

PrE(P)Conception: Creating and Implementing a Smartphone Application for Serodiscordant
Couples to Support an HIV-free Future

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Introduction

At present, 36.9 million people worldwide are living with HIV, with 1.1 million living in the United States (Center for Disease Control and Prevention [CDC], 2018; UNAIDS, 2018). The CDC (2018) estimates that 75% of people living with HIV (PLWH) are in their reproductive years and may want a pregnancy in the future (Steiner, Finocchario-Kessler, & Dariotis, 2013). The advancement of antiretroviral (ART) medication has allowed this to become a realistic goal for couples who want a biological child. The use of mHealth and other technology may be a way to assist and support couples with pregnancy planning (Beauchemin, Gradilla, Baik, Cho, & Schnall, 2019).

Several federal governmental policies address the need for comprehensive preventive care across the lifespan of the individual. The Affordable Care Act (ACA) is a response to the need for coordinated access to preventative health care (CDC, 2017). The National Academies of Science, Engineering, and Medicine (Previously the Institute of Medicine) [NASEM] has also stated that active management of HIV care and secure communication between providers and support programs is a necessity for improving the outcomes of PLWH (NASEM, 2015). The National HIV/AIDS Strategy, implemented by the White House Office of National AIDS Policy (WHONAP), seeks to develop HIV high impact HIV prevention programs (2015) that reflect the recommendations of Federal programs.

None of these programs specifically address the needs of serodiscordant couples, the preconception period of life for both the pregnant woman living with HIV (WLWH), her partner,

or the fetus. However, WHONAP and the National HIV Strategy mention several approaches couples can use in the preconception period. These approaches include integrating patient-centered HIV care with linkage to essential services, expanding access to Pre-Exposure Prophylaxis (PrEP), expanding prevention with PLWH, using evidence-based digital and technological tools, and ensuring linkage and retention in care (2015).

The New Jersey Department of Health (NJDOH) and the Edward J. Bloustein School of Planning and Public Policy of Rutgers University list several aims for ending HIV in NJ in their proposed plan for 2017-2021 (2018). These aims, compatible with the National HIV/AIDS Strategies, including testing, linking, and retention in care. The NJDOH and The Edward J. Bloustein School of Planning and Public Policy of Rutgers University started the Access to Reproductive Care and Health (ARCH) Nurses' program to test and link appropriate patients to reproductive care to improve outcomes for patients who may be at risk for HIV and other sexually transmitted infections (STIs). The Francios-Xavier Bagnoud Center (FXB) at Rutgers also has programs that integrate preconception care services with HIV care that includes a resources guide, an extension of the ARCH program, and a quality improvement training program for clinics which provide reproductive care to PLWH (DiStefano, 2019).

Providers fall short of the reproductive rights standards set forth by the American College of Obstetricians and Gynecologists (ACOG), the American Society of Reproductive Medicine (ASRM), and the World Health Organization (WHO) for PLWH (Leech et al., 2018). ACOG, ASRM, and WHO agree that reproductive rights are human rights and that every person, regardless of HIV serostatus, is entitled to information, education, and support to make decisions about reproduction. To ensure that couples can exercise reproductive rights, all three organizations recommend that providers discuss reproductive rights at the beginning of care and

continue to address reproduction through the lifespan. Although these recommendations support reproductive rights for PLWH, many providers do not know how to discuss reproductive health, leading to a lack of knowledge and dissatisfaction among PLWH about reproductive health options (Steiner et al., 2013).

Many providers neglect to address this important aspect of quality of life among PLWH. HIV providers grossly underestimate or do not acknowledge PLWH's desire to reproduce, and do not appropriately address reproductive health (Squires et al., 2011; Steiner et al., 2013). Lack of attention to reproductive health leaves patients uninformed about their options for conception and the steps needed to conceive. The purpose of this proposal is to describe a project to create a smartphone application and determine if it is easy to use and accessible mHealth resource for serodiscordant couples. (Please refer to Appendix A for a list of defined terms that may be useful while reading this proposal).

Background and Significance

HIV is a virus that attacks the immune system, specifically the CD4 cells (CDC, 2019d). HIV can be transmitted sexually, through needle sharing, perinatally through childbirth, or through breastfeeding (CDC, 2019d). There is currently no effective cure for HIV; now classified as a chronic disease managed with antiretroviral medications (CDC, 2019d).

HIV in the United States. Within the 1.1 million PLWH in the U.S., 75% are in their reproductive years and between 25-45% of them report wanting to have a baby in the future (CDC, 2018; Steiner et al., 2013). Women account for one in four PLWH and 19% of new HIV diagnoses; receptive heterosexual contact accounts for 87% of these new infections (CDC, 2019a). Individuals who identify as heterosexual account for 24% of PLWH; 7% are male and

16% female (CDC, 2019a). One in eight women is unaware of their HIV serostatus, accounting for 12% of women with HIV (CDC, 2018); 25% are not diagnosed until after a pregnancy is established (Loutfy, Sonnenberg-Schwan, Margolese, & Sherr, 2013).

HIV in New Jersey. The NJDOH (2017a) estimates there are 37,435 PLWH and women make up about 27% of PLWH in New Jersey (NJ). Heterosexual contact accounts for 56.2% of the HIV diagnoses in women and 42% of women living with HIV (WLWH) are between the ages of 20-49 (NJDOH, 2017b).

HIV in Essex County and Newark. Within Essex County, NJ, there are 9,601 PLWH with 5,547 living in Newark, NJ alone (NJDOH, 2017b; AIDS Vu, 2016). Although only 3% of the total population of NJ lives in Newark, 15% of all residents of NJ who are HIV positive live in Newark. Approximately 40% (2,168) of the 5,547 PLWH residing in Newark are women (NJDOH, 2017b). Essex County has the highest rate of WLWH with 1,096 per 100,000 WLWH (New Jersey Department of Health, 2017b).

Management of HIV with Prevention Strategies

ART has enabled PLWH to have longer lifespans, experience a quality of life comparable to their HIV negative counterparts, and decreased transmission of HIV between partners (Letchumanan, Coyte, & Loutfy, 2015). ART is also a major factor in the development of biologically based prevention strategies.

HIV prevention strategies, PrEP, and Undetectable Equals Untransmittable (U=U) enabled PLWH and their seronegative partners to pursue fertility and conception (Loutfy et al., 2013). PrEP is a pill taken once daily to prevent the transmission of HIV by uninfected persons who are at risk of contracting the virus. The CDC recommends PrEP for those with inconsistent

or no condom use and inject drugs with possible needle sharing (CDC, 2019b). For serodiscordant couples, ART is available for PLWH, and PrEP is available for their HIV negative partners for added protection to prevent transmission of HIV if the couple prefers (The U.S. Department of Health and Human Services, 2018).

Results of the HPTN 052 and PARTNER studies indicate no risk of transmitting HIV through sexual intercourse if the PLWH is virally suppressed (Cohen, Gamble, & McCauley, 2019; Rodgers et al., 2016). Results of the PARTNER I study demonstrated zero transmission after 58,000 acts of condomless sex in both same sex and opposite sex couples (Rodgers et al., 2016). The PARTNER 2 study, which recruited same sex couples, also found a negligible risk of HIV transmission if the HIV positive partner was virally suppressed (Rodgers et al., 2018). The cumulative results of these studies were the foundation for U=U (CDC, 2019c).

Conception Guidelines for Serodiscordant Couples

The current guidelines from ACOG, and ASRM, and the WHO, which state that serostatus is not a factor in reproductive care, was not always the case for PLWH (ACOG, 2017; ASRM, 2015; WHO, 2014). Before the introduction of U=U and PrEP, the guidelines cautioned providers against counseling serodiscordant couples about conception through sexual intercourse (ASRM, 2015). Conception and pregnancy for PLWH were limited to expensive artificial reproductive technologies such as sperm washing, intrauterine insemination (IUI), and in vitro fertilization (IVF) (Kawwass, 2016).

Advancements in ART and the introduction of PrEP and U=U allowed heterosexual serodiscordant couples to conceive a biologically shared child. The U.S. Department of Health and Human Services (DHHS) in conjunction with the National Institute of Health recommends

that the HIV positive partner should be on ART and virally suppressed for six months prior to attempts at conception to effectively eliminate the risk of transmission (USDHHS, 2018). The guidelines of these organizations also recommend limiting the trial of conception to two or three days before and after ovulation. As an added precaution, the HIV negative partner can be prescribed PrEP to decrease the risk of transmission (USDHHS, 2018).

Problem Statement

There is no educational or communication conduit, such as smartphone-based self-management application, available to serodiscordant couples during the preconception period to enable self-management by PLWH who desire pregnancy. , The development of a smartphone application, may bridge the communication gap between patient and provider and improve patient satisfaction while decreasing secondary and perinatal HIV transmission. An application may also become an accessible way for PLWH to understand and take control of their reproductive rights.

Clinical Question

In serodiscordant couples of reproductive age, is a smartphone application with multiple adherence and communication features a tool that couples would find easy to use and useful during the preconception period?

Needs Assessment

In a world that runs on technology, there does not seem to be an application that covers both the need ART and PrEP medication in combination with HIV specific preconception counseling by serodiscordant couples. A search of the two major Operating System application distribution platforms, the Apple App Store and the Android Google Play Store, found no

applications available that combined HIV and preconception. When the investigator entered “HIV” and “preconception” in the Apple App store, the only result was for a provider-free birth control access application.

A CINAHL search with the terms *HIV*, *Serodiscordant*, *Preconception*, and *Smartphone Application*, found no studies that addressed a smartphone application for HIV specific preconception counseling. Although there are programs and applications tailored to PLWH and preconception counseling separately, this gap in the literature suggests that mHealth that combining these features could help PLWH and their partners pursue and achieve reproductive freedom.

The investigator conducted a needs assessment survey of stakeholders and providers who would be able to recommend the application to their patients because of the lack of research about applications for PLWH that combine preconception counseling, ART, PrEP, and U=U, as well as the lack of available applications that targeted preconception counseling for PLWH.. The investigator interviewed 30 providers about their current practice, the reproductive right and wants of their patients, and asked if these providers felt a smartphone application would improve their current practice or rapport with patients. The results from this needs assessment suggested that while providers do not currently use any technology to help PLWH in the preconception period, they would be open to using something in the future.

Aims and Objectives

Aims

The overall aim of this project was to develop and pilot a smartphone application for beta testing. This application is a platform for education, patient self-management, and

communication between providers and patients. The second aim of this project was to see if participants found the application easy to use, felt as though they could incorporate it into their lives, and perceived it as useful.

Objectives

Objectives to achieve the aims include:

- Development of a wireframe software for easy patient accessibility and usability. Wireframes are mockups of applications without the back-end program development. The wireframe had several features that were developed to help patients with self-management including push notifications for medication and appointments, links to guidelines, and a notes section. Beta test the application by having participants walk through the wireframe mockup of the application.
- Have participants critique the layout, usability, and style of the application using the Health-ITUES, a tool used to measure user perceptions of technology.
- Analyze the results of Health-ITUES to determine the feasibility of creating the back end of the application. In this project, the investigator did not develop the back end of the application.

