TITLE PAGE

PROJECT TITLE: Implementation and Dissemination of 'Gabby,' a Health Information Technology (HIT) System for Young Women, into Community-Based Clinical Sites

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STRUCTURED ABSTRACT:

PURPOSE: To disseminate the Gabby Health Information Technology system in the real-world setting of 10 community-based health settings, study the implementation process, and prepare an implementation toolkit to facilitate broader dissemination.

SCOPE: Despite significant endorsement for a preconception approach to reducing the burden of adverse maternal and child health outcomes, preconception care health promotion into communities that can benefit most is often ladened with implementation challenges due to modifiable factors, including limited time during the clinical encounter, provider comfort, and constrained resources. The absence of systematic research and evaluation of eHealth interventions has presented considerable obstacles to understanding opportunities and weaknesses of incorporating these tools into clinical practice.

METHODS: Using a Hybrid Type II implementation-effectiveness design, we evaluated the appropriateness, acceptability, feasibility, and effectiveness of the Gabby System among Black and AA women receiving care at 10 community based clinical sites. Strategies and tools informed by the Consolidated Framework for Implementation Research (CFIR), and the Expert Recommendation for Implementing Change (ERIC) were leveraged to measure and assess study outcomes. Implementation outcomes were based on Proctor's evaluative framework, and effectiveness data was derived directly from Gabby System user data.

RESULTS: Seven sites carried out a 3–6-month Gabby rollout ('implementers'). Among implementers, five successfully enrolled individuals to use the Gabby system. Pre-implementation interview and survey data highlighted contradictory findings, with interviews indicating more positive sentiments towards the Gabby implementation and overall site readiness. However, barriers including technological access, the length of the preliminary health assessment, and changes to operational workflow due to the COVID-19 pandemic, limited implementation appropriateness, acceptability, and feasibility. The average number of health topics flagged at baseline across sites that enrolled users (n=5) ranged from 18– 24 risks, consistent with results from previous RCTs. Post-implementation feedback indicate the need for ongoing support and adaptation to implementation efforts to address challenges and improve implementation feasibility. An eight-module Gabby implementation manual, informed by a modified Delphi panel, was developed during the study.

CONCLUSION: Implementation of Gabby Preconception Care system was viewed positively and risk assessment and interventions to reduce preconception risk among AA/Black women at Community Health Center and Healthy Starts sites was successful, but technological access, and changes to operational workflow limited implementation appropriateness, acceptability, and feasibility.

KEY WORDS: Preconception Care, Implementation Science, Health Information Technology

Limit: 250

Current Word Count: 322

PROJECT PURPOSE: The project's purpose is to disseminate the Gabby Health Information Technology system in the real-world setting of 10 community-based clinical sites, study the implementation process, and prepare an implementation toolkit to facilitate broader dissemination. In order to achieve this goal, we carried out the following objectives:

1. Recruited 10 Community Based Clinical Sites comprised of Healthy Start sites Community Health Centers nationwide at which staff recruited young African American and Black women to use the Gabby system for a period of at least three-six months;
2. Conducted site-level needs and resource assessments to guide implementation efforts;
3. Performed in-person and virtual training at each site around implementation of the Gabby system into the clinical workflow of the 10 sites;
4. Assembled a preliminary, revised, and final Gabby Implementation toolkit.
5. Analyzed each step of the implementation process and disseminated the results of this work to the information technology, clinical, and health services research communities.

PROJECT SCOPE

Background. There are persistent health disparities in birth outcomes despite over 30 years of research in this area. Black women are approximately twice as likely to deliver a low birth-weight (LBW) infant as white women (14% and 7.3%, respectively).[1] Leaders in the United States were alarmed in the early 1980's when the information surfaced that the country's ranking in infant mortality among developed countries had slipped from 12th in 1960 to 19th. [2,3] Health and public policy leaders initiated national programs to improve poor pregnancy outcomes, with the bulk of the effort directed towards caring for women during pregnancy and assisting women to enter early prenatal care.[4] Subsequently, the percentage of US women accessing early and adequate prenatal care increased, growing from 76.3% to 83.9% in 2004.[3] However, this increase in prenatal care utilization has not eliminated the disparities in birth outcomes between blacks and whites. Efforts to improve the health of women before pregnancy represent an important initiative in addressing racial disparities among African American women. Innovative approaches to delivering preconception care are necessary.[5,6]

Context. Community-based clinical sites, such as the Healthy Start program and primary care clinics, provide important avenues to examine PCC delivery and novel implementation approaches using HIT for Black and African American women.[7] These settings were created to engage under-resourced and disparate communities and have traditionally served as a platform to reduce significant barriers to care access.[8,9] Healthy Start programs and primary care clinics exist standalone and within organizations nationally and provide support to women at high risk for adverse perinatal outcomes before, during, and after pregnancy using culturally appropriate social services. In 2016, the Healthy Start program launched a mandate for all sites to emphasize PCC in their metrics, leaving many sites eager to identify tools to support the delivery of such education.[10] Primary care clinics have also faced difficulty integrating PCC into practice as very few payments and funding streams are tied to PCC services.[11] Implementation of the Gabby intervention can serve as a prototype to examine the use of web-based tools to support operational workflow in healthcare settings, and improve preconception health behaviors nationwide.[12,13,14]

Setting and Participants. Ten community-based clinical sites participated in the study. All sites were recruited between March 2017 and June 2020. We aimed to implement Gabby at geographically diverse locations to account for the variability in contextual factors that may impact implementation. Research staff amended the initial eligibility for sites to respond to growing interest to include organizations that serve less than 50% Black and African American women. With the exception of one participating site, all sites were asked to implement Gabby for six months. The duration of this one site was shortened to three months due to a delayed start date and the closeout of the implementation period for all sites. For each site that expressed interest, an introductory call (via phone or Zoom) was scheduled to provide additional information about the aims of the implementation such that the site contact could make an informed decision as to whether this pilot was suitable for their organization.

Primary Care Clinics. To recruit our primary care clinics, we utilized the National Association of Community Health Centers (NACHC) website to identify Federally Qualified Health Centers and other community health centers located in settings with a high proportion of Black and African American residents based on zip code data. Emails were sent to site directors listed on the NACHC website introducing the research team, the goals, and potential benefits of the study, and providing detailed information supporting Gabby's efficacy. Research staff followed up on these emails by calling each site after four weeks. If there were no response with sites after 4 weeks, these sites were removed from our recruitment lift. Additionally, the research team leveraged pre-existing connections with clinicians and providers in leadership roles across the nation to source Primary Care Clinics to collaborate with our team.

Healthy Start Programs. Healthy Start program sites were recruited similarly to our primary care clinics. However, many of these program sites were familiar with the Gabby intervention due to research staff presence at national conferences and their pre-existing relationships with the research team from prior Gabby clinical trials.

Eligibility criteria for clients or patients at each site included the following: 1) Received services from the respective implementation site at the time of enrollment, 2) self-identified as female and Black or African American, 3) 18-39 years old, 4) spoke English, 5) were not currently pregnant at the time of study enrollment, and 6) had access to a computer and the internet. Site staff at implementation sites were solely responsible for all participant outreach, recruitment, and follow-up. Study research staff did not have any direct contact with participants throughout the project. champions were identified by organizational leadership to be the primary point of contact with research staff and lead implementation efforts to recruit clients and patients. The site champion(s) roles ranged from executive leadership, middle management, and patient-facing providers.

PROJECT METHODS

Study Design. We conducted a non-blinded Hybrid Type II Implementation-Effectiveness cohort trial. Using a mixed-methods approach, we analyzed the implementation and clinical effectiveness of the Gabby system on Black and African American women served at 10 community-based clinical sites. Details of our methods and study design have been previously published and activities are presented below. In brief, we utilized a select bundle of ERIC strategies to prepare sites for implementation, assess site readiness, make adaptations based on identified barriers and facilitators, provided technical assistance during implementation, and conducted post-implementation feedback interviews with site staff to measure and evaluate study outcomes.

The Intervention: Gabby Preconception Care System. The Gabby Preconception System (‘Gabby’) was created as a tool to support preconception care screening and education for Black and AA women. During development over the past 12 years, qualitative feedback from Black and African American women of reproductive age was collected at each iteration to inform system changes, character design, voice, personality, and content development to ensure that the system would be engaging and relatable for the patient population this innovation was intended for. Gabby, short for Gabrielle Union, presents as a Black nurse and is intended to be a self-guided system created to reduce inequities in maternal and child health by increasing patient education and empowerment as well as emulating racial concordance between patient and providers. Using Embodied Conversational Agent technology, Gabby mimics face-to-face interactions through nonverbal gestures and evidenced-based communication practices. At initial login, Gabby walks an individual through a comprehensive health survey to a) identify preconception risk factors and b) assess an individual’s readiness to work on the risk. The system uses Prochaska and DiClemente’s Transtheoretical Model to explain that behavior state of change (SOC) is a process rather than a singular event to move women along the five stages (pre-contemplation, contemplation, preparation, action, and maintenance). Relevant health topics are populated on a My Health To Do-List (MHTDL) based on the results of the health survey which serves as a home screen for users. Health topics are categorized as either 1) ‘Staying Well’ (i.e. getting the flu vaccine) risks where Gabby ultimately suggests consulting a provider to resolve the risk or 2) ‘Living Well’ health topics (i.e. eating a healthier diet) where Gabby works with the individual over time and uses best practices in

behavior change theory and techniques, like Motivational Interviewing and Shared Decision Making, to support an individual. For each topic, Gabby describes what the topic is, why it matters for a future pregnancy and why it matters now and provides individual agency regarding whether they would like to discuss the topic further. The action item is marked as resolved or complete after the client goes through the content related to that topic. A total of 104 possible risks are screened across 13 domains of care based on the work of the Center for Disease Control and Prevention Content of Preconception Care clinical workgroup.[15] In addition to the tailored list of health topics, features of the MHTDL home screen include a blog, glossary, and list of external resources for more educational information.

