated application audit logs that detail no significant downtime has occurred.

The first key element of the research is the classification of features with confirmation of the categories by subject matter experts through personal interviews. The assumption relating to the personal interviews is that all participants are indeed knowledgeable in the classification of application features and will provide honest feedback. Any possible negative consequence of

this assumption is mitigated by validating that those interviewed are credentialed physicians and application developers with direct and related mHealth experience.

The final assumption is in relation to the second key component of the research. This is the review of the statistical utilization data. The researcher assumes that all data is collected and reported accurately by the application developer. The application has been reviewed and found to be compliant with the Centers for Medicare and Medicaid Meaningful Use program criteria for data collection and reporting.

Literature Review

Review Process

An electronic literature search was conducted using PubMed and OVID for articles and studies relating to mHealth uses, benefits, and limitations. The search strategies used included terms of "mHealth", "eHealth", "health information technology", "mobile technology", and "smart phones". To understand the scope of the issue related to chronic diseases and the potential impact of mHealth on these conditions, searches were conducted on diabetes and self-management principles as well. Searches were limited to articles published in English and through the period of January 2005 through October 2014.

Diabetes Impact

Chronic diseases like diabetes are nearing epidemic levels and represent a significant burden on health care systems. It is estimated that approximately 50% of the population is living with at least one chronic disease (Hung, Hon, Chen, Franklin, & Tang, 2013). The utilization of health services associated with chronic diseases, like diabetes, is high with little evidence that this trend is decreasing. In recent years, chronic conditions accounted for 76% of physician visits, 81% of inpatient stays, 91% of prescription medications, and nearly 98% of home health care visits (Schwartz, Day, Wildenhaus, Silberman, & Wang, 2010). Diabetics constitute a large population of these high health service utilizers. The number of emergency visits associated with diabetes alone has increased 5.6% in the last decade (Arora, Peters, Agy, & Menchine, 2012). The average number of physician office visits increased 43% for diabetes related issues (Schwartz, Day, Wildenhaus, & Silberman, 2010). The strain placed on the health care system by these patients is not sustainable.

The cost associated with these conditions make up nearly 75% of health care spending (Steinhubl, Muse, & Topol, 2013). Considering that the U.S. healthcare system spends approximately two trillion dollars a year, the financial burden of treating these patients represents a significant area of opportunity to control the ever rising healthcare costs. In fact, the U.S. spends more than any other developed country on healthcare, but this has not translated to better health outcomes in any population of patients (Wilson, Benjamin, & Skoufalos, 2014). Despite this investment, nearly 80% of deaths are attributable to the two most common chronic diseases, cardiovascular disease and diabetes (Beratarrechea, Ciapponi, & Rubinstein, 2014).

Type 1 diabetes is one of the more prevalent chronic conditions that require intensive management (Quinn, Gruber-Baldini, et al., 2008). Nearly 9.3% of the population has diabetes and the prevalence is expected to be at 26.5% of the population by the year 2050 (Cotter, Durant, Agne, & Cherrington, 2014). It is the seventh leading cause of death (Brooke & Thompson, 2013). The World Health Organization projects that diabetes deaths will increase by two-thirds between the years of 2008 and 2030 (Pulman, Taylor, Galvin, & Masding, 2013). Diabetes alone is estimated to account for up to 15% of national health care budgets. The indirect costs associated with diabetes would be in addition to this 15% and are difficult to estimate when you consider diabetes complications such as ischemic heart disease, hypertension, neuropathy, and retinopathy (Mohammadzadeh, Safdari, & Rahimi, 2014).

While there continues to be significant attempts to reduce the prevalence of diabetes, there has not been demonstrated improvement in the management of these patients. Only 7% of diabetics meet recommended glycemic, lipid, and blood pressure goals (Quinn, Gruber-Baldini, et al., 2008). One cause of the low levels of control in diabetes, specifically in the pediatric population is that these patients often struggle with the complex guidance involved to effectively

manage target HbA1C levels (Goyal & Cafazzo, 2013). One estimate has adherence to diabetes treatment regimens as low as 50% (Breland, Yeh, & Yu, 2013). Diabetes management is particularly difficult with pediatrics due to the effect of puberty on glycemic control and other behavioral and psychological factors that contribute to worsening blood glucose levels (Markowitz, et al., 2014). These factors combined make pediatric diabetics an ideal population to focus on for improved self-management tactics.

While the prevalence of diabetes grows, the capacity of the health care system to effectively treat diabetics is insufficient. Only 20% of primary care physicians perceive they have resources necessary to manage patients with diabetes effectively (Quinn, Gruber-Baldini, et al., 2008). When considering specialist resources, a study found that the number of pediatric endocrinologists is insufficient to address the number of children diagnosed with diabetes in the U.S. (Pena, Watson, Kvedar, & Grant, 2009). It is clear that to manage the ever increasing population of diabetics, we cannot rely on providers alone.

Due to the inadequate provider capacity, management of chronic conditions often falls on patients and their caregivers. It is estimated that nearly 30% of all U.S. adults are informal caregivers (Hung, et al, 2013). Of those informal caregivers, nearly seven million are long distance caregivers which inhibit close monitoring (Aikens, Zivin, Trivedi, & Piette, 2014). Almost 26 million Americans are tasked with diabetes and pre-diabetes monitoring (Wilson, Benjamin, & Skoufalos, 2014). This represents a large population that must be educated and trained in the skills necessary to manage chronic diseases like diabetes as effective self-care is highly dependent on coordination of parents and caregivers thoughts and behaviors (Froisland, Arsand, & Skarderud, 2012).

The American Diabetes Association (ADA) recognizes the criticality of enabling patients and informal caregivers to self-manage. The ADA has gone further to state that people with diabetes are directly controlling their care plans. Furthermore, support to informal caregivers has been proven to improve diabetes outcomes. High quality care requires an engaged patient, self-management education, and education on problem solving skills (Wilson, Benjamin, & Skoufalos, 2014). However, this group often lacks the tools needed to monitor health status and support self-care (Aikens, Rosland, & Piette, 2014).

Parents must learn not just about the disease itself, but how to adjust treatment based on the child's symptoms. This is challenging for parents as adherence to the care plan and communication in general decreases in adolescence (Pena, Watson, Kvedar, & Grant, 2009). In a survey of parents with diabetic patients, results showed that there is a lack of structure and systems in place to adequately monitor and react to the child's needs (Pena, Watson, Kvedar, & Grant, 2009). Specific findings included:

- 57.2% of parents were concerned their child is not conducting glucose readings.
- 24.2% said the treatment plans given by health care providers are too complex to understand.
- 35.1% had concerns they did not have enough knowledge about managing their child's diabetes.

Due to the increasing costs related to treating chronic conditions, hospitals are being forced to shift care from the expensive acute care delivery model to condition management delivered in homes (Schwartz, Day, Wildenhaus, Silberman, & Wang, 2010). With the changes in reimbursement methodologies, the virtualization of healthcare delivery systems is inevitable (Levin, 2014). The best way to reduce health care costs is to empower patients to manage and

ultimately prevent chronic disease and manage appropriate health utilization (Mohammadzadeh, Safdari, & Rahimi, 2014).

Diabetes Self-Management

Historically, diabetes management has centered on focusing on glucose management alone. Now providers are not just focused on selling insulin to the diabetic, but in addressing the whole disease (Morrissey, 2013). To make living with diabetes easier, patients must have systems to regularly manage their symptoms and adapt their lifestyles accordingly (de Jongh, Gurol-Urganci, Vodopivec-Jamsek, Cark, & Atun, 2012). This requires behavior-based interventions that focus on preventing long-term disease complications, and providers are looking to self-management strategies to accomplish this (Tate, et al., 2013).

A good example of behavior modification integral to self-management is physical activity. Regular physical activity reduces morbidity and mortality associated with diabetes. It is recommended that the general population is physically active for at least 150 minutes per week (Johnston & Klasnha, 2013). However, only 25% of the population meets national physical activity recommendations (Fanning, Mullen, & McAuley, 2012). Coincidently, the U.S. has seen a dramatic increase in obesity, which is a significant public health concern. This has been particularly noticeable in the pediatric diabetic population, where 60% of patients are overweight or obese (Rossi, et al., 2013). An active lifestyle can reduce complications from diabetes and is an important treatment aspect in the diabetic's care plan (Johnston & Klasnja, 2013). Patients will have to considerably modify their lifestyle to positively impact this trend.

