TITLE PAGE

ABSTRACT

Purpose: The purpose of this innovative, developmental grant was to develop a Fast Health Interoperability Resources (FHIR) compliant, mHealth application to improve screening, brief intervention, and referral to treatment for risk and protective factors in pregnant women.

Scope: Perinatal outcomes in the United States consistently rank lower than other developed countries and fail to meet the Healthy People 2010 and 2020 goals. Research suggests that pregnant women and their infants have improved outcomes with attention to risk and protective factors, and technology has the potential to provide comprehensive assessment and treatment for risk and protective factors during pregnancy.

Methods: *StartSmart*^{TM} was developed through an iterative process based upon Davis' Technology Acceptance Model with prototype development, alpha testing, and beta testing that incorporated patient and provider feedback in each phase. *StartSmart*^{TM} includes screening, decision support, and brief interventions for the following factors: weight status and related conditions (underweight, overweight/obese, gestational weight gain, gestational diabetes mellitus), substance use (alcohol, drugs, tobacco), emotional conditions (anxiety, depression, domestic violence), and protective factors (immunizations, prenatal vitamins, physical activity, sleep). Development of the prototype included consultation with expert clinicians, scientists, and patients to optimize screening of pregnant women for prenatal risk and protective factors as well as generating clinical decision support, tailored patient recommendations, and provider prompts for brief motivational interviewing counseling. The process included foundational needs assessments (focus groups and individual interviews) with providers and pregnant women. After the prototype was developed, patients and providers were interviewed to provide feedback on *StartSmart*^{TM}. Refinements were made and a beta test of the refined version was conducted. Also, a systems engineer with workflow expertise observed the use of *StartSmart*^{TM} in the clinic setting and conducted process mapping to understand the impact on patient flow as well as workload for medical assistants and front desk staff. Future interoperability with electronic health records was tested by establishing *StartSmart*^{TM} connectivity with a publicly available and FHIR-compliant server.

Results: A prototype of decision support prenatal screening technology based upon the SBIRT framework was developed with patient and provider feedback. Alpha testing of the prototype was used to refine and improve acceptability and usability. Beta testing revealed patient and provider satisfaction with the screening technology and the individualized patient education materials.

Key Words: decisions support, SBIRT, tailored patient education, Davis' Technology Acceptance Model, prenatal screening

PURPOSE

Objectives:
1. The first aim of the project included developing a prototype mHealth technology, *StartSmart[TM],* based upon an expanded Screening, Brief Intervention, and Referral to Treatment (SBIRT) model.

2. The second aim included alpha testing and refinement of *StartSmart[TM]* based upon patient and provider feedback.

3. The third aim was to beta test and refine based upon patient interviews and providers surveys regarding acceptability and usability.

SCOPE

Background and Prevalence

Many conditions and lifestyle factors during pregnancy impact a woman's health as well as the health of her child – some effects lasting long after birth.[1] Despite advancements in perinatal healthcare, infant morbidity and mortality have seen little improvement in this country[2] and rates of severe maternal morbidity have continued to rise.[3] Evidence points to a link between poor perinatal outcomes and **pregnancy health risks** such as mental health conditions, substance use, and chronic diseases, including obesity and diabetes, during pregnancy.[4] **Protective factors** that can influence pregnancy outcomes include immunizations, nutrition, physical activity, and sleep, yet pregnant women are not consistently counseled on these.[5] Adherence to perinatal guidelines is limited due to time constraints and clinic demands.[6] Chart reviews of 25,408 pregnant women[7] reported lower incidence of pregnancy health risks compared to national statistics[8] (smoking 13% compared to national average of 19%; depression 3% compared to 11%, and postpartum depression 2% compared 12%), suggesting under recognition of perinatal health risks in busy practices.[7]

Pregnancy health risks: Mood disorders can cause serious health conditions by compromising the immune, cardiovascular, neuroendocrine, and central nervous systems, leading to adverse birth outcomes such as preterm delivery.[9] Psychobiological markers of stress during the first trimester result in delayed fetal maturation, and researchers hypothesize that maternal stressors, such as anxiety and/or depression, may impact the offspring's growth and development long-term.[10] Accumulating evidence suggests that maternal psychological and social stress during pregnancy is associated with behavioral, cognitive, and interactional difficulties as a result of these fetal health alterations.[10,11] A recent review revealed that gestational depression may have negative effects on the developing fetus (hyperactivity, irregular fetal heart rate), newborns (increased cortisol and norepinephrine levels, decreased dopamine levels, altered electroencephalogram [EEG] patterns, reduced vagal tone, stress/depressive-like behaviors, and increased rates of premature deaths and neonatal intensive care unit admission), and children (increased salivary cortisol levels, internalizing and externalizing problems, and central adiposity).[12] Research also suggests that failure to prevent or alleviate anxiety and depression during pregnancy contributes to the chronicity of mental illness across generations.[13-17] Studies show one in six pregnant women are exposed to domestic violence, and higher rates of depression and post-traumatic stress disorder have been found in these women after delivery.[18] Children living with mothers abused during pregnancy displayed more behavioral problems, especially depression and anxiety.[19] Maternal substance use during pregnancy can result in devastating outcomes.

Prenatal alcohol exposure has been linked to birth defects of major organ systems, growth disorders, and damage to multiple structures in the brain resulting in permanent and lifelong disabilities.[20] Maternal smoking can cause premature birth and/or intrauterine growth restriction resulting in low birth weight, and increases the risk for maternal conditions such as placenta previa, placental abruption, decreased maternal thyroid function, and ectopic pregnancy.[21] Clinical studies indicate prenatal exposure to heavy marijuana use may lead to cognitive and behavioral outcomes in childhood and altered executive function in adolescence.[22] With the legalization of recreational marijuana use in Colorado, it is unknown how many pregnant women may be exposing their fetus to marijuana.

Maintaining a healthy weight (body mass index [BMI]) prior to and during pregnancy and eating a healthy diet can lower the risk of gestational diabetes, preeclampsia, birth defects, intrauterine growth restriction, and later chronic disease.[23] While obesity itself as a risk factor cannot be resolved during pregnancy, gestational weight gain can still be mitigated to improve perinatal outcomes.[24] In addition, the rising prevalence of gestational diabetes mellitus could soon affect one in five pregnant women,[25,26] and it is feared that identification and

treatment will be cost prohibitive to the health care system.[27,28] Increasing evidence supports a 30-50% risk of subsequent diabetes in women with gestational diabetes mellitus and a high risk of metabolic disease in off-spring, particularly if born with excess adiposity.[29-31]

Protective factors that can influence pregnancy outcomes include immunizations, nutrition, physical activity, and sleep. Vaccines recommended during pregnancy include the inactivated influenza vaccine (IIV) during influenza season (can be given any trimester) and the tetanus, diphtheria, and accellular pertussis (Tdap) vaccine (ideally given between 27-36 weeks to protect the newborn from potentially fatal infections).[32,33] Colorado ranks second in the U.S. for refusal of vaccine administration,[34] highlighting the potential to improve this important health indicator during the prenatal period. A healthy diet is essential for optimal pregnancy outcomes as well. Folic acid is particularly important for healthy fetal development in the first few weeks after conception,[35] and has been shown to reduce the risk of some birth defects, such as spina bifida.[36] Most women of reproductive age do not have adequate dietary folate intake, and daily folic acid supplementation is necessary to ensure adequate folate levels.[37] However, many women do not take prenatal vitamins or folic acid during early pregnancy, with compliance ranging from 9-55%, depending on race/ethnicity, education, income, and other characteristics.[38] Prenatal physical activity is associated with adequate gestational weight gain,[39,40] improved course of delivery,[41,42] reduced incidence of gestational diabetes mellitus,[39] preeclampsia,[43] and many psychological benefits.[44,45] Disturbed maternal sleep is associated with an inflammatory process, gestational diabetes mellitus, hypertension, depression, longer labors, and cesarean section delivery.[46]

Context
Evidence suggests that decision-support technology, self-management, and behavior change programs have the potential to increase healthy behaviors.[47-49] The use of computer algorithms to tailor interventions and education based on user data can make information more relevant, engaging, and effective.[47-49] Technology can facilitate decision support for both clinicians and patients.[50-53] Technology decision support has been shown to significantly improve screening and referral for maternal depression compared to clinician reminders,[54] as well as significant improvements in patient outcomes for brief interventions for smoking during pregnancy.[55] Self-administered and computer-administered instruments have been found to elicit more accurate responses than face-to-face interviews with both the general population and specifically pregnant women.[56,57] A study screening pregnant women on sensitive information and risky behaviors including smoking cigarettes, using drugs, drinking alcohol, and intimate partner violence reported a higher prevalence of these behaviors using technology than reported in published studies using other reporting means.[58] Pregnant women were more likely to report positive responses to sensitive topics when using a computer screen.[58]

A systematic review[59] suggested decision-support technology improves patient outcomes in ambulatory care settings. Despite advances in technology, the review emphasized the need for further research to: (1) expand decision support technology to include multiple conditions simultaneously, (2) determine which members of the team should receive clinical decision support, (3) assess what impact technology has on clinical outcomes, and (4) evaluate how technology is best integrated into the workflow and deployed across diverse settings. Extending the reach of technology is mobile health (mHealth), defined as wireless and mobile technologies designed to improve research, health care services, and health outcomes.

Purpose
The purpose of this grant was an iterative development of mHealth technology that facilitates self-administered screening of pregnant women and automates decision support to improve brief motivational interviewing (MI) counseling and referral for treatment when indicated.

Setting and Participants
This project took place at the University of Colorado Hospital (UCH). The University of Colorado Health System (UCH and four partner institutions) has 4,500 deliveries per year. A heterogeneous mix of patient and provider types were used to assure development of a system for diverse payer mix populations including 41% private insurance and 59% Medicaid. Providers included obstetricians, family practice, and certified nurse midwifes.