Data Sources, Collection and Study Activities. The strategies used across pre-implementation, mid-implementation, and post-implementation intervals to elicit data collection are described below.

Pre-Implementation Approaches and Strategies Employed across Implementation Stages

1. *Introductory Calls.* An initial 30 - 60-minute introductory call gauged site interest and any initial reservations to the possibility of implementing an online preconception care educational tool. Additionally, within the scope of this call, the site champion(s) were identified.

2. *Site Socio-demographic Survey.* The site sociodemographic survey that was sent to each site champion pulled questions from the Census in addition to metrics from the Healthy Start programs' mandatory reporting figures. The survey collects information on staff and patient demographics, service catchment areas, and operational capacity and workflow.

3. *Process Mapping.* A technique to better understand site operations and processes and visualize an existing entry point for Gabby System implementation. In collaboration with site staff, we discussed possible techniques to implement Gabby that included a hands-off approach by site staff (where site staff are only involved in enrolling participants and do not do outreach or follow-up), or an approach with higher touchpoints with participants to motivate and encourage the use of the Gabby System.

4. *Readiness Survey to Evaluating Barriers and Facilitators.* Site champion(s) identified 3-8 staff members (based on staff capacity and size) who represented various organizational perspectives, including leadership, administrative and frontline staff, to partake in pre-implementation readiness interviews and surveys to assess site readiness to implement, staff knowledge of the Gabby System and organizational culture and priorities. These interviews were conducted in-person or via Zoom, consent was collected at the start of the interview and stakeholders who completed the interview and corresponding Qualtrics survey were compensated $25.

   Pre-implementation semi-structured stakeholder interview guide, grounded in the CFIR determinants framework, utilizes 42 questions to gauge site readiness, staff perceptions of the Gabby System, site culture and perceived challenges and opportunities to implementation. All five domains of the CFIR determinants framework were leveraged. Research staff added a 'Clients' domain to accurately capture patient-level characteristics and feedback from the site perspective. At the time of our implementation and as we were piloting the interview guide, we realized that existing CFIR constructs did not capture all of the themes that were emerging. Therefore, the research team added novel thematic codes to align with our data.

   Following transcription and coding for all pre-implementation site readiness interviews, coding reports were generated for each construct by creating tables that displayed all the quotes that were coded under that respective construct. Once the coding reports were created, research staff read through each quote and drafted collective messages - digestible and concise summary statements that encapsulated the general idea of each quote. Further analysis was conducted through an evaluative coding approach , in which research staff assigned each quotation a positive, negative, neutral, or mixed designation. Designations were modified from the existing Evaluative Coding Rating Categories

described by Damschroder et al to criteria that captured the nuances of our work. Positive designations were assigned to quotes that described a certain construct as having a positive influence on implementation. Negative designations were assigned to those that described a negative influence. Neutral designations were assigned to quotes that described a construct as having no impact or influence. Mixed designation was utilized to outline quotes that described constructs as having both positive and negative influences on implementation, resulting in an overall mixed influence.

5. *In Person and Virtual Site Visits and Trainings.* In-person and virtual site visits were facilitated to provide in-depth training on the design of the Gabby system, features of the administrative and enrollment page, device compatibility and ideas to introduce the Gabby system based on ideas that were presented during the process mapping and stakeholder interviews. After initial sites established that this comprehensive training may be irrelevant for staff members who would not be as involved in implementation, sites were given the option of a combined training- the first portion would include all staff members and broadly detail an overview of the Gabby system and implementation so all staff would be aware. The second portion of the training would comprehensively review aspects of the administrative page and enrollment for staff who would be directly involved in implementation.

Mid-Implementation Approaches and Strategies Employed across Implementation Stages

1. *Technical Assistance Calls.* Technical Assistance calls served as a reminder for the site champion to reinvigorate recruitment efforts, check in with site staff on implementation progress and an avenue for the research staff to share “lessons learned” or tips from other implementation sites for outreach and engagement techniques. Therefore, it is important to distinguish that Site 1 was the first site that implemented the Gabby System and therefore could not benefit from any lessons learned. This site served as a valuable pilot to navigate unanticipated challenges to implementation, work through technical bugs in the administrative page and Gabby System health survey and understand the impact of the site champion and site culture on implementation.

2. *Monthly Implementation.* Logs Site champions were asked to complete monthly implementation logs that capture the number of people that were approached about using the Gabby System, the number of people who enrolled, any technical issues that occurred and a description of any provider follow-up that happened (i.e., a doctor's appointment was scheduled to review the health topics that Gabby flagged during the health survey).

3. *Social Media.* To respond to the rise of social media use among the study population, and sites’ requests for a Gabby social media platform to support recruitment and engagement efforts. the research team developed a comprehensive social media plan. This encouraged our team to reflect on our existing Gabby social media presence from previous studies and revisit our social media campaign. The social media plan included three weekly posts composed of historical figures, scientific facts, relevant cultural pieces and more. A podcast segment was highlighted once a month to accompany weekly graphics, cartoons, text, and. Supported by prior research, posting with frequency and varied content works to build social media profiles and attracts followers. Social media management tools like Hootsuite and Bitly were used to frontload social media content and alleviate research staff’s burden to post. The social media team, led by our Qualitative Expert, created engaging and timely content around MCH, health equity, mental health, and Black women’s health issues. The social media team identified best practices in social media to determine posting frequency, content type and methods to improve user engagement. Research institutions, implementation sites and non-profits related to Black women’s health were followed and shared to enhance our social media presence. All social media posts were reviewed by the Qualitative Expert before being approved for posting

Post-Implementation Approaches and Strategies Employed across Implementation Stages

1. *Post-Implementation Staff Interviews.* Staff members who completed pre-implementation readiness interviews and surveys were invited to participate in a post-implementation interview. In the event of staff turnover, site champions identified additional staff members who were involved throughout Gabby mid-implementation efforts to participate in a post-implementation interview. Staff members were compensated $25 for their time. Interviews were audio-recorded, transcribed, and coded accordingly to identify emerging qualitative themes. The purpose of post-implementation interviews was to clarify questions raised in other data sources, examine staff perceptions about the Gabby system, better understand the process and execution of implementing the Gabby system within the site's existing workflow and clinical context, and elicit recommendations for future iterations of implementation.

Measures for Implementation Acceptability. Acceptability refers to the extent to which 'stakeholders perceive an intervention or innovation as acceptable, agreeable, or satisfactory' for their organization. We assessed acceptability from the perspective of site staff during all three phases of the implementation (pre-, mid-, and post-). However, due to limitations in participant engagement (as described above), we were unable to include individuals who used the Gabby system in post-implementation focus groups and interviews. To capture acceptability, we conducted post-implementation staff interviews and surveys. We analyzed a subset of questions from the overall interview and survey to measure the outcome.

Measures for Implementation Appropriateness. Appropriateness refers to the perceived compatibility or relevance of an innovation or evidence-based practice for a specific practice setting, provider, or consumer, as well as its ability to address a particular issue or problem. In this project, we assessed appropriateness solely during the post-implementation phase using site staff interviews and survey responses. Similar to the assessment of acceptability, we analyzed only a subset of questions from the larger interview guide and survey that were specifically tailored to explore appropriateness.

Measures for Implementation Feasibility. Feasibility refers to the degree to which a 'new treatment or innovation can be effectively implemented or utilized' in a particular setting. In this study, feasibility was assessed midway through the process using both quantitative and qualitative methods. Quantitative measurements of feasibility included participant usage data, such as the number of participants enrolled, the number of participants who completed at least one login, the total number of logins, and the overall amount of time spent in the system. These data were collected directly from the Gabby server and analyzed using descriptive statistics. In addition, monthly implementation logs completed by site staff were used to determine how many individuals were eligible and introduced to the Gabby system, as well as how many of them actually enrolled during the implementation period. Qualitative feedback from technical assistance calls was analyzed using thematic coding to identify implementation issues and explore new recruitment approaches.

