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Context-appropriate innovative solutions for improving the access to quality intra- and immediate postpartum care in India

Kumar, Somesh

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**Context-appropriate innovative solutions for improving the access to
quality intra- and immediate postpartum care in India**

Somesh Kumar

university of
 groningen

Context-appropriate innovative solutions for improving the access to quality intra- and immediate postpartum care in India

PhD thesis

to obtain the degree of PhD at the
University of Groningen
on the authority of the
Rector Magnificus Prof. C. Wijmenga
and in accordance with
the decision by the College of Deans.

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Wednesday 11 December 2019 at 16:15 hours

by

Somesh Kumar

born on 26 January 1976
in Darbhanga, India

Supervisors

Prof. J. Stekelenburg

Prof. S.A. Reijneveld

Co-supervisor

Dr. Y.M. Kim

Assessment committee

Prof. T.H. van den Akker

Prof. M.J. Postma

Prof. R.A.C. Ruiter

List of Abbreviations

AMTSL	Active management of third stage of labor
ANC	Ante natal care
ANM	Auxiliary nurse midwife
ASHAs	Accredited Social Health Activists
CHC	Community Health Center
FRU	First Referral Unit
JSY	Janani Suraksha Yojana
QoC	Quality of Care
PHC	Primary Health Center
PPFP	Postpartum Family Planning
PPIUCD	Postpartum intrauterine contraceptive device
LMICs	Low and Middle Income Countries
MNH	Maternal and newborn health
MDG	Millennium Development Goals
MMR	Maternal mortality ratio
NRHM	National Rural Health Mission
GoI	Government of India
SC	Sub Centre
SCC	Safe Childbirth Checklist
SDGs	Sustainable Development Goals
UP	Uttar Pradesh
WHO	World Health Organization

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CHAPTER

1

General Introduction

General Introduction

The overarching purpose of this thesis is to elucidate the extent to which context appropriate innovations, interventions and strategies have been effective in improving access to quality intrapartum and immediate postpartum care for mothers and newborns India. Second , it addressed the processes which can drive the rapid scale up of these innovations in a time-sensitive manner, in a complex resource limited setting. Finally, this thesis gives recommendations on ‘what to do’ and ‘how to do’ with respect to innovations for increasing access to quality intra- and immediate post-partum care, to avert preventable deaths of mothers and newborns. The introduction section below gives a brief over-view of the health system in India, the problem statement in which this thesis is grounded and the broad conceptual framework that is adopted to understand, approach and answer the specific research questions related to the multidimensional problem and hence the multifaceted innovative solutions that are investigated.

1.1 India country context and the health system

India, the second most populous country globally with a population of >1.2 billion people, accounted for about 15% of global maternal deaths in 2015. It was the second highest contributor to global maternal mortality after Nigeria (1).].

India adopts a federal structure to governance and is a union of 28 states and 9 union territories, with Health being a state subject in the country. Given the vastness of the country, there is great disparity in the health status between the various states of India, with the North, Eastern and Central states contributing disproportionately highly to the overall maternal and neonatal disease burden of the country than the southern states. The research contributing to this thesis is primarily conducted in the the north, central and east Indian states of India, which are more resource constrained than the rest of the country.

The health system in India is mixed consisting of a public sector, a private-for-profit and a private not-for-profit sector. The private health care system in India caters to more than 70% healthcare seekers (72% in

rural and 79% in urban) (2). For maternity care however, the public sector contributes much more – 70% in rural areas and around 46% in urban areas (2). The three tier public health system consists of the following:

- **Primary Health Care:**
 - **Sub centers:** They are the most peripheral and first contact point between the health system and the community and expected to cater to a population of 5000 people.
 - **Primary health centers:** They serve as the first contact point between the community and a medical doctor and are envisioned to provide integrated curative and preventive health care to a population of 30,000 people with emphasis on preventive and promotive aspects of health care.
 - **Community health centers:** Community health centers (CHCs) are established and maintained by the State Governments in an area with a population of 100,000- 120,000 people. In hilly or difficult to reach or tribal areas, CHCs cater to a population of 80 000.

- **First referral units:** An existing facility (district hospital, sub-divisional hospital, CHC) serves as fully operational first referral unit (FRU) if it is equipped to provide round-the-clock services for emergency obstetric and newborn care , in addition to all emergencies that any hospital is required to provide
- **Tertiary care hospitals:** Tertiary care is specialized consultative health care, usually for inpatients and for those referred from a primary or secondary health care level (the first referral units).

Table 1: Key Health and Demographic Indicators of India

Serial no.	Indicator	Status
<i>Demographic and socioeconomic statistics</i>		
1	Human Development Index rank (2014)	130
2	Gender inequality index rank (2014)	130
3	Poverty headcount ratio at \$ 1. 25 a day (% of population) (2010)	32.7
<i>Mortality and global health estimates</i>		
4	Maternal mortality ratio (per 100,000 live births) (2015)	174
5	Neonatal mortality rate (per 1000 live births) (2017)	24
6	Under five mortality rate (per 1000 live births) (2017)	38.5
<i>Sustainable development goals</i>		
7	Life expectancy at birth (years) (2016)	70.3 (Female) 68.8 (Both sexes) 67.4 (Male)
8	Births attended by skilled health personnel (%) (2010 – 2016)	85.7
9	Coverage of essential health services (%)	57 (against Sustainable Development Goals target of 100%)
10	Skilled health professionals density (physicians/nurses/midwives per 100,00 population)	30.2 (against Sustainable Development Goals target of 44.5)
<i>Other key health or health services related indicators</i>		
11	Total Fertility Rate (2016)	2.3
12	Infants exclusively breastfed for the first six months of life (%) (2015-16)	54.9
13	Diphtheria tetanus toxoid and pertussis (DTP3) immunization coverage among one year olds (%) (2017)	88

Source: World Health Organization, National health Profile, India, 2018

Table 1 summarizes the key health and demographic indicators on India. The maternal mortality ratio is 174 per 100,000 live births with 85% births being attended by skilled health personnel. The total fertility rate is above the replacement levels at 2.3.

1.2 High Maternal and Neonatal mortality due sub-optimal access to quality reproductive, maternal, newborn and child health (RMNCH) services

Maternal and newborn health continue to remain an important issue in the era of sustainable development. There are an estimated 210 million pregnancies and 140 million live births happening every year globally (3) and ensuring that these women and newborns receive good quality of care has remained a challenge. Good progress in terms of decline in maternal mortality was seen during the Millennium Development Goals era. Maternal deaths declined by 44% globally. However, this decline varied across the globe with many countries falling short of the target of 75% reduction in MMR. Only nine of 95 countries with high maternal mortality achieved this target. (4).

In India, in 2015, the estimated number of maternal deaths was higher than in any other country apart from Nigeria (5). Although India made substantial progress in bringing down the maternal mortality ratio from 556 per 100000 live births in 1990 to 174 per 100000 live births in 2015, it still fell short of the Millennium Development Goal (MDG) of reducing MMR by 75% (6). India continues to account for a quarter of global maternal deaths (4). With respect to neonatal mortality, India accounts for more than a quarter of global neonatal deaths. Nearly 0.75 million neonates died in India in 2013, the highest for any country in the world (7). While India saw a commendable decline in under five mortality between 1990 and 2015, faster than the global decline, the decline in neonatal mortality has been much slower (7). With respect to neonatal mortality, globally, there was a decline of 51 per cent from 37 deaths per 1,000 live births in 1990 to 18 in 2017. However, this decline

was smaller than the reduction in mortality among children aged 1-59 months (63%) (8). This problem of inadequate decline in maternal and neonatal mortality has persisted despite knowledge of what it takes to reduce maternal and child mortality in low and middle income countries (9, 10).

Family Planning (FP) is recognized as a key life-saving intervention for mothers and their children (11). FP can avert more than 30% of maternal deaths and 10% of child mortality if couples space their pregnancies more than 2 years apart (12). Closely spaced pregnancies within the first year postpartum are the riskiest for mother and baby, resulting in increased risks for adverse outcomes, such as preterm, low birth weight and small for gestational age and the risk of child mortality is highest for very short birth-to-pregnancy intervals (13). If all couples waited 24 months to conceive again, under-five mortality would decrease by 13%. If couples waited 36 months, the decrease would be 25% (14), and maternal mortality could decrease by 30%. Family planning has important implications for maternal health as well. Contraceptive use reduces the number of high-risk and high-parity births, thereby reducing maternal mortality. Access to contraceptives also helps to prevent unwanted pregnancies, some of which result in unsafe abortions—one of the leading causes of global maternal deaths (15).

Postpartum women are among those with the greatest unmet need for FP (16). Yet they often do not receive the services they need to support longer birth intervals or reduce unintended pregnancy and its consequences. (16) According to an analysis of Demographic and Health Surveys data from 27 countries, 95% of women who are 0–12 months postpartum want to avoid a pregnancy in the next 24 months; but 70% of them are not using contraception (16). Post-partum family planning (PPFP), therefore, helps women who have an unmet need to space and limit future pregnancies, while helping to lower rates of maternal and child death.

In India, the 2005-06 National Family Health Survey reported that 61% of births were spaced less than

three years and 22% of married women had an unmet need for family planning (17). A subsequent stratified analysis suggested that 65% of women in the first year post-partum had an unmet need for family planning (18). This unmet need for family planning, especially among the postpartum women, has resulted in the problem of too many and too soon pregnancies among the young women in India, which contributes to the problem of high maternal and neonatal mortality.

1.3 Problem statement

India has a long way to go to achieve the Sustainable Development Goals (SDGs) and attaining the SDGs requires addressing the immense burden of adverse RMNCH (Reproductive, Maternal, Newborn and Child Health) outcomes. Since 2005, India has taken significant strides in reducing maternal and child maternal mortality rates as well as increasing access to family planning services. This is, at least in part, due to improved access to RMNCH care through initiatives such as the National Rural Health Mission (19), which expanded health care access in rural areas, and the Janani Suraksha Yojana, a conditional cash transfer program that incentivized institutional deliveries. However, India's share of the global burden

of premature maternal and child deaths remains substantial. This is mainly due to weak implementation and poor quality of maternal and newborn health care as well as closely spaced pregnancies due to suboptimal access to Family Planning services, leading to poor health outcomes. There is increasing recognition of the fact that ensuring access to and availability of health care without attention to quality will not yield the desired improvements in health outcomes [20]. In addition to strengthening quality of maternity care, it is also critical to ensure access to wide range of Family Planning services so that the pregnancies are optimally spaced, which enables the mothers and newborns to survive and thrive in their lives. Finally, there is a need to strengthen the availability of competent of human resources for health in the country, especially the nurses, to be able to sustainably expand access to quality RMNCH care for underserved populations and communities.

1.4 Conceptual framework

The overarching purpose of my research and this thesis is to investigate what kind of interventions and innovations are needed to address the barriers to access to quality MNH and FP services in resource

Figure: Conceptual Framework of the thesis

constrained settings in India and what is the optimum process of testing and scaling-up of these innovations in a way that harmonizes the need for scientific rigor in testing these innovations and the political urgency for scale-up of these innovations.

As a result of global efforts towards MDGs 4 and 5, significant progress has been booked in access to skilled attendance (SBA) and to essential interventions. However, increased access to SBA and facility based care without optimum quality of care does not achieve optimal health outcomes for mothers and newborns [20]. The health systems of Low and Middle Income Countries (LMICs) have innate barriers that limit their capacity to ensure delivery of quality services to clients accessing services at the health facilities. These barriers include lack of adequate number of competent human resources, shortage of supplies and equipment, lack of management capacity to ensure optimum utilization of resources, fragmentation of the health system and lack of accountability to deliver quality care to clients.

Quality of care around the process of childbirth is critical to improving health outcomes for mothers and newborns, but it is equally important to enable the women and their partners to space and limit their pregnancies to ensure that both the mothers and the newborns survive and thrive in their lives. The increased access to institutional care during the childbirth in LMICs as a result of the push towards improved coverage of SBA has afforded a golden opportunity to the health systems to be able to provide family planning services when the women is in the facility for childbirth. Post-partum family planning, is a great opportunity for both the health system as well as the clients, to ensure that pregnancies are spaced or limited, as per the reproductive intentions of the women. Increased spacing also increases the survival of mothers and newborns (21, 22).

While low and middle income countries have increased investments to improve access to SBA for childbirth, but there is a need to introduce innovations to mitigate the innate health system barriers listed above to enable provision of quality services as these health

system barriers cannot be addressed overnight. These innovations need to address the most important determinants to quality of care, i.e. production of competent human resources including pre-service training for nurses, provision of enabling environment to improve adherence to safe and effective clinical practices, and an increase the accountability of the system to deliver quality care.

Additionally, these innovations should be introduced and evaluated in a manner that enables rapid scale-up of the innovations if they are found to be successful. It is important to ensure a balance between the scientific rigor of evaluating these innovations and aligning to the political urgency to scale-up the successful innovations rapidly to avert the preventable deaths of mothers and newborns.

This thesis investigates the degree to which the various promising innovations have been effective in strengthening the quality of intrapartum- and immediate postpartum care for mothers and newborns in resource constrained settings of India. Having evaluated which interventions are successful, the thesis then goes to investigate the accelerators which can drive the rapid scale up of these innovations in a time-sensitive manner in LMICs. Based on the results of this investigation, this thesis gives recommendations to other resource constrained settings on ‘what to do’ and ‘how to do’ with respect to innovations for increasing access to high-quality intra- and immediate post-partum care, to enable them to avert preventable deaths of mothers and newborns.

1.5 Aim and research questions of my thesis

The central purpose of my thesis is to answer the following two questions:

1. To what degree were context appropriate innovations, interventions or strategies aimed at improving quality of intrapartum and immediate postpartum care in India able to achieve the intended outcomes?
2. What process was optimum for adoption of

innovative interventions leading to quality improvement, institutionalized and scaled up through a health systems approach in a complex resource constrained setting?

For answering the first question, I describe the effect of four innovative interventions which were introduced and rolled out in the public health system of India with the aim of improving quality of maternity care. The interventions were:

- a) Introduction of the safe childbirth checklist in labor rooms of selected health facilities (Chapter 2)
- b) Using a virtual platform for training pre-service nursing students in government aided nursing colleges of one state of India (Chapter 3)
- c) Introducing post-partum intra uterine contraceptive device for post-partum family planning in public health facilities (Chapters 4 and 6)
- d) Implementation of a package of strategically bundled services to increase the access to PPFP services in one state of India (Chapter 5).

For answering the second question, I describe the critical factors which facilitated quick scale up of the safe childbirth checklist program once the safe childbirth checklist was proven to be an effective intervention for public health facilities in India (Chapter 7).

1.6 Outline [to be done after competition of all chapters
[to be done after competition of all chapters)]

1.6 Outline of the thesis

Chapter 1 of my thesis presents the introduction which includes an overview of the health system of India as well as the conceptual framework guiding this thesis. **Chapter 2** evaluates the effectiveness of safe childbirth checklist in improving adherence of health service providers to evidence based practices during childbirth in public health facilities of Rajasthan, India (paper 1). **Chapter 3** evaluates the effect of virtual classroom training in improving knowledge and skills of general nurse midwifery students related to maternal and

newborn health, in Bihar, India. **Chapter 4** describes the experience of post-partum women with post-partum intra uterine contraceptive device in eight states of India. **Chapter 5** evaluates the effect of a package of interventions on knowledge, awareness and practices regarding post-partum family planning of both women and service providers in Bihar. **Chapter 6** determines the one-year continuation of post-partum intra uterine contraceptive device as achieved under a large-scale national program in India. **Chapter 7** identifies the key factors, which act as accelerators for scale up of proven interventions in the health systems of low and middle-income countries. **Chapter 8** discusses the findings, including an assessment of policy implications for India, conclusions and recommendations.

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CHAPTER

2

Effectiveness of the WHO SCC on improving adherence to essential practices during childbirth in resource constrained settings

RESEARCH ARTICLE

Open Access

Effectiveness of the WHO SCC on improving adherence to essential practices during childbirth, in resource constrained settings

Somesh Kumar, Vikas Yadav, Sudharsanam Balasubramaniam*, Yashpal Jain, Chandra Shekhar Joshi, Kailash Saran and Bulbul Sood

Abstract

Background: India accounts for 27 % of world's neonatal deaths. Although more Indian women deliver in facilities currently than a decade ago, early neonatal mortality has not declined, likely because of insufficient quality of care. The WHO Safe Childbirth Checklist (SCC) was developed to support health workers to perform essential practices known to reduce preventable maternal and new-born deaths around the time of childbirth. Despite promising early research many outstanding questions remain about effectiveness of the SCC in low-resource settings.

Methods: In collaboration with the Ministry of Health SCC was modified for Indian context and introduced in 101 intervention facilities in Rajasthan, India and 99 facilities served as comparison to study if it reduces mortality. This Quasi experimental Observational intervention-comparison was embedded in this larger program to test whether a program for introduction of SCC with simple implementation package was associated with increased adherence to 28 evidence-based practices. This study was conducted in 8 intervention and 8 comparison sites. Program interventions to promote appropriate use of the SCC included orienting providers to the checklist, modest modifications of the SCC to promote provider uptake and accountability, ensuring availability of essential supplies, and providing supportive supervision for helping providers in using the SCC.

Results: The SCC was used by providers in 86 % of 240 deliveries observed in the eight intervention facilities. Providers in the intervention group significantly adhered to practices included in the SCC than providers in the comparison group controlling for baseline scores and confounders. Women delivering in the intervention facilities received on an average 11.5 more of the 28 practices included compared with women in the comparison facilities. For selected practices provider performance in the intervention group increased as much as 93 % than comparison sites.

Conclusion: Use of the SCC and provider performance of best practices increased in intervention facilities reflecting improvement in quality of facility childbirth care for women and new-born in low resource settings.

Keywords: Safe Childbirth Checklist, Intervention, Practices, Low resource settings

* Correspondence: Sudh.Balasubramaniam@Jhpiego.org
Johns Hopkins University, 221, Okhla phase 3, New Delhi 110020, India

Background

Achieving the desired reduction in preventable maternal and child mortality remains the unfinished agenda of the Millennium Development Goals (MDGs) [1–4]. This has remained unachieved despite knowing what works for reducing maternal and child mortality in developing country contexts for many years [5, 6]. It has been estimated that globally, better care during labor and birth, and care of new-borns immediately after birth can avert up to 1.49 million maternal and new-born deaths and still births. (6) There is an urgent need to fill the gap between evidence and its translation to practices during care provision, particularly in developing country settings.

Nowhere is the need for filling this gap greater than in India. With the burden of 0.76 million neonatal deaths, India tops the list of countries with high Neonatal Mortality Rate (NMR) [7]. India has infant and under-five child mortality rates of 42 and 52 per 1000 live births respectively, and about 70 % of infant deaths and more than half of under-five child deaths in India occur in the neonatal period, the first 4 weeks of life [8].

While the infant mortality rate (IMR) has declined steadily, early neonatal mortality rate (ENMR) has virtually remained static since the last decade [9]. Considering the fact that neonatal deaths account for up to 40 % of under-5 deaths [3], the need for focusing on perinatal care in India is an urgent local and global priority.

The three-delay framework (decision to seek, reaching, receiving adequate care), used for understanding maternal and newborn mortality in developing countries applies well to the Indian context for maternal and newborn mortality [10–12]. Acting on the best available evidence that having mothers deliver in institutions rather than homes improves birth outcomes, India invested heavily on improving institutional delivery rates through programs such as Janani Suraksha Yojna (JSY a conditional cash transfer program for women delivering at institutions.). Rates of institutional delivery have more than doubled since the advent of National Rural Health Mission (NRHM), and currently more than 74 % of total births in India are occurring at institutions [13]. However, various studies have failed to show a commensurate reduction in maternal and neonatal mortality [14, 15]. Thus, just having a contact with the health system for deliveries has not proven to be enough for improving outcomes, which suggests a need to focus on the quality of care during these contacts. Experience from JSY also indicates that while the focus on bringing women to institutions may have influenced the first and second delay in care, the third delay, i.e., in timely and high-quality care provision at institutions is still a challenge [14].

It is well known that the capacity for quality of care for maternity services is influenced by skills of health workers in performing essential practices, availability of

essential resources, presence of appropriate and evidence-based guidance for action, and an overall enabling environment including effective organization of health care services [1–4]. In the Indian context, as in many settings, accountability and motivation of health workers to translate this capacity for quality into action are additional important influencers of quality of care. The Indian government has developed many guidelines focusing on quality of perinatal care and has invested resources on training health workers through skill building programs for childbirth related care [16, 17]. However, these initiatives have not translated into improved quality of care. A recent study in Delhi points out the widespread non-adherence to evidence-based practices in both public and private sector maternity care institutions [18]. Thus, in the Indian context, there is a strong felt need to develop and test tools and technologies that can help health workers to translate evidence into action.