Review of Literature

There is a gap in the literature about mHealth tools that target the preconception period for PLWH. The investigator searched the Cumulative Index of Nursing and Allied Health Literature (CINAHL), Scopus, Google Scholar, and PubMed using the PRISMA guidelines. Additional sources were found by reviewing the reference articles. Key terms used in this search included *pregnancy* OR *preconception* AND *serodiscordance* OR *Serodiscordant* OR

HIV AND mHealth OR smartphone OR cellphone. Many studies were found in broader searches, such as HIV AND preconception; for example, this search retrieved 6,757 articles from CINAHL, 18,731 articles from PubMed, and 73,802 articles from Scopus. Articles included in this review of literature were published between 2016 to 2019, limited to English language only, full articles; articles were reporting the results of open access studies were excluded.

Many of the articles or studies discussed PLWH with disease-related complications or guidelines for care during pregnancy and a few studies addressed the improvement of health during the preconception period. Additionally, when pregnancy was substituted for preconception in the search, only nine results in Scopus, four results in CINAHL, and nine in PubMed were found. The search resulted in no articles when the key terms, including *Pregnancy AND serodiscordance AND smartphone* or *Preconception AND HIV AND Smartphone*, were used. Searches that included mHealth, smartphone, cellphone, or application yielded few results; only nine articles were found that addressed preconception or pregnancy during HIV regarding mHealth. (Refer to Appendix B for a PRISMA Diagram of the search; Appendix C has a table of evidence for the studies used).

The review of literature overall suggested a gap in preconception care available to PLWH. There is a variance in the amount of PLWH who desire children and the preconception care provided to PLWH. The literature suggests that PLWH may benefit from an mHealth tool such as a smartphone application to bridge the gap that remains in care once the provider does preconception counseling. The literature also suggests an overlap exists between beneficial preconception application features and smartphone features for PLWH to retain care and improve outcomes. These shared features were the basis of the PrE(P)Conception application.

PLWH Reproductive Rights and Desires

Results of several studies suggest that women living with HIV (WLWH) or women with partners living with HIV do not communicate their desire to have children (Finocchario-Kessler et al., 2012). In a study of 181 WLWH in Baltimore, MD, 59% desired to have a child and of those women, 66% intended on having a child in the future; this means 74 participants intended to have children (Finocchario-Kessler, 2010). The researchers then asked to what degree of certainty these 74 women knew they wanted to become pregnant and 82% stated they were moderate to very certain (Finocchario-Kessler, 2010).

HIV Serodiscordance and Barriers to Conception

Providers do not communicate with WLWH about family planning and childbearing. The Women Living Positive study reported that 48% of participants were never asked by their provider about their plans to conceive; 57% had not had a discussion about appropriate HIV treatment during pregnancy before conception, and of those who were already pregnant 42% answered either “not very aware” or “not at all aware” of treatment options for pregnant women with HIV (Squires et al., 2011). A “secret-shopper” style research study found that only 63% of providers offered reproductive services to PLWH; 51% referred patients to known HIV reproductive services, 18% referred to another facility but were not sure the next facility could help, and 31% could not identify a facility that would offer treatment to PLWH (Leech et al., 2018).

A major barrier to addressing preconception needs of PLWH is the focus of researchers. Steiner et al. (2013) found that the primary focus of research early in the epidemic was men who have sex with men. Another focus of HIV research before the development and use of ART was the prevention of perinatal HIV transmission.

Societal factors may influence how WLWH are treated during the preconception period not only by providers, but by people in their community also (Hoyt, Storm, Aaron, & Anderson, 2012). In one study, 61% of participants wanted pregnancy, but 59% felt society did not want them to have children (Steiner et al., 2013). The study revealed that gaps exist in preconception education for WLWH; participants stated that they felt their providers look at universal and not individual aspects that affect conception and the risk of HIV transmission during conception and throughout pregnancy (Jones et al., 2016). (2016) Results of another study indicated that 64% of participants said they wanted to discuss their desire to have children with their provider and 74% of those who wanted to discuss pregnancy felt their provider would be supportive; however, 70% of participants did not have any discussion with their providers about having a child (Mindry et al., 2010).

The Benefits of mHealth

According to Pew Research Center for Internet and Technology (2019), 96% of adults in the United States own a cellphone and 81% have smartphones; the percentage of people with smartphones has increased from 35% in 2011. One-fifth of all smartphone users have at least one health-related application (Fox & Duggan, 2012). Beta-testing and other usability testing are considered best practices for the design of new health applications (Weinger et al., 2011). User-centered designs, such as beta testing with participant input to improve the design, engages users and allows them to incorporate features and formats into the mobile device that want and remove the features that they do not want (McCurdie et al., 2012).

The use of mobile and wireless technologies to improve or achieve health goals, also called mHealth, can help patients obtain better outcomes (WHO, 2018). Most applications of mHealth models for PLWH consist of push notifications, medication tracking, self-conducted

health surveys, adherence using electronic bottle cap reminders, linkage to physical activity videos, and testimonial videos (Beauchemin et al., 2019). Research indicates mHealth modalities, such as eLearning, smartphone applications, and remote monitoring affect the self-management of PLWH (Cooper, Clatworthy, & Whetham, 2017). The general focus of mHealth interventions that target PLWH is educational or motivational messages with informative content, medication and appointment reminders, exercise and diet encouragement, access to pertinent websites, self-care guidelines, and self-management instructions (Mehraeen, Safdari, SeyedAlinaghi, Mohammadzadeh, & Mohraz, 2018). mHealth in HIV care also includes medication adherence and linkage and retention in care (Mehraeen et al., 2018). mHealth in the context of HIV self-management increased motivation, patient engagement, medication adherence, improved patient-provider rapport and increased overall satisfaction with care (Mehraeen et al.,

High Impact mHealth Strategies for HIV

High-impact prevention strategies promoted by the CDC include online and distance programs; however, these programs are not specific to serodiscordant couples. The SMART (Sharing Medical Adherence Responsibilities Together) Couples program, Testing Together program, and Connect program are intended to prevent secondary transmission by encouraging adherence to ART and PrEP, using safe sex practices, and communication within the couple relationship (CDC, 2016). The ‘Every Dose Every Day’ program, uses a mix of posters, eLearning, and a smartphone application to provide support to people taking ART or PrEP (CDC, 2016). Unlike a smartphone application that has this information in a convenient portable location, the CDC programs span several days, do not apply to or are not accessible to

serodiscordant couples, and do not provide information about secondary and perinatal transmission of HIV.

Serodiscordant couples reported that they felt more comfortable using a text message system because it ensured confidentiality about their HIV status or serodiscordant couple status and discretion in response to adherence enquires (Muwonge et al., 2018). Text messages were an effective way to engage and keep women in care, especially those with limited health literacy (Duggal et al., 2018).

Text messages via mHealth may have an impact on health behaviors. Garafalo et al., (2016) noted a self-reported increase in medication adherence rates among 105 HIV positive youth with poorly controlled viral levels, which increased from 28% to 64% of participants at >90% adherence at a 3-month follow-up, 61% at 6-month follow-up, and 65% at the 12-month follow-up using text message reminders. In contrast, results of a meta-analysis of three randomized control trials that compared the effect of text messages versus usual care for ART adherence showed that text messages do not significantly affect adherence to ART (Mbuagbaw et al., 2013). This contradiction may be related to several factors; the Garafalo et al., (2016) study used a convenience sample of young adults, who tend to be more smartphone savvy. Another factor may be the need for convenience and confidentiality in the case of serodiscordant couples. However, differences in results between studies indicate that more research is necessary about the effect of text messages on care for PLWH.

mHealth Preconception Programs

Several applications focus solely on preconception or conception care, which are readily accessible to the public, although some are more popular than others. Patel, Blandford, &

Stephenson (2018) searched for preconception care smartphone applications and then analyzed their user reviews to see what makes one application popular. The researchers found only 22 applications within the two most popular user platforms, the Apple Store and the Google Play Store. Out of the 22 applications available, only 16 had user reviews. Word of mouth from other users influenced the use of certain applications, which increased the traffic to these applications and the likelihood of users rating the applications. Traffic to applications that might be more user friendly generated more reviews, whether positive or negative, with the increase in users (Patel et al., 2018). The research by Patel et al. (2018) indicates that satisfaction with these applications was inconclusive because only very satisfied and very dissatisfied users typically write reviews. The open-ended reviews of these applications ranged from simple one-word answers to detailed descriptions of what they liked and disliked about the applications. Out of 158 responses were rated as usefulness, 138 were positive; out of 136 responses suggested satisfaction, 111 were positive; and out of 57 responses for usability, 18 were positive (Patel et al., 2018).

Online programs are available for preconception planning. Barta et al., (2018) noted a statistically significant increase in patient-reported discussions with providers about reproductive health during a well-woman visit in the group of women using the MyFamilyPlan website. A study of 1, 878 participants also saw favorable results using mHealth for preconception counseling; the researchers found the Smarter Pregnancy online program successful in improving lifestyle and nutrition factors throughout pregnancy, as evidenced by blood sample biomarkers (van Dijik et al., 2016). Participants that used the Smarter Pregnancy online program had a 64.86% compliance rate of diet, exercise, and lifestyle changes and 54.7% had either a “positive” or “very positive” experience with overall high participant rated usability of the program with

improvements of nutrition and lifestyle changes (van Dijik et al., 2016). The National Preconception Health and Health Care Initiative (NPHHCI) developed an application for preconception available to women who plan to conceive (NPHHCI, 2018). There are also several applications, such as the OviaHealth line of mobile applications that provide conception education and planning, including ovulation cycles, necessary lab work, genetic concerns, and embryonic development during pregnancy (Ovia Health, 2018). These applications help PLWH by supporting preconception and fertility information but are not specific to their HIV related needs, such as viral suppression and medication adherence.

A quantitative study of preconception mHealth strategies suggested that mHealth is favorable from the patient standpoint, but attitudes varied among the providers (Willcox et al., 2015). Participants who were patients indicated that the mHealth model was convenient and beneficial to their antenatal care and expressed an increase in engagement, understanding of risk, and responsibility. However, providers viewed simultaneous use of mHealth with routine antenatal care was more beneficial compared to using it as a stand-alone care model; providers were also concerned about the risk of misleading information or misinformation distribution within mHealth (Willcox et al., 2015).

mHealth, Preconception, and HIV

There were no studies about preconception counseling and mHealth for PLWH, but several studies that used mHealth to reduce perinatal transmission in the antenatal period. This study did not use mHealth to educate the patient or increase communication with the provider before attempts to conceive, but instead looked at mHealth interventions and their effect on retention of patients in care and their quality of life after 24 months postpartum (Awiti et al., 2016). Awiti et al., (2016) used weekly text messaging to determine if it was a cost-effective

way to increase adherence and retention in HIV care by texting the participant questions about how they were feeling with response options of “ok,” or “problem.” If the participants answered “ok,” they were automatically texted the following week; if there was a problem, participants were then instructed to go to the clinic (Awiti et al., 2016). Participants of both genders, as well as the healthcare workers who used the text messaging service found it convenient and time efficient. The participants found it to be a beneficial experience overall, stating that they missed fewer appointments and felt less stigma from clinic staff; the participants also thought that their questions and concerns were answered more efficiently. One problem the participants had was the lack of privacy with text messages with phone sharing (Awiti, 2016).