Measures for Intervention Effectiveness. We used de-identified end-user reported data derived from the system to assess Gabby's ability to: (1) Identify health risks - we assessed the extent to which the real-world clients we are reaching are similar to the research participants who originally tested the system in the research setting; (2) Influence behavior change – for each risk identified in the risk assessment, our goal was to assess a user's current stage of change for that risk and then periodically thereafter. Stage of Change questionnaires were administered at baseline, 3 months, and 5.5 months to clients and patients who enrolled and subsequently logged into the Gabby System. As with previous Gabby analyses, our primary measure of effectiveness was to assess the degree to which the rate of stage of change varied from baseline to each time point (3 and 5.5 months) for all enrolled participants. We conducted exploratory analyses to enhance our review of the Gabby system's effectiveness, including homework completion, flagged health topics, and discussed health topics. All measures used to estimate effectiveness were obtained from the system server.

Development of Gabby Implementation Toolkit. The Gabby research team developed an Implementation Toolkit through WordPress to serve as an online "Wikipedia" or resource that implementation site staff members, external stakeholders and interested researchers. The toolkit was initially created to address common questions and gaps in knowledge that arose during the pre-implementation process so sites would

have an online resource to refer to during the implementation. Lessons learned and site feedback collected during the pre- and mid-implementation processes guided much of the toolkit content. WordPress features like fonts, live Twitter feed, collapsible sections, ability to enlarge images were incorporated into the toolkit to increase engagement and creativity. The toolkit underwent rigorous rounds of review and feedback from the research team before being reviewed by an advisory modified Delphi panel. The modified Delphi panel consisted of a site champion to provide feedback from an implementing site's perspective, experts in the fields of graphic design, health literacy, implementations and dissemination science, and health IT. Modified Delphi panel members were compensated for their participation. The research team developed a comprehensive survey to collect feedback from advisory panel members. Members commented on the flow and understandability of the content, gaps in information provided, as well as aspects of the website that were confusing or redundant. The finalized toolkit was consolidated and distributed in March 2021 to all remaining implementation sites.

Limitations. The majority of our study activities took place during the COVID-19 pandemic. Among our 10 participating sites, only one had the opportunity to implement prior to the pandemic. To identify adaptations and modifications made as a result of COVID-19, we added questions to the pre- and post-implementation interview guides and technical assistant calls. Due to organizational travel restrictions, we switched from in-person site visits to fully virtual training. Similarly, for many of our sites, in-person implementation site recruitment and participant outreach occurred virtually. A more detailed description on the impact of COVID-19 is provided below. We recognize the significant value of eliciting the perspectives directly from individuals with lived experience to provide additional insight to our findings. Therefore, another limitation is that while we initially planned to interview end-users who were enrolled and/or used the Gabby System, due to low enrollment and low usage rates, we were unable to interview any end-users to assess their perspectives on the utility, design, and content of Gabby.

Table 1a: Site Operational and Demographic and Characteristics across our ten participating sites

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8	Site 9	Site 10
Operational										
Existing Preconception Curriculum										
Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Desire for More Preconception Education										
Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Concerns Recruiting 25-50 Participants										
Yes	No	No	No	Yes	No	Yes	Yes	Yes	No	Yes
Care Location PCC, ICC and PP (%)										
On-site	26-50%	0-25%	26-50%	26-50%	o-25%	26-50%	76-100	76-100	76-100	26-50%
At Clients Home	26-50%	76-100	51-75%	51-75%	76-100	26-50%	0-25%	0-25%	26-50%	0-25%
Other	0-25%	0-25%	0-25%	0-25%	0-25%	0-25%	0-25%	0-25%	0-25%	0-25%
Does same staff member carry out intake and case management										
Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No
Who performs the intake for preconception and inter-conception/postpartum clients?										
Case Manager/Case Worker	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No
Nurse/Nurse Practitioner	No	No	Yes	Yes	No	No	No	No	No	No
Community Worker/ Social Worker	Yes	Yes	No	No	Yes	Yes	No	No	No	No
Other (receptionist, administration)	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	No
Personnel responsible for PCC/ICC/PP Case Management										
Case Manager/Case Worker	Yes	Yes	No	Yes	No	Yes	No	No	No	No
Nurse/Nurse Practitioner	No	No	Yes	No	No	No	Yes	Yes	Yes	Yes
Community Worker/ Social Worker	No	No	No	No	Yes	No	No	No	No	No
Other (receptionist, administration)	No	No	No	No	No	No	No	No	No	No
Computer with Internet Access onsite										
Yes	Yes	No	Yes	Yes	Yes	No	No	No	No	No
Availability of time computer or laptop with internet access available for client use?										
<50% of time	No	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes
>50% of time	Yes	No	Yes	Yes	Yes	No	No	No	No	No

Table 1b: Site Demographic and Characteristics across our ten participating sites										
	Site 1	**Site 2**	**Site 3**	**Site 4**	**Site 5**	**Site 6**	**Site 7**	**Site 8**	**Site 9**	**Site 10**
Demographic										
Geographic Setting										
Urban area	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	No
Urban cluster/Suburban	No	Yes	No	No	Yes	No	No	Yes	No	Yes
Rural	No	No	No	No	No	No	No	No	No	No
Site Composition										
Stand Alone	No	No	Yes	No	Yes	No	No	No	No	No
Health Department	Yes	No	No	Yes	No	No	No	Yes	No	Yes
Health System/Hospital	No	No	No	No	No	Yes	Yes	No	Yes	No
Other	No	Yes	No	No	No	No	No	No	No	No
>50% AA/Black women served										
Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No
# Preconception Clients Seen Annually										
<400 clients	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
# Clients Seen in Past Year										
<500 clients	No	Yes	No	Yes	Yes	N/A	No	Yes	Yes	Yes
% Clients Reproductive age (15-49 yrs)										
<75%	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes
>75%	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No
Estimated Racial Makeup of Staff (%)										
White	70	80	20	25	60	25	60	80	70	80
Black	20	20	80	75	40	75	40	10	25	15
Asian	0	0	0	0	0	0	0	0	5	5
Other	10	0	0	0	0	0	0	0	0	0
Estimated Ethnic Makeup of Staff										
Hispanic	40	25	10	0	10	0	20	20	20	25
Non-Hispanic	60	75	90	100	90	100	80	80	80	75
Estimated Ethnic Makeup of Clients										
Hispanic	40	25	25	10	30	80	40	20	30	10
Non-Hispanic	60	75	75	90	70	80	60	80	70	90
Estimated Racial Makeup of Clients										
White	40	60	20	15	15	30	20	70	30	10
Black	60	40	80	85	85	70	80	25	70	90
Asian	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0
Primary Language Spoken by Clients										
Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

RESULTS

Site operational and demographic and characteristics across our ten participating sites. Data are shown in Tables 1a and 1b.

Findings from CFIR Pre-implementation Readiness Interviews.

1. *Characteristics of the Individual.* Three CFIR constructs designed to elucidate staff perception of knowledge and beliefs about the implementation and intervention, motivations for implementing the system at their respective site and overall confidence with the success of the implementation.

   [Positive] Staff believed that Gabby provided a thorough risk assessment, was a Black-identifying character that clients could relate to and provided consistency in her messaging. Participants also perceived Gabby to be knowledgeable about a range of topics and provided tailored education and messaging. They felt that Gabby was user-friendly and could foster a level of comfortability regarding embarrassing questions or topics since she was not an in-person physician or nurse and asked

questions in a non-biased way to encourage those who may feel judged during a clinical encounter. Overall, most participants expressed strong confidence in being able to implement for various reasons including having a strong supportive team.

> *I'm very confident. I don't think I have a problem with talking to my clients. The majority of my clients really trust me, and so I think that's a big thing. If I'm introducing something to them, I think they would be – they know that I wouldn't introduce something that would harm them or that was not trustworthy. Site 5_03 - F; 30608-31040*

> *I just think it'll be a great opportunity to be on the cutting edge of technological advancement for our clients in something that will be able to help them. And then maybe if we see some things that are not working or could be a little bit improved on, you know, having that input. Site 3_01 - L; 22689-23096*

> *I mean, I qualify myself. I'm a black woman. I'm 32. I'm not really trying to have a kid, but you know, nothing is in the woodworks, and so, I think just for me, seeing what it can offer the patients. I mean, it could be a reflection of me, and things that I can even take and use myself, and even show the patients, you know, "Well, hey, this is what I learned about myself." People are more likely to do stuff when you do it, or if you've tried it. They're more trusting, like, "Oh, okay." Site 10_02- F; 11772-12304*

[Negative] Concerns were raised by site staff who had a chance to test the Gabby system, Some staff members expressed negative feedback about Gabby's voice, stating that it sounded robotic and muffled, and that they would have preferred if the tool was available as a mobile application, A few staff shared that Gabby's voice may be disengaging to clients. Additionally, some staff reported difficulties with navigating the system, particularly when trying to end or advance a conversation with Gabby. Technical difficulties such as freezing during testing were also experienced by site staff.

