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An Evidence-Based Evaluation Tool To Assist Healthcare Providers In Their Assessment Of Effective mhealth Applications For The Management Of Chronic Health Conditions

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AN EVIDENCE-BASED EVALUATION TOOL TO ASSIST HEALTHCARE PROVIDERS IN THEIR ASSESSMENT OF EFFECTIVE MHEALTH APPLICATIONS FOR THE MANAGEMENT OF CHRONIC HEALTH CONDITIONS

by

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Dedication

I dedicate this dissertation to Frank Henry Hummel, my Grandfather. He only had an 8th grade education, but never stopped learning throughout his life. My Grandfather instilled a love for learning and a desire to help others. I am so honored to be his Granddaughter. While my Grandfather is not physically here to celebrate this achievement, I know he is here in spirit.

Acknowledgements

I did not achieve this degree without the support, assistance, and guidance from key individuals. First, my husband, Michael, has been my biggest supporter. When I felt like quitting, he encouraged me to stay the course. I could not have achieved this degree without Michael's love and support.

I am so honored to have an extremely dedicated dissertation committee. Dr. Joan Culley is a committed mentor, who provided me with numerous chances to expand my research experience. As the committee chair, she guided my progress through every step. Dr. Robin Estrada also invested her time and knowledge to my success. As the qualitative expert on my committee, she offered significant input and guidance during the process. Dr. Swann Adams' diverse experience in public health also shaped my research. Her input was valuable in shaping and directing the research. Finally, Dr. Brian Habing assisted with the essential statistical and factor analysis. As the psychometric expert, his guidance was crucial throughout the process. All committee members have selflessly invested in my education and success. I am honored to have these individuals assist in this achievement.

I would also like to thank the College of Nursing faculty and staff. They are a dedicated team of people who work tirelessly to provide an outstanding educational experience.

Abstract

Mobile health (mHealth) apps are considered a viable option to improve chronic disease management. Healthcare providers are now recommending mHealth apps for patient use to assist in managing chronic diseases. However, healthcare providers may have difficulty locating effective, evidence-based mHealth apps for patients as there are currently over 325,000 available health apps (Research2Guidance, 2017). Limited evaluation tools are available to assist healthcare providers in this process. Therefore, our goal was to develop an online mHealth evaluation tool to assist healthcare providers in the selection of evidence-based mHealth apps.

After creating a comprehensive pool of mHealth features, healthcare providers provided feedback on the important and essential mHealth features. This feedback guided the development of a mHealth evaluation tool that included 32 mHealth features. Next, healthcare providers tested the mHealth evaluation tool via an online survey using pre-selected mHealth apps. The results of the proof-of-concept testing showed a strong match with the Gold Standard score that was determined by the research team. This proof-of-concept testing demonstrated the evaluation tool correctly identified high quality mHealth apps and provided essential feedback on future revisions to the mHealth evaluation tool.

Preface

This journey began several years ago while caring for patients in the medical intensive care unit at Grand Strand Regional Medical Center in Myrtle Beach, SC. While assisting my patients manage chronic health conditions, I attempted to locate effective mHealth apps for them to use. Unfortunately, the process was extremely time consuming and tedious with only a handful of effective, patient-centered mHealth apps located. I quickly realized the field of mHealth apps could benefit from an experienced nurse who understands the needs of patients but had no idea of how to participate in the mHealth development process.

I assumed my education was complete after obtaining a Master's in Nursing Informatics. However, Dr. Linda Francis encouraged me to pursue my PhD. As I progressed through the PhD program, I realized the degree opened new avenues for influencing the field of mHealth apps. My experience in locating effective and evidence-based mHealth apps for my patients was a universal problem that all healthcare providers experienced. This was the catalyst for the development of an easy and quick online evaluation tool for healthcare providers to find evidence-based apps.

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List of Abbreviations

Apps .... mobile applications

BP ....blood pressure

CDSS .... clinical decision support system

CEU ....continuing education units

CINHAL .... Cumulative Index to Nursing and Allied Health Literature

COPD .... chronic obstructive pulmonary disease

eHealth .... health services via the Internet and technology

HbA1c .... hemoglobin A1c

Health-ITUM .... Health IT Usability Evaluation Model

HTN ....hypertension

HR .... heart rate

IBM SPSS .... software package for statistical analysis

IT ....information technology

MARS .... Mobile App Rating Scale

MeSH ....medical subject headings

mHealth .... mobile health applications

MSE .... mean standard error

NIH .... National Institutes of Health

ONC .... Office of the National Coordinator for Health Information Technology

ORBIT .... Obesity-Related Behavioral Intervention Trials

REDCap .... Research Electronic Data Capture

SD .... standard deviation

SMS .... short message service

WHO .... World Health Organization

CHAPTER 1

INTRODUCTION

History and Background of Mobile Applications

The creation and advancement of mobile phone technology has dramatically changed how individuals interact and communicate with family, friends, co-workers, society, and even healthcare providers. Mobile phone technology has developed at a rapid pace since its introduction in the early 1990s. In 1993, Nokia released the first phone with short message service (SMS) or text messaging capability (Gayomali, 2012). Mobile applications (apps) first appeared in 1998 in the form of a monochromatic video game (MelonMobile, 2013). Other mobile app milestones include the delivery of instant e-mails via the Blackberry in 1999, the development of the Ericsson R380 Smartphone in 2000, and SMS capability between networks along with the first BlackBerry Smartphone with wireless e-mail in 2002 (Appschopper Blog, 2015; MelonMobile, 2013). Since the development of these very basics apps, mobile apps have evolved into complex software applications that operate on a mobile platform with or without wireless connectivity (U.S. Food and Drug Administration, 2014). The extensive advancements in mobile app technology since 2002 include the release of the first iPhone with pre-loaded apps in 2007 and the launch of the Apple App Store and Google Play in 2008. Theses mobile phone advancements are embraced by American adults with 95% owning a smartphone, which they may access up to 150 times each day (Pew Research Center, 2018; Walsh, 2013).

Mobile Application in Healthcare (mHealth)

The mobile app phenomenon is also expanding into the healthcare field, and is included in the broader term of eHealth, which is a blending of medical informatics, public health, and business to deliver health services via the Internet and technology (Eysenbach, 2001). According to the World Health Organization's (WHO) Global Observatory for eHealth, mHealth was first described as the utilization of mobile technology to manage and monitor a variety of health and wellness elements, such as appointment reminders, trending biometric measurements, patient education, and healthcare provider feedback (Kay, 2011). The integration of novel, technology-based interventions in healthcare delivery has the potential to enhance patient-provider communication, improve patient outcomes, and reduce costs (Aitken, Murray & Gauntlett, 2013).

This emerging field is viewed as a mechanism to enhance patient-centered care, which has the potential to improve patient outcomes (Ricciardi, Mostashari, Murphy, Daniel, & Siminerio, 2013). Organizations ranging from WHO, National Institutes of Health (NIH) and Office of the National Coordinator for Health Information Technology (ONC; a division of the Department of Health and Human Services) have recognized the potential of mobile phones and mHealth apps to enhance wellness and disease management, and improve healthcare outcomes (Kay, 2011; Kumar et al., 2013; Ricciardi et al., 2013). WHO officials noted the potential of mHealth to change healthcare delivery and enhance existing healthcare systems; and, the Director of the ONC proposed mHealth as an option for improving access and quality of healthcare (Kay, 2011; The Office of the National Coordinator for Health Information Technology, 2014). Furthermore, experts at a recent NIH mHealth Evidence Workshop called for increased mHealth research that incorporates a scientific multidisciplinary approach (Kumar et al., 2013).

The mHealth field continues to grow at an exponential rate with over 325,000 mHealth apps currently available for download in the U.S. (Research2Guidance, 2017). Based upon the extensive number of mHealth apps, the process of finding effective and evidence-based mHealth apps becomes very difficult for patients and healthcare providers (i.e., physicians, physicians' assistants, advanced practice nurses). Therefore, patients frequently rely on the advice and guidance of the healthcare provider when selecting an appropriate mHealth app. Several surveys on mHealth reveal that healthcare providers influence patients' use of mHealth. Digitas Health reported that 90% of patients stated they would use a mHealth app if recommended by a healthcare provider (Digitas Health, 2013). Another survey discovered that 30% of patients downloaded a mHealth app based upon a recommendation from the healthcare provider (Adams, Shanker, & Tecco, 2016). Therefore, patients and healthcare providers may benefit from an evaluation tool to assist in locating effective and evidence-based mHealth apps.

Evaluation Tools for mHealth Apps. A search of the current mHealth literature identified seven potential evaluation tools for mHealth: 1) Designing

Health Literate Mobile Apps (Broderick et al., 2014); 2) Framework for Evaluating Mobile Mental Health Apps (Chan, Torous, Hinton, & Yellowlees, 2015); 3) Health IT Usability Evaluation Model (Health-ITUM; Brown, Yen, Rojas, & Schnall, 2013); 4) heuristic evaluation of a mobile consumer health application (Monkman & Kushniruk, 2013); 5) Mobile App Rating Scale (MARS; Stoyanov et al., 2015); 6) The Practice Guide To Evaluating App Usability (mHIMSS, 2012); and 7) Suitability of Assessment Materials (Doak, Doak, & Root, 1996). An analysis of these tools revealed a focus predominately on information technology (IT) features with minimal attention to evidence-based practice, standards of care, behavior change techniques, and do not necessarily reflect the evidence from studies involving mHealth apps (see Chapter 3). While IT features are important to any mobile technology, they do not necessarily assist with chronic disease management or promote positive health outcomes. It is unclear how technology elements impact patient outcomes. For example, several evaluation tools include background color and white space; but, how does background color and white space improve patient outcomes? A literature search did not yield any studies that explored the correlation between any specific technology elements within the evaluation tools and patient outcomes.

Additionally, the seven evaluation tools are in a paper format with one tool up to seven pages in length (Stoyanov et al., 2015). Some of the evaluation tools served only as a checklist or guide to develop or assess a mHealth app without any type of scoring or rating system (Broderick et al., 2014; Chan et al., 2015). The evaluation tools that included a rating scale required the user to manually calculate the rating score and provided minimal guidance on the interpretation of the score (mHIMSS, 2012; Monkman & Kushniruk, 2013; Stoyanov et al., 2015). This analysis identified two specific gaps in the current evaluation tools: 1) lack of evidence-based practice included in mHealth evaluation tools, and 2) lack of evidence on how specific technology elements (i.e., screen color, font size, linear flow, etc.) directly influences patient outcomes. Based upon this gap, we felt that healthcare providers could benefit from an evidence-based evaluation tool to evaluate effective mHealth apps for their patients.

Hypothesis and Specific Aims

The purpose of this research is to develop and conduct proof-of-concept testing of a mHealth evaluation tool for healthcare providers using the domains and features in the current evaluation tools along with the evidence-based findings from a research synthesis (Donevant, Estrada, Culley, & Adams, 2016). We hypothesized that an evidence-based mHealth evaluation tool would correctly identify effective, evidence-based mHealth apps. Our aims included:

1. conduct a research synthesis to identify mHealth features that correlate with statistically significant patient outcomes;
2. define a comprehensive pool of domains and features for a mHealth evaluation tool utilizing findings from the research synthesis on mHealth studies and the analysis of current mHealth evaluation tools;

3. refine the comprehensive pool of domains and features based upon feedback from healthcare providers on the: essential, important, and nonessential elements in mHealth apps;
4. develop a mHealth evaluation tool for healthcare providers using the refined comprehensive pool of domains and features;
5. conduct proof-of-concept testing of the developed mHealth evaluation tool on mHealth apps that manage chronic health conditions.

Methods

Theoretical Framework: Prior to developing the research methodology, the research team recognized the importance of an appropriate theoretical framework to guide the research. The purpose of a theoretical framework is to organize the concepts (i.e., patient, provider, mHealth) with the aim of answering questions that direct practice and research (Meleis, 2017). Therefore, the selected theoretical framework must conceptualize and guide the use of mHealth technology in the context of chronic health management.

A search of potential theoretical frameworks identified a potential framework – The Supportive Accountability Framework developed by Mohr and colleagues (Mohr, Cuijpers, & Lehman, 2011). This framework clearly defines the relationship between the patient, the healthcare provider, and the mHealth app by explaining the role of each construct (see Figure 1.1). However, one missing element is the shared responsibility between the patient and the healthcare provider to actively interact via the mHealth app. In the current model, only the

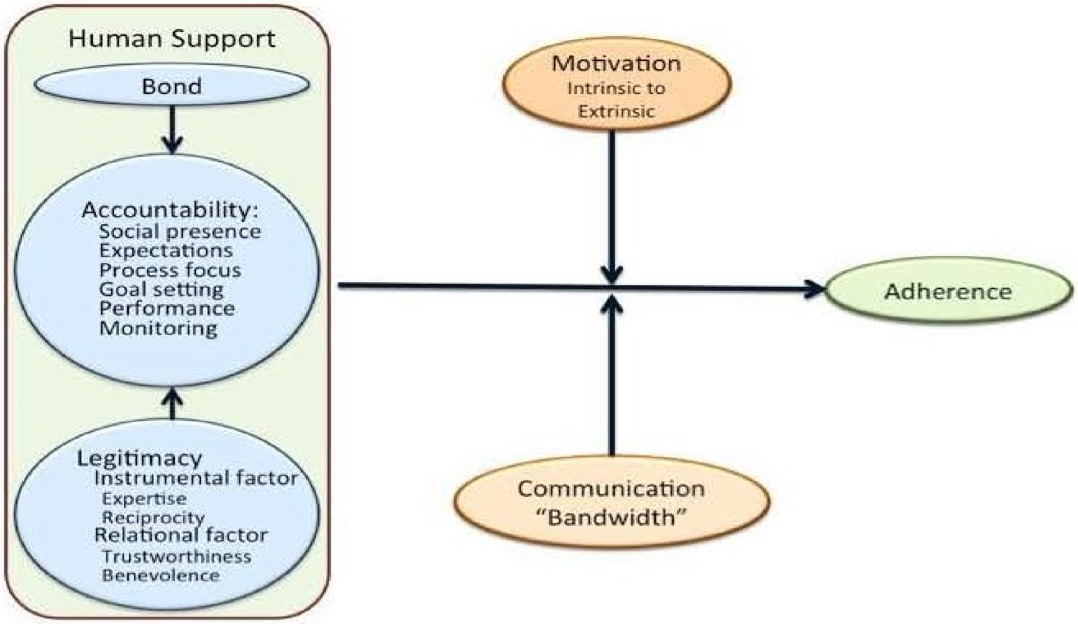

Figure 1.1 Supportive Accountability Framework (Mohr et al., 2011)

patient is accountable for a social presence, expectation, process goals, goal setting performance, and monitoring. However, if the healthcare provider is not actively participating in the process then the Supportive Accountability Framework does not work. Based upon this discovery, we recommended some slight revisions to reflect more of a collaborative model. In this proposed model, the concepts and constructs of the modified framework are simplified and re-arranged to reflect the balanced collaboration between the patient and the healthcare provider (see Figure 1.2).

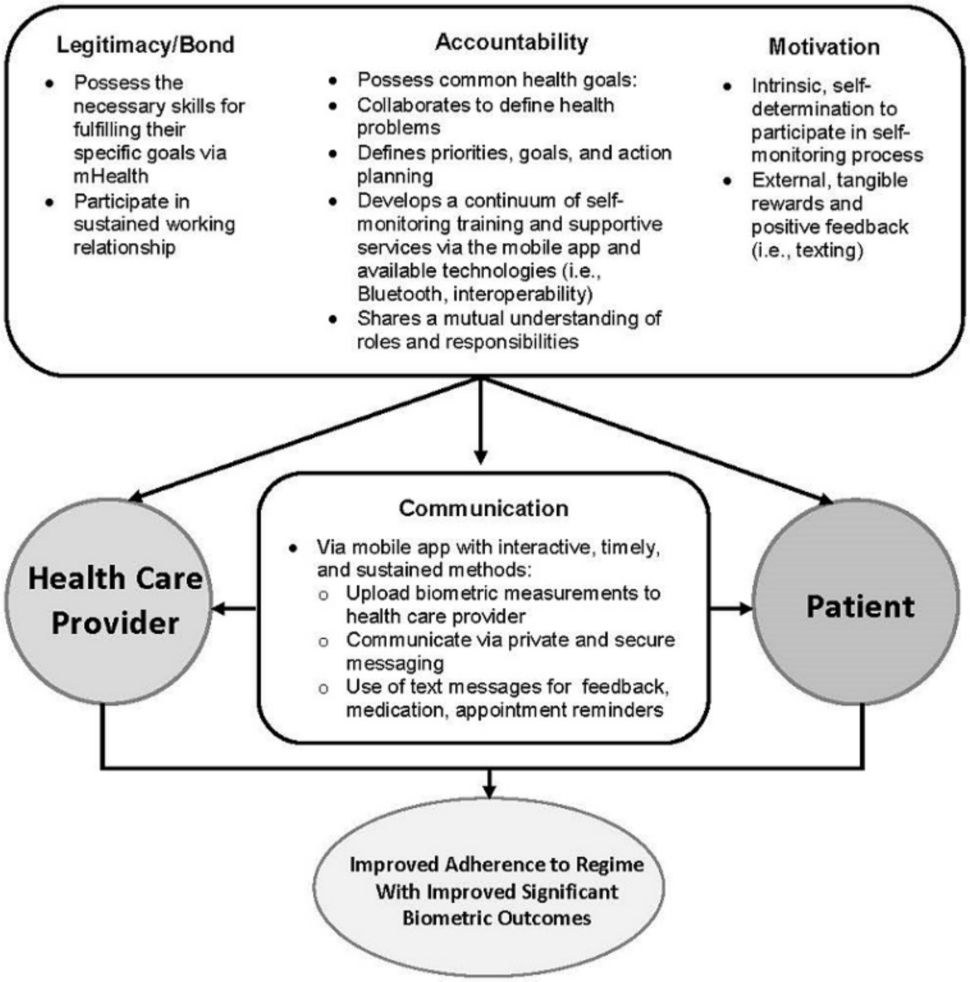

Figure 1.2 Revised Supportive Accountability Framework

Methodological Model. The Obesity-Related Behavioral Intervention Trials (ORBIT) model was used to guide the research trajectory (Czajkowski et al., 2015), which included the five specific aims described above. The ORBIT model was designed to guide the process of translating behavioral scientific findings into behavioral treatments to prevent and manage chronic diseases. Because the ORBIT model and mHealth have the same purpose - prevent and manage chronic health conditions, the ORBIT model is an appropriate model to direct this research. The methodical path of the model provided a systematic process to develop a mHealth evaluation tool through a robust chain of evidence (see Figure 1.3).