Pregnant women were invited to participate in the development, refinement, and assessment of acceptability of the prenatal screening application. Inclusion criteria are: pregnant women who are 18 years of age or older, English-speaking, and who are attending their first or second prenatal appointment. Exclusion criteria include: pregnant women who are monolingual in a language other than English or have a health condition that interferes with completing the assessment such as cognitive impairment. Translation and validation with pregnant Spanish-speaking women will occur later. High-risk pregnancy conditions will be factored into the

treatment algorithms by referring the high-risk women to specialty treatment via the tailored recommendations and will not prohibit a woman from participating in the study. Demographics were collected on participants in all phases of the study and include standard prenatal screening questions for marital status, ethnicity, socioeconomic status, number of pregnancies and births. Client measurements of height, weight, blood pressure, immunization status, and glucose tolerance test laboratory findings will be entered by clinic staff.

METHODS

Design

Aim 1: Prototype Development

Iterative Development Process

The prototype development of *StartSmart*[TM] was a user-centric, data driven approach based upon the Davis' Technology Acceptance Model with end users who are engaged in technology development from initial concept through alpha and beta testing.[60] Fast Healthcare Interoperability Resources (FHIR), is a standard for electronic exchange that provides a framework and standards for the exchange, integration, sharing, and retrieval of information from electronic health records (EHRs). The prototype was FHIR compliant for future integration with EHRs. *StartSmart* uses a comprehensive Screening, Brief Intervention, and Referral to Treatment (SBIRT) approach with decision support and individualized patient education at the point of care, for the assessment and treatment for pregnant patients.[61] The SBIRT framework has primarily been used for perinatal substance use disorders and to some extent mood disorders.[62] An extended SBIRT model was used to develop *StartSmart* which: (a) screens for prenatal risk/protective factors, (b) uses motivational interviewing in a brief intervention to improve risk/protective factors, and (c) refers/treats when problems are identified[62]

Figure 1. Iterative development using the Davis' Technology Acceptance Model (TAM)
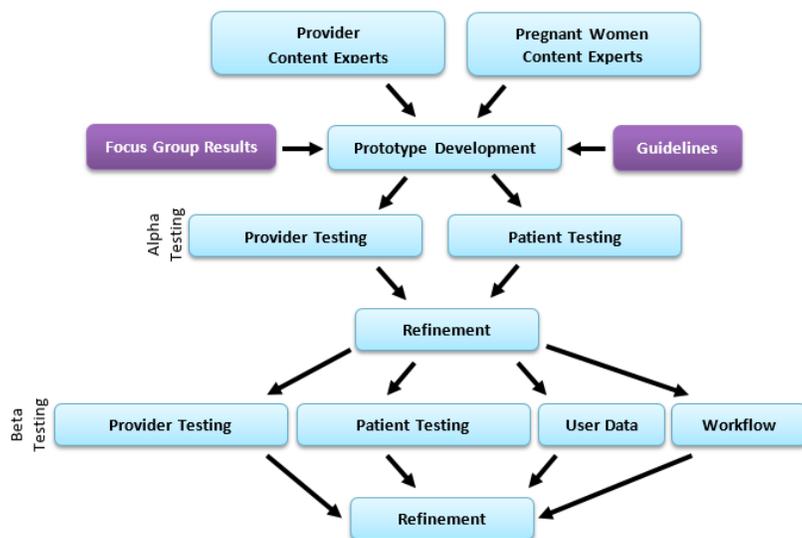
The TAM [60] guided the development of *StartSmart*[TM] to facilitate an innovative and standardized SBIRT approach to screening, brief intervention, and referral of pregnant women (see Figure 1). The system was developed with end users' input to facilitate ease of use and increase usefulness. *StartSmart*[TM] generates individualized patient handouts and provider prompts in an effort to aid clinical decision-making, guide provider counseling, and improve adherence to recommendations.

Focus groups and individual interviews with pregnant women and providers were conducted to learn about women's experience with prenatal screening, resources provided, referrals, and visits with specialists.[5] Findings informed the design and development of the technology. Clinical guidelines, expert consultations, and feedback from patients and providers were included during prototype development. Applying the SBIRT approach, the screening measures, cut points, frequency of screening and the recommended interventions for each level are outlined for each risk/protective factor in Table 1.

Pregnant women and experts in prenatal care, including OBs, CNMs, and family practice clinicians who worked with the target population provided input on the development of *StartSmart*[TM]. <u>Provider Content Experts</u> provided input on screening instruments, algorithm, and recommendations for *StartSmart*[TM] to ensure they were consistent, realistic, and evidence-based. Individual interviews and a focus group with four clinicians and scientists were conducted to discuss the development plans. Screening and treatment algorithms were developed with this input for the technology experts to implement (Table 1). Providers identified pregnant women from their practice to participate in development. Patients who agreed to participate were consented by the research team. <u>Patient Content Experts</u> were shown the proposed materials and asked about the best approach to screening questions, informing them about risks, and promoting adherence to the recommendations. Interviews took 40- 45 minutes, the focus group took 1.5 hours and experts received a $50 honorarium.

Table 1. Screening Instruments: Variables, Measures, and Decision Algorithms using SBIRT Framework

Domain[#]	Screen	No/Low Risk	Moderate Risk	High/Severe Risk
Treatment Approach		**Positive reinforcement**	**Brief intervention**	**Referral to specialty treatment**
Emotional Conditions				
Anxiety (once per trimester; 2-5 minutes)	Generalized Anxiety Disorder (GAD)[63]*: 1st use GAD-2; if >3 follow with GAD-7	GAD-2: ≤ 3 GAD-7:< 5 ___Options:___ -Positive reinforcement	GAD-7: 6-10 ___Options:___ -Brief intervention -Educational handouts on anxiety[a]	GAD-7: ≥10 ___Options:___ -Refer to Promise Clinic and/or Perinatal Clinic at Health Dept[a]
Depression (once per trimester; 2-5 minutes)	Patient Health Questionnaire (PHQ)[64]*:1st use PHQ-2; if score >3 follow with PHQ-9	PHQ-2: ≤ 3 PHQ-9: ≤ 9 ___Options:___ -Positive reinforcement	PHQ-9: 10-14[65] ___Options:___ -Educational handouts on depression[a] -Refer if patient prefers[a]	**Suicidality (Question 9): Escort to emergency department** PHQ-9: ≥15 without suicidality ___Options:___ -Refer to Promise or Perinatal Clinic[a]
Intimate Partner Violence (once alone; 2-5 minutes)	Abuse Assessment Screen (AAS)[66]*: 1st use AAS-2; if score >1 follow with AAS-5	AAS < 1 finished AAS>1 follow with Safety assessment (11 items)	AAS > 1 Currently safe ___Options:___ -Educational handout with a safety plan is given[a] -Information on resources[a]	AAS > 1 Unsafe or requests help ___Options:___ Referral to shelter and legal assistance. Information on resources given
Substance Use				
Alcohol (each visit; 2-5 minutes NIDA quick screen)	1st National Institute on Drug Abuse (NIDA) Quick screen*; if positive follow with Audit-C[67,68]*	No alcohol <1 ___Options:___ -Positive reinforcement	Audit-C: 1-2 ___Options:___ -Brief intervention re. harm -Reassess next visit	Audit-C: > 3 ___Options:___ -Health Team Works (referral list)[a] -Families First[a]
Drugs (each visit; part of NIDA quick screen)	NIDA Quick screen*	Quick screen <1 ___Options:___ -Positive reinforcement	Quick screen: 1-2 ___Options:___ - Brief intervention re. harm -Reassess next visit	Quick screen > 3 ___Options:___ -Health Team Works (referral list)[a] -Families First[a]
Tobacco (each visit; part of NIDA quick screen)	NIDA Quick Screen	Quick screen < 1 ___Options:___ -Positive reinforcement	Quick screen 1-2 ___Options:___ -Counseling on risks & handouts[a] -Reassess next visit	Quick screen > 3 ___Options:___ -Colorado Quit Line[a] -Stress management resources[a]
Obesity and Related Conditions				
Underweight (all prenatal visits)	Pre-pregnancy body mass index (BMI); Gestational weight gain (GWG)	BMI 18.5-24.9 kg/m^2 ___Options:___ -Reinforce healthy weight gain (25-35 lbs)	BMI <18.5 kg/m^2 ___Options:___ -Discuss GWG 28-40 lbs -Nutritional handout[a]	BMI <18.5 kg/m^2 + eating disorder ___Options:___ -Refer to counseling[a] -GWG 28-40 lbs
Overweight or Obesity (all prenatal visits)	Pre-pregnancy BMI; GWG	BMI 18.5-24.9 kg/m^2 ___Options:___ -Reinforce healthy weight gain (25-35 lbs)	BMI 25 - 29.9 kg/m^2 ___Options:___ -Discuss GWG 15-25 lbs -Nutritional and activity handouts[a]	BMI ≥ 30 kg/m^2 ___Options:___ -Referral nutrition/activity counseling[a] -GWG 11-20 lbs
GDM (1st visit: If BMI ≥30kg/m^2 or risk factors; Week 28: all)	50g Oral Glucose Tolerance Test (OGTT); if results ≥ 135 mg/dL proceed to 3-hour 100g OGTT	50g OGTT results < 135 mg/dL ___Options:___ -Reinforce diet and activity	50g OGTT results ≥ 135 mg/dL 100g 1 abnormal: Fasting ≥95; 1-hr ≥ 180; 2-hr ≥ 155; 3-hr ≥ 140 ___Options:___ -Set self-management goals around diet and activity[a] for next visit	50g OGTT results ≥ 200 mg/dL Fasting ≥95 OR 100g 2 abnormal: Fasting ≥95; 1-hr ≥ 180; 2-hr ≥ 155; 3-hr ≥ 140 ___Options:___ -Referral to endocrinology/medication
Protective Factors				
Immunizations (Tdap 3rd trimester; influenza during flu season)	Have you had the Tdap/influenza vaccine?	Yes ___Options:___ -Reinforce importance	No (interested in being vaccinated) ___Options:___ -Discuss risks & answer questions[a] -Administer inactivated influenza/Tdap	No (not interested in being vaccinated) ___Options:___ -Discuss risks and give handouts[a] -Follow-up at next visit
Prenatal Vitamin (all prenatal visits; 2 minutes)	1st visit: Are you taking a prenatal vitamin? After 1st visit: Adherence question*	Yes ___Options:___ -Reinforce; prescription Adherence: 0-1 ___Options:___ -Reinforce importance	No (interested in taking) ___Options:___ -Discuss risks[a]; prescription Adherence: 2-3 ___Options:___ -Discuss risks[a]	No (not interested in taking) ___Options:___ -Refer to dietitian[a] Adherence > 4 ___Options:___ -Refer to dietitian[a]
Physical Activity (all prenatal visits; 2 minutes)	Godin-Shepherd[69]*	≥ 150 minutes/week ___Options:___ -Reinforce behaviors -Warn unsafe activities for pregnant women	30-149 minutes/week ___Options:___ -Set self-management goals -Troubleshoot barriers -Reinforce positive behaviors -Referral if desired -Highlight unsafe activities	<30 minutes/week ___Options:___ -Refer to intervention to promote physical activity among sedentary women[a] -Highlight starting slow, encourage walking, activities to avoid
Sleep (all prenatal visits; 2 minutes)	Insomnia Severity Index (ISI)[70]*	Score 0-14 None or subthreshold insomnia ___Options:___ -Positive reinforcement	Score 15-21: Clinical insomnia, moderate ___Options:___ -Educate on sleep hygiene/habits[a]	Score 22-28: Clinical insomnia, severe ___Options:___ -Referral Sleep Center[a]
Nurse/Family Partnership (first visit)	First live birth Low income & <28wks	If not eligible, not referred	If eligible referred to Nurse Family Partnership[a]	

