Protocol

Dissemination of the Gabby Women's mHealth Program in Lesotho

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Background: Lesotho has the second highest HIV and fifth highest tuberculosis prevalence rates worldwide, and a maternal mortality rate (1024/100,000) that is among the highest in Africa. As there are only 6.2 nurses and 0.5 physicians per 10,000 people, both about one-third of the African average, there is an enormous need for eHealth systems to assist the clinical care system.

There are advantages to choosing Lesotho as a site to implement a mHealth application for women. Advantages include: (1) its 2 million people are almost entirely of a single Ethnic group (Basotho) and English is one of two official languages (Sesotho the other), (2) female literacy is greater than 90 percent, (3) the lack of human resources provides the necessity for alternatives to traditional face-to-face medical care, (4) the highly mountainous rural geography provides a barriers to traditional medical care that mHealth could overcome, and (5) 45% of mobile users reported having smartphone devices with internet/Wi-Fi capabilities.[1] 3G data coverage is available in almost 90% of the country and Wi-Fi is found in all government locations, including district hospitals, providing our team with a fundamental base to conduct an internet-based mHealth implementation.

Since 2003, our partner, the Lesotho Boston Health Alliance (LeBoHA) has worked to strengthen the healthcare system of Lesotho, in part by establishing a national network of trained providers that we can now use to disseminate best practices throughout the entire country.

Study Rationale: Preconception care is an effort to focus on engaging young women in their health before they become pregnant since many women enter pregnancy at risk for poor outcomes because of preexisting medical conditions or not following evidence-based preventive action. In 2013, the WHO prioritized research that focuses on developing, delivering, and scaling preconception women's health interventions in low and middle-income countries to optimize health and birth outcomes. The WHO emphasized implementation research as the key step in helping to maximize the coverage and uptake of preconception care to enhance the long-term health outcomes for women and their children.

The Existing Gabby System: "Gabby" is a patient-facing, user-friendly, evidence-based, scalable, culturally adaptive, health communication system designed to improve women's health. Our team has developed and tested several Embodied Conversational Agents (ECAs), which are virtual characters designed using expertise from health communication, psychotherapy, social psychology, sociolinguistics, linguistics, and communication theory. These empathic characters are programmed according to scripts triggered by users' responses and thereby produce tailored, individualized dialogue.

The dialogue content of Gabby is adapted to the woman's readiness for change with regard to a specific task. Ongoing interactions help the user resolve ambivalence and use problem-solving approaches to support participants with a risk-resolution plan. Gabby emphasizes a user's accomplishments so as to build confidence and increase self-efficacy. The system intervenes on general health attitudes and provides counseling on behavior change skills through a process of small commitments that may enable women to more effectively address all of their risk factors.

Gabby was tested in two randomized controlled trials in which participants indicated that they found the system useful, trust Gabby, intend to use the information to improve their own health, and are willing to share it with others.

Purpose/Study Objective: We now seek to adapt and evaluate Gabby to address HIV and TB in a low-income country. We will study the implementation of the modified culturally appropriate app, Nthabi, in

Lesotho in partnership with LeBoHA. We will assess the effectiveness of Nthabi based on the periodic stage of change assessments over the two-month implementation, end-user content knowledge, and system usage.

Hypothesis: We hypothesize that the Nthabi intervention will enable participant progression throughout the stage of change model, resulting in high system usage and increased content knowledge.

The Gabby Women's mHealth Program ("**Gabby).** The "*Gabby Women's Health Program, or* "Gabby", is a patient-facing, user-friendly, evidence-based, scalable, culturally adaptive, health communication system designed to improve women's health. Our team has developed and tested several Embodied Conversational Agents (ECAs), which are virtual characters designed using expertise from health communication, psychotherapy, social psychology, sociolinguistics, linguistics, and communication theory.[2] These empathic characters are programmed according to scripts triggered by users' responses and thereby produce tailored, individualized dialogue - the closest to person-to-person communication that a device can provide.[3,4] The design elements that impact behavior change used within the Gabby are described below.