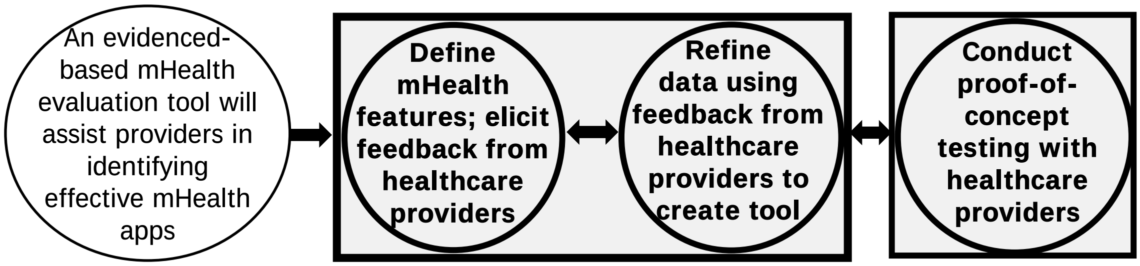

Figure 1.3 ORBIT Model for Development of mHealth Evaluation Tool (Czajkowski et al., 2015)

The first step in the ORBIT process was to develop a hypothesis by identifying a clinical problem (i.e., lack of an evidence-based evaluation tool to identify mHealth apps) and an intervention to solve the problem (i.e., development of an evidence-based mHealth evaluation tool). The second step defined the scientific foundation of the intervention using the existing scientific literature (i.e., review synthesis). The third step in the ORBIT process refined the intervention by examining essential components identified in the scientific literature. The last step of the ORBIT process was to conduct proof-of-concept testing to determine clinical significance. These specific steps assisted in translating the mHealth evidence into an evaluation tool to identify effective and evidence-based mHealth apps.

Research Process. The Institutional Review Board at University of South Carolina reviewed and approved the study. The healthcare provider survey and proof-of-concept testing was conducted in Research Electronic Data Capture

(REDCap;Harris et al., 2009) and statistical analysis was completed with IBM SPSS Statistics for Windows (Version 25.0).

Define and Refine mHealth Features. The first step was to create a comprehensive pool of domains and mHealth features by combining all the features from the seven evaluation tools and nine mHealth features identified in a research synthesis (see Chapter 2). After duplicates were removed, the comprehensive pool included 79 features in 6 domains, and served as the survey to healthcare providers.

The survey was developed in REDCap survey option and was e-mailed to over 17,000 healthcare providers. A total of 347 healthcare providers responded to the e-mail request with 108 providers stating they recommended mHealth apps. A frequency analysis of the results revealed that almost 75% of the features reached a threshold of ≥50% for inclusion in the evaluation tool, and one features achieved a threshold of >50% for exclusion (i.e., social media connection). The remaining 19 features were undecided; therefore, the research team decided inclusion or exclusion via an online survey. In total, 78 features reached the threshold for inclusion in the evaluation tool, which resulted in an excessively large evaluation tool. The team conducted a factor analysis to assist with combining correlating and overlapping features.

The factor analysis identified several moderate to strong correlations, which allowed the combination of multiple overlapping features into a single feature. After combining features with moderate to strong correlations, 32 mHealth features remained, which formed the mHealth evaluation tool. A detailed described of this process is provided in Chapter 3.

Proof-of-Concept Testing of mHealth Evaluation Tool. Before testing the evaluation tool, the research team determined the point values of the responses, the ranges of the app quality scores, pre-selected 6 mHealth apps for testing (2 asthma apps, 2 diabetes apps, and 2 hypertension apps), and Gold Standard score for each app. Next, the mHealth evaluation tool was developed as a REDCap survey with the intent that each provider would evaluate 2 mHealth apps for the same disease. Healthcare providers were recruited through online medical communities and healthcare organizations. We received 26 evaluations (10 asthma, 4 diabetes, and 12 hypertension); however, some providers did not complete the entire evaluation. In total, 36 individual app evaluations were completed.

A comparison between the Gold Standard quality rating and the providers' quality ratings showed a 69% (n=25) agreement. The mean difference between the Gold Standard score and the providers' scores was ±6.42 (MSE, 3.724; SD, 22.343). An analysis of the individual responses revealed 6 feature responses with a high disagreement with the Gold Standard. Further exploration of these features is necessary and may indicate a need for revisions to the feature statements. Complete details of the proof-of-concept testing is provided in Chapter 4.

Overview of Manuscripts and Target Journals

Mobile health has a diverse audience, which offers a variety of peer-reviewed journals. First, healthcare providers may benefit from this research with dissemination options in specific provider journals (i.e., medical, nursing). Next, these findings may assist informaticians and developers by guiding future mHealth development. Finally, other researchers may also use these findings to continue to explore the mHealth field.

The first manuscript was a review synthesis of mHealth studies involving asthma, diabetes, and hypertension (HTN). The review synthesis examined how the specific features included in the mHealth apps (i.e., one-way and two-way SMS, Bluetooth, clinical decision support system, reminders, sharing health data with provider, interactive prompts, electronic diary, setting personalized health goals) correlated with statistically significant outcomes, which provided a unique analysis on mHealth apps. This manuscript was submitted to the Journal of the American Medical Informatics Association.

The next two manuscripts describe the development and proof-of-concept testing of the mHealth evaluation tool based upon feedback from healthcare providers. The first manuscript describes the process of developing the mHealth evaluation tool using feedback from healthcare providers (Chapter 3). The second manuscript details the proof-of-concept testing of the evaluation tool (Chapter 4). Potential journals include the Health Informatics Journal.

The final manuscript is the analysis of the qualitative responses from the initial healthcare provider survey. The healthcare providers' comments offer additional insight into their perspective on mHealth. Potential journals for this manuscript include the Journal of Healthcare Informatics Research.

CHAPTER 2

CORRELATING APP FEATURES WITH OUTCOMES IN MHEALTH STUDIES INVOLVING CHRONIC RESPIRATORY DISEASES, DIABETES, AND HYPERTENSION: A RESEARCH SYNTHESIS[1]

[1] Donevant, S., Culley, J., Estrada, R., Habing, B., & Adams, S. Submitted to *Journal of American Medical Informatics Association,* 3/15/2018.

Background and Significance

eHealth, or the integration of novel, technology-based interventions into healthcare delivery has the potential to enhance patient-provider communication, improve patient outcomes, and reduce costs (Aitken, Murray & Gauntlett, 2013). eHealth blends medical informatics, public health, and business to deliver health services via the Internet and technology (Eysenbach, 2001). The healthcare field is experiencing an exponential growth in mHealth (mobile health), a subfield of eHealth. The World Health Organization's (WHO) Global Observatory for eHealth originally defined mHealth as the utilization of mobile technology to manage and monitor a variety of health and wellness elements, such as appointment reminders, trending biometric measurements, patient education, and healthcare provider feedback (Kay, 2011). Currently, there are an estimated 325,000 health, fitness and medical mobile apps available (Research2Guidance, 2017). This emerging field is viewed as a mechanism to enhance patient-centered care and improve patient outcomes from the perspective of patients and healthcare providers (Ricciardi et al., 2013). For example, Ramirez and colleagues reported 86% of the study participants in California expressed an interest in using mHealth for chronic health management and as a tool to learn about their health (Ramirez et al., 2016).

Self-monitoring of chronic conditions is one way that mHealth can potentially assist patients in improving outcomes. This is especially true when monitoring chronic diseases with specific biometric measurement (i.e., finger stick blood glucose, blood pressure, peak flow) that are recorded by the patient and shared with a healthcare provider for review and feedback. Some of the chronic disease that fall into this category include chronic respiratory diseases (i.e., asthma and chronic obstructive pulmonary disease [COPD]), diabetes and hypertension (HTN). These chronic diseases affect almost 44% of the U.S. population and contributes to over $271 billion in direct healthcare cost within the U.S. (American Diabetes Association, 2016; American Thoracic Society, 2018; Centers for Disease Control and Prevention, 2015a, 2015b; Dieleman et al., 2016). Also, diabetes and HTN increase a patient's risk for development of cardiovascular disease, which adds additional healthcare costs (Song et al., 2016). Based upon the prevalence and similarity in patient management of chronic respiratory disease, diabetes, and HTN, exploring the mHealth literature as a group of chronic diseases may yield more details on the efficacy and elements of mHealth apps.

Objective

An initial look at the mHealth literature reveals mixed results, with some studies reporting no statistically significant differences in patient outcomes (Aitken, M & Lyle, 2015; Monroe, Thompson, Bassett Jr, Fitzhugh, & Raynor, 2015). These disparate outcomes need further analysis to identify the differences between the two groups (i.e. studies with statistically significant outcomes versus studies without statistically significant outcomes). We propose that one possible explanation for the differences in outcomes may be related to the *specific* *features* within the mHealth app. What if the catalyst for health promotion and change is the specific features in the app? With this question in mind, a research synthesis was conducted to specifically identify mHealth features and analyze: 1) types of mHealth features; 2) overall frequency and number of mHealth features used in the studies; and 3) relationship of statistically significant outcomes (i.e., improved biometric measurements) by type, frequency and number of mHealth features.

Materials and Methods

This research synthesis examined primary studies involving asthma, diabetes, and HTN. The purpose of this narrow focus of primary studies was two-fold. First, it allowed an in-depth analysis of mobile technology and features, while providing a novel perspective on mHealth literature by correlating specific mHealth features or groups of features with reported patient outcomes. Secondly, it provided an analysis of behavioral change interventions to maintain or start healthy behaviors such as medication adherence or completion of appropriate biometric measurements. Some findings suggested that behavior change interventions were unique based upon the desired outcome (Hall, Cole-Lewis, & Bernhardt, 2015; Michie, Susan et al., 2011). Stopping a negative health behavior, such as smoking cessation, may require different behavioral change techniques and interventions than starting a healthy behavior. The inclusion of both types of these studies – starting healthy behaviors and stopping unhealthy behaviors - may confound accurate analysis of relevant and successful mHealth features in chronic health conditions. Consequently, this review focuses on behaviors for managing chronic diseases.

Search Process. The search included primary articles focused on app-based interventions in asthma, diabetes, and HTN from the following databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, EBSCO Academic Database, Cochrane Library, and Google Scholar. SMS between networks began in 2002, which allowed greater possibilities for mHealth research (Appschopper Blog, 2015; MelonMobile, 2013). Therefore, the search dates included 2002 to 2018. The search terms included key words in multiple combinations with the use of medical subject headings (MeSH): self-monitoring, mobile application, mobile app, mHealth, text messaging, short-message service, hypertension, high blood pressure, diabetes, asthma, wireless communication, cell phone, mobile phone and mobile device. Finally, reference lists of articles were reviewed to ensure inclusion of all relevant literature. The initial search results yielded 3621 studies.

Inclusion Criteria. Inclusion for the primary studies was dependent upon the utilization of a mHealth app or SMS as an intervention to manage asthma, diabetes, and HTN. In addition, only primary journal articles available via university library sources including inter-library loan and written in English were included.

Exclusion Criteria. Unrelated studies (n=906), qualitative studies (n=47), reviews and meta-analyses (n=164), research design and proposals (n=85), and studies not available through university library (n=9) or not available in English (n=10) were removed from the analysis. Additionally, as the review focus was mHealth, studies that allowed the intervention group to utilize only a web-based health program or combination of mHealth app and web-based health programs were excluded (n=225). Further exclusions included studies that contained scheduled phone calls or in-person coaching as part of the intervention (n=6), as it was difficult to isolate whether the final study outcomes were a result of the phone calls, in-person coaching or the mHealth intervention (Bin-Abbas, Jabbari, Al-Fares, El-Dali, & Al-Orifi, 2014; Ding, Karunanithi, Kanagasingam, Vignarajan, & Moodley, 2014; Fukuoka, Gay, Joiner, & Vittinghoff, 2015; Levy et al., 2015; Naghibi, Moosazadeh, Zhyanifard, Jafari Makrani, & Yazdani Cherati, 2015; Seid et al., 2012). Studies with statistical discrepancies between the text and table(s) of the article were also excluded (Goodarzi, Ebrahimzadeh, Rabi, Saedipoor, & Jafarabadi, 2012; Kim et al., 2016). For example, one study reported a statistically significant change in hemoglobin A1c (HbA1c; p=0.024), yet also reported the p-value as 0.24. While likely a typographical error, these types of errors precluded inclusion in this analysis. Studies with a primary focus of evaluating participant satisfaction or acceptance of the mHealth app were excluded (n=8). While these studies are important to mHealth adoption, the focus of this review is the analysis of mHealth features related to statistically significant measurable outcomes (Burbank et al., 2015; Ferrer-Roca, Cárdenas, Diaz-Cardama, & Pulido, 2004; Markowitz et al., 2014;

Meltzer, Kelley, & Hovell, 2008; Rossi, M. C. et al., 2009; Schiel, Thomas, Kaps, & Bieber, 2011; Stuckey, Melanie, Fulkerson, et al., 2011; Wangberg, Arsand, & Andersson, 2006).

Finally, additional studies were excluded due to: 1) provider exclusively added health information into the app (n=1; Doocy et al., 2017); 2) missing components in statistically reporting that prevented complete analysis (n=7; Faridi et al., 2008; Fatehi, Malekzadeh, Akhavimirab, Rashidi, & Afkhami-Ardekani, 2010; Holtz & Whitten, 2009; Katz, Mesfin, & Barr, 2012; Louch, Dalkin, Bodansky, & Conner, 2013; Skrovseth, Arsand, Godtliebsen, & Joakimsen, 2015; Waki et al., 2015); 3) article retraction (n=1; Zolfaghari, Mousavifar, Pedram, & Haghani, 2012); and 4) an HbA1c instrument change during the study, which potentially resulted in inconsistent readings (n=1; Vähätalo, Virtamo, Viikari, & Rönnemaa, 2004).

After careful review, 61 appropriate studies from 30 different countries were included (see Figure 2.1). Most studies (84%) included at least one intervention group and a control group in either a randomized methodology (n=35) or a quasi-experimental methodology (n=16). The remaining studies followed a pre/post-test methodology with a single intervention group (n=10).

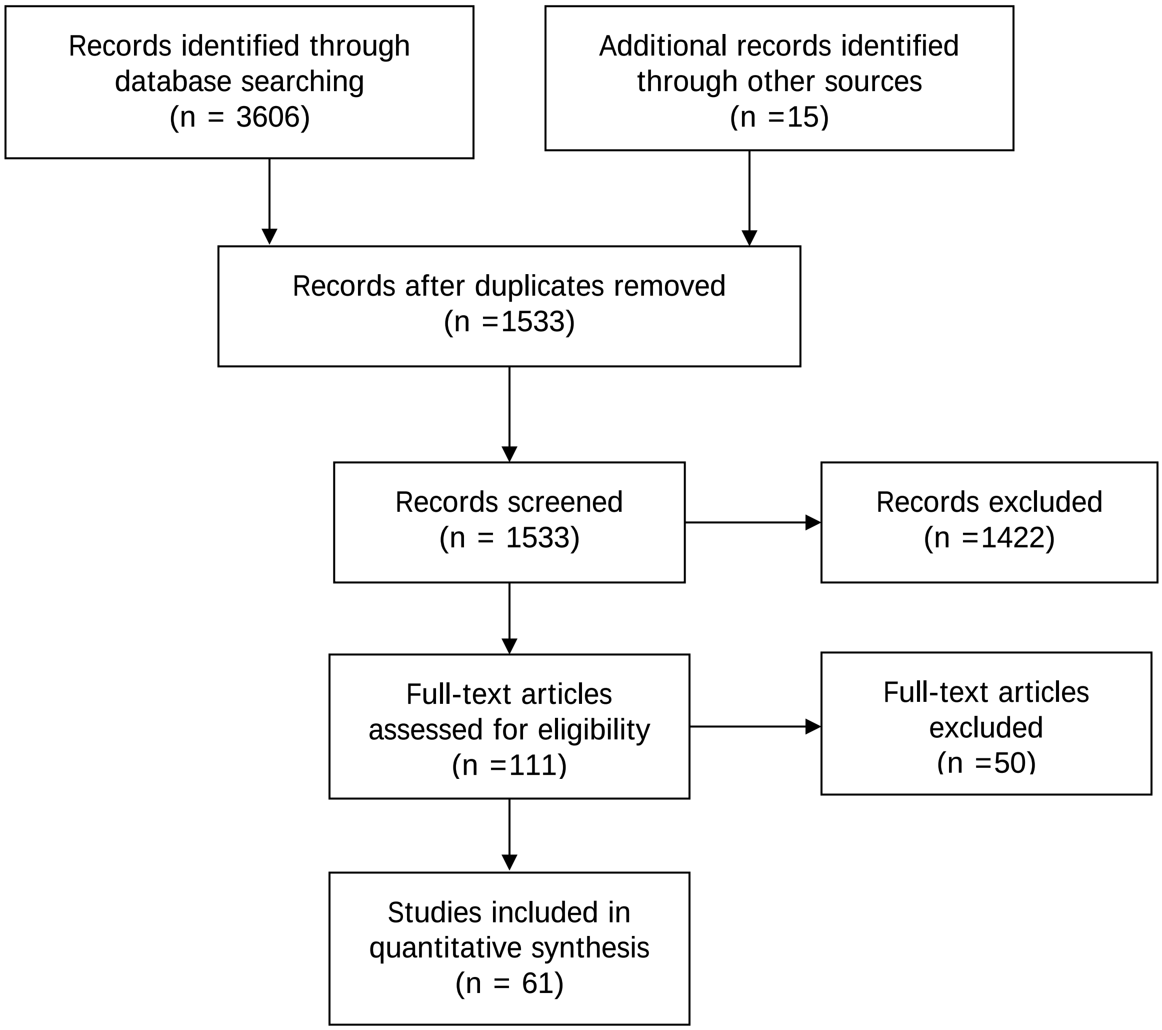

Figure 2.1 mHealth Review Flowchart

Results

When analyzing the studies, some researchers reported statistically significant patient outcomes and proposed mHealth as a novel tool to improve patient's health. In contrast, other researchers reported no statistically significant patient outcomes. After comparing the two groups, it became apparent the difference was specific features utilized within the mHealth app. First, we identified nine mHealth features used in the studies categorized into two distinct classifications of features – passive and interactive. For this review, passive features were defined as features that do not require any additional response or action from the patient within the mHealth app. The passive features included: 1) one-way SMS; 2) electronic diary to store and graphically display biometric measurements (i.e., blood glucose, blood pressure [BP], weight); 3) Bluetooth to upload biometric measurements; and 4) reminders. In passive features, the patient only completes the initial task (i.e., reading the SMS or reminder, taking the biometric measurement).