The term self-management refers to the tasks a person undertakes on their own to minimize the impact of an illness on his or hers health status (de Jongh, et al., 2012). Diabetes self-management tactics are aimed at normalizing blood glucose levels through medication

adherence, diet, and exercise to manage prevent exacerbations and long term complications (Markowitz, et al., 2014). Implementing self-management education at the population level is a significant task for providers. The continuum of care requires constant information sharing between the provider and patient, but this requires information systems that are usable by both clinicians and patients (Morrisey, 2013).

Emphasis is shifting from physician-directed management to patient self-management because 95% of the variance in glycemic control is related to patient level factors and directly controllable by the patient (Vuong, et al., 2012). Schwartz, Day, Wildenhaus, Silberman, and Wang (2010) have set forth an effective self-management framework which includes:

- Patients accept responsibility for managing their care.
- Patients optimize daily functioning to manage limitations created by their condition.
- Patients manage co-morbidities in a holistic manner.
- Technology based intervention programs focused on lifestyle modification.

To create this framework, just-in-time education that is independent of access to a formal caregiver is a fundamental requirement. Education is critical to the framework as there is increasing evidence that adequate self-care is related to improved diabetes outcomes (Quinn, Gruber-Baldini, et al., 2008). Creating a population of patients that are effective in self-management is challenging. As many as 80% of patients have limited health literacy skills, meaning they have trouble understanding complex health information (Hung, Conrad, Hon, Chen, Franklin, & Tang, 2013).

There have been several studies that mobile health interventions can improve health literacy and ultimately self-management. Quinn and Gruber-Baldini, et al. (2008) found that education and feedback to patients and reminders about guidelines had a clinically significant

impact on patient outcomes. Improvement in core behavior changes, such as diet and physical activity, has also been positively impacted through remote mHealth support (Spring, et al., 2012).

Facilitating Diabetes health literacy is particularly complex. The management of diabetes is multi-faceted and includes dietary intake, blood glucose monitoring, insulin injections and obesity management. These tasks are not just complex, but also must be completed several times each day (Wang, et al., 2014). To manage these tasks, diabetics require instant access to a vast amount of information concerning all aspects of their lifestyle. In addition to general education, adolescents with diabetes also often require decision support to effectively aid in glycemic control (Clauson, Kedar, & Douglass-Bonner, 2012). An on-demand mobile health application is ideally suited to empower patients with diabetes to manage their conditions (Pulman, Taylor, Galvin, & Masding, 2013).

With the changing landscape of healthcare shifting to value-based reimbursement and the need to curb healthcare costs, there is a need for disruptive innovation. The introduction of new technologies, products, and services that make care more convenient, accessible, and affordable will facilitate this shift (Williams, 2012). Mobile health applications, or mHealth, are one sign that disruptive innovation is taking place. This is further supported by policy makers that continue to emphasize the importance of healthcare technology in the management of long-term conditions, such as diabetes (Palmier-Claus, et al., 2013). A 2011 World Health Organization study found that 83% of member countries have at least one mHealth initiative. This illustrates that health care and political leaders recognize the potential of mHealth in changing the health care delivery system (Wang, et al., 2014).

Health consumer usage intentions

To assess the potential benefits for mHealth, it is important to understand the available population of users that will take advantage of the technology. Smart phones have many features that make them good candidates for the delivery of behavior interventions such as portability, they are highly valued by individuals, and provide a more convenient and less invasive manner of accessing and sharing health information (Dennison, Morrison, Conqay, & Yardley, 2013). The current literature suggests that mobile technology use is extensive across all demographics. Nearly 83% of people have a mobile phone (Chen, et al., 2012). Cell phone ownership is high among adolescents as well with 78% owning a phone (Markowitz, et al., 2014). Children are getting cell phones earlier as well with a majority receiving their first cell phone at the age of nine or ten (Pulman, Taylor, Galvin, & Masding, 2013). It is predicted that by the year 2020 there will be 50 billion mobile phone owners (Beratarrechea, Willner, Ciapponi, & Rubinstein, 2014). Morrisey (2013) has shown that while not everyone has a computer at home, even those patients on the lowest end of the socioeconomic sale have a cell phone. Accessibility to information at all times is not limited either with nearly 90% of the world's population has wireless coverage (Larkin, 2011). The vast number of mobile technology users makes mHealth an ideal tactic to reach large groups of patients.

Research has shown that vast numbers of mobile technology users are leveraging their phones to access health information. Over one-third of Americans have used their cell phones to access health information and 12% of users have installed at least one health application (Tate, et al., 2013). WebMD reports that nearly 60 million users access their content per month (Hung, Conrad, Hon, Chen, Franklin, & Tang, 2013). These utilization statistics demonstrate that health consumers are already engaging in mHealth.

This electronic health information utilization rate is high among patients with chronic disease and minorities as well. One study found that 86% of patients with chronic illness use online information to gather information about health topics. These users are much more likely to use technology platforms such as social media and discussion forums to obtain health information (Hung, et al. 2013). Using mobile technology to access health information is even higher in minority Americans. This is a promising trend, as minorities tend to have higher incidence of childhood chronic illness, like asthma (Mitchell, Godoy, Shabazz, & Horn, 2014). While use statistics demonstrate growing reliance on mHealth applications, several studies have been conducted to survey patients' perceptions on using mHealth. Pfaeffli et al. (2012) found that 85% of surveyed patients with chronic illnesses would use an mHealth app related to their condition. Narray (2012) conducted a focus group to review a diabetes self-management application and 72% said the technology would be highly useful in improving self-care techniques. Health consumers want easy access to health education and the effective provision of that education will improve mHealth utilization. Nollen et al. (2013) increased the use of their app by over 31% by adding an education component to the features.

Health consumers and providers are not just looking to utilize mobile technology for education; they are looking at the mHealth as a viable method for addressing health provider shortages and access to care limitations. Rai, Chen, Pye, and Baird (2013) conducted an online survey to gather information about patients' intentions on mHealth usage. They found the following:

- 37.9% of participants stated they have started using some type of mHealth initiative.
- 66.6% would favor using mHealth to supplement in person physician visits.
- 47% indicated they would actually prefer mHealth to a face to face physician visit.

This survey demonstrates that mHealth is a viable option for providing care in a remote, non-resource intensive setting.

The reliance on mobile information technology for health sources will only increase. It is estimated that by 2018, there will be 1.7 billion users of mHealth applications (Miller, Cafazzo, & Seto, 2014). Therefore, creating reputable and reliable mHealth platforms is even more important. As patients seek and make decision based on the information provided in the nearly 17,000 health applications currently in the market place, providers will need to take an active role in creating effective mobile applications (Larkinm 2011).

mHealth benefits and challenges.

Results from mHealth interventions are far ranging. These include reduced morbidity, mortality, hospitalization rates, improved patient-provider satisfaction and most importantly better clinical outcomes. In fact, 75% of studies reviewed in one systematic review showed improved clinical outcomes (Beratarrechea, Willner, Ciapponi, & Rubenstein, 2014).

Tate et al. (2013) conducted a literature review to summarize study results that demonstrate the multiple benefits of mHealth over traditional education and patient engagement techniques these include: lower participant burden, more cost effective, real time data collection and feedback, flexible program tailoring, and adaptive interventions. Tate et al. (2013) further point out that content on a mobile platform is instantly available that facilitates real time decision support.

Several health systems have already taken action to initiate mHealth tactics as part of their population health management strategy to improve biometric measures. The University of Chicago implemented a mHealth application that reduced blood glucose values by 1.9% (Morrissey, 2013). Hampton (2012) reviewed mHealth clinical trials and found that mHealth interventions have successfully lowers participants' blood pressure and glucose, two key

biometric measures that are critical to controlling diabetes complications. UPMC has further reduced unnecessary physician revisits by using a mobile app to support diabetes care concepts (Williams, 2012).

The primary clinical outcome monitored in diabetic patients is the HbA1C (Blackman, et al., 2013). Several studies have shown that an mHealth intervention can be effective in reducing HbA1C levels. Kim et al. (2014) conducted an observation study using a smartphone for decision support regarding blood glucose levels that achieved a decrease from 7.7 to 7.3 in HbA1C as compared to the control group. Similar results were achieved by Dick, Chou, Nocon, Chin, and Peek (2014) using mHealth. They were able to demonstrate a .7 decrease in HbA1C. Finally, Bell, Fonda, Walker, Schmidt, and Vigersky (2012) showed that video messages relating diabetes self-care delivered on a mobile platform resulted in a decline of .2% in HbA1c levels.