(a) **Health Risk Assessment**. Among young adults, computer-based interventions can: (1) obtain accurate risk assessment data, (2) provide health promotion that is well-accepted by this age group,[5] (3) show increased knowledge at follow-up[6], (4) be accurate and more enjoyable[7], and (5) be perceived as "anonymous" and "nonjudgmental."[8] When compared to an in-person interview, adolescents reported more of their personal health risks to a computer, thus breaking down barriers to identifying and addressing sensitive health issues. Gabby health education tools are highly effective in capturing health assessment information[9] and increased knowledge of participants at follow-up [10]

(b) "My Health To-Do List." After a user completes a risk assessment, Gabby produces the "My Health To-Do List," which is a customizable list of identified risks and recommendations to minimize or eliminate these risks. The format and content of the "My Health To-Do List" was designed based on feedback from focus group participants. A woman can view this personalized list online at any time and can choose to bring a print-out to an appointment with her clinician. The list is continuously updated in a woman's subsequent interactions.

(c) Tailored Health Content. The clinical conditions addressed by Gabby are categorized into 12 health content areas of preconception care as defined in the CDC report.[11] The system is designed to facilitate a user's in-depth exploration of risks pertaining to her.[12,13,14] Discussion is directed by the woman based upon her interests and motivations. Gabby allows for sophisticated levels of tailoring. Dialogue generated is specific to the responses of each woman at each turn of dialogue based on the risks identified. The content is further tailored based on the woman's interested in pregnancy prevention versus interested in becoming pregnant.

(d) Motivational Interviewing. The dialogue content of Gabby is adapted to the woman's readiness for change with regard to a specific risk. The intervention follows behavioral construct tailoring theory, which builds on Prochaska and DiClemente's Transtheoretical Model that behavior change is a process, not an event, and that people move through five stages[15] that are *pre-contemplation, contemplation, preparation, action, and maintenance*.[16] For example, those women who are pre-contemplative for a specific risk will receive motivational interviewing dialogue to try to move them to contemplation.[17] Ongoing interactions help the user resolve ambivalence and use problem-solving approaches to support participants with a risk-resolution plan. Gabby emphasizes a user's accomplishments so as to build confidence and increase self-efficacy.

(e) Longitudinal Multi-Factor Health Behavior Change. One of the Gabby's key features is its ability to remember and build upon previous interactions.[18] Simultaneous intervention on multiple health behaviors is effective for many combinations of behaviors.[19] Gabby was developed to focus on common

factors whenever possible (e.g., removing barriers to medical care will impact both immunization and chronic disease management behaviors). She intervenes on general health attitudes and provides counseling on behavior change skills that may enable women to more effectively address all of their risk factors. Initiation and maintenance of behavior change may be more successful for some participants if they are engaged in a process of small commitments or "baby steps." [20,21,22,23] This approach allows participants to initiate an action plan about which they feel confident and includes small, achievable behavior changes that further increase confidence. In subsequent interactions, Gabby can follow-up on the action plan to evaluate progress. During an interaction, the agent identifies the degree of progress, reassesses readiness, and recommends next steps.

Gabby Has Proven Efficacy in RCTs. First, AHRQ funds provided support of the first Gabby prototype and feasibility testing. Findings among the first 20 women to use the system include: (1) the majority of participants felt that the health risk assessment was useful (80%) and easy to complete (90%), (2) 80% of participants felt that it was easy to talk to Gabby; 73% trusted Gabby, and 87% felt comfortable telling Gabby everything about their health; 80% would use health information from Gabby to improve their health, and 87% felt that Gabby did a good job answering their questions; (3) For those risks added to the "My Health To Do List," two month outcome phone call data showed that 83% of risks were either resolved or had been acted upon positively.[24] Second, using funds from MCHB, we completed further system development. For those women in the initial trial who reported that they were "pre-contemplative" for a particular risk, we identified that the vast majority decided not to take further action, thereby confirming that they were truly pre-contemplative. Importantly, for those who started out as "contemplative," 67% were found to be in the "Action" or "Maintenance" phase after two months, indicating that Gabby was successful in providing information that led to behavior change in this important subgroup. This discovery led us to add motivational interviewing dialogue for many risks in an attempt to move many women from pre-contemplation to contemplation. Third, we conducted an RCT of 100 women recruited nationally from the Office of Minority Health's *Preconception Peer Educator* program and *Healthy Start* sites. During the six month intervention period, 42 out of 50 women randomized to the intervention arm interacted with Gabby at least once and there were 2,676 minutes of interaction. The average session lasted 18.6 minutes, and the average total interaction was 63.7 minutes. Significant differences in risk resolution were found between the Gabby and control groups: 27.8% (297/1,067) of the reported risks were resolved in the Gabby group, compared to 20.5% (224/1,091) in the control group for whom a letter was sent to the women reporting the risks identified and suggesting she speak with her clinician about those risks ($p<0.01$). Women in the intervention group resolved 8.3 risks on average compared to 5.5 in the control group, ($p<0.01$). Most women in the Gabby group reported that it was easy to talk with Gabby (78%), trusted her and stated that Gabby did a good job of answering their questions. Two thirds reported that they used information from Gabby to improve their health; another 22% planned to do so.[25] Fourth, with funds from NIMHD we conducted a larger RCT of 531 AA women recruited online between March 2014 and July 2017. Women in the Gabby intervention group resolved 8.81 risks on average, compared to 6.95 risks amongst their peers in the control group defined as above ($p<0.05$). Among the 229 women for whom data was collected at both baseline and twelve months, women who received Gabby resolved 10.25 risks compared to 7.98 risks amongst their peers that did not - a difference of 2.27 risks resolved on average ($p = 0.01$).