The WHO Safe Childbirth Checklist has been considered as a promising frugal technology aiming at improving childbirth related care [19]. Building upon the success of the Surgical Safety Checklist in improving quality outcomes in health practices [20], this checklist was developed by WHO to support health workers to perform essential practices and prevent avoidable childbirth-related deaths [21]. The SCC targets high impact best practices around 4 pause points that occur in almost every delivery: admission, pushing, just after delivery and pre-discharge. In a single facility study in Karnataka, the use of SCC significantly improved the delivery of essential safety practices by health workers during childbirth [22]. However, while the study provided initial evidence on the effectiveness of SCC for improving service quality, it reported limitations regarding generalizability of and sustainability of findings due to the study design, nature of intervention, and setting of the study [22]. Considering the urgent need for India to identify solutions to improve quality of childbirth care at scale, evaluation of interventions that promote uptake and adherence with a simple technology like the SCC within realistic program implementation settings represents an important research priority for the country. Moreover, the WHO SCC multi-country collaboration is keenly interested in implementation experience and evidence from multiple settings to generate guidance on how the SCC should be used on a global scale [23].

Responding to the needs described above, a large quasi-experimental design study was conducted in 200 health facilities in the state of Rajasthan in India to understand the effectiveness of the SCC on childbirth-related outcomes within the 'real-world' program and administrative framework in the country. While the larger study was designed with a view to capture effects of SCC use on client outcomes, a smaller sub-study was

conducted to understand the pathway by which the SCC changes these outcomes. Through direct observations in the labour rooms, we tried to assess effectiveness of SCC in bringing changes in adherence to safe care practices by the health workers in intervention facilities as compared to the comparison facilities. In this paper, we are reporting the results of this observational study, nested within the larger quasi-experimental design study, to assess whether women receive more life-saving practices during labour, delivery, and the immediate postpartum period in facilities where SCC was introduced compared to women in facilities where the SCC was not introduced. A separate evaluation is going to assess the impact of the SCC use on in-facility perinatal mortality rates.

Methods

Study design and setting

This is a quasi-experimental observational study implemented in the state of Rajasthan in India from March 2013 to April 2014.

This study compared health providers' use of the SCC and adherence with SCC items in 8 intervention and 8 comparison facilities at the baseline (March- April 2013) and end line (March- April 2014). Intervention and comparison facilities included two district hospitals and six Community Health Centres (CHC)/Sub-District Hospitals (SDH) in each arm, from the intervention and comparison districts matched by average annual delivery load. These facilities were selected randomly from the overall available sample of 13 District Hospitals and 187 CHC/ SDHs.

Intervention

The Government of Rajasthan implemented the SCC program at Community Health Centers (CHC), Sub-district Hospitals and District Hospitals of selected districts with technical support from Jhpiego. Technical assistance of Jhpiego was aimed at pilot testing of SCC, modification in SCC to adapt to the local context, orientation of providers, facility readiness assessments, and conducting post-training follow-up and support visits at pre-defined frequency.

Several modifications to the SCC were informed by an initial pilot test of the SCC and input of a Technical Advisory Group (TAG). Modifications included introduction of a designated space to record maternal and newborn vital signs (e.g., mother's temperature and blood pressure, newborn's weight). The modified SCC included 31 critical practices and retained the original four pause points distributed across two pages. For this checklist there were four pause points: at admission, just prior to or during pushing, immediately after delivery

and prior to discharge. But of this 31 practices only 28 were observed during this study and mentioned in the results.

Prior to the implementation program staff assessed availability of essential drugs, supplies and functionality of equipment required to implement SCC practices in both intervention and comparison facilities. Essential commodities and equipment identified as missing during assessments were provided by the program for both intervention and comparison facilities. Availability of supplies was monitored periodically in both intervention and comparison facilities.

The SCC program included two main components-a 1.5 day orientation of facility-based health workers on using the SCC as a part of their care delivery and post-training on-site support in using the SCC.

After the training, the health workers in intervention facilities attached the SCC to the existing case-sheets of the individual patient. It is important to note that at the time of intervention, templates of case-sheets were already in use at both intervention and comparison facilities. For implementation purposes, the SCC was externally attached to the existing case-sheets in intervention facilities. Case-sheets in comparison facilities remained unchanged.

After the initial training, Jhpiego staff made site visits to the intervention sites on a set frequency, to assess the progress of SCC use in the facility and to address barriers to its smooth implementation of the checklist. The first on-site visit was made to a facility where orientation of all health workers has been completed within 15 days of the completion of orientation. Fortnightly visits continued up to 2 months. After 2 months, the frequency of visits was reduced to once a month for next 6 months. After 6 months, the facilities were visited at least once every quarter for the remaining duration of the study. Visits typically included the following activities: observation of SCC use by on-duty health workers and onsite support in effectively using it, facilitation of the availability of the SCC at the sites, and any administrative barriers to the health workers in using the SCC. Apart from this, Jhpiego staff also facilitated all-staff meetings in the intervention facilities at least once every quarter as a part of the onsite visits where all relevant health workers from the facilities came together and discussed their experiences with SCC use; challenges faced, and suggested remedies to these challenges.

An important characteristic of the SCC program was that implementation approach was developed in close collaboration with the Ministry of Health and was firmly grounded in the existing public health system. For example, resources of the public health system were used to support most implementation activities such as provider orientations. Existing Skilled birth attendants (SBA)

trainers in the public health system were used to orient the providers on the SCC, at training sites which were mostly public sector district hospitals of the state. As far as possible, the system's resources were leveraged to ensure availability of essential supplies in intervention and comparison facilities.

Sample size

The sample size calculation was based on the conservative assumption that the essential practices would be done in 50 % of deliveries, and having 80 % power to detect a 20 % increase in practice coverage. Alpha was set at 0.0017 using Bonferroni's correction considering 28 comparisons. The design effect-adjusted group sample size in comparison and intervention arm was found to be 20 observations per group considering 0.01 intra-class correlation coefficient. This resulted in 960 observations overall in each comparison and intervention arm, total sample size was 240 per pause point per arm. Some clients were observed in more than one pause point.

Sampling method

Every woman delivering in a facility during observation period who was not in active labour and was an appropriate state of mind to consent were approached and those who consented were included in the study until the required number of observations were achieved for a pause point in a facility.

Data collection tools

The number of providers available and the delivery load initial infrastructure, supplies and training status of staff available were collected during baseline using a rapid facility assessment tool. A Periodic assessment tool which had information about the facility type, average delivery load, staff available and supplies was also used every quarter to assess the resource availability and practices. Training data was available from training data formats which updated data as trainings happened. The details of supplies came from the monthly reports of facilities which reported on availability of number of supplies.

Observers used pre-designed structured observation format to collect data on different pause points, which was supplemented by a self-contained step by step procedure guide (Algorithm). This Algorithm clearly defined the practice to be performed by a provider was performed or not. For example for Appropriate hand hygiene is considered to be performed only if Provider had access to running water, soap, gloves and performed six steps of hand washing before each internal examination and wore gloves.

Procedures

Each facility was approached for permission to observe the deliveries. Observers were typically a Graduate Nursing (BSc) school student/intern who had basic knowledge of maternal and childbirth-related practices. Observers were oriented for one day on the checklist and how to use a standardized algorithm to classify practices as being performed, not being performed or not applicable. Supervised observations in the labor room (at least once for each of observers) and 2 days mock sessions were also part of the training. The observers worked in round-the-clock shifts of 8 h each till the time the required sample size was achieved for one facility. Observations were made in the facilities only after at least 6 months were completed after the initial introduction.

The unit of observation was a pause point rather than a delivery. One delivery (if followed from the period of admission to discharge) made for four independent pause point observations. 240 observations were made for each pause point. Each data collector continuously observed care for a pregnant woman at all the pause points applicable to his/her shift at the facilities. These observations lasted for the whole duration for which the provider completed activities relevant to that pause point. Apart from observing practices, the data collectors also observed the SCC use for that pause point. In addition, they made periodic observations and record checks to confirm where activities such as use of partograph were completed. At each pause point, they observed relevant practices where they were performed (admission room, labor room, and post-partum ward). For efficiency of operations, they prioritized observing different pause points on all available cases during one shift rather than following one case from point of admission to discharge.

Providers were recruited in their free time in a private space. Observers explained the study purpose and process to the providers that they would be observed for their practices at four different pause points and obtained informed oral consent at the beginning of the baseline and endline data collection.

Informed oral consent of mothers was taken at the admission for observing her at various points of her child birth using a local vernacular consent form. If the observer was a male, presence of a female attendant was ensured during observation. Mothers who did not consent, were in severe pain, or were in a state in which they were unable to consent were not included for observation.

Each practice was observed at every pause point and was categorised based on the algorithm as practiced, not practiced and or not applicable. Data quality was assured by using standardised formats and algorithms, standardised training, periodic review and mentoring of observers

and data quality checks in data entry. The completed observation forms were entered in CS-Pro and the data was cleaned for inconsistencies using data validation and internal consistency.

Data analysis

Data was analysed using MS excel 2010, Stata version 13.0 and SPSS version 22.0. Frequencies and categorical analysis was done for the cleaned data. Proportions were calculated for all categorical variables. Chi-square test was performed for statistical significance of proportions. A composite index was developed for availability of supplies and equipment based on the availability of such supplies during the time of the study, which was used for the regression analysis. Multiple Linear Regression analysis was done to find the difference in difference (DID) in average number of practices performed during intrapartum and postpartum care in intervention and comparison facilities between baseline and endline. The model estimate was created with robust standard error and considering the clustering at client level and the facility level and adjusting for health worker type and availability of supplies and drugs. Difference in difference of means was determined by an interaction term in the regression model between intervention/comparison and baseline/endline (time) variables. A difference in difference logistic regression analysis was performed for individual practices and DID estimator-which was the interaction term in the model-was calculated for each of the practices. This DID estimator was adjusted for clustering by health worker, and a composite index for supplies, health worker categories.

P value less than 0.0017 was considered statistically significant considering Bonferroni's correction.

Ethical considerations

This observational study was reviewed and approved by Government of Rajasthan and the institutional review board (IRB) of Johns Hopkins Bloomberg School of Public health, Baltimore, USA (IRB 0004816). Verbal Consent of providers and mothers was obtained for participation in this study as per the protocol approved by IRB. Written consent was not obtained as we did not want to record any identifiable information of the client or the provider. Consent was obtained by

allowing the study participant to read the consent form in local vernacular language or loudly read the consent forms to the study participant and the person who administers the consent signed it and left a copy of the consent with the study participant.

Results

The SCC was used in 86 % of the observed deliveries in intervention facilities, which implies successful adoption by a majority of providers in the intervention facilities. Table 1 presents basic background information of the intervention and comparison facilities including workload, human resources and supplies. The facilities in each arm were similar with respect to delivery volume and the number of staff at baseline and endline. The composite index of supplies and equipments increased in intervention and comparison sites to 0.9 at end line. 63 % (12/19) of the total doctors trained on SCC at baseline and 92 % (58/63) 92 % of the nurses trained on SCC at baseline were available in intervention facilities at the end line.

Table 2 illustrates the distribution of clients assessed/attended at the study sites by cadre. In intervention sites 15 % of the women who delivered at the facilities were attended by doctors, 80 % by nursing staff and 5 % by others. In comparison sites the provider cadre distribution was similar. In both groups a larger proportion of providers were doctors at discharge than at any other pause point whereas in others it was predominantly nurses.

Table 3 provides a comparison of practices across all pause points in intervention and comparison facilities during the baseline and endline. In intervention sites, the difference in the number of practices observed at endline compared to baseline was statistically significant for 26 of the 28 practices and 21 of the 28 practices were observed over half the time. Only assessment of breathing at one minute and recording of baby's birth weight did not change significantly, and both of these practices were already observed at least 95 % of the time at baseline. In the comparison group 9 of the 28 practices improved significantly from baseline to endline, however, only four practices were being done more than half of the time.

Table 1 Background information of the facilities in which the safechild birth study was conducted during baseline and endline

Observational Study	Type of facility			Average monthly delivery load		Staff Available		Staff Oriented on SCC		Supply Composite Index
	DH	SDH	CHC	DH	CHC/SDH	Doctor	Nurse	Doctor	Nurse	
Baseline Intervention	2	1	5	462	159	21	56	0	0	0.69
Baseline Control	2	1	5	339	134	23	52	0	0	0.75
Endline Intervention	2	1	5	388	138	19	60	11	55	0.9
Endline Control	2	1	5	277	129	27	55	0	0	0.9

Table 2 Percentage of pregnant women assessed by providers at each pause point in end line in observational study

Pause points	Intervention			Comparison		
	Doctors	Staff nurse	Others	Doctors	Staff nurse	Others
On Admission (N = 240 Deliveries)	14 %	82 %	5 %	18 %	75 %	7 %
Just before pushing (N = 240 Deliveries)	10 %	84 %	6 %	6 %	84 %	10 %
Soon after birth (N = 240 Deliveries)	9 %	85 %	6 %	8 %	84 %	8 %
On Discharge (N = 240 Deliveries)	28 %	70 %	3 %	32 %	65 %	3 %
Overall (N=960 Deliveries)	15 %	80 %	5 %	16 %	77 %	7 %

When a logistic regression model with robust standard error was run for each of the 28 practices adjusting for covariates of clustering by health worker, and a composite index for supplies, health worker, health worker categories) and testing the significance of the interaction term estimating the difference in difference (i.e., time-baseline and endline-and group-intervention and comparison) 16 of the 28 practices had improved significantly more in the intervention than in the comparison group. During the first pause point partograph use, preeclampsia management, HIV testing of mothers and companion briefed on danger signs were statistically significant ($p < .001$). In the second pause point, giving oxytocin to mothers within one minute of delivery and appropriate new born thermal management were statistically significant. In the third pause point blood loss assessment, appropriate maternal infection management, new born assessment for antibiotics, initiation of breast feeding and briefing companion on danger signs were statistically significant. In the fourth pause point appropriate new born infection management, new born feeding assessment and appropriate maternal infection management were statistically significant. These practices in endline intervention group was higher than all other groups. Since the P value of Less than 0.0017 was the cut off due to Bonferroni's correction the difference in difference of proportion of these practices were statistically significant.

Figure 1 illustrates the average number of evidence-based practices included in the SCC performed on each client in intervention and comparison groups at baseline and endline. The mean number of practices increased from 4.5 practices to 6.4 in the comparison group and from 4.3 practices to 17.9 practices in the intervention group.

Table 4 depicts the multiple linear regressions with robust standard error estimation adjusted for health worker type, facility type, supply index and clustering of observations by health workers. The mean difference in difference in practices at pause point one was 4.0 (95 % CI 3.3–4.8), pause point two was 1.6 (95 % CI 1.1–2.3), pause point three was 2.5 (95 % CI 2.0–3.1) and pause point four was 3.5 (95 % CI 2.3–4.7). All these differences were statistically significant ($p < .001$).

On average a client in the intervention facility received 11.5 more SCC (95 % CI-8.5–14.6)) best practices than a

client in comparison sites controlling for baseline values; this difference was statistically significant ($p < 0.001$).

Discussion

In this study, we evaluated the effectiveness of a SCC in ensuring adherence to safe childbirth related practices known to have high impact on reducing preventable maternal and neonatal mortality around the time of delivery as well as an optimal implementation approach for increasing providers' use of the SCC in 'real-life' facility settings. We observed that an overwhelming majority of providers in the intervention facilities did use the SCC during the delivery process. Introduction of the SCC supported by a simple implementation package resulted in a clear improvement in adherence with SCC essential practices in the facilities where it was introduced as compared to the facilities where it was not. Out of the 28 essential practices, women in the intervention facilities received nearly 12 more practices than in the comparison facilities. Given the findings of the study, it appears that introduction of the SCC in association with a light implementation package may be an effective approach for helping to close the "know-do" gap in intrapartum care best practices.

During the study, it was observed that the SCC helped to strengthen the quality of initial assessment and appropriate referral of the women at the time of admission. Inappropriate and delayed initial assessment and referral at the time of admission, classically categorized as the third delay, are major contributors to maternal and newborn morbidity and mortality [10–12]. It is apparent from our observations that the SCC has a good potential to reduce this delay through better assessments at the time of admission.

Adherence to several important maternal clinical care practices proven to reduce the incidence and mortality due to complications like post-partum haemorrhage improved more in the intervention facilities (e.g., adherence with immediate postpartum administration of oxytocin for reduction of PPH.)

Study results also demonstrated increased adherence with several lifesaving interventions for the newborn such as appropriate thermal management which included drying of the baby with dry towel, timely and appropriate

Table 3 Univariate and Multivariate analysis of Provider's adherence to safe child birth checklistpractices (based on 240 observations per pause point during baseline and endline in intervention and control facilities)

Practices	Intervention		P value	Comparison		P value	P value		
	Base line	End line	Baseline Vs Intervention	Endline in	Base line	End line	Baseline Vs Comparison	Endline in	DID modeling-Logistic regression
On Admission									
Assessment and appropriate referral	2 %	88 %	<0.001		3 %	7 %	0.036		< 0.001
Partograph used	13 %	52 %	< 0.001		8 %	0 %	< 0.001		< 0.001
Appropriate Maternal Infection management	0 %	76 %	< 0.001		2 %	8 %	0.008		< 0.001
preeclampsia management	35 %	74 %	< 0.001		14 %	15 %	0.365		.001
HIV tested	16 %	56 %	< 0.001		32 %	29 %	0.314		< 0.001
Companion briefed on danger sign	2 %	66 %	< 0.001		4 %	8 %	0.042		< 0.001
Appropriate hand hygiene	2 %	21 %	< 0.001		0 %	3 %	0.038		0.994
Just Before Pushing (or Before Cesarean)									
Appropriate hand hygiene	2 %	18 %	< 0.001		0 %	5 %	< 0.001		0.972
Oxytocin in one min of delivery	24 %	88 %	< 0.001		32 %	49 %	< 0.001		< 0.001
Cord cut with sterile blade /scissor	8 %	47 %	< 0.001		17 %	32 %	< 0.001		0.008
Assessment of baby breathing in one minute.	95 %	97 %	0.21		94 %	95 %	0.179		0.702
Appropriate NB thermal management	4 %	98 %	< 0.001		16 %	75 %	< 0.001		< 0.001
Appropriate NB Resuscitation ^a	41 %	83 %	< 0.001		29 %	30 %	0.623		0.026
briefing for birth helper in EM	10 %	78 %	< 0.001		15 %	32 %	< 0.001		0.008
Soon After Birth(within 1 h)									
Blood loss assessed in mother	35 %	91 %	< 0.001		49 %	68 %	< 0.001		< 0.001
Appropriate maternal infection management	1 %	74 %	< 0.001		3 %	1 %	0.313		< 0.001
NB Assessed for antibiotics	1 %	43 %	< 0.001		4 %	4 %	0.027		< 0.001
Birth Weight taken	99 %	98 %	0.284		85 %	78 %	0.026		0.665
Initiated breastfeeding in One hour of birth	34 %	86 %	< 0.001		43 %	46 %	0.224		< 0.001
Skin to skin contact with mother	13 %	37 %	< 0.001		2 %	22 %	< 0.001		0.104
Companion briefed on danger sign (M&NB)	4 %	52 %	< 0.001		3 %	5 %	0.176		< 0.001
Before Discharge									
Appropriate maternal blood loss assessment	9 %	70 %	< 0.001		3 %	40 %	< 0.001		0.694
Appropriate maternal infection management	0 %	72 %	< 0.001		2 %	3 %	0.539		< 0.001
Appropriate NB Infection management	0 %	58 %	< 0.001		0 %	2 %	0.043		< 0.001
NB feeding assessment	13 %	81 %	< 0.001		11 %	12 %	0.834		.001
Follow up advise to mother	0 %	54 %	< 0.001		4 %	10 %	0.009		.002
FP options discussed	5 %	43 %	< 0.001		14 %	8 %	0.067		.003
Discharge counselling on danger sign	0 %	47 %	< 0.001		0 %	6 %	< 0.001		.167

^aThis practice is on observation of less number (baseline intervention = 46, endline control = 101, baseline control = 38, endline control = 46)

resuscitation and immediate initiation of breastfeeding. It is noteworthy that in spite of large amount of resources spent on national training initiatives like trainings for Skilled Birth Attendance (SBA) or the national newborn survival training program ('Navjat shishu Suraksha Karyakram'-NSSK), the practices related to essential newborn care like immediate initiation of breastfeeding are still sub-optimal in many parts of India [24–28]. Thus the improved adherence with lifesaving practices by the health workers in SCC intervention sites highlights the potential of SCC in helping translate knowledge and skills into practice.

