STUDY PROTOCOL

Determinants of technology use for a mobile health intervention across public health facilities in rural India: Protocol for implementation research [version 1; peer review: 3 approved with reservations]

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Abstract
This paper presents a research protocol for implementation research (IR) to investigate contextual factors influencing the implementation of ASMAN mobile health intervention and their association with maternal, newborn, and child health outcomes. The IR will cover roughly 16-20 public health facilities across the states of Rajasthan and Madhya Pradesh in India. These facilities will be a sub-sample of 49 facilities covered separately under the outcome evaluation. The study employs a longitudinal mixed-methods multiple case study design with sequential data collection using constructs under the Consolidated Framework for Implementation Research (CFIR) across two phases. The first phase will be exploratory and use qualitative inquiry to contextualize the CFIR constructs. The second phase will employ a mixed-methods explanatory design with both validated and contextualized CFIR constructs and standard quantitative measures collected through outcome evaluation. Findings from this study will provide insights into factors that facilitate or impede the implementation of mobile health interventions and their association with MNCH outcomes in public health facilities in India.

Keywords
mHealth, implementation research, mixed-method sequential design, MNCH, CFIR

Open Peer Review

Reviewer Status ? ? ?

Invited Reviewers
1 2 3

version 1
14 May 2020

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Introduction
In India, the increased coverage of institutional births has not successfully translated to proportional improvement in maternal mortality rate (MMR) and newborn mortality rate (NMR) (Patel et al., 2015). Evidence suggests challenges of inadequate service availability and facility readiness, along with poor quality of care at public health facilities continue to plague the public health system and impede the desired reduction in NMR and MMR (Friberg et al., 2010; Jayanna et al., 2014; Kaur et al., 2019; Rudan et al., 2010). India has also taken steps to combat NMR and MMR by increasing the investment in its public health apparatus such as; capacity building of healthcare providers, operationalizing healthcare facilities for providing 24x7 basic and comprehensive obstetric care services, name-based web enabled tracking of pregnant women to ensure antenatal, intra-natal and postnatal care, to name a few (GoI, 2014; Press Information Bureau, 2014). Among the multiple strategies for reducing NMR and MMR, use of Information and Communication Technology (ICT) interventions have emerged as a promising solution (Howitt et al., 2012).

India, as has the world, is undergoing an increasing development of ICT solutions for health care access and delivery (Bodavala, 2002). Mobile health (mHealth) interventions, a specific example of ICT led solutions, supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices (Kay, 2011; mHealth: new horizons for health through mobile technologies., 2011) offer new opportunities for alleviating a range of global health challenges including Maternal, Newborn and Child Health (MNCH) outcomes (Tamrat & Kachnowski, 2012). These interventions may focus on the demand-side influencers, such as client education and behaviour-change communication, or on service delivery personnels, such as health workers at the facility or community level (Abejirinde et al., 2018; Labrique et al., 2013).

Several mHealth interventions have been introduced to improve MNCH outcomes across low and middle-Income Countries (LMICs) (Martinez et al., 2018; Ruton et al., 2018). The Alliance for Saving Mothers and Newborns (ASMAN) program is one such mHealth intervention. ASMAN, a partnership between the Reliance Foundation, Bill & Melinda Gates Foundation, MSD for Mothers, Tata Trusts and The United States Agency for International Development (USAID), was established in 2017 with the objective of improving maternal and neonatal health outcomes across the two northern states of Rajasthan and Madhya Pradesh ((ASMAN), 2019). These two states were chosen due to persistent levels of high NMR and MMR than national average. ASMAN aims at capacity building and use of technology that enable health care workers to improve their performance and provide quality care for intrapartum and early new-born care at selected public health facilities in two states. The ASMAN intervention is implemented by a consortium, with Jhpiego as the implementer of ASMAN activities in public healthcare facilities, Avalon2 and Bodhi3 developing the digital content and application for PDAs, and Sambodhi4 conducting the external evaluation.

The ASMAN digital platform is a PDA-based (digital tablet in this case) intrapartum and immediate postpartum decision support tool for staff nurses across 81 public health facilities in Rajasthan and Madhya Pradesh. The nurses use this platform to enter real-time data on digitized maternity case sheets that also include a Safe Childbirth Checklist along with provision for vital digital recording. Also, alerts and notifications inform staff about high-risk cases so they can receive timely support. A live dashboard helps health workers and managers monitor all cases in real-time, identify and manage high-risk cases, refer cases to higher centers, and make urgent decisions if necessary. Continual learning that makes use of game-based case scenarios and e-learning modules is also included to keep the nursing staff informed and equipped to handle complicated cases. The final component of this intervention includes setting up remote support centers where specialist doctors help advise or confirm a health worker’s choice of intervention in case of a complication.

