PLUS Application

Project Proposal and Mentoring Plan Example #2

Submission Year: 2019

Background:
Vaccine preventable diseases account for 30% of under-five mortality. Nigeria ranks 6th amongst countries with poor under-five mortality and it has one of the lowest immunization rates worldwide. In 2017, 37% and 40% of Nigerian children aged 12-24 months were under- and unvaccinated respectively. Innovative, cost-effective, region- and country-specific interventions are urgently needed to meet the 2020 Global Vaccine Action Plan targets.

We developed a mobile software program that is both a digital vaccine registry and an automated phone call and text vaccine reminder system. In a randomized controlled trial (RCT) conducted in Ondo State, Nigeria, immunization completion and timeliness were significantly improved by the automated immunization reminder system. (ClinicalTrials.gov Identifier: NCT02819895). Other mHealth interventions like real-time phone call reminders, or automated text reminders plus incentives have also been shown to improve vaccine completion in Sub-Saharan Africa. However, these interventions only address lack of awareness.

Results from our RCT and other study show that supply side (26%) factors [lack of actionable data, vaccine stock-out, poorly directed vaccine outreach programs] and demand-side (74%) factors [lack of awareness, poor access to clinics, mistrust or fear of vaccines, lack of time or other family commitments] are barriers to receiving vaccines.(2) Unfortunately, the current immunization service system is unable to address the majority of these barriers. For example, paper based charting limits the ability to identify children who miss, are due for immunization or those who would benefit from immunization outreach programs, or a real time phone call to reassure parents of the benefits and safety of vaccines.

Mobile health (mHealth) is the application of mobile technologies to support and enhance clinical and public health performance. mHealth can support local health systems lead innovations to overcome immunization uptake (demand-side) and delivery (supply-side) barriers. For example, a digital immunization registry with a dashboard that displays patients due or late for vaccine could help clinic staff prepare clinic or outreach session respectively. Likewise, tools to compare upcoming vaccine schedules and vaccine stock could address supply side barriers encountered. However, studies on how to implement these tools into existing health systems to overcome “last mile” are lacking.

Our long-term goal is to reduce the proportion of under- and unimmunized infants in Nigeria by using evidence-based mHealth interventions, applied in a tiered fashion, to strengthen the immunization delivery system. However, there are limited frameworks for evaluating immunization service outcome and service delivery. Furthermore, the factors that will impede or promote implementation success are poorly understood. By conducting this research-to-practice study, we will develop a deeper understanding of the current policies, identify gaps and create solutions to overcome these gaps. **Our objective** is to develop a generalizable model for implementing and evaluating evidence-based mHealth interventions into the existing health systems in Ondo State, Nigeria. **Outcomes** from this research would be instrumental in

disseminating best practices to other parts of Nigeria, Sub-Saharan Africa and Indiana given the high infant mortality.

Hypothesis:
Our hypothesis is that current immunization service delivery system at the Ondo State Primary Health Care Development Agency (OSPHCDA) and Primary Health Care Centers (PHC) are not optimized and the deficient areas can be greatly improved with interventions supported by available evidence-based mHealth interventions. Guided by an organizational model for innovation implementation, the study will achieve the following **aims.**

1) Conduct a formative evaluation to understand policies, barriers, and facilitators of the local immunization service delivery system.
   a. **Outcomes:** i. a finalized framework and tool to identify gaps in the immunization uptake and delivery process and ii. develop an implementation strategy and outcome package to evaluate the implementation.

2) Using findings from Aim 1, tailor an implementation bundle supported by mHealth to address identified barriers to vaccine uptake and delivery.

3) Pilot and evaluate the final bundled implementation strategy, assessing fidelity and reach (effectiveness) of the strategy.
   a. **Outcomes:** i. fidelity to the components of the implementation bundle component, and ii. bundle effectiveness on vaccine completion, iii. Sequential cost-effectiveness of the implementation bundle.

PROJECT DESIGN AND METHODS:
AIM 1: To conduct formative evaluation:
Aim 1 Study Design: We will use the key components of the consolidated framework for implementation research (CFIR) and collaborative requirements development methodology (CRDM) to assess all components of the immunization health delivery system in Ondo State Nigeria.
1. *Who: Ministry of Health, OSPHCDA and Community Health workers. [CFIR outer context]*
How: we will conduct key informant interviews with at least two senior staff personnel.
2. *Who: Providers and parents at the immunization clinic of Mother and Child Hospital Ondo Town, Ondo State. [CFIR inner context and intervention characteristics]*
How: we will conduct semi-structured focus groups discussions
3. W*ho:*

a. Mothers at the post partum ward of Mother and Child Hospital Ondo Town, Ondo State [CFIR People]
   i. How: We will enroll a cohort of mothers, over 2 months, who deliver at the study site and follow them via phone interviews for the first 8 weeks of the newborn's life

b. Site: the immunization clinic of Mother and Child Hospital Ondo Town, Ondo State. [CFIR inner context and implementation process]
   i. How: evaluate current organizational policies, work flow and technological capabilities.

c. The interviews, surveys and process observations contribute to the process of failure risk analysis. This is mapping and identification of points of potential failure. It is essential to

understanding the requirements of synchronization of people, materials and information flow to identify areas where those requirements are likely unmet - points of potential failure. In addition, the data collected from survey will provide us the distribution of each behavior patterns from providers and parents, which will be used as inputs in the simulation model to evaluate intervention strategies and program design.