Behavior modification is critical to reducing the incidence and complications of chronic diseases. The literature review supports that mHealth can be beneficial in this area. Cotter, Durant, Agne, and Cherrington (2014) conducted a systematic review of diabetic mHealth interventions and found that there were documented improvements in lifestyle modification and disease management and improved glycemic control and ultimately diabetes related complications were reduced. They also showed that in addition to improved health behaviors, mHealth was effective for improving diabetes knowledge. One intervention group showed a 36.7 point increase in diabetes related knowledge (Cotter, Durant, Agne, & Cherrington, 2014). Similarly, Bacigalupo, Cudd, Littlewood, Bissell, Hawley, and Woods (2012) reviewed 21 randomized controlled trials and found that mHealth is successful in modifying patient behaviors. However, it was noted that none of the studies continued to review long term utilization to determine if behavior changes were sustained. This points to the need for

continued application usage reviews to determine if patients will engage in an mHealth application over an extended period of time.

Several studies reviewed demonstrate that mHealth is uniquely positioned to create results in behavior modification in underserved populations. Diabetes is one epidemic that disproportionately affects minorities and the underserved. This group often lacks access to primary care and overuses the emergency room. Aurora, Peters, Agy, and Menchine (2012) conducted an observation study in which diabetic patients were provided an mHealth program with the goal of encouraging healthy eating and improving self-efficacy. The intervention group showed a 26.5% improvement in health eating, a 30.5% increase in physical activity, and self-efficacy scores improved by 7% (Aurora, et al., 2012). In a review of utilization patterns for a diabetes self-management mHealth application, attrition was unrelated to sociodemographic characteristics, which suggests that vulnerable patients will use mHealth (Aikens, Zivin, Trivedi, & Piette, 2014).

To realize the reduction in diabetes related complications that result from behavior modification, it is important that patients are compliant with self-monitoring tactics. mHealth has been proven more effective than paper self-monitoring techniques. Thomas and Wing (2013) showed that adherence to a self-monitoring protocol was 91% for the mHealth group versus 55% for traditional paper protocols.

There is growing evidence that mHealth can be a viable tool to reduce the excessive health service utilization patterns of patients with chronic disease. mHealth can overcome issues related to limited clinical time and poor patient adherence (Poole, 2013). mHealth limits the use of highly paid clinicians by allowing for remote patient monitoring and automated decision support (Morrissey, 2013). For example, WellDoc, a diabetes management application, showed

a 20% reduction in emergency room visits (Chen, et al., 2012). Christus Health implemented a smart phone based disease management program that allowed patient monitoring by mid-level clinicians. Christus leadership went on to state that they felt leveraging mHealth would not only reduce clinician cost, but simultaneously improve clinical outcomes (Morrissey, 2013). Dick et al. (2014) demonstrated a net cost savings of 8.8% through an mHealth intervention, which proved mHealth's potential to reduce healthcare costs across the spectrum of care. In fact, mHealth is likely more effective than even other telehealth interventions. In a systematic review conducted by Baron, McBain, and Newman (2012), they found that multiple studies showed mHealth created better clinical outcomes at a lower cost than traditional telehealth methods.

Researchers have stated that mHealth will fundamentally change the role of the hospital and office visits allowing a reduction in resource consumption. Patients will have access to their own data and create a shift away from the doctor dominated world of medicine to one of symmetry between physicians and patients (Hayes, Markus, Leslie, & Topol, 2014). This creates a patient population that feels better prepared for clinical encounters, asks more relevant questions, and is more likely to improve their health (Hung, et al., 2013).

mHealth has the potential to increase access to health care, enhance the efficiency of health care services, improve diagnosis of diseases, and support public health programs. The research further indicates that mHealth can provide significant benefit in supporting self-management of long term illness (de Jongh, et al., 2012). There are significant gaps in the information though regarding the long term acceptability and usage of mHealth applications.

Continued and sustained use of mHealth emerged as a common challenge in much of the literature reviewed. Cotter, Durant, Agne, and Cherrington (2014) were successful at improving diet and physical activity, but also noted that application utilization consistently declined over

time and further research was indicated in utilization patterns and engagement over time. Tate et al. (2013) reviewed mHealth approaches and acknowledged that two great impediments were long term maintenance of utilization and the ability of the application to hold the interest of children. Just as adherence to needed health behaviors for diabetes management is a struggle, adherence to mHealth poses similar challenges.

Most studies describe the effectiveness in changing the primary outcome of HbA1C, blood glucose monitoring, and self-management tactics during the controlled intervention period. However, very few studies address the actual mHealth reach beyond the control group, implementation tactics, and sustainable use (Blackman, et al., (2013). Although mobile technology is within just about anyone's reach, attrition is a significant challenge and little research is available about usage behaviors or health related apps (Helander, Kaipainen, Korhonen, & Wansink, 2014).

mHealth – Implications for Effective Design

While ownership of mobile devices is high, that alone is not an indicator of actual usage patterns or behaviors (Tate, et al. 2013). About 25% of all app downloads are used only once. An intelligent design that facilitates sustained use to recognize the full benefits of mHealth is needed. Poor usability is a primary cause for failed adoption of health technologies (Price, et al., 2014). This is evident as several studies showed decreasing usage of mHealth overtime which stemmed from a disconnect between design concepts and reality (Tatara, Arsand, Skrovseth, & Hartvigsen, 2013).

Prior research has shown that patients will not engage in a technology that is difficult to use or perceived as irrelevant to their needs. An ineffective application can actually increase costs and negatively impact patient outcomes as compared to no app at all. A patient who has a

bad experience with an app is less likely to seek further treatment in general (Price, et al., 2014). One study showed an actual negative impact on blood glucose from a group of dissatisfied mHealth users as compared to a control group (Kim, Choi, Baek, Yang, Choi, & Yoon, 2014). To address these concerns an app must consider the appeal of usability and familiarity, integration into domestic routines, and perceived impact on care (Palmier-Claus, et al., 2013). Failure to incorporate a design that considers usability and perceived benefit may be the cause for higher attrition rates in mHealth studies (Dyer, Kansagara, McInnes, Freeman, & Woods, 2012).

mHealth designs have to be based on principles proven to be accepted by patients. Using intuition is insufficient to ensure usable or useful information systems (Poole, 2013). A majority of mHealth applications are created by technology firms. Each small developer includes multiple features to show development skill, but with no clear guiding principle about what patients find beneficial (Tomlinson, Rotheram-Borus, & Swartz, 2012). Even the current research is not geared towards defining optimal mHealth interventions. Current studies are largely focused on if having an mHealth application is better than no application (Tomlinson, et al., 2012).

The enthusiasm for mHealth and consumers appetite for alternative health resources is creating an explosion of mobile health applications. However, these initiatives often fail to incorporate evidence based practices about changing behavior (Levin, 2014). Findings from multiple studies show that there is a general lack of awareness of the literature among developers (Sama, Eapen, Weinfurt, Shah, & Schulman, 2014). There remains a lack of research on utilization on core app features, specifically on young adults, which is unfortunate as this group

represents the best potential for mHealth adopters (Dennison, Morrison, Conway, & Yardley, 2013).

Delone and McLean Framework

The purpose of this research project is to evaluate what feature categories of mHealth applications are demonstrated to have sustained use for pediatric diabetic patients, with sustained use being defined as six months. It is clear from the literature review that while the potential of mHealth is apparent, health care providers and application developers struggle to engage patients in mHealth for a prolonged period of time. Failure to sustain use will ultimately decrease the impact mHealth will have on healthcare. To adequately identify categories of mHealth features, functionality of an application will be classified into information and system categories using the Delone and McLean Information Success Model. According to this model, an application must contain elements of a certain quality in these categories in order to promote intention to use the application, user satisfaction, and ultimately the desired net benefits (Delone & McLean, 2003).

Information features are defined as those that passively deliver content to the end user. For example, a glossary of terms would be an information element. System features are defined as application characteristics that facilitate active delivery of decision support. An example of a system feature may be a dietary log in which a patient enters caloric intake to track eating behaviors or the delivery of behavior modification guidance based on the log entries. A system feature requires the end user to actively pull or provide content through an interactive design element versus the passive push of content through an information feature.

If information systems are to make a meaningful contribution a well-defined outcome measurement system is used. Researches have used different aspects of success, which makes comparison of systems success difficult (Delone & McLean, 1992). The multi-dimensional and

interdependent nature of information systems success requires the thoughtful design information and system design principles. mHealth developers should use the information and system quality framework to create an application that drives use and user satisfaction to ultimately create a net benefit at the individual and organizational level.

Summary

The literature review shows that mHealth has been proven to improve diabetic clinical outcomes such as HbA1C, weight, and blood pressure. mHealth also has the ability to improve self-management that allows diabetics to quickly identify and react to symptoms and make better decisions regarding their care. However, with over 500 pilot studies, there is still little known about the best design strategies to create the most effective application (Tomlinson, Rotheram-Borus, Swartz, & Tsai, 2012). In particular, few studies have been conducted to assess the usability of mobile apps with adolescent patients (O'Malley, Dowdall, Buris, Perry, & Curran, 2014). This study will serve to provide that needed information on effective application attributes to promote sustained use of mHealth. Evidence based research on design principles is an area that is clearly lacking in the current literature.