There is limited empirical evidence on the effectiveness of mHealth interventions and research often does not investigate the mechanism of action behind the successful adoption of mHealth interventions and its association with positive patient outcomes (Damschroder et al., 2009; Kaplan et al., 2010; Marcolino et al., 2018). A multi-country review found that while mHealth interventions have shown to have positive effects on health outcomes, the “how” behind a successful intervention remains unclear (Cresswell et al., 2013). In the case of India, while mHealth interventions implement technology-enabled solutions, the determinants of their uptake and interaction with public health functionaries at the facility remains unexplored.

A systematic review of mHealth evaluations in India recommended implementation research (IR) as a pragmatic approach to unpacking the black box of mHealth interventions in India (Bassi et al., 2018). IR offers a robust set of tools that are useful in understanding this complex intervention and investigate questions concerning implementation, specifically the act of carrying an intention into effect (Peters et al., 2014; Sturke et al., 2014). The study proposes to conduct IR for ASMAN intervention with the aim to understand the role of contextual factors associated with implementation and adoption of mHealth interventions along with studying the public health care provider’s interactions with technology. The IR will also explain the findings from a separate outcome evaluation for ASMAN intervention. The outcome evaluation will collect quantitative data on knowledge and skill of healthcare workers,

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1 Jhpiego, India. Website: https://www.jhpiego.org/countries-we-support/india/
2 Avalon Information Systems Private Limited, India. Website: http://www.avaloninfosys.com/
3 Bodhi Health Education, India. Website: https://bodhihealthedu.org/
4 Sambodhi Research and Communications Private Limited, India. Website: http://sambodhi.co.in/
and intrapartum and newborn practices in the public health facility.

**Research objective**

The primary objective of the IR study is to investigate the determinants for mHealth uptake in public health facilities in India. Specifically, the IR study aims to answer the following research questions:

1. What are the contextual factors influencing the successful implementation of the ASMAN intervention in a public health facility?
   a. How was the digital technology implemented in each facility, and how did the implementation process vary by facility type?
   b. What is the extent of digital technology implementation and use in each facility, and how does its implementation and use vary by facility type or across states?
   c. What are various factors that influence the implementation and use of technology and the difference across facilities and states?

2. What are the types of facilitators and barriers and how are they associated with improved intrapartum and newborn care practices?

**Interventions to be measured**

The IR aims to assess the implementation dynamics behind all the mHealth intervention activities under ASMAN (Figure 1). Specifically, the IR will investigate the mechanism of action and nuanced interaction between public healthcare service providers and ASMAN interventions such as digitized case sheets, digital vital's recording, remote call-center support, technology learning aids, audio-video tutorials and game-based learning. The IR will also attempt to triangulate the insights with quantitative findings on MNCH outcomes from the separate outcome evaluation.

**Methodology**

The study proposes a longitudinal mixed-methods multiple case study design with the facility as a unit of analysis to answer the research questions. Case study methods are well-suited for studying implementation processes, which tend to be fluid, non-linear, and context sensitive (Ferlie et al., 2005; Van de Ven et al., 2008). In addition to permitting in-depth analysis of individual cases, case study methods offer analytic strategies for systematically comparing patterns observed across cases (Miles & Huberman, 1994; Yin et al., 1978).

The study will use the Consolidated Framework for Implementation Research (CFIR) as the theoretical guide of measures within the ambit of the design. CFIR is a meta-theoretical

![Figure 1. Processes and intended results for ASMAN intervention.](image-url)
framework and includes constructs from a synthesis of existing implementation theories. CFIR is primarily a determinant framework used to understand and/or explain influences on implementation outcomes (Nilsen, 2015). It offers an overarching typology—a list of constructs to promote theory development and verification about what works, why, and where across multiple contexts (refer to Table 1) (Damschroder et al., 2009). CFIR provides a comprehensive general structure for unpacking the complex process of real-world implementation across multiple settings, multiple levels, and multiple phases. At the same time, the use of CFIR can be highly flexible and promotes the selection and use of constructs from within the CFIR that are most relevant for the study settings (Damschroder et al., 2009).

But the CFIR constructs are yet to be contextualized to the Indian setting. Using the longitudinal mixed-methods multiple case study design, the study will collect data sequentially across two phases. In phase 1 of data collection, the study will assess health facilities, using CFIR as a theoretical guide, identifying factors that influence the implementation of ASMAN intervention. In phase 2, health facilities reporting common factors will be followed up to re-confirm the validity of identified factors and their association with MNCH outcomes. Together, the design components will give us a more comprehensive understanding of the unexplored domains of contextual factors influencing the implementation of ASMAN intervention. The design will also align with timelines for the concurrent outcome evaluation.