In contrast, interactive features require patients to provide a response or complete an action within the mHealth app. Interactive features included: 1) interactive prompts; 2) direct upload of biometric measurements to the patient's healthcare provider for review and timely feedback; 3) action treatment plan/personalized health goals with healthcare provider; 4) two-way communication (i.e. texting, messaging, e-mail) between the healthcare provider and patient that is tailored to the patients' biometric measurements, health goals, or health beliefs; and 5) clinical decision support system (CDSS).

Defining and explaining each feature assists in understanding the unique elements in mHealth features and provides the basis for this analysis. Each feature may be used independently (i.e., only feature in mHealth app) or in conjunction with other features. The features are discussed according to the distinct classifications - passive and interactive.

Passive Features. As defined above, passive features did not require the patient to perform any additional task or response within the mHealth app. Still, they delivered essential self-monitoring elements by providing education or health tips, displaying previous biometric measurements, uploading biometric measurements automatically, and reminding the patient of upcoming events, tasks or medications. The passive features are discussed in-depth to explain the unique elements of each.

One-way SMS and Messaging. One-way SMS, also known as unidirectional messaging, are messages sent from the healthcare provider to the patient. The patient can only read the message and does not return a message to the healthcare provider. In the reviewed studies, these messages were intended to educate, inform, and motivate the patient on specific health conditions and behaviors. Examples included: “Physical activity helps to maintain normal blood sugar and blood pressure” and “Were there many missed walks this month? No worries start today” (Ramachandran et al., 2013). Bell and colleagues (2012) used a slightly different approach by sending daily video messages to the patients instead of written messages. The frequency and timing of the messages varied between studies from one per month to daily (Bell et al., 2012; Gatwood et al., 2016; Shariful Islam et al., 2015; Wong et al., 2013).

Twelve studies used one-way SMS as the only mHealth feature (Bell et al., 2012; Bin Abbas, Al Fares, Jabbari, El Dali, & Al Orifi, 2015; Celik et al., 2015; Gatwood et al., 2016; Haddad et al., 2014; Marquez Contreras et al., 2004;

Pfammatter et al., 2016; Ramachandran et al., 2013; Shariful Islam et al., 2015; Shetty, Chamukuttan, Nanditha, Raj, & Ramachandran, 2011; Van Olmen et al., 2017; Wong et al., 2013). One-way SMS makes a presumption about the patient's health behavior (i.e. patient is not taking medication). These presumptions may be incorrect and may potentially serve as a barrier. Furthermore, previous reviews exploring the efficacy of SMS suggest that one-way SMS is not as effective as two-way SMS (Holcomb, 2015; Orr & King, 2015; Poorman, Gazmararian, Parker, Yang, & Elon, 2015).

Electronic Diary. This feature stores biometric measurements and graphically displays the information for the patient to identify patterns and trends in the biometric measurements. The electronic diary was an essential element in the self-monitoring of behaviors and outcomes as described by Michie and colleagues (2013). No studies used an electronic diary feature exclusively. Thirteen studies included an electronic diary feature in conjunction with other mHealth features (Cingi et al., 2015; Clements & Staggs, 2017; Earle, Istepanian, Zitouni, Sungoor, & Tang, 2010; Holmen et al., 2014; Kirwan, Vandelanotte, Fenning, & Duncan, 2013; Larsen, Turner, Farmer, Neil, & Tarassenko, 2010; Liu et al., 2011; Offringa et al., 2017; Patel et al., 2013; Rossi, Maria CE et al., 2010; Rossi, M. C. et al., 2013; Stuckey, M., Russell-Minda, et al., 2011; Wayne, Perez, Kaplan, & Ritvo, 2015).

Bluetooth Technology. This wireless technology allows medical devices (i.e., glucometers, BP cuffs, scales, etc.) to communicate and share data with the mHealth app (Department of Homeland Security, 2016). The sharing of data occurs automatically and does not require any additional actions from the patient; this feature may increase patient compliance by providing tools to simplify the monitoring of chronic diseases while reducing data entry errors. Only one study exclusively used Bluetooth (Chau et al., 2012).

Reminders. A reminder is a message that reminds the patient about an upcoming action or task (i.e., take medication, attend appointment). The patient is not required to input any data or information in response to the reminder. One study used a reminder as the sole mHealth feature (Strandbygaard, Thomsen, & Backer, 2010). Twenty-two other studies included a reminder feature in addition to other features (Bobrow et al., 2016; Brar Prayaga et al., 2018; Brath et al., 2013; Burner et al., 2018; Capozza et al., 2015; Cho, Lee, Lim, Kwon, & Yoon, 2009; Cingi et al., 2015; Dobson et al., 2015; Franklin, Waller, Pagliari, & Greene, 2006; Hussein, Hasan, & Jaradat, 2011; Istepanian et al., 2009; Kirwan et al., 2013; Logan et al., 2012; McGillicuddy et al., 2013; Nundy et al., 2014; Offringa et al., 2017; Patel et al., 2013; Read, 2014; Vervloet et al., 2014; Vervloet et al., 2012; Yoo et al., 2009; Zhou, Chen, Yuan, & Sun, 2016).

Interactive Features. Interactive features differ from passive features as they require responsive actions and patient-specific input. The patient engages with the mHealth app and healthcare provider by sharing health data and setting treatment plans or health goals, answering tailored health questions and receiving feedback or guidance based on biometric measurements. A detailed description of the interactive features is provided.

Interactive Prompts. This feature moves beyond a reminder and requires the patient to enter an appropriate response. Most prompts in the studies elicited additional information from the patient such as symptoms, refill medications, change appointments, and biometric measurements (Bobrow et al., 2016; Brar Prayaga et al., 2018; Burner et al., 2018; Capozza et al., 2015; Liu et al., 2008). These prompts were typically communicating with a computer, which differentiates them from the personalized two-way SMS with the provider. One study used interactive prompts exclusively (Tasker, Gibson, Franklin, Gregor, & Greene, 2007). Thirteen additional studies included interactive prompts with other mHealth features (Abaza & Marschollek, 2017; Bobrow et al., 2016; Brar Prayaga et al., 2018; Burner et al., 2018; Capozza et al., 2015; Cook, Modena, & Simon, 2016; Dobson et al., 2015; Liu et al., 2008; McGillicuddy et al., 2013; Nundy et al., 2014; Patel et al., 2013; Ryan et al., 2012; Tasker et al., 2007; Yoo et al., 2009).

Action Treatment Plan/Personalized Health Goals with Healthcare Provider. The collaborative development and recording of health plans and goals allows the patient to be an active participant in the health process. Goals and planning were an essential element of behavior change techniques described by Michie and colleagues (2013). This self-management tool assisted the patient in successfully managing a chronic disease (Lenferink et al., 2017). A personalized health plan provides the patient with specific steps or actions to improve health or control a specific health situation. These plans are based upon the provider's medical expertise and previous experience with the patient. Nine studies utilized an action treatment plan or personalized health goals with other features (Charpentier et al., 2011; Cingi et al., 2015; Liu et al., 2008; Logan et al., 2012; Read, 2014; Rossi, Maria CE et al., 2010; Rossi, M. C. et al., 2013; Stuckey, M., Russell-Minda, et al., 2011; Zhou et al., 2016).

Two-way or Tailored Communication Between the Healthcare Provider and Patient. Two-way communication includes SMS, messaging and e-mail between the healthcare provider and patient. The healthcare provider provides feedback on biometric measurements or provides changes to the patient's health regime. In addition, content-tailored SMS messages encourage changes in health beliefs and behaviors, which have potential to influence patient outcomes. Some customized SMS messages originated from surveys and questionnaires that provided insight into the patient's health beliefs and understanding of the disease process and management. Goal setting also guided the content of SMS messages (Franklin et al., 2006). Examples of personalized, two-way SMS included: "Your fasting blood glucose level is very high compared with the appropriate target level for Type 2 diabetes (< 7.2 mmol / l). If this high level recurs often, diabetic complications might result. Reduce your calorie intake and avoid foods high in fat. In addition, plan for regular exercise after your meals" and "Hi <patient name>- Another pretty good week - just a bit concerned about some odd higher levels in the morning - looks like some of those are forgotten doses - would that be right? Otherwise all are getting better and no real hypos. Be aware you may need to tweak basal if those highs are not related to forgotten doses. Your thoughts?" (Kirwan et al., 2013; Yoo et al., 2009). This personalization recognized the patient as a unique individual with unique health needs and goals. Twenty-one studies used two-way communication in conjunction with other mHealth features (Cho et al., 2009; Cingi et al., 2015; Dobson et al., 2015; Franklin et al., 2006; Han et al., 2015; Hussein et al., 2011; Kerr et al., 2016; Kirwan et al., 2013; Lim et al., 2011; Lv et al., 2012; Nundy et al., 2014; Ostojic et al., 2005; Peimani et al., 2016; Petrie, Perry, Broadbent, & Weinman, 2012; Rossi, Maria CE et al., 2010; Rossi, M. C. et al., 2013; Stuckey, M., Russell-Minda, et al., 2011; Waki et al., 2014; Wayne et al., 2015; Yoo et al., 2009; Zhou et al., 2016).

Upload Biometric Measurements to the Healthcare Provider for Review and Timely Feedback. The feature includes the automatic transfer of health data directly to the healthcare provider via e-mail or electronic health record. Accessibility to timely health data allows the provider to offer feedback or make judicious changes to the patient's medication regime to promote improved disease management and prevent costly hospital visits. One study showed how sharing biometric data allowed the provider to make necessary and timely changes to the medication regime to improve optimal biometric readings. McGillicuddy and colleagues (2013) reported the intervention group had twice the number of medication changes to successfully achieve a regulated blood pressure compared to the control group. Timely data sharing also has the potential to reduce the number of hospital visits. Ostojic and colleagues (2005) stated the control group had >3 times the number of hospital visits (n=7) compared to the intervention group (n=2). The sharing of biometric readings requires the participation of both patient and healthcare provider and appears to successfully advance the collaborative management of chronic health conditions. Twenty studies included this mHealth feature in combination with other features (Benhamou et al., 2007; Cho et al., 2009; Cingi et al., 2015; Cook et al., 2016; Dobson et al., 2015; Hussein et al., 2011; Kerr et al., 2016; Kirwan et al., 2013; Larsen et al., 2010; McGillicuddy et al., 2013; Nundy et al., 2014; Ostojic et al., 2005; Rossi, Maria CE et al., 2010; Rossi, M. C. et al., 2013; Ryan et al., 2012; Stuckey, M., Russell-Minda, et al., 2011; Waki et al., 2014; Wayne et al., 2015; Yoo et al., 2009; Zhou et al., 2016).

One essential element of uploading of biometric measurements is providing timely feedback to the patient. If the healthcare provider never reviews the uploaded data, then the patient continues with the same regime, which may not be effective. Two studies provided feedback via a written letter mailed to the patient (Earle et al., 2010; Istepanian et al., 2009). It is unclear why traditional mail was used rather than the quick, secure communication methods available through mHealth (i.e., SMS, e-mail), and if the delayed communication impacted the lack of statistically significant outcomes in these studies.

CDSS. A CDSS provides patient-specific feedback when critical or abnormal readings appear or when the patient needs additional information for disease management (HealthIT.gov, 15 Jan 2013). CDSS provided patients with appropriate feedback on biometric parameters, information specific to their chronic disease such as insulin or medication doses and when to call the provider or go to the emergency department. The CDSS complexity varied from very basic color-coated alerts (Ryan et al., 2012) to complex insulin algorithms (Yoo et al., 2009). One study utilized only CDSS (Orsama et al., 2013). Sixteen additional studies combined CDSS with other features (Charpentier et al., 2011; Cook et al., 2016; Holmen et al., 2014; Larsen et al., 2010; Lim et al., 2011; Liu et al., 2011; Logan et al., 2012; Orsama et al., 2013; Rossi, Maria CE et al., 2010; Rossi, M. C. et al., 2013; Ryan et al., 2012; Stuckey, M., Russell-Minda, et al., 2011; Vervloet et al., 2014; Vervloet et al., 2012; Waki et al., 2014; Yoo et al., 2009; Zhou et al., 2016).

Discussion

Next, we explored the mHealth features used in each study along with any statistically significant outcomes. For studies involving two or more groups (i.e., intervention and control), we only include outcomes reported between groups. The purpose of using a control group is to isolate the independent variable's effect (i.e., mHealth app), which strengthens the study outcomes. For single intervention group studies, we report the within group outcomes. All reported outcomes compare baseline data with the final data. We did not include data comparisons between baseline and final data collection. Furthermore, subgroup outcomes were not included in the analysis since the subgroup methodology was not clearly defined prior to the studies, which does not meet best practice standards (Wallach et al., 2017). Finally, three studies included two intervention groups that introduced an additional independent variable (i.e., intensive insulin therapy, bi-weekly telemedicine consultations, face-to-face health counseling) into the analysis (Charpentier et al., 2011; Franklin et al., 2006; Holmen et al., 2014). While all intervention groups used mHealth, the addition of new independent variable clouds the analysis of mHealth efficacy. For these studies, we only included the comparison between the standard care control group and the standard care mHealth intervention group. Table 2.1 provides details on each study with features and statistically significant outcomes.

Frequency of Features. Once we identified the mHealth features, we analyzed features and outcomes to identify potential trends and patterns. A frequency analysis revealed the most commonly used feature was reminders (n=23) and the least frequent was an action treatment plan/personalized health goals (n=9).

Table 2.1 mHealth Studies with Features and Outcomes

Authors	Year	Passive Features				Interactive Features					Outcomes
		One-way SMS and Messaging	Electronic Diary	Bluetooth Technology	Reminder	Interactive Prompts	Action/Treatment Plan or Personalized Goals	Two-way or Tailored SMS and Messaging	Upload Data to Provider	CDSS	
Brath et al	2013			X	X						Significant increase in adherence of metformin (P=0.04). Significant decrease in total cholesterol (P=0.02), systolic & diastolic BP (P=0.02/P=0.0003).
Burner et al	2018	X			X	X					Significant increase in self-monitoring of glucose (P=0.02).
Capozza et al	2015	X			X	X					No significant difference between baseline & endpoint.
Celik et al	2014	X									Significant increase in knowledge and skills on insulin injection technique (P<0.001). Significant decrease in HbA1c (P<0.05).
Charpentier et al	2011						X			X	Significant decrease in HbA1c (P<0.001).
Chau et al	2012			X							No significant difference between baseline & endpoint.
Cho et al	2009			X	X			X	X		Significant decrease in HbA1c (P=0.001) and 2-hour postprandial glucose (P=0.001).
Cingi et al	2015		X		X		X	X	X		Significant improvement in Asthma Control Test scores (P=0.000). Significant fewer unplanned hospital and follow-up office visits (P=0.015).
Clements & Staggs	2017		X	X							No significant difference between baseline & endpoint.

Authors	Year	Passive Features				Interactive Features					Outcomes
		One-way SMS and Messaging	Electronic Diary	Bluetooth Technology	Reminder	Interactive Prompts	Action/Treatment Plan or Personalized Goals	Two-way or Tailored SMS and Messaging	Upload Data to Provider	CDSS	
Cook, Modena, & Simon	2016					X			X	X	Significant increase in % of participants with well-controlled asthma (P<0.0001); % of participants with achieved asthma control (P<0.0001); & mean Asthma Control Test score (P<0.001). Significant decrease in systemic steroid use (P=0.046).
Dobson et al	2015				X	X		X	X		Significant decrease in mean HbA1c (P=0.001).
Earle et al	2010		X`	X							No significant difference between baseline & endpoint.
Franklin et al	2006				X			X			Significant improvement in self-efficacy for diabetes (P=0.03) and visual analogue adherence scores (P=0.042). Significant increase in diabetes social support from diabetes team in blood-glucose testing, diet, and exercise (P<0.001).
Gatwood et al	2016	X									No significant difference between baseline & endpoint.
Haddad et al	2014	X									Significant increase in knowledge (P=0.0002). Significant improvement in HbA1c (P=0.0001).
Han et al	2015							X			Significant increase in Diabetes Quality of Life Youth Impact on Diabetes Score (P=0.003).
Holmen et al	2014		X	X						X	No significant difference between baseline & endpoint.