There is much hope being placed on mHealth. Mobile communications are part of our everyday life and have the potential to transform our healthcare (Ray, 2010). Secretary Sebelius of the U.S. Department of Health and Human Services referred to mHealth as the biggest technology breakthrough of our time and its use will address the national health care challenge (Steinbuhl, Muse, & Topol, 2013). To realize this potential, program development will have to be focused on creating effective and efficient applications that are based on a technology acceptance model that reviews utilization patterns to qualify intention to use and perceived

usefulness of features to create proven design principles that serve as a foundation for future mHealth interventions.

Methods

Introduction

Chapter three contains a description of the methodology used to conduct a case study to classify core mHealth application functionality and review utilization of those features over a six month time period. Specifically, the purpose of this research study is to determine what features will facilitate sustained use to realize the maximum benefit of mHealth technologies. The major components of this chapter include the assumptions and rationale for a case study, the feature classification framework, the procedure for confirmation by subject matter experts of the classification schema, the process for collection and analyzing data, and finally the known limitations of the study.

Research Design

A qualitative research design is selected to conduct the case study of mHealth design review. Qualitative research is defined as an inquiry process that explores a social or human problem (Creswell, 1998). Qualitative research seeks to answer the "what" and "how" questions. A "what" question may be focused on answering a program question and the "how" question looks at the effects the effects of the study on stakeholders (Hatch, 2002).

A case study approach is selected based on its appropriateness for this particular study. According to Yin (2009), a case study is qualitative work that investigates a phenomenon within a specific boundary. Merriam (1988) presented examples of bounded phenomenon to be a program, event, person, process, or institution. In the case of this study, the boundary evaluation is the mHealth program. Creswell (1998) goes on to define case study characteristics to include examining a particular subject bounded in time, gathering extensive materials from multiple

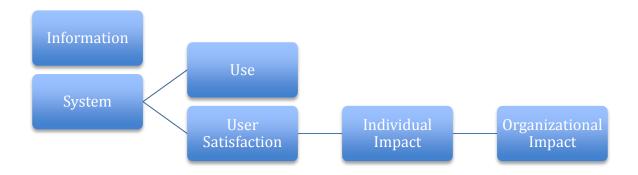
sources to provide a detailed picture of the case, and using the researcher as an instrument of data collection.

The case study is the preferred methodology in examining contemporary events but when the relevant behaviors cannot be manipulated (Yin, 2009). mHealth is one of the most current topics in healthcare, therefore the case study is ideally suited for researching this field. The research question in this study is what types of mHealth application functionality promote sustained use by pediatric diabetic patients? In summary, the researcher's selection of a case study provides the best method to study the research question in review and mHealth functionality and utilization in general. First, the program to be studied is a bounded system in the form of an mHealth application. Second, a case study approach allows for the researcher to serve as a data collection instrument when collecting input on the classification of application features. Third, the classification of the application features provides significant descriptive detail on the program. Finally, the results are presented in a manner that will benefit all mHealth stakeholders.

Classification Framework

First, the current functionality of the mHealth application will be classified by the researcher into information and system categories using the Delone and McLean Information Success Model. According to this model, there is a direct relationship between information and system quality on use and user satisfaction. The elements of use and user satisfaction in turn directly impact the individual impact of an information system. Finally, individual impact will drive the overall impact of the system at the organizational level (Delone & McLean, 1992). Figure 1 details the model and the correlating relationships.

Figure 1 – Delone and McLean Information System Success Model



By review of information and system functionality and then utilization of those features, a more effective design plan for mHealth applications can be created as developers will have evidence based guidance on what features are used more frequently and for longer periods of time.

Information features are defined as those that passively deliver content to the end user.

System features are defined as application characteristics that facilitate active delivery of decision support. A system feature requires the end user to actively pull or provide content through an interactive design element versus the passive push of content through an information feature.

Feature categorization

The researcher will complete an inventory of core application features. First, the development list of functionality will be obtained from the application creator. This list was created for user accepted testing and therefore is comprehensive for each feature. The inventory process will consist of a page by page review for each functionality in the development catalog

in the actual application to include how feature is accessed, data entry process, and display of results if indicated. Each feature reviewed will be documented using a standardized naming system.

The naming system will use common information system nomenclature to make the categories generalizable to other mHealth applications. This categorization will be the system that will later be confirmed through the triangulation process with the subject matter expert interviews. Categories of content utilized will be based on core functionality. Core functionality is defined as those features that deliver the key value proposition of an application and in which all other features can be rolled up into. Examples of core functionality categories to be used include:

- Medical Content this is general health education that is displayed in a narrative form.
- Glossary this is a narrative table that provides definitions for key medical terms.
- Journals the journal is any electronic logging system that allows end users to document health behaviors.
- Quizzes exams that test medical knowledge.
- Decision Support content that is aimed at assisting an end-user with making a health related decision based on specific symptoms or events.

The goal of a qualitative study is to provide high quality data that is accurate. Credible research requires the researcher to remain objective. The researcher will enhance validity to this study through triangulation. Triangulation involves using multiple sources in an investigation to produce understanding. Qualitative researchers use this technique to ensure the protocol is well developed (Creswell, 1998). In the case of this study, subject matter experts are used to confirm the researcher's system for classifying and naming application features, thus reducing bias.

Once the inventory of features is completed, to provide the triangulation of the classification, subject matter experts that are also key stakeholders in mHealth will then confirm the system. The experts need to represent the technology and the clinical side of mHealth. Therefore, clinicians that can speak to effective health education elements will be used to represent the medical aspect of mHealth. Application developers and information technology leaders will be interviewed, as they are experts in information system design principles. Their expertise will allow for the technology aspect of mHealth to be considered in addition to the clinical side.

The first expert will be the lead developer for the application under review. This expert will be selected because he has the most expertise in the original intent of the application features. The second expert will be a general healthcare developer. This expert has developed multiple applications that span the healthcare operations spectrum from patient management to revenue cycle and thus can speak to the applicability of the categories in a more generalized view of health applications. The two clinical experts will be physicians. The first physician is a pediatrician that specializes in the treatment of diabetics. Not only is this physician a subject matter expert in the knowledge base of pediatric diabetes, he has also developed mHealth platforms for diabetic patients and conducted research in the field of telemedicine effects in pediatric diabetics. This blend of clinical and technical knowledge makes him an ideal candidate for the triangulation process. Finally, the last expert is an obstetrics physician. This physician will be selected as she is acutely aware of the importance of patient education on the care process through her work in pre-natal care. She has been a significant contributor in providing content and user experience guidance for a similar application. Furthermore, she is on the information technology significant interest group for a large integrated delivery network and is responsible

for driving patient and physician technology initiatives providing her with a broad view of how technology facilitates population health management strategies.

The researcher will review the classification system with the subject matter experts identified above. Table 1 is a prototype that will be used to facilitate the discussion and gain insight into the agreement and disagreement with the classification system used by the researcher. This prototype will be updated as the inventory of feature is completed. Subject matter experts will be asked if they agree or disagree with first the researcher's category schema of information and second the specific classification of core application functionality into those categories.

Table 1 – Classification schema

Feature Medical Content	Description Health education that is displayed in a narrative form.	Researcher Classification Information
Nutrition Dictionary	Library for look up by food item that provides key nutrition facts such as carb count.	Information
Quizzes	Exams that test medical knowledge of the end user.	System
Journals	Electronic logging system that allows end users to document health behaviors.	System
Decision Support	Content that is aimed at assisting an end- user with making a health related decision based on specific symptoms or events.	System

Gathering the subject matter experts' insight into the classification schema is important as it creates validity of the schema to be generalized across mobile health applications. In order to create that validity, it is critical that experts have the needed knowledge to advise on the

categories described above. To facilitate the discussion, the experts will first be given an introduction into the Delone and McLean model, then an explanation on how the categories relate to the model, and finally a crosswalk on how the application features were categorized into the schema.

There is clearly the possibility that an expert may disagree with the preliminary classification of features. Should this occur, the first action will be to note the source of the disagreement. Secondly, the panel of five experts allow for a majority consensus of the classification. Should the panel majority disagree with the researcher; the majority judgment will be used in the final research.