Jennings, Ong’ech, Simiyu, Sirengo, & Kassaye (2013) implemented a motivational text message service in Kenya to decrease perinatal transmission that contacted WLWH and their partners. The researchers reported that most of the participant’s feedback was positive, with many users who enjoyed the easy and confidential use of smartphones. Still, due to the high rate of phone sharing, the researchers stated that the results may be skewed and future studies should ensure that participants have access to a personal cellphone (Jennings et al., 2013). Several limitations may have affected results, including a sample that was engaged in prenatal programs, possibly decreased mobile phone literacy, and a noted gap in the use of mHealth in the preconception period for PLWH (Jennings et al., 2013).

Summary

The literature provides evidence that mHealth benefits both PLWH and people in the preconception period. However, there does not appear to be an application that covers the overlapping needs that exist within the population of PLWH and people desiring a pregnancy (Duggal et al., 2018; Garafalo, 2016; Mehraeen et al., 2018; Muwonge et al., 2018; Patel et al.,

2018; van Dijk et al., 2016; Willcox et al., 2015). During a search of Operating System platforms, the investigator found several applications for PLWH as well as applications for people in the preconception period, but none that combines the two. A notable gap exists in the development of a user-friendly and accessible application for PLWH in the preconception period. The investigator hopes to bridge this gap with the implementation of a smartphone application that is not only easy to use but also useful to PLWH who also want to conceive a child.

Theoretical Framework

Davis' Technology Adaptation Model (TAM) (1989) focuses on user acceptance and practicality of new technological implementations. The TAM model postulates that prototyping and beta-testing are the best way to ensure that innovative technology is used and accepted by the user of the product (Davis et al., 1989). This model explains the reasons end-users are unwilling to use a new program. However, it would be economically beneficial and generate significant performance gains, which translates to mHealth as improved patient outcomes (Davis et al., 1989).

Davis et al., (1989) created TAM using the framework of Theory of Reasoned Action (Fishbein & Ajzen, 1980) and the Theory of Planned Behavior (Ajzen, 1985). The Theory of Reasoned Action states that behavioral intentions are influenced by intrinsic factors, such as personal beliefs, and extrinsic factors, such as societal norms and motivations to comply (Fishbein & Ajzen, 1980). Ajzen's second Theory of Planned Behavior (1985) states that attitudes, societal norms, and perceived control influence the intention, and in turn, behavior. Davis et al. (1989) applied these theories to technology to create TAM. In the TAM framework, external factors, such as societal norms of smartphone applications, participant experience with

smartphone applications, and whether the participant is comfortable with using an application as part of their healthcare, all have an external influence on the attitude toward the application and intention of use.

The TAM model postulates that external factors influence the ease of use and perceived usefulness, the user's attitude, behavioral intentions toward technology use and finally, the actual use of the new system (Davis et al., 1989). Functionality and usability characteristics, as well as removing interface barriers, are keys to creating an app that end-users are more likely to use (Davis et al., 1989). The primary factor that influences usability is what users intend to use the technology for and whether they can explain these intentions with regard to attitudes, suggestive norms, usefulness, and user perceived ease of use (Davis et al., 1989).

The TAM model postulates that any innovative technology should beta-test to ensure that actual end-users find the interface easy to use, that it is both efficiently and esthetically appealing. If a feature does not appeal to the end-user, alterations should occur before back-end development. Davis et al., (1989) also state that in the prototype stage of development, technology can be easily changed after beta testing to increase the end-user acceptance through fine-tuning the technology. This fine-tuning can be done before back end development to provide more suitable interface characteristics for users and increase the likelihood of continued use after back-end development.

The TAM model predicts the likelihood that participants will use the technology in the future and perceive its benefit. This usability stems from intended behaviors within a specific context toward a specific target (Davis et al., 1989). Intended behaviors are the end intentions of users and the likelihood of technology use after development. The user, under influence of external factors, considers perceives usefulness, and perceived ease of use of the technology or

does not (Davis et al., 1989). Davis et al. (1989) states that the target is the adaptation of a new piece of technology. The defined context is the environment or situation in which the new technology will be used.

The flexibility of the PrE(P) Conception wireframe prototype had little to no programming, equipment, or expense and made beta testing of the application feasible in this project. When the theory is applied to this project, the willingness of PLWH or partners of PLWH who want a biologically shared child to use is the behavior, the smartphone application is the target, and the preconception period is the context. The project seeks to elicit participants' perception of the usability of the Pre(P) Contraception application during the beta-testing period. The researcher beta-tested the application by assessing how participants perceive the usefulness and necessity of the application, ease of use, and participants' attitudes toward the application by having participants complete the Health-ITUES questionnaire, which is based on the TAM model. The Beta Testing and questionnaire provided an assessment of the behavioral intent to use the application and predict actual usage of the application. (Please refer to Appendix D for the TAM framework into this project.)

Methodology

This DNP project was a one-group posttest-only pilot project design. The Health-ITUES, a post-intervention Likert scale survey, was administered after beta testing the application's wireframe.

Setting

This project was conducted in a clinical setting that provides primary care to PLWH in an urban setting in northern NJ. As per AIDSVU (2016), the area where the office is located has a

population of PLWH who are 65.9%, Black, 27.5%, Hispanic, and 3.2% White. This program provides services to adults, children, and families living with HIV and is funded through the François Xavier Bagnoud Foundation, the CDC, and the NJDOH. The PI conducted the project in this setting during office hours, with previously scheduled appointments whenever possible, as to not inconvenience the participants.

Project Population

This project included a purposeful sample of men and women diagnosed with HIV or had a partner living with HIV who receive primary care at the practice. Participants were included if they were English-speaking women and men over the age of 18 years of age and under the age of 50 with a diagnosis of HIV or a partner living with HIV. Potential participants owned smartphones, had used a smartphone previously or knew about smartphone applications and how to use them. HIV negative couples, a primary language other than English, or no previous use of a smartphone application excluded a person from participation. The desired sample size for this pilot project was 20 participants. However, only 13 participants were recruited.

Participant Recruitment. Subjects were recruited using flyers distributed in a primary care office. The principal investigator recruited participants during office hours through direct recruitment after the formal introduction of the primary investigator by the provider (Appendix H). The recruitment period lasted for three months.

Benefits and Risks of Participation. There was no expected discomfort or physical risk associated with participation in this project. During participation in this project, any information collected, including participant's names and personal health information, was assigned a number

and only research staff had access to the link between participant information and the number assigned to their data.

Consent Procedure. Consent was constructed using the recommended IRB template. The investigator described in detail all elements of the project and ensured the participant was aware that they could withdraw from the project at any time without consequence. The participants were given an opportunity to ask questions. See Appendix I for the consent form that was used for participants.

Participant Cost and Compensation. There was no financial cost to the participants. Researchers asked participants to take part in this project during regular office hours if possible, during their scheduled office visits, as not to inconvenience them. Compensation for participation was a \$20.00 Amazon gift card in appreciation for their time and participation.

Project Intervention

The intervention of this project was the beta-testing of a new application for serodiscordant couples in the preconception period using a wireframe to navigate through the application before back-end development. This wireframe was a software mock-up of the application that provided adherence features such as periodic appointment reminders, daily medication reminders, guidelines about reproductive rights, and features to enhance communication such as a notes section. The goal of this project was to see if participants perceive benefits from and intend to use this application after the beta-testing and prototyping period. Please refer to Appendix G to see screenshots taken from the application wireframe.

Application Design

After approval by the Doctor of Nursing Practice (DNP) Project Chair and Project Team Member, the application building process began. The first step was to design the screens of the application on a wireframing software. The investigator accomplished this by buying cloud space on the website balsamiq.com that hosts cloud space for application wireframes and assisted in developing screen to screen movement within the application. This website space came with a small cost paid for by the investigator. This website also allowed the investigator to add button functionality to the wireframe, which helped participants navigate through the application with ease. The investigator and Team Members reviewed and ensured that the prototype was without grammatical errors or other issues.

Push Notifications. The use of push notifications was expected to allow participants to self-manage a medication schedule and keep track of taken and missed doses using a daily checklist-style log. Daily notifications and log aimed to remind couples to take medication and help improve medication adherence to help them achieve viral suppression in the HIV positive partner and prevent transmission in the HIV negative partner if they choose to include PrEP into their preconception plan. A calendar feature was also available to plan and notify participants about upcoming doctor appointments, lab work, and other events during the preconception period. The calendar feature sent push notifications to the participants a week before and the day of the events scheduled to improve the follow through of lab work and doctor appointments.

Important Links. Another feature of the application to improve self-management was a page dedicated to accessible links to current guidelines from ACOG, USDHHS, and WHO. These links were readily and easily accessible to the participants and to guide them about times to try conception, and medication options and regimens. This information is important for patient self-management.

Note Feature. A note feature was incorporated into the application in lieu of a patient portal due to restriction from the wireframe. This feature allowed participants to write down questions that they have for providers between visits. The purpose of this feature was to improve communication with providers for couples who are not sure how to start a conversation about reproductive health. This feature included a group of sample questions and prompts used in the Ask Me 3 educational program such as, “What is my main problem?” “What do I need to do?” and “Why is it important for me to do this?” (Institute for Healthcare Improvement, 2017). Other prompts include the questions “What do I need to do next?” “Why is it important that I get to viral suppression?” and “What is important to know before the next step?”

Data Collection Instruments

Demographic Survey. The investigator collected demographic information such as gender, age, HIV status, the participant’s experience using smartphone applications, and desire to have a child at any point in the future. This data was collected using a demographic survey (Appendix E).

The Health-ITUES. The investigator evaluated the efficacy of the application using an altered version of the Health-ITUES, which allows the participant to evaluate the application and give the investigator feedback to be analyzed. The Health-ITUES was customized to evaluate the PrE(P)Conception application. Participants reviewed and then evaluated the application using the Health-ITUES after using and clicking through the wireframe of the PrE(P)Conception application. The data collected from the Health-ITUES post-test quantified attitudes, behavioral intentions, and actual predictive use of the application after back-end development. The Health-ITUES is a validated tool that uses 5-point Likert scale after the participant uses the application and is strongly correlated to the Post-Study System Usability Questionnaire (PSSUQ) that was

used before the Health-ITUES development to evaluate the usability of mHealth such as health websites (Schnall et al., 2018). The developers of the tool state that it quantified values for quality of work goal (goal of application), perceived usefulness, perceived ease of use, and user control (Schnall et al., 2018).

The researchers who developed the tool state that it quantified values for quality of work goal (goal of application), perceived usefulness, perceived ease of use, and user control (Schnall et al., 2018).

Schnall et al. (2018) created the Health-ITUES based on the TAM framework, the theoretical framework of this proposal. The Health-ITUES uses the concepts developed by Davis et al., (1989) to quantify participants' perceived usefulness of the technology, their comfort level with the application or perceived ease of use of the technology, how well the participants think this will help with the end-goal of the conception of a child, and ultimately whether they believe they will use this technology. The Health-ITUES also estimates the likelihood that the participant will use the application after back-end development (Schnall, et al., 2018). Questions from the Health-ITUES are organized in four domains of Impact: Perceived Usefulness with nine items, Perceived Ease of Use with five questions, and User Control with three questions. Scores for each of these categories are calculated to determine its significance for the application. The modified Health-ITUES for the PrE(P)Conception application is available for review in Appendix F.