Authors	Year	Passive Features				Interactive Features					Outcomes
		One-way SMS and Messaging	Electronic Diary	Bluetooth Technology	Reminder	Interactive Prompts	Action/Treatment Plan or Personalized Goals	Two-way or Tailored SMS and Messaging	Upload Data to Provider	CDSS	
Hussein, Hasan, & Jaradat	2011				X			X	X		Significant decrease in HbA1c (P=0.001).
Islam et al	2015	X									Significant decrease in mean HbA1c (P=0.0001).
Istepanian et al	2009			X	X						No significant difference between baseline & endpoint.
Kerr et al	2016							X	X		Significant decrease in body weight (P=0.02) and body mass index (P=0.02) in feedback only group.
Kirwan et al	2013		X		X			X	X		Significant decrease in HbA1c (P=0.001). Significant improvement in Summary of Diabetes Self-Care Activities general diet score (P<0.05).
Larsen et al	2010		X	X					X	X	Significant decrease in HbA1c (P=0.05). Significant increase insulin dose (P=0.006).
Lim et al	2011			X				X		X	Significant decrease in HbA1c (P<0.05), postprandial 2-h glucose level (P=0.007), and number of hypoglycemic events (P<0.05).
Liu et al	2011		X							X	Significant increase in Forced Expiratory Volume (P<0.05), Peak Expiratory Flow Rate (P<0.05), and Quality of Life physical activity scores (P=0.045). Significant decrease in unscheduled visits to the hospital (P<0.05).

Authors	Year	Passive Features				Interactive Features					Outcomes
		One-way SMS and Messaging	Electronic Diary	Bluetooth Technology	Reminder	Interactive Prompts	Action/Treatment Plan or Personalized Goals	Two-way or Tailored SMS and Messaging	Upload Data to Provider	CDSS	
Liu et al	2008					X`	X				Significantly higher walking distance (P<0.001) & days of walking (P<0.01). Significant decrease in Borg Dyspnoea Scale (P<0.01), unscheduled visits (P<0.01) & hospitalizations (P<0.01). Significant increase in Quality of Life physical summary scale (P<0.001).
Logan et al	2012			X	X		X			X	Significant decrease in mean daytime systolic BP (P=0.003), 24-hour systolic BP (P=0.005), mean daytime diastolic BP (P=0.003), 24 hours diastolic BP (P=0.006), & depressions scores (P=.032). Significant number of participants achieved target BP (P<.05).
Lv et al	2012							X			Significant increase in Perceived Control of Asthma Questionnaire-6 score (P=0.046), Standard Asthma Quality of Life Questionnaire score (P=0.008).
Marquez Contreras et al	2004	X									No significant difference between baseline & endpoint.
McGillicuddy et al	2013			X	X				X		Significant increase in medication adherence (P<0.05). Significant decrease in systolic BP (P=0.009).

Authors	Year	Passive Features				Interactive Features					Outcomes
		One-way SMS and Messaging	Electronic Diary	Bluetooth Technology	Reminder	Interactive Prompts	Action/Treatment Plan or Personalized Goals	Two-way or Tailored SMS and Messaging	Upload Data to Provider	CDSS	
Nundy et al	2014				X	X		X	X		Significant decrease in HbA1c (P=0.01), outpatient visits (P=0.01), outpatient costs (P=0.01), & total costs (P=0.004). Significant improvement in Brief Diabetes Distress Screening Instrument (P=0.01).
Offringa et al	2017		X		X						Significant increase in frequency of blood glucose monitoring (P<0.01).
Orsama et al	2013									X	Significant decrease in HbA1c (P=0.022) & weight (P=0.021).
Ostojic et al	2005							X	X		Significant decrease in cough (P<0.05) & night symptoms (P<0.05).
Patel et al	2013		X		X	X					Significant improvement in medication adherence (P<0.000).
Peimani et al	2015	X						X			Significant decrease in Body Mass Index (P<0.001/P=0.002) and fasting blood sugar (P=0.003/ P=0.026) in both intervention groups. Significant decrease in HgA1c (P=0.05) in tailored SMS group. Significant decrease in triglycerides (P=0.003) in non-tailored SMS group. Significant improvement in self-care inventory scores (P<0.0001/ P<0.0001), diabetes self-care barriers (P<0.0001/P<0.0001), & diabetes management self-efficacy (P<0.0001/P<0.0001) in both intervention groups.

Authors	Year	Passive Features				Interactive Features					Outcomes
		One-way SMS and Messaging	Electronic Diary	Bluetooth Technology	Reminder	Interactive Prompts	Action/Treatment Plan or Personalized Goals	Two-way or Tailored SMS and Messaging	Upload Data to Provider	CDSS	
Petrie et al	2011							X			Significant improvement in mean adherence (P<0.05), self-reported adherence (P<0.05), asthma perception of timeline (P=0.006), preventer necessity (P=0.01), & personal control (P=0.009)
Pfammatter et al	2016	X									Significant increase in fruit intake (P<0.001), vegetable intake (P<0.001), & physical activity (P<0.001). Significant decrease in fat intake (P<0.001).
Ramachandran et al	2013	X									Significant lower incident of Type 2 diabetes (P=0.015)
Read, E.	2014			X	X		X				Significant improvement in exercise stage (P<0.05), steps/day (P<0.05), & predictive VO2 max (P<0.05). Significant decrease in waist circumference (P<0.05), weight (P<0.05), diastolic BP (P<0.05), & total cholesterol (P<0.05).
Rossi et al	2013		X				X	X	X	X	Significant decrease in long-acting insulin dose (P=0.04). Significant improvement in Diabetes Treatment Satisfaction Questionnaire hyperglycemia score (P=0.004) & Diabetes Specific Quality of Life Scale social relations score (P=0.04).

Authors	Year	Passive Features				Interactive Features					Outcomes
		One-way SMS and Messaging	Electronic Diary	Bluetooth Technology	Reminder	Interactive Prompts	Action/Treatment Plan or Personalized Goals	Two-way or Tailored SMS and Messaging	Upload Data to Provider	CDSS	
Rossi et al	2010		X				X	X	X	X	Significant decrease in triglycerides (P=0.04). Significant improvement in Diabetes Treatment Satisfaction Questionnaire score (P=0.04), Short Form-36 general health score (P=0.02), & Short Form-36 role emotional score (P=0.05).
Ryan et al	2012					X			X	X	No significant difference between baseline & endpoint.
Shetty et al	2011	X									No significant difference between baseline & endpoint.
Strandbygaard, Thomsen, & Backer	2009				X						Significant improvement in mean medication adherence rate (P=0.019).
Stuckey et al	2011		X	X			X	X	X	X	Significant decrease in waist circumference (P=0.002), Body Mass Index (P=0.03), diastolic BP (P=0.046), total cholesterol (P=0.009), training & resting HR (P<0.000/P=0.008). Significant increase in VO2 max (P<0.000) & steps/day (P=0.003).
Tasker et al	2006					X					No significant difference between baseline & endpoint.
Van Olmen et al	2017	X									No significant difference between baseline & endpoint.
Vervloet et al	2014				X					X	Significant improvement in refill adherence (P<0.01/P=0.001).

Authors	Year	Passive Features				Interactive Features					Outcomes
		One-way SMS and Messaging	Electronic Diary	Bluetooth Technology	Reminder	Interactive Prompts	Action/Treatment Plan or Personalized Goals	Two-way or Tailored SMS and Messaging	Upload Data to Provider	CDSS	
Vervloet et al	2012				X					X	Significant number of doses taken within agreed time (P=0.003), within 1 hour of agreed time (P=0.006), within 2 hours of agreed time (P=0.002); within 3 hours of agreed time; (P=0.004), and within 4 hours of agreed time (P=0.007). Significant increase in awareness of medication use (P=0.041).
Waki et al	2014			X				X	X	X	Significant decrease in HbA1c (P=0.015) & fasting blood sugar (P=0.019).
Wayne et al	2015		X					X	X		Significant decrease in Body Mass Index (P=0.04), negative affect subscale (P=0.007), & mental composite score (P=0.03).
Wong et al	2013	X									No significant difference between baseline & endpoint.
Yoo et al	2009			X	X	X		X	X	X	Significant decrease in Low Density Lipids (P=0.025), HgA1c (P=0.001), total cholesterol (P=0.001), & adiponectin (P=0.001).
Zhou et al	2016				X		X	X	X	X	Significant decrease in HbA1c (P<0.01), fasting blood glucose (P<0.01), 2-hour post-prandial glucose (P<0.01). Significant improvement in data knowledge score (P<0.01), & self-care behavior score (P<0.01).

Figure 2.2 displays the frequency of each mHealth feature in the studies. The overall average feature frequency was 16.6 times (27%). On average, each feature was used in less than one-third of the studies. Researchers used interactive features slightly more frequently (53%) than passive features (47%).

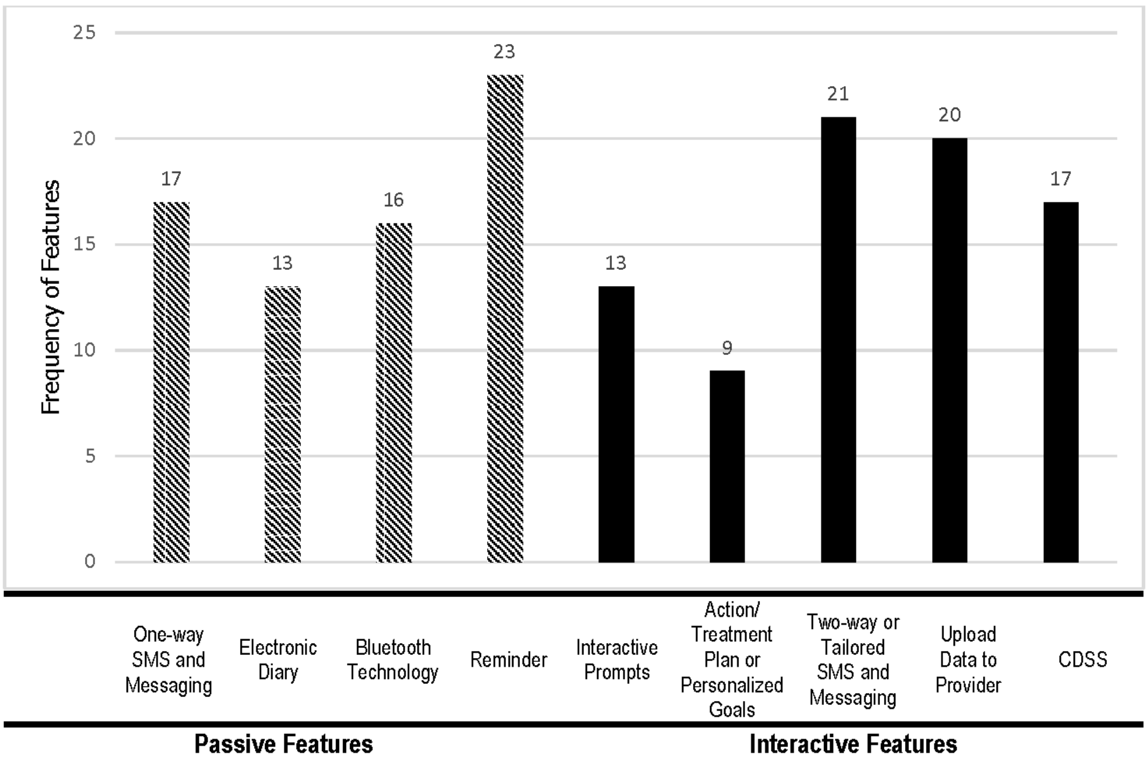

Figure 2.2 Frequency of Features in All Studies

Another analysis evaluated the number of mHealth features used in each study (see Figure 2.3). A higher number of studies used a lower number of mHealth features. Closer examination showed 36 (59%) studies utilized two or fewer mHealth features. This continues to be consistent with prior findings that mHealth is not harnessing the available technology to assist patients with self-monitoring and not including the self-management recommendations (Aitken, M & Lyle, 2015; Chomutare, Fernandez-Luque, Årsand, & Hartvigsen, 2011).

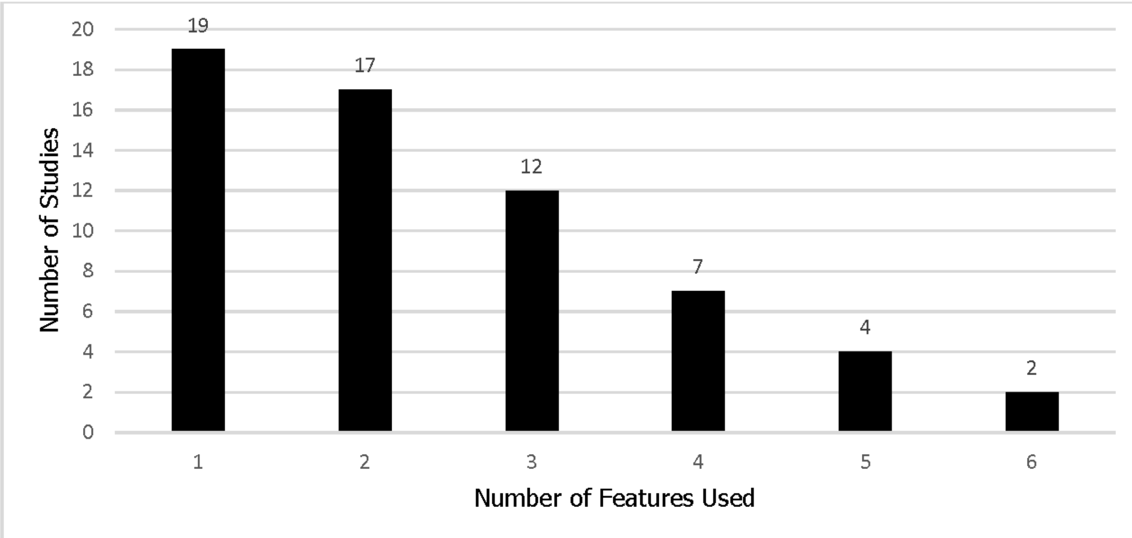

Figure 2.3 Number of Features Used in Each Study

Features and Outcomes. An essential element of this review was to examine the relationship between mHealth features and statistically significant patient outcomes, defined as statistically significant ($P \leq 0.05$) outcomes reported by the researchers. The studies were divided into two groups – studies with statistically significant outcomes (n=43) and studies without statistically significant outcomes (n=18). Since the review focused on chronic health management, we recognized statistically significant outcomes related to improved biometric measurements (i.e., BP, HbA1c) or measurable improvement to health regime (i.e., medication adherence, increase activity, reduced office visits). Four studies reported statistically significant outcomes in Quality of Life scores, self-efficacy, and Perceived Control of Asthma scores (Benhamou et al., 2007; Franklin et al., 2006; Han et al., 2015; Lv et al., 2012). While these tools are certainly essential elements of overall health, they did not meet the criteria of measurable improvements in chronic health management (i.e., improved biometric measurements). Therefore, these studies were included with the studies without statistically significant outcomes since they did not report any statistically significant biometric outcomes.

A comparison of the two groups revealed the studies without a statistically significant outcome used a higher number of passive features (66%) than interactive features (34%; see Table 2.2). This group used one-way SMS as the most frequently used feature (n=7; 24%), and the action treatment plan/ personalized goals was not used at all. In contrast, the group with statistically significant outcomes used fewer passive features (42%) and a slightly higher number of interactive features (58%). The most frequently used feature was reminders (n=20; 16%), and the least frequent feature was the action treatment plan or personalized goals (n=9; 8%).

Further investigation showed the number of studies that exclusively used passive features, interactive features, or a combination of passive and interactive features (see Table 2.3). Studies without statistically significant outcomes exclusively used passive features at a much higher rate (56%) than studies with statistically significant outcomes (21%). A slightly different trend is observed in studies with statistically significant outcomes, which predominately used a combination of passive and interactive features (63%).

Table 2.2 Feature Frequencies by Outcomes

mHealth Features	Studies without Significant Outcomes		Studies with Significant Outcomes	
	Number	Percentage	Number	Percentage
Passive Features				
One-way SMS and Messaging	7	24.1%	10	8.4%
Electronic Diary	3	10.4%	10	8.4%
Bluetooth Technology	6	20.7%	10	8.4%
Reminder	3	10.4%	20	16.6%
Passive Feature Totals	**19**	**65.60%**	**50**	**41.80%**
Interactive Features				
Interactive Prompts	3	10.4%	10	8.4%
Action Treatment Plan/Personalized Goals	0	0%	9	7.5%
Two-way or Tailored SMS and Messaging	3	10.4%	18	14.9%
Upload Data to Provider	2	6.8%	18	14.9%
CDSS	2	6.8%	15	12.5%
Interactive Feature Totals	**10**	**34.40%**	**70**	**58.20%**

Table 2.3 Comparison of Studies by Classification of Features

Classifications of Features	Studies without Significant Outcomes		Studies with Significant Outcomes	
	Number	Percentage	Number	Percentage
Used Only Passive Features	10	56%	9	21%
Used Only Interactive Features	4	22%	7	16%
Used Combination of Both	4	22%	27	63%

These findings generated additional questions on the direct impact and interaction of the mHealth features. For example, Bluetooth technology (i.e., passive features) assists in uploading the biometric measurements into the mHealth app to share with the provider and analysis by the CDSS (i.e., interactive features). It is unclear how the combination of these three features impacts the statistically significant outcomes. This identifies a gap that needs further exploration.

Finally, examining the mHealth features by year failed to show an increase in the mean number of features from 2004 to 2018. During this time, technology advances have greatly increased from basic flip phones to Smartphones; yet, the mean number of mHealth features did not. Table 2.4 shows the mean number of mHealth features gradually increases from 2004 to 2010 when it peaks at 3.7 features per study.