> *I struggled with the computerized voice or the robotic kind of – you know I struggled with that. That would make me a little concerned in how that would capture the attention span of our clients. Site 2_03-A; 17372-20074*

> *At certain moments, it was a little muffled and a few times –especially when I tried to take the health assessment – like I would answer I think it was 21 questions and then it would freeze. Site 2-F; 15234-16332*

> *Gabby wanted to continue to gab and it wouldn't let me go. So, I finally had to just exit out of the whole thing. So, I couldn't find it and then I have a daughter who's 25 who was sitting next to me and she's, of course, in this technology age, right? She's like, "Mom, you just have to do this" and she couldn't find it. So, she's 25. That's that demographic that we want to reach kind of. So, I thought to remind myself to bring that up in this conversation. Site 2_03 - A; 17372-20074*

[Mixed] Some staff viewed the technology as a potential barrier, while others believed that the system could be easy to navigate as end-users move through the process. Some staff expressed liking having a virtual advocate that can be used anywhere while other staff felt that Gabby should not replace in-person relationship building, which is important for clients. While staff reported seeing value in the program, some believed that clients may not unless incentivized to use the system. Several staff expressed uncertainty about the implementation's success, depending on finding eligible participants, while others believed that implementation would be simple. Finally, staff believed that recruitment itself would be easy, and implementation would go well, but keeping participants engaged in the long term may be challenging, and the patient population that matches the eligibility criteria may not be sufficient to meet their goals.

> *I'm sure we can implement it. It's just a matter of finding opportunities with the selective candidacy that you guys are having a requirement on. But the implementation part, that seems simple enough. Site 8_04- L; 35975-36176*

Interviewee: I think that definitely you guys have the right idea. I do believe that. I think we can maybe soften up in the way that we ask some of those questions and I think really give them some type of concrete information on why and what it's gonna be used for and what's the purpose. Yeah. Site 2_07 - F; 37883-39104

I would say I am somewhat confident. Not more or less because I don't know how to implement it to them. It's more or less on how do we receive it or how they will be able to get access to the Gabby System based on the obstacles that we talked about…Just on the information I'm bringing to them on the Gabby System, what the Gabby does, why it does what it do, and can it help them moving forward in their own personal life. That I am very confident about based on talking to you and based on the training that we've gotten with the Gabby System. But again, I'm still wary on how they will retrieve those information and how they will implement this on the Gabby System and their own personal life and their own household. Site 5_05 - F; 38548-3940

[Neutral] Site staff commented about preferring to have a trial run/practice with the system prior to the roll out, so they could better assist end-users with navigating the system should they have questions. Others mentioned that they were still unclear about who Gabby really was, as they had not received much direct information about the system. As a result, they could not speak with confidence about it, as they had limited knowledge. For instance, some staff were introduced to Gabby through a flyer, which provided only limited information about the system.

How confident are you that you will successfully implement the Gabby system at your site?

Interviewee: I guess I'm kind of neutral with it at the moment. I played around with it again last night probably for maybe even a couple hours, honestly, just to go through every little part of the system and I tried to click on things that I wanted more education on just to see what would be offered differently from what I already know. Site 2_07 - F; 11657-12603

2. *Misinformation about Gabby*. In addition to capturing levels of influence, there were some instances of misinformation related to Gabby that were unique to this domain. For example, some staff members perceived Gabby as a questionnaire system designed solely to help pregnant women or those trying to conceive. Others believed that Gabby could assist women who have experienced a miscarriage, function as a virtual nurse providing answers to questions related to pregnancy, or that individuals could connect with Gabby at their doctor's office

3. *Domain Inner Setting:* Nine CFIR constructs and five novel codes to elucidate staff perception of knowledge and beliefs about the implementation and intervention, motivations for implementing the system at their respective site and overall confidence with the success of the implementation.

   [Positive] Participants discussed availability of resources such as technology and transportation to supplement implementation, supportive administration, and an enthusiastic front-line team. Gabby was also seen as compatible with the site's current efforts between pregnancies, post-partum care, and preconception education. Moreover, Gabby aligned with the site's values of prioritizing equity, diversity, and client-driven care. Other facilitators included a culture where staff who went above and beyond their respective roles, openness to change within the organization, strong leadership engagement in community care delivery, and honesty. Participants also described how Gabby fit within their priorities for the site in the next year and could help answer questions that would typically be addressed in a medical home.

   It enhances them ten-fold because – like I said – all of a sudden now I think healthcare in general is required to keep to this 15 minute visit, which is really it's impossible to really do a lot in that amount of time and so this is really gonna enhance that and it's gonna enhance the work that we do too especially if people really use the Gabby system and go

online because – when I went online – I noticed all of these websites that they could go to so that they could get health information, heathy eating, losing weight, exercise and I thought, "Oh, this is great." So, it's gonna be great for us. Site 9_06 - L; 15267-15976

Okay. So, we have Surface Pros. The majority of our staff has Surface Pros. So, even if we go on a home visit with a client, we can utilize it that way. [...] But, the good thing is that a lot of our clients do have Medicaid. And with Medicaid, they are offered free transportation to and from appointments. So, again, I think it will be a lot of it on our staff's shoulders to promote it. But, I think transportation can – I'm not gonna say it's not an issue because clients do say, "Oh, I don't have transportation." But, I think that if we can catch the clients that are already here, that would be the ideal thing is to to catch the clients that are already here.

So, we do have bus tokens. So, we do offer bus tokens but outside of that, we don't have really anything as far as to provide transportation for our clients other than just calling their Medicaid plan and arranging a ride for them for an appointment. Site 3_03 - F; 31600-33087, Site 9_06 - L; 15267-15976

I definitely want to see more education opportunities not only for our clients but also for our staff because we have to buy back into them. So, even if it's not something that with directly them having a certain certification or a certain credential, even though it may not benefit us, if we put money back into the employee, they will want to stay. And even if they don't, they're able to leave with a new certification or a residual income. But definitely, I want to see more trainings. I want to definitely see more community programs come into our office. So, I think Gabby will be something great. I want to get parenting classes here, Lamaze classes, just more, more, more, more, more. We already have a lot of things that we do here, but I don't think that you can ever truly do enough for the people that you serve. So really, just more everywhere. Site 3_03 - F; 45311-47549

[Negative] Participants described that clients and patients struggle to take part in organizational events and opportunities due to other life challenges such as transportation or affordable childcare. Staff also discussed the fact that their existing enrollment and intake processes already take roughly an hour to complete therefore this additional request may seem burdensome. Several participants, particularly those representative of Healthy Start sites, discussed a high degree of staff turnover. Finally some staff expressed concerns regarding the lack of technology/limited computers for clients to use to use Gabby both in the office and at home posing potential barriers.

That's really tough. We really struggle with trying to do group events. We often will do things like [...] effective black parenting classes and 12 women show up to the first class, 10 to the second class, eight to the third class, and then maybe five to the last class. So, it's just really hard to keep group stuff going or having – And any time we do any even so we have like weekly breastfeeding support groups. [...] So, for us, the biggest issue in trying to bring clients anywhere for no matter what is providing the transportation and then childcare. If it's an evening event, having to provide a meal. So, that's another cost that. Site 2_05 - L; 52176-53379

I know that our enrollment process right now is a struggle because the enrollment takes about an hour. And, so I'm like, guys we have got to streamline this. I was like, when I have my kids in the office for an hour, I'm about to lose my mind. Site 3_01 - L; 47720-4808

So, that's one thing about these jobs and one of the challenges I've had, not only as the Director of the Agency, but turnover in case management is frequent. And I used to go home and beat up myself, "Oh, I must be doing something wrong." But I found out as I was in a lot of the meetings and hear a lot of the other project directors, it was basically the norm. They don't last. If you got somebody to last past five years, they're good. But usually they don't last past three years. Especially with some of the stuff that they have to deal with. And some of them don't know how to dissect, or divide it away from them when they leave. So, they take it with them. Site 5_01 - L; 9001-9667

[Mixed] Participant comments predominantly centered on prior initiatives for implementation where things may not have wet so well so hesitancy with new initiatives. The decision on whether to use incentives was also mixed with some sights stressing that not having incentives would potentially be a barrier and others have a culture where instead of incentivizing, the organization attempts to mitigate barriers by providing transportation and relevant material on the topic of interest. There were mixed sentiments about how well Gabby would fit into the structure of the site with some sites expressing Gabby will fit seamlessly and others described Gabby as being "disruptive because of existing workflow.

