EFFECTIVENESS AND IMPLEMENTATION OF MPATH-CRC: A MOBILE HEALTH SYSTEM FOR COLORECTAL CANCER SCREENING

Wake Forest Baptist Comprehensive Cancer Center (WFBCCC)

WFBCCC # TBD

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Version Date:	February 12, 2018
Amended:	February 22, 2023

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1.0 Introduction and Background

In September 2016, the Cancer Moonshot Blue Ribbon Panel's report highlighted excessive mortality from colorectal cancer (CRC), the problems of health disparities, the need for interventions that inform patients of CRC screening tests, and the need for research to rapidly translate evidence-based CRC screening interventions into practice.[1] This study directly addresses all four of these Cancer Moonshot priorities by examining the implementation of an innovative mobile health (mHealth) CRC screening intervention that is accessible by members of health-disparate populations. Lessons learned from this study will inform the scale-up of this CRC screening intervention, as well as the implementation of other mHealth interventions.

Screening for CRC is widely recommended but underused. CRC screening tests are cost-effective, and they reduce both CRC mortality and incidence by detecting and removing pre-cancerous polyps.[2–5] Regular screening for CRC beginning at age 50 is widely recommended by several groups, including the United States Preventive Services Task Force.[6–9] Nonetheless, over 35% of Americans are unscreened.[10]

Screening rates are even lower among underserved populations, contributing to health disparities.[10,11] Those with less education, limited income, or rural residences are less likely to be screened, and thus more likely to present with advanced-stage CRC and die from it.[12–16] Limited health literacy, which affects over 33% of American adults further interfering with patients' ability to access, interpret, and apply health information to their care.[17–21]

Barriers to CRC screening include patient factors (lack of knowledge, low self-efficacy, fears, negative attitudes)[22–28] and provider/system factors (lack of time, failure to offer screening options, lack of patient support).[29–33] Meaningful increases in CRC screening will require an easily implemented intervention that addresses patient, provider, and system barriers while also being accessible to low income and low literacy individuals.[34,35] We created our mPATH-CRC (mobile PAtient Technology for Health-Colorectal Cancer) intervention to tackle these needs.

mPATH-CRC is our iPad-based application, designed for individuals with low literacy, which patients use during routine health care visits.[36] Because most Americans over age 50 have seen a doctor within the past year, including 75% of adults with less than a high school education, interventions in medical practices have a potential broad reach.[37] mPATH-CRC also sends automated text messages to help patients complete their screening tests, which extends support beyond the medical encounter. 95% of US adults own a cellphone, and there is no digital divide along racial or socioeconomic lines, which creates an opportunity to encourage healthy behaviors and potentially reduce health disparities.[38–41] Our mPATH-CRC intervention leverages the high prevalence of medical encounters and cellphone ownership to maximize its reach.

While several tests exist for CRC screening, most clinicians encourage colonoscopy, the most invasive and costly option.[33,42] Because CRC screening rates are higher when patients can choose fecal occult blood testing, there is a critical need for interventions to help patients decide which test they prefer.[11,43] Our mPATH-CRC program uses a validated decision aid to inform patients of the commonly used screening tests and help them select their best option,[44] a direct recommendation of the Cancer Moonshot Implementation Science Working Group Report.[1] In our previous randomized, controlled efficacy trial of 450 patients, mPATH-CRC more than doubled CRC screening rates (30% vs 15%, p=0.0001).[45] This efficacy trial demonstrated the potential for mPATH-CRC to improve screening rates,

but the implementation was led by our research team, thereby restricting its potential for scale-up in a real-world context. This major gap is now addressed in this planned Type III hybrid implementation trial.

Translating mPATH-CRC into widespread use could increase receipt of CRC screening in the US from its current low level of 58% to over 70%, the target set by Healthy People 2020.[46,47] However, the optimal strategies for implementing mHealth interventions in clinical care remain unknown. Three recently published reviews identified over 500 articles and conference proceedings on mHealth studies, none of which prospectively examined competing implementation strategies.[48–50] Accordingly, this study will impact public health in two key ways: implementing mPATH-CRC in community practices to decrease CRC mortality, and determining the best strategies for implementing and sustaining the growing number of other mHealth interventions that currently lack an evidence base for implementation.

2.0 Objectives

2.1 Primary Objective

2.1.1 **In a cluster-randomized controlled trial of 22 primary care clinics, compare the implementation outcomes of a "high touch" evidence-based mHealth implementation strategy with a "low touch" implementation strategy.** We will first refine the "high touch" strategy based on input from focus groups with stakeholders. We will then rigorously evaluate the strategy in sites with different geographic settings (urban, suburban, and rural), clinic structures, and patient populations served. Our primary implementation outcome will be the proportion of all patients who complete mPATH-CRC in the 6th month following the implementation date. Secondary outcomes will include Reach, Adoption, Maintenance, and Fidelity. Additional secondary outcomes include Acceptability, Appropriateness, and Feasibility. We will also measure implementation costs to estimate the cost per patient reached as an exploratory outcome.

2.2 Secondary Objective

2.2.2 **In a pragmatic trial, estimate the effect of mPATH-CRC on completion of CRC screening within 16 weeks of visit.** We will query the electronic health record (EHR) at each study clinic to identify individuals aged 50 – 74 with no evidence of current CRC screening at the time of their clinic visit. We will then examine in the EHR whether these individuals complete CRC screening within 16 weeks of their index visit. The primary effectiveness analysis will compare the proportion of patients who complete screening between the pre- and post-implementation period in the "high touch" vs. "low touch" clinics. A secondary analysis will explore whether there is a dose-response relationship between use of mPATH-CRC and screening rates across all clinics.

2.2.3 **Determine the factors that facilitate or impede the maintenance of mHealth interventions like mPATH-CRC.** We will assess all clinics 12 months after implementation to identify those with high, low, and variable levels of maintenance. Using mixed methods that incorporate in-depth interviews with clinic staff, providers, and administrators, we will identify theory-based and organizational factors associated with sustained use of technology-based

interventions like mPATH-CRC. These results will provide critical information to guide future large-scale dissemination and implementation trials.

3.0 Study Population

This study will include three distinct populations of participants: 1) healthcare providers and staff at primary care practices, and 2) all adult patients seen in the participating study sites 3) all adult patients seen in the participating study sites who are deemed eligible for CRC screening. Providers and staff will participate through focus groups, surveys, and interviews. The provider/staff inclusion criteria vary according to the phase of the study. Therefore, for simplicity, the provider/staff inclusion criteria are described with the experimental methods for the relevant study activity (Section 4.0). The patient inclusion and exclusion criteria are detailed below.

3.1 Patient Inclusion Criteria: All Patients

3.1.1. Age 18 and older
3.1.2. Spanish or English-speaking
3.1.3. Have appointment scheduled with provider (Physician, PA, or NP) at participating study site

3.2 Patient Inclusion Criteria: CRC Screening Portion

3.2.1. Have appointment scheduled with provider (Physician, PA, or NP) at participating study site
3.2.2. Age 50 – 74
3.2.3. Spanish or English-speaking
3.2.4. Due for routine CRC screening, defined as:
- No colonoscopy within the prior 10 years
- No flexible sigmoidoscopy within the prior 5 years
- No CT colonography within the prior 5 years
- No fecal DNA testing within the prior 3 years
- No fecal blood testing (guaiac-based test with home kit or fecal immunochemical test) within the prior 12 months

3.3 Inclusion of Women and Minorities

3.3.1 Women and men of all races and ethnicity who meet the above-described eligibility criteria are eligible for this trial.

3.3.2 Patients will be participating in a pragmatic trial that will include Spanish and English-speaking adult patients who are seen in community-based primary care practices in North Carolina. Therefore, the study sample demographics will reflect the demographics of the clinics' population. We will query the electronic health records to obtain data for all age and language eligible patients seen in the 22 study clinics over a 24-month period. Therefore, we are unable to estimate a precise sample, but we estimate this pragmatic trial will include a minimum 30,000 patients. Based on the clinics' population estimates, we expect approximately 55% of participants to be women. Similarly, we expect

approximately 2% of study participants to be Hispanic/Latino, 10% to be Black/African-American, 1% to be Asian, and < 1% to be American Indian/Alaska Native.

3.4 Registration Procedures

Patients will be participating in a pragmatic trial in which patient data collection will occur by retrospective electronic chart review. All patients will receive current guideline-recommended care, and we will request a waiver of patient Informed Consent. Therefore, it is impractical to register patients with the Cancer Center, and any such registration would jeopardize patient confidentiality.

Clinic staff and providers will participate in surveys, interviews, and/or focus groups. No sensitive information will be collected from clinic staff or providers. Therefore, we are requesting a waiver of signed consent. We will give all participating staff and providers a study information sheet explaining the purpose of the study, the nature of the data to be collected, and the voluntary nature of their participation.

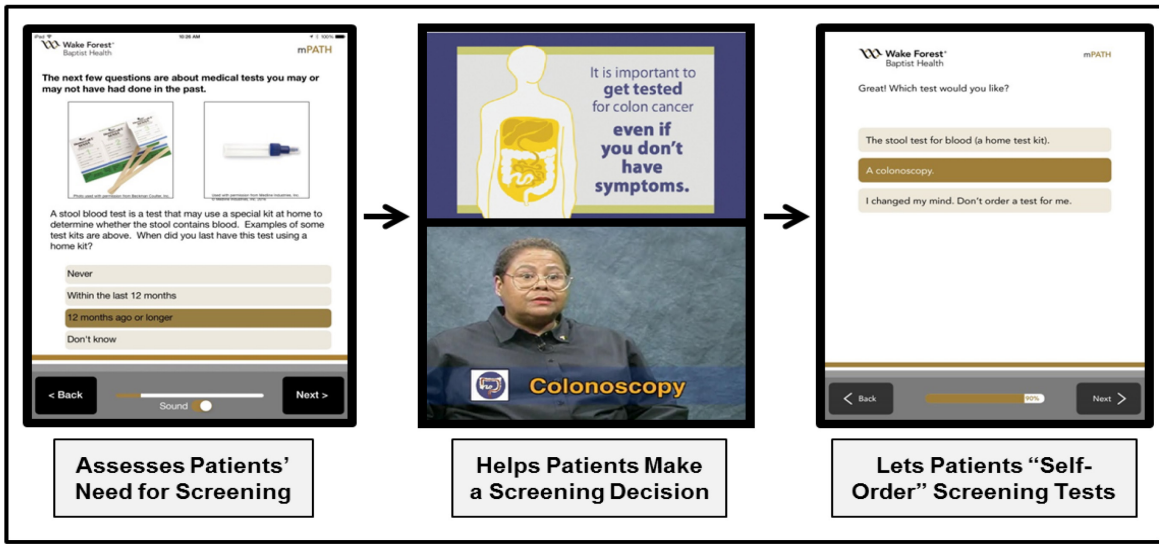
4.0 Experimental Methods

Using a Type 3 hybrid implementation-effectiveness design, we will evaluate a theory-based "high touch" implementation strategy compared to a "low touch" implementation strategy for incorporating mPATH-CRC in routine practice in 22 geographically diverse primary care practices. The study will include an implementation trial (to compare the implementation outcomes of both strategies), a pragmatic trial (to estimate the effect of mPATH-CRC on completion of CRC screening), and a mixed-methods study (to determine the factors that facilitate or impede the maintenance of technology-based interventions).

4.1 The mPATH Intervention

mPATH is a self-administered iPad program that patients use in primary care clinics to help them receive CRC screening. The mPATH program also includes health questions to assist

Figure 1. Overview of the mPATH-CRC Program



clinics with patient check-in, thereby incentivizing its use for all patients. Clinic staff hand the mPATH-Check In program to patients upon check-in so that they may use it immediately before their medical visit. To overcome literacy and usability barriers each question is written in simple lay language. One question is displayed per screen, with large intuitive response buttons (**Figure 1**). The mPATH-CheckIn program determines patients' screening status (due, possibly due, or current) by asking patients three items about their screening history and by connecting with the EPIC electronic health record.