From data gathered in these studies, we conclude that Gabby is (1) well-functioning, (2) feasible, (3) used by participants, (4) effective in determining individual risk status, and (5) effective in assisting women in reducing their personal health risks. Participants find the system useful, trust Gabby, intend to use the information she shares to improve their own health, and are willing to share it with others. We now feel confident in adapting, disseminating and evaluating Gabby in low income countries.

C. APPROACH

Goal and Tasks Associated with Each Objective.
Our GOAL is to study the dissemination and implementation of Gabby into ten districts hospitals in Lesotho in partnership with LeBoHA using existing educational infrastructure using a type 3 hybrid design, with a primary focus on implementation and dissemination and a secondary focus on effectiveness.[26] We will utilize (a) Proctor's Implementation Strategies and the CDC's Framework for Program Evaluation to examine implementation outcomes, and (b) stage of change data to measure clinical effectiveness outcomes. The management of this project and the experience of our team is described in the Budget Justification.

C.2.1 Conduct Pre-Implementation Activities (Objective 1). To be completed during Months 1-12.

(a) Engage District Hospitals as Implementation Sites. There is a great enthusiasm among our partner LeBoHA about participating in this project and we do not anticipate difficulty recruiting participants to use Gabby in all 10 district hospitals in Lesotho (see letter of support).

(b) Conduct Focus Groups to Inform System Adaptation. In month 3, we will conduct two focus groups comprised of FMSTP registrars and Family Planning nurses at two district hospital sites. In month 7, we will conduct one focus group in the Berea district with Community Health Workers from two health centers and another with system end-users. The groups will obtain formative feedback as the system is developed to (1) adapt the system content and dialogue, (2) support the iterative cultural enhancement of the system, and (3) provide a real world check of the system logic, dialogue, content, character's appearance, comfort level and usability from the perspective of actual participants. Focus groups will contain between 6-10 participants held in a private room at the Leribe and Butha-Buthe district hospitals. Sessions will be co-facilitated by Boston University and LeBoHA staff (see Appendix A). All focus groups will be audio recorded and transcribed verbatim by a professional transcription service. Grounded theory techniques will be used to analyze interview data. Content categories, patterns, and themes will be identified across the interview data, and supporting evidence from transcripts will be reviewed with research team members to corroborate these findings.

(c) Adapt Existing Gabby Risk Assessment and Dialogue. Using information from the focus groups, in months 3-7, we will: (1) prepare design specifications for software development, (2) adapt intervention dialogues; (3) modify the risk assessment tool (see Appendix B) to include screening for those conditions most relevant to Lesotho that will include a greater emphasis on HIV and other STIs, tuberculosis, healthy eating, importance of ongoing medical care, healthy relationships, among others as finalized by the focus groups, (4) adapt the system to deliver individually tailored and culturally-appropriate health promotion messages for each risk identified, and (5) test (debugging) the system to ensure that the system works as designed. HIV and TB modules will be greatly expanded to include longitudinal behavioral change techniques along with additional stage of change process measures to inform best practices for HIV and TB risk reduction.