Figure 2. Tablet-based screening
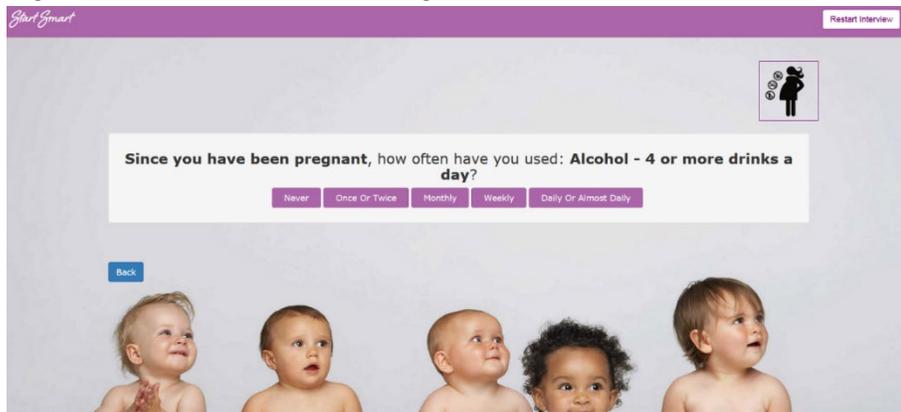
FHIR-compliant technical development of the *StartSmart^TM* prototype was completed with the screening questions, programming of algorithms, and tailored recommendations based upon on findings from research, content expert interviews, as well as the clinical utility and integration with prenatal practice. *StartSmart^TM* was written at the 6th grade reading level. Using a tablet computer, each screen has a single question that must be answered before moving on to the next (Figure 2). Pregnant women entered self-report data, and the clinic medical assistant (MA) entered measurements (e.g., height, weight, blood pressure, immunizations, laboratory findings) after the pregnant woman completes the screening. Staff then generated individualized handouts, including a provider summary (Figure 3), individualized patient education including a graphic depiction of gestational weight gain (Figure 4), and resources. The tailored recommendations based upon treatment algorithms formed the basis for the provider-patient counseling using the SBIRT framework to increase the patient's understanding of any health risks and provide options for brief intervention and referral as needed. Referral processes followed those outlined in the last column of Table 1.
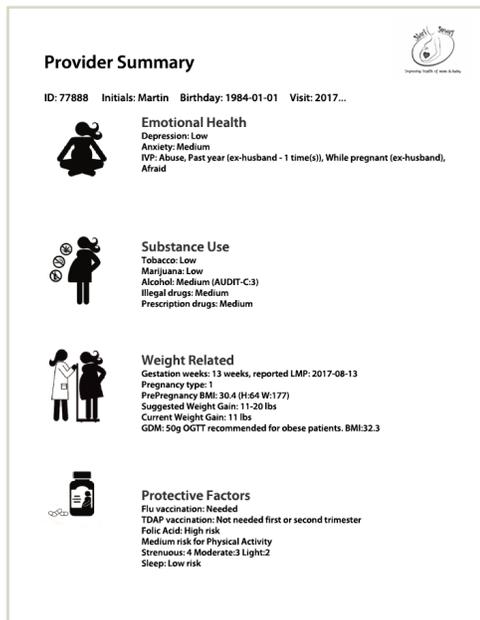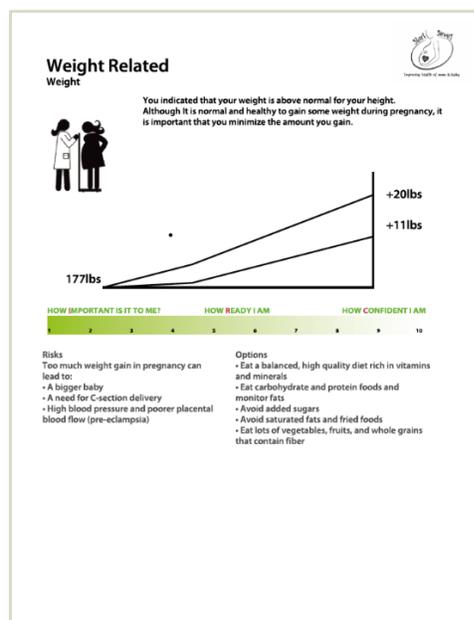
Figure 3. Provider Summary   **Figure 4. Patient Weight-related Education**

Aim 2: Alpha Testing and Refinement
Design
Alpha testing of *StartSmart^TM* used qualitative methods including provider and patient interviews. Data were used to refine the technology.

Procedures
Alpha testing of the *StartSmart^TM* technology was conducted with expert clinicians and pregnant women from a midwifery clinic and an obstetrical clinic. Research staff asked the pregnant women at their first or second prenatal visit to participate in the testing of a new technology to improve prenatal care. A member of the research team enrolled the patient and walked them through navigating the screening questions. Those agreeing to participate signed an electronic informed consent on the first screen of the *StartSmart^TM* technology and then completed the screening questions (8-10 minutes to complete) on the touch-screen tablet. A research team member worked with staff to complete standard clinic measures and enter the woman's

height, weight, BP, immunizations, and labs before generating the patient and provider handouts. Handouts consist of a patient and provider summary for risk and protective factors, individualized recommendations including a graphic depiction of gestation weight gain, along with a list of local resources. These summaries were printed and given to the care provider prior to his or her encounter with the patient. Individualized recommendations based upon algorithms developed from the evidence were provided to the participant along with counseling prompts to the provider. After the prenatal visit, the risk summary and brief intervention recommendations were sent home with the patient and findings documented in the patient's chart.

Data Collection
Interviews with pregnant women and providers were conducted to assess usability. Data suggests the majority of usability problems will be detected with 3-4 subjects and 7 will identify the majority of problems with usability.[71] The interview questions were guided by the SBIRT theory and attention to usefulness and usability[72] of the technology and took between 15 and 20 minutes. If safety was a strong concern such as with domestic violence or suicidality, clinic staff were to escort the patient to the emergency room on site for evaluation. None of the patients screened required this level of support.

a) Pregnant women were interviewed by a research team member after completing the *StartSmart*[TM] screening using the "think aloud technique,"[73] a cognitive engineering method used to inform the design of clinical information systems. Participants were asked about any challenges they had with navigation and layout (e.g., if they understand where to go, if a link did not work, or if they navigated in a way they did not expect) and utility (e.g., pages were slow to load, material difficult to understand, questions that were confusing). Pregnant women were asked about the best approach to help them understand the risks and promote adherence to the guidelines. A research team member asked if the screening questions, graphics, and patient handouts were clear and understandable. If questions or recommendations were confusing or not clear, pregnant women were asked what could make the questions easier to understand or more applicable to their culture or people like them.

b) Providers were interviewed about their experience with *StartSmart*[TM] and handouts after using the prototype. Providers were asked to give feedback on the screening questions, brief MI interventions, and referral to treatment algorithms as well as the patient education materials. Providers were asked about the feasibility of using the materials to provide the brief intervention or referral to treatment, and about training needs to inform implementation of the technology for beta testing.

Aim 3: Beta Testing - Refinement, Feasibility, and Acceptability
Design
A mixed methods approach was used for beta testing to assess feasibility, usability, and acceptability of the technology for screening, brief intervention, referral, and to assess the women's intentions regarding the recommendations. Evaluation of usability and acceptability based upon the Technology Acceptance Model included user (patient and provider) perceptions of usefulness and usability or ease-of-use.[60]

Implementation
Dr. Paul Cook (SBIRT trainer and MI expert) collaborated with the research team to design provider training materials for lunch-and-learn workshops focused on implementing the technology and counseling patients using MI to screen, provide the brief intervention, and refer to specialty care, if indicated, for each risk and protective factor. Provider training materials (presentations, manuals, and handouts) were developed using case-based scenarios and role-playing sessions with time allotted for demonstrating the use of the technology, answering questions, role-playing techniques for discussing sensitive topics, and helping providers to develop confidence in using MI for the targeted conditions and specialist referrals when needed. Providers and clinic support staff were trained on: (1) the use of the *StartSmart*[TM] technology in practice, including the touch-screen interview and printout generation procedures and (2) discussion with the patient regarding the prenatal screening findings (emotional conditions, substance use, weight status and related conditions, and protective factors). Dr. Cook collaborated with the research team to deliver training. Providers were confident in providing MI counseling but were concerned with workflow when implementing the technology. Workshops were conducted at the clinic and also video recorded to accommodate various schedules. Ongoing case coaching by the research team took place monthly with providers during implementation to problem solve implementation of the technology, work flow issues, and use of MI counseling. Providers were coached on use of the tailored patient education materials to triage patient risks and focus their time on the top priorities. Providers were comfortable with MI counseling and focused most of their attention on workflow.