If patients are due for CRC screening, mPATH-CRC displays an 8-minute previously-validated CRC screening decision aid that includes graphics, animations, and video testimonials from patients and physicians, consistent with Social Cognitive Theory.[51,52] mPATH informs patients of the benefits and risks of screening (including costs and complications) and lets them "self-order" either of the two most commonly recommended tests (fecal occult blood testing and colonoscopy).[9,44] Self-ordered tests are automatically routed to the patient's primary care provider for approval, allowing providers to overrule an order in the rare case it is felt inappropriate.

mPATH tells patients with specific risk factors (such as family history of CRC) to discuss screening with their provider, since screening guidelines differ for these high-risk individuals.[6,8] When patients are done using mPATH, a clinic staff member collects the iPad.

mPATH checks its usage database on startup and only ascertains patients' screening status if the patient has not completed the CRC questions in the prior 6 months, an approach validated by Miller in a prior study of a substance abuse screening system in primary care practices.[54] mPATH automatically sends data wirelessly to a central server and deletes the data once transmission confirmation is received, thereby preventing any data loss. Although all currently interested clinics have wireless networks, any clinic without an existing wireless network will be given a wireless router. All clinics can access their data and generate customized reports via a secure web interface.

mPATH runs outside the EHR but directly receives and sends data to EPIC-based EHRs, a commonly used EHR in the US[55] and the platform used by all Wake Forest-affiliated practices.

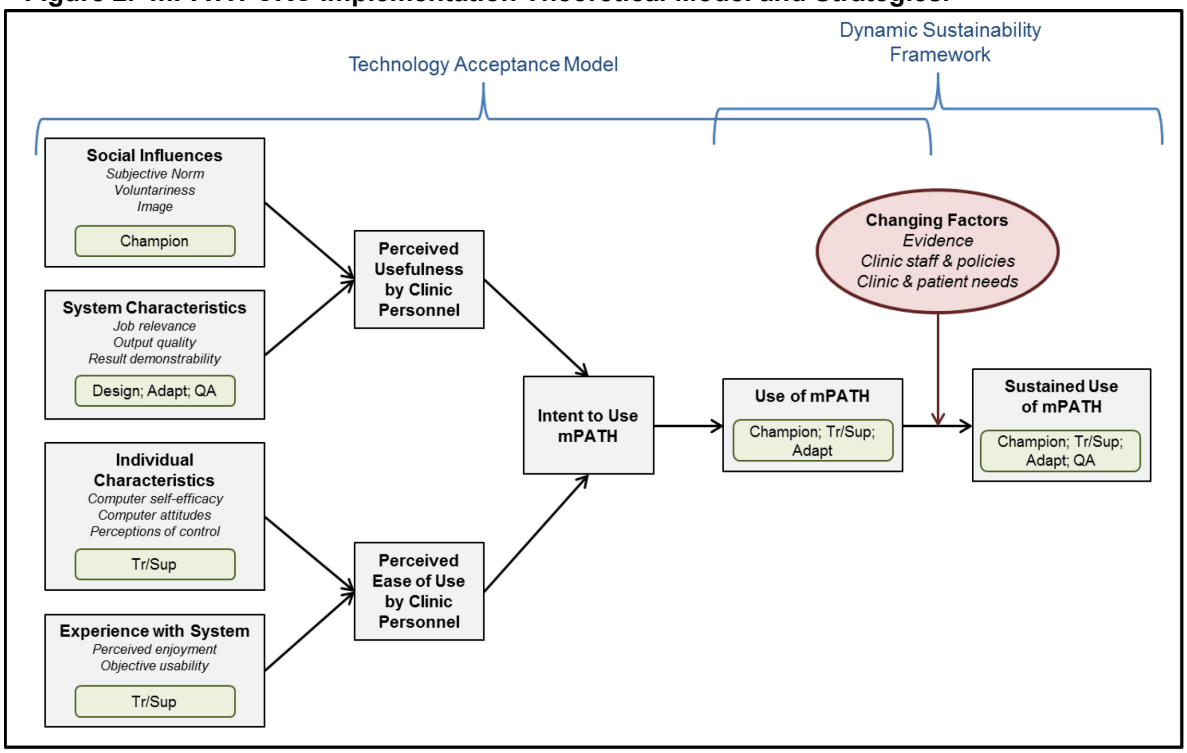
4.2 Framework for Implementing mPATH

Our strategy for implementing mPATH is based on the Technology Acceptance Model (TAM) to guide initial implementation and the Dynamic Sustainability Framework to guide maintenance, or continued use over time. The TAM posits that implementation of a new technology is determined by social influences and characteristics of the technology (which determine its *perceived usefulness*) and employees' characteristics and experiences (which determine its *perceived ease of use*).[56–58] After implementation, the Dynamic Sustainability Framework incorporates *adaptability* of mPATH as a means to promote maintenance.

Our "high touch" implementation strategy leverages evidence-based implementation strategies in conjunction with these two models (**Figure 2**). Each clinic will have a *clinic champion* who will guide implementation and contribute to the Social Influence construct of the TAM. The research team will provide facilitation through a pre-implementation meeting with the clinic champion, an on-site kick-off training session, and regular follow-up phone conferences with the champion.[59] During the follow-up phone conferences, topics known to promote implementation and sustainability will be discussed, including reviewing quality assurance reports, identifying performance gaps, and brainstorming barriers.[59–63] Clinics can also use a reporting function in mPATH to generate custom reports of data collected and receive "real time" feedback. We

expect that these features, and adaptations to mPATH to meet check-in needs, will increase the perceived usefulness of the program. Training and support through a hands-on kick-off session, follow-up technical assistance, and repeated trainings as needed will increase staff self-efficacy, perceptions of control, and usability.[60,64] Altogether, these multiple activities will increase intent to use mPATH, use of mPATH, and sustained use of mPATH. We will measure the key constructs of these models to determine their impact on implementation and maintenance (Section 5.0).

Figure 2. mPATH-CRC Implementation Theoretical Model and Strategies.



Components of Implementation Strategy (green boxes): **Design** = mPATH design features; **Champion** = clinic champion; **Adapt** = adaptations to mPATH program; **Tr/Sup** = training and support provided to clinics; **QA** = QA reports given to clinics

4.3 Pilot-Testing Implementation Strategy and Materials

4.3.1. Focus Groups and Interviews

A formative evaluation of our implementation strategy[65] will include a review of the strategy and training materials with four focus groups and individual semi-structured interviews. Each focus group will include six to 10 clinic staff who are involved with checking in and rooming patients, such as front desk staff, medical assistants, and nurses. Two focus groups will be recruited from clinics that participated in the randomized-controlled efficacy trial of mPATH (R01CA178941), and the other two from primary care clinics new to mPATH-CRC. A trained moderator will use a moderator's guide (**Appendix A.3**) to explore the facilitators and barriers to implementation, strategies for minimizing barriers, the adequacy of draft training plans, and additional support or training materials desired.

A trained interviewer will also conduct individual semi-structured interviews with two providers (doctors or advanced practice professionals) and one administrator at each of the four clinics, for a total of 12 interviews. Interviews will be conducted using an interview guide (**Appendix**

A.4) in person or via telephone (using a screen sharing program such as Webex to share visual materials) according to what is most convenient for the interviewee.

All focus group and interview participants will complete a brief demographic survey that includes items assessing attitudes about technology (**Appendix A.5**) which will help the research team interpret their responses.

Focus groups and interviews will be audio recorded and the content summarized. Each participant will receive a $50 gift card. Revisions to the implementation strategy and materials will be informed by the focus group and interview results.

4.3.2. Pilot Testing Training Materials, Surveys, and the mPATH Program

We will pilot test our training materials, surveys, and the mPATH program with two primary care clinics in the Wake Forest Baptist Health network. Each clinic will receive the kick-off training described in Section 4.4.1. Following the kick-off training session, we will ask clinic staff to complete the staff baseline survey described in Section 4.4.4.6. We will then let each clinic use the mPATH program. After six months, we will ask clinic staff to complete the follow-up survey described in Section 4.4.4.6

4.4 Implementation Trial

In a randomized-controlled cluster study of 22 primary care clinics, we will compare the implementation outcomes (as defined by the RE-AIM framework)[66] and implementation costs of the "high touch" strategy to a "low touch" strategy. The components of each strategy and their timing are outlined in **Table 1**.

Table 1. Comparison of Implementation Strategies

High Touch Strategy	Low Touch Strategy
Pre-Implementation Activities	
• **Clinic champion identified**	• N/A
Implementation Kick-Off	
• **On-site training with key clinic personnel** • **On-site training with providers** • **At elbow support on day of launch**	• On-site training with key clinic personnel
Months 1 – 6	
• **Phone/email technical support, as needed.** • **Access to QA data** • **Scheduled phone-calls with clinic champion to review QA data and explore potential barriers.** • **Additional on-site trainings as requested.** • **Monthly "shout-out memos" highlighting staff performance**	• Phone/email technical support, as needed • Access to QA data
Months 7 - 12	
• **Phone/email technical support, as needed**	• Phone/email technical support, as needed

Red text indicates items unique to High Touch Strategy

4.4.1. "High Touch" Implementation Strategy

The "high touch" strategy consists of pre-implementation activities, training, and ongoing support.

Pre-implementation activities. At each site, we will identify a clinic champion who will guide the local implementation effort. Champions typically arise through self or peer-nomination.[67] This person typically plays a central role in implementing new systems and has a demonstrated ability to communicate effectively, navigate the organizational environment, promote a project, and work well with others.[67,68] We will identify the champion by asking clinic administrators, lead nurses, and lead physicians who meets these qualities and would be willing to serve in this role. Each champion will then help the team identify a nursing super-user and a front desk super-

user. Lastly, each clinic will identify an alternate champion to assist with implementation and provide continuity if the champion is unavailable due to vacation or illness. The alternate champion may be one of the super-users. We designed mPATH for use by patients before medical visits, but the timing and location of use can vary. However, each clinic may adjust the implementation to meet their unique needs.

Kick-off training session. Two members of the study team will visit each practice to conduct a training session for clinic staff identified by the local clinic champion. This training will include hands-on practice with mPATH, including scenarios where patients "self-order" tests, to increase staff's comfort with the program, increase their self-efficacy, and demonstrate its usability.

A separate brief training session will be held for the clinic providers. The provider training will include an overview of the mPATH program and its functionality. Because providers will not directly interact with the mPATH program, the provider training will not include hands-on practice scenarios.

At-elbow support. The study team will provide at-elbow technical support the day the clinic launches mPATH in their practice.

On-Going Support: The study team will conduct a conference call with the clinic champion and alternate 2-3 business days after the launch date, and then at weeks 2, 4, 8, 16, and 24 post-launch to discuss the clinic's experiences with mPATH, review QA reports generated from mPATH data (frequency of use, patient demographics), explore the need for adaptations, and provide support. If program usage is below goal levels, barriers will be reviewed with the clinic champion and additional on-site training offered. Clinics may request technical support and additional training at any time, and clinics can self-generate reports to self-monitor mPATH-CRC implementation.

4.4.2. "Low Touch" Implementation Strategy

Clinics randomized to receive the low touch implementation strategy will receive: 1) the initial kick-off on-site training session and implementation materials (identical to the "high touch" group), and 2) access to phone/email technical support as requested. No adaptations will be made to the mPATH program for "low touch" clinics, nor will study staff proactively reach out to them after the kick-off training session.

