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]

Vikas Choudhry¹, Bryan Weiner², Prachi Karkhanis¹, Vijay Avinandan¹, Nehal Shah¹, Nupur Bahl³, Rajni Wadhwa⁴, Pompy Sridhar⁵, Dharmendra Chandurkar¹

1Sambodhi Research and Communication Pvt Ltd, Noida, Uttar Pradesh, 201301, India
2Department of Global Health, University of Washington, Seattle, WA, 98115, USA
3Reliance Foundation, Mumbai, Maharaashtra, India
4Alliance for Saving Mothers and Newborns, Mumbai, Maharaashtra, India
5MSD for Mothers, Mumbai, Maharaashtra, India

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
Corresponding author: Vikas Choudhry (vikas.choudhry@sambodhi.co.in)

Author roles: Choudhry V: Conceptualization, Funding Acquisition, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; Weiner B: Conceptualization, Methodology, Writing – Review & Editing; Karkhanis P: Conceptualization, Methodology, Project Administration, Writing – Review & Editing; Avinandan V: Writing – Original Draft Preparation, Writing – Review & Editing; Shah N: Conceptualization, Methodology, Project Administration; Bahl N: Conceptualization, Writing – Review & Editing; Wadhwa R: Conceptualization, Writing – Review & Editing; Sridhar P: Conceptualization, Writing – Review & Editing; Chandurkar D: Conceptualization, Funding Acquisition, Methodology, Project Administration, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: This study was funded by the Bill and Melinda Gates Foundation (Grant ID OPP1083531). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Copyright: © 2020 Choudhry V et al. This is an open access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

How to cite this article: Choudhry V, Weiner B, Karkhanis P et al. 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] Gates Open Research 2020, 4:51 https://doi.org/10.12688/gatesopenres.13128.1

First published: 14 May 2020, 4:51 https://doi.org/10.12688/gatesopenres.13128.1
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 (Gol, 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 personnel, 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, Avalon and Bodhi developing the digital content and application for PDAs, and Sambodhi 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 (Danschroder 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,

---

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 the 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 vitals 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
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 qualitative 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. The

### Table 1. Number of interviews of healthcare providers in each state.

| Facility Type | Number of Facilities | Number & cadre of healthcare providers | Total IDI’s in each facility type |
|---------------|----------------------|----------------------------------------|----------------------------------|
|               |                      | Medical Officer in-charge | Labor Room in-charge | Staff Nurse |                      |
| DH            | 2                    | 1                         | 1                     | 2–3        | 8–10                  |
| SDH           | 2                    | 1                         | 1                     | 2–3        | 8–10                  |
| CHC           | 2                    | 1                         | 1                     | 2–3        | 8–10                  |
| PHC           | 2                    | 1                         | 1                     | 1–2        | 6–8                   |
| Total IDI’s in Each State of Madhya Pradesh and Rajasthan | | | | | 30–38 |

### Table 2. Sampling approach.

| Item                                    | Rajasthan | Madhya Pradesh | Total |
|-----------------------------------------|-----------|----------------|-------|
| No. of ASMAN districts for study        | 4–5       | 4–5            | 8–10  |
| No. of selected facilities for outcome evaluation | 24        | 25             | 49    |
| No. of DH for implementation research  | 2         | 2              | 4     |
| No. of SDH for implementation research | 2         | 2              | 4     |
| No. of CHC for implementation research | 2         | 2              | 4     |
| No. of PHC for implementation research | 2         | 2              | 4     |
| Total facilities for implementation research | 8        | 8              | 16    |
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 3. Number of interviews with other stakeholders. |
|-----------------|-----------------|
| Respondents     | Total Interviews |
| District Program Managers | 2–3 per state |
| State Program Managers | 1–2 per state |
| Implementing partners | 8–10 |
| Funding partners | 2–4 |
| Total IDI’s in Both States | 20–24 |

| Table 4. Consolidated Framework for Implementation Research constructs. |
|-----------------|-----------------|-----------------|
| Individual characteristics | Inner setting | Outer setting | Intervention characteristics | Process |
| -Self-efficacy | -Priority | -Formal and informal support | -Planning |
| -Age | -Workload | -Relative advantage | -Engaging |
| -Education | -Shared understanding | -Source Evidence and strength | -Executing |
| -Knowledge and beliefs about the intervention | -Implementation climate | -Systemic support | -Reflecting & evaluating |
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.
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 site 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 implementa