Assessment of the well-being of the mother and newborn both at the time of admission and at the time of discharge also improved significantly more in the facilities where the SCC was used. This reflects the important role of the SCC in standardizing facility-based procedures for effective admitting and discharging the clients. Assessments of client at the time of admission to review whether care needed for a client's condition can be provided at the facility and assessments at the time of discharge to ensure that a client with any imminent complications is not discharged into communities, are important system characteristics to improve maternal and newborn health outcomes. However, supportive services such as counselling for Family Planning and discharge counselling on danger signs did not improve significantly and this, we believe, was due to the scarcity

of adequate human resources to support optimal discharge processes for mother and newborn.

An important innovation of the SCC implementation strategy in this study involved slight modification in the SCC to include documentation of maternal, foetal and newborn vital signs at key pause points followed by a provider signature. We believe that this modification of the SCC helped to promote use of the SCC at the point of care as a part of the client record and also increased provider accountability since the SCC effectively became a part of the client records. Many studies have emphasized the importance of accountability mechanisms in ensuring delivery of quality services to clients [29–31]. In the absence of robust systems to measure quality of services rendered to clients, accountability of providers to provide quality services is low in public health facilities in India. We believe that in this context, the SCC, by virtue of the mandatory recordings of the client vitals with provider signature on the SCC, has been effective in increasing the accountability of the providers which in turn has resulted in increased provider adherence with essential practices.

During the study period, a significant improvement was seen in certain practices in comparison facilities also, such as, the use of oxytocin for active management of third stage of labour, cord cutting with sterile blade and appropriate newborn thermal management. Since these practices are dependent on availability of relevant supplies, It is likely that the project component to ensure availability of essential supplies in both the intervention and comparison facilities contributed in part to this observed increased adherence with these best practices. Additionally, as a part of a nursing education strengthening national initiative, in-service provider trainings in some of the comparison facilities were conducted by the government, which may explain the improvement in adherence to these practices. It is worth mentioning that among all the practices listed in the SCC, adherence with routine care practices (relevant for every mother and newborn) increased the most (such as administration of immediate post-partum oxytocin for active management of third stage of labour, initiation of immediate breast feeding). Adherence with the more

Table 4 Linear regression model estimates of difference in difference in mean number of practices at various pause points observed during the Safe child birth checklist study

Pause point	Number of practices	Mean difference in difference of practices (95 % CI) ^a	P Value (t-test)	R ² value
At admission	07	4.0 (3.3–4.8)	<0.0001	0.44
Before delivery	07	1.6 (1.1–2.3)	<0.0001	0.62
One hour after delivery	07	2.5 (2.0–3.1)	<0.0001	0.55
Before discharge	07	3.5 (2.3–4.7)	<0.0001	0.65
All practices	28	11.5 (8.5–14.6)	<0.0001	0.76

^afor a DID estimator by logistic regression with robust standard error and adjusted for health worker clustering for observations, health worker type, supplies and drugs and facility type

complex SCC practices which require greater provider knowledge, experience and skills (e.g., resuscitation of a newborn and correct completion of the partograph) improved at a lesser rate than that for simpler routine best practices. Of note, adherence with practices rooted in social-cultural and behavioural context like hand-washing and skin-skin to contact did not improve as a result of using the checklist.

The SCC was developed by WHO to improve adherence to life saving practices in the intra- and immediate post-partum period. The SCC was piloted in one facility of Karnataka state of India in 2010, where in controlled settings, it increased adherence to some practices [22]. A similar study was conducted in one tertiary care centre of Sri Lanka where adherence to best practices as well as adherence to SCC was studied [32]. However, since both these studies were limited to just one facility and were done in controlled settings, there was a need for evidence on the effectiveness of the SCC at a scale and in resource constrained settings of developing countries like India.

The SCC, like any other checklist, is supposed to act as a reminder tool for the user, to help in minimize human errors and promote reliable human actions during complex procedures such as surgery and childbirth. However, the learning of the program in which the study was nested throws a whole new light on the way the SCC works in the developing country contexts such as India. As acknowledged globally, provider adherence to clinical practices is a function of multiple influencing factors, including provider competency and motivation and availability of essential commodities, equipment and human resources among other factors [1–4].

Two additional important determinants of adherence with best practices in the Indian context include provider accountability and nurse empowerment to participate in clinical decision making and initial management of complications. We believe that in the Indian context, the modifications in the SCC as part of the implementation strategy helped to ensure that the SCC functioned not only as a memory tool for providers but also as a framework for improving accountability (5,6) of providers due to a blended use of the SCC as checklist and a partial patient record. The adapted SCC, by virtue of being recommended by the government for use, being the part of case records, and having added prompts for managing complications such as birth asphyxia, severe pre-eclampsia and eclampsia and post-partum haemorrhage, empowered the nurses to do initial management of maternal and newborn complications, which earlier they used to refer to doctors. Since a vast majority of vaginal deliveries are conducted by the nurses in the public health facilities, this empowerment of nurses has resulted in improved prevention and initial management of maternal and newborn complications. This mechanism

of effect of the SCC has a major implication for similar resource constrained settings globally where deliveries are conducted mainly by nurses and availability of doctors is mostly sub-optimal.

Since additional programmatic components were limited to Jhpiego staff facilitating the activities, and mostly system's resources were used for orientations and availability of any needed resources, the results of this study can be generalized to other low and middle Income countries with similar settings although further adaptation of the implementation strategy may need to be done to suit these settings. The fact that the SCC implementation strategy in this study was firmly grounded in the local public health system makes the possibility of scale up more feasible.

Key features of the implementation package that are likely generalizable to other settings include implementation within the local health system context with local system stakeholders, initial modification of the SCC based on local context, strategies to promote integration of the SCC into routine processes of maternity care (e.g., documentation of vital signs directly onto the SCC and use of the SCC as a partial individual patient record), strategies to promote provider accountability (e.g., provider signature after documentation of vital signs on SCC), empowerment of lower provider cadres to implement best practices for complications, and support for key commodities. Further research is needed into implementation strategies that may increase adherence with the most complex SCC interventions (such as complications care) and with SCC practices linked to behavioural and cultural resistance (e.g., handwashing, skin to skin care for newborn, etc.)

The study did have few limitations. Potential Hawthorne effect would have occurred due to observation of practices. But was minimized by silent observation without affecting the work there might have been some effect due to observation. But this remained the same in intervention and comparison facilities. We had a different set of observers during baseline and endline as we had nursing interns as observers. But they were trained in a standardized way using the same tools and the same trainers.

Conclusion

Use of the SCC and provider performance of best practices increased in intervention facilities reflecting improvement in quality of facility childbirth care for women and new-born in low resource settings.

Abbreviations

CHC: Community Health Centre; CI: Confidence Interval; DH: District Hospital; DID: Difference in Difference analysis; ENMR: Early Neonatal Mortality Rate; IMR: Infant Mortality Rate; IRB: Institutional Review Board; JSY: Janani Suraksha Yojna; MDG: Millennium Development Goals; NMR: Neonatal Mortality Rate; NRHM: National Rural Health Mission; NSSK: Navjat Shishu Suraksha Karyakram; SBA: Skilled Birth Attendants; SCC: Safe childbirth checklist; SDH: Sub-district hospital; TAG: Technical Advisory Group; WHO: World Health Organisation

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Authors' contributions

SK conceptualization of project, Principal investigator of the project, leading manuscript drafting. VY Designing and Implementing research, Development of tools, Manuscript drafting. SB Designing of study, supervising data collection, study analysis and drafting manuscript. YJ Implementing research, development of tools, Drafting manuscript. CJ Data compilation, cleaning, analysis, field monitoring and drafting. KS Preparation of tools, overseeing data collection and drafting manuscript. BS Conceptualization, reviewing and guiding analysis and manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Availability of data and materials

The datasets of the current study will be available from the corresponding author on reasonable request Sudh.Balasubramaniam@Jhpiego.org.

Ethics approval and consent to participate

This observational study was reviewed and approved by Government of Rajasthan and the institutional review board (IRB) of Johns Hopkins Bloomberg School of Public health, Baltimore, USA (IRB 0004816). Johns Hopkins School of public health institutional review board is one of Jhpiego's designated IRBs of record as documented with the U.S. government's office of human subject's protection. Verbal Consent of providers and mothers was obtained for participation in this study as per the protocol approved by IRB. Written consent was not obtained as we did not want to record any identifiable information of the client or the provider. Consent was obtained by allowing the study participant to read the consent form in local vernacular language or loudly read the consent forms to the study participant and the person who administers the consent signed it and left a copy of the consent with the study participant.

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CHAPTER

3

Effectiveness of virtual classroom training in improving knowledge and the key maternal neonatal health skills of general nurse midwifery students in Bihar, India: A pre- and post-intervention study

Effectiveness of virtual classroom training in improving the knowledge and key maternal neonatal health skills of general nurse midwifery students in Bihar, India: A pre- and post-intervention study

Neeraj Agrawal, Somesh Kumar, Sudharsanam Manni Balasubramaniam *, Saurabh Bhargava, Pallavi Sinha, Bhawna Bakshi, Bulbul Sood

Jhpiego, an affiliate of John Hopkins University, 221, Okhla Phase 3, New Delhi, India 110020

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SUMMARY

Background: In 2008–09, the National Health Systems Resource Center of India reported overall quality of nurse-midwifery education in Bihar as grossly sub-optimal. To address this, we implemented a competency-based training using virtual classrooms in two general nurse midwives (GNM) schools of Bihar. The students from remotely located nursing institutions were now able to see live demonstrations of maternal and newborn health (MNH) practices performed by a trained faculty on simulation models at instructor location.

Objective: To evaluate the effectiveness of virtual classroom training in improving the MNH-related skills of the nursing-midwifery students in Bihar, India.

Design: This study used a pre- and post-intervention design without a control group.

Settings: Students from two public GNM schools of Bihar.

Participants: Final-year students from both the GNM schools who have completed their coursework in MNH.

Method: A total of 83 students from selected GNM schools were assessed for their competencies in six key MNH practices using objective structured clinical examination method prior to intervention. A 72 hour standardized training package was then implemented in these schools through virtual classroom approach. Post-intervention, 92 students from the next batch who attended virtual training were assessed for the same competencies.

Results: The mean student score assessed before the intervention was 21.3 (95% CI, 19.9–22.6), which increased to 62.0 (95% CI, 60.3–63.7) post-intervention. This difference was statistically significant. When adjusted for clustering using linear regression analysis, the students in post-intervention scored 52.3 (95% CI, 49.4–55.3%) percentage points higher than pre-intervention, and this was statistically significant.

Conclusion: Virtual classroom training was found to be effective in improving knowledge and key MNH skills of GNM students in Bihar, India.

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Introduction

Optimum midwifery services is among the most effective ways in providing high-quality maternal, newborn care and thus in reducing maternal and infant mortality especially in developing countries (Renfrew et al., 2014; ten Hoope-Bender et al., 2014). Some of the key causes for maternal and neonatal deaths like infection, post-partum hemorrhage, eclampsia, birth asphyxia, and pre-term birth can be averted through competent nursing-midwifery care (WHO, 2014a). With the launch of Global Strategies for Women's and Children's Health in 2010, many developing countries started prioritizing their focus on improving access to quality midwifery services to women during

intra-partum, post-partum period by scaling up the numbers of competent nurses-midwives as part of their national agenda (UNFPA, 2011).

In India, the current shortage of nursing-midwifery workforce is a major human resource constraint for providing quality maternal and child health services and thus in achieving Millennium Development Goals 4, 5 by 2015 (Hazarika, 2013). Although significant improvements have been observed in the percentage live births attended by skilled health personnel from 1992–93 to 2007–08 (WHO and UNICEF, 2010), there exists an acute shortage of more than 2 million nursing staff (WHO, 2014b).

In Bihar, the scenario is even more alarming as the shortfall in the number of staff nurses is around 50% in the medical college hospitals and much higher in the public health facilities. Similarly, the shortfall of the multipurpose health workers, i.e. auxiliary nurse midwives (ANMs), in the existing public health facilities of Bihar is approximately 28% (NHSRC, Nursing services in Bihar, 2009). Apart from shortage in

* Corresponding author. Tel./fax: +91 11 49575100.

E-mail address: sudh.balasubramaniam@jhpiego.org (S.M. Balasubramaniam).

numbers, inadequate level of clinical competency of these nurse-midwives is another challenge in improving quality of MNH services especially in remote areas. In 2008–09, the National Health Systems Resource Center of India conducted a study on the nursing services in Bihar and reported overall quality of nursing-midwifery education in existing institutions as grossly sub-optimal (NHSRC, *Nursing services in Bihar*, 2009). The study also highlighted other key concerns like inadequate faculty strength, infrastructure, suboptimal academic/clinical training, and poor structural management in the existing nursing education system. A high variance in the knowledge and clinical skills of the available faculty was also observed. The report also flagged an urgent need to improve institutional teaching methods, student evaluation system, and inclusion of advance practical training methodologies for betterment of the overall educational quality.

During the past decades, with the advancement in modern information technology, use of Internet for knowledge sharing and teaching has increased tremendously. Several studies have demonstrated that virtual classrooms are an efficient and effective way to enhance students' learning (Bertsch et al., 2007; Hortos et al., 2013; Mosalanejad et al., 2014). A virtual classroom is a set up where qualified trained faculty located at the central institution teaches a class of students in remotely located schools through Internet-based information technology interphase. A study was conducted to evaluate the effectiveness of virtual versus traditional teaching in achieving competencies among nursing students in Iran. The study reported that virtual teaching was more effective in achieving higher theoretical knowledge but no significant difference was found between the virtual and traditional teaching groups on practical competencies through objective structured clinical examination (OSCE) (Mosalanejad et al., 2014).

The usefulness of lectures attended via interactive video conferencing versus in-person was studied among 52 medical students attending a University of Vermont medicine clerkship program in the United States. Students were asked to attend half of the lectures in person and the rest half via videoconferencing. The mean student scores attending lectures via both methods were found almost similar, suggesting that technology-mediated learning can be used for effective clinical learning at off-site locations (Bertsch et al., 2007). Another study conducted to understand the level of satisfaction also generated evidences for its acceptability among the users (Callas et al., 2004).

Considering the current shortage of nursing-midwifery faculty and resultant sub-optimum educational quality in most ANM and GNM schools of Bihar, we implemented a virtual classroom training program in selected ANM and GNM schools, with the college of nursing (CoN), Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, as an instructor location as it had adequate training infrastructure and trained faculty. The objective of this intervention was to improve the knowledge and skills of nursing-midwifery students.

The Virtual Classroom Training Program

CISCO is an American multinational corporation having expertise in designing and manufacturing high-quality networking equipment. Using Cisco's Education Enabled Development (CEED) technology, virtual classrooms were established in 4 ANM and 3 GNM institutions of Bihar, India. Another virtual classroom was established at CoN, IGIMS Patna, as an instructor location. CEED is an energy-efficient cloud-based video interaction solution, developed by Cisco technologies, with a vision to provide quality education to rural areas at a very affordable price of less than 1 US dollar per child per month (Cisco's 'Dwara' to connect educators, 2013). This method allows teachers and students from remote areas to connect with experts from urban settings (instructor location) through live streaming of training sessions for efficient delivery of education and skills development courses. Each virtual classroom was having some basic technology components needed for successful operation like CEED box, central processor unit integrated with a liquid crystal display (LCD) projector. All peripheral components

like Internet line, public address (PA) system, universal serial bus (USB) drives, keyboard, camera were connected to it.

A 72 hour virtual training package was developed by Jhpiego—an international health organization affiliated to John Hopkins University, based on national curricula for second-year ANM and third-year GNM students, incorporating evidence-based techniques such as case-based learning, clinical simulations, demonstrations, practice, and feedback. The training package was focused on building midwifery knowledge and clinical skills of students in areas like antenatal, intra-partum, immediate post-partum, and neonatal care. This virtual classroom training using 72 hour package was designed as a supplement to regular classroom training. Almost all essential MNH practices which a competent nurse-midwife is supposed to know like management of second stage of labor (mgt. of SOL), active management of third stage of labor (AMTSL), essential new born care (ENBC), new born resuscitation (NBR), plotting of partograph, infection prevention (IP), methods of family planning were included in this comprehensive training package. Virtual training using this package was conducted for final-year GNM students of 2 schools from September 2013 to December 2013. Table 1 illustrates component-wise breakdown of the 72 hour training package.

This study was designed to evaluate the effectiveness of this virtual classroom training in improving the MNH knowledge and clinical skills of nursing-midwifery students using OSCE as the evaluation tool. Although some earlier studies demonstrate the benefits of virtual training, to the best of our knowledge, there are no studies conducted so far to assess the effectiveness of virtual training in improving knowledge and clinical skills of nursing-midwifery students in resource-constrained settings like India. It was anticipated that the findings from the study will add to the existing knowledge base and help find solutions to address the current shortfall in nursing faculty and find ways to improve institutional capacity and quality nursing education in resource-limited settings.

Methods

Study Design

This was a pre- and post-intervention study design to evaluate the effectiveness of virtual classroom training in improving knowledge and clinical skills related to MNH among GNM students. Pre- and post-intervention data were collected from the students from 2 participating GNM schools of Bihar. Complete study data were gathered in two phases approximately 12 months apart. Pre- and post-intervention data were collected in the month of March 2013 and Feb 2014, respectively.

Study Site and Population

All available students from the selected 2 GNM schools, i.e. Shri Krishna Medical College and Hospital (SKMCH), Muzaffarpur, and Patna Medical College and Hospital (PMCH), Patna, of Bihar who were in their final year of enrollment and had completed their course work in maternal and neonatal health were invited to participate in the study. To start with, students from both the GNM schools were assessed for their MNH knowledge and clinical skills. A 72 hour standardized

Table 1
Breakdown of 72 hour virtual classroom training package.

S. No	Components	No. of hours
1.	Antenatal care	17
2.	Intra-natal care and immediate postpartum care	27
3.	Postnatal care	6
4.	Newborn care	8
5.	Family planning	4
6.	Others	10
	Total	72

training package was then administered among the final-year students from the next batch along with their attendance of regular teaching sessions. Post-intervention data were collected from the trained cohort who had attended the virtual classroom training.

The pre and post cohorts included in the study were different as the intervention was targeted at the final-year students. The 72 hour package was administered to a new batch of final-year GNM students as the cohort assessed at pre-intervention had already passed out by the time the intervention was implemented.

Sample Size

Sample size calculation was not conducted as all eligible students were invited to be a part of this assessment. In 2013, prior to implementation of the intervention, 83 GNM students out of the total, i.e. 94, from 2 GNM schools were assessed for their competencies in key MNH skills using the OSCE method. The rest of the students were either denied or absent during the day of assessment. Conversely, all 92 students who attended virtual training participated in the post-intervention assessment for skill assessment. Competency of a student was defined as a score of 75% or above in the OSCE (averaged across 6 stations).

Data Collection Tools and Process

A standardized pre-tested OSCE checklist was used for clinical skill assessment of the students. The questionnaires of the checklist were broadly divided into six sections to cover some of the key MNH practices taught as a part of the intervention. Each section of the OSCE checklist was designed to test clinical decision making skills of the students against the pre-determined standards. Two of the sections, i.e. use of partograph and infection prevention, were nonobserved practices and signified 'knowledge' whereas four sections, i.e. management of second stage of labor, active management of third stage of labor, essential newborn care, and newborn resuscitation, were the observed practices and signified 'clinical skills'. For observed practices, student clinical knowledge and skills were evaluated with the use of simulation models and mannequins against the set OSCE standards. For plotting of partograph and infection prevention, scenario-based questions were administered among participants as a part of knowledge assessment related to those practices. One skill station for each given practice of the checklist was established and scoring was done against each critical step which is essential to be performed as subsets to complete a given practice. The participants were evaluated in batches and it was ensured that the groups of students waiting to be evaluated did not get exposed to the OSCE stations before the evaluation. On an average, 10 minutes' time was allotted to perform a skill at each station. The total duration to complete OSCE assessment for 6 participants was approximately 60 minutes and the maximum possible OSCE score a participant can attain was 76. All participants were evaluated using the same standardized checklist by a group of standardized observers of Jhpiego, India, trained by the study investigator team prior to start data collection.

Statistical Analysis

Data were analyzed using software package 'STATA' version 13 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP). The mean scores of participants at pre- and post-intervention assessments were compared and tested for statistical significance using paired t-test. Differences in the two groups for their competencies were also calculated using Pearson chi-square test. Maximum allowable alpha error considered was 5%. Linear regression modeling with robust standard error estimation was also performed to adjust the clustering effect by school.