Participant enrollment for beta testing of the *StartSmart*[TM] technology was conducted in a midwifery clinic and a community obstetrics clinic. A member of the research team was present at the clinic to enroll the participants and obtain consent. Those agreeing to participate signed an electronic informed consent on the first screen of the *StartSmart*[TM] technology and then completed the screening questions (8-10 minutes to complete). The clinic's medical assistant (MA) entered the woman's data (height, weight, BP, immunizations, and labs) but required research staff assistance in generating the patient and provider handouts. The printed risk summaries were given to the care provider prior to his or her encounter with the pregnant woman, saving the clinicians' time in completing the assessments. A member of the research team facilitated implementation of the technology by helping the patient navigate the screening, coaching the MA on entering patient measurements, and generating the decision support/education materials that outline the recommendations. The research team provided ongoing coaching on the use of *StartSmart*[TM] with clinic champions to ensure integration with work flow. The plan for independent clinic implementation of the technology screening was challenging and the clinic required ongoing research team support.

A pregnant woman's risk summary was based upon responses to screening questions, which informed the brief MI counseling to increase the pregnant woman's understanding of her health risks and provide specific options for collaborative goal setting and care planning. The individualized recommendations were based upon algorithms developed from the evidence-prioritized topics for provider counseling. In addition, provider prompts were generated for screening items that scored above the threshold to guide clinician counseling. Providers were given handouts to discuss risks, priorities, and options with the women using MI techniques.

Data Collection
After refinement of *StartSmart*[TM] based upon feedback from Aim 2, the revised mHealth application was implemented in the clinics for a three-month trial period. Patient interviews occurred in months 2, 3 and 4.

a) <u>Pregnant women feasibility and acceptability</u> was evaluated during *StartSmart*[TM] implementation.
   1. Acceptability was evaluated by conducting exit interviews with the pregnant women who participate in the electronic screening/brief intervention/referral counseling after the clinics had been using the revised system for at least one month. After completing their prenatal appointment, women were asked to complete a short exit interview. Women were queried regarding the ease of use, clarity of questions, understanding of risks, and feedback on individualized handouts and the impact they had on their intentions to change behaviors, implement brief interventions, or follow through with a referral if applicable. They were asked for feedback about the provider-patient brief intervention, resources and recommendations, as well as their intent to change related to the provider counseling, decision aids, and referrals, if applicable. The exit interviews took 10 - 20 minutes.
   2. Feasibility was evaluated by the proportion of new prenatal patients who completed data submitted via *StartSmart*[TM] compared to the total number of new patients. At the completion of the three-month implementation trial period, user data were obtained from *StartSmart*[TM] and compared to the total number of new prenatal clients seen over the three-month period.

b) <u>Provider and clinic staff acceptability</u> was evaluated at the completion of the three-month trial by online surveys and *StartSmart*[TM] use records.
   1. Usability and ease of use survey based on the Technology Acceptance Model was administered via online survey. Valid measurement scales were used based upon their ability to predict user acceptance of technology, 6 items on perceived usefulness and 6 items on ease of use. The scales have high convergent, discriminant, and factorial validity[60].
   2. Additional items were added to the survey including: feedback on the quality of the training materials; additional needs related to screening, educating, or referring; experiences with the *StartSmart*[TM] technology including attitudes and barriers to use of technology for screening/brief intervention/referrals; intent to continue to use *StartSmart*[TM]; and effect on clinic flow. Space was provided for comments.[74]
   3. Acceptability was measured by the number of new prenatal patients who completed data submitted via *StartSmart*[TM] electronic screening after implementation in the clinic compared to the total number of new patients.
   4. The number of pregnant women who screened positive for all variables of interest will be used to power a future randomized clinical trial.

c) <u>Workflow</u> was explored by Dr. Ozkaynak through observations at each site during their prenatal visits when *StartSmart*[TM] was used to understand the impact on patient flow, workload for MAs and front desk

staff. Information gained during observations was used to educate staff on the optimal implementation of the technology.

d) <u>Future interoperability with EHRs</u> was tested by establishing *StartSmart*^{TM} connectivity with a publicly available and FHIR-compliant server established for these development purposes.[75] A trial of hypothetical *StartSmart*^{TM} data was transmitted and stored on the test server.

Data Analysis

Qualitative data from both interviews and focus groups with providers and pregnant women were transcribed verbatim as they were obtained and uploaded into ATLAS.ti software to facilitate management of the data. Content analysis was conducted using a modified constant comparative method of analysis.[76] Analysis began with microanalysis coding the transcripts line by line. Codes were examined to unitize the data clusters. Data clusters were examined for overall themes regarding the suggested changes needed for the technology navigation, screening questions and patient education materials. Data informed the development/refinement of the technology prototype.[76] Quantitative data from provider surveys, *StartSmart*^{TM} user data, and participant screening responses were analyzed using descriptive statistics.

RESULTS

Prototype development. The **expert clinicians** (Table 2) provided guidance on the preferred screening instruments, resources and practice guidelines for the areas of concern. Most experts (5 of 6) were very satisfied with the proposed plan for screening. One suggested adding screening for intimate partner violence (IPV). A midwife stated, "One of our patients was murdered by her husband in the past two months, so we feel strongly about screening for IPV." The team consulted with Jacqueline Campbell, PhD, RN and Professor at Johns Hopkins, an expert on IPV and the safest way to screen and provide resources to this population. We were advised to include the findings of IPV screening on the clinician summary sheet and to embed the resources in the middle of the resource sheet so that the clinician could point them out to the patients who screened positive without calling attention to the issue if the abusive partner was accompanying her to the visit. We were advised to omit IPV information from the educational handouts for the patients. The mental health expert provided insight into the algorithm for referral for IPV, "We need a low threshold to refer to a mandated reporter. The [provider] does not want to be the reporter. We need to get the woman to a social worker for reporting and resources." The clinicians acknowledged they are mandated reporters, but they wanted a system in place where the social worker makes the call.

One of the midwives suggested including a graph of the maternal weight gain to aid in understanding of weight gain in during pregnancy. The midwife provided examples of graphs that she had used in her previous practice. There was much discussion among providers around this topic, one stating "Weight is a touchy issue." Providers expressed concern over the terminology obese and suggested using overweight moderate and high risk. Providers decided to include the graph but avoid the use of obesity in the education materials. The use of an initial quick screen (Patient Health Questionnaire [PHQ] 2 Screen) followed by comprehensive screening (PHQ 9) as the most efficient approach to assess depression was recommended. Clinicians liked the summary sheet with prompts for motivational interviewing to counsel the patient. Clinicians suggested identifying specific prenatal visits for the screening, "We have the proposed timing for screening at every trimester consistent with guidelines, but in my experience if we identify a specific visit, it is going to be more successful. So, at the new prenatal visit, at the 28-week visit, and the 36-week visit. Otherwise, it will be forgotten." Other thoughts on the timing of screening for substance use were expressed, "The proposed frequency of screening at each visit for substance use is a lot. We currently screen at the first visit and that is it. There is a subset of patients that will be offended that we keep asking." After discussion, consensus was reached on screening once a trimester. Clinicians liked the support for motivational interviewing counseling.

The patients (see Table 2) reviewed the proposed screening questions and educational materials, and provided mostly favorable comments and a few suggestions for improvement. One of the participants with gestational diabetes stated that more information on the diabetic diet and resources were needed. Other comments suggested that the substance use and IPV questions were important questions to ask patients. One commented, "I am glad you asked about substance use, we need help when we are pregnant." Another patient commented, "No one has asked me about this [IPV] before, this is important to ask." One woman commented, "This is all good, but I don't believe in immunizations." Feedback from patients and providers informed revisions to the technology. No changes contrary to evidence were made based upon patient feedback.

Table 2. Demographics of Providers and Patients

Phase One				
Providers (n=8)			Patients (6)	
Specialty	*Discipline*	*Gender*	*Race/ethnicity*	*Area of Expertise*
GDM Scientist (NIH funded PI)	RN, PhD	female	Hispanic	GDM, overweight
Obstetrician, mental health	MD	male	Hispanic	GDM, obese
Clinic administrator	CNM	female	White	Anxiety, depression, IPV
SUD disorder in pregnancy	ND	female	White	SUD, IPV Immunization refusal
SUD in pregnancy laws	MD	female	White	Screened negative
SUD in pregnancy	SW	female	White	Sleep disorders
IPV (NIH funded PI)	RN, PhD	female		
IPV	SW	female		
Phase Two				
Providers (n=9)			Patients (n=7)	
Specialty	Discipline	Gender	Race/ethnicity	Visit
Midwifery	CNM, PhD	female	Hispanic	ROB
Midwifery (administrator)	CNM, DNP	female	Black	ROB
Midwifery	CNM, DNP	female	Eastern Indian	ROB
obstetrician	MD	female	White	ROB
Midwifery (culturally sensitive care)	CNM, MPH	female	White	ROB
Midwifery (new)	CNM, MS	female	African immigrant	ROB
Midwifery (new)	CNM, MS	female	White	ROB
Midwifery	CNM, MS	female		
Family Practice	FNP, MS	female		

Alpha Testing. **Six additional clinicians** (e.g., midwives, MDs, administrators, and nurses) used the screening instrument and provided feedback on the questions, graphics, navigability, and workflow. Overall feedback was positive (Table 3). Administrators reported that StartSmart was useful to promote adherence to national guidelines. A nurse suggested that the graphics depicting a healthy baby while asking about substance use could influence the response to those questions since patients are aware that drug and alcohol use during pregnancy can lead to an unhealthy baby. She suggested using another graphic would minimize the influence of social desirability. Another suggested, "The education materials need to explain that substance use may have legal implications after the delivery (e.g., babies who test positive at delivery are reported to social services)." The providers were positive about the summary sheet and the educational materials for patients. One provider stated, "I like having the resources for referral on one page." One clinician also commented that the graphics were not appropriate for the Native American or African American populations.