(d) Program Newly Modified Content to Function on Android Devices. Google Android cell phones are the most widely used mobile operating system in Lesotho (64%), surpassing IOS devices four-fold.[2] We will employ a proven methodology for technology development, software management and software management tools. From Months 1-12, the conversational agent program will be ported from the web for use on Android smartphones, and culturally and linguistically tailored for the Lesotho population. The cross-platform Unity-based animation software for the conversational agent will be rebuilt for Androids and integrated with a speech synthesizer integrated into the app on the smartphone as we have previously done.[27] User inputs "widgets" (e.g., menus, checkboxes) will be adapted for the phone. The system will host the dialogue engine, relational database, and application logic on a central server as in the current Gabby system but the new system will exchange dialogue instructions with the server over the wireless link during each turn of the conversation (requiring only a few dozen bytes to be transmitted for each turn of conversation). We previously used this architecture on several exercise

promotion interventions.[28,29] The counseling dialogue content and supporting media (e.g., images, text, charts) for existing Gabby modules will be adapted by reviewing all content with individuals from the target population and revising as needed. The intervention will be developed in English, one of the official languages of Lesotho, which will greatly simplify adaptation of the existing content.

Disseminate the Modified Gabby mHealth Program (Objective 2). To be completed in months 13-21.

(a) Baseline Data Collection. In month 13, we will (1) assess site demographic characteristics; (2) administer adapted versions of the CFIR and RE-AIM instruments in the form of individual interviews (Appendix C). Site characteristics data will be collected via survey links that will be emailed to FMSTP registers and semi-structured interviews will be conducted using the Zoom web conferencing platform.

(b) Staff Training. The Boston based research staff will provide a 6 hour training during a required one week FMSTP monthly training contact sessions at Motebang Hospital via the Zoom network (Month 15). Topics will include: (1) Maternity Outcomes in Lesotho and Preconception Care; (2) What is Gabby and How Does it Work; (3) How to Introduce Patients to Gabby; (4) How to Conduct the Gabby Risk Assessment; (5) How to Assist Patients to Reduce Health Risks Using the "My Health To Do List"; (6) Tips and Challenges to Using Gabby on a mobile device; and (7) Data Collection/Reporting.

(c) Recruitment. In month 14, the FMSTP registrars will recruit 20 women from each of the 10 district hospitals for a 200 of total participants. Inclusion criteria are: (1) female resident of Lesotho; (2) age18-28 years; (3) English speaking; (4) have access to an android smartphone with internet or Wi-Fi access (e.g., hospital, at home, school, local library); and (5) are not pregnant. Each district hospital site will have a separate administrative page on the Gabby server where women will be enrolled with a unique username and password.

(d) Implementation Roll Out. In months 14-16 women will be asked to use Gabby for three months and to discuss the relevant content areas identified by the risk assessment. Gabby will track progress and cross off risks once resolved. We will encourage FMSTP registrars to meet with participating women twice during the time they are using the system to discuss the health risks triggered and interventions suggested by Gabby.

(e) Learning Communities and Support. The Boston based teams will be available for telephone support during weekdays for any implementation issues that arise. Each month during implementation, the Boston team will organize a one hour "Learning Community" webinar using the Zoom web conferencing designed for registrars and interested staff at the district hospitals. The webinar will provide tips that we have learned and provide facilitated discussion among sites about what works and challenges faced.

Implementation and Effectiveness Outcomes (Objective 3). To be completed during months 22-24.

(a) Principles Guiding Evaluation. The evaluation will begin from the time that we initiate engagement with the implementation partners and continue throughout implementation efforts. The evaluation is guided by the 6-step framework described by the CDC.[30]

(b) Evaluation of Implementation Outcomes. Four implementation outcome measures as described by Proctor[31] will be assessed to measure the uptake of implementation. During Months 21-22, we will explore the (a) acceptability of the intervention by focusing on the perceived satisfaction of site staff and end-users, (b) adoption, or the intent for staff to utilize the intervention as part of clinical workflow, (c) appropriateness, or the perceived fit and compatibility of the intervention with the population served, and (d) feasibility, or ease of use of the intervention. The evaluation of implementation outcomes will be a mixed-methods design consisting of process and formative measures designed to capture performance and practice change, organizational characteristics, and dynamics that influence implementation efforts.