> *One thing I've learned about new initiatives, sometimes we can put something together, but somebody may see something really simple and flip it totally in a different direction. That's probably not with this, but I've seen different programs that we've had. And when we take it to, for instance, our support group, we worked on that support group six months … So, I'm just saying it's different things that may come out of here, that's why I want to follow-up and document, that we can share with you all along the way that may be different than somebody else is doing. Or we may need to change something. I don't know. Site 5_01 - L; 54997-56000*

> *Well, there was a little pushback at the beginning about, "Why do we need to do this?" or whatever with some of the – some providers and staff, nursing staff, but now there's – I mean it's just part of what we do, which is good. […] Whenever you institute anything that's new, it's hard in the beginning and not necessarily because there are people that aren't on board, but they're just not used to doing it and so it's something that just has to be consistent by whoever's in charge of it or whatever has to just consistently present it so that people start to see the value of it and it becomes part of what they do. So, I think the huddle now has become something a part of what we do. -Site 9_06 - L; 34417-3565*

> *It's probably gonna be disruptive at first because we have settled on a whole series of set interventions for the community health workers that distinguishes them from nurses and social workers. They're also part of the home visiting teams. So, we'll have to find a way. We'll have to find a space where it would best fit in within our existing process. It will not be right at the very beginning, again, because you want to establish that trust relationship and going through 140 question screening thing is probably not high on the client's list of priorities at the moment.Site 3_05 - L; 44211-45453*

[Neutral] Participant comments included current site priorities outside of the Gabby system which including conducting additional trainings, providing more staff development opportunities, expanding client services, current programing and initiatives, and network communications where participants did not clearly emphasis how it was going to aid the implementation but provided a description of the availability and qualitative of those communications and social networks. Sites also discussed outreach and recruitment efforts and population served that may or may not influence any aspect of the implementation. Noteworthy is that several sites discussed having a large homeless population that they served.

> *And the newest one we have is a fatherhood program, whereas now, we're not just working with the moms. We have a fatherhood program case manager that will be working with the dads. So, they would try and get the family as a whole and becoming a one-stop shop where we're hoping to meet most of their prominent needs. Again, a lot of time, the pressure in education sometimes [is focused on] the mom. And our intent is trying to get the dads more involved to be a better role model and being involved in the kid's life. And to do that, you have to see the family as a whole and not just one-sided. Site 5_05 - F; 43439-44292*

> *Our evaluators did a […] design study on our clients and they found that compared to other pregnant African American women on Medicaid and County who were not in [site], our clients were statistically more likely to be in extreme poverty, to be homeless, in*

abusive relationships, to go without food. I mean the list goes on – have an unwanted pregnancy. The list goes on and on and on. Site 2_05 - L; 49933-50429

We do have community care workers is what they're called. They come and specifically work with our patients that have county care that need a bit higher level of care. They're kind of potentially falling through the cracks or need a little bit more hand holding I guess you could say. But those teams come – there's two staff members that come on Wednesday and then one or two other staff members that come on Thursday. So, we meet because sometimes we might have a common patient or they have somebody that they may want to refer or I may want to refer. Site 9_02 - F; 12788-13343

4. *Domain - Outer Setting.* – One CFIR construct, and three novel codes indicative of the outer setting used in this project highlighted attributes of the site's external environment, like funding, funder requirements and external agencies that could support or hinder the implementation of the Gabby system.

[Positive] Participants indicated that the Gabby implementation could be used to leverage additional funding culture and that Gabby supplements current site services and expands reach , having partnering sites to provide social services to clients, gabby being more efficient in comparison to what is offered, advocacy efforts to increase funding and the possible role of gabby to help secure more funds.

We have the HRSA screening tools that we're mandated to use. They are very long, very unwieldy, and also very intrusive, especially when a home visitor is new and having to – they don't really have a strong rapport built with the client yet, and so I think Gabby is a great way to kind of get around that because it's self-report to a nonhuman entity. Site 1_07 - L; 17239-17590

I'm not too sure, because I'm not involved with the funding part. However, I do think if we do implement this and we get this going, we may be able to utilize this to push for more funding in a way because we're in such a rural area and they don't have internet and things of that nature. I think they may see that as a benefit of having Gabby and so they may give us more funding to provide laptops or to offer internet service at a low cost or something of that nature.Site 5_03 - F; 33373-34617

We have one of our sister departments in the City of [city]. They're called Healthy Beat, but they're the STD program from Metro Health. Because Healthy Start is in the Metro Health Department within the City of [city]. So, we bring in a lot of sister departments who bring immunization, dental. I mean the importance of health.Site 1_03 - A; 16106-16497

[Negative] Participants described existing organizational requirements to provide other newer services (mental health, access to clinicians, and engaging fathers) to help close gaps that may have to become a priority before Gabby and funding cuts and needing to keep up with metrics and markers for funders.

We have experienced a significant funding cut from the bureau, so we will be cutting our program in half in terms of personnel, scaling down, so as we move forward with successive and follow-up interviews, just keep in mind that that may impact staff responsiveness and just their attitude, general attitude as we move forward.Site 1_07 - L; 11239-11566

The grant is written 60/40. 60 percent case management, 40 percent community outreach from a community perspective. But they want you to put all the budget in the case management component, and a small component in outreach. And the community is what sustains it. And you're not really investing that infrastructure in there to sustain it because you want the clinical and all the numbers for congress. But it defeats the long term purpose of it. Site 5_01 - L; 62462-64650

[Neutral] Very few neutral statements were collected in the outer setting however, participants discussed of organizational culture and how it impacts site operations and workflow.

> *One of the things is that we don't have that many office visits. And Healthy Start don't encourage them, they want that home visit, in the home. They really don't. They accept it, but they really want you to go into that home and go through all the process of the environmental scan of the home. And do the thing with the child and do all the documentation of the home itself, and the person that's in it. Site 5_01 - L; 20846-21253*

5. *Domain: Intervention Characteristics.* Three CFIR constructs and seven novel codes providing description, feedback and perceptions about the Gabby system that may impact implementation.

[Positive] Participants described attributes of the Gabby intervention that would aid implementation included staff perception that the tool was high in evidence strength and quality, that the impact would be long-term and that Gabby was a more upstream approach to health. Respondents also alluded to the fact that Gabby can support patients and clients where access to health care information is already a challenge. Many participants expressed that they could foresee Gabby having a long-term impact at their site despite mixed concerns about a short-term implementation. Individuals enjoyed that Gabby was culturally appropriate with a good level of literacy. Gabby was presented as a "user-friendly" system that can help clients, a community educator and Gabby could home with clients.

> *I think that this is a more upstream approach to dealing with those disparities that our families are dealing with. I think that Healthy Start has been a very reactive program and proactive in hoping that the next pregnancy would be a healthy one and that mom would take care of herself and feel that they were ready and all of those things. But I think that this is that upstream approach of let's have this conversation early. Site 4_03 - L; 31085-31898*

> *The other thing I found – while the information was great – I love the fact that it seems to be very culturally sensitive. I appreciate that it moves us through the motivational interviewing stage of pre-contemplation to contemplation, trying to get us to the place where we take action and then maintain. I like that. Site 2_03 - A; 18666-18987*

> *So, it is nice to have a technology-driven system and I mean even with WIC, it's not so much – as much as an interactive person, but we do online classes as well. So, it's a simple way that a client can go online and learn about something that they want to learn about. You know get information on what pertains to them and – you know factual information, research information, not just, you know, you should try this, I think it might be okay. No, it's like, you know, data-driven.Site 3_06 - A; 19006-21765*

[Negative] Participants highlighted that aspects of the Gabby intervention that could negatively impact implementation included that clients and patients may not feel as though Gabby was beneficial health education, not having the technology or internet access needed to use Gabby, Gabby not being human and health survey questions regarding ma or sexual health may prompt end-user discomfort. Some participants felt that the system was outdated, found the health survey too lengthy and could not relate to the body language of the system. There were some concerns that Gabby was not available in other languages (i.e. Spanish). Participants indicated that to increase the longevity of the system, Gabby should be a mobile application.

> *We know that physicians are predominantly white and male. And so you present a black, animated figure so that figure is gonna talk to me instead of the white male doctor? I also see that as a barrier like, "Okay, so I'm not good enough for human contact. You'll just put me in front of the black animation so that we can connect better." So, that's one sort of thought I had and I would say that the other one would just be you know in just the grittiness I guess of the animation. Like it's not fluid, you know? Site 2_06; 22251-22763*

> *But I think the part that one of the issues is when we use technology, it takes away from human interaction and human genuineness. So, if it's a time if Gabby were to ask me a question and she as walking me through it and she asked me a question about sexual health, she can't – even though if I answer it untruthfully – it's not like she can look at me*

and tell you know read my body language. So, I think we're kind of missing out on the point that you know body language is really important and having that human-to-human interaction is really important and that's where you really want to pull information and really be able to read people in those moments than just clicking you know a button. Site 2_07 - F; 23394-24095

[Mixed] Participants described potential investment costs associated with the intervention amid other operational requirements, need for additional follow up despite a comprehensive screening, and the sustainability of Gabby in the site and organization. Participants were mixed regarding the relative advantage the system would have, one hand they enjoyed that it was online, data driven and tailored, but on the other hand if clients did not have access to a computer, they wouldn't be able to use it, and Gabby's voice may impact engagement.