Table 3. Expert Consultants Feedback on Prototype Development Plans	
Phase One: Prototype Development	
Provider	*Revisions Made based upon feedback*
Overall, providers approved of the screening tools, graphics, algorithm, education materials, and support for MI.	Changes as outlined below.
Add intimate partner violence (IPV) screening; omit education materials; embed the resources.	Consulted with Dr. Campbell at Johns Hopkins and followed her recommendations on IPV screening, education, and resources.
Include weight gain graphic; avoid use of obese terminology.	Add weight gain graph. Edited language on weight counseling.
Use National Institutes of Drug Abuse (NIDA) quick screen for first step.	Added NIDA quick screen as an initial step, algorithm skips additional questions if negative.
Pregnant Women	
Overall, patients approved of the screening questions, approach to screening, and education materials.	
Include more resources on diabetic diet.	Expanded patient education on diabetic diet and resources.

During the alpha testing using the think aloud technique, **patients** commented about the navigability and usability. Many of the patients reported favorable responses (Table 4). Multiple participants reported that the app and questions were "good" and that in general use of it was "easy." An ethnically diverse participant stated, "The tablet-based screening is a better way to ask about [IPV] because in my culture we are not allowed to talk about it, but we can answer the question on the tablet." Another participant said, "Even though there were a lot of questions, I don't think there was a question not worthy of answering or asking".

Users encountered a few problems when completing the screening including sensitivity of touch screen, navigation, and layout. "So, I am trying to go back, and I push back, but it is stuck." There was confusion regarding the physical activity questions with the type of physical activity (strenuous, moderate, and mild) and the time frame each question was referencing. Multiple participants suggested that the physical activity questions should appear on the same screen. "To me, it would make more sense if they [physical activity questions] were all on the same page." Another participant recommended, "You could also make the boxes bigger, because the questions and the boxes only take up a third of the screen so if you made the font size in the boxes bigger maybe. Because my fingers are big, and I accidentally touched both boxes that resulted in the wrong answer."

Suggestions for improvement included question clarity, improved layout, and navigation. One participant stated, "When the question is the same length, it's hard to tell if it's switched screens so I think that it's the same question, and I don't realize the words have changed." It has moved on to the next question. "Maybe if it flashed... or maybe if they were like numbered? Just so you can tell that it's switched [questions]." Other suggestions were to be clearer on what time period the questions were referring to, such as, "Before pregnant or right now?" Another patient stated, "How many times have you been pregnant is a little confusing. Like zero before this one, or one because I'm currently pregnant? I'm not really sure how to answer this question."

Table 4. Patient and Provider Feedback and Revisions	
Phase Two: Alpha Testing	
Provider Feedback	*Revisions Made based upon feedback*
Overall, screening and education materials are acceptable, support for MI useful, and summary is helpful and support evidence based practice.	
Concerns about workflow.	Additional training for providers and research staff for support with workflow.
Graphics not appropriate for Black or Native American populations.	Plans for future cultural adaptation for Black and Native American populations.
Pregnant women in third trimester don't sleep well.	Patient education rephrased, many women in third trimester of pregnancy have trouble sleeping…
Graphics on substance use questions encourage the right response.	The happy healthy babies were removed from the pages that asked about substance use.
Pregnant Women "Think aloud interviews"	
Overall, navigation was smooth, approach acceptable, and education materials useful.	We added a progress bar indicating how many questions were left to answer.
Some navigation and sensitivity issues in early interviews.	Adjustments to sensitivity were made.
Some formatting suggestions including size of buttons and physical activity questions on one screen.	Industry standards are currently used, will explore this further in future work. Reformatted exercise questions to one page.
Tablet-based screening appropriate for sensitive topics. In my culture we cannot talk about this but it is okay to answer on the tablet.	

Beta testing.
Patient Exit Interviews
Following verbatim transcription of the patient exit interviews they were coded qualitatively. Ten main codes emerged relating to the StartSmart screening tool and the screening process. They were Acceptability, Communication, Cultural Acceptability, Education materials, Impression, Negative, Neutral, Positive, Screening tool and Suggestion. To aid in the revision of the screening tool, interview data was used to determine which aspects of the process and tool should be targeted for improvement. Overall, a few screening questions related to physical activity were identified by patients as needing improvement. Additional suggestions included the need for branching logic depending on how far along a woman is in her pregnancy, modifying answer options in the case of the sleep question to allow for patients to indicate too much sleep rather than too little, adding a progress bar and revisions to time frame for questions (i.e., including this pregnancy, how many times have you been pregnant?). All of these changes were incorporated. Finally, pregnant women were asked if the provider used the education materials in the counseling and if they were likely to make changes that were suggested. Overall patient responses were positive, "She went over it and everything seemed to look normal, so there was nothing really that needed to be addressed....I wanna say maybe [we spent] about two minutes.

She asked me if I had any questions, and I let her know 'no'." Another responded, "Yes the provider reviewed the information with me and it was helpful." Another patient responded about the consistent messaging between the handouts and her WIC appointments, "when I go over to my WIC I'm told I'm gaining more weight than I'm supposed to be for this pregnancy, so I mean we kinda had a longer discussion about that." Patients also responded that they were unsure about the impact of the counseling on their plans for behavior change.

Feasibility

De-identified patient responses were collected for select testing days on three separate months. Demographics of participants screened revealed a diverse sample (see Table 5). Feasibility being reported as the proportion of new prenatal patients who completed the electronic screening to the total number of new patients. Follow up interviews were also completed with 15 patient users, whose responses were analyzed with the help of Atlas.ti qualitative analysis software. The following indicate results of all analysis.

Table 5. Demographics for Screening Participants			
	Mean	*Standard Deviation*	*Range*
Age	27.59	5.15	20-38 years
Times Pregnant	2.26	1.15	1 - 4
BMI	28.36	6.49	19 - 40
Race/Ethnicity			
Hispanic	1	5%	
Black	6	30%	
Caucasian	3	15%	
Asian/Pacific Islander	2	10%	
Other	6	30%	
Two or More	2	10%	

Feasibility calculations (Table 6) did reveal slight improvements in usage from 33 % to 46% of patients as the project progressed, which the research team attributes to repeated attempts to engage the providers and quickly troubleshoot any workflow problems as they arose.

Table 6. *StartSmart*™ User Data

Testing Month	Patients Screened	Total new OB patients	Feasibility
March	3	9	33%
April	5	14	36%
May	6	13	46%

Screening Data

Screening outcomes were assessed for the four broad intervention categories: Emotional health, Weight Status, Substance Use, and Protective Factors. Patient risk categories were assigned either low, medium or high risk based on their individual screening responses and the screening algorithm. Totals for each intervention category across risk levels are provided in Table 7. There were 11 instances of High risk, five for protective factors, four for weight status and 2 for substance use; 29 documented instances of Medium risk, thirteen for protective factors, ten for weight status, five for emotional health, and one for substance use; and 36 instances of low risk. Individuals who screened as high risk for any factor were counseled and referred. Those of medium risk received provider counseling only.

Table 7. Summary of Screening Risk Factors by Category

Risk Level	Emotional Health	Weight Status	Substance Use	Protective Factors	Total*
Low	14	5	16	1	36
Medium	5	10	1	13	29
High	0	4	2	5	11

*Note: Since patients risk level was assessed for each category rather than being reported as one overall risk level per patient the total column represents the number of instances that risk level was assigned to a patient and is therefore greater than the total number of patients.

Provider Surveys

At the conclusion of patient data collection, employees of the University Nurse Midwives Faculty Practice were invited to complete an online follow up survey. The survey consisted of 28 questions that utilized both 5 point and 7 point Likert scales to measure engagement with and perceptions of StartSmart use in the clinic setting with 12 specifically targeted usefulness and ease. Twenty-eight participants completed the survey (Table 8). Responses indicated that providers and staff found the tool to be both easy to use and useful (Table 9).

Table 8. Provider Descriptive Statistics

Role in Clinic	Number of Providers
Obstetrician	2
Certified Nurse Midwife	10
Medical Assistant	12
Other	4
Total	28
Time in Clinic	
Full time	21
Part time	7
Total	28
Average Number of Patients per Week	Number of Providers
1-25	8
26-50	6
51-75	4
76-100	5
>100	5
Total	28
Used StartSmart	Number of Providers
Never	15
One time	4
Two to five times	3
>5 times	6
Total	28

Respondents who used StartSmart during the pilot testing were invited to respond to the questions about usefulness and ease. Responses indicated that providers and staff found the tool to be both useful (Table 9) and easy to use (Table 10).

Table 9. Provider Survey Results on Usefulness

	Tasks quicker	Improve job performance	Increase productivity	Enhance effectiveness	Make job easier	Useful in my job
Extremely likely	1 (8%)	1 (8%)	0	1 (8%)	0	1 (8%)
Quite likely	3 (23%)	3 (23%)	4 (30%)	3 (23%)	3 (23%)	3 (23%)
Slightly likely	3 (23%)	2 (15%)	1 (8%)	4 (30%)	3 (23%)	3 (23%)
Neither	3 (23%)	5 (38%)	3 (23%)	4 (30%)	4 (30%)	4 (30%)
Slightly unlikely	1 (8%)	2 (15%)	4	1 (8%)	3 (23%)	2 (15%)
Quite unlikely	2 (15%)	0	1 (8%)	0	0	0
Extremely unlikely	0	0	0	0	0	0

Table 10. Provider Survey Results on Ease of Use

	Learning to use easy	Easy to get it to do what I want	Clear & understandable	Flexible to interact with	Easy to become skillful	Easy to use
Extremely likely	3 (23%)	3 (23%)	3 (23%)	3 (23%)	4 (30%)	3 (23%)
Quite likely	6 (46%)	5 (38%)	6 (46%)	4 (30%)		6 (46%)
Slightly likely	4 (30%)	1 (8%)	2 (15%)	1 (8%)	2 (15%)	2 (15%)
Neither	0	4 (30%)	2 (15%)	4 (30%)	2 (15%)	2 (15%)
Slightly unlikely	0	0	0	1 (8%)	0	0
Quite unlikely	0	0	0	0	0	0
Extremely unlikely	0	0	0	0	0	0

Qualitative data revealed the providers did not have any additional training needs but they were concerned about implementation of the technology with minimal disruption to their workflow, one stated, "we need to fine tune the flow in the clinic". Overall comments were positive including the following, "StartSmart was a helpful resource", "I love the idea of StartSmart. It helped me to efficiently ask about things I otherwise wouldn't have time for". Finally, a suggestion for future development was offered, "I have concerns about the amount of paper that is generated and would prefer to use a system like this only if it is able to send the patient emails with the information."