Table 2. Characteristics of study clinics

	WFCP	Cornerstone	KY
Organizational structure	Academic medical center	Medical center affiliate	Federally-qualified health center
# of primary care clinics	15	26	9
# of counties with clinics	7	10	8
% of clinics in rural counties	20%	23%	89%
# of FTE clinicians	39	103	38
Patient visits per year	163,083	393,651	108,662
Payer mix			
Medicaid	7%	10%	48%
Medicare	42%	36%	18%
Commercial insurance	50%	51%	24%
Uninsured	1%	3%	9%
Patient race/ethnicity			
White, non-Hispanic	83%	78%	99%
Black/African-American	12%	13%	0%
White, Hispanic	3%	2%	0%
Other	2%	7%	1%

4.4.3. Study Sites

We will conduct the trial in community-based primary care practices in North Carolina, chosen to reflect diversity in geography and populations served. Practices will be affiliated with the Wake Forest Health Network (**Table 2**). Pilot data from target clinic systems show significant diversity in terms of payer mix (7%-10% Medicaid vs 48%) and racial diversity (76%-83% white). To increase racial diversity further, we will selectively enroll clinics with greater diversity. Counties where the clinics are located range from rural to urban. No currently identified clinics use tablet devices with patients, and we will exclude any additional clinics that already use tablets. Each potential study clinic will complete a baseline clinic overview questionnaire (Appendix B). Data from this questionnaire will be used to construct our final study clinic sample. All clinics will receive at least one study iPad (preloaded with mPATH) per full-time equivalent clinician. All clinics will keep the study iPads at the end of the study, encouraging participation.

4.4.4. Study Cohort

mPATH is designed to be given to all English or Spanish-speaking patients on clinic check-in. Therefore, our implementation outcomes cohort will include all adult (18 and over) English or Spanish-speaking patients who are seen in the study clinics in the 12 months following the initial clinic mPATH launch date. Our effectiveness outcome will include all English or Spanish speaking patients aged 50-74 who are eligible for CRC screening based on EHR records in the 12 months prior to and 12 months following the initial clinic mPATH launch date. We can capture all data needed for this cohort because all the clinics have searchable electronic health records.

4.4.5. Implementation and Clinic Randomization

We will randomly implement mPATH-CRC in 2 clinics (1 “high touch” and 1 “low touch”) until all 22 clinics are enrolled. To control for major organizational differences that could impact implementation, we will first select 2 clinics of similar size, then randomly assign one to receive the “high touch” strategy and the other the “low touch” strategy.

4.4.6. Data Collection

Baseline clinic personnel survey (Appendix B): At the initial kick-off training visit, we will administer a baseline survey to all clinic personnel (e.g., administrators, nurses, providers) who are involved with the implementation of mPATH-CRC, as identified by the local clinic champions. All surveys will assess constructs of the Technology Acceptance Model and the Dynamic Sustainability Framework.[56,69] Clinic personnel who do not complete the baseline survey (i.e., new hires) will complete it with their first follow-up survey (described below).

Follow-up clinic personnel survey (Appendix B): Because clinic environments and experience with the mPATH system will evolve over time, we will administer a follow-up survey 6 months and 12 months after the initial on-site training. If a clinic site decides to stop using the mPATH program prior to a scheduled follow-up survey, one final follow-up survey will be administered within 6 weeks of the practice discontinuing use of mPATH. The follow-up survey will assess organizational characteristics, individual characteristics, and experience with the mPATH-CRC system. Each person will receive a $10 incentive for each survey completed.

Clinic Contact and Cost Database (Appendix B): All study team contact with the clinics, and all technology costs associated with implementing and maintaining mPATH will be recorded in a secure, electronic database. Data will include date of contact, mode of contact (i.e., in-person,

phone, email), person initiating contact, purpose of contact, and the roles of staff involved in the contact. These data will allow us to compare the cost of the "high touch" and "low touch" intervention strategies and associations between the amount of support given and specific implementation outcomes.

4.5 Pragmatic Trial

To determine mPATH-CRC's effectiveness, we will nest a pragmatic trial within the implementation study. We will query the electronic health record (EHR) at each study clinic to identify unscreened individuals aged 50 – 74 who completed a clinic visit with a physician or advanced practice professional 4 to 12 months prior to the implementation launch date, and 0 to 8 months after the implementation kick-off launch date. Specific inclusion criteria are detailed in Section 3.0. We will then examine in the EHR whether these individuals complete CRC screening within 16 weeks of their index visit.

4.6 Mixed-Methods Study

The mixed-methods study will examine the facilitators and barriers to maintenance (sustained use of mPATH-CRC over time). In the 12th month after each clinic's launch date, we will identify sites who have maintained use of the mPATH program throughout the study period. To supplement the quantitative data gathered with our clinic surveys (Section 4.4.6), we will conduct semi-structured interviews with four members of each clinic: the clinic champion, one clinician, one front desk team member, and one medical assistant/nursing team member. The clinic champion will assist in the identification of the other team members for interviews based on their experience with the mPATH program. All participants will receive a $50 gift card. Using an interview guide (Appendix C), we will explore how mPATH-CRC was incorporated in the clinic's work flow and factors that affected maintenance such as intervention adaptations, organizational characteristics, and the champion's role. There will be a separate version of the interview guide for clinics who have very low (or no) usage of mPATH during their participation in the study.[56,69,70] Members of clinics that opt to discontinue use of mPATH will be interviewed as soon as practical after they discontinue use. We will interview representatives from study clinics until thematic saturation is reached. These semi-structured interviews, expected to last approximately 30 minutes, will be conducted by phone or video conference and analyzed by staff trained in qualitative methods. Interviews will be audio recorded and transcribed verbatim. Transcripts will be imported into ATLAS.ti software,[71] iteratively reviewed, coded by concept, and analyzed thematically to describe the implementation and sustainability experience. Themes will be compared among clinics to determine any differences.

5.0 Outcome Measures

5.1 Definition of Time Points

The Implementation Date will be defined as the date of the clinic launch at each site. A "month" is defined as a 4 week time period. "Week 1" commences the day of clinic launch.

5.2 Primary Outcome

mPATH-CRC Reach: Proportion of all Spanish or English-speaking patients, ages 50 – 74, who are eligible for CRC screening and complete the mPATH-CRC program in the 6th month (weeks 21 – 24) following the implementation date. Patients who use mPATH™-CheckIn and are told they are due for CRC screening but advised to discuss screening with their doctor due to detected risk factors are also counted as having used mPATH™-CRC.

5.3 Secondary Outcomes

5.3.1 mPATH™-CRC Reach (by month): The proportion of patients aged 50-74 who are eligible for CRC screening who complete mPATH™-CRC or have risk factors identified by mPATH™-CheckIn in months 1-5 following implementation

5.3.2 mPATH™-CRC Reach (by socioeconomic strata): The proportion of patients aged 50-74 who are eligible for CRC screening who complete mPATH™-CRC or have risk factors identified by mPATH™-CheckIn in months 1-6 by socioeconomic strata; this outcome will also be calculated among CheckIn users only

5.3.3 mPATH™-CRC Adoption: The mean usage of mPATH™-CRC among staff and providers over the first 6 months following implementation; usage is calculated for each staff/provider as the proportion of times mPATH™-CRC is completed out of the total times mPATH™-CRC should have been launched.

5.3.4 mPATH™-CRC Acceptability, Appropriateness, and Feasibility: Mean Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM) scores (68) for mPATH™-CRC as assessed on the 6-month clinic personnel survey

5.3.5 mPATH™-CRC Implementation Fidelity: The proportion of patients who use mPATH™-CRC and request a CRC screening test who have a test ordered or have the order dismissed (i.e., “self-order” feature is used as designed) in months 1-6

5.3.6 mPATH™-CRC Maintenance: The proportion of patients aged 50-74 who are eligible for CRC screening who complete mPATH™-CRC or have risk factors identified by mPATH™-CheckIn in months 7-12

5.3.7 mPATH™-CheckIn Reach: The proportion of patients aged 18 or older who complete mPATH™-CheckIn in months 1-6; this outcome will be calculated overall and within socioeconomic strata

5.3.8 mPATH™-CheckIn Adoption: The mean usage of mPATH™-CheckIn among staff and providers over the first 6 months following implementation; usage is calculated for front desk staff as the proportion of times mPATH™-CheckIn is completed out of the total times mPATH™-CheckIn should have been handed out; usage is calculated for nurses/providers as the proportion of times mPATH™-CheckIn is completed and data is transmitted to the EHR out of the total times mPATH™-CheckIn should have been handed out

5.3.9 mPATH™-CheckIn Acceptability, Appropriateness, and Feasibility: Mean AIM, IAM, and FIM scores for mPATH™-CheckIn as assessed on the 6-month clinic personnel survey

5.3.10 mPATH™-CRC Maintenance: The proportion of patients aged 18 or older who complete mPATH™-CheckIn in months 7-12

5.3.11 mPATH™-CRC Effectiveness: The proportion of patients aged 50-74 who are eligible for CRC screening who complete CRC screening within 16 weeks of their index visit to the clinic. Effectiveness is determined by comparing the proportion who complete screening in a pre-implementation cohort (months 12 - 4 before implementation) to a post-implementation cohort (months 1 - 8 after implementation).

5.3.12 CRC screening tests ordered: The outcome is defined as the proportion of patients aged 50-74 who are eligible for CRC screening who have a CRC screening test ordered (colonoscopy, flexible sigmoidoscopy, fecal testing for blood, or fecal DNA testing) within 16 weeks of their index visit to the clinic. This outcome will also be compared between the pre- and post-implementation cohorts.

5.3.13 Facilitators and barriers to maintenance (sustained use of mPATH™-CRC over time): These will be identified through semi-structured interviews. Interviews will explore how mPATH™-CRC was incorporated in the clinic's work flow and factors that affected maintenance such as intervention adaptations, organizational characteristics, and the champion's role. Interviews will be conducted with four members of each selected clinic: the clinic champion, one clinician, one front desk team member, and one medical assistant/nursing team member.

5.4 Exploratory Outcomes

5.4.1 mPATH™ Implementation Cost: Cost to implement and maintain usage of the mPATH™ program from the perspective of a healthcare system considering implementation, including hardware (i.e., iPads, cases, charging cabinets), cloud data storage fees, training, and technical support. Clinic staff training costs will be computed using training time and national average wage values for nursing and other staff from the Bureau of Labor Statistics. Technical support costs will include travel and support staff time costs associated with the initial training, and any follow-up trainings. Ongoing costs to maintain usage of mPATH™ include costs to train new employees or replace hardware and technical support costs related to follow-up training, troubleshooting, and adapting the program as needed

5.5 Data Sources

5.5.1 Electronic health record (EHR) and appointment schedules: Each clinic's EHR and appointment schedules can be queried to identify patients scheduled for visits, patients who completed visits, patient demographics, and patient clinical care data.

5.5.2 mPATH-CRC database: The mPATH program database includes patients' medical record numbers, age, gender, date/time of use, length of time in program, and responses to questions. (Appendix B)

5.5.3 REDCap Database: We will have a secure REDCap database that contains all clinic staff surveys and details on cost and contact with clinics.

6.0 Analytic Plan

6.1 Sample Size and Power

6.1.1 Primary outcome: Our primary objective is to assess differences in mPATH-CRC Reach proportion of participants who complete the mPATH-CRC program or have risk factors identified by mPATH-CheckIn) in the 6th month between the two implementation strategies. Using formulae found in Hemming et al.,[72] **Table 3** shows the number of clinics necessary to detect differences in Reach ranging from .15 to .20 with 80% and 90% power for intraclass correlations (ICC) ranging from .03 to .08, assuming an average sample size per clinic of 30 with a cluster sample size coefficient of variation (CV) of 25%. These latter numbers are based on estimated numbers of eligible patients seen monthly, obtained from a survey of the participating clinics. Since these data will be obtained from the EHR, we will use all eligible patients at each site. We will recruit a total of 22 clinics, which will provide at least 80% power to detect a difference of 15% if the ICC is 0.03 or lower. If the ICC were as high as 0.08, we would have over 80% power to detect a difference of 20%. These calculations assume average utilization across all sites of 50%. Power increases as rates move away from 50% in either direction.

Table 3. Total number of clinics needed to detect the specified difference in Reach as a function of the power, ICC, and difference.