Table 2.4. Mean Number of Features by Study Year

Study Year	**Number of Studies Per Year**	**Mean Number of mHealth Features Per Year**	**Range of mHealth Features Per Year**
2004	1	1.0	
2005	1	2.0	
2006	2	1.5	1-2
2007	1	2.0	
2008	1	2.0	
2009	4	3.3	1-6
2010	3	3.7	2-5
2011	7	2.6	1-6
2012	6	2.0	1-4
2013	8	2.6	1-5
2014	7	2.7	1-4
2015	9	2.6	1-5
2016	5	2.4	1-5
2017	4	2.3	1-3
2018	2	2.5	2-3
	61	2.4	1-6

From 2011 to 2018, the mean number stabilizes between 2.0 to 2.7 features per study. After 14 years of mHealth studies, there is still a limited adoption of available mHealth features. We question the reasoning behind low inclusion rates of mHealth features. One possible explanation is a lack of collaboration between mHealth developers and medical professionals during the development process. Developing an evidence-based mHealth app requires the collaboration of multidisciplinary experts. Cost may also act as barrier to the inclusion of available mHealth features. The inclusion of more features requires a significant amount of time, which translates into increased costs for the developer. Recuperating these costs may be difficult. Other barriers may include the complexity of including features that upload (i.e., Bluetooth) and export to electronic health records (i.e., interoperability). An obvious gap exists between available mHealth features and inclusion rates.

Limitations. One limitation was the lack of consistency in describing mHealth features in the articles. The intervention section did not always include a clear description of the mHealth features. Sometimes we found discrepancies between the description of the mHealth intervention and the screen shots included in the article (Kirwan et al., 2013). This phenomenon may occur because a lack of clearly defined mHealth features. We hope this review initiates a discussion on these features that may result in universal definitions.

Directions for future research. While these initial findings strongly suggest mHealth features can positively influence health outcomes, we recognize this is the first step in examining the impact of the nine mHealth features. Further analysis is necessary to fully understanding the correlation of the types (i.e., passive, interactive) and number of features to statistically significant outcomes. Additional areas for future research include the assessment of mHealth features for other chronic health conditions and overall health and wellness (i.e. weight loss, smoking cessation). Expanding the number of studies along with the types of health conditions will assist in validating these initial findings.

Conclusion

Additional exploration is necessary to identify why more mHealth features are not included in mHealth apps. This process would focus on feedback from mHealth developers to identify barriers to the inclusion of mHealth features. Once barriers are identified, steps can be taken to find solutions.

To our knowledge, this is the first research synthesis that specifically examines mHealth features related to statistically significant outcomes. This research synthesis advances mHealth evidence by correlating passive and interactive mHealth features with positive patient outcomes and validates the findings of other reviews regarding two-way SMS. Our findings suggest that specific mHealth features within the app are the catalyst to promote improved patient outcomes. We are proposing a shift from the mHealth app to the mHealth features.

In addition, these results suggest that mHealth apps under-utilize available technology and fail to include the recommended standards of care for self-monitoring. There is a need for mHealth developers to incorporate more specific, evidence-based features that assist patients in active chronic health management. It is unclear why this phenomenon continues to occur after 14 years of mHealth evidence, which highlights an obvious gap exists in this area. With further expansion and advances in mHealth, it is crucial that the evidence guides future mHealth development.

CHAPTER 3

DEVELOPING AN EVIDENCE-BASED MHEALTH EVALUATION TOOL FOR HEALTHCARE PROVIDERS

Background

Mobile health applications (apps) are one of the fastest growing areas of healthcare with 46% of Americans actively using some type of mobile health (mHealth) app (i.e., disease management, diet, fitness; Adams et al., 2016) However, patient use of mHealth depends on a number of factors including recommendations from the healthcare provider (Adams et al., 2016). Digitas Health reported that 90% of patients stated they would use mHealth if recommended by a healthcare provider (Digitas Health, 2013). Another survey, found that 30% of patients reported downloading a mHealth app based upon a recommendation from the healthcare provider (Adams et al., 2016). It is apparent that patients rely on healthcare providers to guide the selection and use of a mHealth app to manage chronic health conditions and promote health.

One barrier in selecting efficient mHealth apps is the excessive number of available mHealth apps. Currently, more than 325,000 mHealth apps are available for download in the U.S. with fewer than 10% including evidence-based practice and elements that promote positive behavior health changes (Aitken, M & Lyle, 2015; Research2Guidance, 2017). With such an enormous number of available mHealth apps, the process of finding effective and evidence-based mHealth apps can be tedious and time consuming especially for healthcare providers who have significant time constraints. One solution would be a mHealth evaluation tool to assist healthcare providers in the selection of patient-centered and evidence-based mHealth apps.

We identified seven potential mHealth evaluation tools or guides in the current literature: 1) Designing Health Literate Mobile Apps (Broderick et al., 2014); 2) Health IT Usability Evaluation Model (Brown et al., 2013); 3) Heuristic Evaluation of a Mobile Consumer Health Application (Monkman & Kushniruk, 2013); 4) Mobile App Rating Scale (MARS; Stoyanov et al., 2015); 5) The Practice Guide To Evaluating App Usability (mHIMSS, 2012); 6) Suitability of Assessment Materials (Doak et al., 1996); and 7) Towards a Framework for Evaluating Mobile Mental Health Apps (Chan et al., 2015). These tools primarily focus on information technology (IT) features with minimal attention to evidence-based practice, standards of care, and behavior change techniques (see Table 3.1). While IT features are certainly important, they do not necessarily assist with chronic disease management or promote positive health outcomes. Additionally, all evaluation tools are in a paper format with one tool up to seven pages in length (Stoyanov et al., 2015). Some evaluation tools served as a checklist or guide to develop or assess a mHealth app without any type of scoring or rating system (Broderick et al., 2014; Chan et al., 2015). The evaluation tools with a rating mechanism required the user to manually calculate the scores, which included adding, averaging and calculating weighted scores (Doak et al., 1996; mHIMSS, 2012; Stoyanov et al., 2015). In addition, the user received no guidance on the scoring system, and speculated on score's interpretation. It is apparent that healthcare providers need a provider focused mHealth evaluation tool available in a quick and easy format to aid in the identification of evidence-based mHealth.

We propose the development of an online mHealth evaluation tool that calculates the total evaluation score based upon responses and provides immediate feedback on the potential efficacy of the mHealth app to assist healthcare providers in the selection process. Since the healthcare provider is the end-user, it is essential to include the healthcare provider in the development process. This article describes our development process of a mHealth evaluation tool using feedback from healthcare providers.

Specific Aims

The Obesity-Related Behavioral Intervention Trials (ORBIT) model was used to guide this research (Czajkowski et al., 2015). The ORBIT model was originally designed to develop behavioral interventions that promote physical health outcomes, which improves general health and wellness. The overall goals of the ORBIT model and mHealth, improve patient outcomes, are identical. Therefore, the ORBIT model is an appropriate model to guide and direct this research. The methodical path of the model provided a systematic process to develop a mHealth evaluation tool through a robust chain of evidence (see Figure 3.1).

According to Czajkowski and colleagues (2015), this phase of the process defines the basic elements of the tool using the scientific evidence, and refines the tool to promote efficiency. This article focuses on the first steps of the

Table 3.1 Summary of Current mHealth Evaluation Tools

mHealth Evaluation Tool	Purpose	Domains (# of Features)	Rating Scale	Strengths	Weaknesses
Designing health literate mobile apps (Broderick, et. al., 2013)	Checklist for mHealth developers to guide the development of health literate apps.	• Users (3) • Actionable Content (5) • Display Content (9) • Organization (7) • Engagement (5) • Evaluation (5)	None	• Addresses mHealth literacy.	• Not evaluation tool • Not designed for the healthcare provider • No assessment of evidence-based practice or patient outcomes.
Assessment of the Health IT Usability Evaluation Model (Health-ITUM) for evaluating mobile health technology (Brown, Yen, Rojas, & Schnall, 2013)	Assess the usability of mHealth technology	• Error prevention (1) • Completeness (1) • Memorability (1) • Information needs (1) • Flexibility/ Customizability (1) • Learnability (1) • Performance speed (1) • Competency (1) • Other outcomes (1)	Positive, Negative, and Neutral	• Included minority participants	• Does not address content or features of mHealth app. • Not designed for healthcare provider. • Raters were adolescents.
Framework for Evaluating Mobile Mental Health Apps (Chan, Torous, Hinton, & Yellowlees, 2015)	Uses telemental health guidelines	• Usefulness dimension (4) • Usability dimension (5) • Integration & infrastructure dimension (5) • Workfow (7)	None	• Focused on the healthcare provider • Included assessment of outcome	• Not evaluation tool • Does not provide a rating scale • Focuses on mental health

mHealth Evaluation Tool	Purpose	Domains (# of Features)	Rating Scale	Strengths	Weaknesses
Suitability Assessment of Materials (Doak, Doak, & Root, 1996).	Systematic method to assess the suitability of health information for a specific audience.	• Content (3) • Literacy Demand (5) • Graphics, Lists, etc. (5) • Layout/Typography (3) • Learning Stimulation & Motivation (3) • Cultural Appropriate (2)	Superior=2 points Adequate=1 point Not Suitable=0 point	• Included assessment of cultural aspects.	• Not specific for mHealth. • Expects the user to know how to calculate the Flesch Reading Ease scale. • No assessment of evidence-based practice or patient outcomes
Selecting a mobile app: Evaluating the usability of medical applications, (mHIMSS App Usability Work Group, 2012)	Assist healthcare providers or IT staff in selecting mobile apps for practice or hospital organization	• System Usability (10)	5-point Likert Scale Sum of scores multiplied by 22.5.	• Simple to use • Clearly focused questions	• Subjective assessment (like, think, believe). • No assessment of evidence-based practice or patient outcomes
A health literacy and usability heuristic evaluation of a mobile consumer health application, (Monkman, & Kushniruk, 2013)	Identify interface and information design problems in mHealth apps.	• Screens (2) • Content (9) • Display (7) • Navigation (7) • Interactivity (4)	Rate the heuristic violation as: Mild, Moderate, or Severe	• Simple to use • Clearly focused questions	• Not designed for the healthcare provider. • No assessment of evidence-based practice or patient outcomes
Mobile app rating scale: A new tool for assessing the quality of health mobile apps (Stoyanov, et. al., 2015)	Classify and rate the quality of mHealth apps for researchers	• Engagement (5) • Functionality (4) • Aesthetics (3) • Information (7) • Subjective quality (4)	5-point Likert scale. Calculate the domain mean; the overall mean; & the subjective quality mean.	• Assed the inclusion of evidence-based practice.	• Lengthy & time-consuming • 30-min. training video prior to use. • Not designed for healthcare provider. • Tested by two researchers • No assessment of evidence-based practice or patient outcomes

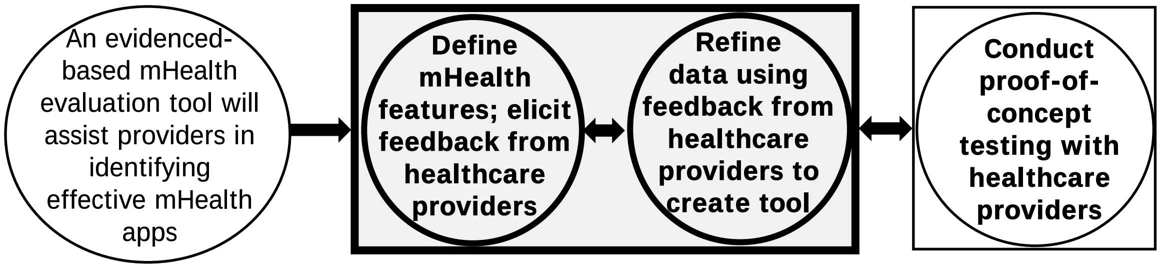

Figure 3.1 ORBIT Model to Define and Refine mHealth Features (Czajkowski et al., 2015)

development process presented in the bolded box in Figure 3.1. The proof-of concept testing is described in Chapter 4.

Specifically, the aims for this phase of the development process included:

1. define a comprehensive pool of domains and features utilizing the current mHealth evaluation tools described above and findings from a research synthesis on mHealth studies (Donevant et al., 2016);
2. obtain feedback from healthcare providers on the: “essential”; ”important”; and “nonessential” elements in mHealth apps via an Research Electronic Data Capture (REDCap; Harris et al., 2009) survey;
3. develop a mHealth evaluation tool for healthcare providers using the feedback from the survey.

Methods

Prior to the start of the study, the Institutional Review Board at University of South Carolina reviewed and approved the study. The healthcare provider survey was conducted in REDCap, an online secure research database (Harris et al., 2009), and IBM SPSS Statistics for Windows (Version 25.0) was used for frequency analysis and factor analysis of the survey results.

Define Comprehensive Pool of Domains and Features. The first step was to define a comprehensive pool of domains and features for inclusion in the mHealth evaluation tool (DeVellis, 2012). The comprehensive pool of domains and features included the current mHealth evaluation tools described above with the findings of a research synthesis that identified nine mHealth features correlated to statistically significant outcomes (Donevant et al., 2016). Since our goal was to produce an evaluation tool that identified evidence-based mHealth apps, it was crucial tool included the evidence on mHealth features.

Initially, the comprehensive list included a total of 156 features from the evaluation tools (n=147) and the mHealth research synthesis (n=9). Next, duplicate items were combined into a single item. For example, several tools included a performance feature: “Performance speed: Users are able [to] use the system efficiently” or “How accurately/fast do the app features (functions) and components (buttons/menus) work?” (Brown et al., 2013, p. 1084; Stoyanov et al., 2015, p. 3). These were combined into a single feature statement to alleviate redundancy and generate a manageable survey. Once all duplicate items were combined, the comprehensive pool included 6 domains with 79 features (see Table 3.2).

Table 3.2 Comprehensive Pool of Domains and Features

App Login/Registration
1. The app requires a login for access.
2. The app includes a simple and obvious registration and login.
3. The app utilizes a password protected login.
App Engagement
1. The app includes fun activities such as games that advance health knowledge and encourage positive health behavior change.
2. The app provides interesting and relevant activities such as quizzes, readings, and videos.
3. The app offers options to send reminders to the patient.
4. The app presents instructions on performing actions and tasks (entering data, uploading biometric measurements, etc.).
5. The app explains the health benefits of completing actions and tasks (entering data uploading biometric measurements, etc.).
6. The app includes an engaging and interactive home screen that is simple and direct.
7. The app incorporates a clinical decision support system to guide the patient in making health decisions.
8. The app provides clear, concise, and informative alerts.
9. The app performs calculations automatically (age based upon date-of-birth).
10. The app asks questions to engage the patient in the healthcare process.
11. The app allows the patient to input clinical and medical data (medical history, sleep hours, blood pressure, etc.) for self-monitoring.
12. The app uses Bluetooth to upload biological measurements (blood pressure, glucose levels, etc.).
13. The app allows the patient and provider to create specific measurable and achievable health goals.
14. The app permits the patient to customize and tailor app settings to meet the individual health needs.
15. The app encourages continued use of the app for optimal health management.
App Communication Modalities
1. The app allows connection with social media (Facebook, Twitter, Instagram).
2. The app uploads the patient's biometric measurements to the healthcare provider for review.
3. The app incorporates a health focused app community.
4. The app allows two-way communication with the healthcare providers (texting, e-mail, EHR).
5. The app includes a robust privacy policy that meets HIPAA standards.
App Content
1. The app uses appropriate content for desired population (age, culture, socioeconomic status, etc.).
2. The app includes accurate evidence-based clinical information and standards of care.
3. The app clearly displays content in the center of the screen and above the fold (content is visible without scrolling).
4. The app groups similar topics and categories together.
5. The app uses text written in plain language (avoids jargon and medical terms, uses short sentences of 15-20 words, limit paragraph size, use labels that reflect the user's knowledge).
6. The app displays the most important information first.
7. The app uses clearly defined and meaningful headings, labels, and icons.
8. The app effectively uses clearly labeled links.

9. The app uses comprehensive and relevant content congruent with the topic and goal of the app.
10. The app contains content within its stated scope.
11. The app incorporates evidence-based behavior change techniques to encourage behavior changes.
12. The app includes action-based content with a positive and realistic approach.
13. The app emphasizes health behaviors and skills rather than facts.
14. The app uses clear and unambiguous lists or entry-form choices.
15. The app presents information for a particular task on a single screen.
16. The app clearly defines its purpose.
17. The app presents content at a 5th grade or lower reading level.
18. The app increases the patient's knowledge, awareness, and understanding.

App Functionality

1. The app features function properly.
2. The app uses a minimum of steps to perform functions.
3. The app responds to actions and tasks in <3-4 seconds.
4. The app helps the user prevent and correct mistakes.
5. The app functions the same way from session to session.
6. The app incorporates an easy-to-learn and use format.
7. The app contains easily accessible and highly visible home and menu screens.
8. The app meets the needs of patients with disabilities (hearing, visible, etc.) with appropriate adaptive features.
9. The app uses a single data entry location for patient data that is used in multiple locations.
10. The app accounts for different levels of technology skills (experienced, novice, inexperienced).
11. The app flows in a logical, accurate, and appropriate movement between screens.
12. The app uses linear information paths (each topic has its own pages that follow a logical sequence).
13. The app offers search/browse options.
14. The app provides information feedback on completed actions and tasks.
15. The app displays explanatory messages (hourglass, sliders, beachballs, etc.) when processing actions and tasks.
16. The app includes shortcuts to actions and tasks.
17. The app uses consistent, intuitive, and simple taps, swipes, and scrolls.
18. The app uses a back button to return to previous screens.
19. The app integrates with other apps such as e-mail, calendar and maps.
20. The app workflow matches clinical practice and patient needs.

App Aesthetics

1. The app uses a hierarchical arrangement of buttons, icons, menus, and content.
2. The app offers large screen buttons or the ability to enlarge the screen.
3. The app incorporates images that facilitate learning.
4. The app includes audio features.
5. The app contains clear, logical, and accurate graphics.
6. The app uses captions to explain the graphics.
7. The app uses appropriate white space with minimal clutter.
8. The app uses consistent format, fonts, and layouts.
9. The app includes an easily readable font with appropriate size and does not use all caps.
10. The app uses bold colors with contrast and avoids dark backgrounds.
11. The app incorporates colors that convey meaning (red indicates urgency).
12. The app uses visual features.