Workflow issues were a challenge in implementing the technology. The tablet-based screening was to be handed to the patient by the front desk staff at check-in to complete while waiting for her appointment. The support staff who completed the weight, height, blood pressure, immunizations, and labs were to enter those into the technology and generate the provider summary and individualized educational materials prior to the provider entering the clinic room. As anticipated, initially there were a fair number of concerns and a significant amount of resistance on the part of the support staff when they were asked to add additional tasks to their current workflow. Universal adoption of this approach to screening along with integration of the technology with the medical record to eliminate the need for double entry may overcome these barriers and facilitate adoption.

In addition, alternative workflow approaches may assist with staff adherence and patient completion such as texting the patient the link to *StartSmart*[TM] prior to their visit.

Using the rapid, responsive, relevant research approach,40 suggestions from workflow observations as well as feedback from pregnant women and providers were used to refine the technology's graphics, screening questions, tailored recommendations, resources, provider training and workflow recommendations. All suggestions from patient and provider interviews, focus groups, and surveys were discussed and used to revise the application. There was not adequate funding to create the Spanish version or format for Native American or African American specific populations, but additional funding is being sought for those activities.

Interoperability
StartSmart's ability to integrate with the electronic health record was demonstrated by establishing a connection to a standards-based publicly available server. The ability to both send and store, and then retrieve and read the StartSmart interview on a publicly available server was established. This step insures the possibility of integration with the electronic health record when the healthcare institution is ready for integration.

Challenges and Strategies for Improvement
The research team encountered numerous difficulties implementing the technology and subsequent data collection, the majority of which centered around workflow. The introduction of any new process creates some anxiety in providers and support staff. In addition, since the screening tool was not integrated into the current electronic health record, implementation of *StartSmart* presented some additional workflow challenges for providers and support staff.

The planned workflow was for the front desk staff to hand the technology to the patient at check in and have the medical assistant generate the handouts prior to the provider entering the room. There was reluctance by some front desk staff to engage in this new activity. There was also resistance by medical assistants to have the additional tasks added to their workload. Medical assistants had to log into the StartSmart server with unique credentials to enter the patient's height, weight, blood pressure, and check the electronic health record and enter laboratory results prior to printing out the education materials after the patient finished the tablet-based screening. Materials then had to be delivered to the patient and left at the door for the provider. Workflow challenges resulted in education materials being presented to the patient and the provider during or following the provider interview rather than prior to the provider entering the room as planned. The issue of timing was further exacerbated for individuals who did not have enough time to compete the screening prior to being taken back to an examination room, and patients that did not return the iPad to staff until leaving the clinic after the visit was completed.

Maintaining provider and staff engagement in the project over time was also an issue. The constant rotation of medical assistants between different providers necessitated training and retraining of clinic staff during the data collection window. Illustrated quick reference guides helped MAs navigate the StartSmart online dashboard in the absence of a research assistant facilitating the printing of handouts. Front office staff had to be introduced to the researchers frequently, informed of the project goals, and reminded to inform researchers when an eligible OB patient checked in. Support staff were most engaged in the research project when approached by the provider directly and informed how important the study was. Constant communication between the researchers, the providers and the clinic staff helped to keep the study in the forefront of everyone's mind, but only yielded temporary and slight improvements in patient participation.

Participant recruitment remained a challenge throughout the data collection process. The inclusion criteria were clear, however finding English speaking return OBs who were willing to participate was difficult. While a handful of potential candidates refused based on lack of interest, or incentive, women being seen at the clinic for gynecological rather than obstetric needs, or not speaking English were the main reasons for exclusion. Over the course of data collection the research team calculated that between 20%- 40**%** of patients on any given day required interpretive services and were therefore ineligible to participate. StartSmart data collection at the clinic site also coincided with participant recruitment for a vaccine study further limiting the recruitment pool. Individuals who did not show up for their appointments and left without being seen due to insurance issues also reduced the number of eligible study participants.

Strategies for Future Work
Other issues during implementation and data collection and proposed solutions are listed below. Success of implemented changes varied and served to inform our final recommendations for improvement and future

study application. Staffing with one research assistant did not allow for following a patient from recruitment through to the placement of the education materials without missing opportunities to recruit additional patients. Future work requires initially staffing with an additional research staff to work with both front desk and back office staff to orient them to the technology and the process including patient screening, printing on their own and getting the website bookmarked on their browser to facilitate the ease of signing into the external browser. We anticipate the need for research staff to reengage the front office staff during daily shift changes to get eligible patients identified for recruitment into the study. We propose having signage and iPad at the front desk to be handed out by receptionists and let them know we are testing until engaging a champion to take that role. Additionally, we experienced the MA's forgetting the process for generating and printing educational materials and not handing off the provider summary and education materials prior to the providers entering the patient room. To address this, we created a quick reference guide with screen shots of what to do and where to go to facilitate the MAs printing off educational materials. Future plans include earlier engagement of support staff in the planning, recruitment, identifying a champions (front desk, administrator, back office, & provider), and placing reminder signage near the printer along with intermittent incentives for high performers. Universal adoption of the technology by the clinic administration and providers will strengthen the commitment by support staff to integrate the extra work into their workflow. For future work, we propose: universal adoption, expectations made clear by administration, a planning period with ample time to solicit input from support staff, and identification of champions at the front desk, back office, and among the provider and administrator levels; eliciting a plan for provider engagement requesting support staff assistance, providing a quick reference guide, and establish independent use of iPad screening in clinic on days even when the research team is not present.

Discussion

Clinical guidelines to assess for risk and protective factors during pregnancy are recommended.[77-85] However, often assessment and appropriate treatment/referral practices are limited due to barriers at the provider and systems levels.[86] *StartSmart* was designed to address these provider- and system-level barriers, and ultimately, enhance maternal/child outcomes. The development and alpha testing findings of *StartSmart* reported here suggest that involving patients and clinicians in the development of mHealth to screen and counsel patients on risk and protective factors during pregnancy results in an acceptable and useful tool that is responsive to the needs of both patients and providers. Technology has been shown to improve care to pregnant patients for a variety of conditions.[54-56,87] To our knowledge, *StartSmart* is the first mHealth application to address comprehensive screening of pregnancy risk and protective factors developed in collaboration with end users (patients and providers).The use of the Davis' Technology Acceptance Model with feedback from clinicians and patients at each phase in the development of *StartSmart* enhances the usability and acceptability.[60] Consistent involvement of clinicians and patients throughout the development resulted in favorable feedback and a responsive application that has high potential for future clinical adoption. Both clinicians and patients reported *StartSmart* to be feasible with high satisfaction and usability. Furthermore, *StartSmart* targeted key provider-level barriers related to lack of knowledge and skills related to screening, brief intervention, treatment, and referral by incorporating the SBIRT framework and principles of motivational interviewing. Promoting patient understanding of risks and provider confidence in counseling on the risk and protective factors during pregnancy may ultimately improve numerous maternal/child health outcomes.

StartSmart has the potential to dramatically improve the clinician's ability to efficiently adhere to the multitude of practice guidelines aimed at improving birth outcomes. *StartSmart* targets known systems-level barriers by its ability to integrate with the electronic health record to optimize workflow. Policies on interoperability for the successful integration of mHealth with electronic health records are essential for optimal care. *StartSmart* is responsive to both the voiced needs of providers and inherent conditions in today's healthcare systems. There is overwhelming evidence that technology decision support, self-management, and behavior change programs have increased healthy behaviors[50-52,88] and may improve patient outcomes.[89] mHealth technology that includes decision support, individualized brief intervention, and referral to treatment has been shown to improve evidence-based practice.[90] Technology to assimilate the best available evidence and provide point-of-care brief interventions is an area of tremendous potential. Integrating mHealth technology into prenatal visits for screening, brief intervention, and referral addresses provider barriers of time (through patient data entry), awareness (by provider prompts), resources (by automating clinical processes), and comfort (by giving clinicians specific protocols and suggested scripts).

Limitations of the study include development of the application in one health system with a diverse patient population. Further testing is planned in additional systems. In addition, for convenience, providers were asked

to identify pregnant women who would screen positive for the risk factors to provide feedback on *StartSmart*. The providers' relationships with the women during phase one may have introduced bias and may have influenced their response. Although *StartSmart* is currently available only in English, we plan to test a Spanish version in the future. The technology was developed for English-speaking patients and needs to be culturally adapted for those whose first language is not English.

Integration of this technology for screening, brief intervention, and referral to community resources into the electronic health record has the potential to overcome barriers to evidence-based healthcare for pregnant patients. Future research is needed to translate and culturally adapt for other cultures, evaluate the efficacy of technology for screening, as well as strategies to promote implementation to reduce the impact on workflow.

CONCLUSIONS

Guidelines exist for care to improve birth outcomes by assessing and counseling on pregnancy risk and protective factors. Work volume and short visits with limited time for counselling complicate the ability of clinicians to address pregnancy risk and protective factors. A systematic process for addressing these risk and protective factors is needed to improve birth outcomes. Technology like *StartSmart* can aid providers in addressing these risk and protective factors in an individual and targeted manner. Clinical decision support and mHealth provides a more efficient and effective way to address pregnancy risk and protective factors, which may improve maternal/child health. Involving patients and clinicians in the development of the technology leads to a more acceptable and useful product.