	80% Power						90% Power					
Diff/ICC	.03	.04	.05	.06	.07	.08	.03	.04	.05	.06	.07	.08
.15	22	26	29	33	36	40	30	34	39	44	48	53
.20	12	14	16	18	20	22	16	19	22	24	27	29

6.1.2 Effectiveness outcome: A secondary objective is to assess the effect of mPATH-CRC on screening rates (effectiveness) comparing 8 months of data prior to implementation to 8 months of data following implementation. The detectable difference (difference in screening rates pre vs post) depends on the sample size, power, ICC, and cluster sample size CV. We will assume a screening rate in the pre-implementation group of 15%, as observed in the control group in our R01 study.[45] Using SS/Power formulae for cluster designs[72,73], **Table 4** shows the differences in screening rates we will be able to detect with 80% and 90% power for ICCs ranging from 0.03 to 0.06, assuming an average monthly sample size of 30 patients per clinic in the EHR, a cluster sample size CV of 25%, and no change in the screening trends over time. Because of the diminishing return of cluster designs, additional patients have little effect on the detectable difference, although we will use all the patients in the EHR. We see that we will be able to detect a 10% difference in screening rates (15% vs 25%) with 80% power even if the ICC is as large as 0.04. We estimate that a minimum of 30 patients per clinic per month will meet inclusion criteria for this analysis (based on age, language, and screening status) and will be available through the EHR, so we will be amply powered for assessing the secondary aim.

Table 4. Detectable difference in screening rates as a function of the Power and the ICC (22 Clinics)

	80% Power				90% Power			
ICC	.03	.04	.05	.06	.03	.04	.05	.06
	.087	.100	.113	.125	.102	.118	.133	.146

To evaluate whether the effect of mPATH-CRC on screening rates differs by implementation strategy, the period (pre vs post) by strategy ("high touch" vs "low touch") interaction can be evaluated. Based on the control group from the previous randomized-controlled efficacy study, we anticipate a screening rate of 15% for "low touch" and pre- implementation. An increase in

the screening rate from 15% to 25% from pre to post, corresponds to an odds ratio (OR) of 3. Similarly, assuming a screening rate in the "low touch" group of 15%, and a screening rate of 25% in the "high touch" group, also corresponds to an OR of 3. By design, we anticipate half of the patients being in the "high touch" group and half in the post period, and that strategy and period are independent. Based on these assumptions, **Table 5** shows the interaction OR that can be detected with 80% power for ICCs ranging from 0.03 to 0.06, assuming an average monthly sample size of 30 patients per clinic in the EHR (for 8 months pre and 8 months post), a cluster sample size CV of 25%, and no change in the screening trends over time.

Table 5. Detectable interaction odds ratio difference in screening rates as a function of the ICC (22 Clinics)

	80% Power			
ICC	.03	.04	.05	.06
	2.903	3.462	4.097	4.819

6.2 Analysis of Primary Outcome

We will assess the primary hypothesis (that the "high touch" vs. "low touch" implementation strategy will result in greater use of the intervention) using a mixed effects logistic regression model with mPATH-CRC Reach (Y/N) as the individual-level outcome, implementation approach as the primary independent variable, site as a random effect, and the stratification factor clinics size as a covariate per the design. A descriptive approach will also be utilized where mPATH-CRC Reach is estimated and reported along with an exact 95% confidence interval for each month (for months 1-6 following implementation), and within socioeconomic strata for "high touch" and "low touch" clinics separately. In secondary analyses, we will assess effects of clinic-level covariates (e.g. volume, rurality, organizational culture) and patient level covariates (e.g. age, gender, race/ethnicity) on Reach. We will include arm-by-covariate interactions to determine if the effect of the implementation strategy differs depending on levels of the covariates. This secondary analysis will allow us to determine effects of the implementation strategy in clinics with varying organizational factors and populations. The proposed approach allows us to incorporate participant- and cluster-level covariates, but there are other analysis methods we could employ. For example, we could use a clinic-level analysis (e.g. analysis of covariance) on the mean implementation rates within each clinic, or another individual-level approach (e.g. generalized estimating equations). Alternative methods and their strengths and weaknesses are well-documented.[74–76] These alternate approaches will be used in a sensitivity analysis to determine effects of the modeling assumptions on the results.

6.3 Analysis of Secondary Outcomes

The key secondary outcome of effectiveness of mPATH-CRC will be evaluated by comparing the proportion who complete CRC screening within 16 weeks of their index visit to the clinic between a pre-implementation cohort (months 12 - 4 before implementation) and a post-implementation cohort (months 1 - 8 after implementation). Similar to the model described for mPATH-CRC Reach above, effectiveness of mPATH-CRC will be evaluated using a mixed effects logistic regression model. For an overall assessment of the effectiveness, completing CRC screening within 16 weeks (Y/N) will be the patient-level outcome, implementation cohort will be the primary independent variable, site will be a random effect, and the stratification factor clinic size will be a covariate per the design. Pre- vs post-implementation changes will also be compared between the "high touch" and "low touch" implementation strategies and between dose levels defined based on mPATH™-CRC usage by incorporating interactions into the mixed effects logistic regression models. An interrupted time series analysis (segmented

regression)[77,78] will also be used to estimate the effect of the intervention within each clinic (using interaction terms with clinic within a linear model) adjusting for any trend that was occurring in screening prior to the implementation. This model provides estimates of the time trends before and after the intervention as well as the change in screening rates due to the intervention. Linear contrasts will be used to compare the changes in screening rates and trends between the "high touch" clinics and the "low touch" clinics. As in Section 6.2, we will assess the effects of cluster- and patient-level covariates and their interactions with implementation strategy in secondary analyses. The same basic approach outlined in Section 6.2 will also be used to compare other binary implementation outcomes between the "high touch" and "low touch" strategies. Continuous implementation outcomes are measured at the provider/staff level, rather than the patient level. Linear mixed effects models will be used to compare these outcomes between the "high touch" and "low touch" strategies, with implementation approach as the primary independent variable, site as a random effect, and the stratification factor clinic size as a covariate per the design.

6.4 Length of Study

Study Timeline

Study Task	Year 1				Year 2				Year 3				Year 4				Year 5			
	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Develop mPATH Implementation Materials	X																			
Implementation Focus Groups	X	X																		
Revise Implementation Materials		X																		
Develop and validate EHR queries		X	X	X																
mPATH-CRC Implementation				X	X	X	X	X	X	X	X	X	X	X						
Implementation Data Collection				X	X	X	X	X	X	X	X	X	X	X	X	X				
Effectiveness Data Collection							X	X	X	X	X	X	X	X	X	X				
Maintenance Data Collection/Clinic Interviews						X	X	X	X	X	X	X	X	X	X	X	X			
Data Cleaning				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Data Analysis and Results Dissemination																	X	X	X	X

7.0 Data Management

Clinic survey data will be stored in the Research Electronic Data Capture (REDCap) system, a web-based application for building and managing online surveys and databases. REDCap was developed in the CTSA network and implemented at Wake Forest specifically around HIPAA security guidelines. REDCap provides an intuitive interface for users to enter data, has real-time validation rules at the time of entry, and maintains audit trails.

All extracted clinical datasets and datasets containing data from combined sources will be stored on a central Wake Forest data server using industry standard encryption (e.g., AES-256 bit) to protect personal health information.

All iPad interaction data will be temporarily stored on each iPad using secure Advanced Encryption Standard 256 bit encryption (AES-256) software to protect personal health information. The iPad

software automatically sends the data to the central data storage server and removes the data from the iPad after confirmation that the data were sent and received. All study site databases will be stored in an encrypted, HIPAA-compliant Cloud-based server with continuous data backup.

8.0 Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form and in study datasets. An honest broker will mediate the electronic health record data queries to limit the exposure of patient identifying information. Our analyses require us to have full dates of visits (to determine the success of implementation over time), age, and 5-digit zip codes, and GEOIDs (to determine rural or urban residency). Therefore, the honest broker will create a limited data set for analysis. The day that each clinic launches mPATH will be called day 0, with each subsequent or previous date recorded as an integer relative to day 0. This will add additional protections for patients by obscuring dates in the dataset. Any collected patient identifying information corresponding to the unique study identifier will be maintained in a linkage file, stored separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Subject identifying information will be destroyed three years after closure of the study, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

9.0 Data Safety and Monitoring

The only anticipated risks specific to this study are loss of data confidentiality. The mPATH study database is hosted on an encrypted secure server maintained by Wake Forest Information Technology & Services (ITS). The database is password protected, and only authorized individuals are granted access. ITS routinely monitors for any security weaknesses or breaches. In the unlikely event of a data breach, ITS will notify the PI who will convene an internal Data and Safety Monitoring committee to review the event and determine the appropriate response. The Data and Safety Monitoring committee will be comprised of the PI, Project Manager, study statistician, and study programmer. Other individuals may be added to the Data and Safety Monitoring committee at the PI's discretion. In addition, the PI will promptly review any participant or other-reported concerns regarding the study. The PI will report any loss of data confidentiality or other adverse event to the Wake Forest IRB and the NIH within 2 business days of the discovery the event.

10.0 Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

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Appendix A – Implementation Strategy Qualitative Study Materials

A.1. Focus Group Invitation Telephone Script (clinics that participated in prior trial)

This is [name of caller] calling on behalf of Dr. David Miller at Wake Forest Baptist Health. Your clinic was kind enough to participate in his prior study of the mPATH iPad app about colorectal cancer screening. The study showed that the app doubled the number of patients who were screened for colorectal cancer. I'm calling now to invite your clinic to participate in a research focus group to help us learn how mPATH might be implemented in primary care clinics. If you are willing to participate, we would meet with your clinic staff and providers at your clinic site for a group discussion that would last no more than 60 minutes. Each person who participates in the focus group will receive a $50 gift card as a thank you for their time. We would schedule this meeting for the day and time that works best for your practice. Would you be interested in participating?

[If yes]: Great. What days/times are generally best for your group, and I'll work with you to get the meeting scheduled.

A.2. Focus Group Invitation Telephone Script (clinics that did not participate in prior trial)

This is [name of caller] calling on behalf of Dr. David Miller at Wake Forest Baptist Health. We have developed an iPad program call mPATH that helps patients get screened for colorectal cancer screening. We recently completed a study that showed the app doubled the number of patients who were screened for colorectal cancer. We now would like to talk to a few practices to figure out how to best implement mPATH in primary care clinics. I'm calling now to invite your clinic to participate in a research focus group to help us learn how to do that. If you are willing to participate, we would meet with your clinic staff and providers at your clinic for a group discussion that would last no more than 60 minutes. Each person who participates in the focus group will receive a $50 gift card as a thank you for their time. We will not ask your clinic to implement mPATH. We simply want to hear your opinions about how clinics might use it in the future. We would schedule this meeting for the day and time that works best for your practice. Would you be interested in participating?

[If yes]: Great. What days/times are generally best for your group, and I'll work with you to get the meeting scheduled.

A.3. Implementation Strategy Focus Group Moderator's Guide (Wake Forest Clinics)

FG Purpose: To learn how mPATH can be implemented successfully in primary care clinics. The main overarching questions to answer are:

1. What would make clinic staff want to use mPATH with patients?
2. How do clinic staff think mPATH would be best incorporated into clinic flow?
3. What type of training and support will clinics need to use mPATH?

The guide will:

I. Explore the facilitators and barriers to implementation
II. Strategies for minimizing barriers
III. The adequacy of draft training materials
IV. Additional support or training materials desired
V. Focus groups will also comment on the set of clinic check-in questions proposed for the mPATH-CRC iPad app

Focus groups will be audio recorded and the content summarized. Revisions to the implementation strategy and materials will be informed by the focus group results.

Date:

Moderator(s):

Note Taker(s):

Start time: **End time:**

I. WELCOME

Hello and welcome to our session. My name is Nicole Puccinelli-Ortega. I am today's focus group moderator. This is Donna; she will be assisting with the focus group. She will record our discussion and take notes on what we say, to ensure we don't miss anyone's comments.

We want to thank you for being here today. We appreciate your willingness to share your thoughts with us. The reason you are here today is obtain your feedback about a program called mPATH. mPATH is a user-friendly iPad program designed to increase the efficiency and quality of care in primary care offices. While in the waiting room, patients use mPATH to

answer standard check-in items and assess their need for routine cancer screening. mPATH then transmits this information to the electronic health record, reducing data entry by nursing staff.