**Sampling plan and participants**

Under the ambit of longitudinal multiple case-study design, the study will select public healthcare facilities that are a part of ASMAN intervention and assess them across two rounds of data collection. Overall, the study will cover 8 to 10 ASMAN-implementation districts, and 16 ASMAN-implementation public healthcare facilities across Rajasthan and Madhya Pradesh. A separate outcome evaluation of 49 ASMAN-implementation public healthcare facilities in the same districts, conducted earlier in 2019, will act as the sampling frame for choosing the facilities. The study will adopt a three-step process for facility selection to ensure the representativeness. First, the study will use quantitative results of the 49 facilities on health outcomes as the sampling frame. Second, 16 facilities (8 facilities from each state) will be selected purposively based on their performance in health outcomes. Third, the study will use quantitative results of the 49 facilities on health outcomes as the sampling frame. Second, 16 facilities (8 facilities from each state) will be selected purposively based on their performance in health outcomes. Third, the study will also try to ensure representativeness among facilities, by selecting 2 District Hospitals (DH), 2 Sub-District Hospitals, 2 Community Health Centers (CHCs), and 2 Primary Health Centers (PHCs) in each state (refer to Table 2). Thus, we plan to adopt a maximum variation sampling in order to capture the heterogeneity of facilities and stakeholders and make it more representative of target groups. In phase 1, the selected 16 facilities will be assessed to help contextualize CFIR. Phase 2 will follow up with the same health facilities from phase 1 using the contextualized CFIR constructs and answer the overall research questions.

The study will conduct in-depth interviews (IDIs) with healthcare providers in the selected public health facilities.
data collection will include staff nurses, labor room in-charge, and medical officers or head of the department, previously covered under the outcome evaluation and depending on their availability at the time of interview. Healthcare providers who have not been covered in the previous outcome evaluation will be excluded from the study. Overall, the study plans to conduct 30 to 38 interviews (refer to Table 1). We also plan to interview the program managers at district and state level in the respective state governments (refer to Table 3). From the funding partners, the study will conduct IDIs with the Program Management Unit of ASMAN. From the implementation partners, the study will interview program teams at Jhpiego, Avalon, and Bodhi (Refer to Table 3). Remote Support Center staff will also be interviewed to gain an understanding of their perspective on the ASMAN intervention. We anticipate about 60–65 participants to participate in each phase, although the precise number will be dependent on attaining saturation in addressing the research questions. The qualitative interviews conducted under IR will be supplemented by quantitative interviews with the same participants under the previous outcome evaluation. The survey instrument used during the outcome evaluation will include direct observation of delivery in within the health facility’s labor room, infrastructural assessment of the health facility, and provider’s frequency of using ASMAN technology on a 5-point Likert scale. The outcome evaluation also included the Health ITUES questionnaire consisting of 20 questions rated on a 5-point Likert scale, comprising of four sub-scales: (1) quality of work life, (2) perceived usefulness, (3) perceived ease of use, and (4) user control of the ASMAN technology (Schnall et al., 2018).

**Measures**

The CFIR will guide the IR from an implementation perspective. CFIR is a meta-theoretical framework synthesizing 19 multidisciplinary theories, several frameworks, and 37 constructs used in dissemination and IR. Relevant constructs under CFIR will be used to collect data from the selected health facilities. Since the CFIR constructs lack contextualization to the mHealth context in India, the study uses phase 1 to harmonize them with the ASMAN intervention. In phase 1, the study will develop qualitative interview tools based on CFIR constructs and tailored based on the participant’s roles and responsibilities. Table 4 summarizes some of the key domains and relevant constructs as per the CFIR. The key areas of inquiry for phase 1 is provided in Table 5. In phase 2, the study will employ a mixed-methods explanatory design to re-assess the same health facilities on the contextualized constructs that have emerged as significant influencers of the implementation during phase 1 (Creswell et al., 2004; Ivankova et al., 2016). The survey will attempt to follow the same respondents in the health facilities. The key areas of inquiry for phase 2 of the study will be developed using findings from phase 1.

From the quantitative side, phase 2 will borrow findings from the outcome evaluation measures and documentary evidence such as intrapartum and newborn practices, facility infrastructure, and readiness, knowledge and skill of healthcare providers, and the motivation of healthcare providers and their perception of work climate.

**Ethical considerations**

Sigma institutional review board, a third-party ethical oversight agency in India, has reviewed and approved the study. All ethical guidelines mandated by Sigma will be followed strictly through the study. Apart from these, the study will seek necessary approvals from participants, state and health departments, and other relevant departments before and during the study rollout. Participants will be assigned random identification codes and will not be identified by their names or any other demographic detail. All information regarding the IR will be disclosed to participants and guardians via an informed consent form before collecting data. A set of trained research investigators will procure the consent. Data collected from the participants will be kept confidential and will only be accessed by researchers for analysis.