App Description and Credibility

1. The app store provides an accurate description of the app.

2. The app originates from a reputable developer and organization.
3. The app offers an option for users to share feedback with app designers.
4. The app includes printer-friendly tools and resources.
5. The app was tested with the results reported in scientific literature.
6. The app reviews in iTunes or Google Play offer unbiased and relevant feedback on the app.

This comprehensive pool of domains and features served as the online survey in the REDCap platform (See Appendix A). The research team elected to use three category responses – 1) "Essential," feature must be in the app; 2) "Important," prefer the feature to be in the app; and 3) "Nonessential," feature had no relevance when selecting the app. These three options provided simple, yet effective response options.

Decision Logic for Inclusion and Exclusion of Features. The research team defined the features' inclusion and exclusion criteria in the evaluation tool prior to the start of the survey. Any response with $\geq$50% would be included and any response with <10% was excluded from the evaluation tool. The research team would determine inclusion or exclusion in the evaluation tool for responses <50% and >10%. Details for inclusion and exclusion decision logic are provided in Table 3.3. The nine mHealth features were exceptions to this rule. Since these features originate from the evidence, it was decided to include these nine features as "Essential."

REDCap Survey. The REDCap survey request was e-mailed to 17,302 healthcare providers with a cover letter explaining the purpose of the survey. The e-mails were obtained from North Carolina licensing board and publicly available e-mails posted on websites. In addition, we posted the survey request

Table 3.3 Decision Logic for the Inclusion/Exclusion of Features

Decision Logic			
Essential	**Important**	**Nonessential**	**Outcome**
≥50%	<50%	<50%	Include feature as Essential
<50%	≥50%	<50%	Include feature as Important
<50%	<50%	≥50%	Exclude feature
>10% to <50%	>10% to <50%	>10% to <50%	Research team decides inclusion/exclusion
<10%	>10% to <50%	>10% to <50%	Research team decides inclusion/exclusion
>10% to <50%	<10%	>10% to <50%	Research team decides inclusion/exclusion
>10% to <50%	>10% to <50%	<10%	Research team decides essential or important

in online communities for providers (i.e., Nurse Lounge, Reddit, Jonas Scholar) and shared with several healthcare organizations (i.e., South Carolina American Medical Association, South Carolina Academy of Physician Assistants, etc.). All responses were anonymous and no identifying information was collected including e-mail, which may potentially contain all or part of an individual's name. The survey was available from September 2017 to January 2018.

Upon accessing the survey, the healthcare provider was asked, "Do you recommend mobile health apps to your patients?" We believed the experience of healthcare providers who recommended mHealth apps offered an essential perspective on the decisive mHealth features. Therefore, the survey focused on providers who recommend mHealth apps. Based upon this criterion, a "No" response resulted in a thank you message with a link to exit the survey; and, a "Yes" response allowed the participant access to the survey.

The REDCap survey included two instructional videos explaining the research and survey instructions. After viewing the videos and reading the informed consent, the healthcare providers could agree or not agree to participate in the survey. Any healthcare provider who did not consent to participate, received a thank you message with an exit link.

Results

REDCap's online secure database stored the survey results and allowed remote access by the research team. Once the survey was closed, the raw data was exported directly from REDCap to SPSS for review and analysis. The analysis provided the foundation for the development of the evaluation tool.

Refining the Comprehensive Pool with Feedback from Healthcare Providers. A total of 347 healthcare providers responded, with 108 (31%) "Yes" responses to the first question about recommending mHealth apps to patients. One response did not respond to any further questions and another did not consent to participate in the survey, which resulted in 106 survey responses. The demographics of the healthcare providers are provided in Table 3.4.

The next step was to obtain the frequency statistics on the responses and apply the decision logic to determine the inclusion and exclusion of the features. Almost 75% (n=59) of the features had a frequency of $\geq$50% in the "Essential" or "Important" categories. Only one feature received $\leq$50% in the "Nonessential" category, "The app allows connection with social media (Facebook, Twitter, Instagram)." The remaining features (n=19) had frequencies between >10% and <50% and required the research team to determine the inclusion or exclusion in the evaluation tool. The research team was provided with a REDCap

Table 3.4 Demographics of Healthcare Providers

Categories	Number	Percentage
Type of Healthcare Provider		
Physician	37	34.9%
Physician Assistant	0	0.0%
Nurse Practitioner	64	60.4%
Prefer Not to Answer	5	4.7%
Type of Practice		
Acute Care Facility	28	26.4%
Long-Term Care	3	2.8%
Medical Office	52	49.1%
Hospice	2	1.9%
Other*	19	17.9%
Prefer Not to Answer	2	1.9%
Years in Medical Practice		
<10 years	41	38.7%
10-20 years	30	28.3%
21-30 years	18	17.0%
>30 years	17	16.0%
Prefer Not to Answer	0	0.0%
Gender		
Male	28	26.4%
Female	76	71.7%
Prefer Not to Answer	2	1.9%
Age		
20-30 years of age	8	7.5%
31-45 years of age	35	33.0%
46-60 years of age	50	47.2%
>60 years of age	13	12.3%
Prefer Not to Answer	0	0.0%
Race/Ethnicity		
American Indian/Alaskan Native	1	0.9%
African American	12	11.4%
Asian	5	4.7%
Caucasian	82	77.4%
Hispanic, Latino, or Spanish	3	2.8%
Native Hawaiian or other Pacific Islander	0	0.0%
Prefer Not to Answer	3	2.8%

* Home health, Outpatient psychiatric office, Anesthesia, Urgent Care, Mental health office, Health department, College health, Medical office/acute care facility, Methadone clinic, Addiction treatment, Neurology/academia, Academic primary care hospital, Child advocate

survey that included the 19 undecided features, which allowed the research team to provide feedback on these features. The responses were added the existing responses, and the additional feedback placed all 19 features in either the "Essential" or "Important" categories. A total of 78 features were ranked "Essential" or "Important" by healthcare providers and the research team.

Next, a factor analysis was completed to condense the features and prevent overlap between the features (DeVellis, 2012). The analysis used the Dimension Reduction option in SPSS with Quartimax rotation and the option to suppress small coefficients <0.3. These results identified features with moderate to strong correlations, which allowed the combination of multiple features into a single feature. For example, a strong to moderate correlation (0.416 to 0.856) was observed between: 1) "The app utilizes a password protected login;" 2) "The app requires a login for access;" and 3) "The app includes a robust privacy policy that meets HIPAA standards." These features were transformed into a single statement: "The app includes a robust privacy policy with a required password protected login that meets the HIPAA standards." This process was completed on all moderate to strong correlations, which resulted in 32 combined feature statements organized in 6 domains.

When two or more features were merged into a new feature, the original responses were averaged together into a new variable for analysis. Frequency statistics were obtained on the new variables. The new statistics showed 22 "Essential" and 10 "Important" features achieved the ≥50% threshold. The revised domains and features serves as the foundation for the mHealth evaluation tool. Table 3.5 shows the revised domains feature statements with the final category (i.e., “Essential” and “Important”).

Limitations: Ideally, a large sample size is preferred for a factor analysis for generalizability. In this case, the purpose of the factor analysis was to identify correlations to reduce the number of variables. In addition, future testing (i.e., proof-of-concept, pilot testing, efficacy trial, and effectiveness research) of the mHealth app will assist in validating the evaluation tool for generalizability.

Conclusions

This is the first step of developing a mHealth evaluation tool for healthcare providers that include mHealth evidence and input from healthcare providers. During this step of the development process, the healthcare provider’s feedback was essential in guiding the development of the evaluation tool. The next step is the proof-of-concept testing on the evaluation tool, which also utilizes healthcare providers. Ultimately, the mHealth evaluation will be offered in an online format for healthcare providers to quickly access and evaluate any mHealth app with instant feedback.

Table 3.5 Revised Domains and Features

Domain and Feature Statements	Category
App Login/Registration	
1. The app includes a robust privacy policy with a required password protected login that meets HIPAA standards.	Important
2. The app includes a simple and obvious registration and login.	Essential
App Engagement	
1. The app includes fun, relevant activities such as games and quizzes that advance health knowledge and encourage positive health behavior change.	Important
2. The app encourages continued use of the app for optimal health management by allowing the patient to customize and tailor the settings to meet individual health goals.	Essential
3. The app presents population appropriate (age, culture) instructions and health benefits of performing actions and tasks (entering data, uploading biometric measurements, etc.).	Essential
4. The app incorporates a clinical decision support system to guide the patient in making health decisions by providing clear, concise, and informative alerts.	Essential
5. The app allows the patient and provider to create specific, measurable, and achievable health goals by emphasizing health behaviors and skills rather than facts.	Essential
App Communication Modalities	
1. The app use Bluetooth to upload the patient's biometric measurements to the app.	Essential
2. The app allows two-way communication with healthcare provider (texting, e-mail, messaging via EHR).	Essential
3. The app automatically shares the information with the patient's provider for review and feedback.	Essential
App Content	
1. The app displays similar topics and categories together in the center of the screen and above the fold (content visible without scrolling).	Important
2. The app flows in logical and linear information paths (each topic has its own page that follows a logical sequence) between screens with visible back button.	Important
3. The app provides explanatory and feedback messages (hourglass, sliders, beachballs, etc.) when processing and completing actions and tasks.	Important
4. The app uses an engaging screen that displays the important information first on a single screen.	Essential
5. The app contains content within its stated scope and purpose.	Essential
6. The app includes evidence-based clinical information and standards of care.	Essential
7. The app uses text written in plain language at a 5th grade or lower reading level that (avoids jargon and medical terms, short sentences of 15-20 words, limit paragraph size, use labels that reflect the user's knowledge).	Essential
8. The app uses clearly defined and meaningful links, headings, labels, and icons.	Essential
9. The app includes action-based behavior change techniques with a positive and realistic approach (asking questions, inputting clinical and medical data, reminders) to encourage behavior change and an increase in the patient's knowledge, awareness, and understanding.	Essential
10. The app workflow includes shortcuts to actions and tasks to match clinical practice and patient needs.	Essential

11. The app uses a minimum number of steps to perform actions and tasks that operates the correctly from session to session with a response of < 3-4 seconds.	Essential
12. The app contains comprehensive and relevant congruent content on easily accessible and highly visible screens that includes an easily readable font with appropriate size (not using ALL CAPS).	Essential
App Functionality	
1. The app includes tools and resources: integration with other apps (calendar, maps, e-mail), health focused app communities, search/browse options, and printers.	Important
2. The app accommodates different levels of technology skills and needs including patients with disabilities (adaptive features for hearing, vision, etc.).	Essential
3. The app uses a single data entry location for patient data that is used in multiple locations such as calculations for age based upon date of birth.	Essential
4. The app uses consistent, intuitive, and simple format (taps, swipes, and scrolls) in an easy-to-use format that helps the user prevent and correct mistakes.	Essential
App Aesthetics	
1. The app uses a hierarchical arrangement of buttons, icons, menus, lists, entry-form choices, images, and content that can be enlarged while incorporating colors the convey meaning (red indicates urgency).	Important
2. The app utilizes consistent format, fonts, and layout that uses contrasting bold colors with appropriate white space (avoiding dark backgrounds) and minimal clutter.	Important
3. The app contains clear, logical, and accurate graphics, audio, or video with captions to enhance learning.	Important
App Description and Credibility	
1. The app reviews in iTunes or Google Play offer unbiased and relevant comments and allows the users to share feedback with the app designers.	Important
2. The app store provides an accurate description including the results of any scientific testing involving the app.	Essential
3. The app originates from a legitimate developer and organization.	Essential

CHAPTER 4

PROOF-OF-CONCEPT TESTING OF MHEALTH EVALUATION TOOL FOR HEALTHCARE PROVIDERS

Background

Patients' adoption rates of mobile health applications (apps) are at an all-time high with 46% reporting the use at least one mobile health (mHealth) app (Adams et al., 2016). Healthcare providers may have contributed to this recent increase in patient adoption of mHealth (Comstock, 2018). One mHealth survey found that 90% of patients reported they would use mHealth if recommended by a healthcare provider (Digitas Health, 2013). Rock Health, a venture fund dedicated to digital health, reported that 30% of patients downloaded a mHealth app based upon the recommendation of a healthcare provider (Adams et al., 2016). Healthcare providers are clearly a factor in patients' use of mHealth apps to manage chronic health conditions and promote health.

However, healthcare providers may struggle with locating effective and evidence-based mHealth apps due to the overwhelming number of mHealth apps. Currently, over 325,000 mHealth apps are available for download in the U.S. with less than 10% including evidence-based practice, standards of practice, and techniques that promote positive health changes (Aitken, M & Lyle, 2015; Research2Guidance, 2017). The process of locating evidence-based mHealth apps can be tedious and labor-intensive for healthcare providers who are busy providing patient care. Limited evaluation tools are available to assist healthcare providers in this process. Therefore, our goal was to develop an online mHealth evaluation tool to assist healthcare providers in the selection of evidence-based mHealth apps.

In a previous article we described the process of developing an evaluation tool specifically for healthcare providers (Donevant, Culley, Estrada, Habing, & Adams, 2018). Healthcare providers used an online survey to identify the “Essential” and “Important” mHealth features from a comprehensive pool of domains and mHealth features. The process generated the beta version of the mHealth evaluation tool from the providers’ perspective (Donevant et al., 2018). This article describes the proof-of-concept testing of the mHealth evaluation tool.

Specific Aims

We selected the Obesity-Related Behavioral Intervention Trials (ORBIT) model to guide the development of the evaluation tool (Czajkowski et al., 2015). The ORBIT model was designed to develop evidence-based behavioral interventions to prevent and treat chronic health conditions. Since mHealth apps incorporate behavior interventions to manage chronic health conditions, the ORBIT model was a logical selection to guide and direct this research. This systematic process provides a methodological chain of evidence to support the development of the mHealth evaluation tool (see Figure 4.1).

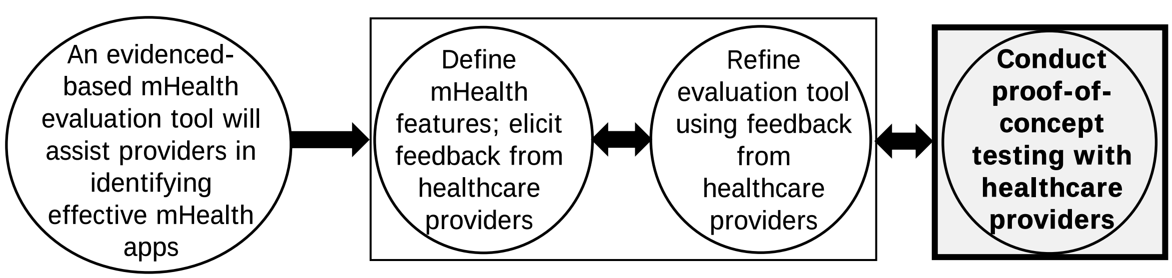

Figure 4.1 ORBIT Model for Proof-of-Concept Testing of mHealth Evaluation Tool (Czajkowski et al., 2015)

The goal of this phase is to determine the clinical benefit of the tool (Czajkowski et al., 2015). Czajkowski and colleagues (2015) explained the testing determines if the intervention merits more rigorous testing. Therefore, sample size calculations were not necessary. The sample selection was obtained from available subjects. The specific aims included:

1. assign the response options for the evaluation tool with the weighted scores;
2. identify the range of potential scores that determine the quality of the app;
3. select mHealth apps for testing – 2 for asthma, 2 for diabetes, and 2 for hypertension (HTN);
4. conduct proof-of-concept testing on the mHealth evaluation tool using the Research Electronic Data Capture (REDCap; Harris et al., 2009).

Methods

The University of South Carolina Institutional Review Board reviewed and approved this study. We used the REDCap survey option to conduct the proof-of-concept testing on the beta version of the mHealth evaluation tool (see Table 4.1). Statistical analysis was conducted in IBM SPSS Statistics for Windows (Version 25.0).