### 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.

**References**

ASMAN: ASMAN Alliance_Alliance for Saving Mothers and Newborns. 2019. Reference Source

Adejinojo IO, Ilozumba O, Marchal B, et al.: Mobile health and the performance of maternal health care workers in low- and middle-income countries: A realistic review. Int J Care Coord. 2018; 21(3): 73–86. Published Abstract | Publisher Full Text | Free Full Text

Bassi A, John O, Praveen D, et al.: Current Status and Future Directions of mHealth Interventions for Health System Strengthening in India: Systematic Review. JMIR Mhealth Uhealth. 2018; 6(10): e11440. Published Abstract | Publisher Full Text | Free Full Text

Bodvala R: ICT applications in public healthcare system in India: A review. 2002. Reference Source

Creswell KM, Bates DW, Sheikh A: Ten key considerations for the successful implementation and adoption of large-scale health information technology. J Am Med Inform Assoc. 2013; 20(e1): e9–e13. Published Abstract | Publisher Full Text | Free Full Text

Creswell JW, Feltons MD, Ivanikova NV: Designing a mixed methods study in primary care. Ann Fam Med. 2004; 2(1): 7–12. Published Abstract | Publisher Full Text | Free Full Text

Damschroder LJ, Aron DC, Keith RE, et al.: Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009; 4: 50. Published Abstract | Publisher Full Text | Free Full Text

Ferlie E, Fitzgerald L, Wood M, et al.: The nonspread of innovations: The mediating role of professionals. Academy of Management Journal. 2005; 48(1): 117–134. Publisher Full Text

Friberg IK, Kinney MV, Lawn JE, et al.: Sub-Saharan Africa’s mothers, newborns, and children: how many lives could be saved with targeted health interventions? PLoS Med. 2010; 7(6): e1000296. Published Abstract | Publisher Full Text | Free Full Text

Gale NK, Heath G, Cameron E, et al.: Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol. 2013; 13: 117. Published Abstract | Publisher Full Text | Free Full Text
Gol (Producer): Steps Taken by Govt. to Accelerate Pace of Reduction for MMR to Achieve MDG Goals. 2014.

Howitt P, Darzi A, Yang GZ, et al.: Technologies for global health. Lancet. 2012; 380(9840): 507–535.
PUBLISHED ABSTRACT | PUBLISHER FULL TEXT

Ioziuba O, Dieleman M, Kraamwinkel N, et al.: “I am not telling. The mobile is telling”: Factors influencing the outcomes of a community health worker mHealth intervention in India. PLoS One. 2018; 13(3): e0194927.
PUBLISHED ABSTRACT | PUBLISHER FULL TEXT | FREE FULL TEXT

Ivankova NV, Creswell JW, Stick SL: Using Mixed-Methods Sequential Explanatory Design: From Theory to Practice. Field Methods. 2016; 18(1): 3–20. PUBLISHED FULL TEXT

Jayanna K, Mony P, Ramesh BM, et al.: Assessment of facility readiness and provider preparedness for dealing with postpartum haemorrhage and pre-eclampsia/eclampsia in public and private health facilities of northern Karnataka, India: a cross-sectional study. BMC Pregnancy Childbirth. 2014; 14: 304. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT | FREE FULL TEXT

Kaplan H, Brady P, Dritz M, et al.: The influence of context on quality improvement success in health care: a systematic review of the literature. Milbank Q. 2010; 88(4): 500–559. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT | FREE FULL TEXT

Kaur J, Franzen SR, Newton-Lewis T, et al.: Readiness of public health facilities to provide quality maternal and newborn care across the state of Bihar, India: a cross-sectional study of district hospitals and primary health centres. BMJ Open. 2019; 9(7): e028370. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT | FREE FULL TEXT

Kay M: [mHealth: New horizons for health through mobile technologies]. 2011. Reference Source

Labrique A, Vasudevan L, Koch E, et al.: mHealth innovations as health system strengthening tools: 12 common applications and a visual framework. Glob Health Sci Pract. 2013; 1(5): 160–171. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT | FREE FULL TEXT