Table 2

Background information of the schools that participated in the assessment.

GNM institutions	Pre-intervention	Post-intervention
Number of schools assessed	2	2
Number of students available	94	92
Number of students attended OSCE	83	92

Ethical Consideration

This study was approved by the institutional review board of Johns Hopkins University. Before initiating the study, each member of the research team of Jhpiego, India, involved in data collection received a research ethics training to improve their understanding of study objectives, how to obtain informed consent and maintain participants' privacy and confidentiality throughout the data collection using John Hopkins School of Public Health (JHSPH) Institutional Review Board (IRB) Human Subject Research Ethics Field Training Guide (JHSPH, 2009). A verbal informed consent was obtained from all the participants prior to start their OSCE assessment.

Results

Table 2: Contains background information of the students who participated in the assessment. 83 out of 94 third-year GNM students were assessed for their competencies in key MNH skills using a structured OSCE checklist prior to implementation of the intervention. Subsequently, a total of 92 students from the next batch of the same institutions was then underwent a 72 hour virtual training and then were assessed as post-intervention group for the same skills. While applying the test of normality (Shapiro–Wilk test) on the OSCE scores each cohort, it was found that they followed a normal distribution ($p > 0.05$). The mean student score assessed prior to intervention was 21.3 out of 76 (95% CI, 19.9–22.6) which increased to 62.0 (95% CI, 60.3–63.7) after the intervention. Statistically significant difference in the mean scores (40.6) of students is seen between pre- and post-intervention assessment ($p < 0.001$). The mean scores in each station at pre- and post-intervention is elaborated in **Table 3**. The mean difference in each station was also statistically significant. The pre- and post-intervention changes in the mean scores related to individual practices are given in **Table 3**.

Reasonable level of skills associated with competency of a student in key MNH practices was defined as a score 75% or above in the OSCE, across the six stations. Surprisingly, none of the students assessed prior to the intervention were found to have the reasonable level of skills associated with competency. However, at post-intervention, a

Table 3

Comparison of pre- and post-intervention scores among the students who attended OSCE.

Name of the practice	Mean score (pre-intervention)	Mean score (post-intervention)	Mean difference	P value
1.Management of second stage of labor	2.3	9.6	7.2	<0.001
2.Active management of third stage of labor	1.8	8.8	6.9	<0.001
3.Essential newborn care	2.2	8.0	5.7	<0.001
4.Newborn resuscitation	0.6	8.8	8.2	<0.001
5.Partograph filling	1.3	7.4	6.7	<0.001
6.Infection prevention	12.8	19.0	6.2	<0.001
Total score	21.3	62.0	40.6	<0.001

Table 4
Comparison of competency among the students who attended OSCE.

Competency status	Competent ^a	Needs improvement	Total	P value (chi-square)
Pre-intervention number (%)	0 (0)	83 (100)	83	<0.001
Post-intervention number (%)	71 (77.2)	21 (22.8)	92	

^a Competency of a student was defined as score of 75% or above in the OSCE (averaged across 6 skill stations).

substantial difference has been observed in the competency where 77.2% of the participants were found competent (Table 4), and this difference was statistically significant. Competency as an outcome was difficult to model as no one was having this as an outcome at pre-intervention stage. Therefore, linear regression modeling was performed adjusting for the clustering effect with robust standard error estimation. On an average, a student at post-intervention scored 52.3% (95% CI, 49.4%–55.3%) marks more than the student at pre-intervention. The average difference in score between the schools was 4.9% (95% CI, 1.9%–8.0%) adjusting for pre-intervention and post-intervention (Table 5).

Discussion

The virtual classroom program was designed with an objective to provide quality MNH training to nursing-midwifery students from institutions with limited infrastructure and faculty strength. It was envisioned that utilization of evidence-based scientific innovations like virtual classrooms training could be an efficient and effective strategy to address local needs of quality education and training for nursing-midwifery students in Bihar.

This study aimed to evaluate whether virtual classroom trainings can improve key MNH-related clinical skills of the nursing-midwifery students using a pre–post study design. The findings of the study reveal a statistically significant change in the mean OSCE score of the students. Also a much higher number of students were found competent in the key MNH (scored 75% or more in OSCE) skills post-intervention compared to none during pre-intervention assessment. Even when adjusted for clustering using linear regression analysis, the students during post-intervention scored 52.3% more marks than pre-intervention. To the best of our knowledge, no studies in the literature of midwifery have shown effect of virtual classrooms in improving the clinical skills of the nursing students in resource-constrained settings.

Though the utilization of similar classroom setting has been studied, no statistically significant differences in the mean scores were found between the students who attended lectures via interactive video conferencing from the remote locations versus in-person while attending medicine clerkship program (Bertsch et al., 2007). Another study while evaluating the effectiveness of live lectures delivered via video-conferencing with that of in-person lectures also reported no statistically significant difference in the performance of medical students who attended the national licensing examination (Hortos et al., 2013). In our study, although the context and location of study were different, statistically significant differences in the mean scores have been

observed in the group of students assessed before and after the implementation of the virtual classroom training program.

Additionally, while evaluating the effectiveness of virtual versus traditional learning, a significant increase in the mean scores in the theoretical exams but not in practical competencies for the students who attended virtual sessions versus the traditional learning group were observed (Mosallanejad et al., 2014). A study conducted in India to evaluate the effectiveness of video-assisted teaching module also concluded that it was highly effective in improving the knowledge of nursing students regarding care of dementia patients (Austin and Balasubramanian, 2012). On the other hand, our study on virtual classroom effectiveness revealed a statistically significant improvement in the practical skills of the students related to MNH. The reason for such a drastic improvement might be that the intervention was focused and designed in such a way where students were encouraged, trained for improving their practical skills.

Competency can be best evaluated in a clinical setting based on hands-on experiences. Considering the students' status, time, and logistics, the best proxy to assess competency was to assess skills associated with it through simulation models.

Our study was a pre- and post-intervention study without a control group as a control group was not feasible due to logistic reasons. Although sample size was not calculated and all willing students were invited to participate, the post hoc power calculation showed a power of more than 90%, hence it makes the study valid. Additionally, the student cohorts assessed before and after the intervention were different as the intervention was targeted at the final-year students who have completed coursework on maternal and new born health, which was one of our inclusion criteria for recruiting the participants. It was unrealistic to assess the same cohort of students before and after implementation of the program. The students whom we assessed at pre-intervention had already completed their course work on MNH skills through traditional learning method before the implementation of virtual classroom training. The post-intervention assessment was conducted among the other cohort of students who have attended 72 hour virtual classroom training along with attendance of regular teaching sessions similar to an earlier cohort. Addressing the time lag between two assessment (pre- and post-intervention), an assumption was made that there would be no significant difference between characteristics of students passing out subsequently from the institutions.

Our study indicates that virtual classroom training is effective in enhancing knowledge and clinical skills of nursing-midwifery students in resource-constrained settings, especially where trained faculty are not available in adequate numbers. Considering the existing shortfall in faculty in nursing educational institutions as well as the sub-optimal educational quality, this technology-based approach could be utilized in consort with traditional learning for student skills enhancement. In the long term, this can help us to improve the quality of graduating nurse-midwives, thereby improving the quality of service provision at the sites where these GNM graduates are posted in the future. Although the tracking of these capacity-built graduate nurse-midwives till their employment will be helpful to understand the long-term impact in reducing maternal and neonatal morbidity and mortality in the study state of India, this was beyond the scope of this virtual classroom training program. Though the outcome of this program is promising, a long-term follow-up of nursing graduates who were trained through virtual classroom training can identify the real impact of the program in improving the standards of care being delivered by them at the time of their deployment to health facilities.

Conclusion

The findings of our study suggest that the knowledge and skills of nursing-midwifery students can be enhanced by leveraging virtual training concept blended with traditional classroom learning. Addressing the current issues of sub-optimal nursing education, infrastructure,

Table 5
Linear regression of the mean scores adjusted for clustering by schools.

Variable	Adjusted mean difference (95% CI)	P value (t-test)	Coefficient of determination Overall P value (F test)
Pre–post-intervention	52.34 (49.4–55.3)	<0.001	0.9
Difference between PMCH and SKMCH	4.9 (1.9–8.0)	<0.001	<0.001

and shortage of faculty, this approach can be utilized to deliver high-quality MNH training to nursing-midwifery students based at remotely located institutions.

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CHAPTER

4

Women's experience with postpartum intrauterine contraceptive device use in India

RESEARCH

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Women's experience with postpartum intrauterine contraceptive device use in India

Somesh Kumar^{1*}, Reena Sethi², Sudharsanam Balasubramaniam¹, Elaine Charurat², Kamlesh Lalchandani¹, Richard Semba^{1,2} and Bulbul Sood¹

Abstract

Background: Postpartum intrauterine contraceptive devices (PPIUCD) are increasingly included in many national postpartum family planning (PPFP) programs, but satisfaction of women who have adopted PPIUCD and complication rates need further characterization. Our specific aims were to describe women who accepted PPIUCD, their experience and satisfaction with their choice, and complication of expulsion or infection.

Methods: We studied 2,733 married women, aged 15–49 years, who received PPIUCD in sixteen health facilities, located in eight states and the national capital territory of India, at the time of IUCD insertion and six weeks later. The satisfaction of women who received IUCD during the postpartum period and problems and complications following insertion were assessed using standardized questionnaires.

Results: Mean (SD) age of women accepting PPIUCD was 24 (4) years. Over half of women had parity of one, and nearly one-quarter had no formal schooling. Nearly all women (99.6%) reported that they were satisfied with IUCD at the time of insertion and 92% reported satisfaction at the six-week follow-up visit. The rate of expulsion of IUCD was 3.6% by six weeks of follow-up. There were large variations in rates of problems and complications that were largely attributable to the individual hospitals implementing the study.

Conclusions: Women who receive PPIUCD show a high level of satisfaction with this choice of contraception, and the rates of expulsion were low enough such that the benefits of contraceptive protection outweigh the potential inconvenience of needing to return for care for that subset of women.

Keywords: Contraception, Complications, Family planning, Intrauterine contraceptive device, Postpartum

Introduction

Family planning can avert nearly one-third of maternal deaths and 10% of child mortality when couples space their pregnancies more than two years apart [1]. Short intervals between births are linked with higher maternal and child mortality and morbidity [2]. Postpartum family planning (PPFP) is the prevention of unintended and closely spaced pregnancies through the first twelve months following childbirth [1]. Postpartum women need a range of effective contraceptive methods to be able to prevent an unplanned pregnancy, within a short interval [1,2].

Among the options available, the multi-year cost of the Copper T380A IUD makes it one of the most cost-effective contraceptive options available. The Copper T

380A intra-uterine contraceptive device (IUCD) is a highly effective, non-hormonal method that can be safely used by all women regardless of breastfeeding status during this interval. According to the World Health Organization Medical Eligibility Criteria, an IUCD can be inserted in the 48 hours postpartum, referred to here as a postpartum IUCD (PPIUCD), or after four weeks following a birth [3]. A 2010 Cochrane review concluded that PPIUCDs were a safe and effective contraceptive method. The public health benefits from PPIUCDs stemmed from the women's increased accessibility to PPIUCDs following facility births, as PPIUCDs could be offered at health facilities after childbirth. This, in turn, decreased opportunity and other costs incurred by clients who may otherwise have to return to facilities to access contraceptive services [4].

* Correspondence: somesh.kumar@jhpiego.org

¹Jhpiego, New Delhi, India

Full list of author information is available at the end of the article

In India, the 2005–2006 National Family Health Survey (NFHS) reported that 61% of births were spaced less than three years [5] and that 22% of married women had an unmet need for family planning. A subsequent stratified analysis suggested that 65% of women in the first year postpartum had an unmet need for family planning [6]. IUCDs are used by only two percent of current users of contraception in India [5]. Recognizing the potential impact of improved family planning programming on maternal and child health, the Government of India has committed to expanding access to family planning as part of achieving Millennium Development Goals 4 and 5, related to reduction of child and maternal mortality. In 2005, the Government of India launched the Janani Sukrasha Yojana (JSY), a conditional cash transfer scheme, to encourage the use of facilities for care at birth [7]. Since the inception of JSY, facility-based births in the public sector have increased from 700,000 in 2005 more than 11 million in 2012 [8].

With increasing numbers of women electing to give birth in health institutions, the Government of India decided to strengthen PPFP and to introduce PPIUCD services in a phased manner, with the first batch of clinician trainings, in 2009. A national training center was established at Safdarjung Hospital in New Delhi, as well as three regional training centers in Mumbai, Jabalpur, and Lucknow in 2009–2010. The provision of PPIUCDs is being rapidly scaled up in India, with facilities in at least nineteen states offering the method in 2013. Previously, concerns about the PPIUCD focused on high expulsion rates. Studies published in the nineties and early 2000 reported rates of about 9–13% [9–11]. However, lower expulsion rates have been reported more recently with improvements in insertion technique [12,13].

PPIUCDs are still emerging as a relatively new contraceptive choice in India. While follow-up data on complications with PPIUCD insertions were available from international sources, given the scale at which PPIUCD services are being introduced in India, it was important to generate country-based evidence on the post-insertion outcomes after the introduction of PPIUCD program. Additionally, information related to the demographic profile of women who accept PPIUCDs, the dynamics of their decision making process, their satisfaction with this method of contraception, and complications with the IUCD have not been well characterized. Therefore, we conducted a prospective, observational study of a large cohort of women who received PPIUCDs in India.

Our specific aims were to determine the demographic characteristics and decision-making among women who accepted PPIUCDs, their perception and satisfaction with PPIUCDs, and complications that occurred after insertion of PPIUCDs. The overarching aims of this study were to inform the stakeholders about the experience of the

PPIUCD program in the country and provide guidance for further scaling up of the PPIUCD program in India. This publication addresses several specific areas within these overarching aims: clients' satisfaction with PPIUCD as a family planning method; the importance of counseling services within the perspective of the overall decision making process of the client and her family for acceptance of a postpartum family planning method; and the post-insertion outcomes of the clients accepting PPIUCD services.

Subjects and methods

Study subjects

The study subjects consisted of 2,733 women, aged 15–49 years, who received PPIUCDs in sixteen health facilities, all hospitals, located in eight states (Assam, Bihar, Jharkhand, Madhyaradesh, Maharashtra, Rajasthan, Uttar Pradesh, Uttarakhand) and the National Capital Territory (Delhi) in India between January 2011 and December 2012. Hospitals were selected by convenience, based upon where Jhpiego programs had trained personnel in the provision of PPIUCDs with funding from the United States Agency for International Development (USAID)'s Maternal Child Health Integrated Program (MCHIP) and the Bill & Melinda Gates Foundation (BMGF). All women who received a PPIUCD and were married were invited to participate in the study. Women were enrolled in the study after standardized oral consent in the local language. Participants were interviewed prior to discharge after receiving a PPIUCD and then six weeks later.

Data collection

Data were collected from participants using a structured questionnaire that included basic demographic information, perception of family planning, satisfaction with PPIUCD counseling and with the method itself. After six weeks, PPIUCD clients were again interviewed using a structured follow-up questionnaire that was used to collect information about the clients' overall satisfaction with the method, problems or complications related to the method, and retention of the PPIUCD. Family Planning Counselors who received standardized training in the study protocol, collection of data, and research ethics were responsible for administering the questionnaires. The follow-up interview was generally conducted at the same health facility in which the client had received the PPIUCD. In the cases where the client did not return to the health facility for her follow-up visit, she was contacted by telephone for the follow-up interview. The Institutional Review Board of the Johns Hopkins Bloomberg School of Public Health approved the study. A letter of support was also obtained from the Ministry of Health & Family Welfare, Government of India.

Statistical analysis

Continuous variables were reported using mean (standard deviation) and categorical variables were reported using percentages. For two group comparisons, a student *t*-test was used to compare means of continuous variables, and chi-square tests were used to compare categorical variables. Logistic regression models were used to examine the relationship between demographic and other covariates with problems or complications associated with IUCD. All analyses were conducted using Stata 10 and 12 (Stata Corporation, College Station, TX) and SAS (v.9.1.3, SAS Institute, Cary, NC) with a type 2 error of 0.05.

Results

A total of 2,733 women were enrolled in the study after receiving a PPIUCD prior to discharge, and 1,730 women (63.3%) were interviewed at the six-week follow-up visit. Table 1 shows the demographic characteristics of study participants; women that received a PPIUCD in selected health facilities and were interviewed upon exit. Results showed that study participants were an average (SD) age of 24 (4) years, some (about one-quarter) had no formal education, and around half had one living child. Just over half (54%) of the interviewed women responded that they wanted more children. More than half of the participants were from Uttar Pradesh and Madhya Pradesh states, as expected from sample estimations.

The period during which women received counseling and other factors related to decision making are shown in Table 2. More than half of the women received PPFP counseling during antenatal care visits. About two-thirds of women had not previously used family planning methods in the past. While more than half of the women based their decision to use a PPIUCD based on discussing with multiple individuals, more than 70% of the women choosing to use a PPIUCD as a contraceptive method received PPFP counseling by a dedicated counselor at the facilities, and many stated they made the own decision to use a PPIUCD before delivery, either during antenatal care or before delivery. Nearly all women were satisfied at the time of interview about their decision to have a PPIUCD inserted. Amongst study participants, 54% had heard of IUCDs before they received PPFP counseling, and of this group, only 7% of those who had heard of IUCDs before had used an IUCD before.

The timing of PPIUCD insertion and perceptions of pain are shown in Table 3. About half of the IUCDs were post-placental insertions and nearly one-third were inserted during C-section. About three-quarters of women reported no pain at all during or after insertion. Only a small proportion of women (1-2%) reported that the insertion was painful or very painful during or after insertion. At six-week follow-up interview, the complications of expulsion or infection associated with IUCD use are shown in Table 4.

Table 1 Demographic characteristics of clients who accepted Post-Partum Intrauterine Contraceptive Device (PPIUCD) and were interviewed at the time of discharge from the facilities

Demographic characteristics ¹		Mean (SD) or number (%)
Age, years		24 (4)
Education (%)	No schooling	582 (23)
	Primary school	494 (19)
	Secondary school	534 (21)
	Senior secondary	408 (16)
	Intermediate	269 (9)
	Graduate and above	304 (12)
Parity (%)	One	1422 (53)
	Two	890 (33)
	Three	271 (10)
	Four or more	100 (4)
Location (%)	Assam	479 (18)
	Bihar	227 (8)
	Delhi	199 (7)
	Jharkhand	92 (3)
	Madhya Pradesh	638 (24)
	Maharashtra	117 (4)
	Rajasthan	83 (3)
	Uttar Pradesh	745 (28)
Fertility intentions (clients wanted more children)	Uttarakhand	131 (5)
	Yes	1453 (58.6)
	No	1224 (45.2)
Clients who have heard of IUCD	No response/did not know	22 (0.8)
	Yes	1450 (53.5)
Clients who have used IUCD in the past (of the clients who have heard of PPIUCD) (n = 1450)	No	1241 (45.8)
	Yes	94 (6.5)
	No	1329 (91.7)

¹Missing data (age, 22; education, 143; parity, 47).

The results show self-reported expulsion rate of roughly 3.8% among clients, with more than three-quarters of women reporting no complaints with their PPIUCD. Only 5.4% of women suffered from symptoms suggestive of infection after the insertion. Symptoms that were considered suggestive of infection included lower abdominal pain, fever, foul smelling/abnormal vaginal discharge, painful intercourse, and bleeding after intercourse. Other self-reported side normal effects of PPIUCD insertion included cramps and abdominal pain which 8.9% of women reported experiencing, along with 5.5% reporting minor menstrual problems. There were no cases of uterine perforation.

Table 2 Counseling and decision-making about PPIUCD at baseline

Characteristic ¹	Mean (SD) or number (%)
Number of antenatal clinic visits	5.2 (3.1)
Period of counseling (%)	
Antenatal clinic	1408 (52)
Early labor	988 (36)
After delivery	367 (14)
During postpartum stay	335 (12)
Satisfied with counseling (%)	
Yes	2616 (98)
No	50 (2)
Family planning methods used in the past (%)	
No methods	1827 (67)
IUCD	389 (14)
Injectable	6 (0.2)
Condoms	381 (14)
Pills	93 (3.4)
Others	15 (0.6)
Decision-making in PPIUCD as the method of family planning (%)	
Self, alone	590 (22)
Self, after consulting with family	261 (10)
Husband	160 (6)
Mother	13 (0.5)
Mother-in-law	16 (0.7)
Sister	5 (0.2)
Multiple options	1664 (61.5)
Counseling provider (multiple responses allowed)	
ASHA	96 (96.5)
Counselor	1942 (71.1)
Doctor	1147 (42.0)
Nurse	439 (16.1)
ANM	59 (2.2)
Aganawadi worker	45 (1.7)
Timing of decision to choose PPIUCD as family planning method (%)	
Antenatal clinic	1039 (39)
Before delivery	1021 (38)
After delivery	610 (23)
Satisfied about decision to use PPIUCD (%)	
Yes	2631 (99.6)
No	2 (0.4)

¹Missing data (Previously used IUCD, 1300; satisfied with counseling received, 67; satisfied with decision to use PPIUCD, 100).