Data Set Description

The mHealth application in review has the ability to track utilization across all features of the application. As an end user accesses the application, each click is tracked and stored in a data warehouse. Specific data available since the application's inception in March 2014 include:

- Number of patients invited to use the application
- Number of patients that have activated application
- Number of content views in total and by content area
- Number of journal entries completed

Each of these data sets is accessible at the application start and day-by-day to allow for a complete time interval review. All data is stored in a HIPAA compliant database that has personally identifiable health information, such as name, date of birth, etc. is blinded from the reviewer. Users are assigned an enrollment number that allows for utilization review at the patient level, but removing the ability to identify the users. The researcher has requested and

been granted access to all de-identified data in database through an agreement with the application developer.

Data Analysis

The challenge in data analysis is to organize massive amounts of data into meaningful themes and create a logical conclusion through the analysis of those patterns (Hatch, 2002). In this case study, the researcher collected data from personal interviews and from a data set of application utilization statistics.

The classification schema review will be conducted via telephone with the designated expert. The researcher will use the standard rubric as defined in Table 1 to facilitate the discussion. The completed rubrics will be saved in a secure folder location. The total rating for each feature as information or system will be tallied for a majority total of the experts' review. Each feature will then be reviewed for discrepancies between the researcher's and the experts' classification. When there is a discrepancy, the researcher will update the feature classification to be in alignment with the experts' opinion.

Once the features are classified, the researcher will then conduct a review of utilization statistics of those specific application features to determine optimal design for mobile health applications to answer the research question of what types of mHealth application functionality promote sustained use by pediatric diabetic patients. Statistics will be obtained at the start of the application, the one-month, three month, and six-month time intervals to answer the following subsequent research questions.

- What percentage of invited patients that actually initiate the application?
- The number of times the following features are accessed at the prescribed time intervals:

- Medical Content
- o Journal
- Quizzes
- Decision Support
- What differences in utilization patterns exist based on age of user?

The data is provided in the form of Microsoft Excel downloads to allow for the data to be categorized above with the various utilization statistics available at the feature line item level. The data is system generated and directly uploaded to the database. The database itself has controlled access with the data presented in read only format, so manipulation of the values cannot occur. To further ensure that the data is accurate, final data summaries will be presented to the primary database architect to confirm that the data used matches that available in the database master tables. These controls increase the reliability of the study by maintaining the chain of evidence (Yin, 2009).

The final piece of data analysis is reporting of results. This is the packaging of what was discovered in a text, tabular, or figure form (Creswell, 1998). Creswell (1998) further points out that there is no standard format for case study research, however results must be presented accurately in a format that educates the reader. The researcher will present results in the following segments:

- Results around the discussion of the use of Delone and McLean model for mHealth feature classification from the triangulation process.
- Results of the discussion of the specific category classification confirmation interviews from the triangulation process.

- Results on the utilization of each category of functionality at the indicated time intervals of one, three and six months.
- Results around functionality utilization themes.

Results will be presented in a combination of narrative and table format. The narrative format will be used to provide detailed descriptions of the utilization patterns for the mHealth application. The narrative will be supported by tables to clearly outline actual statistics on the core features for efficient cross-reference.

Through the review of the results, it is anticipated that additional discussion will incur about further implications the identified statistics and themes may have. This discussion will be noted and detailed for further research needs.

Limitations

The case study has a number of inherent limitations. The first is that case studies lack rigor in the research methodology (Yin, 2009). This concern is addressed by having systematic procedures such as triangulation and unbiased data sources. A second common concern is that case study results are not generalizable to a greater population (Yin, 2009). However, the results are generalizable to a theoretical proposition, which is the desired result of this research. The researcher is looking to create a general theoretical framework for mHealth development that supports sustained use. A third complaint is that case studies are cumbersome and often produce reports that are not easily understood (Yin, 2009). Again, through a systematic multi-methods approach to reporting the data as detailed above, the results of this study will be presented in a manner that is summarized for rapid consumption and application. Finally, some researchers feel that case studies lack a causal relationship (Yin, 2009). While it is true that the case study will prevent a direct link between cause and effect, in this case mHealth and health outcomes,

there is benefit in reviewing how patients utilize mHealth applications, which as shown by the Delone and McLean (1992) model, will ultimately impact individual outcomes.

There are three specific limitations of this study. The first is that results are limited to one application reviewed for a small patient population of pediatric diabetic patients in central Ohio. This can limit the generalizability to all mHealth applications and all patient populations. Secondly, several of the subject matter experts in the technology field had direct involvement in the design of application under review. This may bias their opinion of classification of features. However, with the multiple experts reviewing the application will mitigate this bias.

A direct measure of user satisfaction will not be reviewed as part of this study. Delone and McLean (2003) indicate that the efficacy of information and system functionality ultimately drive use and user satisfaction. Therefore, for the purpose of this study, those categories will be reviewed as drivers of user satisfaction, but a direct measure will not be obtained.

Finally, the researcher's own bias is a limitation. Through the researcher's work and interest in mHealth, there are preconceived thoughts about mHealth functionality and how those features should be presented. The use of a standard information technology model, in this case the Delone and McLean IS model, and triangulation of both the classification schema and the actual categorization results by subject matter experts will help mitigate this bias.

Summary

This chapter provided an overview of the research methodology utilized. The researcher presented the rationale for selecting a case study approach and the Delone and McLean information success model. Application features were classified into core functionality with classifications confirmed through personal interviews with clinical and technical subject matter experts. Next, application feature utilization was reviewed to determine how frequently and over

what time period certain functions are used. Utilization data was categorized and trended over the review period. Finally, results will be presented in a narrative form with supporting tables for key statistics.

Results

Review of Methods

A case study approach was completed for this study. The case evaluated is mHealth utilization in a mobile application created for the education and engagement of pediatric diabetic patients. For the purpose of this study, a pediatric patient is defined by the America Academy of Pediatrics standards as a patient aged from birth to 21 years old. Using this same framework, patients aged six to eleven are classified into the age group of middle childhood and patients aged 12 to 18 are classified as early adolescence (Williams et al., 2012).

Feature categorization

The application that was the subject of this case study was first inventoried to identify all core features for utilization by patients following the process detailed in the Methods section of this paper. The final list of features for utilization review along with the updated definition is provided below.

- Medical Content: This is all content in the application that provides health education in a
 narrative form. This included written and graphic information on disease management
 techniques and a glossary of medical terms.
- Nutrition Dictionary: This is a library that contains the nutritional facts such as calories and carbohydrate count for food.
- Health Quizzes: These are exams that allow the end user to interact with the application and test their knowledge on key diabetes management elements.

- Journaling: This is an interactive system that allows the end user to log their blood glucose, insulin levels, and food intake with the goal being to provide long term tracking of behaviors and visibility for providers into disease management behaviors.
- Nutrition Log: This log is similar in functionality to journaling. However, the key
 difference is that end users specifically log nutrition choices and allows the patient to rate
 the quality of their diet choices.
- Sick Day Protocol: This is interactive content that allows the end user to input their current condition. The application then provides direction on the next indicated intervention.

The functionality listed above was then classified as an information or system category per the Delone and McLean Information System Model. An information category was defined as one that passively delivers content to an application user. In contrast, a system category is one that facilitates actively delivery of content and requires the user to interact with the application to receive content. The final classification is presented in Table 2.

Table 2: Final Feature Classification

Feature	Researcher Classification	
Medical Content	Information	
Nutrition Dictionary	Information	
Health Quizzes	System	
Journaling	System	
Nutrition Log	System	
Sick Day Protocol	System	

Subject matter expert triangulation

Through the methods research, it was recognized that to provide validity to the case study, the feature classification schema and results would need to be validated through a triangulation process. This was accomplished by engaging subject matter experts to review the

use of the Delone and McLean Information System model as the classification framework and then validate the feature classification. The guiding document for the discussion can be found in Appendix B.

First, an introduction to the Delone and McLean Information System Model was provided. The application of the information and system categories from the model and the application to mHealth features were then discussed with each expert. The expert was asked to provide commentary if the selected model was in deed applicable to the case study and provided the appropriate framework for the classification schema. Next, the inventory of core features was reviewed with supporting screen shots of the functionality. Finally, each expert was asked to provide feedback on if they agree or disagree with how the feature was classified into the information and system categories.

The first subject matter expert discussion conducted is a pediatric endocrinologist that has also developed mHealth applications for use with pediatric diabetic patients. The discussion with expert 1 was conducted via telephone. Expert 1 indicated that the Delone and McLean framework was applicable to the case study. He also commented that the framework could be a good foundation for evaluating other mHealth applications as well. Expert 1 agreed that each feature in Table 2 was classified correctly in his opinion. He did go on to state that the journal features should be described as "journaling" versus simply "journals" as that would reduce any potential misinterpretation in the medical community regarding a research journal and the physical act of a patient logging information. This change was subsequently made to the feature classification descriptions and used for further expert reviews.