Our goal today is to obtain your opinions about how best to implement mPATH into a primary care clinic's workflow. I will be asking for your feedback about the iPad program, our proposed clinic workflow strategy and our training plan. There are no right or wrong answers. Everything we talk about will be considered confidential. We will use the information from our conversations to inform our study team about the best way to implement mPATH in other clinics. There will not be any names used and no one outside of this room will know specifically who said what. Please do not share other people's names or comments outside of the group. We will audio record today's conversation and take notes. This helps us remember what you all said. The notes and the audio will be kept in our offices and will not be shared with anyone outside our project.

You will be asked to complete a brief paper questionnaire at the end of our group discussion, and you will each receive a $50 gift card for your participation today. I will send around a sheet where I will collect your information, so I can make sure that everyone who is here receives their gift card for participation.

The session should last between 30-45 minutes. Before we get started, are there any questions?

We would like for you to speak freely, sharing your ideas and opinions, even if they are different from others.

There are no right or wrong answers.

All your views are important, whether positive or negative.

We want to get as many different points of view as we can.

Please remember to silence your cell phones!

Since this is a group discussion, you do not have to wait for me to call on you to speak, but please try to speak one at a time. As I mentioned, we will be taking written notes as well as

recording the session. This is to make sure that we do not miss anyone's comments. Is that okay with everyone?

OK, first, let's go around the room and say your first name and your favorite thing to do on a warm summer day.

II. MAIN QUESTIONS

Let's get started.

Motivators and Barriers

First, let me demonstrate the mPATH iPad program so you can see how it looks and how we are thinking clinic staff will use it.

1. What are your first impressions of this program?

   Follow-up question:

   a. Based on what you've seen in the demonstration, tell me what about it would be helpful to you in your clinic.
   b. Tell me what would not be helpful.

2. What would motivate your team to use this iPad app?
   Follow-up questions:

   a. We programmed the app to ask patients the standard clinic check-in questions, hoping that would save nurses some time. Do you think that feature is helpful or not helpful?
   (probe): Tell me why you say that.

   b. What else could the app do that would make your job easier and make you excited to use it?

3. What would make you not want to use it?

4. Patients will independently answer the check-in questions on the iPad, and the program will transmit the answers to the standard nursing check-in note in WakeOne. The nurses will get to see the patient's answers in the WakeOne note before they sign off on the note.
   What are your thoughts about that process?

   (probe):Tell me about any concerns you may have.

Clinic Workflow

I am going to walk you through what we are envisioning to be the typical pattern of patient check in and how staff and patients will hand off and use the iPad.

(Display clinic workflow poster/slide illustration and walk through the flow.)

5. What are your immediate thoughts about this workflow?

   Follow-up questions:

   a. What do you like about the workflow? And why?

   b. What don't you like about the workflow? And why?

   c. Are the front desk staff the best people to hand the iPad to patients? Why or why not?

6. The app includes audio narration and a video about colon cancer screening. If we gave patients disposable earbuds when they are handed the iPad, do you think they could use the app in the waiting room? Why or why not?

   Follow-up questions:

   a. Do you think audio in the video is important? Or do you think reading closed captions would be enough?

   b. How could patients use the app without earbuds? Would it disturb other patients?

7. What is the longest time you think patients could use the app before it would interfere with clinic flow?

   Follow-up questions
   a. On average, how long do patients wait from check-in until the doctor sees them?

8. How many iPads would a clinic of your size and patient volume need to ensure this process didn't interfere with patient flow?

9. If a patient is 50 or older, the app will determine if they are due for colon cancer screening. If they are due, it will help them get a test ordered. If your clinic decided to use this program, would it be best to offer it to all patients on check-in, or only those who are 50 and older? Why?

Training and Support

In a few months, we will be helping some clinics incorporate the mPATH program into their workflow. Now I will tell you about the training and support we are planning to give those clinics so you can tell me what you think about our plans.

We will first ask each clinic to identify a person working in the clinic, a "clinic champion," who will help keep the program going and serve as our main contact. If the clinic wants us to add additional check-in questions to the mPATH program, we can do that for them. We will also hold a 45 minute on-site training session with the clinic staff to give them practice using the mPATH program. Afterwards, we will provide the clinics with as needed technical support by phone, email, or in person.

10. What do you think about this training plan?

    a. Follow-up questions: What would work well? What could be better?

11. How do you suggest we find the right person for the "clinic champion" role?

Follow-up questions:

a. Who would we contact to find a champion?

b. If your clinic decided to use this program, who at your clinic would be the champion? What is his/her role here?

12. How much time is reasonable for you to attend an on-site training session?

Follow-up question:

a. If we were to hold a training session for your clinic, when would be the best time for that?

13. Do you think most clinic staff would watch a webinar or on-line video that provides an overview of the program prior to the training session?

Follow-up questions:

a. Is this something staff could do during free time at work (like during lunch or other free time)?

b. What would be a reasonable length of time for a webinar or on-line video?

14. What is the best way for the clinic champion to communicate with us if the clinic needs technical support or help?

a. (Prompt:) by phone, email, text, video chat?

b. Follow-up question: What is a reasonable time for us to be able to reply or respond back to clinic champions when they have technical or other questions?

III - CLOSING

- You have all had a lot of really important things to say, and I appreciate your openness and willingness to share. Would anyone like to share any other comments before we end?

Provide participants with questionnaires and ask that they complete them on paper. Then, give $50 to participant and have them sign saying they received it.

A.4. Implementation Strategy Interview Guide (Wake Forest Clinics)

Interview Purpose: To learn how mPATH can be implemented successfully in primary care clinics. The main overarching questions to answer are:

1. What would make clinic staff want to use mPATH with patients?
2. How do clinic staff think mPATH would be best incorporated into clinic flow?
3. What type of training and support will clinics need to use mPATH?

The guide will:

VI. Explore the facilitators and barriers to implementation
VII. Strategies for minimizing barriers
VIII. The adequacy of draft training materials
IX. Additional support or training materials desired
X. Interviews will also comment on the set of clinic check-in questions proposed for the mPATH-CRC iPad app

Interviews will be audio recorded and the content summarized. Revisions to the implementation strategy and materials will be informed by the interview results.

Date:

Interviewer:

Start time: **End time:**

I. WELCOME

I want to thank you for speaking with me today. I appreciate your willingness to share your thoughts with me. The reason we are doing this interview is obtain your feedback about a program called mPATH. mPATH is a user-friendly iPad program designed to increase the efficiency and quality of care in primary care offices. While in the waiting room, patients use mPATH to answer standard check-in items and assess their need for routine cancer screening. mPATH then transmits this information to the electronic health record, reducing data entry by nursing staff.

The purpose of the interview is to learn from you your opinion on how best to implement mPATH into a primary care clinic's workflow. I will be asking for your feedback about the iPad program, our proposed clinic workflow strategy and our training plan. There are no right or

wrong answers. Everything we talk about will be considered confidential. I will use the information from our conversations to inform our study team about the best way to implement mPATH in other clinics. I will audio record today's conversation and take notes. This helps us remember what you all said. The notes and the audio will be kept in our offices and will not be shared with anyone outside our project. I would like for you to speak freely, sharing your ideas and opinions. You are the expert and there are no right or wrong answers.

You will be asked to complete a brief paper on online questionnaire at the end of our discussion, and you will receive a $50 gift card for your participation today.

The interview should last between 20 and 30 minutes. Before I get started, are there any questions?

II. MAIN QUESTIONS

Let's get started.

Motivators and Barriers

First, let me demonstrate the mPATH iPad program so you can see how it looks and how we are thinking clinic staff will use it.

<u>Clinic Staff (nurses, nursing assistants, med assistants, front desk staff)</u>

1. What are your first impressions of this program?

   Follow-up questions:
   a. Based on what you've seen in the demonstration, do you think this would be helpful to you in your clinic? Why or why not?

   b. What would motivate your team to use this iPad app?

   c. What would discourage your team from using the app?

2. We programmed the app to ask patients the standard clinic check-in questions, hoping that would save nurses some time. Do you think that feature is helpful or not helpful?

   (Probe, if needed) Tell me why you say that.

Follow-up question:

   a. What other features could the app do that would make your job easier and make you excited to use it?

3. Patients will independently answer the check-in questions on the iPad, and the program will transmit the answers to the standard nursing check-in note in WakeOne. The nurses will get to see the patient's answers in the WakeOne note before they sign off on the note.
   Tell me your thoughts about that process.

   Follow-up question:
   a. Tell me your concerns.

Clinic Workflow

I am going to walk you through what we are envisioning to be the typical pattern of patient check in and how staff and patients will hand off and use the iPad.

(Display clinic workflow poster/slide illustration and walk through the flow.)

4. What are your immediate thoughts about this workflow?

   Follow-up questions:

   a. What do you like about this workflow? And why?

   b. What don't you like about this workflow? And why?

   c. Are the front desk staff the best people to hand the iPad to patients? Why or why not?

5. The app includes audio narration and a video about colon cancer screening. If we gave patients disposable earbuds when they are handed the iPad, do you think they could use the app in the waiting room? Why or why not?

   Follow-up questions:

   a. Do you think audio in the video is important? Or do you think reading closed captions would be enough?

   b. How could patients use the app without earbuds? Would it disturb other patients

6. What is the longest time you think patients could use the app before it would interfere with clinic flow?

   Follow-up questions:

   a. On average, how long do patients wait from check-in until the doctor sees them?

7. How many iPads would a clinic of your size and patient volume need to ensure this process didn't interfere with patient flow?

8. If a patient is 50 or older, the app will determine if they are due for colon cancer screening. If they are due, it will help them get a test ordered. If your clinic decided to use this program, would it be best to offer it to all patients on check-in, or only those who are 50 and older?

   (Probe, if needed) Tell me more.

For Clinic Manager ONLY

9. Could our team email you later to get a list of the intake questions your clinic routinely asks patients?

For Physicians (MDs, NPs, PAs) ONLY

As you saw, if patients are between 50 and 75, mPATH asks them about their colon cancer screening history and desire to be screened. mPATH will generate a summary of each patients usage so you know what they said. Here are two examples of what the printed summary would look like. (show examples of mPATH app output)

10. Would you find this printout helpful or not helpful? Why or why not?

11. What do you think about the length of the printout?

    Follow-up question:

    a. Is it too much information or not enough?
       (Prompt if needed): Tell me what you would remove (if too much information)
       (Prompt, if needed): If not enough information, what else would you want to know?

12. Would you rather have this information printed and left for you outside the exam room door, or would you rather have it electronically sent to WakeOne?
(Probe, if needed): Tell me more about your answer.

Follow-up question:

a. If sent to WakeOne, where would you want the information to appear in WakeOne? In your In Basket, in a procedure note, somewhere else?

Training and Support (for everyone – if time permits)

In a few months, we will be helping some clinics incorporate the mPATH program into their workflow. Now I will tell you about the training and support we are planning to give those clinics so you can tell me what you think about our plans.

We will first ask each clinic to identify a person working in the clinic, a “clinic champion,” who will help keep the program going and serve as our main contact. If the clinic wants us to add additional check-in questions to the mPATH program, we can do that for them. We will also hold a 45 minute on-site training session with the clinic staff to give them practice using the mPATH program. Afterwards, we will provide the clinics with as needed technical support by phone, email, or in person.

13. Tell me your thoughts about this training plan.

Follow-up questions:

a. What about it works well?

b. What could be better?

14. How do you suggest we find the right person for the “clinic champion” role?

Follow-up questions:

a. If your clinic decided to use this program, who at your clinic would be the champion?

b. What is his/her role here?

c. Who is the best person at a clinic to contact to find a champion?

15. What is the best way for the clinic champion to communicate with us if the clinic needs technical support or help?

    (Prompt if needed): What is the best means of communication, by phone, email, text, video chat?

    Follow-up question:

    a. What is a reasonable time for us to be able to reply or respond back to clinic champions when they have technical or other questions?

III - CLOSING

You have all had a lot of really important things to say, and I appreciate your openness and willingness to share. Would anyone like to share any other comments before we end?

Provide participant with questionnaire or send them link to survey and ask that they complete it. If completing survey online, tell them survey will include an item telling us where to mail their gift card. If in person interview, give $50 gift card to participant and have them sign saying they received it.