Evaluation Questions. Direct user input improves the user experience (Følstad, 2017). The investigator included open-ended evaluation question surveys after completion of participant input about how the project could be improved. The investigator used the information as a process evaluation of the application itself. The application can be adjusted using these

evaluation questions to add, remove, or improve features of the application as suggested by the participants and make changes before back end development and application distribution.

Adding questions to this evaluation would also be part of the process evaluation of this project to improve the application and user experience continually.

Data Analysis

Demographic data was collected through a multiple-choice survey created by the investigator. These answers were used to describe the sample and analytical statistics were used to evaluate the effectiveness of the intervention. The results from the Health-ITUES tool, in the form of ordinal data, were used to calculate mean, median, and standard deviation. Cronbach's alpha was calculated within the Usefulness and Ease of Use subsets to test the reliability of the questions due to the altering the Health-ITUES to accommodate the PrE(P)Conception application.

The investigator analyzed the results of this project using Microsoft Excel with the same process suggested by the creators of the Health-ITUES survey, which included calculation of the mean, standard deviation (SD), and median of the survey (Schnall et al., 2018). Results should predict if participants will use the new technology after back end development as per the TAM framework (Davis et al., 1989). Confidence Intervals (CI) were also calculated to find any outliers within the statistics. The investigator analyzed the results of the demographic survey, but this convenience sample was limited in diversity.

Resources, Economic Consideration, and Budget

The investigator was the sole financier of this project. The cost of the balsamiq.com cloud space was \$9 a month or \$90 yearly in an up-front sum. There were additional costs,

including recruitment and participant compensation materials, that are elaborated on in the budget table (Appendix K). After the project, if the cost of the application development becomes substantial during application creation, the investigator may reach out to Rutgers University for the financial planning of long-term housing for the wireframe. An application for grant funding is being considered by the primary investigator through the National Science Foundation to fund the development of the application.

Project Timeline

The application construction timeline lasted from February 2019 to April 2019 for initial application creation through fine-tuning of the application; this initial period started in Project Planning and continued through June 2019. The project was implemented after IRB approval on October 1, 2019. Recruitment lasted from November 12th, 2019 through February 11th, 2020 to ensure adequate participation within the project. From February 11th to 20th, the project results were analyzed and subsequently disseminated to the Rutgers University community via a poster presentation on April 6th. Please refer to Appendix J for the Gantt timeline of this project.

Evaluation Plan

The participants evaluated this project through open-ended questions. These questions included, “What are things you enjoyed using about the application?” “What did you not like about the application?” “What would you add or take away to improve the application?” These questions elicited suggestions for improvements to the application (Davis, 1989; Muwonge et al., 2018). See Appendix L for evaluation questions.

Data Security and Maintenance

Data were de-identified upon collection and remained de-identified throughout the analysis. Only aggregate data were reported in this project. After data was collected from the participant, the primary investigator (PI) assigned a randomized ID number for participant demographic information and Health-ITUES responses. The PI's master list and participant consents were kept apart from the actual surveys, which were stored in a locked cabinet at the designated storage site at all times. The only data apart from the master list that had any identifying information is the signed informed consent forms. Consent forms were kept in a secure location separate from the data Health-ITUES and the master list.

The data collection items were kept in the office of the DNP Project Chair at Rutgers University (65 Bergen St., Newark, NJ) in a building that requires ID for entrance, within a locked cabinet inside a locked office. The primary investigator stored the signed consent forms. After completion of the project, closure from the IRB, and submission of the final manuscript, all data was destroyed according to the guidelines of the Rutgers University and IRB guidelines. The hard copy of the consents and any other hard copy survey records will be held securely by the investigator for a minimum of 3 years if the project is not published as per Rutgers Data Retention and Record Keeping protocols, which follow the USDHHS guidelines for Non-Funded, Non-FDA Regulated, Non-Published projects.

Results, Recommendations, and Discussions

Demographic Results

The participants were all African American, living with an HIV diagnosis, identity as heterosexual, had children and desired more children, and had previously used a smartphone. The main difference between participants was age, gender, and marital status. 0% of participants

were 18-20 years old, 46% of participants were 21-29 years old, 23% of participants were 30-39 years old, and 31% of participants were 40-49 years old. Participants were 77% female and 33% were male; 92% of participants were single and 8% were married.

Health-ITUES Results

Schnall et al., (2018) advised that if the aggregate mean is over 3.0, it predicts that participants will use after application development. The total mean of this project was 4.42, 95% CI [4.05, 4.79], which suggests this group of participants found the application useful and easy to use. The aggregate mean indicates a predictive high likelihood that this population would use the application after back end development (Davis, 1989; Schnall et al., 2018). Table 1 in Appendix M shows the subset results of the Health-ITUES survey for all participants and Table 2 for the aggregate results.

The subsets of the Health-ITUES included impact, usefulness, ease of use, and control. These subsets also had means and medians calculated. The average mean for effects was 4.38, 95% CI [4.01, 4.75]. The average mean for usefulness was 4.43, 95% CI [4.06, 4.80]. The average mean for ease of use was 4.46, 95% CI [4.09, 4.83]. The average mean for control was 4.33, 95% CI [3.96, 4.70]. Refer to Tables 1 and 2 in Appendix M for the aggregate results of the Health-ITUES survey subsets including mean, SD, and median and Table set 3 for descriptive statistics. The investigator also calculated reliability within the Usefulness and Ease of Use subsets to test reliability of the questions because the Health-ITUES was altered to reflect the PrE(P)Conception application. The Health-ITUES produced acceptable internal reliability scores for Usefulness ($\alpha=0.92$) and Ease of Use ($\alpha=0.95$); reliability scores of 0.71 to 0.95 are generally viewed as acceptable (Tovakol & Dennick, 2011). The subsets of Impact and Control

were not calculated due to their subsets with only three questions. See Tables 2b for Usefulness and 2c for Ease of Use in Appendix M.

Women, with a mean of 4.55 found the application more useful and easier to use compared to men with the cumulative mean of 3.80 95% CI [4.05, 4.79], impact mean of 3.56 for men compared to 4.63 for women 95% CI [4.01, 4.75], ease of use mean of 4.07 for men and 4.58 for women 95% CI [4.09, 4.83], and control mean of 3.78 for men and 4.50 for women 95% CI [3.96, 4.70]. The mean scores that fall outside the 95% CI indicate these statistics are not true to the cumulative sample. Participants in the 40-49 age group found the application less impactful than other age groups; their impact subset mean was 3.92, falling below the lower limit of the cumulative population mean for the impact subset. All data for married participants are likely skewed because there was only one married participant; however, all means for married participants fall within the cumulative CI and the subset CIs.

The results of this project suggest that users perceive this smartphone application as useful, would improve their quality of life if developed and would be a positive addition for PLWH in the preconception period. Participants found the application easy to use and felt that it would facilitate care by the provider. These results provide evidence that the investigator should develop the back end and create the application.

Although the outcome of this project correlated with the anticipated results, the investigator has some suggestions for process evaluation. The project could benefit from a wider net of recruitment from multiple sites with recruitment from sites, such as another primary care site, HIV specialty clinics, and infectious disease offices instead of the convenience sample used. This project could be modified to include providers to elicit their perceptions of the application

and find out if they would recommend this application to their patients who are considering preconception planning.

Evaluation of the Project

Participants stated that they enjoyed the application overall and found it very simple to navigate and easy to use. Many participants questioned how soon they would be able to use the application after they completed all parts of the survey. A common recommendation from participants were cosmetic improvements such as making the application more colorful. Another improvement from the participants was a request for a double-lock or passcode system, which the primary investigator plans to add before final development.

Participants found the application easy to use in both its format and the features it included. Participants found the application's direct and to the point format as the biggest benefit to them. The investigator would like to make some of the changes suggested by the participants in this study before back end development. These changes include adding a passcode for entrance to the application and making the application more colorful and welcoming. The investigator would also like to add different modes for the user to customize their experience and enable the application to adapt through changes within the attempts to conception, pregnancy, and postpartum phase. This may also contribute to patients' retention and continuation of care throughout these crucial periods.

Limitations

This project incurred some unintended setbacks. The investigator of this project found that recruitment took longer than expected. Although the setting had a sizable population of PLWH, many did not meet all the project's inclusion criteria. Many patients were not over 18,

English speaking, or heterosexual. A few participants who met the criteria had never been sexually active and declined participation in the study. Although this limited the sample, the investigator was able to focus more time on presenting and explaining the application and cater to each participant.

The sample lack of diversity and was smaller than requested by the Rutgers University IRB. The goal of the project was to recruit 20 participants. The investigator was able to recruit only 13 participants during the three-month recruitment period. Overall, the investigator was able to achieve the aims and objectives, even with the limited number of participants. This project should be recreated in a population of PLWH that has a higher concentration of heterosexual individuals of reproductive age participants.

Impact of PrE(P)Conception

Economic Impact and Cost of Project

This project did was not expensive to produce, but it did require a good amount of time. In total, this project cost the investigators less than \$1,000. In perspective of the impact it could have on this population, the cost to validate the results could be worth replicating the project in another community. This project might be cost effective for serodiscordant couples trying to conceive a biologically shared child by eliminating the need to use expensive reproductive resources such as IVF. This application is anticipated to cut down on costs to the patient and also their children if the transmission of HIV is prevented during the antenatal period. The healthcare costs of perinatally infected children are \$12,663, which includes \$9505 for HIV-related drugs, \$2164 for hospitalization, and \$994 for laboratory tests (Sansom et al., 2006). The lifetime treatment cost is \$113,476 for nine years of survival, \$151,849 for 15 years, and

\$228,155 for 25 years (Sanson et al., 2006). Prevention interventions during the prenatal period saves \$418,000 in HIV treatments in a lifetime and added 4.45 Quality of Life Years saved (Lin, Farnham, Shrestha, Mermin, & Sansom, 2016). This application would also remain free to download for users with the use of advertisements within the application. Without cost to users, the application could be accessible to more PLWH.

Impact on Healthcare Quality and Safety

This application was expected to enhance the reproductive autonomy of HIV serodiscordant couples. In today's technology forward age, many people have their smartphone easily available, making a smartphone application an easy and accessible way for providers to encourage patients to communicate their needs, educate the patient, and track medication adherence. This application's features keep these couples informed, increase their likelihood of following through with bloodwork and appointments, increase satisfaction with care and, therefore, enable PLWH to be more involved with their care.

mHealth usage in the preconception and antenatal period is popular among people in their reproductive years (Garafalo, 2018). Technology has made it easier to access information within seconds. With so many options and easy access to applications by patients outside of the provider's office, technology and access to accurate and up to date information are pertinent to patient care. This application has the potential to change the culture of care for PLWH or those whose partners have HIV during the preconception period and allow these individuals to exercise their reproductive rights. The results of this project to determine the feasibility of PrE(P)Conception application indicate that its use may encourage patients to become autonomous in their healthcare and self-manage their health during the preconception period.