Assign the response options for the evaluation tool with the weighted scores. With the domains and features refined, the research team defined the response options and the weight of the category (i.e., "Essential"

Table 4.1 Domains and Features for mHealth Evaluation Tool

Domain and Feature Statements	Category
App Login/Registration	
1. The app includes a robust privacy policy with a required password protected login that meets HIPAA standards.	Important
2. The app includes a simple and obvious registration and login.	Essential
App Engagement	
1. The app includes fun, relevant activities such as games and quizzes that advance health knowledge and encourage positive health behavior change.	Important
2. The app encourages continued use of the app for optimal health management by allowing the patient to customize and tailor the settings to meet individual health goals.	Essential
3. The app presents population appropriate (age, culture) instructions and health benefits of performing actions and tasks (entering data, uploading biometric measurements, etc.).	Essential
4. The app incorporates a clinical decision support system to guide the patient in making health decisions by providing clear, concise, and informative alerts.	Essential
5. The app allows the patient and provider to create specific, measurable, and achievable health goals by emphasizing health behaviors and skills rather than facts.	Essential
App Communication Modalities	
1. The app use Bluetooth to upload the patient's biometric measurements to the app.	Essential
2. The app allows two-way communication with healthcare provider (texting, e-mail, messaging via EHR).	Essential
3. The app automatically shares the information with the patient's provider for review and feedback.	Essential
App Content	
1. The app displays similar topics and categories together in the center of the screen and above the fold (content visible without scrolling).	Important
2. The app flows in logical and linear information paths (each topic has its own page that follows a logical sequence) between screens with visible back button.	Important
3. The app provides explanatory and feedback messages (hourglass, sliders, beachballs, etc.) when processing and completing actions and tasks.	Important
4. The app uses an engaging screen that displays the important information first on a single screen.	Essential
5. The app contains content within its stated scope and purpose.	Essential
6. The app includes evidence-based clinical information and standards of care.	Essential
7. The app uses text written in plain language at a 5th grade or lower reading level that (avoids jargon and medical terms, short sentences of 15-20 words, limit paragraph size, use labels that reflect the user's knowledge).	Essential
8. The app uses clearly defined and meaningful links, headings, labels, and icons.	Essential
9. The app includes action-based behavior change techniques with a positive and realistic approach (asking questions, inputting clinical and medical data, reminders) to encourage behavior change and an increase in the patient's knowledge, awareness, and understanding.	Essential
10. The app workflow includes shortcuts to actions and tasks to match clinical practice and patient needs.	Essential

11. The app uses a minimum number of steps to perform actions and tasks that operates the correctly from session to session with a response of < 3-4 seconds.	Essential
12. The app contains comprehensive and relevant congruent content on easily accessible and highly visible screens that includes an easily readable font with appropriate size (not using ALL CAPS).	Essential
App Functionality	
1. The app includes tools and resources: integration with other apps (calendar, maps, e-mail), health focused app communities, search/browse options, and printers.	Important
2. The app accommodates different levels of technology skills and needs including patients with disabilities (adaptive features for hearing, vision, etc.).	Essential
3. The app uses a single data entry location for patient data that is used in multiple locations such as calculations for age based upon date of birth.	Essential
4. The app uses consistent, intuitive, and simple format (taps, swipes, and scrolls) in an easy-to-use format that helps the user prevent and correct mistakes.	Essential
App Aesthetics	
1. The app uses a hierarchical arrangement of buttons, icons, menus, lists, entry-form choices, images, and content that can be enlarged while incorporating colors the convey meaning (red indicates urgency).	Important
2. The app utilizes consistent format, fonts, and layout that uses contrasting bold colors with appropriate white space (avoiding dark backgrounds) and minimal clutter.	Important
3. The app contains clear, logical, and accurate graphics, audio, or video with captions to enhance learning.	Important
App Description and Credibility	
1. The app reviews in iTunes or Google Play offer unbiased and relevant comments and allows the users to share feedback with the app designers.	Important
2. The app store provides an accurate description including the results of any scientific testing involving the app.	Essential
3. The app originates from a legitimate developer and organization.	Essential

and “Important”) responses. The decision was made to offer three response options for the feature statements: 1) “Included throughout the app” – the feature was included throughout the app; 2) “Included partially” – the features was only used partially throughout the app; and 3) “Not included” – did not include the feature at all. These three options offered a simple response matrix while providing appropriate selection options for the healthcare provider. The weight of the response depended upon the category (i.e., “Essential” or “Important”) and the response option (i.e., “Included throughout the app”, "Included partially", "Not included"). The "Essential" category had a weight double the "Important" category (see Table 4.2).

Determine the app quality based upon the potential scores. The next step was to determine the quality of a mHealth app based upon the scores. During this process, we replicated different response combinations to determine possible scores. The lowest possible score was "0" and the highest was "108."

Poor-Quality Range. The "0" provided the lowest score of the poor-quality app. In this category, none of the "Essential" features were included. Since the "Essential" features included the evidence-based features, the absence of these features would not indicate a quality app to achieve positive outcomes. The upper threshold would completely include the "Important" features (i.e., score of 20).

High-Quality Range. Since the "Essential" features contained the mHealth evidence, a high-quality app must completely include the "Essential" features to promote positive outcomes. However, the "Important" features were preferences and not supported by evidence. For example, displaying similar content on a single screen above the fold (i.e., content that is visible without scrolling) may be aesthetically preferred, but there is no evidence that this promotes positive patient outcomes. Based upon this, a high-quality app would need to include all the "Essential" features, but not necessarily any of the "Important" features.

Table 4.2 Points Based upon Response Option and Category

Response Option	Category	
	Essential	Important
Included throughout the app	4	2
Included partially	2	1
Not included	0	0

The high threshold of a high-quality app was a score of 108 and included all the "Essential" and "Important" features throughout the app. Alternatively, the low threshold of a high-quality app would still completely include the "Essential" features, but not include the "Important" features (i.e., score of 88).

Moderate-Quality Range. The moderate-quality range falls between the high threshold of the poor-quality app (i.e., score of 21) and the low threshold of the high-quality app (i.e., score of 87). This range only partially includes the "Essential" features, which indicates the mHealth app only partially includes the evidence. With only partial inclusion of the evidence, the mHealth may not necessarily optimize positive patient outcomes.

The final quality ranges included: 1) poor-quality app – 0 to 20; 2) moderate-quality app – 21 to 87; 3) high-quality app – 88 to 108. See Table 4.3 for additional details on the potential scores based upon potential responses.

Select mHealth apps for testing. The proof-of-concept testing process required the healthcare provider to use the evaluation tool to assess two pre-selected mHealth apps for each chronic disease - asthma, diabetes, and HTN. This methodology allowed for comparison between the scores of the two apps

Table 4.3 Potential Scores Based Upon Response Options and Categories

Essential	Important	Score	Quality of App
"Not included"	"Not included"	0	Poor
"Not included"	"Included partially"	10	Poor
"Not included"	"Included throughout the app"	20	Poor
"Included partially"	"Not included"	44	Moderate
"Included partially"	"Included partially"	54	Moderate
"Included partially"	"Included throughout the app"	64	Moderate
"Included throughout the app"	"Not included"	88	High
"Included throughout the app"	"Included partially"	98	High
"Included throughout the app"	"Included throughout the app"	108	High

and to a Gold Standard score determined by the research team. The criteria for the pre-selected apps included 1) free to use and 2) available in iOS and Android platforms. Figure 4.2 provides the pre-selected apps with the Gold Standard score.

Conduct proof-of-concept testing. Three separate evaluation tools (i.e., one for asthma, one for diabetes, one for HTN) were created in the REDCap survey option (See Appendix B). Each survey allowed the healthcare providers to evaluate both pre-selected apps in a single survey. Furthermore, the evaluation tools were developed to automatically calculate the quality score and provide a recommendation based upon the responses.

Healthcare providers were recruited through healthcare organizations (i.e., state nurse practitioner organizations, state physician assistant organizations, state medical organizations) and online medical communities (i.e., Reddit, Nurse Lounge, Jonas Scholar, etc.). Each organization or online medical community randomly received one of the three evaluation tools (i.e., one for diabetes,

Type of App	App Information	Gold Standard (Score)
Asthma	AsthmaMD	High (99)
	Asthma Tracker	High (88)
Diabetes	One Drop	High (90)
	Diabetes Connect	Moderate (61)
Hypertension	iHealth MyVitals	High (99)
	Smart BP	High (98)

Figure 4.2 Selected mHealth Apps for Testing

asthma, and HTN). All responses were anonymous and did not collect any identifying information including e-mail.

Results

Once the healthcare providers gave consent to participate in the testing, access to the survey was granted. A total of 26 providers began the mHealth assessment - 4 diabetes evaluations, 12 HTN evaluations, and 10 asthma evaluations. The combined provider demographics from all surveys are provided in Table 4.4.

Table 4.4 Demographics of Healthcare Providers

Categories	Number	Percentage
Type of Healthcare Provider		
Physician	0	0.0%
Physician Assistant	11	42.3%
Nurse Practitioner	12	46.2%
Prefer Not to Answer	4	11.5%
Type of Practice		
Acute Care Facility	5	19.2%
Long-Term Care	0	0.0%
Medical Office	14	53.9%
Hospice	2	7.7%
Other*	4	15.4%
Prefer Not to Answer	1	3.8%
Years in Medical Practice		
<10 years	8	30.8%
10-20 years	5	19.2%
21-30 years	10	38.5%
>30 years	2	7.7%
Prefer Not to Answer	1	3.8%
Gender		
Male	6	23.1%
Female	19	73.1%
Prefer Not to Answer	1	3.8%
Age		
20-30 years of age	6	7.7%
31-45 years of age	16	61.5%
46-60 years of age	4	15.4%
>60 years of age	4	15.4%
Prefer Not to Answer	0	0.0%
Race/Ethnicity		
American Indian/Alaskan Native	1	3.8%
African American	4	15.4%
Asian	8	30.8%
Caucasian	11	42.4%
Hispanic, Latino, or Spanish	0	0.0%
Native Hawaiian or other Pacific Islander	1	3.8%
Prefer Not to Answer	1	3.8%

*ER, Retail health, Pediatrics, Urgent care

The intent was to have each healthcare provider evaluate two apps on the same chronic disease. However, some providers did not complete either evaluation or opted to complete only one evaluation. A total of 36 evaluations were completed (16 asthma evaluations, 8 diabetes evaluations, 12 HTN evaluations). A comparison between the Gold Standard quality rating and the providers' quality ratings showed a 69% (n=25) agreement. The mean difference between the Gold Standard score and the providers' scores was $\pm$6.42 (MSE, 3.724; SD, 22.343).

Furthermore, an analysis of individual responses revealed 6 feature responses with a >50% incident of disagreement with the Gold Standard. These features include: 1) "The app includes a simple and obvious registration and login." (n=13); 2) "The app incorporates a clinical decision support system to guide the patient in making health decisions by providing clear, concise, and informative alerts." (n=15); 3) "The app includes fun, relevant activities such as games and quizzes that advance health knowledge and encourage positive health behavior change." (n=18); 4) "The app use Bluetooth to upload the patient's biometric measurements to the app." (n=15); 5) "The app includes tools and resources: integration with other apps (calendar, maps, e-mail), health focused app communities, search/browse options, and printers" (n=16); and 6) "The app accommodates different levels of technology skills and needs including patients with disabilities (adaptive features for hearing, vision, etc." (n=16). It is unclear why these features have a high number of discrepancies from the Gold

Standard and needs further exploration to identify the reasoning behind the discrepancies. These feature statements may need revisions to provide clarification.

Limitations. We recognize that the low response rate is a limitation to this proof-of-concept. However, Czajkowski and colleagues (2015) reported that a small sample size is acceptable since the proof-of-concept is not testing for significance. In this case, the proof-of-concept testing did show the evaluation tool correctly identified effective mHealth apps. In addition, the submitted responses provide guidance on revisions to the evaluation tool.

Conclusion

This proof-of-concept testing suggests that the developed evaluation tool may be used to accurately rate mHealth apps. The next step is to explore the features with high number of discrepancies between the responses and the Gold Standard. It may be helpful to talk with providers to assess their interpretation of the feature statements. This would assist in identifying how to revise the feature statements for universal understanding.

To our knowledge, this is first evidence-based evaluation tool specifically developed for healthcare providers with feedback and guidance from healthcare providers. Our goal is to provide healthcare providers with evidence-based tools to identify evidence-based mHealth apps. This proof-of-concept study shows the evaluation is an efficient and accurate method to identify mHealth evaluation tools and provides a solid foundation to guide the future testing to continue the development of the evaluation tool.

CHAPTER 5

CONCLUSION AND RECOMMENDATIONS

Conclusion of Research

This research provides the foundation for the mHealth evaluation tool for healthcare providers. Based upon the Obesity-Related Behavioral Intervention Trials (ORBIT) model, the next steps include pilot testing, efficacy trails, and effectiveness research (see Figure 5.1). Each type of testing has a unique purpose in the testing of the evaluation tool.

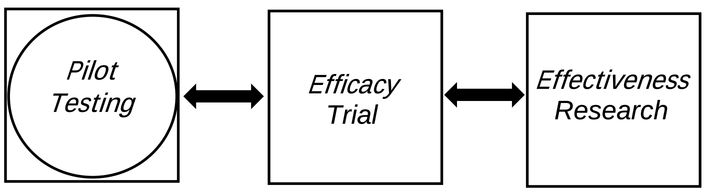

Figure 5.1 Future Research Trajectory for mHealth Evaluation Tool (Czajkowski et al., 2015)

Pilot Testing. According to Czajkowski and colleagues (2015), the pilot testing includes a randomized design with a larger sample. The purpose of the pilot testing is to determine statistical significance compared to a control group. One feasible option includes a control group using one of the existing evaluation tools compared to the results with an intervention group that used the online mHealth evaluation tool.

Efficacy Trial. The purpose of an efficacy trial it test the intervention in a controlled setting (Singal, Higgins, & Waljee, 2014). The trial uses a strict inclusion and exclusion criteria. In the case of the mHealth evaluation tool, the healthcare providers included in the testing would need to recommend mHealth apps to patients. This would result in a homogenous patient population.

Effectiveness Trial. The goal of the effectiveness trial is to test the intervention in a real-life setting. Therefore, the population is more inclusive and heterogeneous than the efficacy trial. This allows for generalizability.

Once the evaluation tool is tested, it will be offered in an online platform that any healthcare provider can access for free. One option is to save the evaluations for other providers to review. If more than one evaluation is completed on the same mHealth app, the average scores and responses could be shared. In addition, expert healthcare professionals can review app content and write a blog for other healthcare providers. My goal is to have this site as the go-to website for mHealth apps.

Other mHealth Research

The review synthesis revealed several gaps that need further exploration. First, it is unclear why the number mHealth features has not increased despite significant increases in technology. Focused discussions with developers may provide some insight into this phenomenon. Next, we identified types of features used in mHealth studies. It may be worth exploring the interaction between the passive and interactive features to identify any improved outcome by specific combinations (i.e., use of Bluetooth with sharing with provider). This information would help the future development of mHealth apps.

Implications for Nursing Research, Education, and Practice

As mHealth continues to expand, it is becoming more prevalent in all types of healthcare research, education and practice. The findings of the research synthesis indicate the importance of focusing on app features. That may lead to a greater awareness of the potential of the features. As nursing researchers become aware of the impact of the features, they can expand the number of mHealth features during a mHealth study.

As mHealth becomes more mainstream, mechanisms to inform and educate nurses about the potential of mHealth apps and how to develop effective mHealth apps. This information can be integrated into the nursing education, CEU offerings, and conferences. For example, a course on chronic diseases could include mHealth apps for chronic disease management.

Nurses in many healthcare roles may assist in the adoption and use of mHealth apps by patients for management of chronic health conditions. The mHealth evaluation tool can help nurses identify and recommend evidence-based mHealth apps to patients.

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APPENDIX A

REDCAP SURVEY ON MOBILE HEALTH APPS

Survey on Mobile Health Apps

Welcome to the Mobile App Survey that is seeking feedback from healthcare providers on mobile health apps.

Thank you for reviewing and considering!

Introduction

Hello, my name is Sara Donevant and I am a PhD candidate at University of South Carolina College of Nursing. I am exploring the expanding world of mobile health apps. Please watch this short video for more details on my research and how you can help.

Do you recommend mobile health apps to your patients?

- o Yes
- o No

Survey Instructions

Please watch this brief video providing instructions on completing the survey.

Risks and Benefits:
No apparent risks are expected by participating in this survey. This study has been reviewed and approved by the University of South Carolina Institutional Review Board. All responses are confidential and stored on a secure server. In addition, no personal identifying information is obtained.

You will not receive any compensation for participating in the survey; however, you will be assisting in the development of an evaluation tool to aid in the identification of mobile health apps that improve patient outcomes.

Voluntary Consent:

- Yes
- No

By answering "yes", you voluntarily give your consent to participate in this survey on important and not important elements of mobile health apps. You are free to withdraw from the survey at any time.

Demographics

Type of Healthcare Practitioner

- Physician
- Physician Assistant
- Nurse Practitioner

Primary Type of Practice:

- Acute Care Facility
- Long Term Care Facility Medical Office
- Hospice
- Other

If other, specify the type of practice: ______________________________

Years in Medical Practice:

- < 10
- 10 - 20
- 21 - 30
- >30

Sex:

- Male
- Female

Age Range:

- 20 - 30 years of age
- 31 - 45 years of age
- 46 - 60 years of age
- >60 years of age

Race/Ethnicity:

- American Indian/Alaskan Native
- African American Asian
- Caucasian
- Hispanic, Latino, or Spanish
- Native Hawaiian or other Pacific Islander

App Login / Registration

Which login and registration features are nonessential, important, and essential when selecting mobile health apps for patients?

	Nonessential	Important	Essential
The app requires a login for access.	O	O	O
The app includes a simple and obvious registration.	O	O	O
The app utilizes a password protected login.	O	O	O

App Engagement

Which patient engagement features are nonessential, important, or essential when selecting a mobile health app for patients?

	Nonessential	Important	Essential
The app includes fun activities such as games that advance health knowledge and encourage positive health behavior change.	O	O	O
The app provides interesting and relevant activities such as quizzes, readings, and videos.	O	O	O
The app offers options to send reminders to the patient.	O	O	O
The app presents instructions on performing actions and tasks (entering data, uploading biometric measurements, etc.).	O	O	O
The app explains the health benefits of completing actions and tasks (entering data, uploading biometric measurements, etc.).	O	O	O
The app includes an engaging and interactive home screen that is simple and direct.	O	O	O
The app incorporates a clinical decision support system to guide the patient in making health decisions.	O	O	O

	Nonessential	Important	Essential
The app provides clear, concise, and informative alerts.	O	O	O
The app performs calculations automatically (age based on date of birth).	O	O	O
The app asks questions to engage the patient in the healthcare process.	O	O	O
The app allows the patient to input clinical and medical data (e.g., medical history, sleep hours, BP, etc.). for self-monitoring.	O	O	O
The app uses Bluetooth to upload biological measurements (e.g. blood pressure, glucose levels, etc.).	O	O	O
The app allows the patient and provider to create specific, measurable, and achievable health goals.	O	O	O
The app allows the patient and provider to create specific, measurable, and achievable health goals.	O	O	O
The app permits the patient to customize and tailor app settings to meet individual health needs.	O	O	O
The app encourages continued use of the app for optimal health management.	O	O	O

App Communication Modalities

Which communication modalities are nonessential, important, and essential when selecting a mobile health app for patients?