DATA ANALYSIS:
We will use a deductive analytic approach based on the CFIR framework in tandem with an inductive approach based on grounded theory. The study team will hold intensive coding sessions early in the project and use an iterative process to further refine interview questions, codes, and determine themes. All interviews will be audio recorded, transcribed, double checked, and entered into Atlas-it to help store and facilitate access to data for coding and analysis. A preliminary code list based on the components of CFIR will be developed. We will conduct ongoing analyses of transcripts, coding with these preliminary codes, and adjust interviews based on early results; however, the lead questions will remain the same.

We will use an inductive, interpretive approach that borrows concepts from analyses used in grounded theory(9) and other qualitative techniques(10,11) to identify and explore areas not covered by CFIR. Observations will be summarized by research staff in written form for analysis. Through an iterative, consensus-building process, we will review the transcripts and written observations to identify emergent themes related to barriers and facilitators of implementation, consistent with techniques described by Crabtree and Miller.(11) Initially, one international and local Co-PI will independently read responses. We will hold regular (in person and phone) meetings to discuss our findings and revise our codes accordingly. We will repeat this process on fresh sets of survey responses until we have a set of defined codes. Once we have a defined set of codes, we will code the blocks of responses independently, with approximately 20% in common to maintain inter-rater reliability. Results from the site evaluation, Change Process Capability Questionnaire and the adapted technology acceptance model will inform the implementation phase.

AIM 2: Create an implementation bundle supported by mHealth interventions:
Based on findings from aim 1, through an iterative process, we will redesign our implementation bundle supported by mHealth interventions for the implementation context as evaluated in Aim 1 and, when required, create new mHealth interventions.

AIM 3: Pilot Implementation
We will pilot the implementation bundle along with the designed operations/workflows in a single study site. The PHC at Mother and Child Hospital, Ondo Town, Ondo State, Nigeria. This will be in close collaboration with the OSPHCDA.
Study Subjects: We will recruit, consent, and enroll patient volunteers when they present for their first immunization clinic visit. We estimate enrolling 800 subjects from the study site PHC over an 18 month period. These subjects will receive the implementation bundle and be surveilled to two study end points 14 weeks (the global bench mark for vaccine reporting − receipt of the 3rd dose of the pentavalent vaccine based on the Nigerian routine immunization schedule) and 12 months (the completion of the vaccine series). Although recruitment of patients prior to first immunization would be ideal in a larger study, our previous work indicates that greater than 95% of families attend their first immunization clinic – completion of vaccination protocols is where the need for vaccination supports emerges.
Data Analysis: Data on fidelity, barriers, and facilitators in utilizing the registry by clinic staff at

the PHC and by administrative staff at the OSPHCDA. We will compare the proportion of infants completing the Penta 3 and all prescribed immunizations to the state average (75%) and the site average (85% based on findings from our completed RCT) prior to our pilot. We will perform sequential cost effectiveness of each component of the implementation bundle.

MENTORSHIP PLAN:
Mentoring Committee: I will meet with my mentoring committee every 6 months to secure career
advice and guidance for my research project. Each panel meeting will use the following format: (1) I will write an agenda and updated timeline, (2) I will update the panel on my progress and plans for next steps, (3) I will receive immediate verbal feedback from the panel, and (4) I will write up minutes and distribute them to all members for approval and feedback. All members of the panel have agreed to review manuscripts and grant proposals generated by this project.

Mentors and Collaborators:
XXXXXX* MD (IU) is a senior medical informatics researcher whose research interests include informatics interventions in resource-constrained environments, decision support systems and open communities of practice. He is very active in international health information architecture development efforts, both through his leadership of the World Health Organization (WHO) Collaborating Centre in Medical Informatics and in the formation of a new adaptive technical assistance community that supports national planning and implementation of health information sharing architectures (OpenHIE). Dr. XXXXXX helped write the Nigeria eHealth policy. He also is providing technical informatics assistance to the software program.

YYYYYY* PhD (Purdue U) is the Academic Director of LASER PULSE Consortium funded by USAID and the Associate Director of ACME* Center for Healthcare Engineering. She is a senior researcher in the area of healthcare system engineering and her research interests include workflow design and process mapping, system integration and modeling, and decision modeling. She is very active in health research that engages community partnership and international development. She has experience in designing, implementing, and deploying IT solutions and interventions using the integrated system approach in US as well as lower- and middle-income countries. Her most recent development of E+ Health, funded by Melinda and Bill Gates Foundation, is being field tested in Uganda. This technology is specifically designed considering the limited infrastructure and resources in the district health centers to provide the linkage between the patient records and medical supply chains to improve maternal health. Dr. YYYYYY* is an ABCDE* Fellow and FGHIE* Fellow.

ZZZZZZ* PhD (IU): Dr. ZZZZZZ* is an ACE* Investigator in the Institute's Center for Health Services Research, Associate Director for the VA Center for Health Information and Communication, Research Director for the ACT Center of Indiana (Ash* Signature Center), and Associate Research Professor in the Birch University* Psychology Department. She brings expertise in qualitative and implementation science research, including extensive experience with policy development, fidelity measurement, and real-world implementation of evidence-based mental health services.

DDDDDD* MD (IU) is a senior medical informatics researchers whose research interests include informatics interventions in resource-constrained environments, decision support systems and open communities of practice. He is one of the founders of OpenMRS, a software platform and a reference application which enables design of a customized medical records

system with no programming knowledge (although medical and systems analysis knowledge is required). Dr. DDDDDD* has been involved in the design and development of computer applications for medicine at Maple* Institute for nearly four decades with a focus on physician order entry. He helped create the Ginko Order Entry system*, one of the premier computerized physician order entry systems. He has extensive programming experience, is board-certified in clinical informatics and continues to practice medicine as a board-certified general internist while mentoring medical residents and informatics fellows.

*Names of individuals and organizations have been changed.