Discussion

This study of PPIUCD use in India showed that most women were satisfied with their choice of immediate insertion of an IUCD and that the rates of problems and complications were relatively low. Most of the women made the decision to use a PPIUCD as a method of contraception during the antenatal period or before delivery, signifying the importance of counseling in the antenatal period and before delivery. While about 54% of the women used the method for spacing their pregnancy, the remaining women accepted this method even though they did not

Table 3 Timing of PPIUCD insertion and perceptions of pain related to insertion in 2711 women in India

Characteristic	Mean (SD) or number (%)
Timing of PPIUCD insertion (%)	
Immediately after delivery	1379 (51)
During C-section	838 (31)
Within 48 hours	299 (11)
Do not know	195 (7)
Client perception of pain during insertion (%)	
No pain at all	1863 (71)
Little discomfort	631 (24)
Somewhat painful	87 (3)
Painful/very painful	44 (2)
Client perception of pain after insertion (%)	
No pain at all	1950 (76)
Little discomfort	487 (19)
Somewhat painful	112 (4)
Painful/very painful	11 (1)

want any more children. The large proportion of women accepting the method to limit future childbearing indicates the important place PPIUCDs hold, as a long-acting reversible method, within the basket of PPF methods.

A majority of women (87.6%) reported the acceptance of PPIUCD as a contraceptive method due in part to the fact that it is a long acting method. Additionally, 22% of women accepting a PPIUCD cited the free-of-charge services as one reason for choosing the method. Some women, about 12.7%, also stated that they were at least partially influenced by the infrequent follow-up trips to

Table 4 Findings and satisfaction with IUCD at six weeks following IUCD insertion in 1730 women in India

Variables ¹	Number (%)
Findings reported (%)	
None	1344 (78)
Expulsion	63 (4)
Infection	91 (5)
Abdominal pain	138 (8)
Menstrual/bleeding problems	82 (5)
Medical attention sought for problems (%)	
Yes	405 (77)
No	121 (23)
Reason for removal (%)	
Complications	73 (70)
Husband is opposed	4 (4)
Want to use other method	4 (4)
Other	23 (22)
Woman happy with choosing PPIUCD (%)	
Yes	1420 (92)
No	125 (8)
Husband happy with choice of PPIUCD (%)	
Yes	1011 (69)
No	84 (6)
Don't know	367 (25)

¹Missing data (happy with choosing PPIUCD, 185; husband happy with PPIUCD, 268).

the facility when choosing the PPIUCD, while 20.5% considered the non-hormonal nature of the method when choosing. Of importance, only half of women had heard of the IUCD before they were counseled at the facility and only 7% had ever used one. This implies that a vast majority of clients accepting PPIUCD services are first time users of IUCDs, underscoring how offering services like PPIUCDs shifts the PPF method mix through access to long-acting reversible methods.

Nearly all women were satisfied with their choice of IUCD at the time of insertion and over 90% reported that they were happy with the IUCD at six weeks following insertion. A previous study from Orissa among interval IUD users found that about three-quarters of women were satisfied with this mode of contraception after one year [14]. The present study is somewhat suggestive that satisfaction rates are higher with PPIUCD than with interval IUD use, but the follow-up time in the two studies is not directly comparable.

In the present study, the expulsion rate was about 3.6%, which compares to the expulsion rate of 5.6% reported among 210 women in a clinic in Hubli, Karnataka state in India [15], 1.6% among 3000 women in a hospital in Paraguay [12], and 5.6% among women among 305 periurban Lusaka, Zambia [13]. Another study of 1317 women in north India reported a cumulative expulsion rate of 10.7% by six months [16]. Higher expulsion rates of around 9-16% have been reported in earlier studies [9-11,17]. One recent study from Turkey of PPIUCD among women after C-section reported an expulsion rate of nearly 18% [18]. Requests for removal of IUCD was 5.9% in the present study, compared with 7.6% reported in Hubli, India [15], 3.4% among women in Paraguay [12], and 3% among women in Zambia [13].

About 5 % of women in the present study reported infections. This rate is higher than the rate of 0.1% reported among women in Paraguay [12]. A limitation of the present study is that infection was based upon self-report and was not corroborated by medical records or microbiological confirmation. A small proportion of the study group, 120 women (3.8%), had their PPIUCD removed within the first six weeks of insertion. Women most commonly reported expected side effects of IUCDs as the reasons for the removal, including bleeding and abdominal pain. These findings suggest that there is room for strengthening PPIUCD counseling services, particularly regarding normal side effects and complications that arise from method use.

The present study is limited in that long-term expulsion rates could not be determined since follow-up was only conducted at six weeks following birth. Further studies could be conducted that involved one or two year follow-up assessments. Although the present study included a large sample of women from eight states and

a territory in India, the findings cannot necessarily be generalized to all of India since the hospitals involved were a convenience sample rather than a sample representative of the country.

Expansion of access to PPIUDs in India may provide an opportunity to address the high proportion of births with short intervals and improve maternal and child health outcomes. More study is needed to assess the effects of PPIUD on continuation and birth spacing in the future.

Conclusions

Women who receive PPIUCD show a high level of satisfaction with this choice of contraception, and the rates of expulsion were low enough such that the benefits of contraceptive protection outweigh the potential inconvenience of needing to return for care for that subset of women.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

SK, RS, and BS conceived the study. SB analyzed the data. SK, RS, EC, and KL drafted the manuscripts. SK, RS, and BS extensively reviewed and revised the article. All authors read and approved the final manuscript.

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Author details

¹Jhpiego, New Delhi, India. ²Jhpiego, Baltimore, USA.

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CHAPTER

5

Effectiveness of a package of Postpartum Family Planning services in India

Effectiveness of a package of Postpartum Family Planning services in India

Somesh Kumar, Anand Bairagi, Ashish Srivastava, Vineet Srivastava, Kaustubh Wagh, Minati Rath, Jelle Stekelenburg, Bulbul Sood

Abstract

Through this study, we evaluate the effect of a package of post-partum family planning interventions in improving level of awareness, knowledge and practices of post-partum women as well as health care providers in Bihar, India. We conducted cross sectional surveys before and after the intervention in 18 public health facilities and their catchment areas across 5 districts of Bihar. We used a standard questionnaire to interview post-partum women (n= 972 at baseline; n= 981 at end line) and health care providers (n= 251 for baseline and end line). After the intervention, we found significant improvements in knowledge of all cadres of health service providers regarding return to fertility among postpartum women. We also saw significant improvements in knowledge of post-partum women regarding return to fertility, knowledge of three or more modern family planning methods and the three criteria of lactational amenorrhoea method. Proportion of post-partum women who reported receiving family planning counselling at health facility also significantly increased.

Background

Post-partum family planning (PPFP), which is defined as use of family planning within the first 12 months of childbirth, can improve maternal and neonatal health outcomes by reducing 10% of child deaths (Conde-A & Belizan, 2000) and 32% of maternal deaths (Cleland et al, 2006). In India, like other low and middle income countries (LMIC) with similar context, more than 90% women return to sexual activity and 62% return to menses within twelve months after giving birth (Ross & Winfrey, 2001; Mumah, Machiyama, Mutua, Kabiru, & Cleland, 2015). Only 26% women use any method of contraception in their first year postpartum and 65% of them have an unmet need for family planning (Ross & Winfrey, 2001; Ali, Mohamed M. & Shah, 2004). Similar findings have been reported from other multi-country analysis as well (Ross & Winfrey, 2001; Ali, Mohamed M. & Shah, 2004; Moore et al, 2015;

Rossier, Bradley, Ross & Winfrey, 2015). Return to sexual activity, return to ovulatory cycle and non-use of contraception within the first 12 months of childbirth lead to 61% of all births that occur before the recommended three years postpartum birth to birth interval (Ross & Winfrey, 2011). Hence, improving awareness about healthy timing and spacing of pregnancy, return to fertility within the first few weeks after childbirth and improving access to contraception for women in their first year postpartum assumes significance from a policy and program perspective. Studies have been conducted on different interventions based on timing and nature of administration (during antenatal period, postnatal period, both antenatal and post-natal and integration with other services) to improve postpartum family planning in low and middle countries (Cleland, Shah & Daniele, 2015). Studies conducted during antenatal period show that high-intensity antenatal counseling of

women may be needed to produce an improvement in contraceptive uptake. Combined antenatal and postnatal interventions have shown substantial impact on contraceptive use at various points in the first year postpartum. Few programs actively integrate family planning counseling and services with child immunization services, and even fewer have examined the impact of such integration (Cleland, Shah & Daniele, 2015). However, most of these studies have been undertaken on a small scale in study and pilot settings and there is no study that evaluates the effect of a comprehensive PPFP program, which includes a package of interventions, implemented at a reasonable scale in resource constrained health systems.

The objective of this study was to assess the baseline status, as well as to evaluate a package of PPFP interventions on improving level of awareness, knowledge and practices of post-partum women and health care providers in Bihar. The learnings from this study can inform policy makers and program managers in India, and in similar such settings globally, on the design and planning for implementation of comprehensive programs for addressing the disproportionately large unmet need for family planning among women in their first year after childbirth.

Methods

A before and after intervention cross sectional study was done in the catchment areas of eighteen public health facilities of five districts of Bihar (Muzaffarpur, Saran, Madhubani, Gaya and Bhagalpur) in April-May 2012 (baseline) and March 2014 (end line). Post-partum women and health care providers were identified from the catchment areas and interviewed at each time point to determine the change in level of awareness, knowledge and practices related to post-partum family planning after implementation of the PPFP package. Health care providers included doctors, nurses, auxiliary nurse midwives (ANMs) and accredited social health activists (ASHAs) affiliated to the intervention facilities.

ANMs are health staff which provide basic healthcare services. They serve a population of about 5000 through

a health center as well as by going door-to-door. They are responsible for implementing the national health programs apart from providing basic maternal and newborn and family planning services. ASHAs are community health workers who serve a population of about 1000. They are women between the age of 25 and 45 years with a minimum level of formal education. They are trained to work as an interface between the villages and public health system and receive performance based incentives for promoting different health care programs. ASHAs are provided with training to acquire knowledge, skill and confidence for performing roles in immunization, referral and escort services for family planning, antenatal care and child health.

Study setting

Bihar has a population of 100 million, total fertility rate [TFR] of 3.4 and contraceptive prevalence rate (CPR) of 34.1% (IIPS, 2006). More than 90% of women in Bihar want to either delay or avoid future pregnancy within a year of their child birth but 75% of women do not use any method of contraception (MCHIP). The government of Bihar developed a strategy to focus on increasing access to contraception within the extended postpartum period (one year after child birth) in 2011 (Jhpiego, 2015). The interventions were implemented in five districts of the state with a population of about 20 Million, reaching out to around 3.5 million eligible couples to generate evidence for further scale-up.

Intervention

The package of interventions included provision of quality counselling, integration of PPFP services at maternal new born child health platforms and increasing awareness of and demand for PPFP services (Jhpiego, 2015). Postpartum period was defined as the first year after the last child's birth (MCHIP). Facility based health care providers at different levels were trained in a two day training session on counselling skills. These trainings included the technical content of counseling, the approaches of counseling and communication skills. The doctors and nurses based at facilities were trained in clinical contraceptive services through a 3 day

training on PPIUCD services and a two day refresher training on contraceptive technology update. A short refresher training on postpartum sterilization was designed for orienting the existing female sterilization service providers on the clinical technique and program requirements for providing postpartum sterilization services. Master trainers who were trained in clinical and training competencies imparted these trainings. Field based health workers (ANMs and ASHAs) were trained on delivery of key family planning messages during provision of antenatal care, immunization sessions and postnatal home visits through one-day short orientation sessions. These workers were supported by developing an eco-system of enablers in form of service delivery tools, supervision systems and monitoring systems to increase awareness among the communities through integration of PPFP messages in all the existing contacts of the women with the health system, from the antenatal period to the first year postpartum.

Sample

We included a sample of postpartum women residing in the catchment area of the 18 intervention facilities who delivered within the last nine months from the date of interview. To obtain this sample, we listed the villages in the catchment area of these facilities and randomly selected nine villages per facility using simple random sampling. The survey therefore involved 162 villages. On reaching the selected village, the investigators approached the ASHA and Anganwadi worker (community based nutritional worker) to collect the details of the postpartum women who had delivered in past nine months. From the demographic and personal details in the registers, 9 women who delivered in institutions and 9 women who delivered at home were selected from each village using random sampling through pseudo random number generation in excel. The first three available and consenting postpartum women in each category were interviewed after obtaining oral consent; 972 and 981 postpartum women were interviewed in total before (during baseline) and after (end line) the intervention respectively. We did not do a prior sample size calculation although we ensured the representation of all villages belonging

to the catchment areas of the eighteen intervention facilities in the sampling frame.

After the initial round of data collection and preliminary analysis, we found that some of the relevant information on return to fertility, birth to birth interval and family planning counseling was not captured with the original questionnaire. Hence we added and modified the questions of the original questionnaire and administered this modified questionnaire to a smaller sample of 324 post-partum women who were randomly selected from the same catchment areas and communities using the same methodology. The modified questionnaire was administered during the end line survey to the entire sample of 981 postpartum women. To ensure that the 324 women who were administered the modified questionnaire were similar to the 971 originally interviewed women; we analyzed these samples for some relevant background characteristics and found them to be similar to each other. Additionally, there was non-response on some questions among these 324 women and the non-response rates ranged from 0 to 26%.

Doctors and nurses from the intervention facilities were selected by convenience sampling; those who were available in the facilities on the day of data collection and consented to participate were included. The ASHAs and ANMs linked to the 18 intervention facilities were randomly selected (by excel generated pseudo random numbers) from facility catchment areas. 5 ANMs and 5 ASHAs per facility were selected.

Procedure and measures

Once the selection was done, consenting post-partum women and health care providers were interviewed using standardized questionnaires (supplementary files 1-5) in the local language. The questionnaire consisted of questions on demographic and socio-economic profile (for post-partum women) as well as on knowledge, awareness and practices related to post-partum family planning.

The interviewers ensured confidentiality and privacy of participants during the interview. For ensuring data

quality, all interviewers underwent a common 3 day training which included components of basics of post-partum family planning, discussion on questionnaires for women and providers and ethical principles. Ten percent of the data was cross-verified by the data supervisors by back-checking with the respondents.

Analysis

Data was analyzed using SPSS version 22.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, version 22.0. Armonk, NY: IBM Corp.). We first described the background characteristics and knowledge and practices using proportions. Next, we assessed the effects of the package of PPFPP intervention on awareness, knowledge and practices of post-partum women and health care providers by comparing pre and post rates. We assessed the statistical significance of the differences by using chi square tests. A p value of less than 0.05 was considered statistically significant.

Ethics approval and consent to participate

The study was carried out with the permission from Government of Bihar. The institutional review board of Johns Hopkins Bloomberg School of public health (JHIRB No. - IRB00004138) approved the study, including a waiver of written consent. Oral informed consent was obtained from the study participants.

Results:

A total of 972 (at baseline) and 981 (at end line) women were included and interviewed. No statistically significant differences were found between the characteristics (age, education etc.) of the participants.

A total of 27 doctors and 46 nurses were interviewed in the baseline and 18 doctors and 53 nurses during the end line. A total of 89 and 90 ANMs and 89 and 90 ASHAs, in baseline and end line respectively, were interviewed.

There was an improvement in knowledge about return to fertility (among partially breastfeeding and fully breastfeeding women) and about the best time for counseling on postpartum family planning across all cadres of service providers. For knowledge on return to fertility among fully breast feeding women, maximum improvement was seen in doctors (48.1% vs 100%) whereas for knowledge on return to fertility among partially breast feeding women, maximum improvement was seen in nurses (18.2% vs 90.6%). For knowledge of best time to counsel on post-partum family planning, the maximum improvement was seen in ASHAs (3.4% vs 78.9%). Improvements in knowledge about these three aspects were statistically significant for all cadres.

Table 1: Demographic and socioeconomic profile of Postpartum Women Interviewed for the study during baseline and end line

Characteristics	Baseline – Endline Comparison	
	Baseline (n = 972)	Endline (n = 981)
Mean Age (SD)	25.4 Years (SD: 4.3)	25.9 Years(SD:4.4)
Education		
Illiterate	61.2	60.9
Literate	38.8	39.1
Mean age at marriage	17.6 Years (SD: 2.0)	17.8 Years (SD: 1.9)
Number of living children		
Up to 2 children	51.9	47.9
More than 2 children	48.1	52.1

Table 2: Knowledge of facility based health providers and community based health providers about return to fertility among partially breastfeeding and fully breastfeeding women and the best perceived timing for counseling

	Doctor			Nurse			ANM			ASHA		
	Baseline (n=27)	Endline (n=18)	p value	Baseline (n=46)	Endline (n=53)	p value	Baseline (n=89)	Endline (n=90)	p value	Baseline (n=89)	Endline (n=90)	p value
Knowledge about Return to Fertility among Fully Breastfeeding Postpartum women												
At or After Six months	48.1	100	<0.001	75	96.2	p < 0.001	85.4	84.4	p = 0.843	76.4	85.6	0.12
Knowledge about Return to Fertility among Partially Breastfeeding Postpartum women												
At or After 4 weeks	25.9	88.9	p < 0.001	18.2	90.6	p < 0.001	7.9	72.2	p < 0.001	6.7	31.1	< 0.001
Perception about appropriate timing for Post-partum family planning counselling												
During ANC	48.1	83.3	p < 0.001	27.3	90.6	p < 0.001	48.3	74.4	p < 0.001	3.4	78.9	< 0.001
During Post-Partum stay	18.5	0	p < 0.001	36.4	0	p < 0.001	32.6	3.3	p < 0.001	48.3	0	< 0.001

Table 3: Knowledge related to healthy timing and spacing of pregnancy among post-partum women

Characteristics	Baseline – Endline Comparison percentage		P value
	Baseline (n = 324)	Endline (n = 981)	
Knowledge on return to fertility			
Fully breast feeding women			
Don't Know	48.5	21.7	p < 0.05
As early as after Six months	28.4	67.5	
Others*	31.1	10.8	
Partially breast feeding			
Don't Know	54.3	24.8	p < 0.001
As early as after four week	2.8	35.2	
Others*	42.9	40.0	
Knowledge on birth to birth interval			
Don't know	6.5	0.8	p =0.713
Up to 1 Year	19.7	8.6	
Min. gap of 24 months	23.5	37.7	
Min. gap of 36 months or more	50.3	52.9	

Characteristics	Baseline – Endline Comparison percentage		P value
	Baseline (n = 324)	Endline (n = 981)	
Knowledge of three or more modern methods of family planning	Baseline (n = 972)	Endline (n = 981)	
Know 3 or more Modern Family Planning Method	83.5	96.1	p < 0.01
Source of knowledge of family planning	Baseline (n = 948)	Endline (n = 959)	P value ¹
TV	16.3	18.4	P=0.695
Hoardings	1.9	2.3	P=0.843
Doctor	2.3	20.0	p < 0.001
ANM	8.5	55.9	p < 0.001
ASHA	41.0	85.0	p < 0.001
Newspaper	4.4	5.2	P=0.791
Relative/Friend	77.8	64.5	p < 0.05
Radio	17.1	7.6	p < 0.05
Proportion of women knowing three criteria of LAM	0.0	38.5	p < 0.001

Among post-partum women, there was an improvement in knowledge about return to fertility (both for fully and partially breast feeding women) as well as 3 criteria of lactational amenorrhoea (LAM) from baseline to end line. The proportion of women who knew about 3 or more modern family planning methods also increased significantly although there was no improvement in knowledge about birth to birth interval.

There was a statistically significant increase in the percentage of post-partum women receiving any contraceptive counseling as well as those who received all the important information related to contraceptives like - available contraceptive choices, likely adverse events, return to fertility and healthy timing and spacing of pregnancies - from baseline to end line.

Proportion of post-partum women who were offered at least three modern contraceptive methods at health facilities also significantly increased.