I think definitely we'd have to make sure we have the technology and resources in place. It'll definitely take the cost of time for sure for the training of the staff and then time to implement with the client. It might take away from their home-visit time but I think if planned properly, we can implement it. Site 1_01; 44354-44664

And if it's a lot for me and I have a college degree and I have really good health and I'm teaching about health, for me this was overwhelming. So, I can't imagine how it is for someone else that – after you finish answering all these questions – then what? You know Gabby asks us these questions. We answer the questions, but how do we fix things or what happens after that? Say that I'm still dealing with that chronic health or whatever it may be. What happens? I just told you all my business and now how are you gonna help me with some of these things? [...] So, there's no really follow up afterward – no connection to resources. So, it was just more like a survey almost like but there was nothing else behind that. […] Some of my coworker that did complete the Gabby they kind of felt the same way like, "What was the point of it?" Site 2_07 - F; 14362-16481

I would say with our clients, maybe – and definitely an advantage is that you can access it online. They don't have to kind of wait for an appointment or anything like that. They could kind of log in and be able to use the system. So, I think that's a really good thing. But then, on the other side, for the clients that don't have access to – or a client that don't have access to online, or a smartphone, or anything like that – because we do have some clients that don't have access to those things at home. Site 3_07 - F; 17438-17949

[Neutral] Participant commentary included perceptions of how to measure successful outcomes of the system and future recommendations. Participants also discussed both short- and long-term outcomes that could be collected using surveys and other forms, as well as decrease in adverse health behaviors/outcomes. Ideas to expand gabby capabilities includes use of closed captions, support groups and having an option for users to engage with a live individual.

One of the things is that we don't have that many office visits. And Healthy Start don't encourage them, they want that home visit, in the home. They really don't. They accept it, but they really want you to go into that home and go through all the process of the environmental scan of the home. And do the thing with the child and do all the documentation of the home itself, and the person that's in it. Site 5_01 - L; 20846-21253

I think kind of almost how we see success […] with our program now before Gabby. And that means, repeat moms, when they tell their friends about it. We have a lot of referrals that come from friends because they've been through the program. And so, I think to me is the ideal situation for us is to be like at the end of two years we have graduation from the moms who have been in the program for two years and have essentially went through it. In the same way to be able to have a mom who started preconceptually with Gabby, got pregnant, healthy baby, two years later here she is now with a healthy baby. Site 1_06 - L; 38185-40654

We have a few patients who are hearing-impaired. So, I don't specifically remember us discussing about Gabby and hearing impaired, if those same words were able to be close-captioned. Site 9_08 - L; 43467-43651

6. *Domain: Intervention Participants (Clients).* A novel domain, consisting of 4 codes created by research staff to capture feedback and staff perceptions of how clients may respond to Gabby from the perspectives of site staff

   [Positive] Factors that participants believed that would support implementation efforts is that Gabby might appeal to different learning styles, highlight unhealthy behaviors and help to encourage clients and patients to advocate for themselves.

   I think it would give them another avenue for education because everybody has a different learning style and so this might appeal to the learning style of one of our clients or some of our clients as opposed to what we're currently doing. Site 2_02 - A; 27517-27768

   Well, I hope that it'll be helpful in the way of advocating and encouraging clients to discuss some of those topics regarding their specific health needs and being familiar with the wording and the vocabulary so that they feel a level of advocacy. You know we try to provide as much education as possible, but I think this is more self-paced and at your own speed. So, my hope is that the client will feel inspired and they'll be able to really use this as a self-paced education and then tie it into advocacy for themselves. Site 2_01 - L; 29053-29855

   I think they'll like it a lot. I think, like I said, it will be a confidence booster because I'll go and talk to clients and they may not know how to communicate with a healthcare provider. They may not know how to state what's wrong. We go over that a lot with our clients. They can describe a symptom to us or something that's going on with us, and they trust us, but when it comes to someone outside of us – a healthcare provider or any type of other provider – they are not as trusting with those providers, so they may not know how to verbalize or communicate with them and tell them what's going on, or they may feel intimidated. Site 5_03 - F; 31584-32714

   [Negative] Participants described that clients and patients not having the technology to use Gabby, not being able to prioritize Gabby, not taking the risk assessment because it's too long and not finding alignment with clients and patients' current values.

   I think that the African American community in our city experiences a lot of tragedy and a lot of senseless violence and trauma. And so, they might not be susceptible to, you know, number one we're the Health Department, so we're a government entity. You know, that's always something else to think about. But again, I think that that's where you build a relationship with X to help bridge that. But I think that reality is, is that we live in the world that we live in and sometimes things are gonna take a higher priority than checking my website once a week and making sure I'm getting information I need. Site 4_03 - L; 46856-47747

   But, I think the main barrier is the client and them seeing it as a necessity and them seeing it as something that is going to benefit them. If they can see the benefit from it and they can see it bettering themselves, then you won't have a problem doing it at all. Site 3_03 - F; 28312-30026

   Too long. I think it'd be a little frustrating for some people. We have a difficult time as it is in getting our enrollment completed with a lot of – You know we work with families that is some environments can be chaotic or that might not be their priority because they're homeless. They don't have anywhere to live. They don't have anywhere to sleep. They don't have any food you know. So, we try to break down social determinants of health and – even though this is really important – their health but it's like the Maslow's

Hierarchy. You know if the top of it is not being addressed, then anything else under that is really hard to try to work on. Site 2_07 - F; 34327-35064

[Mixed] Participants provided commentary regarding assumptions of how clients and patient may respond to Gabby. There was consensus across sites that there may be some initial hesitancy and critique that will later be met with more openness in addition to engaging a group of end-users that can benefit most from the Gabby system.

I think that first of all, they'll be critical. They'll be critical and say, "Y'all need to fix her voice." But I think that they will say that Gabby gave them an opportunity to get information that they probably wouldn't have had privy to on a deeper level [...] where they really had time to absorb it and soak it up. When you go to a doctor's office you don't have time to absorb anything. They want you in and out and if they give you handouts most of the time you stuff them in something and you don't pull them out or read them. You want to know something you Google it real quick and not all times do you even Google – you can't Google what you don't know.So, prompting questions helps you get on the right course. So, I think that will be appreciated, and I think that they'll be honest about the experience. They'll be honest whether they didn't like it or they did. So, and they'll tell us if it's something that we should continue or not I do believe.Site 4_01 - A; 42942-44172

That's a sticky one because sometimes even the ones with the greatest needs are sometimes the ones that's hardest to reach. So, it's that when we introduce it, building that rapport, establishing that trust, because those are the ones that's sticky. So, it just kind of depends. So that's why I say the case managers would be the first one of contact for that because for those difficult or the highest need clients, it takes a lot to kind of break down some of those barriers with them. But once they trust you, they trust you. And, if you say hey listen, I need to do this, then they're going to do it. But it's just getting to that point to where you can break through some of those barriers with them. Site 3_01 - L; 36043-36867

Some will be receptive and some will be like, I don't have time. There's going to be a mixture. And the ones I think would be more receptive are the ones that are more self-sufficient. They don't need us as much or don't need other social agencies as much because they have a lot going on. They're pretty self-sufficient and you might say, oh, this works for me because that's less I got for you to come visit me because I can do this here from home [inaudible] [00:52:01] on the phone or I'm working for a time and school at night and this, that, and the other. Site 3_02 - L; 41332-42198

7. *Domain: Implementation Process.* Four CFIR constructs and five novel codes highlighting strategies or tactics that may impact the implementation process. Includes CFIR constructs related to engaging appropriate individuals in the implementation and use of the intervention, reflecting on the implementation process, and evaluating the experience.

[Positive] Participants felt that approaching the facilitators to the implementation process including carrying out the implementation as a group effort where all staff played a key role and will directly impact/conduct activities associated with the implementation. Many participants amplified the importance of having site champions with existing relationships with the patients and clients who are dedicated to making sure that there are opportunities in place to troubleshoot if needed. Several participants alluded to the importance of social media to help outreach potential clients and patients who would be eligible. Participants expressed that pre-implementation process maps and the constant communication with research staff helped make the experience more positive.

Everybody. I will say that that is one thing about our staff. If we're doing something, if we're promoting something, if we're trying to implement something, we do it across the board. So, we're gonna educate all of our staff. All of our staff will receive – I don't if it's a

training or whatever you want to call it, but all of our staff will receive training information on Gabby, how to access it, how to use it and how to show clients how to use it as well. Site 3_03 - F; 33692-34557

[Site champion], who is our lead person on this project, who has the largest population of young women in that age range that we are dealing with – She, above all other providers here, has more young women in this age range than any population. She's also very well-used to interacting with them via our portal. So, she outshines us all with respect to the interactions she has with her young women with the portal. She also has longevity, in the fact that she's known a lot of these patients for, some of them, over 10, 15 years. And when it comes to requesting participation in a project, because of that relationship she has with these patients, they more than likely want to participate and learn. She, herself, spends a lot of time interacting and teaching her patients, with respect to pre-conception counseling, et cetera, et cetera, and I would think this would also help to significantly decrease the amount of teaching that she has to do with the patients. Site 9_08 - L; 30106-31073