**Data analysis plan**

The study aims to identify determinants of mHealth interventions by attempting to arrive at literal and theoretical replications. Multiple case study design can be used to either predict

<table>
<thead>
<tr>
<th><strong>Table 3. Number of interviews with other stakeholders.</strong></th>
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<tr>
<td><strong>Respondents</strong></td>
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<tr>
<td>District Program Managers</td>
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<tr>
<td>State Program Managers</td>
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<tr>
<td>Implementing partners</td>
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<tr>
<td>Funding partners</td>
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<tr>
<td><strong>Total IDI’s in Both States</strong></td>
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<th><strong>Table 4. Consolidated Framework for Implementation Research constructs.</strong></th>
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<td><strong>Individual characteristics</strong></td>
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<tr>
<td>-Self-efficacy</td>
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<tr>
<td>-Age</td>
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<tr>
<td>-Education</td>
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<tr>
<td>-Knowledge and beliefs about the intervention</td>
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</tbody>
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similar results (a literal replication) or predict contrasting results but for predictable reasons (a theoretical replication) (Yin, 2014). First, the study will conduct a thematic analysis using framework method to analyze the qualitative data captured through IDIs (Gale et al., 2013). The study will employ pattern-matching logic to guide the data analysis (Yin et al., 1978). The qualitative data will lead to a starting list of codes, supplemented with emergent codes as analysis proceeds. Then a within-case analysis of each public health facility in a state will be conducted to assess the degree to which the construct emerges in the data (its “salience”) and positively or negatively affect implementation (its “valence”). The study will also check for construct strength and valence between cases (across facilities in both states). Putting together the results, the within-case analysis of salience and valence will help us identify which contextual factors from the CFIR operate as potential barriers or facilitators to implementation and use.

The within-case analysis will be followed by a between-case analysis to investigate how those potential barriers and facilitators vary by facility type and state. The cases (facilities) will be arrayed into a 3x2 table with facility type by state. Using replication logic, each case will be treated as if it were an experiment where the conditions are either intentionally repeated from one case of the next, or systematically varied. Literal replication occurs when cases in the same cell exhibit similar patterns for theoretically predictable reasons (i.e., they are the same facility type and state). Theoretical replication occurs when cases in different cells exhibit similar patterns for theoretically predictable reasons (i.e., they differ by facility type or state or both). This analysis will indicate whether identified barriers and facilitators are unique to specific cases, common to similar cases, and different among different cases.

Phase 2 will investigate the relationship between contextualized CFIR constructs and MNCH outcomes in the public health facility collected via outcome evaluation, articulated in research question 2 under research objectives. The study will test the hypothetical relationships by using three criteria proposed by Trochim (Trochim, 2007) and Miles and Huberman (Miles & Huberman, 1994). The first criterion will look for the overall covariance of the constructs (e.g., whether facilities exhibiting a strong implementation climate for mHealth also exhibit high implementation effectiveness or positive patient outcomes, i.e., accrual). The second criterion will look for explicit attributions or the identification of plausible mechanisms to link the two constructs (e.g., participants attribute a strong implementation climate to the deployment of appropriate implementation policies and practices). The third criterion will look for indications of temporal precedence for the hypothesized relationship. In this, the study will rely primarily on documentary evidence for establishing temporality but will also consider participants’ accounts of the sequence of events. Together, the study will apply the three criteria across the cases to determine if cross-case variation in implementation is consistent with the hypothesized relationships in the model.

Table 5. Key areas of enquiry.

<table>
<thead>
<tr>
<th>Respondent Group</th>
<th>Key areas of enquiry</th>
<th>Data Collection Tool</th>
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<tbody>
<tr>
<td>Funding Partners, Program Management Unit, Implementing Partners.</td>
<td>1. How was the ASMAN intervention conceptualized?</td>
<td>Quantitative survey from Outcome Evaluation</td>
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<tr>
<td></td>
<td>2. What were the triggers and challenges faced by both the states that influenced the intervention design?</td>
<td>Qualitative Interviews</td>
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<td></td>
<td>3. How has the ASMAN intervention been tailored to fit the local needs of health facilities across both the States and facility level?</td>
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<td></td>
<td>4. How well do you think the intervention will meet the needs of the individuals served by the organization?</td>
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<td></td>
<td>5. What are the factors (internal and external) that influence the roll-out of ASMAN intervention?</td>
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<td></td>
<td>6. In what ways was the implementation process similar/different for different facility levels and across states? Was the implementation training customized as per the facility levels?</td>
<td></td>
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<tr>
<td>Staff Nurse, Labor room in-charge, Medical Officer</td>
<td>7. How satisfied you are with technology innovations for documenting delivery cases?</td>
<td>Qualitative Interviews</td>
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<td></td>
<td>8. How has ASMAN game been a positive addition to clinical training?</td>
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<td></td>
<td>9. To what extent do you agree that using Safe delivery app enables you to remember clinical protocols more quickly?</td>
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<td></td>
<td>10. What are your views regarding quality of the design of the intervention?</td>
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<td></td>
<td>11. How well does the intervention fit with existing work processes and practices in your setting?</td>
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<td></td>
<td>12. What barriers do you face while using the intervention? What additional resources and skills are required to adhere to this intervention?</td>
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<td></td>
<td>13. How confident are you about using the intervention? What gives you that level of confidence?</td>
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Also, the study will create within-case and between-case data displays that cross-tabulate the quantitative and qualitative data to facilitate the use of pattern-matching logic (Miles & Huberman, 1994).