A.5. Implementation Strategy Participant Demographic Questionnaire

Please answer the following questions.

1. How long have you worked at Wake Forest/Cornerstone outpatient clinics: _____

2. Your position title/role: _____

3. Your current age: _____

4. Gender: ____

5. I could complete a job using a computer program…

   …if there was no one around to tell me what to do as I go. [ ] Yes [ ] No
   …if I had just the built-in help facility for assistance. [ ] Yes [ ] No
   …if someone showed me how to do it first. [ ] Yes [ ] No
   …if I had used a similar program before this one to do the same task. [ ] Yes [ ] No

6. Please rate the following statements on a scale of 1-7. (1 = strongly disagree, 2 = moderately disagree, 3 = somewhat disagree, 4 = neutral, 5 = somewhat agree, 6 = moderately agree, 7 = strongly agree)

   ___ Computers do not scare me at all.

   ___ Working with a computer makes me nervous.

   ___ Computers make me feel uncomfortable.

   ___Computers make me feel uneasy.

A.6. Implementation Strategy Focus Group Moderator's Guide (non-Wake Forest Health Network Clinics)

FG Purpose: To learn how mPATH can be implemented successfully in primary care clinics. The main overarching questions to answer are:

1. What would make clinic staff want to use mPATH with patients?
2. How do clinic staff think mPATH would be best incorporated into clinic flow?
3. What type of training and support will clinics need to use mPATH?

The guide will:

I. Explore the facilitators and barriers to implementation
II. Strategies for minimizing barriers
III. The adequacy of draft training materials
IV. Additional support or training materials desired
V. Focus groups will also comment on the set of clinic check-in questions proposed for the mPATH-CRC iPad app

Focus groups will be audio recorded and the content summarized. Revisions to the implementation strategy and materials will be informed by the focus group results.

Date:

Moderator(s):

Note Taker(s):

Start time: **End time:**

I. WELCOME

Hello and welcome to our session. My name is _____. I am today's focus group moderator. This is _____; s/he will be assisting with the focus group. S/he will record our discussion and take notes on what we say, to ensure we don't miss anyone's comments.

We want to thank you for being here today. We appreciate your willingness to share your thoughts with us. The reason you are here today is obtain your feedback about a program called mPATH. mPATH is a user-friendly iPad program designed to increase the efficiency and quality of care in primary care offices. While in the waiting room, patients use mPATH to answer standard check-in items and assess their need for routine cancer screening. mPATH then informs the office staff of patients' answers so they can update the electronic health record as needed.

Our goal today is to obtain your opinions about how best to implement mPATH into a primary care clinic's workflow. I will be asking for your feedback about the iPad program, our proposed clinic workflow strategy and our training plan. There are no right or wrong answers. Everything we talk about will be considered confidential. We will use the information from our conversations to inform our study team about the best way to implement mPATH in other clinics. There will not be any names used and no one outside of this room will know specifically who said what. Please do not share other people's names or comments outside of the group. We will audio record today's conversation and take notes. This helps us remember what you all said. The notes and the audio will be kept in our offices and will not be shared with anyone outside our project.

You will be asked to complete a brief paper questionnaire at the end of our group discussion, and you will each receive a $50 gift card for your participation today. I will send around a sheet where I will collect your information, so I can make sure that everyone who is here receives their gift card for participation.

The session should last between 30-45 minutes. Before we get started, are there any questions?

We would like for you to speak freely, sharing your ideas and opinions, even if they are different from others.

There are no right or wrong answers.

All your views are important, whether positive or negative.

We want to get as many different points of view as we can.

Please remember to silence your cell phones!

Since this is a group discussion, you do not have to wait for me to call on you to speak, but please try to speak one at a time. As I mentioned, we will be taking written notes as well as recording the session. This is to make sure that we do not miss anyone's comments. Is that okay with everyone?

OK, first, let's go around the room and say your first name and your favorite thing to do on a warm summer day.

II. MAIN QUESTIONS

Let's get started.

Motivators and Barriers

First, let me demonstrate the mPATH iPad program so you can see how it looks and how we are thinking clinic staff will use it.

1. What are your first impressions of this program?

   Follow-up question:

   a. Based on what you've seen in the demonstration, tell me what about it would be helpful to you in your clinic.
   b. Tell me what would not be helpful.

2. What would motivate your team to use this iPad app?
   Follow-up questions:

   a. We programmed the app to ask patients the standard clinic check-in questions, hoping that would save nurses some time. Do you think that feature is helpful or not helpful?
   (probe): Tell me why you say that.

   b. What else could the app do that would make your job easier and make you excited to use it?

3. What would make you not want to use it?

4. Patients will independently answer the check-in questions on the iPad, and the program will show the patients' answers to the person who is rooming the patient. The rooming staff would then enter the answers into the electronic health record.
   What are your thoughts about that process?

   (probe):Tell me about any concerns you may have.

Clinic Workflow

I am going to walk you through what we are envisioning to be the typical pattern of patient check in and how staff and patients will hand off and use the iPad.

(Display clinic workflow poster/slide illustration and walk through the flow.)

5. What are your immediate thoughts about this workflow?

   Follow-up questions:

   a. What do you like about the workflow? And why?

   b. What don't you like about the workflow? And why?

   c. Are the front desk staff the best people to hand the iPad to patients? Why or why not?

6. The app includes audio narration and a video about colon cancer screening. If we gave patients disposable earbuds when they are handed the iPad, do you think they could use the app in the waiting room? Why or why not?

   Follow-up questions:

   a. Do you think audio in the video is important? Or do you think reading closed captions would be enough?

b. How could patients use the app without earbuds? Would it disturb other patients?

7. What is the longest time you think patients could use the app before it would interfere with clinic flow?

   Follow-up questions
   a. On average, how long do patients wait from check-in until the doctor sees them?

8. How many iPads would a clinic of your size and patient volume need to ensure this process didn't interfere with patient flow?

9. If a patient is 50 or older, the app will determine if they are due for colon cancer screening. If they are due, it will help them get a test ordered. If your clinic decided to use this program, would it be best to offer it to all patients on check-in, or only those who are 50 and older? Why?

Training and Support

In a few months, we will be helping some clinics incorporate the mPATH program into their workflow. Now I will tell you about the training and support we are planning to give those clinics so you can tell me what you think about our plans.

We will first ask each clinic to identify a person working in the clinic, a "clinic champion," who will help keep the program going and serve as our main contact. If the clinic wants us to add additional check-in questions to the mPATH program, we can do that for them. We will also hold a 45 minute on-site training session with the clinic staff to give them practice using the mPATH program. Afterwards, we will provide the clinics with as needed technical support by phone, email, or in person.

10. What do you think about this training plan?

    a. Follow-up questions: What would work well? What could be better?

11. How do you suggest we find the right person for the "clinic champion" role?

    Follow-up questions:
    a. Who would we contact to find a champion?

b. If your clinic decided to use this program, who at your clinic would be the champion? What is his/her role here?

12. How much time is reasonable for you to attend an on-site training session?

    Follow-up question:
    a. If we were to hold a training session for your clinic, when would be the best time for that?

13. Do you think most clinic staff would watch a webinar or on-line video that provides an overview of the program prior to the training session?

    Follow-up questions:
    a. Is this something staff could do during free time at work (like during lunch or other free time)?

    b. What would be a reasonable length of time for a webinar or on-line video?

14. What is the best way for the clinic champion to communicate with us if the clinic needs technical support or help?

    a. (Prompt:) by phone, email, text, video chat?

    b. Follow-up question: What is a reasonable time for us to be able to reply or respond back to clinic champions when they have technical or other questions?

III - CLOSING

- You have all had a lot of really important things to say, and I appreciate your openness and willingness to share. Would anyone like to share any other comments before we end?

Provide participants with questionnaires and ask that they complete them on paper. Then, give $50 to participant and have them sign saying they received it.

A.7. Implementation Strategy Interview Guide (Non-Wake Forest Health Network Clinics)

Interview Purpose: To learn how mPATH can be implemented successfully in primary care clinics. The main overarching questions to answer are:

1. What would make clinic staff want to use mPATH with patients?
2. How do clinic staff think mPATH would be best incorporated into clinic flow?
3. What type of training and support will clinics need to use mPATH?

The guide will:

I. Explore the facilitators and barriers to implementation
II. Strategies for minimizing barriers
III. The adequacy of draft training materials
IV. Additional support or training materials desired
V. Interviews will also comment on the set of clinic check-in questions proposed for the mPATH-CRC iPad app

Interviews will be audio recorded and the content summarized. Revisions to the implementation strategy and materials will be informed by the interview results.

Date:

Interviewer:

Start time: **End time:**

I. WELCOME

I want to thank you for speaking with me today. I appreciate your willingness to share your thoughts with me. The reason we are doing this interview is obtain your feedback about a program called mPATH. mPATH is a user-friendly iPad program designed to increase the efficiency and quality of care in primary care offices. While in the waiting room, patients use mPATH to answer standard check-in items and assess their need for routine cancer screening. mPATH then informs the office staff of patients' answers so they can update the electronic health record as needed.

The purpose of the interview is to learn from you your opinion on how best to implement mPATH into a primary care clinic's workflow. I will be asking for your feedback about the iPad program, our proposed clinic workflow strategy and our training plan. There are no right or

wrong answers. Everything we talk about will be considered confidential. I will use the information from our conversations to inform our study team about the best way to implement mPATH in other clinics. I will audio record today's conversation and take notes. This helps us remember what you all said. The notes and the audio will be kept in our offices and will not be shared with anyone outside our project. I would like for you to speak freely, sharing your ideas and opinions. You are the expert and there are no right or wrong answers.

You will be asked to complete a brief survey at the end of our discussion, and you will receive a $50 gift card for your participation today.

The interview should last between 20 and 30 minutes. Before I get started, are there any questions?

II. MAIN QUESTIONS

Let's get started.

Motivators and Barriers

First, let me demonstrate the mPATH iPad program so you can see how it looks and how we are thinking clinic staff will use it.

1. What are your first impressions of this program?

   Follow-up questions:
   a. Based on what you've seen in the demonstration, do you think this would be helpful to you in your clinic? Why or why not?

   b. What would motivate your team to use this iPad app?

   c. What would discourage your team from using the app?

2. We programmed the app to ask patients the standard clinic check-in questions, hoping that would save nurses some time. Do you think that feature is helpful or not helpful?

   (Probe, if needed) Tell me why you say that.

Follow-up question:

   a. What other features could the app do that would make your job easier and make you excited to use it?

3. Patients will independently answer the check-in questions on the iPad, and the program will show the patients' answers to the person who is rooming the patient. The rooming staff would then enter the answers into the electronic health record.

   Tell me your thoughts about that process.

   Follow-up question:
   a. Tell me your concerns.

Clinic Workflow

I am going to walk you through what we are envisioning to be the typical pattern of patient check in and how staff and patients will hand off and use the iPad.

(Display clinic workflow poster/slide illustration and walk through the flow.)

4. What are your immediate thoughts about this workflow?

   Follow-up questions:

   a. What do you like about this workflow? And why?

   b. What don't you like about this workflow? And why?

   c. Are the front desk staff the best people to hand the iPad to patients? Why or why not?

5. The app includes audio narration and a video about colon cancer screening. If we gave patients disposable earbuds when they are handed the iPad, do you think they could use the app in the waiting room? Why or why not?

   Follow-up questions:

   a. Do you think audio in the video is important? Or do you think reading closed captions would be enough?

   b. How could patients use the app without earbuds? Would it disturb other patients

6. What is the longest time you think patients could use the app before it would interfere with clinic flow?

   Follow-up questions:

   a. On average, how long do patients wait from check-in until the doctor sees them?

7. How many iPads would a clinic of your size and patient volume need to ensure this process didn't interfere with patient flow?

8. If a patient is 50 or older, the app will determine if they are due for colon cancer screening. If they are due, it will help them get a test ordered. If your clinic decided to use this program, would it be best to offer it to all patients on check-in, or only those who are 50 and older?

   (Probe, if needed) Tell me more.