Discussion

This study, which is the first of its kind to assess the effect of a comprehensive PPFP strategy, demonstrates that a package of interventions which includes provision of quality counselling, access to contraceptive services, integration of PPFP services with other health service delivery platforms, increasing awareness of service providers and demand for PPFP services in the communities, leads to improved service delivery at facility and community levels and in increased awareness about PPFP at the community level. The results from this study can inform the scale up of a context-appropriate PPFP strategy in similar resource constrained settings in India and globally.

The awareness levels on key concepts of PPFP like return to fertility among partially and exclusively breastfeeding women and on the three criteria of Lactational Amenorrhea method (LAM) was low

*These are participants who gave an incorrect response**Group when compared to others

1. Each Source compared with all other Sources (2 X 2)

Table 4: Status of family planning counselling and services in the facilities

Characteristics	Baseline – Endline Comparison percentage		P value
	Baseline (n = 294)	Endline (n = 485)	
Proportion received family planning counseling at facility	73.1	91.3	p < 0.05
Health worker who counseled	n = 215	n = 443	
Doctor	8.4	45.8	p < 0.001
Staff Nurse / ANM	40.9	65.2	p < 0.001
Counselor	4.2	14.4	p < 0.05
Women receiving information on RTF, methods and side effects during counseling	n = 215	n = 443	
Return to Fertility (RTF)	0.0	73.6	p < 0.001
Percentage of PPW received all information during counseling	26.5	49.2	p < 0.001
Women offered at least three modern methods of contraception	Baseline (n = 215)	Endline (n = 443)	
Proportion of PPW offered at least three modern method	31.6	89.2	p < 0.001

across the cadre of health workers at baseline. This low awareness is perhaps due to the lack of regular technical updates on Family Planning for these public health providers. This lack of awareness about important concepts related to PFP among health care providers, including clinical providers like doctors and nurses, was a significant finding as the clinical providers are usually an important and trusted source of information about family planning for the community (Alege, Matovu, Ssensalire & Nabweya, 2016). Lack of awareness about contraceptive methods among community based health workers, as observed during baseline in our study, has also been observed in Cambodia (The Respond Project, 2013) and Guatemala (Jacobs, Erika, Brambila & Vernon, 2002). This is probably due to the sub-optimal quality of pre-service training as well as non-inclusion of post-partum family planning related concepts in the curriculum of the trainings for the community based health workers. This lack of awareness among health care providers in the facilities of the study area potentially contributed to the sub-optimal delivery of counseling and PFP services at the facilities, as was observed during the

baseline. This finding is consistent with findings of earlier studies which have identified lack of provider knowledge on contraceptive method (vasectomy) as an important barrier to delivery of quality services (Shattuck, Perry, Packer & Quee, 2016).

Recognizing this need for training for community based health workers like ANMs and ASHAs, the PFP strategy included customized capacity building interventions for both facility and community based workers. This update of the knowledge for entire spectrum of healthcare providers was essential to bring about an improvement in the awareness levels and uptake of Family Planning services in the communities served by them. Authors of earlier studies have also reported the importance of trainings of health workers in increasing awareness about contraceptive services among communities (Cleland, Shah & Daniele, 2015; Juma, Mutombo & Mukiira, 2015; Schwandt, Speizer & Corroon, 2017). The increased awareness among the facility based providers after the training interventions resulted in a significant improvement in the quality of counselling services offered at the facilities. This is in

line with earlier studies that have reported that health workers with adequate knowledge about the relevant concepts of Family Planning can play an effective role in improvement of Family Planning services through effective interpersonal communication (Sebastian, Khan & Roychowdhury, 2010). Studies have also suggested that training reduces the provider biases and hence increases the quality of services provided to clients (Speizer, Hotchkiss, Magnani, Hubbard & Nelson, 2000). The improvement in quality of counseling is evident from the fact that majority of women attending the targeted health facilities after the intervention reported being counselled on the key concepts of return to fertility, need for spacing and adverse effects of Family Planning methods, in addition to being offered at least three methods of contraception. In the context of concerns on quality of Family Planning services in busy and resource constrained public health facilities, these findings have the potential to bring about a significant improvement in the dimensions of volunteerism and informed choice during delivery of Family Planning services, through focused involvement of public health facility based health care providers.

For efficiency purposes as well as to maximize the reach of trainings, the PPFP strategy also used integration of PPFP messages into other maternal and child health service delivery platforms like antenatal care services, immunization services and home-based newborn care by frontline health workers. This is in line with earlier studies which have reported the effectiveness of integration of family planning counseling and services with other health care services (Cleland, Shah & Daniele, 2015; Speizer, Hotchkiss, Magnani, Hubbard, & Nelson, 2000; Kuhlmann, Gavin, & Galavatti, 2010).

In our study, we observed an improvement in the awareness of key concepts of PPFP among postpartum women in the catchment areas after the training interventions were delivered. This included increased awareness on return to fertility, three criteria of LAM and three methods of modern contraception. This is in line with existing studies, in which authors have

observed that training interventions for health care providers lead to an improvement in awareness of contraceptive services among communities (Cleland, Shah & Daniele, 2015; Juma, Mutombo & Mukiira, 2015; Schwandt, Speizer & Corroon, 2017). Improving provider awareness and competence has been proposed as one of the core strategies for improving the awareness and access to contraceptives for communities (Malhotra & Bhat, 2014). Given the extremely low levels of awareness among these women during baseline, the reasonably large scale at which this PPFP strategy was delivered and the focused nature of the interventions to increase this awareness through health care providers in absence of any concurrent mid or mass media behavior change campaigns, this improvement in awareness was an important finding for us. In light of the fact that mass media campaigns are resource intensive endeavors and that this strategy was delivered through a resource constrained health system, this finding has implications for design of future post-partum family planning programs, which are focused in nature, in similar settings in India and globally.

We believe that this increase in awareness of women about the key concepts of postpartum family planning as well as modern methods of contraception would translate to increased utilization of PPFP services, especially since service delivery of these services at the health facilities in the catchment areas was ensured as a part of PPFP strategy. This hypothesis was the basis for the design of the PPFP strategy for Bihar and was based on earlier studies that have also demonstrated the benefits of training interventions for the health care providers on access and utilization of FP service (Nalwadda, Tumwesigye, Faelid, Byamugisha & Mirembe, 2011; MCHIP; Mwangi, Warren, Koskei & Blanchard, 2008).

Findings from our study indicate that a package of simple targeted capacity building initiatives for the health care providers along with creating an enabling environment for them for integrating and disseminating the PPFP messages in their regular engagements with clients can be effective in increasing the awareness about key concepts of PPFP among post-partum

women and their communities. Effective capacity building of all cadres of workers involved in these services, effective integration of PPFP messages in the interactions of the health care providers with clients during antenatal, intra-partum and postpartum period as well as developing an ecosystem of enablers in the form of service delivery tools, structured supportive supervision mechanism, data collection systems and regular review mechanisms, are important for successful implementation of these interventions in a program mode, at scale.

A large number of maternal and neonatal deaths and complications can be averted by preventing unwanted pregnancies and by healthy spacing of pregnancies. We believe that the findings from our study will help the program managers and policy makers towards designing effective programs for increasing access to post-partum family planning services for women and their partners, thereby contributing to the achievement of the sustainable development goals.

Strengths and Limitations

Though studies have been undertaken earlier to assess the effectiveness of isolated interventions on PPFP services, this is the first study which evaluates the effects of a comprehensive PPFP program that includes a package of interventions implemented at a scale in a resource constrained setting in India. The study did not have a comparison arm and therefore the fact that other factors or secular trends may have played a role in bringing about the observed changes cannot be ruled out. The respondents during baseline and end line data collection – for both groups of study participants- were different. However, we found no significant difference between the background characteristics of post-partum women interviewed at baseline and end line. Facility based health service providers (doctors/staff nurses) were selected by convenience sampling and therefore the sample included may not be representative of the population. Information on knowledge of return to fertility and ideal birth intervals was obtained from lesser number of post-partum women during the base line and hence the comparisons (baseline-end line) for

these parameters were performed at a lesser power than for the remaining parameters.

Conclusion

The findings of this study demonstrate that effective implementation of a package of interventions at a scale can lead to improvement in the knowledge and awareness levels of health workers and post-partum women. These findings are useful for planning and implementing interventions at a scale to increase access to contraception for post-partum women in similar resource constrained settings, globally.

Abbreviations

PPFP: Post-partum family planning; ANM: Auxiliary Nurse Midwives; ASHA: Accredited Social Health Activists; LMIC: Low and Middle Income Countries; TFR: Total fertility rate; CPR: Contraceptive Prevalence rate; SPSS: Statistical Package for Social Sciences; LAM: Lactational Amenorrhea.

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1. *These are participants who gave an incorrect response**Group when compared to others
Each Source compared with all other Sources (2 X 2)

CHAPTER

6

One-year continuation of post-partum intra uterine contraceptive device: findings from a retrospective cohort study in India

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Original research article

One-year continuation of postpartum intrauterine contraceptive device: findings from a retrospective cohort study in India☆☆☆

Somesh Kumar^{a,b}, Ashish Srivastava^{a,*}, Surendra Sharma^a, Vivek Yadav^a, Atul Mittal^a, Young-Mi Kim^a, Angela Nash-Mercado^a, Sijmen A. Reijneveld^b, Bulbul Sood^a

^a Jhpiego, an affiliate of Johns Hopkins University^b University Medical Center Groningen, University of Groningen, Department of Health Sciences

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ABSTRACT

Objective: To evaluate outcomes of a national postpartum (within 48 h of delivery) copper intrauterine device placement (PPCuIUD) program in six “high-focus states” with high unmet family planning need in India.

Study design: We identified high-volume district hospitals that provided PPCuIUD in six (Bihar, Jharkhand, Uttar Pradesh, Uttarakhand, Madhya Pradesh and Chhattisgarh) Indian states (two per state). Each selected hospital maintained a list of PPCuIUD acceptors with contact phone numbers. We randomly selected 100 women at each site for inclusion in a telephone survey of IUD outcomes at 1 year. Questions regarded IUD expulsion, discontinuation because of symptoms (e.g., pain, bleeding, discharge), discontinuation for other reasons and use of alternative contraception if discontinuation reported.

Results: We could contact 844 of the 1200 randomly selected women, of whom 673 (79.7%) had postplacental insertion (within 10 min of delivery), while 171 (20.3%) had an early postpartum insertion (between 10 min to 48 h after delivery). Of those contacted, 530 women (62.8%) reported continuing with the method beyond 1 year, 63 (7.5%) reported having an expulsion, 163 (19.3%) reported having removals for associated side effects (bleeding, pain and discharge), and 88 (10.4%) reported having removals for other reasons. After removal or expulsion, almost half of the women (46.5%) did not switch to any other modern contraceptive method.

Conclusion: PPCuIUD continuation rate at 1 year was 62.8%. Most removals within 1 year were due to associated side effects. Almost half of the women discontinuing PPCuIUD did not switch to an alternative modern contraceptive method.

Implications: The 1-year continuation rate of PPCuIUD achieved through a large-scale national program in India is satisfactory. The program though needs to address the low uptake of other modern contraceptive methods after discontinuation.

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1. Introduction

India's longstanding Family Planning (FP) program, which started in 1952 [1], has traditionally focused on limiting family size by female sterilization, with more than 50% of FP users relying on them [2]. The program has had limited focus on further aspects of family planning. This highlights the need to increase awareness of and access to spacing methods. Recognizing these needs, the Government of India has undertaken multiple strategies for increasing access to effective methods for spacing births [1].

A central component of these strategies is to strengthen access to postpartum FP services for women of reproductive age. As a part of these efforts, the Indian Government, with technical assistance from Jhpiego, introduced postpartum intrauterine contraceptive device (PPCuIUD) services in 2010–2011 [3]. This was based on global evidence that PPCuIUD is a safe and effective contraceptive method [4,5] and contact with the health system during childbirth provides an opportunity to make FP services accessible to women in resource constrained settings [6].

After the introduction, India rapidly scaled up its PPCuIUD program, which resulted in more than 2.8 million women choosing PPCuIUD over the last 6 years [7]. Other countries have recently reported similar expansions of PPCuIUD services [6]. The rapid expansion of PPCuIUD — in India as well as globally — calls for more evidence on the outcomes of these programs in terms of continuation rates at 1 year and beyond. While global evidence on continuation rates is available for interval intrauterine contraceptive device (IUCD) insertions [8–17], it is limited for

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* Corresponding author. Tel.: +91 11 49575100.

E-mail address: asheishsrivastava@gmail.com (A. Srivastava).

PPCuUDs. The few studies on PPCuUD continuation rates are restricted to hospital settings [18–20], but there is little evidence from any program implemented at scale [21]. Considering the complexities in scale-up of any new intervention in resource-constrained health systems, this lack of program level evidence is a barrier to informed decision making for scale-up of these services globally.

To address this need, we designed a retrospective single-arm cohort study — within a large scale PPCuUD program — to determine the 1-year continuation rate and reported complication rates, including rates of expulsion of PPCuUDs. We also assessed the reported reasons for discontinuation — through removal and expulsion — of PPCuUDs within 1 year as well as the contraceptive switching choices among women who discontinued PPCuUDs.

2. Methods

2.1. Sample

We conducted this retrospective single-arm cohort study in November–December 2015 in six (Bihar, Jharkhand, Uttar Pradesh,

Uttarakhand, Madhya Pradesh and Chhattisgarh) of India's 36 states which are considered “high-focus states” due to poor health indicators including high unmet need for FP.

For sample size estimation, we hypothesized the 1-year continuation rate of PPCuUD to be 60%. This is a conservative estimate based on the findings (76%) of a previous study [22]. We took a conservative estimate considering our study was being done within a large-scale national program. Aiming at determining this estimate with a precision of $\pm 6\%$, i.e., a confidence interval (CI) of 12%, multilevel design effect of 2 (to account for clustering of study participants by district hospitals) and a possible nonresponse/refusal rate of 50%, we calculated a sample size of 1016. We rounded it to 1200 to equally distribute the sample across 12 district hospitals.

In each of the 6 states, we selected 2 district hospitals, that is, a total of 12 district hospitals (Fig. 1). We first made a list of district hospitals that reported more than 100 PPCuUD insertions in the previous year (November 2013 to October 2014). A total of 178 district hospitals out of 227 met this criterion across the 6 states. We then purposively selected 12 of them, 2 per state, based on feasibility of carrying out the data collection as well as the regular practice of recording phone numbers of PPCuUD acceptors in the PPCuUD insertion registers. Family

Fig. 1. Flowchart depicting selection of study participants.

planning service providers at district hospitals maintain PPCuIUD insertion registers. All women had received a Copper T 380A.

At each hospital, we randomly selected records of 100 women from among all PPCuIUD insertions recorded with the telephone contact information for the women from November 2013 to October 2014. Staff at each hospital (usually FP counselors) initially provided us with the total number of insertions recorded during this period. We generated 100 random numbers within this total number using Microsoft Excel and shared these with the hospital staff. The staff pulled the corresponding client records and telephoned these randomly selected women to ask if they would be interested in participating in the study. If the women expressed interest, the hospital staff gave their telephone number to trained interviewers of a research agency.

2.2. Type of PPCuIUD insertions

PPCuIUD insertions, that is, insertions which happen within 48 h of delivery, are further categorized as postplacental insertions and early postpartum insertions. Postplacental insertion after vaginal or cesarean delivery refers to insertion performed within 10 min after expulsion of placenta, whereas early postpartum insertion is done after 10 min but within 48 h of delivery. Women who had decided on taking up PPCuIUD during their antenatal period underwent postplacental insertion, while those who opted for it after their delivery underwent early postpartum insertion. Doctors performed postplacental insertions after cesarean delivery, and both doctors and nurses performed postplacental insertions after vaginal delivery and early postpartum insertions.

2.3. Data collection procedure and measures

We used a pretested semistructured questionnaire for data collection. We pretested the questionnaire with a sample of 10 women from facilities other than the study sites after obtaining their oral consent. This was done prior to data collection and resulted in modifications to some of the questions, including rephrasing or permitting multiple responses to few questions. The authors trained the interviewers in using the questionnaire and study procedures for 2 days and carefully supervised them during data collection to ensure data quality.

Trained interviewers interviewed the women over telephone. The time interval between PPCuIUD insertion and telephonic interview ranged between 13 months and 25 months for study participants. Interviewers obtained an oral consent from the women at the beginning of the call and audio recorded the consent process. They gave women the option to skip questions they did not want to answer or stop the interview if they felt uncomfortable.

During phone interviews, the interviewers collected data on sociodemographic characteristics (age, number and sex of children, education, occupation, income and number of family members) and experience with the PPCuIUD (continued use, removal, expulsion, time interval between insertion and removal or expulsion, associated side effects, reason for insertion, reason for removal and switch to other FP method). The associated side effects (pain, bleeding and discharge) were clubbed as a single option in the questionnaire considering the feasibility of asking medical-history-related questions over the telephone. An updated BG Prasad's scale was used to calculate the socioeconomic status of women [23]. They recorded women's responses on paper copies of the questionnaire.

After the interviews, interviewers abstracted four items from the registers: type of insertion (postplacental insertion after vaginal delivery, postplacental insertion after cesarean delivery or postpartum), type of service provider who inserted the PPCuIUD (doctor or nurse), date of insertion and phone number.

2.4. Analysis

We entered data in Microsoft Excel, double checked all entries and analyzed it using Stata 13.0 (Stata Statistical Software: Release 13; StataCorp LP, College Station, TX, USA) software.

In the analysis, we assessed background characteristics of the respondents and PPCuIUD outcomes at 1 year. We also analyzed reasons for PPCuIUD removal and the contraceptive switching choices among respondents who discontinued use of PPCuIUD.

2.5. Ethical approval

Ekjut Institutional Ethics Committee, an India-based ethics committee, and the Institutional Review Board of Johns Hopkins Bloomberg School of Public Health gave ethical approval for the study. All state governments also gave their prior approval for conducting this study.

3. Results

Of the 1200 women selected randomly, the hospital staff reached 844; the remaining 356 (29.6%) women could not be reached by phone even after three attempts made on different days. A significantly higher proportion of selected women could be reached in Bihar when compared to other states.

All women who could be reached by hospital staff agreed to participate in the study. All women answered the main questions. Four women did not answer about the symptoms they experienced during PPCuIUD use.

3.1. Sample characteristics

Most (57%) women were aged 25 years or above, and 63% had a postplacental insertion after vaginal delivery. More than two thirds of the women had opted for PPCuIUD in order to space pregnancies. Nursing staff did more than half of the insertions (57.3%) (Table 1).

3.2. PPCuIUD outcomes at 1 year by insertion type

The 1 year postpartum continuation rate was 62.8% (95% CI: 59.4%–66.1%), 1 year postpartum removal rate was 29.7% (95% CI: 26.7%–32.9%), and the 1 year postpartum expulsion rate was 7.5% (95% CI: 5.8%–9.4%). Of the 7.5% of women who experienced expulsion by 12 months, 4.7% reported expulsion occurred before 6 weeks, 2.1% reported expulsion between 6 weeks and 6 months, and only 0.7% reported expulsion after 6 months (data not shown). By insertion type, 1-year postpartum continuation rate was highest for early postpartum insertions [67.8% (95% CI: 60.2%–74.7%)], while 1-year postpartum expulsion rate was highest among women who had postplacental insertion after vaginal delivery [9.6% (95% CI: 7.2%–12.4%)] (Table 2).

3.3. Reasons for removal and contraceptive method switching

Among women who had their PPCuIUD removed, almost two thirds (64.9%) cited associated side effects like bleeding, pain in abdomen and discharge as the primary reason for removal (Supplemental Table 1). Nearly half (46.5%) of the respondents whose PPCuIUDs were either expelled or removed did not change to any other modern contraceptive method. Majority of those who did change opted for condoms (Table 3).

4. Discussion

We found that two thirds of the women (62.8%) continue with their choice of PPCuIUD at 1 year postpartum. The 1 year postpartum removal and expulsion rates were 29.7% and 7.5%, respectively. Of those women who had their PPCuIUD removed before 1 year, two thirds cited associated side effects like bleeding, pain in abdomen and discharge as the

Table 1

Distribution of study participants who received PPCuIUD at sampled health facilities in 2013–2014 according to sociodemographic characteristics, provider type, type of insertion and associated side effects experienced ($n=844$).