Marcolino MS, Oliveira JA, D’Agostino M, et al.: The Impact of mHealth Interventions: Systematic Review of Systematic Reviews. JMIR Mhealth uHealth. 2018; 6(1): e23. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT | FREE FULL TEXT

Martinez B, Izen EC, Hall-Clifford R, et al.: mHealth intervention to improve the continuum of maternal and perinatal care in rural Guatemala: a pragmatic, randomized controlled feasibility trial. Reprod Health. 2018; 15(1): 120. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT | FREE FULL TEXT

mHealth: new horizons for health through mobile technologies. 2011. Reference Source

Miles M, Huberman A: Qualitative Data Analysis. In:1994. Reference Source

Nilsen P: Making sense of implementation theories, models and frameworks. Implement Sci. 2015; 10: 53.
PUBLISHED ABSTRACT | PUBLISHER FULL TEXT | FREE FULL TEXT

Patel V, Panikh R, Nandraj S, et al.: Assuring health coverage for all in India. Lancet. 2015; 386(10011): 2422–2435. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT

Peters DH, Adam T, Alonge O, et al.: Republished research: Implementation research: what it is and how to do it: implementation research is a growing but not well understood field of health research that can contribute to more effective public health and clinical policies and programmes. This article provides a broad definition of implementation research and outlines key principles for how to do it. Br J Sports Med. 2014; 48(8): 731–736. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT

Press Information Bureau: Govt. Steps Taken by Govt. to Accelerate Pace of Reduction for MMR to Achieve MDG Goals. [Press release]. 2014. Reference Source

Rudan I, Kaprini L, Tomlinson M, et al.: Evidence-based priority setting for health care and research: tools to support policy in maternal, neonatal, and child health in Africa. PLoS Med. 2010; 7(7): e1000308. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT | FREE FULL TEXT

Ruton H, Musabiyimana A, Gaju E, et al.: The impact of an mHealth monitoring system on health care utilization by mothers and children: an evaluation using routine health information in Rwanda. Health Policy Plan. 2018; 33(8): 920–927. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT | FREE FULL TEXT

Schnall R, Cho H, Liu J: Health Information Technology Usability Evaluation Scale (Health-ITUES) for Usability Assessment of Mobile Health Technology: Validation Study. JMIR mHealth uHealth. 2018; 6(1): e4. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT | FREE FULL TEXT

Sturke R, Harmston C, Simonds R, et al.: A multi-disciplinary approach to implementation science: the NIH-PEPFAR PMTCT implementation science alliance. J Acquir Immune Defic Syndr. 2014; 67(Suppl 2): S163–167. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT

Tarning T, Kachnowski S: Special delivery: an analysis of mHealth in maternal and newborn health programs and their outcomes around the world. Matern Child Health J. 2012; 16(5): 1096–1101. PUBLISHED ABSTRACT | PUBLISHER FULL TEXT

Trostchim W: The Research Methods Knowledge Base. 2007. Reference Source

Van de Ven A, Polley D, Garud R, et al.: The Innovation Journey. 2008. Reference Source

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

Yin R, Quick SS, Bateman P, et al.: Changing Urban Bureaucracies: How new practices become routinized. 1978. Reference Source
Open Peer Review

Current Peer Review Status: ? ? ?

Version 1

Reviewer Report 27 August 2020

https://doi.org/10.21956/gatesopenres.14314.r29268

© 2020 Shorey S. This is an open access peer review report distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

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

© 2020 Ilozumba O. This is an open access peer review report distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

**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.

Reviewer Report 20 July 2020
https://doi.org/10.21956/gatesopenres.14314.r28977

© 2020 Patel A. This is an open access peer review report distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Archana B. Patel
1 Lata Medical Research Foundation, Nagpur, Maharashtra, India
2 Indira Gandhi Government Medical College, Nagpur, Maharashtra, India
3 Adjunct Faculty Research, Sawangi, Maharashtra, India

Overall comments: The protocol is informative, innovative and bold in its approach and outreach. This protocol has immense potential to elaborate the facilitators and barriers to uptake of mHealth interventions and aid in strengthening other operational mHealth interventions. This protocol mentions an appropriate innovative approach of using CFIR constructs contextualising
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.

2. **Is the research conducted in a “real world” setting? If so, is the context and sample population**
Does the research appropriately consider implementation outcome variables?

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.