For Clinic Manager ONLY

9. Could our team email you later to get a list of the intake questions your clinic routinely asks patients?

For Physicians (MDs, NPs, PAs) ONLY

As you saw, if patients are between 50 and 75, mPATH asks them about their colon cancer screening history and desire to be screened. mPATH will generate a summary of each patients usage so you know what they said. Here are two examples of what the printed summary would look like. (show examples of mPATH app output)

10. Would you find this printout helpful or not helpful? Why or why not?

11. What do you think about the length of the printout?

    Follow-up question:

    a. Is it too much information or not enough?
       (Prompt if needed): Tell me what you would remove (if too much information)
       (Prompt, if needed): If not enough information, what else would you want to know?

12. Would you rather have this information printed and left for you outside the exam room door, or would you like to get this information some other way?
    (Probe, if needed): Tell me more about your answer.

Training and Support (for everyone – if time permits)

In a few months, we will be helping some clinics incorporate the mPATH program into their workflow. Now I will tell you about the training and support we are planning to give those clinics so you can tell me what you think about our plans.

We will first ask each clinic to identify a person working in the clinic, a "clinic champion," who will help keep the program going and serve as our main contact. If the clinic wants us to add additional check-in questions to the mPATH program, we can do that for them. We will also hold a 45 minute on-site training session with the clinic staff to give them practice using the mPATH program. Afterwards, we will provide the clinics with as needed technical support by phone, email, or in person.

13. Tell me your thoughts about this training plan.

Follow-up questions:

a. What about it works well?

b. What could be better?

14. How do you suggest we find the right person for the "clinic champion" role?

Follow-up questions:

a. If your clinic decided to use this program, who at your clinic would be the champion?

b. What is his/her role here?

c. Who is the best person at a clinic to contact to find a champion?

15. What is the best way for the clinic champion to communicate with us if the clinic needs technical support or help?

    (Prompt if needed): What is the best means of communication, by phone, email, text, video chat?

    Follow-up question:

    a. What is a reasonable time for us to be able to reply or respond back to clinic champions when they have technical or other questions?

III - CLOSING

You have all had a lot of really important things to say, and I appreciate your openness and willingness to share. Would anyone like to share any other comments before we end?

Provide participant with questionnaire or send them link to survey and ask that they complete it. If completing survey online, tell them survey will include an item telling us where to mail their gift card. If in person interview, give $50 gift card to participant and have them sign saying they received it.

Appendix B – Data Collection Instruments

The following instruments have been submitted to the IRB as pdf files:

Clinic Characteristics Survey

Clinic Staffing Form

Staff Linkage Form

Staff Consent & Contact Information Form

Staff Baseline Survey

Staff Demographics Survey

Clinic Support Log

Follow-Up Clinic Personnel Survey: 6 month timepoint

Follow-Up Clinic Personnel Survey: 12 month

Additional data collection instruments in development:

The final data collection instruments listed below have not yet been developed. Each instrument will be submitted to the IRB for formal review and approval before they are used with any human subjects. The planned data collection instruments and their descriptions are listed below.

Cost Database

All technology costs associated with implementing and maintaining mPATH will be recorded in a secure, electronic database.

mPATH-CRC Database

The mPATH-CRC database will be stored in an encrypted, HIPAA-compliant Cloud-based server with continuous data backup. The database is password protected and meets HIPAA security requirements. The database includes patient medical record numbers, date and time of use, and answers to mPATH-

CRC survey questions (CRC screening history, CRC screening decisions, etc.). The database is password protected and access is limited to those with authorization. When the mPATH-CRC database is queried to construct our study dataset, the medical record numbers will be replaced with an anonymous study identifier by an honest broker. A full copy of the mPATH-CRC survey will be submitted to the IRB for review and approval prior to use with human subjects.

Clinic Query Database

We will query the study clinics' electronic health records and appointment systems to collect the following data elements needed for our planned analyses. Data will be collected for the time periods specified in the Experimental Methods (Section 4.0).

- Patient age
- Patient gender
- Patient race/ethnicity
- Flagged as needing a language interpreter (and language needed)
- Patient marital status
- Patient health insurance
- Patient history of colorectal cancer
- Patient history of colorectal polyps
- Patient family history of colorectal cancer
- Date of visit to clinic
- Name of provider being seen
- Name of nursing staff who roomed the patient
- Dates of any orders for CRC screening tests (and type of test ordered)
- Dates of any completed CRC screening tests
- Results of any completed CRC screening tests

Appendix C – Clinic Personnel Interview Guide

Key Informant Interview Guide: Admin/Check-In Staff
Follow-Up Semi-Structured Interviews for Sites who Completed the Study

A. [High & Low Touch] *I would like to start by asking you some general questions about you and your clinic and then we will discuss some of the facilitators and challenges to implementing mPATH in your clinic.*

1. What is your name?

2. How long have you worked at this clinic? **[if new]**

3. What is your role in this clinic? **[if new interviewee]**. Has your role changed since the last time we spoke? **[if previous interviewee]**

B. Construct: Impact of mPATH on Universal Screening and CRC screening
Now I would like to ask you some questions about the universal screening questions that Wake Forest mandates all clinics ask on a routine basis, which include questions about depression, falls in older adults, and household violence or abuse.

1. Before mPATH, how were patients screened for these risk factors (Probes: at check-in via a paper-based self-completed screener, asking patients directly, using other tablet based screening)? Did you play any role in screening patients? If yes, explain.

2. How has mPATH affected your ability to gather this information on a routine basis? (Probe for positive and negative attributes)

C. Construct: Barriers/Facilitators (appropriateness, workflow)

1. To what extent has mPATH impacted workflow?

2. In what ways did your clinic modify its workflow to accommodate mPATH?
   i. Do you have recommendations on implementation to minimize workflow disruption? If yes, in what way.

3. In your opinion, is your clinic an appropriate setting for mPATH? Probe: Can you tell me more about that (why 'yes' or 'no')

4. How did the stability of the program (crashes, downtime) affect the implementation of mPATH?

5. Are there other factors that made it challenging to implement mPATH in your clinic?

6. What were the most important factors that helped you implement mPATH in your clinic?

7. Is your practice still using mPATH?

   a. **If YES:** In your opinion, what motivates your clinic personnel to use mPATH? Does this differ for front desk staff, nursing staff, and clinicians?

   b. **If NO:** Why did your practice stop using mPATH?

D. Construct: COVID

1. How and to what extent did COVID affect implementation of mPATH?

E. Construct: Resources /Training

1. What resources were needed from your clinic to implement mPATH? Resources could include personnel, space, materials, time, etc.

2. The research team offered several strategies to enhance mPATH implementation. We value your feedback on how effective or ineffective these strategies were?

   High & Low Touch:
   - In-person training (High & Low Touch)
   - Technical support by phone or email

   High Touch ONLY:
   - At elbow support
   - Phone call check ins
   - Shout out memos acknowledging staff who use mPATH the most
   - Highlighting the “missed opportunities” in monthly memos
   - Tableau mPATH usage dashboard

3. What additional support could we have provided to help you implement mPATH?

F. Construct: Program Champion & Leadership

1. Has there been a person or persons in your clinic who were especially important to implementing mPATH for patients? What was this person’s role(s) in the medical center? Probe: administrative staff, nurses, physician, practice manager.

2. What made this person(s) particularly important in the implementation of mPATH?

3. In what ways did you or did you not have the support of clinic leadership for implementing mPATH?

G. Implementation Construct: Scale-Up/Dissemination

We are very interested in your ideas about how to help other clinics implement mPATH into routine care.

1. What would you tell another clinic if they were interested in implementing mPATH?

2. If it were up to you, would you keep using mPATH after the study ends? Probe: Tell me more about why/why not.

Wrap-Up:

Is there anything else we should know about implementing mPATH that we haven't already discussed, or any suggestions you have for the program?

Thank you very much for your time and commitment to the mPATH study.

Key Informant Interview Guide: Admin/Check-In Staff
Follow-Up Semi-Structured Interviews for Sites With Very Low mPATH Usage

A. [High & Low Touch] *I would like to start by asking you some general questions about you and your clinic and then we will discuss what made it easy and what made it difficult to implement mPATH in your clinic.*

1. What is your name (as a reminder, we won't include your name in the transcript we use for analysis)?

2. How long have you worked at this clinic? [if new]

3. What is your role in this clinic? [if new interviewee]. Has your role changed since the last time we spoke? [if previous interviewee]

B. Construct: Impact of mPATH on Universal Screening and CRC screening
Now I would like to ask you some questions about the universal screening questions that Wake Forest mandates all clinics ask on a routine basis, which include questions about depression, falls in older adults, and household violence or abuse.

1. How are patients screened for these risk factors (Probes: at check-in via a paper-based self-completed screener, asking patients directly, using other tablet based screening)? Did you play any role in screening patients? If yes, explain.

2. How did mPATH affect your ability to gather this information on a routine basis? (Probe for positive and negative attributes).

C. Construct: Barriers/Facilitators (appropriateness, workflow)

1. In your opinion, is your clinic an appropriate setting for mPATH? Probe: Can you tell me more about that (why 'yes' or 'no')

2. How could your clinic modify its workflow to accommodate mPATH?

a. Do you have recommendations on implementation to minimize workflow disruption? If yes, in what way.

3. How and to what extent did COVID affect your decision to use/not use mPATH?

4. Are there other factors that made it challenging to implement mPATH in your clinic?

5. Why did your practice stop using mPATH?

E. Construct: Resources /Training

1. What resources were needed from your clinic to implement mPATH? Resources could include personnel, space, materials, time, etc.

2. The research team offered several strategies to enhance mPATH implementation. We value your feedback on how effective or ineffective these strategies were?
   High & Low Touch:
   - In-person training (High & Low Touch)
   - Technical support by phone or email

3. What additional support could we have provided to help you implement mPATH?

F. Construct: Program Champion & Leadership

1. What person or persons would play an important role if you chose to implement mPATH? Were there individuals who were especially opposed to implementing mPATH?

2. What made this person(s) particularly important in the implementation of mPATH? (probe: or to the reason it wasn't implemented?)

3. In what ways did you or did you not have the support of clinic leadership for implementing mPATH?

G. Implementation Construct: Scale-Up/Dissemination

We are very interested in your thoughts about other clinics implementing mPATH into routine care

1. What would you tell another clinic if they were thinking about implementing mPATH?

2. If it were up to you, would you use mPATH in the future? Probe: Tell me more about why/why not.

Wrap-Up:

Is there anything else we should know about implementing mPATH that we haven't already discussed, or any suggestions you have for the program?

Thank you very much for your time and commitment to the mPATH study.

Key Informant Interview Guide: Clinical Personnel & Practice Managers
Follow-Up Semi-Structured Interviews for Sites who Completed the Study

A. [High & Low Touch] *I would like to start by asking you some general questions about you and your clinic and then we will discuss what made it easy and what made it difficult to implement mPATH in your clinic.*

1. What is your name (as a reminder, we won't include your name in the transcript we use for analysis)?

2. How long have you worked at this clinic? [if new]

3. What is your role in this clinic? [if new interviewee]. Has your role changed since the last time we spoke? [if previous interviewee]

B. Construct: Impact of mPATH on Universal Screening and CRC screening

Now I would like to ask you some questions about the universal screening questions that Wake Forest mandates all clinics ask on a routine basis, which include questions about depression, falls in older adults, and household violence or abuse.

1. Before mPATH, how were patients screened for these risk factors (Probes: at check-in via a paper-based self-completed screener, asking patients directly, using other tablet based screening)? Did you play any role in screening patients? If yes, explain.

2. How has mPATH affected your ability to gather this information on a routine basis? (Probe for positive and negative attributes).

3. What are the advantages and disadvantages of using tablet based screening for identifying these risk factors?

Now I want to ask you some questions about the CRC screening module on the blue iPad.