Characteristic	Number (%)
State	
Uttarakhand	128 (15.2)
Madhya Pradesh	138 (16.4)
Chhattisgarh	131 (15.5)
Jharkhand	137 (16.2)
Bihar	188 (22.3)
Uttar Pradesh	122 (14.5)
Age of the client	
<25 years	364 (43.1)
≥25 years	480 (56.9)
Education of the client	
Illiterate/just literate	192 (22.8)
Up to 5th standard	117 (13.9)
Up to 12th standard	396 (47.0)
Graduate/postgraduate	139 (16.3)
Occupation of client	
Housewife	747 (88.5)
Working	97 (11.5)
Number of living children	
0	12 (1.4)
1	369 (43.7)
2	304 (36.0)
3 or more	159 (18.9)
Number of living male children	
0	257 (30.5)
1	452 (53.6)
2	113 (13.4)
3 or more	22 (2.6)
Reason for accepting PPCuIUD	
Spacing	593 (70.3)
Limiting	217 (25.7)
Don't know	34 (04)
Type of insertion	
Postplacental insertion after cesarean delivery	141 (16.7)
Postplacental insertion after vaginal delivery	532 (63.0)
Early postpartum	171 (20.3)
Type of service provider who inserted PPCuIUD ^a	
Doctor	359 (42.7)
Nurse	481 (57.3)
Socioeconomic status	
Lower class	108 (12.8)
Lower middle class	298 (35.3)
Middle class	222 (26.3)
Upper/upper middle class	216 (25.6)
Experienced pain in abdomen/bleeding/discharge ^a	
Yes	314 (37.2)
No	463 (54.9)
Not available (for those who reported expulsion)	63 (7.5)

^a Data missing for four women.

primary reason. After discontinuation (removal and expulsion), almost half of the respondents did not switch to any other modern contraceptive method.

The PPCuIUD continuation rate in our study is comparable with findings of a study done in Turkey [24]. However, it is lower than rates

Table 3

Contraceptive method switching choices among Indian women whose PPCuIUDs were removed or expelled within 1 year of insertion ($n=314$)

Contraceptive methods	Removals Number of clients (percentage)	Expulsion Number of clients (percentage)
Condoms	70 (27.9)	16 (25.5)
Female sterilization	30 (11.9)	4 (6.3)
OCPs	29 (11.6)	5 (7.9)
IUCD	3 (1.2)	1 (1.6)
Injectable	1 (0.4)	1 (1.6)
Male sterilization	1 (0.4)	0
Others	3 (1.2)	4 (6.3)
No contraceptive used	114 (45.4)	32 (50.8)
Total	251 (100.0)	63 (100)

OCPs, oral contraceptive pills.

reported by multiple other studies [25–27]. This difference should be seen in light of the fact that the results of our study may not be generalizable outside India and most of these prospective studies are single-hospital-based studies conducted in controlled hospital settings with smaller sample sizes. The results of our study however demonstrate that a well-planned and executed PPCuIUD program can achieve satisfactory level of continuation rates even when implemented on a large scale.

The expulsion rate at 1 year postpartum in our study (7.5%) is lower than that reported by another study done in Turkey [28] but higher than that reported (5.6% in the period of 6–12 months postpartum) in Zambia by Blumenthal [21]. The estimated expulsion rate of 4.7% until 6 weeks is comparable with the expulsion rate reported by a prospective study done in similar settings in India [3]. These expulsion rates need to be seen from the perspective that when PPCuIUD services were introduced in India in 2010–2011, there were widespread apprehensions due to high expulsion rates resulting from use of wrong insertion techniques. This was addressed through competency-based trainings with the use of a design-modified Kelly's placental forceps for PPCuIUD insertion — which led to expulsion rates of 4% at 6 weeks [3].

The PPCuIUD removal rate at 1 year is comparable to the discontinuation rates of other long-acting reversible contraceptives like levonorgestrel intrauterine systems and progestin implants [29]. A large proportion (45.4%) of women who got their PPCuIUD removed did not opt for any other contraceptive method after removal, while only 6% of the removals were due to the desire for another child. This lack of a switch to other spacing methods has been reported in another study done in similar settings [12]. It may be due to a lack of access to other spacing methods in the peripheral health facilities or a lack of awareness about other available methods among women. Another contributing reason could be limited contraceptive choices in India's public health system.

Discomfort due to bleeding, pain in the abdomen or discharge as main reasons for removal is consistent with findings of previous studies conducted in similar settings [12,16,19]. This finding emphasizes the

Table 2

Distribution of outcomes of PPCuIUD insertion at 1 year among Indian women who received PPCuIUD in 2013–2014 according to type of insertion

Type of insertion*	Total	Continuation (%) (95% CI)	Removal (%) (95% CI)	Expulsion (%) (95% CI)
Postplacental insertion after cesarean delivery	141	66.7 (58.2–74.3)	29.1 (21.7–37.3)	4.2 (1.5–9.1)
Postplacental insertion after vaginal delivery	532	60.1 (55.8–64.3)	30.3 (26.3–34.3)	9.6 (7.2–12.4)
Early postpartum	171	67.8 (60.2–74.7)	28.7 (22.1–36.1)	3.5 (1.3–7.5)
Total	844	62.8 (59.4–66.1)	29.7 (26.7–32.9)	7.5 (5.8–9.4)

* Postplacental insertion: done within 10 min after expulsion of placenta; early postpartum insertion: done after 10 min but within 48 h of delivery.

need for quality pre- and postprocedure counseling for women so that they are aware that these side effects are to be expected and should not come as a surprise. Although we did not probe into the status of counseling in this study, earlier studies have reported that counseling is associated with increased continuation rates of IUCD [13,18,30].

The main strengths of our study are its size and that it has been conducted in a community-based resource-limited setting. It is a multicentric study conducted within a large-scale national program, which has seen more than 2.8 million insertions conducted across 2000 resource-constrained facilities over 6 years [7]. Therefore, our study findings are more representative of the “real-world settings.”

A major strength of our study is that it had no refusals for participation. Hospital staff – whom the women trust and tend to cooperate with – made the initial telephonic call for recruitment. They gave women the option of scheduling telephonic interviews as per their convenience. This facilitated participation and helped in avoiding refusals.

Our study also has some limitations relevant to the interpretation of the study findings. Recall bias may have affected our findings as study participants were interviewed 1 year after they chose PPCuIUD. Also, they were selected from among those PPCuIUD acceptors whose telephone contact numbers were recorded in the PPCuIUD insertion registers of health facilities. PPCuIUD acceptors without telephone numbers were not contacted, which could have led to a selection bias. In addition, purposive selection of the district hospitals and inability to telephonically contact around 30% of the randomly selected women may have led to a selection bias as well. We could not compare their sociodemographic characteristics with those of study participants, as this information was not recorded in the PPCuIUD insertion registers.

In conclusion, the results of this study show that PPCuIUD continuation rates at 1 year within the context of a large-scale national program are satisfactory. Expulsion rates are acceptable and comparable to the findings from other studies [3,28]. The high number of removals due to discomfort caused by associated side effects of pain in abdomen, discharge and bleeding needs to be further addressed, as does the lack of uptake of other contraceptive methods after PPCuIUD discontinuation.

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.contraception.2018.12.003>.

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CHAPTER

7

Harmonizing scientific rigor with political urgency: policy learnings for identifying accelerators for scale-up from the Safe Childbirth Checklist programme in Rajasthan, India

RESEARCH ARTICLE

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Harmonizing scientific rigor with political urgency: policy learnings for identifying accelerators for scale-up from the safe childbirth checklist programme in Rajasthan, India

Somesh Kumar^{1,2}, Priti Dave³, Ashish Srivastava^{1*} , Jelle Stekelenburg^{2,4}, Dinesh Baswal⁵, Deepti Singh¹, Bulbul Sood¹ and Vikas Yadav¹

Abstract

Background: Quick scaling-up of innovative and promising interventions in health systems of low and middle-income countries to rapidly achieve population level benefits is a key challenge. While there is consensus on the need for rigorous scientific evidence on effectiveness of interventions before considering scale-up, there can be significant time lag for the want of gold-standard evidence. The Safe Childbirth Checklist (SCC) programme in India, demonstrated how an innovation was robustly evaluated and scaled up nationally, within a short span of time. In this narrative review, we describe the strategies discussed in various published scale-up frameworks and map them against the strategies adopted by the SCC programme to identify accelerators which facilitated its rapid scale up.

Methods: The narrative review – done from May to June 2017 - involved keyword searches of electronic databases of PubMed, Ovid Medline and Google Scholar. It included the key words ‘pilot’, ‘health innovations’, ‘scale-up’, ‘replication’, ‘expansion’, ‘increased coverage’, ‘conceptual models for scale-up’, ‘frame-works for scale-up’, ‘evidence for scale-up’ in the title of publications,. This search was limited to publications in English after the year 1995. We used snowball sampling approach (by referring to bibliographies of shortlisted publications) to identify additional publications related to scale-up. We then screened the identified publications independently and relevant publications that discussed attributes for a conceptual model for scale-up of public health interventions in low and middle-income countries were shortlisted. We then mapped the strategies we used in SCC program scale up against those described in the shortlisted frameworks to identify seven accelerators which facilitated rapid scale up.

Results: The identified accelerators were: testing the intervention in real world, resource constrained settings; using an appropriate and time sensitive research design; testing the intervention at substantial scale and in diverse settings; using an adaptive and iterative prototyping approach for implementation; sharing data and evidence with key stakeholders on an ongoing basis; targeting bridge resources through strategic engagement of stakeholders and timely integration of scale-up plans with annual planning and budgeting cycles and systems.

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* Correspondence: asheishsrivastava@gmail.com;

Ashish.Srivastava1@Jhpiego.org

¹Jhpiego-an affiliate of Johns Hopkins University, 29, Okhla Phase -3, New Delhi 110019, India

Full list of author information is available at the end of the article

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Conclusion: These accelerators will complement current frameworks and provide guidance to future scale-up initiatives in India and elsewhere.

Keywords: Scale-up, Public health interventions, Low and middle income countries, Safe childbirth checklist programme, Maternal and newborn health

Background

Though impressive progress was made towards achievement of the Millennium Development Goals (MDGs) in low- and middle income countries (LMIC), many missed the MDGs- 4 and 5 goals of reducing under-five child and maternal mortality [1]. A huge burden of preventable maternal and child mortality still exists in LMIC [2, 3]. For example, India still accounts for 25% of all global newborn deaths [4]. This situation has persisted over the last decade despite knowledge of interventions needed to address major causes of maternal and newborn mortality [5–7]. The inability of health systems to scale-up evidence-based interventions to achieve population-level benefits in a time sensitive manner is a challenge. This is particularly important as in many LMIC the political landscape changes rapidly thereby creating a paucity of committed resources to facilitate progression from actionable evidence to scaling up interventions. In addition, newer priorities may emerge that can draw attention or resources from interventions under test for scale-up.

A review of available literature on scale-up strategies reveals that multiple frameworks have been developed to guide the scale-up process based upon critical enabling factors which increase the chances of newly proven interventions being taken up by governments. Most of these frameworks take a sequential, structured approach starting with testing an innovation, and once proven to be effective - promoting its scale-up for increased coverage [8–11]. A general limitation of these conceptual frameworks is that they do not explicitly address the need to make rapid progress, apart from referring to the types of innovations that tend to disperse faster. This is a glaring omission, given the urgency of the problems, ethical obligations and political compulsion to act fast and make rapid progress. Need for urgency is important from an efficiency perspective, but can be at odds with the interests and priorities of the research community, which often favours ‘gold-standard’ and time intensive evaluation methods for evidence generation. The conventional scale-up frameworks also do not address how best to harmonise scientific rigour with the political and ethical urgency to rapidly reduce preventable maternal and child mortality.

WHO developed the SCC in 2009, in collaboration with Harvard University and other global experts, as a

tool to help improve quality of childbirth care. It prompts maternity staff to perform 28 critical practices during admission at the health facility and during delivery, immediately after birth and before discharge of mother and the newborn [12]. In a pilot pre-post intervention study conducted in rural Karnataka, India, in 2010, it was seen that the use of SCC led to a significant improvement in provider adherence to these critical practices [13].

Though the initial study demonstrated the SCC as a promising tool, there was a need to test it at a reasonable scale and assess its impact on neonatal mortality. Jhpiego in partnership with the state Government of Rajasthan (GoR), India implemented a programme to improve the quality of intrapartum care in public sector health facilities of the state from the year 2012 to 2015. In this programme, the WHO Safe Childbirth Checklist (SCC), a tool aimed at improving health provider adherence to 28 essential practices during labour and immediately after birth [12], was tested in 100 public health facilities using a quasi-experimental evaluation approach. The implementation of the SCC programme was found to significantly improve the adherence to safe care practices in the target facilities [14] leading to an 11% reduction in stillbirths and early neonatal deaths [15]. Upon the learning from the SCC experience, the Government of India (GoI) launched a scale-up version in 8 Indian states with highest neonatal mortality rates in 2015. So far, such a rapid scale-up has not happened in any other country despite many focused pilot projects [16–19]; the availability of an SCC implementation guide by WHO, and the SCC featuring in the list of the most promising technologies of the decade [20]. The SCC programme illustrated that it is possible to prove an innovation in a robust manner and secure government commitment and readiness for national scale-up [21] within a reasonably short time span, 3 years in this case.

The aim of this paper is to study in depth the existing scale-up frameworks described for public health innovations in LMICs; and compare the strategies adopted in Rajasthan for rapid scale-up in India with those described in frameworks to identify key accelerators which facilitate rapid scale up. This new knowledge will complement the current frameworks and provide guidance to future scale-up initiatives in India and elsewhere.

Methods

We conducted a narrative review. Narrative review articles describe and discuss the state of the science of a specific topic or theme from a theoretical and contextual point of view [22].

In this study, we followed two main methodological approaches.

- (1) We (SK, PDS, VY and AS) did a literature review to identify peer-reviewed publications and grey-literature on public health innovations scale-up. Using different Booleans of keywords and constructs - 'pilot', 'health innovations', 'scale-up', 'replication', 'expansion', 'increased coverage', 'conceptual models for scale-up', 'frame-works for scale-up', 'evidence for scale-up' in the title of publications, we searched the online databases of PubMed, Ovid Medline and Google Scholar. This search was conducted in May and June 2017. It was limited to publications in English after the year 1995, to capture the learnings from this field from the last two decades of research done in contemporary health systems in low and middle-income countries. We also used the snowball sampling approach (by referring to bibliographies of shortlisted publications) to identify additional publications related to scale-up. Two authors (SK, PDS) then screened the identified publications independently and relevant publications that discussed the attributes for a conceptual model for scale-up were shortlisted. We then included those publications that discussed attributes of scale up frameworks for public health interventions or innovations in low and middle-income countries for further analysis.
- (2) Further, we compared the strategies adopted in Rajasthan that led to rapid scale up within a context of available evidence on effectiveness with those described in the shortlisted frameworks to come up with a list of drivers and accelerators that support rapid scale-up of successful innovations in a time sensitive manner in LMIC settings. To do this, we obtained relevant project documents from the SCC program and reports and drew on authors' implementation experiences and learning.

Results

Through literature review, we identified 11 scale-up frameworks that fitted our search criteria. From these, we selected six (Table 1) that contained common themes, were contemporary (published after 1995, covering the last two decades), and that we felt reflected the current state of art thinking on scale-up theory and practice. These frameworks propose a sequential series of steps that support testing the innovation in the real world (i.e. within

current health system, social and political context) and once proven impactful, to making it scale ready. They also identify several common themes influencing the success of scale-up, such as having a simple and context appropriate innovation; engaging important stakeholders such as the government and communities; using a feedback-based learning approach for testing; integrating innovations within the systems; ongoing advocacy for using data; and building system's capacity to take over the innovations. Apart from a few side mentions, none of these frameworks explicitly calls out the need for or identifies drivers for expediting scale-ups. Spicer describes the attributes of innovations that support rapid diffusion--simplicity, low cost, compatibility and adaptability [9]. Both Spicer and Subramaniam highlight that scale-up requires medium to long-term timeframes, and make the case for longer donor funding cycles and commitment for testing, advocating for adoption, readiness for scale, and scale-up [8, 9]. Barker's framework suggest it can take up to 6 years to go from developing ascendable units to at-scale implementation. Though the Barker framework sets out a sequential process of scaling up, it does acknowledge that streams of work can be initiated at different times and progress at different rates [23]. However, it does not explicitly identify this as a time saving factor.

Comparing the constructs for successful at-scale implementation presented in these frameworks and drawing upon the experience of national scale-up of SCC programme, we identified the following seven 'accelerators' that significantly influence the rapidity of a scale-up (Fig. 1).

Discussion

Testing in the real-world, resource-constrained settings

One of the main tenets of the programme was to test SCC within the reality of a resource-constrained environment, using mostly the system's resources to ensure that the incremental resource requirement was marginal and the system should be able to take these over in case the intervention is successful. This intentional effort was important from the perspective of scalability as there is a tendency for the pilots to be resource intensive to achieve results without giving due consideration to the system readiness. Only one framework, WHO Expand-net, recommends testing the innovation within routine operating conditions and existing resource constraints of health systems [11]. Spicer lists attributes of scalable health innovations such as being aligned and harmonized with the existing systems and priorities [9]. Yamey describes the importance of tailoring scale-up to the local situation and decentralizing delivery [10]. Yamey also touches upon research context for scale-up though it focuses mainly on systematic use of evidence for scale-up and the importance of synchronicity between

Table 1 Overview of existing scale up frameworks

Conceptual models for scale-up	Major constructs influencing scale up	Reference to time sensitivity
Yamey G (2011)	Identifies following factors <ul style="list-style-type: none"> • Choose a simple intervention that is considered valuable. • Develop strong leadership • Ensure active engagement of range of stakeholders, including the target community • Incorporate research into implementation 	Identifies 5 factors associated with faster diffusion of an innovation: <ul style="list-style-type: none"> • Relative advantage • Compatibility • Simplicity • Trialability • Observability Plus, <ul style="list-style-type: none"> • Integrate into existing health systems • Generation of timely evidence. • Timely feedback of monitoring data to implementers
Spicer N, et al. (2014)	Identifies multiple steps to catalyse scale up. <ul style="list-style-type: none"> • Design scalable innovations • Embed scale up in programme design • Build implementer capacity • Advocate on an on-going basis • Generate strong evidence • Involve government throughout project • Invoke policy champions and network of allies • Align with policy and targets • Promote community acceptance and uptake. 	<ul style="list-style-type: none"> • Stresses the need for longer donor timelines and commitment for scale up, as it takes time for programmes to mature and for implementers to advocate and support government. Typical 2–3 year donor funding cycles are too short.
Subramaniam S, et al. (2011)	<ul style="list-style-type: none"> • Tailor scale-up to fit the particular context. • Adopt a “learning by doing” approach, linking knowledge building with action. • Take into consideration the political, social, and economic environment. • Forge strong partnerships and adopt a participatory approach to foster ownership and sustainability • Focus on problem solving, and draw on a variety of quantitative and qualitative monitoring and evaluation methods. Don't over rely on the randomised control trial approach. 	<ul style="list-style-type: none"> • Acknowledges that successful scale up of pilot projects requires a medium to long term timeframe. • Slower, phased implementation, usually from the bottom up, which allows for systematic learning to emerge through incremental expansion based on concurrent, participatory research and adaptation
WHO ExpandNet: 1. Beginning with the end in mind, Planning Pilot Projects and other Programmatic Research for Successful Scale Up (2011) 2. Nine Steps for developing a Scaling Up Strategy (2010)	<ul style="list-style-type: none"> • Adopt a participatory process for innovation testing (including stakeholder involvement in the design, regular provision of feedback on implementation, nurture policy champions and wider networks). • Reach consensus on scaling up expectations • Tailor innovation to prevailing socio-cultural and institutional environment and test innovation under routine operating conditions and within existing resource constraints of the health system • Test ways to strengthen health-systems capacity as part of the project, for example (human or technical) • Advocate to donors and other funding sources for financial support for scale up once innovation proven to have impact • Search and test for sustainable finance • Prepare to advocate for necessary changes in policy regulation, and other health system context. • Promote learning and disseminate information. • Increase the capacity of the user organization to implement scale up. • Increase the capacity of the user team to support scaling up process • Prove support to vertical (institutionalization) and horizontal scale up (expansion/replication) scale up. 	<ul style="list-style-type: none"> • No explicit reference to rapidity but Includes recommendation on advocacy with donors and other funding sources for financial support for scale up once innovation is proven to be successful. This will potentially expedite scale-up. Similarly, participatory process for innovation testing will potentially lead to rapid adoption.
Barker P. M, et al. (2016)	<ul style="list-style-type: none"> • Identifies 4 step sequential scale up process: <ul style="list-style-type: none"> o Set up (prepare ground and test intervention) o Develop scalable unit o Test scale up in different settings 	<ul style="list-style-type: none"> • Although a linear scale up process is presented, the paper highlights it can be organic and iterative, with streams of work initiated at different times and progressing at different rates.