A lot of our clients are on our social media. They really use it a lot – communicate with us a lot on social media. We all have work Facebook pages, and things of that nature, so I think that could be a way that we can start introducing it once we get a social media kit. We're aligned with what you guys want to advertise as far as the Gabby system. I could recommend the start promotion of it, and then – I don't know if you guys would want to – maybe say something about flyers. We do a lot of flyers as far as the local business that we do here or that we're involved in when we hand out our education, and I think our clients really like that a lot, so we have a flyer that we can take with us before we start it. I think that would be great. And then we communicate with our clients a lot through text messaging, so if you guys have a certain type of verbiage that you want us to use, send it over with the social media kit and we can do a text message to all of our clients. Site 5_03 - F; 29283-30557

[Negative] Barriers to the implementation process reported by participants included characteristics of the client population that would make them unable to participant or not being able to provide it to groups outside of those who identified as being Black or African American. Participants also commented on the health screening assessment and potential discomfort that may arise due to the questions posed**.**

Yeah, I think that crisis is another one. So, we have some pretty transient clients that we work with currently. Now of course in this population that might be different. But like we have families, we have moms who are staying with other family members. We've got families that're kicking members out so they're homeless and they're jumping from couch to couch. You know, the car gets totaled. The lights get turned off, like whatever the crisis is that might be keeping them from being able to stick with a routine, a stable approach to something, might be a barrier.Site 4_03 - L; 45027-45831

I thought about this during the training. What if somebody, a provider, for instance because some of our clients have two or three different people going in their home, and they tell them about Gabby. And what if they want to come or they want to know what we're doing. And that's gonna probably happen. How do we introduce them to it? And they may say, "Well, why didn't I get that invitation" because that happens a lot. gonna go, "Well, why didn't we have a white one?" Site 5_01 - L; 30010-30592

Yeah. So, one other issue that came up that I heard from one or two of our community health workers who tested this was they felt that some of the questions were way too intrusive especially around you know, "Have you had sex in the past? Have you had anal sex? Have you had oral sex? Have you had sex with a woman? A Man?" those kind of questions. They themselves felt uncomfortable answering those, which I didn't feel at all. I mean maybe because I'm more used to talking this way. So, I never felt that discomfort,

but I know some of our community health workers have and – if they do – then some of our clients might as well. So, that could be a barrier as well if our staff themselves are not comfortable doing this, then finding ways to give them tools to make them more comfortable with it and maybe talking points on how to introduce this to their staff – I mean to their clients. Site 2_05 - L; 22116-23007

[Neutral] Many participants at the time of readiness interviews did not seem to have specific implementation plans at their respective sites. Some participants did discuss aspects of planning that had been developed to support the implementation process and potential strategies to recruit Gabby users. Ideas for introducing Gabby to patients and clients were preliminary although they pointed to possible use of group-based enrollment, using the time spent in waiting rooms, and during the completion of other intake forms.

But if we could somehow put Gabby in some type of a group setting or whatever because I think the group is gonna be essential for our patients getting excited and motivated about it and really continuing to do it outside of clinic visit. I think that if it's just them on their own and thinking that they're the only one or whatever that's looking at the health information and it's really just about them, I think we're probably gonna get a better response if it's a group of women that are really talking about Gabby and sharing information about how they used Gabby because I had no idea that you had all of those links in there. So, I think that with a group of women together, it could be – it think it'll be better. Site 9_06 - L; 25715-26440)

I'm trying to think. I'm trying to think about every email that I've probably – I'm pretty sure they have a plan just because – at a meeting that I wasn't at but I spoke to some of my community health workers – they wanted us to start practicing to use it so that we can start introducing it to our clients. So, that's the only plan that I heard of. I'm just not sure like if there's a launch date for it or not. Site 2_04 - F; 36100-36623

And I'm thinking, "Okay, who can I ask to get me some money to get some computers." Because sometimes you ask, you get. And I do know people to ask and get money from. So, I've been thinking because it's innovative, it's things that people like. And I'm thinking, "Okay, we can give people the iPads to let them check it out and bring it back." I was sitting up here thinking the whole time when the computer question – because I know it's coming back. So, I'm sitting up here thinking, "Okay, how many of these girls, if we get computers, could we circulate them?" And we check them in. Somehow I think that may be the key. I don't know. I don't know how you feel about that, but that's what I was sitting up here thinking because they're not that expensive. IPads are not that expensive. Site 5_01 - L; 18878-19669

Implementation Appropriateness: Results from survey responses showed that there was significant variation across sites in their perceptions of the appropriateness of the Gabby implementation. Overall, three out of the five sites for which we were able to collect data post-implementation reported modest disagreement that the Gabby implementation was appropriate, while the remaining two sites modestly agreed. Further examination of these outcomes by level of site staff across all implementation sites revealed that frontline staff, who are defined as "individuals who provided patient care or service delivery and may have direct involvement in the recruitment and engagement of participants who used the Gabby system," rated Gabby's appropriateness lower compared to leadership and administrative staff. Themes derived from post-implementation interviews include:

1. *Site/organization compatibility and perceived fit.* Description of how the organizations' structure, mission and climate aligned with implementation and strategies (Gabby administrative page, technical assistance calls, Gabby "cheat sheet", Gabby toolkit, staff reminders) that were described and carried out. Participants appreciated that Gabby identified as a person of color and approached preconception care from a medical lens. However, compatibility and fit were altered by the pandemic as staff had to

tend to more urgent and immediate needs of clients. Some sites also became understaffed during the pandemic and struggled to balance Gabby while meeting organizational needs and deliverables.

2. *Perceptions of consumer compatibility and perceived fit***.** Description of how the Gabby System aligned with the client's current daily life, roles, and routines and over the implementation period. Participants expressed many competing priorities for clients that posed barriers for both this implementation and organizational services. Clients tend to be more focused on "staying above ground", and Gabby was not something they are interested at the time with so many other things on their plates.

Implementation Acceptability: Results from survey data from four out of five sites indicated a modest level of acceptability towards the Gabby implementation, while one site disagreed overall. However, staff at all levels, including leadership and front-line personnel, expressed ambivalence about the system's true acceptability. Post-implementation qualitative interviews revealed several themes regarding the acceptability of the Gabby system, shedding light on facilitators and barriers during the implementation process. These include:

1. *Complexity.* Perceptions of preparedness to implement and navigate the Gabby system, ease of progression through the interface, using computers/other devices to access Gabby, and ease signing up end-users on admin page. Participants described initially feeling extremely prepared to carry out the implementation in terms of having promotional and outreach material, but within a few weeks of the rollout recognizing they had many gaps and required more assistance on how to proceed.

2. *Content and Comfortability.* Perceptions of understanding Gabby script information. Site staff amplified that individual's ability to navigate through the system would depend on their reading level, reading speed and overall comprehension. Although they found Gabby's explanations to be clear, one site recommended having Gabby script content at a decreased reading level and using analogies would help to circumvent some of these concerns.

3. *Device, Navigation and Risk Assessment Complexity:* Difficulties specifically due to needing to use a computer or laptop to access Gabby, navigating the Gabby system, or ease of progression through the system and duration to complete the risk assessment. Participants described that Gabby System was good idea for merging tech and health care, however faced barriers to feasibility particularly for the more vulnerable populations they serve that are a little technologically disadvantaged/behind. The system being on a computer was not entirely accessible throughout the implementation period across most sites.

4. *Recruitment and Registration.* Descriptions of the process, ease and challenges of recruiting and signing up end-users on the admin page. Many sites leveraged more than one engagement modality to recruit clients and discussed the importance of pitching Gabby in a beneficial light. Incentives also were very useful for several sites.

Implementation Feasibility. Two of our implementation sites used an in-person recruitment approach, another two sites used a hybrid approach, and our remaining 3 sites recruited all participants virtually. Over half of our sites chose not to provide incentives to enrolled participants, while others provided perks that included food, points, and gift cards. Two sites utilized an electronic health system platform to engage participants through a patient portal and three reported having a site champion who served as the primary initiator for all recruitment efforts. Among sites who provided information regarding number of participants they approached or outreached, we found that Sites 3 and 4 were able to enroll almost 45% of participants they initially engaged. No clients or patients from two of our implementing sites completed a health survey and three of our implementing sites were able to obtain this information from roughly half of their enrolled client/patient population.

1. *Technical Assistance.* Technical assistance calls were used to help resolve challenges in enrollment or using the Gabby system platform, brainstorming approaches to improve enrollment or engagement

among eligible clients served, and discussing novel ways to navigate follow-up with enrolled participants amid local COVID-19 restrictions. These calls captured some of the nuanced decisions made by implementation sites regarding how involved they wanted site personnel to be regarding the topics identified on their MHDTL page. Research staff also observed that the overall confidence in our implementing sites ability to recruit 25-50 individuals to use Gabby decreased over time. Some sites also expressed avoiding technical assistance calls because they felt 'disappointed' in not being able to progress with recruitment and client usage. We also gained insight about some of the staffing support that site champions wished they had from other colleagues and leadership throughout the process. While many expressed appreciating the unique role of being able to lead Gabby implementation efforts for their team, ideally, they wanted leadership to know the specifics of implementation to feel more supported in the event of staffing changes and turnover.