The second expert consulted is an obstetrics and gynecology physician actively practicing in Central Ohio. In addition to her active medical practice, she has served as a key contributor

for mHealth applications and other information technology initiatives for a health system. Expert 2 also confirmed the selected framework for information and system categories was directly applicable. She went on to validate that the classification of each core feature was correct per Table 2.

Expert 3 is a mobile application developer that was one of the chief developers on the team that created the application under review for this study. Given his expertise and direct contribution to the application, his opinions on the framework and subsequent classification were highly valued. Expert 3 was actually familiar with the Delone and McLean Information System model and had studied this in the application of other information technology frameworks. He agreed that the application to mHealth features and specifically this case study was highly appropriate. Approximately one hour was spent reviewing the feature classifications into the information and system categories alone. There was significant discussion around the core intent of the feature from the developers' perspective and how it was defined as an information or system function. Through this discussion, Mr. Lafyatis agreed that the intent of the feature was accurately captured by the description used as detailed above and then finally that the categories were correctly assigned as provided in Table 2.

The final expert conferred in the triangulation process is a healthcare information technology (HIT) consultant that has developed a wide range of applications from clinical to financial to mobile systems. He has a broad exposure to many aspects of HIT and is well positioned to assess the framework not just within the context of mHealth but as it applies to HIT principles as a whole. Following the guiding presentation, the first portion of the discussion was focused around the framework selected and the applicability to the case study. Expert 4 agreed that Delone and McLean was indeed a proper choice for this study. Next, the feature

classification results were discussed. Expert 4 agreed with the information and system classification for medical content, nutrition dictionary, health quizzes, journaling, and the nutrition log. When the sick day protocol was discussed, Expert 4 questioned rather the results or intervention directions provided was hard coded in the system or specific to the user's situation. His initial thought was that if the information is hard coded and does not vary per input, then that would not be a decision support element and may be better described as an information rather than system feature. The researcher then confirmed with the lead application developer that all of the core information is hard coded. However, the result the end user gets is specific to their input and unique values entered. The intervention recommendation is not a set algorithm but dynamic based on user input. With this clarification, expert 4 agreed with all classifications including that the sick day protocol is a system function.

Upon completion of the subject matter reviews, both the applicability of the Delone and McLean framework and the classification of the application features into information and system categories were completed correctly. The only indicated changes were the verbiage change from "journals" to "journaling" per Expert 1's feedback. The completed rubrics for each subject matter expert discussion can be found in Appendix C.

Data set analysis

The utilization data was provided to the researcher in the form of a website that allowed utilization statistics to be reviewed for each of the statistics under study by individual user. Each unique user had a system-generated code assigned to prevent identification of the actual patient.

Once the user was selected in the dashboard the following statistics were available for viewing:

- User age
- User gender

- Number of times and dates each core content area was accessed in the application.
 - Medical content
 - Nutrition dictionary
 - Health quizzes
 - Journaling
 - Nutrition log
 - Sick day protocols

The researcher went through and individually reviewed each user for the utilization statistics above and documented those in a spreadsheet that tracked statistics in the time period of one, three and six months. This was a direct transposition process and no modification of statistics was done.

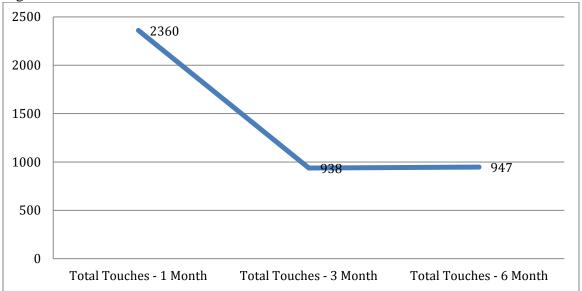
After completion of the raw data spreadsheets, each of the core content areas were classified into the information and system categories as confirmed through the triangulation process. This allowed for a complete and classified data set to be used for the next level of review that included summarization of utilization statistics by content area and framework categories. Further analysis was completed on these statistics by age and gender of the patient. *General User and Utilization Statistics*

The group of users in this study consisted of 137 unique patients. Of those 137 patients, 130 used the application at least one time, leaving seven users with no utilization statistics indicating they never activated the application. The 137 users ranged in age from six to 18 years old. The age groupings were skewed to older users with 90 patients in the early adolescence age group of 12 to 18 and 47 in the middle childhood group of 6 to 11. The genders of the users

were evenly distributed with 73 female, 53.3% of the population, and 64 male patients, representing 46.7% of the population.

There were a total of 4,245 uses recorded during the six-month assessment period. Total uses were highest with in the first month of deployment with 2360 touches, then decreased by 60.3% to only 938 by month three. Overall utilization stabilized somewhat at the six month, actually increasing by 1% over the three-month mark. This trend is demonstrated in Figure 2.

Figure 2: Total uses over time



When aggregate application touches were reviewed by gender, it was discovered that 66.2% of the recorded uses were logged by male patients as compared to 33.8% by female patients recorded uses. Female patients also had the largest decline in total uses decreasing by 94% from month one to month six versus only a 20.5% decline in the same time period for male patients.

Utilization review by age group showed that utilization was similar between the two age groups with 52% of overall touches from the early adolescence group and 48% from the middle childhood group. Figure 3 illustrates that utilization declined over the time frames in a similar fashion between the two groups as well.



Figure 3: Aggregate Utilization by Age Group

Information versus system utilization

For the population studied, 64.4% of application uses were attributed to a system function. The system functions are those that require active interaction from the end user to receive content delivery. For the purpose of this study that includes the features of health quizzes, journaling, nutrition log, and sick day protocol. This is compared to overall utilization of the information category which was 35.6% of total uses.

Both the information and system categories experienced a decline in usage over time. For the information category, use declined by 69.2%, from 930 to 286 uses, from month one to month three. The system category experienced a similar drop in utilization between the first and third month of use of 54.4%. Both categories had a much less decline from the third to six month with the information category declining 3.8% and the system functions 0.31%. Figure 4 shows the relative use and decline of both framework categories.

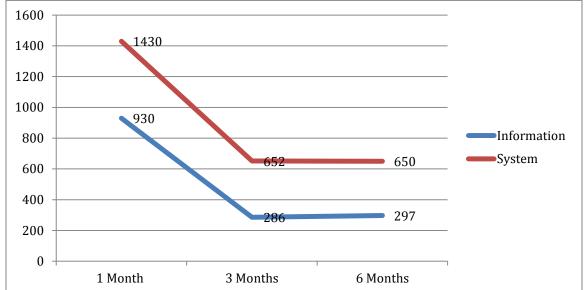


Figure 4: Framework category utilization over time.

Gender differences

Gender differences in utilization patterns were the greatest when assessing the system category. 70.6% of system uses were recorded by male patients versus only 29.4% by female patients. This difference is further noted when looking at the proportion of system specific uses to overall uses with 54.4% of all touches being related to system uses by male patients. This is compared to only 18.9% of uses attributed to female patients accessing system functions. It is also notable with the gender review of information and system utilization that male use of the system functions remained relatively static when compared to female utilization. From month one to month six, male patients only experienced a 14.2% decline in utilization versus a 94.4% decline in female system utilization for the same time period. Figure 5 presents an overview of information and system utilization by gender that further depicts these variances.

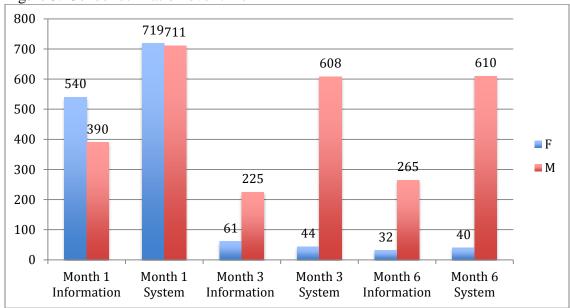
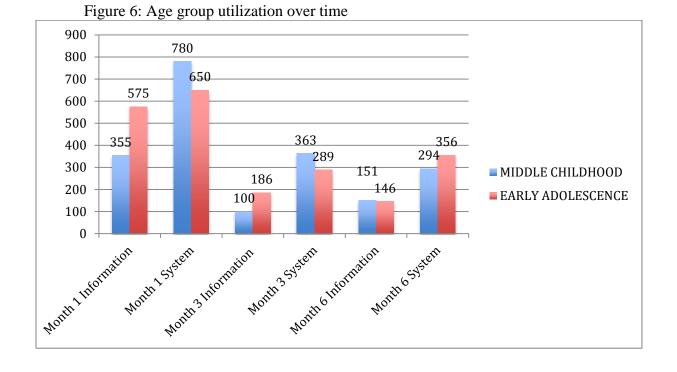


Figure 5: Gender utilization over time

Age group differences

There were clear differences in use for information functions in the early adolescence age group as compared to middle childhood. 59.6% of information uses were recorded by those aged 12 to 18 versus 40.4% for those ages 6 to 11. As noted above, there was a significant decrease overall in the utilization of information features over time. This was more pronounced with the early adolescence group with a 74.6% decrease during the study timeframe as compared to 57.5% decrease in the middle childhood group.