	Nonessential	Important	Essential
The app allows connection with social media (Facebook, Twitter, Instagram).	O	O	O
The app uploads the patient's biometric measurements to the healthcare provider for review.	O	O	O
The app incorporates a health focused app community.	O	O	O

	Nonessential	Important	Essential
The app allows two-way communication with the healthcare provider (texting, e-mail, EHR.	O	O	O
The app includes a robust privacy policy that meets HIPAA standards.	O	O	O

App Content

Which content features are nonessential, important, and essential when selecting mobile health apps for patients?

	Nonessential	Important	Essential
The app uses appropriate content for desired population (age, culture, socioeconomic status, etc.).	O	O	O
The app includes accurate, evidence-based clinical information and standards of care.	O	O	O
The app clearly displays content in the center of the screen and above the fold (content is visible without scrolling.	O	O	O
The app groups similar topics and categories together.	O	O	O
The app uses text written in plain language (avoids jargon and medical terms, uses short sentences of 15-20 words, limit paragraph size, use labels that reflect the user's knowledge.	O	O	O
The app displays the most important information first.	O	O	O
The app uses clearly defined and meaningful headings, labels, and icons.	O	O	O
The app effectively uses clearly labeled links.	O	O	O
The app uses comprehensive and relevant content congruent with the topic and goal of the app.	O	O	O
The app contains content within its stated scope.	O	O	O

	Nonessential	Important	Essential
The app incorporates evidence-based behavior change techniques to encourage behavior change.	O	O	O
The app includes action-based content with a positive and realistic approach.	O	O	O
The app emphasizes health behaviors and skills rather than facts.	O	O	O
The app uses clear and unambiguous lists or entry-form choices.	O	O	O
The app presents information for a particular task on a single screen.	O	O	O
The app clearly defines its purpose.	O	O	O
The app presents content at a 5th grade or lower reading level.	O	O	O
The app increases the patient's knowledge, awareness, and understanding.	O	O	O

App Functionality

Which functionality features are nonessential, important, and essential when selecting mobile health apps for patients?

	Nonessential	Important	Essential
The app features function properly.	O	O	O
The app uses a minimum number of steps to perform functions.	O	O	O
The app responds to actions and tasks in <3-4 seconds.	O	O	O
The app helps the user prevent and correct mistakes.	O	O	O
The app functions the same way from session to session.	O	O	O
The app incorporates an easy-to-learn and use format.	O	O	O
The app contains easily accessible and highly visible home and menu screens	O	O	O

	Nonessential	Important	Essential
The app meets the needs of patients with disabilities (hearing, visible, etc.) with appropriate adaptive features.	O	O	O
The app uses a single data entry location for patient data that is used in multiple locations.	O	O	O
The app accommodates different levels of technology skills (experienced, novice, inexperienced).	O	O	O
The app flows in a logical, accurate, and appropriate movement between screens.	O	O	O
The app uses linear information paths (each topic has its own pages that follow a logical sequence.	O	O	O
The app offers search/browse options.	O	O	O
The app provides informative feedback on completed actions and tasks.	O	O	O
The app displays explanatory messages (hourglass, sliders, beachballs, etc.) when processing actions and tasks.	O	O	O
The app includes shortcuts to actions and tasks.	O	O	O
The app uses consistent, intuitive, and simple taps, swipes, and scrolls.	O	O	O
The app uses a back button to return to previous screens.	O	O	O
The app integrates with other apps such as e-mail, calendar, and maps.	O	O	O
The app workflow matches clinical practice and patient needs.	O	O	O

App Aesthetics

Which aesthetic features are nonessential, important, and essential when selecting mobile health apps for patients?

	Nonessential	Important	Essential
The app uses a hierarchical arrangement of buttons, icons, menus, and content.	O	O	O
The app offers large screen buttons or the ability to enlarge the screen.	O	O	O
The app incorporates images that facilitate learning.	O	O	O
The app includes audio features.	O	O	O
The app contains clear, logical, and accurate graphics.	O	O	O
The app uses captions to explain the graphics.	O	O	O
The app uses appropriate white space with minimal clutter.	O	O	O
The app uses consistent format, fonts and layout.	O	O	O
The app includes an easily readable font with appropriate size and does not use ALL CAPS.	O	O	O
The app uses bold colors with contrast and avoids dark backgrounds.	O	O	O
The app incorporates colors that convey meaning (red indicates urgency).	O	O	O
The app uses visual features.	O	O	O

App Description and Credibility

Which description and credibility features are nonessential, important, and essential when selecting mobile health apps for patients?

	Nonessential	Important	Essential
The app store provides an accurate description of the app.	O	O	O
The app originates from a reputable developer and organization.	O	O	O
The app offers an option for users to share feedback with app designers.	O	O	O

	Nonessential	Important	Essential
The app includes printer-friendly tools and resources.	O	O	O
The app was tested with the results reported in scientific literature.	O	O	O
The app reviews in iTunes or Google Play offer unbiased and relevant feedback on the app.	O	O	O

Please name the top 2 to 3 mobile health apps features you feel are the most important when selecting a mobile health app for your patient:

Name any features you feel are important that were not listed above:

Please share any additional information on your experience with mobile health apps that could assist in the development of an evaluation tool for mobile health apps:

APPENDIX B

MOBILE HEALTH APP EVALUATION-DIABETES

Mobile Health App Evaluation

Welcome to the mHealth App Evaluation developed from feedback provided by healthcare providers. Please download and test the selected mHealth app. Then select an appropriate response for each statement. The survey will provide you with a score and a recommendation based upon the score.

Thank you for testing the mHealth evaluation tool!

Introduction

Hello, my name is Sara Donevant and I am a PhD candidate at University of South Carolina College of Nursing. I recently elicited feedback from healthcare providers on essential and important elements of mHealth apps. Using this information, I developed an evaluation tool to assist healthcare providers to identify quality mHealth apps for chronic health conditions. I would appreciate 15-20 minutes of your time to test the evaluation tool and provide feedback.

Survey Instructions

This evaluation tool provides a series of feature statements to guide your assessment of 2 pre-selected mHealth apps for chronic health conditions (diabetes, hypertension, or asthma). For each statement, please select one of the three options:1) feature is completely included in the app; 2) feature is partially included in the app; and 3) feature is not included in the app. Select "completely included" when all elements of the feature statement are included in the app. In comparison, select "partially included" when some (not all) elements of the feature statement are included in the app. Finally, "not included" indicates none of elements in the feature statement are included in the app.

Based upon your responses, the evaluation tool will automatically calculate a score for the mHealth app, and provide a recommendation on the quality and potential efficacy of the mHealth app.

I have selected two chronic mHealth apps for you to assess. The selected apps are free and available in Apple and Android format. You will complete the first app evaluation. Then receive prompts to advance to the second app evaluation. You do have the option to save your responses and return at any time.

Please watch this brief video providing instructions on completing the survey.

DiabetesConnect Link

One Drop Link

Risks and Benefits:
No apparent risks are expected by participating in this survey. This study has been reviewed and approved by the University of South Carolina Institutional Review Board. All responses are confidential and stored on a secure server. In addition, no personal identifying information is obtained. You will not receive any compensation for participating in the survey; however, you will be assisting in the development of an evaluation tool to aid in the identification of mobile health apps that improve patient outcomes.

Voluntary Consent:

- Yes
- No

By answering "yes", you voluntarily give your consent to participate in in testing an evaluation tool for mHealth apps. You are free to withdraw from the survey at any time.

Demographics

Type of Healthcare Practitioner

- Physician
- Physician Assistant
- Nurse Practitioner
- Other

If other, specify the type of healthcare practitioner: ____________________

Primary Type of Practice

- Acute Care Facility
- Long Term Care Facility Medical Office
- Hospice
- Prefer Not to Answer
- Other

If other, specify the type of practice: ________________________________

Years in Medical Practice:

- < 10
- 10 - 20
- 21 - 30
- >30
- Prefer Not to Answer

Sex:

- Male
- Female
- Prefer Not to Answer

Age Range:

- 20 - 30 years of age
- 31 - 45 years of age
- 46 - 60 years of age
- >60 years of age
- Prefer Not to Answer

Race/Ethnicity:

- American Indian/Alaskan Native
- African American Asian
- Caucasian
- Hispanic, Latino, or Spanish
- Native Hawaiian or other Pacific Islander
- Prefer Not to Answer

Evaluation of DiabetesConnect App

DiabetesConnect Link

App Login and Registration

	Included throughout the app	Included partially	Not included
The app includes a simple and obvious registration.	O	O	O
The app includes a robust privacy policy with a password protected login that meets HIPAA standards.	O	O	O

App Engagement

	Included throughout the app	Included partially	Not included
The app incorporates a clinical decision support system to guide the patient in making health decisions by providing clear, concise, and informative alerts.	O	O	O
The app encourages continued use for optimal health by allowing the patient to customize and tailor the settings to meet individual health goals and needs.	O	O	O
The app presents population appropriate (age, culture) instructions and health benefits of performing actions and tasks (entering data, uploading biometric measurements, etc.).	O	O	O
The app allows the patient and provider to create specific, measurable, and achievable health goals with a focus on health behaviors and skills rather than facts.	O	O	O

	Included throughout the app	Included partially	Not included
The app includes fun, relevant activities such as games and quizzes that advance health knowledge and encourage positive health behavior change.	O	O	O

App Communication

	Included throughout the app	Included partially	Not included
The app use Bluetooth to automatically upload the patient's biometric measurements to the app.	O	O	O
The app allows two-way communication with healthcare provider (texting, e-mail, messaging via EHR).	O	O	O
The app allows the patient to share the information with the patient's provider for review and feedback.	O	O	O

App Content

	Included throughout the app	Included partially	Not included
The app includes accurate, evidence-based clinical information and standards of care.	O	O	O
The app uses text written in plain language at a 5th grade or lower reading level that (avoids jargon and medical terms, short sentences of 15-20 words, limit paragraph size, use labels that reflect the user's knowledge).	O	O	O

	Included throughout the app	Included partially	Not included
The app uses an engaging screen that displays the important information first on a single screen.	O	O	O
The app uses clearly defined and meaningful links, headings, labels, and icons.	O	O	O
The app contains content within its stated scope and purpose.	O	O	O
The app includes action-based behavior change techniques with a positive and realistic approach (asking questions, inputting clinical and medical data, reminders) to encourage behavior change and increase the patient's knowledge, awareness, and understanding.	O	O	O
The app workflow includes shortcuts to actions and tasks to match clinical practice and patient needs.	O	O	O
The app uses a minimum number of steps to perform actions and tasks that operates the correctly from session to session with a response of <3-4 seconds.	O	O	O
The app contains comprehensive and relevant congruent content on easily accessible and highly visible screens that includes an easily readable font with appropriate size (not using ALL CAPS).	O	O	O
The app displays similar topics and categories together in the center of the screen and above the fold (content visible without scrolling).	O	O	O

	Included throughout the app	Included partially	Not included
The app flows in logical and linear information paths (each topic has its own page that follows a logical sequence) between screens with visible back button.	O	O	O
The app provides explanatory and feedback messages (hourglass, sliders, beachballs, etc.) when processing and completing actions and tasks.	O	O	O

App Functionality

	Included throughout the app	Included partially	Not included
The app accommodates different levels of technology skills and needs including patients with disabilities (adaptive features for hearing, vision, etc.).	O	O	O
The app uses consistent, intuitive, and simple format (taps, swipes, and scrolls) in an easy-to-use format that helps the user prevent and correct mistakes.	O	O	O
The app uses a single data entry location for patient data that is used in multiple locations such as calculations for age based upon date of birth.	O	O	O
The app includes tools and resources: integration with other apps (calendar, maps, e-mail), health focused app communities, search/browse options, and printers.	O	O	O

App Aesthetics

	Included throughout the app	Included partially	Not included
The app uses a hierarchical arrangement of buttons, icons, menus, lists, entry-form choices, images, and content that can be enlarged while incorporating colors the convey meaning (red indicates urgency).	O	O	O
The app utilizes consistent format, fonts, and layout that uses contrasting bold colors with appropriate white space (avoiding dark backgrounds) and minimal clutter).	O	O	O
The app contains clear, logical, and accurate graphics, audio, or video with captions to enhance learning.	O	O	O

App Description and Credibility

	Included throughout the app	Included partially	Not included
The app store provides an accurate description including the results of any scientific testing involving the app.	O	O	O
The app originates from a legitimate developer and organization.	O	O	O
The app reviews in iTunes or Google Play offer unbiased and relevant comments and allows the users to share feedback with the app designers.	O	O	O

Overall App Score:

The score for Diabetes Connect is between 0 and 20, which indicates a poor-quality health app. The app includes very few of the essential and important elements necessary in assisting patients with managing diabetes.

Advance to evaluation of One Drop?

- o Yes
- o No

The score for Diabetes Connect is between 21 and 87, which indicates a moderate-quality health app. The app completely and partially includes some of the essential and important elements necessary in assisting patients with managing diabetes.

Advance to evaluation of One Drop?

- o Yes
- o No

The score for Diabetes Connect is between 88 and 108, which indicates a very-high quality health app. The app completely includes the majority of essential and important elements necessary in assisting patients with managing diabetes.

Advance to evaluation of One Drop?

- o Yes
- o No

Evaluation of One Drop App

One Drop Link

ONE DROP

App Login and Registration

	Included throughout the app	Included partially	Not included
The app includes a simple and obvious registration.	O	O	O
The app includes a robust privacy policy with a password protected login that meets HIPAA standards.	O	O	O

App Engagement

	Included throughout the app	Included partially	Not included
The app incorporates a clinical decision support system to guide the patient in making health decisions by providing clear, concise, and informative alerts.	O	O	O
The app encourages continued use for optimal health by allowing the patient to customize and tailor the settings to meet individual health goals and needs.	O	O	O
The app presents population appropriate (age, culture) instructions and health benefits of performing actions and tasks (entering data, uploading biometric measurements, etc.).	O	O	O
The app allows the patient and provider to create specific, measurable, and achievable health goals with a focus on health behaviors and skills rather than facts.	O	O	O

	Included throughout the app	Included partially	Not included
The app includes fun, relevant activities such as games and quizzes that advance health knowledge and encourage positive health behavior change.	O	O	O

App Communication

	Included throughout the app	Included partially	Not included
The app use Bluetooth to automatically upload the patient's biometric measurements to the app.	O	O	O
The app allows two-way communication with healthcare provider (texting, e-mail, messaging via EHR).	O	O	O
The app allows the patient to share the information with the patient's provider for review and feedback.	O	O	O

App Content

	Included throughout the app	Included partially	Not included
The app includes accurate, evidence-based clinical information and standards of care.	O	O	O
The app uses text written in plain language at a 5th grade or lower reading level that (avoids jargon and medical terms, short sentences of 15-20 words, limit paragraph size, use labels that reflect the user's knowledge).	O	O	O

	Included throughout the app	Included partially	Not included
The app uses an engaging screen that displays the important information first on a single screen.	O	O	O
The app uses clearly defined and meaningful links, headings, labels, and icons.	O	O	O
The app contains content within its stated scope and purpose.	O	O	O
The app includes action-based behavior change techniques with a positive and realistic approach (asking questions, inputting clinical and medical data, reminders) to encourage behavior change and increase the patient's knowledge, awareness, and understanding.	O	O	O
The app workflow includes shortcuts to actions and tasks to match clinical practice and patient needs.	O	O	O
The app uses a minimum number of steps to perform actions and tasks that operates the correctly from session to session with a response of <3-4 seconds.	O	O	O
The app contains comprehensive and relevant congruent content on easily accessible and highly visible screens that includes an easily readable font with appropriate size (not using ALL CAPS).	O	O	O
The app displays similar topics and categories together in the center of the screen and above the fold (content visible without scrolling).	O	O	O

	Included throughout the app	Included partially	Not included
The app flows in logical and linear information paths (each topic has its own page that follows a logical sequence) between screens with visible back button.	O	O	O
The app provides explanatory and feedback messages (hourglass, sliders, beachballs, etc.) when processing and completing actions and tasks.	O	O	O

App Functionality

	Included throughout the app	Included partially	Not included
The app accommodates different levels of technology skills and needs including patients with disabilities (adaptive features for hearing, vision, etc.).	O	O	O
The app uses consistent, intuitive, and simple format (taps, swipes, and scrolls) in an easy-to-use format that helps the user prevent and correct mistakes.	O	O	O
The app uses a single data entry location for patient data that is used in multiple locations such as calculations for age based upon date of birth.	O	O	O
The app includes tools and resources: integration with other apps (calendar, maps, e-mail), health focused app communities, search/browse options, and printers.	O	O	O

App Aesthetics

	Included throughout the app	Included partially	Not included
The app uses a hierarchical arrangement of buttons, icons, menus, lists, entry-form choices, images, and content that can be enlarged while incorporating colors the convey meaning (red indicates urgency).	O	O	O
The app utilizes consistent format, fonts, and layout that uses contrasting bold colors with appropriate white space (avoiding dark backgrounds) and minimal clutter).	O	O	O
The app contains clear, logical, and accurate graphics, audio, or video with captions to enhance learning.	O	O	O

App Description and Credibility

	Included throughout the app	Included partially	Not included
The app store provides an accurate description including the results of any scientific testing involving the app.	O	O	O
The app originates from a legitimate developer and organization.	O	O	O
The app reviews in iTunes or Google Play offer unbiased and relevant comments and allows the users to share feedback with the app designers.	O	O	O

Overall App Score:

The score for One Drop is between 0 and 20, which indicates a poor-quality health app. The app includes very few of the essential and important elements necessary in assisting patients with managing diabetes.

The score for One Drop is between 21 and 87, which indicates a moderate-quality health app. The app completely and partially includes some of the essential and important elements necessary in assisting patients with managing diabetes.

The score for One Drop is between 88 and 108, which indicates a very-high quality health app. The app completely includes the majority of essential and important elements necessary in assisting patients with managing diabetes.

Please describe the functionality of the evaluation tool?

Please list any difficulties you experienced while using the evaluation tool

Do you have any suggestions for improving the evaluation tool?