The final product of the analysis will be a theoretically informed and empirically grounded model of organizational mHealth implementation, strongly associated with improved MNCH outcomes.

Discussion

The paper discusses the protocol of an IR study investigating factors that influence the roll-out and adoption of ASMAN mHealth intervention and their association with MNCH outcomes. LMICs globally have attracted investment in mHealth space as a means of alleviating multiple global health challenges, including MNCH (Tamrat & Kachnowski, 2012). In India alone, multiple mHealth solutions have been implemented, aimed at improving healthcare service delivery and patient health outcomes. But despite its programmatic potential, there is a lack of evidence on user acceptability, adoption, and replicability of mHealth solutions (Bassi et al., 2018).

The IR approach aims to unpack the existing heterogeneity within types of public health facilities and across state contexts that are critical to implementing the mHealth solution (Ilozumba et al., 2018). This IR study will identify factors contextual to Indian public health facilities that influence the successful implementation and replication of mHealth solutions such as under ASMAN intervention. Further, the study will investigate whether and how are these factors associated with positive MNCH outcomes.

The IR study has several implications. From an implementation perspective, findings from the study can act as a guide for implementers in public health facilities while introducing technology or inform interim course corrections. From a policy perspective, the findings can contribute to shaping newer perspectives to the designing and evaluation of mHealth based interventions in the Indian context. From a research perspective, the study will add to the existing empirical evidence on mHealth interventions in LMICs in general and India specifically. The findings from the study may also provide the answer to “how” can such interventions be implemented and adopted in different contexts to influence MNCH outcomes.

Limitations

There are several limitations to the methodology. The qualitative interviews to be conducted in phase 1 may not reflect differences across other public health facilities in the entire region. Also, the public health facilities are in northern India and may not reflect the environment in other parts of the country. Another limitation of the study is the possible low construct validity in the selected CFIR constructs. The study will collect a varying number of participants from each health facility based on their availability. Lesser number of participants may affect the construct reliability. For example, too few respondents within a facility may not provide a complete representation of the public health facility.

Data availability

No data are associated with this article.

Acknowledgments

ASMAN program is designed, executed, and funded by 5 development partners-, Bill and Melinda Gates Foundation, MSD for Mothers, Reliance Foundation, Tata Trusts, and USAID. We sincerely thank the Project Management Unit, involved in driving the program interventions for their continuous support and suggestions. We would also like to acknowledge the support provided by the implementing partners - JHPIEGO, Avalon and Bodhi, without whom this project and the study would not have been possible. We also thank the reviewers of this protocol, who helped to improve it with their comments and suggestions.

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Yin R: Case Study Research Design and Methods. 2014. Publisher Full Text

Shefaly Shorey

Alice Lee Centre for Nursing Studies, Yong Loo Lin School of Medicine, National University of Singapore, Singapore, Singapore

Overall well-written paper. Some feedback to enhance the readability of the paper as follows:

1. Please explain all the abbreviations at their first use.

2. Who was the target audience? Only nurses? How about midwives?

3. From the methodology on page 6 it was stated that data were collected via direct observation? But that doesn't seem to be the case? Data were collected via self-administering questionnaires?

4. Measures: The information on CFIR is very confusing. Those 19 theories. 37 construct... are you referring to from your study? If not please provide reference to this opening sentence and provide more information on which constructs were exactly used in this study. You may provide this information via supplementary file.

5. Was the consent taken in written form? Please add this information.

6. The data (qualitative) have been collected from varied care providers. Was there any data triangulation performed?

7. Which framework method was used to analyze the qualitative data?

Hope you will find this feedback useful and I wish you all the best.

Is the rationale for, and objectives of, the study clearly described? Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Women and Child Health with special focus on Technology based Interventions, RCT, Systematic reviews, Multi-Center Trials

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 11 August 2020
https://doi.org/10.21956/gatesopenres.14314.r29269

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Onaedo Ilozumba
Athena Institute, Faculty of Science, Vrije Universiteit Amsterdam, Amsterdam, Netherlands Antilles

The protocol presents an interesting study which has the potential to contribute to the understanding of mHealth interventions, not only in India but other LMICs.