(c) Qualitative Data for Implementation Outcomes. We will conduct pre- and post-implementation interviews and focus groups with health care providers and patients from all 10 district hospitals in

Lesotho to characterize the experience from the perspective of both the provider and patient. We will use a semi-structured interview guides to facilitate a 30-60 minute interviews and focus groups either in-person or via the Zoom web conferencing platform, a method shown to be acceptable for qualitative data collection among geographically dispersed participant populations.[32] Interviews and focus groups will be conducted in English.

Pre-implementation individual interviews will focus on assessing implementation outcomes including site readiness for adopting Gabby, how well FMSTP registrars think Gabby will fit within the district hospital (appropriateness), barriers and facilitators influencing patient and district participation (feasibility and acceptability), and preliminary plans for how Gabby will be used at the end of the study period. We will use a semi structured interview guide modified to include elements from the CFIR Interview Guide and RE-AIM planning tool to guide individual interviews in person (see Appendix C).

Post-implementation focus groups will be conducted with 6-10 patients from each of two district hospital sites. We will ask users to share their perceptions about their Gabby experience including the risk assessment and educational content included in the system, usefulness of the system's features, tools, and resources, engagement, ease of use, and the benefits and challenges of interacting with Gabby (see Appendix D).

Analysis of Qualitative Data. With participant consent, interviews and focus groups will be audio recorded. All interviews will be transcribed verbatim and assigned identification numbers to ensure anonymity. Interview transcripts will be reviewed by a research team member for transcription accuracy and to remove any identifying information. Two research team members will jointly analyze initial interview transcripts using open coding strategies and a coding dictionary. During biweekly team meetings new codes will be discussed, existing codes will be revised, and supporting transcription data will be reviewed to reconcile any coding discrepancies. This iterative process will be repeated until saturation is met which will be identified when no new codes arise and all definitions in the coding dictionary meet consensus.[109] Axial coding will be used to sort and categorize these open codes into specific domains and themes. Constant comparative analysis will be used to examine common domains and themes across interviews, and specific domains will be selected for further analysis. NVivo 10 software will be used to manage all of the transcription data during analysis (QSR International Pty. Ltd., Melbourne, Australia).

(d) Quantitative Data for Implementation Outcomes. Implementation outcomes will include *Site Demographics and Characteristics* collected through RedCap surveys that will allow our team to investigate the association between the demographics of sites and higher levels of implementation success among sites; *Site-level Technical Assistance logs* maintained by our research team in order to track commonly encountered technical issues, document the appearance of any system bugs, and estimate the time spent identifying and resolving problems; and *Client usage data from the server interrogation* records participant-level information, including number of logons for each client enrolled, minutes of system usage per logon, and all responses to dialogue or decisions within the system, including risks chosen to discuss.

(e) Evaluation of Effectiveness Outcomes. The second portion of our evaluation focuses on assessing the clinical effectiveness of the Gabby mHealth program in Lesotho. Clinical effectiveness data include: (1) Using de-identified data derived from the Gabby server, we will identify Health Risks from the risk assessment that were triggered by all women when they first log-on to Gabby. The definitions of how risks are defined and what responses trigger each risk are defined in appendix B. The distribution of risks will be compared among district hospitals. The frequencies of risks triggered will be compared to other populations (e.g., *Healthy Start* participants, college students) who have completed the Gabby risk assessment in the past. Also using de-identified data derived from the Gabby server, we will collect the Baseline and Follow-up Stage of Change Data collected by Gabby as part of the system dialogue for each risk triggered by a women in the risk assessment. Follow-up stage of change data will allows us to track

progress (or regression) in the changes associated with each health risk (e.g., folic acid use, minutes of daily exercise, number of cigarettes smoked per day). We will analyze of Stage of Change data by calculating the proportion of women who have (1) advanced to the maintenance stage, and (2) progressed from pre-contemplation, contemplation, preparation, and action to a higher stage, that could be one or more steps. The former represents the type of measures that have been typically employed as outcome measures for studies focusing on individual risk factors. The latter is more sensitive, but not been widely employed in previous research.

Disseminate the Results. (Objective 4). In months 23-24, we will disseminate our results to the information technology, health services, global health and public health research and policy communities through presentations at national and international conferences and interviews with journalists and consumer publications including those in low income countries, and academic publications in peer reviewed journals.

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