When a review of both the information and system utilization was conducted by age group, there was increased utilization of system over information functions across both age groups. Utilization for system features by the early adolescent and middle childhood groups were 30.5% and 33.9% respectively. This is compared to only 21.4% and 14.3% of total uses spent on an information function for the same respective age groups. Utilization by age group is summarized and presented at the indicated time intervals in Figure 6.



Discussion

Discussion of Results

There are many studies that have shown the promise of mHealth. This is evident by multiple studies cited in the literature review including one by Bacigalupo et al. (2012) that studied 21 randomized controlled trials and found mHealth to be effective in improving clinical outcomes, specifically HbA1C levels, overall successful in the trial outcomes. It is notable though that most of the studies cited through the literature review were focused on push methodologies versus pull meaning that content is actively pushed to a patient through a provider interaction such as text messaging. This methodology does not drive towards the true benefit of mHealth which is the increased autonomy for patients to improve self -management and eventually reduce healthcare resource utilization.

There also remains a gap in the literature about the design elements of a mobile application that create sustained use and ultimately sustained benefit to the individual and the organization. This is critical to recognizing the return on investment for providers and correlating applications developed for these patients. This population represents nearly 15% of the healthcare budget (Mohammadzadeh, Safdari, & Rahimi, 2014). The prevalence of diabetes is expected to increase from 9.3% to 26.5% of the population by 2050 making the care needs of these patients unsustainable with the current resources (Cotter, Durant, Agne, & Cherrington, 2014). The criticality of engaging the diabetic population to drive them to lower cost care environments and improve self-management becomes more apparent when one considers that only 7% of diabetics have continued glycemic control (Quinn, Gruber-Baldini, et al., 2008). To start to review the promise of mHealth as a mechanism to address the issues of the diabetic

population, the purpose of this study is to address what types of mHealth application functionality promotes sustained use for self-management improvement.

The first hurdle in recognizing the benefits of any information system is to first engage users to actually initiate interaction with the application. With this specific study, 94.9% of the population activated the application, which indicates that there is indeed interest with this group on using a mobile application to support their diabetes. This is a promising start as it is estimated that approximately 35.1% of parents felt they did not have enough knowledge about managing their child's diabetes (Pena, Watson, Kvedar, & Grant, 2009). The application is a viable method to address that need as demonstrated by the supporting literature that found that nearly 75% of mHealth interventions improved the selected clinical outcome (Beratarrechea, Willner, Ciapponi, & Rubenstein, 2014). This is also consistent with a study conducted that indicated 72% of polled diabetes patients would use a mobile application as part of their care plan (Narray, 2012).

The largest challenge with mHealth has been in creating sustained use. The results of this study showed that creating strategies to engage users throughout the first few months after the activation of the application is important to creating sustained use. There was a 60.3% decrease in utilization from the first month to the third month of use. However, there was actually a 1% increase in overall use from month three to six. This indicates that if a provider can facilitate patient use patterns early on, application utilization will stabilize. To clear the challenge of progressing from initial implementation to engraining the application use into patients' normal routines, providers should focus on support immediately after the distribution of the application through the first 60 days.

When considering what specific features encourage sustained use, system features, or those that require dynamic interaction from the end user, were used more frequently over time in the pediatric diabetic population studied. 64.4% of total uses were of a system feature versus only 35.6% of total uses attributed to an information feature. Clinical guidelines for diabetic treatment emphasize the importance of education, yet only 18% of available applications have an education component (El-Gayar, et al. 2013). An information feature intent is primarily around education so it is important for providers and developers to consider the best method for presenting this content to end users. Given, the increased utilization and higher continued utilization of system features, future design elements should focus on delivering content through a system feature.

The usage of current system features is promising as one goal of mHealth is to mitigate over utilization of healthcare resources by improving the self-management of patients with chronic disease (Hayes, Markus, Leslie, & Topol, 2014). To achieve this goal, the application must be able to provide real time decision support to patients to allow them to first understand and then take the appropriate intervention. The system features under review for this study were focused primarily on those topics and again, there was a strong engagement in these features.

Upon review of information and system feature sustained use it was noted that the overall use across the time periods showed a similar decline in both categories. This indicates that the engagement tactics used to clear the early adoption challenge could be universally applied to both categories for content.

The results from reviewing the utilization patterns by gender showed some interesting differences between male and female users. Despite having nine more female patients in the study, 66.2% of total uses were recorded by male patients. Male patients also continued use of

the application more so than female patients with only having a 20.5% decline versus 94% decline over the time period reviewed respectively. Greenberg, Sherry, Lachlan, Lucas, and Holmstrom (2010) completed a study that showed that male children played video games at twice the weekly average of females. With the higher utilization of system features across the population, male patients may have better engaged with the application because of their documented propensity for video games and related information technology, such as mobile applications. To developers and providers, the significant difference in use between male and female patients indicates that design features, specifically system features, should be geared towards the gender of the end user to fully engage the patient.

The final area for review was utilization by age group. Similar to gender, both age groups studied preferred system features over information. However, there were differences in the utilization patterns of those categories across the age groups. The early adolescent group started using information features more at the beginning, but then had a significant decrease in information use over time. Whereas the middle childhood group actually increased information use throughout the time period reviewed. A few things of note on these utilization nuances, early access to information for those aged 12 to 18 may indicate that this group is better equipped to understand the importance of the educational materials and more academically inclined to read static content. This is compared to those aged 6 to 11 which may still rely on a parent or caregiver to process the education content for them. As their age and acclimation to the application increases, their ability to process and find value in the information increases as well. As it relates to future design principles, information content may need to be age specific based on the literacy capacity of each age group and change over time to keep engagement in the materials. The need for evolution of the content is supported by the considerable decline in use,

approximately 74%, by the early adolescence group. This is consistent with Tate et al. (2013) concern that keeping the attention of children is a significant challenge in mHealth adoption. Evolution of the current materials and introduction of new materials on a periodic basis can help mitigate this challenge.

As developers and providers consider the need for change in the application, it is important to note that overall use of the application declined in a similar fashion between the two age groups, but was much more pronounced with female versus male patients. This indicates that while content needs to be gender and age specific, gender specific content should also consider the pace at which content should be updated to engage female patients *Conclusions and Implications*

There were several implications of this study for the future design principles of mHealth applications. First, there is a clear interest in using the applications as evident by the high initiation rate of the application under review. The challenge for this and future applications is to encourage ongoing use. Through the utilization review, it became evident that if providers can engage a patient during the initial adoption period, in this study the time period between start and three months, utilization then stabilizes indicating that it becomes part of the patient's routine. The implication of this for stakeholders is that a very concentrated effort around a thoughtful implementation plan for the application is needed. Simply allowing the patient to download the application with no adoption support will not create the desired sustained use and ultimate benefit of the application. In essence, this should be implemented, controlled, and monitored like any care plan element. Frequent evolution of content can further support utilization, specific to the information features.

Across the population, system features were shown to have higher utilization statistics. This indicates that this group of pediatric diabetics is looking for more content that engages them and requires them to interact versus the fixed delivery of content. The higher use of system versus information features was evident across all age and gender groups. In order for mHealth to recognize its full potential and for providers to obtain a reasonable return on investment from this technology, future designs should incorporate more system features. Content that historically has been provided through an information feature, such as a glossary or nutrition dictionary, should be reviewed to see where system or gamification design principles can be applied to shift this content from a static to dynamic delivery model.

One key area that developers need to focus on customizing content is by gender. Male patients are consistently using the mobile application more and have better long term use patterns. While some of this is likely attributable to the trend that males are more likely to use technology like video games than females, there are still design elements that can be undertaken to encourage use for female patients. Both actual content and the methodology for which that content is delivered should be customized based on gender and the specific needs of each group as they progress through adolescence.

The Delone and McLean Information System Model used to categorize mHealth functions were validated by both information technology and clinical experts as a viable framework for mHealth studies. Future application developers should evaluate the use of this model as a guiding tool for design infrastructure so there is a common methodology and nomenclature used across mHealth features that would allow for easier efficacy comparisons for future studies.