The main comment for the authors is in regards to the proposed data collection. The study intends to unpack the black box and shed light on "successful implementation" of the ASMAN project as well as their association with "MNCH outcomes." Thus it seems that first, a definition of a successful intervention is required. It seems that these might be presented in Fig 1 but they are not made explicit. Based on this definition it might be remiss to have no measures of MNCH outcomes. Secondly, there is no attempt to address the end-users. While the health workers are the relevant target group for questions around adoption. The research study would be strengthened by a more holistic approach to assessing implementation. This one-sided approach might be related to a concurrent outcome evaluation which is frequently mentioned related to this study. In that case it is important to clearly describe how these results will be integrated because the proposed study objectives cannot fully be realised without the integration of adoption, implementation and outcomes.

Additionally, it would be helpful to present more details on the 2019 outcome evaluation sampling
strategy. What health outcomes are the 8 facilities per state selected on? Is the goal to capture maybe well performing and poor performing? How exactly is this also combined with the plan to ensure representativeness among facilities?

Why will this study only interview staff that where previously interviewed? Is there going to be a comparison of results?

It is also not completely clear what exactly will be done in Phase 2 of the study.

**Is the rationale for, and objectives of, the study clearly described?**
Yes

**Is the study design appropriate for the research question?**
Yes

**Are sufficient details of the methods provided to allow replication by others?**
Partly

**Are the datasets clearly presented in a useable and accessible format?**
Not applicable

*Competing Interests:* No competing interests were disclosed.

*Reviewer Expertise:* mHealth, maternal health, evaluation, human resources for health

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
Indian setting. It could prove useful for other implementation research studies on how to use the CFIR. However, it can be made clearer for the reader in the first read itself.

A common method of explaining the pathway to change is to present a Program Impact Pathway with their processes, outputs, outcomes and final goal. Figure 1 requires all these elements to be articulated clearly. CFIR provides the context but not the pathway.

1. The team has articulated in-depth with regards to protocol constructs and its significance, particularly for phase I. However for phase II evaluation methods, what the outcomes are, their definition, at what time points they will be collected, who/how will they be collected and how the data will be managed/monitored for quality and then triangulated with the CFIR context needs to be described.

2. It will be good to write about the reflections of the CFIR contribution on IR. How do you expect it to help specifically? Which components mainly? Since this is a protocol paper, an expectation is harmless to mention.

3. Please justify why specifically CFIR framework was used?

4. Can you please elaborate how CFIR is going to be used throughout the research process, especially analysis? An analysis plan using the framework or certain components of the framework will give more clarity.

As per the generalised requirements on the peer review guidelines, this protocol answers the following question aptly;

- Is the rationale for, and objectives of, the study clearly described? – Yes, except maternal and neonatal practices/outcomes not enumerated.
- Is the study design appropriate for the research question? - Yes.
- Are sufficient details of the methods provided to allow replication by others? – Yes, but a Program Implementation Pathway would provide more clarity.
- Are the datasets clearly presented in a useable and accessible format? – Not applicable.

Additionally the following key questions on implementation research were also considered to assess whether the current research design answers them or not:

1. Does the research clearly aim to answer a question concerning implementation?
   Yes, for phase I of implementation. Phase II needs more clarity.

2. Does the research clearly identify the primary audiences for the research and how they would use the research?
   Yes.

3. Is there a clear description of what is being implemented (for example, details of the practice, programme, or policy)?

A clear description of the main ASMAN study is required to provide a better understanding. Some more clarifications are needed, which have been mentioned in the comments.

1. Does the research involve an implementation strategy? If so, is it described and examined in its fullness?
   Requires some more clarification, which have been mentioned in the comments.

1. Is the research conducted in a “real world” setting? If so, is the context and sample population
described in sufficient detail?
Yes

1. Does the research appropriately consider implementation outcome variables?
This needs some more clarification on the outcome variables for association of MNCH outcomes. Adding a table would be better idea for the list of outcomes, their definitions and time points of data collection in the study. Moreover the terminology used for the “MNCH outcomes” should remain consistent throughout the protocol to avoid confusion. At some places, MNCH outcomes, sometimes intra partum and newborn care practices and somewhere reduced maternal and neonatal mortality has been used and how can child outcomes being assessed, when the intervention is restricted to facility based practices during intrapartum and post partum periods?

1. Does the research appropriately consider context and other factors that influence implementation?
Yes

1. Does the research appropriately consider changes over time and the level of complexity of the system, including unintended consequences?
Outcome evaluation measures that need to be impacted through the IR and adoption of ASMAN PDA should be known a priori to have an unbiased assessment of impact of the intervention. Additional outcome measures may be added after Phase I.