1. Before mPATH, what role did you play (if any) in helping identify patients who were due for CRC screening? ***(for providers and nursing staff only)***

2. Since mPATH, how has your role changed in helping identify patients who are due for CRC screening?

3. Reflecting on your approach to CRC screening before and after mPATH, which method has worked best for your clinic? Probe: explain more ***(for providers and nursing staff only)***

C. Construct: Barriers/Facilitators (appropriateness, workflow)

1. To what extent has mPATH impacted workflow?
2. In what ways did your clinic modify its workflow to accommodate mPATH?
    a. Do you have recommendations on implementation to minimize workflow disruption? If yes, in what way.
3. In your opinion, is your clinic an appropriate setting for mPATH? Probe: Can you tell me more about that (why 'yes' or 'no')
4. How did the stability of the program (crashes, downtime) affect the implementation of mPATH?
5. How and to what extent did COVID affect implementation of mPATH?
6. Are there other factors that made it challenging to implement mPATH in your clinic?
7. What were the most important factors that helped you implement mPATH in your clinic?
8. Is your practice still using mPATH?
    a. **If YES:** In your opinion, what motivates your clinic personnel to use mPATH? Does this differ for front desk staff, nursing staff, and clinicians?
    b. **If NO:** Why did your practice stop using mPATH?
9. We noticed that many clinics used the pink CheckIn iPad a lot more than the blue CRC iPad. Why do you think that was the case?

D. Construct: Impact of mPATH on screening and clinic operations.

1. Has mPATH affected CRC screening among your eligible patients?
    i. If yes, in what way.

2. In what ways did mPATH affect your and your patients' approach to informed decision making about CRC screening? ***(providers and nursing staff only)***

3. Has mPATH affected other aspects of your clinic operations? If yes, in what way.

E. Construct: Resources /Training

1. What resources were needed from your clinic to implement mPATH? Resources could include personnel, space, materials, time, etc.

2. The research team offered several strategies to enhance mPATH implementation. We value your feedback on how effective or ineffective these strategies were?

High & Low Touch:

- In-person training (High & Low Touch)
- Technical support by phone or email

High Touch ONLY:

- At elbow support
- Phone call check ins
- Shout out memos acknowledging staff who use mPATH the most
- Highlighting the "missed opportunities" in monthly memos
- Tableau mPATH usage dashboard

3. What additional support could we have provided to help you implement mPATH?

F. Construct: Program Champion & Leadership

1. Has there been a person or persons in your clinic who were especially important to implementing mPATH for patients? What was this person's role(s) in the medical center (or your practice)? Probe: administrative staff, nurses, physician, practice manager.

2. What made this person(s) particularly important in the implementation of mPATH?

3. In what ways did you or did you not have the support of clinic leadership for implementing mPATH?

G. Implementation Construct: Scale-Up/Dissemination

We are very interested in your thoughts about other clinics implementing mPATH into routine care

1. What would you tell another clinic if they were thinking about implementing mPATH?

2. If it were up to you, would you keep using mPATH after the study ends? Probe: Tell me more about why/why not.

Wrap-Up:

Is there anything else we should know about implementing mPATH that we haven't already discussed, or any suggestions you have for the program?

Thank you very much for your time and commitment to the mPATH study.

Key Informant Interview Guide: Clinical Personnel & Practice Managers
Follow-Up Semi-Structured Interviews for Sites With Very Low mPATH Usage

A. [High & Low Touch] *I would like to start by asking you some general questions about you and your clinic and then we will discuss what made it easy and what made it difficult to implement mPATH in your clinic.*

1. What is your name (as a reminder, we won't include your name in the transcript we use for analysis)?

2. How long have you worked at this clinic? [if new]

3. What is your role in this clinic? [if new interviewee]. Has your role changed since the last time we spoke? [if previous interviewee]

B. Construct: Impact of mPATH on Universal Screening and CRC screening
Now I would like to ask you some questions about the universal screening questions that Wake Forest mandates all clinics ask on a routine basis, which include questions about depression, falls in older adults, and household violence or abuse.

1. How are patients screened for these risk factors (Probes: at check-in via a paper-based self-completed screener, asking patients directly, using other tablet based screening)? Did you play any role in screening patients? If yes, explain.

2. How did mPATH affect your ability to gather this information on a routine basis? (Probe for positive and negative attributes).

3. What are the advantages and disadvantages of using tablet based screening for identifying these risk factors?

Now I want to ask you a question about screening for colon cancer.

4. What role do you play (if any) in helping identify patients who are due for CRC screening? ***(for providers and nursing staff only)***

C. Construct: Barriers/Facilitators (appropriateness, workflow)

1. In your opinion, is your clinic an appropriate setting for mPATH? Probe: Can you tell me more about that (why 'yes' or 'no')

2. How could your clinic modify its workflow to accommodate mPATH?

    a. Do you have recommendations on implementation to minimize workflow disruption? If yes, in what way.

3. How and to what extent did COVID affect your decision to use/not use mPATH?

4. Are there other factors that made it challenging to implement mPATH in your clinic?

5. Why did your practice stop using mPATH?

E. Construct: Resources /Training

1. What resources were needed from your clinic to implement mPATH? Resources could include personnel, space, materials, time, etc.

2. The research team offered several strategies to enhance mPATH implementation. We value your feedback on how effective or ineffective these strategies were?

High & Low Touch:

- In-person training (High & Low Touch)
- Technical support by phone or email

3. What additional support could we have provided to help you implement mPATH?

F. Construct: Program Champion & Leadership

1. What person or persons would play an important role if you chose to implement mPATH? Were there individuals who were especially opposed to implementing mPATH?

2. What made this person(s) particularly important in the implementation of mPATH? (probe: or to the reason it wasn't implemented?)

3. In what ways did you or did you not have the support of clinic leadership for implementing mPATH?

G. Implementation Construct: Scale-Up/Dissemination

We are very interested in your thoughts about other clinics implementing mPATH into routine care

1. What would you tell another clinic if they were thinking about implementing mPATH?

2. If it were up to you, would you use mPATH in the future? Probe: Tell me more about why/why not.

Wrap-Up:

Is there anything else we should know about implementing mPATH that we haven't already discussed, or any suggestions you have for the program?

Thank you very much for your time and commitment to the mPATH study.

Appendix D – Effect of mPATH on Screening for Depression, Fall Risk, and Safety

Wake Forest policy requires primary care clinics to screen patients aged 18 and older for depression, fall risk, and safety at home at each provider visit. Nursing staff conduct this screening during the rooming process by asking patients standardized questions and recording their responses in the electronic health record.

We designed mPATH to save staff time by having patients answer these same screening items on an iPad and then transmitting their answers to WakeOne. It is possible that mPATH will increase detection of depression, fall risk, and safety concerns because: 1) mPATH systematically asks these screening items of all patients, and 2) patients may feel more comfortable answering these items in an iPad survey than during an in-person interview.

To determine the effect of mPATH on the performance of this screening, we will examine a limited use dataset comparing the 2 months before a clinic started using mPATH to the 2 months after the clinic began using mPATH. Because clinics may need some time to fully adopt mPATH, we will exclude the first two weeks following the launch of mPATH.

Study Population

We will create a limited use dataset containing patients who are seen in one of the first six Wake Forest Baptist Health primary care clinics that are participating in the mPATH Effectiveness and Implementation trial.

Patient inclusion criteria:

- Age 18 or older
- Completed a provider visit at the study clinic during the 60 days prior to the clinic launching the mPATH program (the “pre” time period), or completed a provider visit at the study clinic during days 14 – 73 after the launch of mPATH (the “post” time period)
- Have a preferred language of English or Spanish

Patient exclusion criteria:

- Requiring a language interpreter for a language other than Spanish

Experimental Methods

The limited use dataset will contain the following data elements for each completed patient visit:

- Date of clinic visit (where each date is indicated by a number relative to the clinic’s Launch Date)
- Clinic (designated by a unique study clinic identifier)

- Type of visit completed (for example, new patient visit, return patient visit, annual exam)
- Patient age
- Patient gender
- Patient race/ethnicity
- Patient primary insurance
- Nursing staff who roomed the patient (designated by a unique study identifier)
- Whether patient used mPATH-CheckIn program (Y/N)
- Whether nursing staff used mPATH Nursing Module to transmit mPATH data to WakeOne (Y/N)
- Whether patient has a diagnosis of depression in the problem list in the EHR (Y/N)
- Whether patient has an antidepressant medication listed in the active medication list (Y/N)
- Results of depression screening items
- Results of fall risk screening items
- Results of safety at home screening items

The study dataset will be maintained using the procedures outlined in **Section 8.0 (Confidentiality and Privacy)**. Of note, we are taking the following additional safeguards to further protect patient confidentiality:

1. Dates of clinic visits will be designated using numbers relative to each clinic's launch date, rather than using the actual date
2. Clinics will be designated with a unique study clinic identifier instead of clinic name
3. Nursing staff will be designated with a unique study identifier instead of actual name

Definition of Time Periods

- The day a clinic launches mPATH will be designated as that clinic's Day 0
- The "pre" time period will be Days -60 to -1 (the 60 day period before mPATH Launch)
- The "post" time period will be days 14 to 73 (the 60 day period commencing 2 weeks after mPATH Launch)

Outcome Measures

Primary outcome: The primary outcome will be the proportion of patients seen in each time period ("pre" vs. "post") who screen positive for depression, fall risk, or safety concerns at home.

Secondary outcomes: Secondary outcomes will include the proportion of patients in each time period who:

- Screen positive for depression using the PHQ-2 items. In addition, the outcomes below will be assessed:
  - Have a PHQ9 score >14 (indicating moderately severe depression or severe depression)
  - Have a PHQ9 score >19 (indicating severe depression)
  - Have a PHQ9 score >14 and are not currently taking a medication for depression

    - Have thoughts of self-harm
- Screen positive for fall risk at home. In addition, the outcomes below will be assessed:
    - Have fallen in last 6 months
    - Have had a fall with injury
- Screen positive for safety concerns at home. In addition, the outcome below will be assessed:
    - Report that conflicts turn into fights

Analytic plan

Our primary analysis will compare the proportion of patients seen in the "pre" time period to the "post" time period who screen positive for either depression, fall risk, or safety at home. If a patient is seen more than once in a given time period, only the patient's first visit in that time period will be included in the analyses. We will estimate the proportion who screen positive for each time period and report along with 95% confidence intervals. A chi-square test will be used to provide an unadjusted comparison between the "pre" and "post" proportions. Logistic regression models will then be used to compare the "pre" and "post" proportions while controlling for clinic and patient demographic variables. We will use the same analytic methods for our secondary outcomes. We will also conduct a sensitivity analysis for our primary outcome where we consider all patients' visits during a given time period (and not limit analyses to a patient's first visit in the time period only). For this sensitivity analysis, we will compare the proportion of patients who meet our primary outcome definition at any visit during the "pre" and "post" time periods.

Analytic adjustments due to COVID19 pandemic: Due to the COVID19 pandemic, all practices stopped using mPATH in March 2020, which is prior to the closure of the 60-day "post" time period for clinics #5 and #6 in our sample. Therefore, we will truncate the "post" time period for these two clinics to 30 days. To determine if this truncated time period affected our overall results, we will conduct the following sensitivity analyses: (1) limiting the analyses to only the first 4 clinics to enroll, and (2) limiting data collection to 30-days post- for all 6 clinics.

Appendix E – Data Transfer from non-Wake Forest Health Network Clinics

The following was the original plan for

In Wake Forest Health Network clinics, mPATH connects to the electronic health record (EHR) to import basic patient demographic data (e.g., patient name, medical record number, age) and prior colorectal cancer screening history information to determine if screening is needed. For clinics outside of the Wake Forest Health Network, this data will be imported to mPATH using secure file transfers. Non-WFHN clinics will upload a weekly flat file using Secure File Transfer Protocol to an encrypted, HIPAA-compliant Cloud-based server. The mPATH program will process the file, encrypt needed data elements, and then delete the original data file to protect data security. Additional data safeguards are outlined in Section 8.0. Formal data use agreements will be executed with all participating external sites. The flat file will include the following elements for patients who have upcoming scheduled appointments in the clinic(s):

Patient medical record number
Patient first name
Patient middle name
Patient last name
Patient date of birth
Date of last resulted FIT in chart
Date of last resulted Colonoscopy in chart