While this study has provided significant visibility into the mHealth utilization patterns of pediatric diabetics over a period of time, there several areas in which additional research building on this study could further the knowledge of creating effective mHealth interventions. First, mHealth applications cannot continue to be designed in a vacuum without patient input. Using the Delone and McLean framework, a focus group with patients is needed to gather further insight into how both information and system features can be improved to support increased and continued application use.

The second area in need of additional research is for a time period that exceeds the six months reviewed during the course of this study. As discussed several times throughout this paper, both individual and organizational benefits of mHealth will only be realized when there is sustained use throughout the continuum of care. This period is clearly longer than six months and thus additional research on utilization patterns for a longer duration is indicated to see if usage patterns shift beyond the six month mark.

Finally, the literature review suggested that most of the studies completed to date that show positive clinical outcomes as the result of mHealth interventions were largely focused on using provider pushed text messages. That type of intervention while reduces health system utilization does still require consumption of finite health provider resources. There continues to be a need for research that shows mHealth that is delivered in a manner that does not require direct provider interaction can also have positive clinical outcomes.

Summary

During the literature review, it was revealed that there is significant interest in the use of mHealth to engage patients in their own care and as a primary tactic in population health management strategies. There was a considerable amount of research that demonstrated patients

did have an interest in leveraging mobile technology for health education and care plan management. The literature went on to show that there have been multiple studies actually confirming that mHealth can positively impact clinical outcomes, including HbA1C levels in diabetics.

Despite the wealth of information on the potential of mHealth, there was no definitive research that stated what specific features are used most and that would encourage sustained use of the application. In an effort to answer this research deficit, a case study was completed to evaluate utilization of a pediatric diabetic mobile application over a six month time frame. The research question addressed by this study is what types of mHealth application functionality promotes sustained use for self-management of diabetes?

Given that there is limited industry standard methodologies around mHealth, the first step was to identify a common framework that would allow for standard identification and naming of mobile application functionality. The Delone and McLean Information System model was selected as it provides the infrastructure around common information technology functions that drive use and ultimately translates into individual and organizational benefit. The specific features of the application under review were categorized into the information and system categories. As the application of this framework is new to mHealth, the researcher when through a triangulation process in which experts in both the healthcare and information technology field were asked to confirm the validity of the model selected and the application to the feature classification.

After the classification of application features, utilization of information and system functionality was reviewed at the one, three, and six month intervals. The review demonstrated a significant reduction in use from the one to three month interval, but a stabilization of use

between the three and six month marks. The results further showed a distinct difference in category usage, with more uses focused on system features. With respect to gender differences, there also was a noticeable trend that uses by male patients exceeded uses by females.

The implications of this study are that facilitating early adoption during the first 30 to 60 days of implementation is critical to sustained use. Developers also need to consider modifying content based on gender to improve female acceptance. Finally, having a clear plan around frequent content evolution to hold the attention of end users is required for sustained use. With the execution of these recommendations, mHealth can better fulfill the promise of enhanced patient engagement, reduced healthcare resource utilization, and improved chronic disease management.

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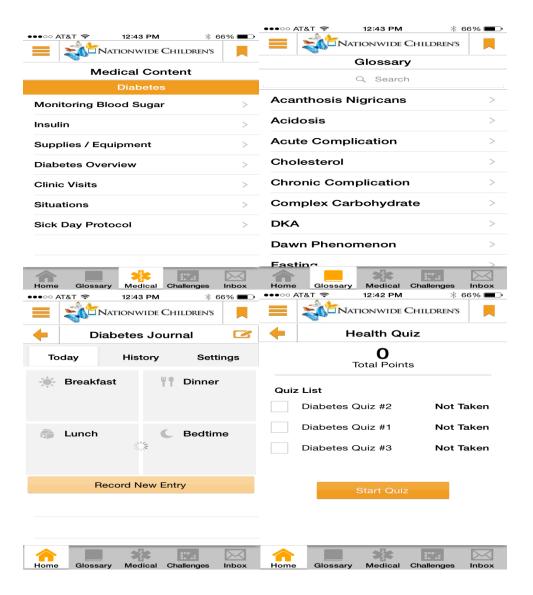
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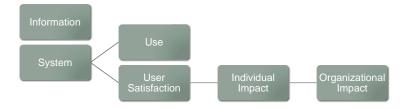
Appendix A – Application Screens



Appendix B: Triangulation Guiding Presentation

MHEALTH FEATURE CLASSIFICATION

Delone and McLean IS Model

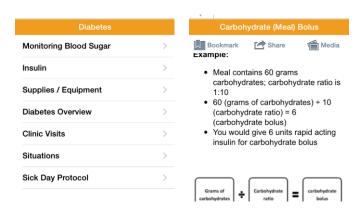


Categories of Features

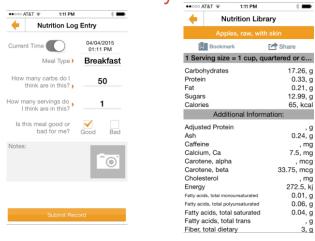
- Information features are defined as those that directly delivers content to the end user.
 - · Passive push of content
- System features are defined as application characteristics that facilitate active delivery of decision support.
 - Requires end user to pull or provide interaction for delivery of content

Feature	Description	Researcher Classification	
Medical	Health education on key disease	Information	
Content	management topics that is displayed in a		
	narrative form.		
Nutrition	Library for look up by food item that	Information	
Dictionary	provides key nutrition facts such as carb		
	count.		
Health Quizzes	Exams that test medical knowledge of the	System	
	end user on key self-management topics.		
Journaling	Electronic logging system of blood glucose	System	
	levels and insulin intake to provide		
	feedback to providers and long term		
	tracking of behaviors.		
Nutrition Log	Electronic logging of eating behaviors with	System	
	tracking of quality of choices.		
Decision	Content that is aimed at assisting an end-	System	
Support / Sick	user with making a health related decision		
Day Protocol	based on specific symptoms or events		
-	without the intervention of a provider.		

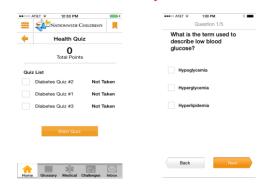
Medical Content - Information

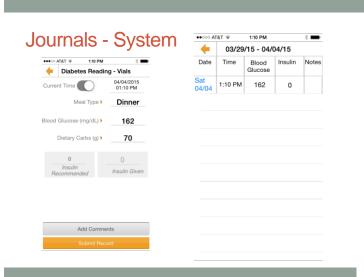


Nutrition Dictionary — Information

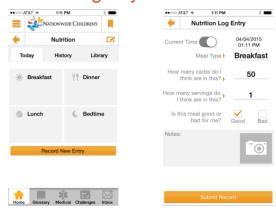


Health Quizzes - System

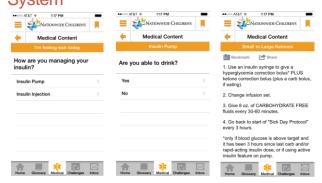




Nutrition Log - System



Decision Support / Sick Day Protocol - System



Appendix C – Subject Matter Expert Triangulation Rubrics

Expert 1 Triangulation Results			
Feature	Researcher	SME Classification	Indicated Updates
	Classification	Yes or No	
Medical	Information	Yes	
Content			
Nutrition	Information	Yes	
Dictionary			
Health Quizzes	System	Yes	
Journaling	System	Yes	Updated nomenclature to
			Journaling for active
			description.
Nutrition Log	System	Yes	
Sick Day	System	Yes	
Protocol			

Expert 3 Triangulation Results			
Feature	Researcher	SME Classification	Indicated Updates
	Classification	Yes or No	
Medical	Information	Yes	
Content			
Nutrition	Information	Yes	
Dictionary			
Health Quizzes	System	Yes	
Journaling	System	Yes	
Nutrition Log	System	Yes	
Sick Day Protocol	System	Yes	

Expert 3 Triangulation Results			
Feature	Researcher	SME Classification	Indicated Updates
	Classification	Yes or No	
Medical	Information	Yes	None
Content			
Nutrition	Information	Yes	None
Dictionary			
Health Quizzes	System	Yes	None
Journaling	System	Yes	None
Nutrition Log	System	Yes	None
Sick Day Protocol	System	Yes	None

Expert 4 Triangulation Results			
Feature	Researcher	SME Classification	Indicated Updates
	Classification	Yes or No	
Medical	Information	Yes	None
Content			
Nutrition	Information	Yes	None
Dictionary			
Health Quizzes	System	Yes	None
Journaling	System	Yes	None
Nutrition Log	System	Yes	None
Sick Day Protocol	System	Yes	None