Impact on Healthcare Policy

mHealth improves access to care, quality of care, and decreases health care costs. Participants stated that many aspects of the application increased their access to education, communication with their providers, and because it would be free, it is an inexpensive way to meet their goals. The application holds patients accountable because providers can remotely access their medication log and lab results prior to their appointments and can intervene if necessary.

mHealth enables self-tracking of personal data to manage chronic conditions (Morgan, 2016). This self-management and tracking would meet global health policies intended to decrease both horizontal and vertical transmission of HIV. Global health policies advocate for patient self-management such as the 90-90-90 WHO initiative to end the HIV epidemic that encourages patients to better manage their chronic conditions such as HIV. Pre(P)Conception meets the requirements to support the 90-90-90, a WHO initiative (UNAIDS, 2019; Abougi, et al., 2018).

Weiler (2016) suggests that mHealth brings support to patients who are trying to self-manage their chronic conditions and Centers for Medicare & Medicaid Services (CMS) have taken notice. mHealth applications help to supplement provider care with Medicaid reimbursements to providers. CMS has recommended increasing the amount of research done in regard to mHealth and chronic conditions to provide support and sustain services to people with chronic conditions as the population grows (Weiler, 2016).

Impact on Practice

Practice improvements can be made to care given to PLWH in the preconception period using PrE(P)Conception. The literature suggests that better care is provided to patients and healthcare costs are lower for both patients and providers alike (Morgan, 2016; Weiler, 2016; Abougi, et al., 2018; Garafalo, 2018). By using the patient portal aspect of the application, providers can view and guide patients remotely prior to visits and correct missteps in care before their scheduled visit. Patients may experience a decrease in time to reach viral suppression. Patients can decrease the cost associated with expensive reproductive technology. Many providers in New Jersey are part of the Elimination of Mother-to Child HIV Transmission (EMCT) Stakeholders Group. This group may benefit in many ways from implement this application as part of their practice to decrease transmission.

Impact on Education

mHealth improves patient knowledge about health conditions and offer a time- and cost-effective form of education to patients (Ochalek, Heil, Higgins, Badger, & Sigmon, 2018). The only way we can know if patient will benefit from the application is if they are likely to use the application after development. Participants found this application easy to use and felt the application would help them manage preconception in conjunction with management from their provider.

The results of this study suggest that participants found the application useful and easy to use and would therefore likely use the application after back-end development. This suggests that patient education and self-management may improve as a result. For example, the links section may increase patient education about the guidelines that their providers should be using to guide their care. By educating patients about the correct guidelines and the next steps in their care, they can self-manage their care and actively participate in decision making.

One interesting anecdote from this study that was noted by the investigator was that during the Needs Assessment, providers stated that their populations would not benefit from a links section within the application, however, the links section was overwhelmingly popular with the participants and they frequently commented that this was something they were looking forward to using in the application. Many stated that this would increase their knowledge about the disease and their treatment that they may not be getting from their provider.

Plans for Sustainability and Translation

After the prototyping and beta-testing of the application, sustainability will be dependent on back end development and then possible general release of the application through The Apple Store or Google Play Store. Word of mouth advertising, as well as online or social media advertising, will be factors in getting and keeping the application in use with the target population. The cost after development is also a factor in the sustainability process.

In some instances, amateur application designers may apply for a Limited Liability Corporation (LLC) to protect the investigators' creative and financial interests in the application. The back end of the application can also be protected by Trademarking with a United States Patent or copyrighted with a United States Copyright. While the cost of the wireframing software is low, it is unforeseen how expensive the back-end development and cloud storage for this part of the project will be. If these aspects of the project are inexpensive, the investigator may finance the project. If development is expensive, the investigator may need help from an outside source; buyout of the application or payment from the user for the application is also an option.

The investigator also hopes this application will develop into a patient portal for quicker communication with providers for input of medications, lab work, and appointments directly into the application for the patients. This feature would also enable providers to view when patients miss important appointments or miss several days of medication logging in a row so they can follow up with the patient.

This project will be disseminated in several ways. The first route of dissemination will be through a poster presentation to the Rutgers University Community and the site where data was collected. After this poster presentation, the investigator would like to present the results of the project to the Association of AIDS Care Nursing, Association of Women's Health, Obstetrics, and Neonatal Nursing, and the American College of Nurse Midwives. The primary investigator plans to present this project to several organizations and request funding to have the application's back end professionally developed. Once the application is developed, it would be available to practitioners to recommend and patients to access from the application stores on multiple platforms.

Conclusion

mHealth has been suggested in the literature to improve both outcomes for PLWH and people living in the preconception period. The investigator was able to incorporate features suggested by the literature to improve both pregnancy and HIV outcomes into the PrE(P)Conception application. The only way that patients will see improvement is if they are using the application. After beta-testing the application, the results of this study suggest that participants found this application useful and easy to use and as per the TAM framework by Davis (1989) this suggests that participants would likely use the application after back-end development. This application may also decrease the healthcare costs, not only to patients

seeking reproductive technology, but the healthcare system in terms of neonates born with HIV.

The literature suggests that this application may improve how patients educate themselves, how providers practice, and help achieve the 90-90-90 WHO initiative to eliminate the HIV epidemic.

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Appendix A

Definition of Key Terms

The U.S. Department of Health and Human Services' AIDSinfo (2019) definition glossary to aid with clarification:

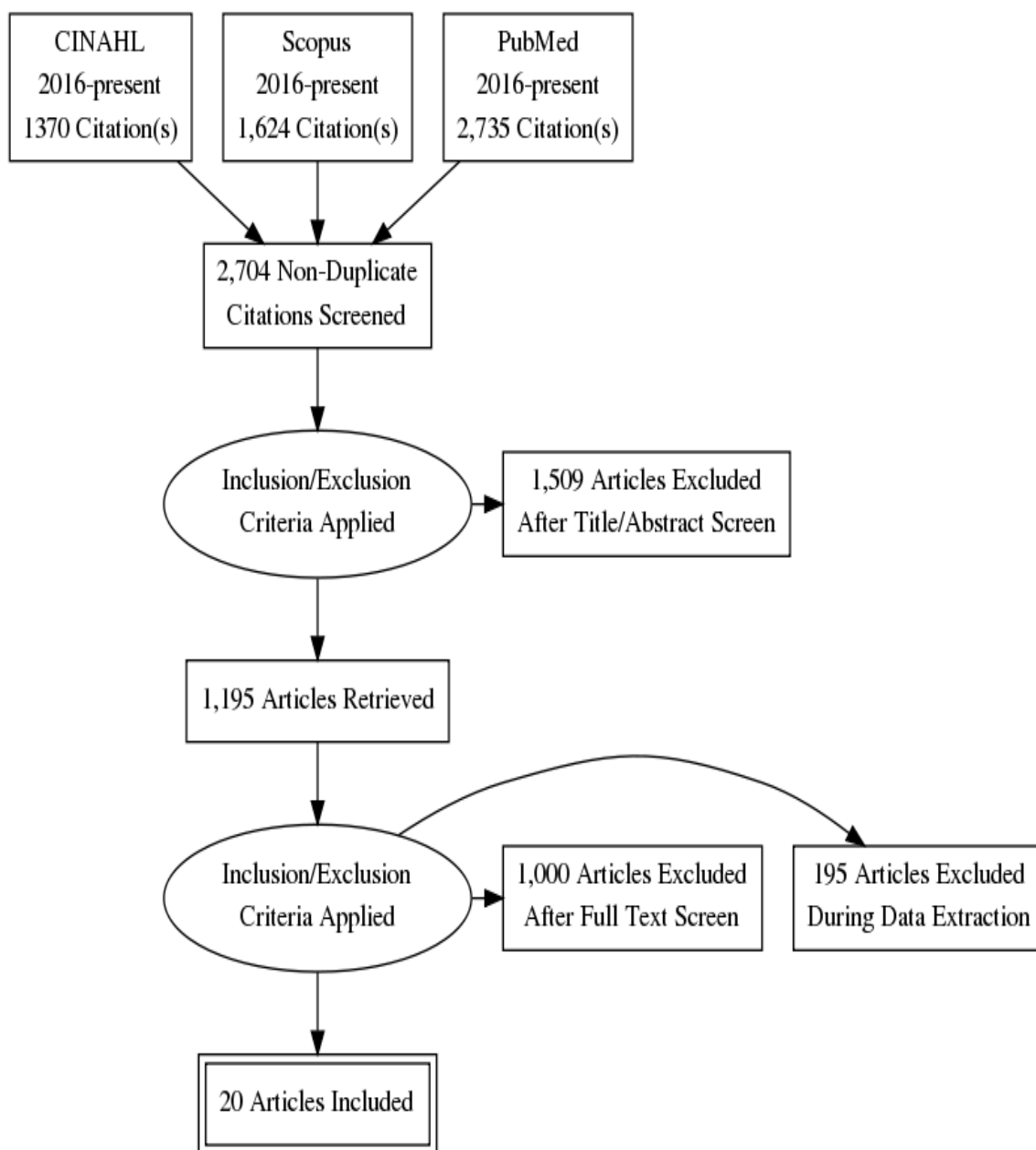
- **Actual System Use:** The use of new technology outside of the initial intervention or introduction to the technology.
- **Antiretroviral therapy (ART):** Synonyms are Combination Therapy, Combined Antiretroviral Therapy (cART), Highly Active Antiretroviral Therapy (HAART). The daily use of a combination of HIV medicines (called an HIV regimen) to treat HIV infection.
- **Attitude Toward Use:** Positive or negative feelings toward the information technology.
- **Behavioral Intention:** the power of one's interest in performing certain behaviors user subjectivity on their possibility of using a particular technology.
- **Health-ITUES:** Health Information Technology (IT) Usability Evaluation Scale. A validated tool used to measure the actual usability after the initial introductory period to the new technology.
- **People Living with HIV (PLWH):** Infants, children, adolescents, and adults who have HIV/AIDS.
- **Perceived Ease of Use:** The degree to that a person believes that using a particular system would be free from effort.
- **Perceived Usefulness:** The degree that a person believes that using a particular system would enhance his or her job performance.