LIST OF PUBLICATIONS AND PRODUCTS

Manuscript revision – under review
Gance-Cleveland, B., Leiferman, J., Aldrich, H., Nodine, P., Anderson, J., Nacht, A., Martin, J., and Carrington, A. (in press). Using the technology acceptance model to develop StartSmart™: mHealth for screening, brief intervention and referral to treatment for risk and protective factors in pregnancy. *J Midwifery and Women's Health.*

Presentations
Ozkaynak, M., Gance-Cleveland, B., Gilbert, K., Kebpci, A., Metcalf, N., and Aldrich, H. (2018). Workflow challenges of a mobile clinical decision support system (StartSmart) for Prenatal Clinics. American Medical Informatics Association (AMIA) Conference. November 2018, San Francisco, CA

Gance-Cleveland, B. (June 2018) StartSmart™: Decision support technology for prenatal screening. University of Colorado, College of Nursing. Grand Rounds, June 2018, Denver, CO.

Gance-Cleveland, B. (Apr 2018). StartSmart: Decision support technology for prenatal screening. Podium presentation. AMIA Clinical conference, Scottsdale, AZ.

Gance-Cleveland, B., Aldrich, H., Leiferman, J., Cook, P., Ozkaynak, M., Nacht, A., Anderson, J., and Hernandez, T. (Jan 2018). Start Smart: Decision support technology to improve evidence-based perinatal care. Abstract accepted for poster presentation at 2018 Doctoral Education Conference at Naples Grande Beach Resort. Naples, FL.

REFERENCES
1. Barker DJP, Winter PD, Osmond C, Margetts B, Simmonds SJ. Weight in infancy and death from ischemic heart-disease. *Lancet.* 1989;2(8663):577-580.
2. Child Mortality Estimates. United States of America: under-five mortality rate. http://www.childmortality.org/index.php?r=site/graph&ID=USA_United%20States%20of%20America. Published 2014. Updated January 5, 2015. Accessed August 19, 2015.
3. Centers for Disease Control and Prevention. Reproductive health: severe maternal morbidity in the United States. http://www.cdc.gov/reproductivehealth/MaternalInfantHealth/SevereMaternalMorbidity.html. Published 2014. Updated January 22, 2014. Accessed August 19, 2015.
4. Callaghan W, Creanga A, Kuklina E. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstet Gynecol.* 2012;120(5):1029-1036.
5. Leiferman J, Sinatra E, Huberty J. Pregnant women's perceptions of patient-provider communication for health behavior change during pregnancy. *Open J Obstet Gynecol.* 2014;4(11):672-684.

6. Riley M, Galang S, Green L. The impact of clinical reminders on prenatal care. *Fam Med.* 2011;43(8):560-565.
7. University of Colorado Department of Obstetrics. University Health Perinatal Database. In. Anschutz Medical Campus, Aurora, CO2005-2009.
8. Robbins C, Zapata L, Farr S, et al. Core state preconception health indicators — Pregnancy Risk Assessment Monitoring System And Behavioral Risk Factor Surveillance System, 2009. *MMWR.* 2014;63(ss03):1-62.
9. Coussons-Read ME, Okun ML, Nettles CD. Psychosocial stress increases inflammatory markers and alters cytokine production across pregnancy. *Brain, behavior, and immunity.* 2007;21(3):343-350.
10. Sandman CA, Davis EP, Buss C, Glynn LM. Prenatal programming of human neurological function. *International Journal of Peptides.* 2011(ID 837596):1-9.
11. Entringer S, Buss C, Wadhwa P. Prenatal stress, development, health and disease risk: a psychobiological perspective - 2015 Curt Richter Award Paper. *Psychoneuroendocrinology.* 2015;62:366-375.
12. Gentile S. Untreated depression during pregnancy: short- and long-term effects in offspring. A systematic review. *Neuroscience.* 2015 [epub ahead of print].
13. Seimyr L, Edhborg M, Lundh W, Sjogren B. In the shadow of maternal depressed mood: experiences of parenthood during the first year after childbirth. *Journal of psychosomatic obstetrics and gynaecology.* 2004;25(1):23-34.
14. Milgrom J, Ericksen J, McCarthy R, Gemmill AW. Stressful impact of depression on early mother–infant relations. *Stress and Health.* 2006;22(4):229-238.
15. Figueiredo B, Costa R. Mother's stress, mood and emotional involvement with the infant: 3 months before and 3 months after childbirth. *Archives of women's mental health.* 2009;12(3):143-153.
16. Hipwell AE, Goossens FA, Melhuish EC, Kumar R. Severe maternal psychopathology and infant-mother attachment. *Development and psychopathology.* 2000;12(2):157-175.
17. Murray L, Sinclair D, Cooper P, Ducournau P, Turner P, Stein A. The socioemotional development of 5-year-old children of postnatally depressed mothers. *Journal of child psychology and psychiatry, and allied disciplines.* 1999;40(8):1259-1271.
18. Bailey B. Partner violence during pregnancy: Prevalence, effects, screening, and management. *Int J Womens Health.* 2010;2:183-197.
19. Shah P, Shah J. Maternal exposure to domestic violence and pregnancy and birth outcomes: a systematic review and meta-analyses. *Journal of women's health (2002).* 2010;19(11):2017-2031.
20. National Institutes of Health. 10th special report to the U.S. congress on alcohol and health: highlights from current research. http://pubs.niaaa.nih.gov/publications/10report/intro.pdf. Published 2000. Updated June 2000. Accessed August 19, 2015.
21. U.S. Department of Health and Human Services. How tobacco smoke causes disease: the biology and behavioral basis for smoking-attributable disease. In: *Reports of the Surgeon General, U.S. Public Health Service.* Atlanta, GA: Center for Disease Control and Prevention; 2010.
22. Behnke M, Smith VC, Committee on Substance Abuse, Committee on Fetus and Newborn. Prenatal substance abuse: short- and long-term effects on the exposed fetus. *Pediatrics.* 2013;131(3):e1009-e1024.
23. Streuling I, Beyerlein A, Rosenfeld E, Hofmann H, Schulz T, von Kries R. Physical activity and gestational weight gain: a meta-analysis of intervention trials. *BJOG: an international journal of obstetrics and gynaecology.* 2011;118(3):278-284.
24. Thangaratinam S, Rogozinska E, Jolly K, et al. Effects of interventions in pregnancy on maternal weight and obstetric outcomes: meta-analysis of randomised evidence. *BMJ (Clinical research ed).* 2012;344:e2088.
25. Metzger B, Gabbe S, Persson B, et al. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. *Diabetes care.* 2010;33(3):676-682.
26. Sacks D, Hadden D, Maresh M, et al. Frequency of gestational diabetes mellitus at collaborating centers based on IADPSG consensus panel-recommended criteria: the hyperglycemia and adverse pregnancy outcome (HAPO) study. *Diabetes care.* 2012;35(3):526-528.
27. The American College of Obstetricians and Gynecologists. Committee opinion no. 504: Screening and diagnosis of gestational diabetes mellitus. *Obstetrics and gynecology.* 2011;118(3):751-753.

28. National Institutes of Health Consensus Development. National Institutes of Health consensus development conference statement: diagnosing gestational diabetes mellitus. *NIH Development Conference: Diagnosing Gestational Diabetes Mellitus.* 2013;122(2 Part 1):358–369.

29. Dabelea D, Hanson R, Lindsay R, et al. Intrauterine exposure to diabetes conveys risks for type 2 diabetes and obesity: a study of discordant sibships. *Diabetes.* 2000;49(12):2208-2211.

30. Dabelea D, Knowler W, Pettitt D. Effect of diabetes in pregnancy on offspring: follow-up research in the Pima Indians. *The Journal of maternal-fetal medicine.* 2000;9(1):83-88.

31. Boney C, Verma A, Tucker R, Vohr B. Metabolic syndrome in childhood: association with birth weight, maternal obesity, and gestational diabetes mellitus. *Pediatrics.* 2005;115(3):e290-296.

32. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guidelines for vaccinating pregnant women. http://www.cdc.gov/vaccines/pubs/preg-guide.htm. Published 2013. Updated March 2014. Accessed August 19, 2015.

33. Centers for Disease Control and Prevention. Updated recommendations for use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap) in pregnant women: Advisory Committee on Immunization Practices (ACIP), 2012. *Morbidity and Mortality Weekly Report,.* 2013;62:131-135.

34. Centers for Disease Control and Prevention. Vaccination coverage among children in kindergarten-United States, 2012-13 school year. *Morbidity and Mortality Weekly Report.* 2013;62(30):607-612.

35. U.S. Food and Drug Administration. Food safety for moms-to-be: before you're pregnant - Folic Acid. http://www.fda.gov/Food/ResourcesForYou/HealthEducators/ucm089330.htm. Published 2014. Updated October 17, 2014. Accessed August 19, 2015.

36. De-Regil L, Fernandez-Gaxiola A, Dowswell T, Pena-Rosas J. Effects and safety of periconceptional folate supplementation for preventing birth defects. *The Cochrane database of systematic reviews.* 2010;6(10):1-135.

37. National Institutes of Health. Folate: dietary supplement fact sheet. http://ods.od.nih.gov/factsheets/Folate-HealthProfessional/. Published 2012. Updated December 14, 2012. Accessed August 19, 2015.

38. Khodr Z, Lupo P, Agopian A, et al. Preconceptional folic acid-containing supplement use in the national birth defects prevention study. *Birth defects research Part A, Clinical and molecular teratology.* 2014;100(6):472-482.

39. Tobias DK, Zhang C, van Dam RM, Bowers K, Hu FB. Physical activity before and during pregnancy and risk of gestational diabetes mellitus: a meta-analysis. *Diabetes care.* 2011;34(1):223-229.

40. Phelan S, Phipps MG, Abrams B, Darroch F, Schaffner A, Wing RR. Randomized trial of a behavioral intervention to prevent excessive gestational weight gain: the Fit for Delivery Study. *The American journal of clinical nutrition.* 2011;93(4):772-779.

41. Clapp III JF. The course of labor after endurance exercise during pregnancy. *American Journal of Obstetrics and Gynecology.* 1990;163(6 Pt 1):1799-1805.