Intervention Effectiveness. Of the five sites for which we were able to collect usage information for, Site 4 participants used the Gabby system for an average of 61 minutes (SD: 40.79) with the remaining sites having averages that ranged between 19-27 minutes. In this study we also sought to examine changes along self-reported stage of change to evaluate the effectiveness of the Gabby implementation. However due to a lack of data collected at the 3- and 5.5-month time point from participants, we are only providing descriptive statistics at baseline for each site. At baseline, participants across all sites that implemented the Gabby system fell between planning/preparation or reaching action along the stage of change continuum for topics identified during the health survey on average. The average number of health topics flagged at baseline across sites ranged from 18.6 – 24.9 across sites enrolled.

Table 2. Baseline Stage of Change and Risk Triggered Across Sites

Site	Mean SOC	SD SOC	Mean # Triggered	SD # Triggered	Mean # Discussed	SD # Discussed
Site 2	3.9	0.5	24.2	7.3	24.2	7.3
Site 3	3.6	1.2	18.6	5.5	18.4	5.2
Site 4	3.6	1.9	21.1	4.8	17.4	7.3
Site 7	3.6	1.1	23.5	4.8	23.5	4.8
Site 9	4.6	1.1	24.9	5.2	24.4	5.5

Post-Implementation Feedback. During post-implementation interviews, we elicited feedback on the Gabby System, reported barriers and challenges, recommended modifications or changes, and perceptions about future use and new resources needed for implementation. Staff members suggested that research staff send monthly reminder/check-in emails during the implementation process to keep staff informed of updates and progress. Site champions recommended adding a button on the electronic medical record platform to remind staff about the Gabby implementation and outreach to eligible women. Participants discussed opportunities to integrate Gabby data into medical health records to promote care continuity and real-time access to Gabby for questions. Staff turnover and new hires during implementation highlighted the need for more retraining opportunities and reconsideration around the role of a site champion. Staff suggested having more than one site champion and support outside of business hours to accommodate clients who use Gabby in the evening as immediate issues had to wait until the following business day for resolution. Sites also highlighted the challenge of balancing confidentiality with the ability to follow up on and manage risks identified by the system. Initially, site staff perceived the implementation process to be straightforward, but as it progressed, they realized it was harder than anticipated to engage and recruit women to use Gabby. Across all sites, the most consistent feedback was related to increasing access to the Gabby system by having it available on mobile devices, allowing users to save their responses to the risk assessment, and shortening the length of the assessment or breaking it up throughout the system. One site expressed a desire to have a "re-do" of the implementation period, as they were not prepared to launch Gabby virtually during the start of the pandemic, but they have since built the necessary infrastructure to do so.

COVID-19 Pandemic: The COVID-19 pandemic had a substantial impact on the implementation of the Gabby System, requiring significant adaptations to be made to accommodate the remote communication and engagement of clients. Site operations, hours, services, and programming were all affected, making it challenging to enroll and follow up with clients. Many Healthy Start sites were forced to close their offices to clients, leaving only chrome books and travel laptops as options for those in need. As a result of the pandemic, Gabby-related activities also had to transition to over-the-phone interactions, such as walking individuals through the risk assessment. This shift to remote communication made it difficult to capture continued involvement, and more incentives would have been helpful during this adjustment period. Interestingly, Site 3 reported enrolling the bulk of its members due to the pandemic, but barriers still existed in engaging them to use the system. All communication was strictly done through phone, texting, or zoom, making it challenging to establish a rapport regarding Gabby with clients and patients. COVID-19 also rearranged many priorities for clients and patients, including fear around family, friends, health and the unknown. Additionally, sites faced significant personnel challenges, with a high degree of staff turnover and staff contracting COVID-19 through the nature of their work.

Creation of a Gabby Implementation Toolkit. The final iteration of the Gabby toolkit comprises of eight evidence-informed modules. Module 1: Welcome to the Gabby System; this module provides the background, evidence base, and development of the Gabby System. Module 2: How the Gabby System Works; this module highlights the health behavior techniques used to engage client users, defines how we measure progress and provides an overview of key features of the Gabby System. Module 3: How to Begin Implementation; this module outlines the steps you need to take to implement the Gabby System at your community-based site. Included are step-by-step instructions on how to implement as well as various factors that should be considered before implementation. Several documents that can be referenced to assist you in the implementation process are included. Module 4: Outreach and Engagement Efforts; this module includes information regarding outreach and engagement strategies. It also describes the importance of using social media and virtual platforms to engage with clients. Module 5: Monitoring and Evaluation; this module reviews methods that can be used to monitor and evaluate process and implementation outcomes. Module 6: Informing Sustainability; this module helps you think about your goals and what changes need to be made to sustain and maintain the Gabby System at your site. Module 7: Lessons Learned; this module uses case studies to provide examples of potential implementation challenges and how pilot sites addressed them. Module 8: FAQs; this module includes common questions and answers regarding Gabby System implementation. Link to toolkit: https://sites.bu.edu/gabbytoolkit/

DISCUSSION

In this type II hybrid implementation-effectiveness study, we found that a significant portion of the challenges experienced across all sites was rooted in many of the themes that were generated during pre-implementation readiness assessments. Among participating sites, only half were able to enroll individuals to use the Gabby system. Pre-implementation data from interviews and surveys showed contradictory findings, with interviews indicating more positive sentiments towards implementation and overall site readiness. The use of implementation strategies varied significantly across sites, highlighting the importance of adapting strategies to meet the unique needs of organizations. While implementing sites found technical assistance calls from research staff useful in identifying alternative recruitment sources and tailoring recruitment materials, ongoing barriers such as technological access to the Gabby system, the length of the preliminary health assessment, and changes to operational workflow due to the COVID-19 pandemic served as defining limitations to implementation feasibility. Ambivalence towards the appropriateness and acceptability of the Gabby system and implementation process indicates that barriers experienced was highly influential to the sites overall experience. These findings were corroborated through post-implementation interview feedback where sites a desire to have engaged in learning communities to facilitate recruitment and engagement efforts and increase self-efficacy in implementing Gabby again in the future based on lessons learned. Post-implementation feedback also highlights the importance of ongoing support and adaptation in implementation efforts to address challenges and improve implementation feasibility. Due to the absence of participant information at 5.5

months, we were unable to interpret the effectiveness of the Gabby system in terms of participant stage of change.

CONCLUSION

This study underscores the importance of considering organizational context when implementing interventions. Evaluating readiness, acceptability, and appropriateness can shed light on organizational structures that are critical to implementation feasibility and effectiveness. Participant-level data is essential to understanding barriers to engagement and usage of eHealth interventions, particularly among marginalized populations. Despite the significant challenges faced during implementation, positive feedback regarding the intervention's evidence and quality, as well as its potential impact, was received. It is important to acknowledge and account for the complex barriers that exist for Black and African American women and furthermore design interventions that address the unique needs of Black and African American women to reduce disparities in maternal and child health and promote racial equity for this marginalized group.

SICNIFICANCE

This work introduced Gabby into Healthy Start and Community Health Center (CHC) sites serving low-income, African American and Black women, a group AHRQ has identified as a high priority population. The dissemination of a low-cost, user-friendly, culturally competent, evidence based, scalable intervention to improve the health of young AA women is critical to reaching a number of Healthy People 2030 objectives including: 1) Maternal, Infant, and Child Health: reducing the number of infant deaths (MICH-1.3) and preterm live births (MICH-9.1); and 2) Reproductive and Sexual Health service delivery to females aged 15-44 years (FP-7.1).

LIST OF PUBLICATIONS and PRODUCTS

Peer reviewed publications to date.

1. Walter AW, Julce C, Sidduri N, Yinusa-Nyahkoon L, Howard J, Reichert M, Bickmore T, Jack BW. Study protocol for the implementation of the Gabby Preconception Care System - an evidence-based, health information technology intervention for Black and African American women. BMC Health Serv Res. 2020 Sep 21;20(1):889. PubMed Central PMCID: PMC7504872.

Peer reviewed abstracts and poster presentation.

2. Sidduri N, Julce C, Yinusa-Nyahkoon L, Walter AW, Kolli A, Verdieu A, et al. Tailoring a Select Bundle of ERIC Strategies to Implement the “Gabby” Health IT System at Community-Based Sites. Poster Presented at: AcademyHealth 14th Annual Dissemination and Implementation Conference: December 2021; Virtual Meeting.

3. Julce C, Walter AW, Yinusa-Nyahkoon L, Howard J, Sidduri N, Zhang Z, Fernandez, J., Bickmore T, Jack B. (2018, December). Implementation of a health information technology system for young black and African American women in a community-based clinical site. Poster presentation at the 11th Annual Conference on the Science of Dissemination and Implementation in Health

Manuscripts in preparation.

4. Julce C. Reichert M, Sidduri N, Walter A. Yinusa-Nyahkoon, Verdieu A, Howard J, Fernandez J, Bickmore T. Jack BW. Use of a Web-Based Preconception Health Information Technology System Designed for Black and African American Women: Results of a Hybrid Type II Implementation-Effectiveness Study

Gabby Implementation Toolkit. Can be found at https://sites.bu.edu/gabbytoolkit/

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