This manuscript can be further improved by specifying whatever has been mentioned in the comments below.

Comments by section:

1) Title:
Comment 1: The title could be more specific to include how and where the intervention is being and for what outcomes. “Determinants of technology use for a mobile health intervention across public health facilities in rural India for intrapartum and postpartum care and their health outcomes: Protocol for implementation research using CFIR”.

2) Introduction:
This paper reviews mHealth interventions in India and its application for Public Health. ASMAN is a PDA solution to assist staff nurses to improve intra and post-partum care.

This paper is a protocol for an IR study for ASMAN intervention with the aim to understand the role of contextual factors associated with implementation and adoption of mHealth interventions along with studying the public healthcare provider’s interactions with technology. The IR will also explain the findings from a separate outcome evaluation for ASMAN intervention. The outcome evaluation will collect quantitative data on knowledge and skill of healthcare workers, and intrapartum and newborn practices (although there is inconsistency in the paper regarding this
outcome) in the public health facilities.

- **Comment 1: Pg. 3, Para 2, Line 6:** For the reference of Kay, et.al, 2011, why is the title mentioned?

- **Comment 2: Pg 3, Para 4, Line 3:** The abstract mentions 49 health facilities, whereas here 81 public health facilities have been mentioned. This needs clarification. Secondly, 16 facilities (8 facilities from each state) will be selected purposively based on their performance in health outcomes. What health outcomes? How will the performance be assessed in an unbiased manner and then categorized? The ASMAN digital platform is a PDA-based (digital tablet in this case) **intrapartum and immediate postpartum** decision support tool for **staff nurses** across 81 public health facilities in Rajasthan and Madhya Pradesh.

- **Comment 3: Pg 3, Para 4, Line 7:** "The nurses use this platform to enter real-time data on digitized maternity case sheets that also include a Safe Childbirth Checklist along with provision for vital digital recording". Does this sentence imply checklist along with provision for digital recording of vitals? Then please rearrange the wordings to make it clear or use words that are not likely to be misunderstood, for vitals also mean RR, HR etc and Vital data may mean important data.

- **Comment 4: Pg 3, Para 4:** The components of ASMAN need to be clarified more elaborately. The reason why the paper may sound a little unclear is because the reader is unaware of ASMAN, its components, what it accomplishes, how, etc. This can be achieved by giving a little background of the intervention. A tabulated description of the ASMAN trial with all its intervention components, who will be responsible for which activity, and what will be the expected of each activity will be helpful to better understand this IR's objectives. It will bring better perspective. A small diagram or figure may also do. It will also put figure 1 into perspective for the reader and not leave them guessing the intervention components. If it includes treatment protocols, then which protocols? Or is it safe childbirth checklist with m-partograph? They are being managed in the facilities. So please describe the services available at DH, SDH, CHC, PHC. Whether they have C section services, blood bank, etc. at facilities higher than a PHC.

- **Comment 5: Pg 3, Para 6, Line 8:** "The study proposes..." It will be helpful to mention CFIR contextual factors instead of just “contextual factors” for the objectives of the study.

- **Comment 6, Pg 4, Line 1:** The abstract states - "This paper presents a research protocol for implementation research (IR) to investigate contextual factors influencing the implementation of ASMAN mobile health intervention and their association with maternal, newborn, and **child health outcomes**." This is inconsistent with the statement in the introduction which states just “intrapartum and newborn practices” and not child health outcomes.

### 3) Research objective:

- **Comment 1: Pg 4:** It will be a good idea to mention CFIR in your objectives since you are using its contextual factors for the IR.
- **Research question 1.a.**
  *How was the digital technology implemented in each facility, and how did the implementation process vary by facility type?*

- **Comment 2: Pg 4:** When the intervention is broken up into its components and the persons responsible for that component then it is possible to understand where the variations occur. For e.g. Different persons are perhaps responsible for these different tasks – “Childbirth Checklist along with provision for vital digital recording. Also, alerts and notifications inform staff about high-risk cases so they can receive timely support. A live dashboard helps health workers and managers monitor all cases in real-time, identify and manage high-risk cases, refer cases to higher centres, and make urgent decisions if necessary”. Who sends the alerts? Who is the implementer here? Will variability in use of the said technology, across various levels of implementers also be studied? If so, that needs to be included in this statement. Who does the training? What about variability in training? How are remote doctors engaged? What is their incentive?

- **Research question 2.**
  *What are the types of facilitators and barriers and how are they associated with improved intrapartum and newborn care practices?*

- **Comment 4, Pg 4:** The improved intrapartum and newborn care practices should be enumerated in the methods section. Fig 1 states maternal and neonatal mortality, which is not the same as intrapartum and newborn care practices. And how will that be evaluated/compared with – a before/after design or comparative across facilities or step wedge design, or difference-in-difference design. How do they vary with the variation in the process measures? This is unclear. The analytical design for the quantitative component needs to be clarified in the research objective, methods and analysis.