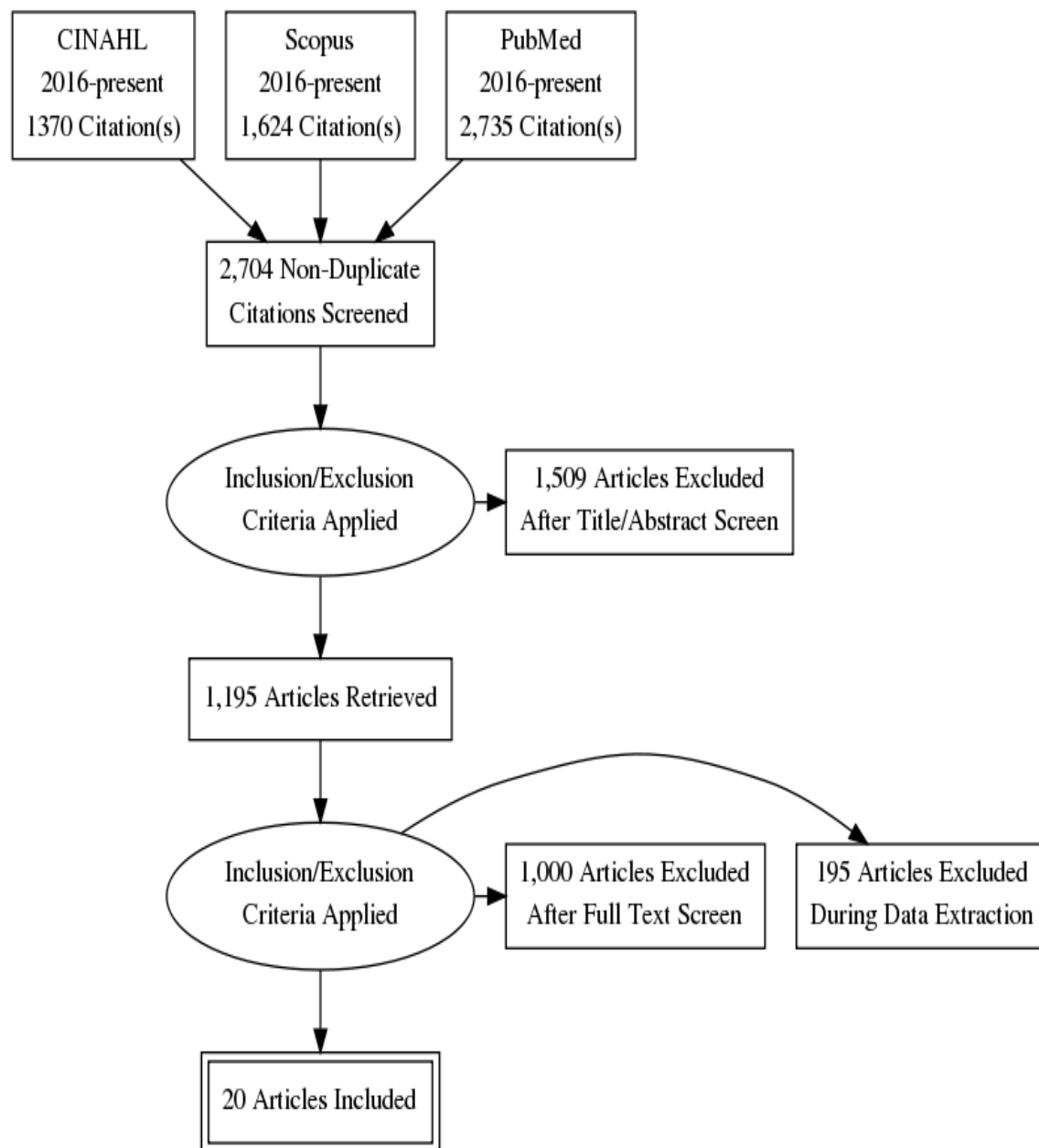
- Perinatal transmission: Synonyms are Maternal-Child Transmission, Mother-to-Child Transmission (MTCT), Vertical Transmission. When a mother with HIV passes the virus to her infant during pregnancy, labor and delivery, or breastfeeding (through breast milk).
- Pre-Exposure Prophylaxis (PrEP): An HIV prevention method for people who are HIV negative and at high-risk of HIV infection.
- Secondary Transmission: Synonym is horizontal transmission. The transfer (spread) of HIV that occurs during sex or needle sharing as the result of contact with the semen, vaginal fluid, or blood of a person with HIV.
- Serodiscordant Couple: Synonyms are Discordant Couple or Mixed-Status Couple, specifically about HIV.
- Serostatus: The state of either having or not having detectable antibodies against a specific antigen, as measured by a blood test.
- Undetectable=Untransmittable (U=U): Synonym is Treatment as Prevention (TasP). When the viral load of HIV in the blood is too low to be detected. A person's viral load is considered "durably undetectable" when it stays undetectable for at least 6 months after a first undetectable test result. When a person is undetectable and in viral suppression, they are considered unable to transmit the virus.
- Usability: the extent to that a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use.

Appendix B

Search Strategy

The researcher performed an electronic search in CINAHL, Scopus, and PubMed.





Appendix C

Table of Evidence

Author/Year	Sample/Setting	Level and Design	Interventions and Outcomes	Results	Limitations
Awiti et al., (2016)	4-7 facilities. n=600 pregnant WLWH in Kenya	Level II Two-arm RCT	Use of a WelTel (mHealth Patient Engagement Service for Healthcare Providers) system to send weekly messages to WLWH during pregnancy and their HIV-exposed infants in care until infants are aged 24 months. Outcomes measured as adherence to the WelTel SMS interventions, ART,	Effectiveness of mHealth for PMTCT retention. Trial results and the cost-effectiveness evaluation will use to inform policy and potential scale-up of mHealth among mothers living with HIV.	None noted.

			perceived facilitators/barriers of the WelTel, and cost effectiveness.		
Batra et al., (2018)	n=292	Level II Cluster RCT	MyFamilyPlan, an online tool using preconception health education and self- assessment tool including 27 demographic items outlined by the national preconception health guidelines.	Exposure to the website was associated with a significant increase in discussion of reproductive health with a provider during a well- woman visit as per patient self-reporting.	Only 9% of those approached agreed to take part in the study. No demonstrated change in select preconception health behaviors associated with this brief intervention and did not have enough power to capture

					<p>changes.</p> <p>The follow up time of one week was not the best indicator of whether changes will actually be made.</p>
Beauchemin et al., (2019)	<p>n=20 PLWH (end-users)</p> <p>4 biomedical informatics professionals (expert)</p>	<p>Level V</p> <p>Three-step usability evaluation</p>	<p>All participants completed 26 tasks to rate functionality and usability of the application by using <u>Health Information Technology Usability Evaluation Scale (0-5 with a higher score indicating higher perceived usability)</u></p>	<p>The research suggests that a walkthrough by both experts and users were useful in forming refinements to the WiseApp and finalization of a mHealth app for PLWH to better self-manage their health.</p>	None noted.

Finocchario-Kessler et al., (2010)	n=181 WLWH of reproductive age from two clinics in Baltimore, MD	Level II Cross-Sectional Survey	The researchers used an audio computer-assisted self-interview about fertility desires and intentions using questions from standardized childbearing motivations scale.	<p>59% (n= 107) expressed a desire to have a child in the future, among whom 66% (n= 71) intend to have a child.</p> <p>Among the 71 WLWH who intended to have a child, 37% would like to be pregnant within one year, and 82% were moderately to very certain about this decision.</p> <p>33% of the sub-population who wanted a pregnancy did not intend to have one. 52% of the women in the</p>	None noted.
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				discrepancy group said their serostatus as the reason they do not intend to have a child.	
Garafalo et al., (2016)	n= 105 poorly controlled HIV-positive young-adults	Level II RCT	<p>Text message reminders sent daily to improve adherence among poorly adherent PLWH, aged 16–29.</p> <p>Adherence measured by a self-reported visual analogue scale (VAS; 0–100%) for 6- and 12-month periods.</p> <p>Satisfaction measured by</p>	<p>Results suggested a significant improvement in adherence and viral suppression with text message intervention.</p> <p>The researchers considered the intervention practical and scalable.</p>	<p>Participants self-reported the results.</p> <p>Convenience sample population.</p>

			8-item Client Satisfaction Questionnaire		
Jennings et al., (2013)	n=45 including WLWH enrolled in PMTCT, their male partners, community health workers, and nurses.	Level VI Qualitative Study	The researchers implemented gender-specific encouraging text messages to follow-up with preconception, prenatal, and postpartum care for WLWH to prevent prenatal transmission of HIV.	Results suggest this platform holds considerable potential.	<p>Current communication such as brochures, radio, women's groups, or facility-based counseling not discussed in the research.</p> <p>Courtesy bias of participants' response to the questions rather than the participant's actual</p>

					<p>experiences.</p> <p>The limited number of characters hindered the efficacy of communication</p>
Mbuagbaw et al., (2013)	3 randomized control trials with a total of 1166 participants.	Level I Meta-analysis of RCT	Summary statistics of categorical variables and outcomes within all three RCTs.	<p>The researchers found that within the two large Kenyan studies, there was a significant improvement in medication adherence and in the third there was no improvement.</p> <p>The researchers found that by running a meta-analysis, improvements can be made to future implementation to</p>	None Noted.

				involve the subpopulations who would benefit from the use of certain text message systems.	
Mehraeen et al., (2018)	n=42 Studies	Level I Systematic Review of RCTs	N/A systematic Review of several RCTs.	The researchers found three main categories (clinical data entry, demographic information, and technical capabilities) of mHealth self-management applications in PLWH for mHealth self-management.	None noted.
Mindry et al., (2012)	n=93	Level II Cross- Sectional Survey	Cross-sectional survey given to participants at their provider locations.	39 % of the participants reported a desire to have children, two-thirds of clients did not discuss their desires,	Participants may want to have a child but not have the means to see a

				or methods of safe conception, with providers.	provider that can aid them or services that they can afford to use.
Muwonge et al., (2018)	n=142 ≥18 years of age, sexually active, and serodiscordant couple at enrollment	Level VI Single Qualitative Study	Partners Mobile Adherence to PrEP participants received SMS surveys daily for 7 days before and after each face-to-face visit. Participants from this convenience sample were given an exit survey.	Research from this study suggests that 95% of couples in serodiscordant couples in Kenya and Uganda felt SMS surveys were “easy” or “very easy”, 74% had no challenges, and 72% preferred SMS surveys over in-person visits for various reasons.	Participants were from a convenience sample, already had access to cellphones, and self-reported their adherence.
Squires et al.,	n=700 WLWH	Level II	Researchers gave	55% (n=385) of participants	None noted.