42. Misra DP, Strobino DM, Stashinko EE, Nagey DA, Nanda J. Effects of physical activity on preterm birth. *American journal of epidemiology.* 1998;147(7):628-635.

43. Sorensen TK, Williams MA, Lee I-M, Dashow EE, Thompson ML, Luthy DA. Recreational physical activity during pregnancy and risk of preeclampsia. *Hypertension.* 2003;41(6):1273-1280.

44. Poudevigne MS, O'Connor PJ. A review of physical activity patterns in pregnant women and their relationship to psychological health. *Sports Medicine.* 2006;36(1):19-38.

45. Gaston A, Cramp A. Exercise during pregnancy: a review of patterns and determinants. *Journal of science and medicine in sport / Sports Medicine Australia.* 2011;14(4):299-305.

46. Nodine P, Matthews E. Common sleep disorders: management strategies and pregnancy outcomes. *Journal of midwifery & women's health.* 2013;58(4):368-377.

47. Strecher VJ. Computer-tailored smoking cessation materials: a review and discussion. *Patient Educ Couns.* 1999;36(2):107-117.

48. Strecher VJ, Shiffman S, West R. Randomized controlled trial of a web-based computer-tailored smoking cessation program as a supplement to nicotine patch therapy. *Addiction.* 2005;100(5):682-688.

49. Crutzen R, de Nooijer J, Brouwer W, Oenema A, Brug J, de Vries NK. Internet-delivered interventions aimed at adolescents: a Delphi study on dissemination and exposure. *Health Educ Res.* 2008;23(3):427-439.

50. Rabin BA, Gaglio B, Sanders T, et al. Predicting cancer prognosis using interactive online tools: a systematic review and implications for cancer care providers. *Cancer Epidemiol Biomarkers Prev.* 2013;22(10):1645-1656.

51. Garg AX, Adhikari NK, McDonald H, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. *JAMA.* 2005;293(10):1223-1238.

52. Perrin EM, Flower KB, Garrett J, Ammerman AS. Preventing and treating obesity: pediatricians' self-efficacy, barriers, resources, and advocacy. *Ambul Pediatr.* 2005;5(3):150-156.

53. Tang PC, Newcomb C. Informing patients: a guide for providing patient health information. *Journal of the American Medical Informatics Association : JAMIA.* 1998;5(6):563-570.

54. Carroll AE, Biondich P, Anand V, Dugan TM, Downs SM. A randomized controlled trial of screening for maternal depression with a clinical decision support system. *J Am Med Inform Assoc.* 2013;20(2):311-316.

55. Tsoh J, Kohn M, Gerbert B. Promoting smoking cessation in pregnancy with video doctor plus provider cueing: a randomized trial. *Acta Obstet Gynecol Scand.* 2010;89(4):515-523.

56. Thornberry J, Bhaskar B, Krulewitch CJ, et al. Audio computerized self-report interview use in prenatal clinics: audio computer-assisted self interview with touch screen to detect alcohol consumption in pregnant women: application of a new technology to an old problem. *Comput Inform Nurs.* 2002;20(2):46-52.

57. Center for Substance Abuse Treatment. Substance abuse treatment: addressing the specific needs of women. Substance Abuse and Mental Health Services Administration. Treatment Improvement Protocol (TIP) Series 51 Web site. http://www.ncbi.nlm.nih.gov/books/NBK83252/. Published 2009. Updated December 2009. Accessed September 14, 2015.

58. Mears M, Coonrod D, Bay R, Mills T, Watkins M. Routine history as compared to audio computer-assisted self-interview for prenatal care history taking. In. *J Reprod Med.* Vol 50. 2005/12/21 ed2005:701-706.

59. Lobach D, Sanders GD, Bright TJ, et al. Enabling health care decisionmaking through clinical decision support and knowledge management. Agency for Healthcare Research and Quality. http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0046315/. Published 2012. Updated April 2012. Accessed August 19, 2015.

60. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. *MIS Quarterly.* 1989;13(3):319-340.

61. Hargraves D, White C, Frederick R, et al. Implementing SBIRT (Screening, Brief Intervention and Referral to Treatment) in primary care: lessons learned from a multi-practice evaluation portfolio. *Public Health Rev.* 2017;38(31).

62. Substance Abuse and Mental Health Services Administration. Screening, brief intervention and referral to treatment (SBIRT) in behavioral health care. 2011:701-706.

63. Spitzer R, Kroenke K, Williams J, Lowe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med.* 2006;166(10):1092-1097.

64. Arroll B, Goodyear-Smith F, Crengle S, et al. Validation of PHQ-2 and PHQ-9 to screen for major depression in the primary care population. *Ann Fam Med.* 2010;8(4):348-353.

65. Manea L, Gilbody S, McMillan D. Optimal cut-off score for diagnosing depression with the Patient Health Questionnaire (PHQ-9): a meta-analysis. *CMAJ.* 2012;184(3):E191-196.

66. Breiding M, Basile K, Smith S, Black M, Mahendra R. Intimate partner violence surveillance: uniform definations and recommended data elements, version 2. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. http://www.cdc.gov/ViolencePrevention/intimatepartnerviolence/index.html. Published 2015. Updated 2015. Accessed September 14, 2015.

67. National Institute on Drug Abuse. Screening for drug use in general medical settings: resource guide. http://www.drugabuse.gov/sites/default/files/resource_guide.pdf. Published 2010. Updated 2010. Accessed August 19, 2015.

68. Barry K, Caetano R, Chang G, et al. Reducing alcohol-exposed pregnancies: a report of the national task force on fetal alcohol syndrome and fetal alcohol effect. Centers for Disease Control and Prevention. http://www.cdc.gov/ncbddd/fasd/documents/redalcohpreg.pdf. Published 2009. Updated March 2009. Accessed August 19, 2015.

69. Godin G, Shephard RJ. Godin Leisure-Time Exercise Questionnaire. Medicine and Science in Sports and Exercise. http://www.godin.fsi.ulaval.ca/Fichiers/Quest/Godin%20leisure-time.pdf. Published 1997. Updated June 29, 1997. Accessed August 19, 2015.
70. Bastien C, Vallieres A, Morin C. Validation of the insomnia severity index as an outcome measure for insomnia research. *Sleep Med.* 2001;2(4):297-307.
71. Nielsen J, Landauer TK. A mathematical model of the finding of usability problems. Paper presented at: Proceedings of ACM INTERCHI'93 ConferenceApril 1993; Amsterdam, The Netherlands.
72. Reeder B, Meyer E, Lazar A, Chaudhuri S, Thompson HJ, Demiris G. Framing the evidence for health smart homes and home-based consumer health technologies as a public health intervention for independent aging: a systematic review. *Int J Med Inform.* 2013;82(7):565-579.
73. Thyvalikakath T, Dziabiak M, Johnson R, et al. Advancing cognitive engineering methods to support user interface design for electronic health records. *Int J Med Inform.* 2014;83(4):292-302.
74. Bauer NS, Carroll AE, Downs SM. Understanding the acceptability of a computer decision support system in pediatric primary care. *Journal of the American Medical Informatics Association.* 2014;21(1):146-153.
75. HL7. Welcome to the FHIR Server. http://fhir.healthintersections.com.au/. Accessed October 12, 2015.
76. Denzin NK, Lincoln Y. *Handbook of Qualitative Research.* Vol 3. Thousand Oaks, CA: Sage; 2000.
77. American College of Obstetricians and Gynecologists. Practice bulletin no. 180: gestational diabetes mellitus. *Obstetrics & Gynecology.* 2017;130(1):e17-e37.
78. American College of Obstetricians and Gynecologists. Intimate partner violence, committeee opinion 518. *Obstetrics & Gynecology.* 2012;119:412-417.
79. American College of Obstetricians and Gynecologists. Screening for perinatal depression, committee opinion 630. *Obstetrics & Gynecology.* 2015;125:1268-1271.
80. American College of Nurse Midwives. ACNM position statement on addiction. http://www.midwife.org/ACNM/files/ACNMLibraryData/UPLOADFILENAME/000000000052/Addiction%20in%20Pregnancy%20May%202013.pdf. Accessed February 12, 2019.
81. U.S. Preventative Services Task Force. Folic acid for the prevention of neural tube defects: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2009;150(9):626-631.
82. Herring SJ, Platek DN, Elliott P, Riley LE, Stuebe AM, Oken E. Addressing obesity in pregnancy: what do obstetric providers recommend? *J Womens Health (Larchmt).* 2010;19(1):65-70.
83. American College of Obstetricians and Gynecologists. Psychosocial risk factors: perinatal screening and intervention, committee opinion no. 343. *Obstet Gynecol.* 2006;108(2):469-477.
84. American College of Obstetricians and Gynecologists. Update on immunization and pregnancy: tetanus, diphtheria, and pertussis vaccination, committee opinion no. 566. *Obstet Gynecol.* 2013;121(6):1411-1414.
85. American College of Obstetricians and Gynecologists. Influenza vaccination during pregnancy, committee opinion no. 732. *Obstet Gynecol.* 2018;131(4):e109-e114.
86. Nagpal J, Sachdeva A, Sengupta Dhar R, Bhargava VL, Bhartia A. Widespread non-adherence to evidence-based maternity care guidelines: a population-based cluster randomised household survey. *BJOG.* 2015;122(2):238-247.
87. Mears M, Coonrod D, Bay R, Mills T, Watkins M. Routine history as compared to audio computer-assisted self-interview for prenatal care history taking. *J Reprod Med.* 2005;50(9):701-706.
88. Tang PC, Newcomb C. Informing patients: a guide for providing patient health information. *J Am Med Inform Assoc.* 1998;5(6):563-570.
89. Ebell M. AHRQ White Paper: Use of clinical decision rules for point-of-care decision support. *Med Decis Making.* 2010;30(6):712-721.
90. Gance-Cleveland B, Aldrich H, Schmiege S, Tyler K. Virtual obesity collaborative with and without decision support technology. *Int J Qual Health Care.* 2016;28(3):316-323.