4) **Methodology:**

- **Comment 1, Pg 4, Para 1, Line 2:** Is the facility treated as a case or as a unit of analysis? The term should be consistently used. If it is a case-based study and the facility is treated as a case, then it is implied that it becomes the unit of analysis.

- **Comment 2, Pg 4, Para 2:** The explanation on why CFIR as theoretical guide has been used can be explained in the discussion and not in the methods section.

- **Comment 3, Pg 4, Figure 1:**
  i) A detailed Program Impact Pathway that includes the processes and outputs at each phase of implementation research i.e. Development, implementation and evaluation are helpful. Figure 1 needs to be more descriptive regarding the processes and their outputs. ii) Please check the spelling of ‘remote’ and ‘intermediate results’.

- **Comment 4: Pg 4:** A figure depicting the study design is required.

- **Comment 5, Pg 4:** As mentioned earlier, the anticipated (from phase I) improved intrapartum and newborn care practices should be enumerated in the methods section. Fig 1 states maternal and neonatal mortality, which is not the same as intrapartum and
newborn care practices mentioned in the paper previously. And how will that be evaluated/compared with – a before/after design or comparative across facilities or how they vary with the variation in the process measures? This is unclear. The quantitative component analytical design needs to be clarified in the research objective, methods and analysis. Providing the list of variables/indicators of MNCH outcomes, their definition, at what time points they will be collected, who/how will they be collected as a separate table will be a good idea.

- **Comment 6, Pg 5**: Table 1: “Number of Interview of healthcare providers in each state”. This table can be summarized in the text.

5) **Sampling plan and participants:**

- **Comment 1, Pg 5, Para 1, Line 13**: “Second, 16 facilities (8 facilities from each state) will be selected purposively based on their performance in health outcomes.” What were these outcomes? Please explain and how will this performance be evaluated?

- **Comment 2, Pg 5**: Please explain how purposive sampling of previously evaluated facilities doesn’t rule out bias.

- **Comment 3, Pg 5**: Please explain ‘purposive sampling based on performance of health outcomes’. It leads the reader to believe that only well performing or badly performing facilities will be selected, which may not necessarily be the case.

- **Comment 4, Pg 5**: Please explain expected outcomes as a part of the CFIR framework from this protocol.

6) **Measures:**

- **Comment 1, Pg 6, Para 2**: “The CFIR will guide the IR from an implementation perspective. CFIR is a meta-theoretical framework synthesizing 19 multidisciplinary theories, several frameworks, and 37 constructs used in dissemination and IR. Relevant constructs under CFIR will be used to collect data from the selected health facilities.”
  1. The theoretical explanation of what is CFIR and why CFIR has been used is a part of the discussion and not methods.
  2. How it will be used to achieve the objectives of this study will be a part of the methods.
  3. The key areas of inquiry for phase 1 are provided in Table 5. This table can have one more column to explain which construct of the CFIR, the questions will address. This way the contextual triangulation can be explained.

- **Comment 2, Pg 6, Para 4**: “From the quantitative side, phase 2 will borrow findings from the outcome evaluation measures and documentary evidence such as intrapartum and newborn practices, facility infrastructure and readiness, knowledge and skill of healthcare providers, and the motivation of healthcare providers and their perception of work climate.”
  1. This needs to be explained as this is the ultimate goal, to be able to impact maternal and neonatal outcomes. What will be measured (practices or morbidities or mortality), how will impact be defined, what quantitative change the researchers would help validates the success of the implementation? How will the processes and their variation help to explain the outcomes? What analysis will be used to explain these variations?
7) Data analysis plan:

Comment 1, Pg 7: The first phase analysis has been explained well. I am not familiar with analysis that contextualizes the CFIR constructs with quantitative maternal and neonatal outcomes. I am concerned that these outcomes and how they will be analysed with respect to these constructs in not entirely clear, since they are not enumerated. For e.g. Birth asphyxia protocol, skin to skin contact or early initiation of breastfeeding are the neonatal practices. Maternal/neonatal complications at birth are morbidities. Using the CFIR constructs the facilities could be categorized as Excellent, Good, Average, Poor implementers and modelled to assess their impact on a range of the outcomes. Or the impact of each construct of CFIR can be assessed on the outcome. Since the outcomes have not been enumerated it is not clear how this is being analysed.

8) Limitations:

Comment 1, Pg 8: To address the limitation mentioned about low construct validity, why are the authors not considering the idea of interviewing a replacements sample of participants to address the complete representation of public health facility.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Partly

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Maternal and Neonatal health community based trials, M Health, IR, epidemiology research

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.