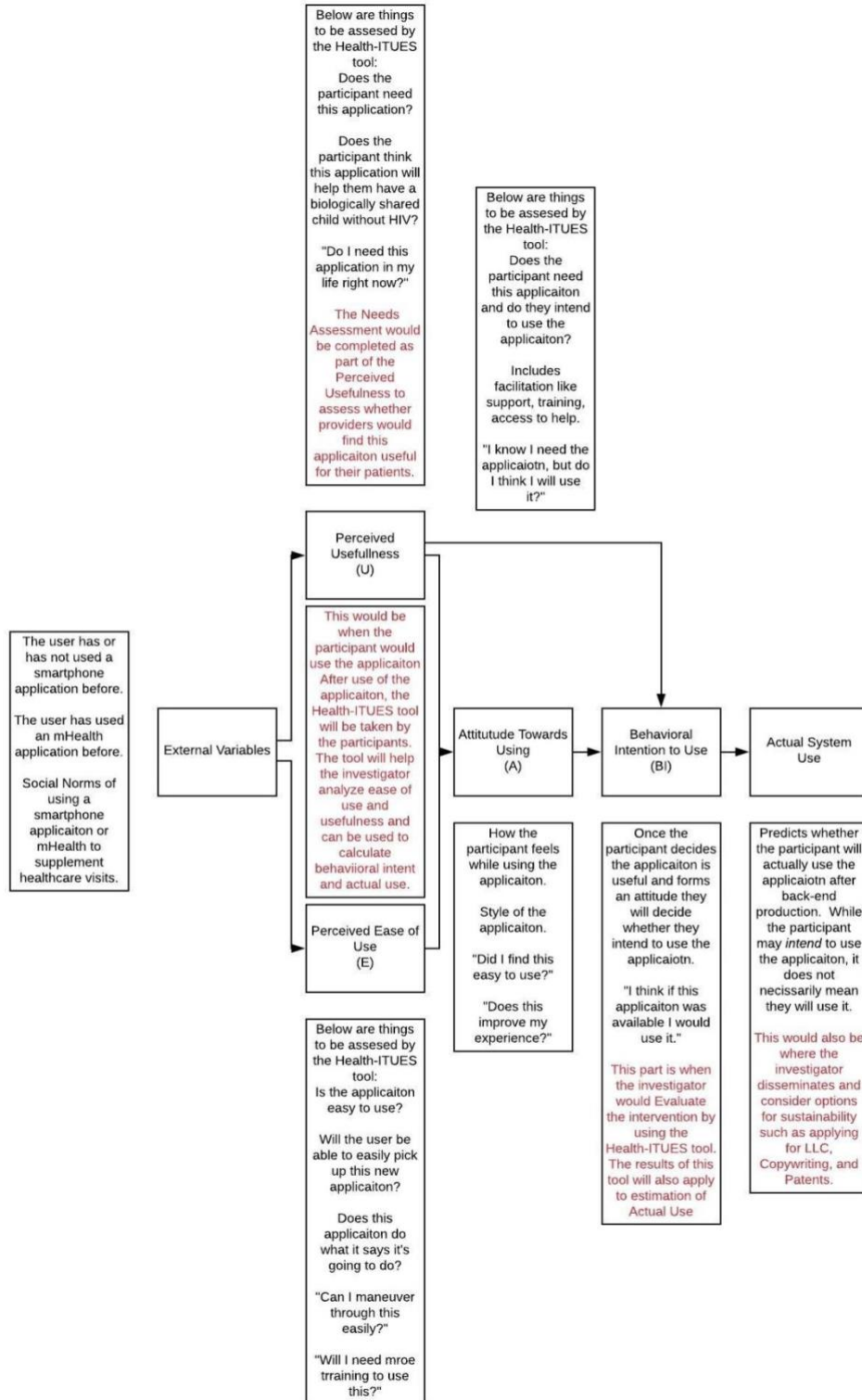
(2011)	receiving combination antiretroviral therapy for 3 years or more	Cross-Sectional Survey	participants survey with 45 questions.	<p>had never discussed gender-specific HIV treatment issues with their HIV care providers. Of the 45% (n= 315) who did discuss these issues, 96% (n=299) were satisfied.</p> <p>61% of the women surveyed said they wanted a pregnancy but 59% felt that society strongly urge them not to have children.</p> <p>Of these 61% that wanted a child, those who used a nurse practitioner or a physician's</p>	
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				<p>assistant as their primary care provider, only 48% felt this social stigma versus 62% who had an infectious disease or family practice specialist.</p>	
Steiner et al., (2013)	<p>n=41 articles</p> <p>About (1) early epidemic, 1981-1991 (n = 5), (2) changes in the epidemic, generally 1992-2006 (n= 18), and (3) current context, 2007 to May 2012 (n</p>	<p>Level I</p> <p>Systemic Review of RCT</p>	<p>Systemic Review with inclusion criteria of articles with dates from 1981-2012 containing keywords "HIV," "AIDS," "fertility intentions," "fertility desires," "pregnancy," "reproduction," "reproductive health," "childbearing," "prevention of mother- to-</p>	<p>The researchers suggest that there is a need in maximizing and applying risk-reduction within the context of Treatment as Prevention.</p>	<p>None noted.</p>

	= 18)		child transmission," "antiretroviral therapy," "communication," "discussions," "preconception counseling"		
Willcox et al., (2015)	n=15 pregnant or postpartum women.	Level II Qualitative Study	12 in-depth interviews with health professionals including two from each category: obstetricians, General practitioners, midwives, dietitians, physiotherapists, and community pharmacists.	Participants were asked about websites, video messaging, applications, texts, and social networks and whether they felt antenatal care was worse, the same, or improved with the use of these resources.	Having only two representatives for each Health professional role. Convenience sample population.

Appendix D

TAM Theoretical Framework



Appendix E

Demographic Survey

PrE(P)Conception Demographic Survey

What is your preferred gender?

- ☐ Male
- ☐ Female
- ☐ Transgender Male
- ☐ Transgender Female
- ☐ I prefer not to answer

What range best describes your age?

- ☐ 18-20
- ☐ 21-29
- ☐ 30-39
- ☐ 40-49

Please specify your ethnicity.

- ☐ White
- ☐ Hispanic or Latino
- ☐ Black or African American
- ☐ Native American or American Indian
- ☐ Asian / Pacific Islander
- ☐ Other
- ☐ I prefer not to answer

What is your marital status?

- ☐ Single
- ☐ Married
- ☐ Widowed
- ☐ Divorced
- ☐ Separated

Are you currently diagnosed with HIV?

- ☐ Yes
- ☐ No
- ☐ My partner is diagnosed with HIV
- ☐ I prefer not to answer

Do you desire to have children at any point in the future?

- ☐ Yes
- ☐ No

Have you ever used a smartphone application?

- ☐ Yes
- ☐ No

Appendix F

Health-ITUES Questionnaire

Health-ITUES

Please answer the following questions using the scale below:

Strongly Agree 5 Somewhat Agree 4 Neutral 3 Somewhat Disagree 2 Strongly Disagree 1

Impact

1. I think that PrE(P) Conception would be a positive addition for persons living with HIV.
 2. I think that PrE(P) Conception would improve the Quality of Life of persons living with HIV.
 3. PrE(P) Conception is an important part of meeting my information needs related to preconception management while living with HIV.
-

Perceived Usefulness

4. Using PrE(P) Conception would make it easier to manage the preconception period along with care from my provider.
5. Using PrE(P) Conception would enable me to understand tasks in the preconception period more quickly along with care from my provider.
6. Using PrE(P) Conception would make it more likely that I would be able to manage the preconception period along with care from my provider.
7. Using PrE(P) Conception would be useful during the preconception period.
8. I think PrE(P) Conception presents a more equitable process for self-management of the preconception period along with care from my provider.

9. I would be satisfied using PrE(P) Conception for management of the preconception period along with care from my provider.
10. I think I would be able to manage the preconception period in a timely manner because of PrE(P) Conception along with care from my provider.
11. I think using PrE(P) Conception would increase my ability to manage the preconception period along with care from my provider.
12. I would be able to better manage the preconception period whenever I use PrE(P) Conception along with care from my provider.

Perceived Ease of Use.

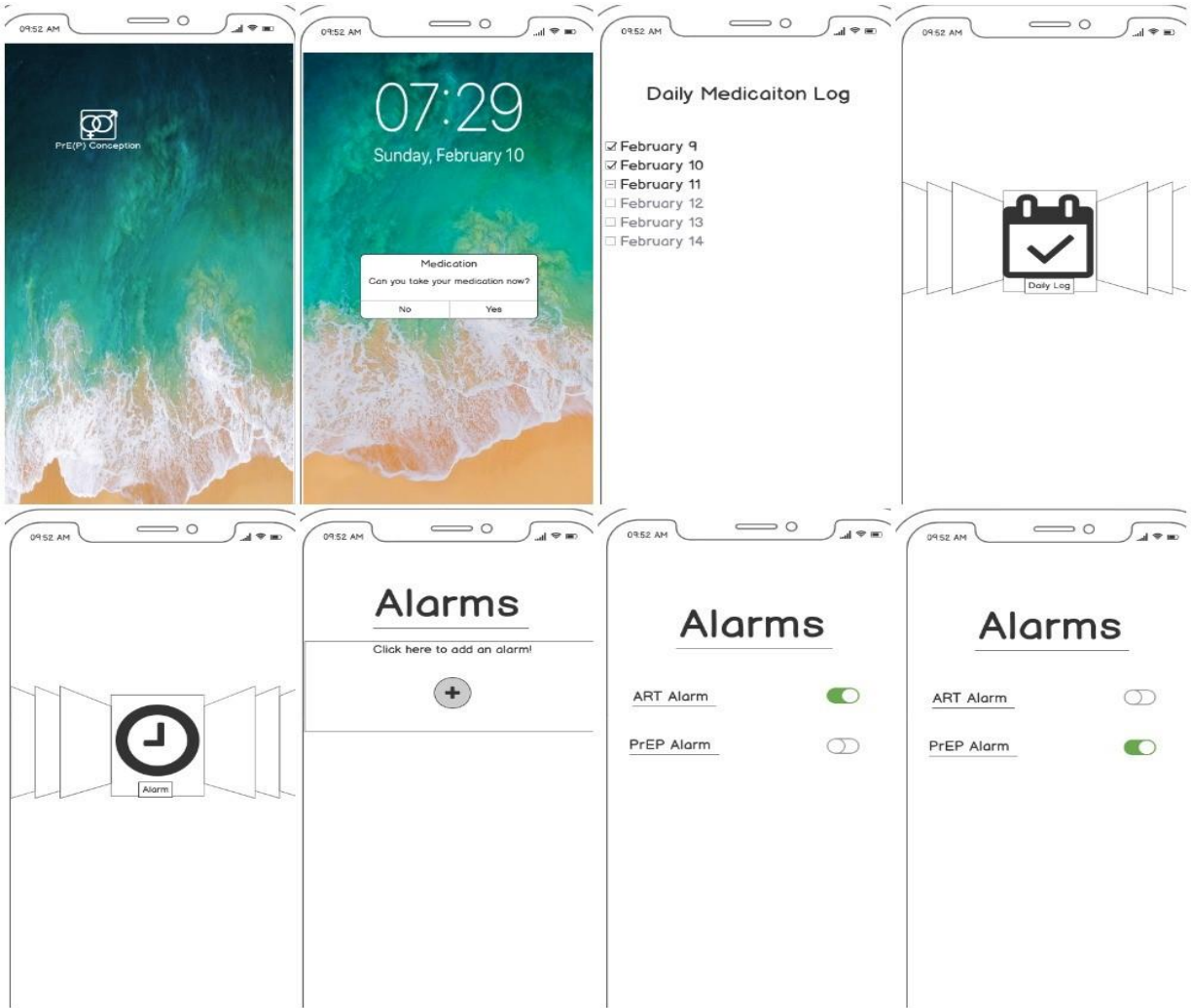
13. I am comfortable with my ability to use PrE(P) Conception.
14. Learning to operate PrE(P) Conception is easy for me.
15. It is easy for me to become skillful at using PrE(P) Conception.
16. I find PrE(P) Conception easy to use.
17. I can always remember how to open and use PrE(P) Conception.

User Control

18. PrE(P) Conception gives notifications that clearly tell me what to do next.
19. Whenever I make a mistake using PrE(P) Conception, I would be able to recover easily and quickly.
20. The information such as online link, push notifications, checklists, and timers used within PrE(P) Conception are clear.

Appendix G

PrEP Conception Application Wireframe Screenshots





Appendix H

Recruitment Flyer

Are you or your partner HIV Positive?
Would you like to have children in the future?



The PrE(P)Conception Application Investigators are looking for participants who are:
18 or older.

In a heterosexual serodiscordant couple.

Desire a child at some point in the future.

- This project is developing a smartphone application for couples in serodiscordant relationship who desire a biologically shared child.
- Participants will be asked to test a smartphone application prototype and asked questions about their experience with the application.
- This project will take approximately 20-30 minutes, during one session, at The FXB Center. In return participants will be compensated with a \$20 Amazon gift card.

Jessica Wahler, a DNP Nursing Student at Rutgers, is conducting this study. If you are interested in participating or have more questions, please contact her via email at [REDACTED]

Version #1 4/11/19

CONSENT FORM

FOR MOBILE/ELECTRONIC DEVICE OR TECHNOLOGY STUDY

Invitation:

You are invited to participate in a research study that is being conducted by Jessica Wahler, a DNP student at Rutgers University. This consent form is part of an informed consent process for a research study and it will provide information to help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand. After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

Purpose of Study:

The purpose of this research study is to determine if a smartphone application is useful and easy to use for serodiscordant couples in the preconception period. Approximately 5-10 subjects will participate in the study, and each individual's participation will last approximately 20-30 minutes.

Study Procedures:

The study procedures involves participants first completing a demographic survey, then reviewing a smartphone application by navigating the click-through wireframe, and finally answering a 20-question survey about the application.

Data Collection:

This research is confidential. Confidential means that the research records will include some information about you and this information will be stored in such a manner that some linkage between your identity and the response in the research exists. Some of the information collected about you includes signed participant consent forms. No other identifiable data such as name, address, or phone number will be collected.

Access to Research Data:

The research team and the Institutional Review Board at Rutgers University are the only parties that will be allowed to see the data, except as may be required by law. If a report of this study is published, or the results are presented at a professional conference, only aggregate data results will be stated.

Data Destruction:

All study data will be kept for a minimum of three (3) years unless the project becomes published or funded. The information will be destroyed as per IRB requirements.

Data Transmission & Storage:

Research data will be collected via paper survey forms delivered and collected by the primary investigator. Please note that we will keep this information confidential by limiting individual access to the research data and keeping it in a secure location. The research data will be stored within a locked cabinet, within a locked room within a security protected building at 65 Bergen street in Newark, NJ.

General Risks:

There is some possibility that others may see your demographic or application review surveys while you are completing them. Measures to protect security in these instances are described below. Any known potential loss of confidentiality will be disclosed here.

Risks of participation include:

There is no expected discomfort with participation in this project and the physical risk to participants is minimal. Some questions that participants may be asked to answer may cause you to think about feelings or experiences that may make you sad or upset. During participation in this project, any information collected, including your name and personal health information from the informed consents, will be assigned a number and only research staff will have access to the link between your information and the number assigned to it. This will limit and exclude any breach of confidentiality.

Benefits:

You have been told that the benefits of taking part in this study may be insight into information about the preconception period for serodiscordant couples. However, you may receive no direct benefit from taking part in this study. You will receive a gift card for completing the entire study.

Voluntariness:

Participation in this study is voluntary. You may choose not to take part, and you may withdraw at any time during the study procedures without any penalty to you. In addition, you may choose not to answer any questions that you are not comfortable. If you decide to take part and choose to later withdraw from the study, then you may do so at any time by contacting the researcher. After withdrawing from the study, your data and/or health information will no longer be used or

shown in the study, except to the extent that the law allows the researchers to continue using and disclosing your information.

You should be aware that the researchers may continue to use and disclose data only once the data had already been stripped of all identifiers. If you wish to withdraw your permission for the research use or disclosure of your data and/or health information in this study, you may do so in writing by contacting Jessica Wahler at [REDACTED]

Questions about the Research:

If you have any questions about the study or study procedures, you may contact myself at

[REDACTED]

If you have any questions about the study or study procedures, you may contact myself at atimw410@sn.rutgers.edu. You may also contact my faculty advisor Darcel Reves at [REDACTED], by email at [REDACTED] and by phone at [REDACTED]

Questions about Participant Rights:

If you have any questions about your rights as a research subject, you may contact the IRB Administrator at Rutgers, the State University of New Jersey at:

Arts & Sciences Institutional Review Board

Office of Research and Regulatory Affairs

335 George Street, Suite 3200

New Brunswick, NJ 08901-8559

Telephone: 732-235-2866

Email: human-subjects@ored.rutgers.edu

You will be given a copy of this consent form for your records. Sign below if you agree to participate in this research study:

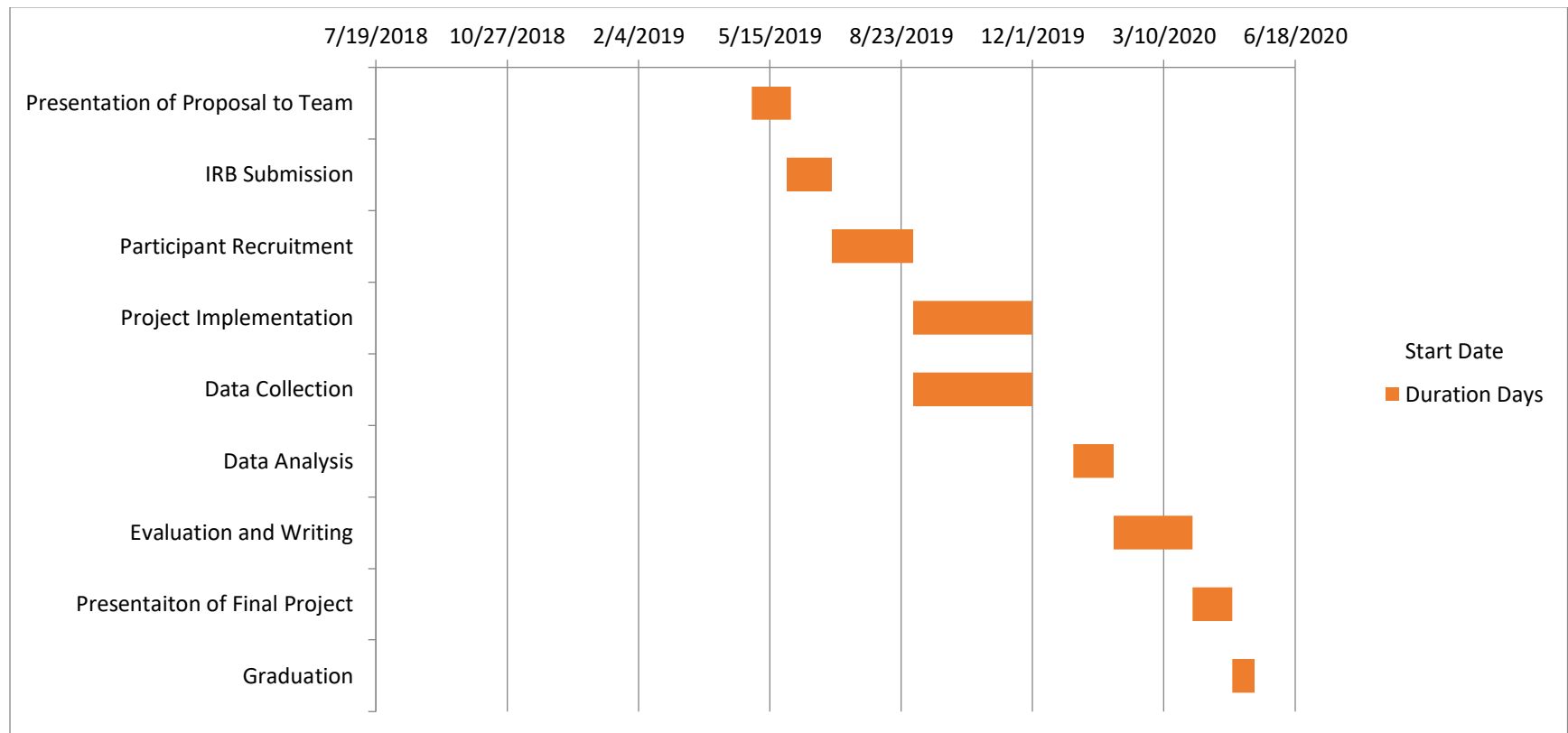
Subject (Print) _____

Subject Signature _____ Date _____

Principal Investigator Signature _____ Date _____

Appendix J

Gantt Timeline



Appendix K

Budget for the Project

Items	Reason	Quantity	Cost
Flyers	Recruitment	100 (@ \$0.04/piece)	\$4.00
\$20 Amazon Gift Cards	Participant Compensation	20 (@ \$20/card)	\$400
Balsamiq Cloud (yearly)	Wireframe Housing and Development	1	\$90/year
Project Poster Print	For dissemination	1	approx. \$60

Appendix L

Open-Ended Participant Questions for Evaluation

“What did you like about this application?”

“What did you dislike about this application?”

“What would you change about the application to improve your experience?”

Appendix M

Results Tables

Table 1. Cumulative Mean, Standard Deviation (SD), and Medians.

<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Median (range)</i>
13	4.42	0.68	4.5 (2-5)

Table 2a. Cumulative Subset Means, SD, and Median for all participants.

Health-ITUES Subset	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Median (range)</i>
Impact	13	4.38	0.85	5 (2,4,5)
Usefulness	13	4.43	0.65	5 (3,4,5)
Ease of Use	13	4.46	0.56	4 (3,4,5)
Control	13	4.33	0.77	4 (2-5)

Table 2b. Cronbach's Alpha for Usefulness

Cronbach's Alpha (α)	<i>n</i>
0.915	9

Table 2c. Cronbach's Alpha for Ease of Use

Cronbach's Alpha (α)	<i>n</i>
0.95	5

Tables 3. Demographics Tables

Table 3a. Cumulative Mean, SD, and Median Between Male and Female Participants

Demographic	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Median (range)</i>
Male	3	3.8	1.36	4
Female	10	4.55	2.70	5

Table 3b. Cumulative Mean, SD, and Median Subsets for Male and Female Participants

Demographic/ Subset	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Median</i>
Male	3			
Impact		3.56	0.88	4
Usefulness		4.15	0.6	4
Ease of Use		4.07	0.46	4

Control		3.78	0.83	4
Female	10			
Impact		4.63	1.15	5
Usefulness		4.51	1.27	5
Ease of Use		4.58	0.45	5
Control		4.5	2	5

Table 3c. Cumulative Mean, SD, and Median Between Age Groups of Participants

Demographic	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Median (range)</i>
21-29	6	4.54	1.12	5
30-39	3	4.40	0.62	4
40-49	4	4.24	1.36	4

Table 3d. Cumulative Mean, SD, and Median Subsets for Between Age Groups of Participants

Demographic/ Subset	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Median</i>
21-29	6			
Impact		4.67	1.73	5
Usefulness		4.46	0.83	5
Ease of Use		4.67	0	5
Control		4.44	1.53	4
30-39	3			
Impact		4.44	0.58	4
Usefulness		4.44	0.71	4
Ease of Use		4.27	0.45	4
Control		4.44	0.58	4

40-49	4			
Impact		3.92	1.15	4
Usefulness		4.36	1.24	4
Ease of Use		4.30	0.84	4
Control		4.08	2.08	4

Table 3e. Cumulative Mean, SD, and Median Between Single and Married Participants

Demographic	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Median (range)</i>
Single	1	4.43	1.76	5
Married	12	4.25	0.72	4

Table 3f. Cumulative Mean, SD, and Median Subsets Between Single and Married Participants

Demographic/ Subset	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Median</i>
Single	1			
Impact		4.42	2.00	5
Usefulness		4.43	1.80	4.5
Ease of Use		4.48	0.45	4.5
Control		4.36	3.06	4
Married	12			
Impact		4.00	0	4
Usefulness		4.44	0.73	5
Ease of Use		4.20	0.84	4
Control		4.00	1.00	4

IRB Approval Letter