Table 1 Overview of existing scale up frameworks (Continued)

Conceptual models for scale-up	Major constructs influencing scale up	Reference to time sensitivity
	<ul style="list-style-type: none"> o Go to full scale • Enabling factors include: <ul style="list-style-type: none"> o Develop and engage leaders in their key role of guiding and supporting large scale change. o Accommodate context into design by starting with a deep dive situational analysis with key stakeholders. o Maintain a culture of urgency and persistence, and will to stay the course in proving an innovation and bringing it to scale. o Adoption of a learning approach which includes the continuous feedback of data to identify and close gaps in performance. o Communicate real time data and results on a regular basis. 	<p>Though not explicitly stated, this would be time saving.</p> <ul style="list-style-type: none"> • Stresses rapid scale up will not occur in an unreceptive environment. • Country case studies suggest it can take up to 6 years to go from develop scalable unit to full scale.
Paina L and Peter D, (2012)	<ul style="list-style-type: none"> • Examines characteristics of scale up using an alternative model drawing on an understanding of complex adaptive systems (CAS): <ul style="list-style-type: none"> o Scale up occurs within complex and dynamic health systems, and the lens of CAS allows for better planning, implementation, monitoring and evaluation of scale up. o Lessons from CAS suggest giving more attention to local context, incentives, institutions, and paying greater attention to unintended consequences undermining scale up. o Includes adopting an approach that engages key stakeholders, through the transparent use of data on an on-going problem solving and adaption. 	<ul style="list-style-type: none"> • CAS is a slow and deliberate approach. However, it recognises that a small stimulus can create a large or rapid change. • Phase transitions or tipping points can lead to rapid scale up. Acknowledges the importance of identifying the conditions under which rapid transitions can occur.

Fig. 1 Accelerators for rapid scale-up of innovation

implementation and research [10]. Caffè warns against setting up boutique projects, that are resource intensive and fail to be adopted by the government even if proven effective [24]. The need for testing of the innovation in real-world, resource-constrained settings needs to be deeply understood and elaborated for the public health community to realize the importance of achieving time-sensitive scale-up of interventions.

While the WHO SCC tool was designed to be used in most clinical settings [12, 20], the implementation team knew it was imperative to test it within the ‘real-world’ Indian health system to ensure successful scale-up by the government. For this reason, many intentional efforts were made in the SCC pilot in Rajasthan to keep it as simple and resource-light as possible. For example, the needed resources for training health providers on use of the WHO SCC and for ensuring availability of necessary drugs and equipment at the facility were largely sourced from within the health system. The orientation of health care providers on the use of SCC was restricted to just one and half days, and was undertaken at local training sites. This caused minimal disruption to the already staff crunched health system, a factor which has been seen as a challenge for scaling-up training programs [25]. Additionally, the trainers were selected from the existing pool of government trainers ensuring scalable training models.

We consider that choosing the setting in which an innovation is tested is critical in determining the speed of scale-up as it reduces the time otherwise taken up in modifying and adapting the innovation post-pilot to fit into system’s context. In addition, a resource light approach means minimal requirement of additional time for fund raising and securing supply systems. Alignment with existing national policies and guidelines saves time and eliminates the need to advocate for and support development of new policies and strategies.

Appropriate and time sensitive research design

The existing frameworks emphasize on the need to generate robust evidence on intervention impact to inform scale-up. However, they do not provide guidance on the type of evaluation that are appropriate or on the importance of generating evidence in a timely manner for public health innovations. Spicer explores in detail the attributes of evidence for catalysing scale-up, but mostly from a presentation of information perspective. His framework lists various types of evidences such as quantitative evidence on outcomes and impact, cost-effectiveness, qualitative process data, mapping and needs assessment [9]. Subramaniam recommends a “learning by doing approach” and Spicer reports implementers favouring approaches with “flexibility to redesign and learn-do cycling” for successful scale-up [8, 9]. None of the frameworks

recommend any hierarchy of the type of effectiveness measure that should trigger scale-up, i.e. should it always be at the level of impact on lives saved or can it occur on the basis of intermediate measures of effectiveness such as improved adherence to evidence-based practices.

Further, there has been recent acknowledgment in the literature that randomised control trials (RCTs) are not always the most appropriate method for testing an intervention [9, 26]. While they may be the gold standard approach for testing the efficacy of a drug or vaccine, they are not appropriate for proving effectiveness of an intervention embedded within a complex environment. Quasi-experimental methods – preferably, supplemented with qualitative methods may be more relevant as they shed light on ‘how’ and ‘how much’ the intervention has achieved impact [26]. Specifically, studies with quasi-experimental design that use control groups and pre-tests are considered adequate for evaluating interventions implemented in community settings [27]. Barker recommends testing of necessary infrastructure required for full-scale implementation and building capability of the system as an integral part of the testing phase itself [23]. An implementation research design allows for better understanding of these factors, whereas the gold standards tend to adjust or nullify the effects of these to ensure comparability among the study groups. For this reason, for the SCC pilot, we selected a quasi-experimental impact evaluation. This was supplemented with routine monitoring data, health provider interviews, an observational study on adherence to clinical practices in intervention and control sites and a cost effectiveness analysis.

Once the positive results of SCC on adherence to practices became available, and it was apparent the SCC was having a wider impact on quality of childbirth care [14], the GoI was keen to proceed with national implementation. Intermediate results on practice related outcomes were thought to be adequate to trigger scale-up as many of the key practices (such as newborn resuscitation with a bag and mask, and use of magnesium sulphate for management of pre-eclampsia and eclampsia) in the SCC have been independently proven to be lifesaving through independent studies [28–31].

Three aspects are worth highlighting in the manner in which the evidence generated through the SCC programme facilitated rapid scale-up. First, the decision to opt for a quasi-experimental evaluation design over an RCT saved considerable time and permitted mid-course adaptations. Second, as a result of the study design, important information was obtained regarding the system’s capacity to implement the intervention and required resource planning for scaling it up during the pilot phase itself. Third, GoI considered the intermediate results on improvement in adherence to key practices sufficient for decision-making. By the time an 11%

perinatal mortality reduction was confirmed [15], the national scale-up was under planning.

Testing at substantial scale and in diverse settings

There is often a tendency to undertake pilot studies for innovative interventions at a small scale, in controlled, and not-so diverse settings. This limits the applicability of the evidence generated from the study for scale-up in diverse settings. The SCC was tested in over hundred facilities located in seven districts of Rajasthan, catering to a population of about fifteen million. Additionally, the SCC was implemented at two levels of the health facilities--District Hospital and Community Health Centre—where most of the deliveries are conducted in Indian settings.

The ExpandNet framework refers to the limitations of conducting small scale, resource intensive pilots. While they may deliver positive impact, they are usually context specific and often fail to deliver results when taken to scale in different settings [11]. Barker stresses the importance of testing an intervention at scale, including different levels of the health system [23]. As the SCC was tested in a diverse range of health facilities and settings, there was confidence that it would work across the country. Furthermore, selection of the state was crucial from the perspective of extrapolation of evidence. Rajasthan is among the Empowered Action Group (EAG) states with weak health systems and indicators [32]. Thus, It could be inferred that, if SCC implementation was possible there, it will most likely work in other states of the country as well. Through this approach, there was considerable timesaving as the need for further testing in multiple settings and contexts after the successful pilot was eliminated.

Adaptive and iterative prototyping approach to implementation

Almost all scale-up frameworks speak of the need to adopt an adaptive design approach that is to “learn while doing” and undertake modifications based on the emerging evidence. This iterative prototyping approach requires investments to be made in the generation of good-quality real-time monitoring data as well as special studies during the course of programme. This approach also sheds light on the “how” an innovation has been impactful, especially on the pathways of scaling up [33].

Through the course of implementation, the learning and adaptive approach used in the SCC programme showed that SCC is much more than a memory tool as originally envisioned. It provides a framework of action for multiple dimensions of quality of childbirth care such as improving resource availability, better supervision, and developing health worker competency building programs. Improved accountability as a result of the SCC being made an integral part of the client case-sheet

was a new learning for the project implementers. This increased the SCC's appeal to GoI, and their willingness to take it up on a national scale. Similarly, through the implementation, it was realized that there was a need for some on-site support to help the providers in institutionalizing the use of the SCC. Acting on this need, the SCC program sourced additional technical assistance to provide onsite support to the health providers to institutionalize SCC's its use as a routine part of childbirth care. However, care was taken to ensure that this supportive supervision was minimal and something that the government could take up if they decided to go for scale-up. This was in line with earlier evidence where supportive supervision was reported to be a successful strategy for improving programme outcomes and health workers' capacities [34, 35].

These efforts to iterate and prototype the interventions as well as the theory of change through the rigorous use of data helped the SCC to be scale ready by the time the implementation research was over, thereby improving the rapidity of scale-up.

Sharing data and evidence on an ongoing basis

All frameworks report that sharing evidence in an ongoing and effective manner is critical for successful scale-up of an innovation. Spicer also reports that “well-presented information makes a humungous impact” and that apart from externally funded quantitative surveys on outcomes and impacts, other types of evidence including qualitative process data, first-hand experience and gaps assessments information is also important for scale-up. “Early and ongoing advocacy” was another factor reported as important for scale-up [9]. Barker also specifically reports the importance of real-time data as a powerful influencer of buy-in for scale-up [23].

The SCC programme included a full-scale of programme monitoring and evaluation activities that generated data on a periodic basis from all the available systems - reporting by facilities, monitoring and observation data reported by program officers, and specially designed studies for assessing adherence to safe care practices. This data was shared on a periodic basis with relevant stakeholders. Clinical leaders, programme managers, and policy makers were kept informed of the progress. Consistent sharing of data primed the government stakeholders in owning evidence and acting on it swiftly. This cut out the additional step of having to advocate separately for scale-up once the intervention has been shown to be impactful.

Target bridge resources through strategic engagement of stakeholders

Most frameworks stress on the importance of engaging stakeholders throughout the programme implementation

cycle for improving ownership and chances for scale-up. Yamey emphasises engagement of local implementers and other technical partners and using both state and non-state actors as implementers [10]. Both Barker and Yamey report the importance of local leadership for scale-up of successful innovations [10, 23]. However, apart from the importance of engaging local government and non-government implementation actors, we learned that engaging donors throughout the implementation process was one major factor influencing the speed of subsequent scale-up, should the pilot show positive results. The WHO Expandnet framework recognises the importance of early donor engagement to secure this funding [11].

In the SCC program, data was regularly shared with government authorities and donors. Multiple learning and exposure visits to programme sites by government policy makers and various donor representatives were organized to give them first-hand experience of the programme. In addition, GoI also kept these donor agencies engaged. This stakeholder engagement was instrumental in building GoI's confidence in rapidly scaling up the innovation. Additional donor funding played an important catalytic role in kick-start the programme after its launch while government's own funding was being secured. Due to the early and regular engagement with the donor agencies, securing additional donor funds for supporting this national initiative was not difficult.

Timely integration of scale-up plans with the annual planning and budgeting cycles and systems

Many of the scale up frameworks refer to the need to align the proven innovation to existing policies, planning, and budgeting systems to support national uptake and expansion. These are key considerations in the process of institutionalising a successful innovation. An important aspect of institutionalisation is securing adequate and sustainable funding for scale up. This remains a significant challenge to scale-up, as most innovations have to compete for financial resources with the existing programs [8, 9]. This is an unexplored area in current scale up frameworks.

One way of overcoming this challenge is by ensuring the innovation is integral to current delivery mechanisms, and able to tap into existing funding streams, rather than requiring additional funds. Further, alignment of timelines of the pilot activities, such as data sharing and advocacy, to government's planning and budgeting cycles can also improve the availability of resources at the time of scale-up thereby reducing the time-lag between the emergence of the evidence and subsequent scale-up.

Once the SCC was showing promising results on provider behaviour, the programme team supported the

state government teams to reflect the SCC programme in the Rajasthan government's annual national health mission budget in a timely manner. As a result, the new national quality improvement programme, centred around the SCC, was able to tap additional funds in time for scale-up. Moreover, as the SCC was well integrated into the existing maternal and newborn health programme, in reality, this did not require new funds, but a reallocation of funds within budget items in most cases. For example, the scale-up programme was able to utilise the existing training budget requested by the states for conducting refresher trainings.

These seven accelerators identified through our SCC pilot experience are important additions to the existing scale-up frameworks. These new insights can serve as a complement to current frameworks and provide valuable guidance to implementers for improving the rapidity of future scale-up initiatives in India and elsewhere.

Strengths and limitations

This study is first of its kind and identifies and describes key accelerators to scaling up proven innovations within the health systems of LMICs. It draws upon the recent experience of authors in scaling up the SCC program in India – which has been able to harmonize scientific rigour with political urgency. The authors have not come across any literature which attempts to understand the nuances of ensuring time sensitive scale up of effective interventions which can avert countless deaths by minimizing the time lag between pilot and scale-up. Coming from a typical resource constrained setting, the findings are applicable to multiple such settings across low and middle income countries.

This study has a few limitations. The review of literature was limited to published and grey literature in English language only; relevant publications in other languages were not included. Also, shortlisting of relevant scale-up frameworks from published literature was based on authors' assessment and not on any objective criteria. However, since this was not supposed to be a systematic literature review, this was a conscious decision by the authors.

Conclusion

The SCC programme demonstrates that it is possible to harmonise public health and political urgency without compromising on scientific rigour. The SCC programme's experience illustrates how adherence to the main principles laid out in the scale-up frameworks such as choosing an appropriate intervention, testing the intervention rigorously, engaging important stakeholders through evidence-based advocacy, and mobilization of resources for scale-up lead to innovation uptake and expansion. However, the SCC programme provides

important additional lessons on how to minimise the time lag between proving an intervention and its scale up. We recommend seven main accelerators for rapid scale-up of proven interventions.

The most important accelerator is the selection of the most appropriate, time sensitive and robust research design. Most impact evaluations have adopted RCT as the gold standard methodology. However, the long duration combined with limited transferability of proven innovations (due to the context specific nature of success) has led many to recently question this methodology. The SCC experience endorses this viewpoint. A related point, that has not received much attention, is what type of impact measure should trigger scale-up. Should it always be related to mortality reduction or are intermediate measures such as behaviour change adequate? Again, the SCC experience would suggest provider behaviour change is adequate if these changes themselves are recognized as effective in reducing mortality or morbidity.

While most frameworks speak of a sequential series of steps (pilot test, advocate, scale-up, etc.), the SCC programme illustrates that it is possible to initiate these streams of work in parallel and save considerable time. For example, the groundwork for scale-up was initiated well before the end of the pilot, based on the evidence on provider behaviour change. The national initiative guidelines were written during the third year of the pilot. Being flexible and responsive to government demands was finely balanced with the need to protect the integrity of evaluation. Actual scale-up only commenced once data collection for pilot's evaluation was over.

We urge that these seven accelerators be incorporated into the scale-up frameworks, to guide future testing and scale-up in a timely manner. In light of the huge remaining burden of preventable maternal and newborn deaths, it is imperative that more attention is given to how progress can be made quickly. The SCC programme provides important lessons and guidance on how this can be achieved.

Abbreviations

Gol: Government of India; GoR: Government of Rajasthan; LMIC: Low- and middle income countries; MDG: Millennium Development Goals; RCT: Randomised control trials; SCC: Safe Childbirth checklist

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Authors' contributions

SK & PDS conducted an initial literature scoping exercise. SK, PDS, VY and AS conducted the literature searches, collected and collated articles, and drafted this paper. JS, DB, DS and BS reviewed the draft in detail and contributed to the final version of the manuscript. All authors read and approved the final manuscript.

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Author details

¹Jhpiego-an affiliate of Johns Hopkins University, 29, Okhla Phase -3, New Delhi 110019, India. ²Department of Health Sciences, Global Health, University Medical Centre Groningen, University of Groningen, Groningen, the Netherlands. ³Children's Investment Fund Foundation (CIFF), London, United Kingdom. ⁴Department of Obstetrics and Gynaecology, Leeuwarden Medical Centre, Leeuwarden, the Netherlands. ⁵Maternal Health Division, Ministry of Health & Family Welfare, Government of India, New Delhi, India.

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CHAPTER

8

Discussion of findings, conclusion & recommendations

Discussion of findings, conclusion & recommendations

India has large annual birth cohort of 27 million (1). As a result of recent policy interventions to promote institutional deliveries, there has been a dramatic, more than 15 fold, increase in number of deliveries in health facilities over the last 12 years (2). This dramatic increase of institutional deliveries has necessitated the need for using innovative interventions to strengthen the quality of care. The readiness of the health system was not optimal to provide quality of care due to innate resource constraints in terms of competent human resources, commodities/supplies and accountability. The increase in institutional deliveries also afforded an unprecedented opportunity for the health system to improve access to family planning services, the unmet need for which was very high during the postpartum period (3), resulting in closely spaced pregnancies (4) and resultant sub-optimal maternal and neonatal health outcomes.

The overarching aim of this research was two-fold:

- to assess the outcomes of the innovative strategies, approaches and interventions, which were introduced for improving the access to quality of intra partum and immediate post-partum care in India in light of the tremendous increase in institutional deliveries; and
- to investigate the optimum pathway for rapid scale-up of the successful innovative interventions to expand the coverage of these interventions to larger populations in order to avert preventable deaths of mothers and newborns in India.

Derived from these overarching aims, a series of specific research questions were formulated. These

were related to outcomes of the WHO safe childbirth checklist, a process innovation in improving quality of intra- and immediate postpartum care; effectiveness of virtual classroom training, a technology innovation on quality of general nurse midwifery students, women's perspectives on use of the postpartum IUCD device as well as the one-year continuation rates of the users of the postpartum IUCD devices.

In addition to sharing the results of the assessment of the outcomes of these innovative interventions, this research also investigates the optimum pathway for testing and scale-up of innovations in resource constrained settings in a manner that harmonizes scientific rigor with the political urgency, given the high maternal and neonatal mortality.

In this general discussion, the main findings are summarized and discussed. Furthermore, methodological issues and the implications of these strategies, policy and future research are addressed

Research Questions and main findings

Research Question 1: Does implementation of Safe childbirth checklist in public health facilities of India lead to an improvement in adherence to evidence based practices by health service providers during childbirth? Main findings: 16 of the 28 evidence-based practices were performed significantly more in the intervention group when compared with the comparison group. The mean number of practices increased from 4.5 practices to 6.4 in the comparison group and from 4.3 practices to 17.9 practices in the intervention group. On average a client in the intervention facility received 11.5 more

SCC (95 % CI-8.5–14.6)) best practices than a client in comparison sites controlling for baseline values; this difference was statistically significant ($p < 0.001$).

Research Question 2: Does competency based trainings of nursing students using technology innovation of virtual classrooms lead to an improvement in their MNH (maternal & newborn health) related skills?

Main findings: The mean OSCE (Objective Structured Clinical Examination) score (measure of MNH skills) of students who had undergone the 72 hour virtual class room training (62 out of 76) was significantly more than those students who had not undertaken the training (21.3 out of 76). Keeping OSCE score of 75% or more as the criteria for competency, it was observed that none of the students in pre-intervention batches were competent. However, after the roll out of virtual classroom training, 77.2% of the students of post-intervention batches were found to be competent. It was found that on an average, a student in the post-intervention batch scored 52.3% marks more than a student in the pre-intervention batch.

Research Question 3: What are the experiences of women in India with post-partum intra uterine contraceptive device (PPIUCD) in terms of decision-making, satisfaction with the method and outcomes at 6 weeks post insertion?

Main Findings: Majority of women who opted for PPIUCD (91.7%) were first time users of IUCD and over half of them (53%) had one living child. Around 58% women reported they do intend to have more children in future. Only a small proportion of women (1-2%) reported that the insertion was painful or very painful during or after insertion. At 6-week follow up interview, more than three quarters of women (78%) reported having no complains with PPIUCD, 3.8% reported having an expulsion, 5.4% reported having symptoms that were suggestive of infection, 8.9% reported having cramps and abdominal pain and 5.5% reported having menstrual irregularity. At insertion, almost all women (99.6%) stated that they were

satisfied with their decision to opt for PPIUCD and at 6 weeks follow up, 92% women reported that they were happy with the decision of opting for PPIUCD.

Research Question 4: What is the one-year continuation rate of post-partum intra uterine contraceptive device (PPIUCD) among women in India and what are common reasons for discontinuation and contraceptive switching patterns among women who discontinue the method within one year?

Main Findings: One-year continuation rate of PPIUCD among Indian women as achieved under a large-scale national PPIUCD program was 62.8%. The removal rate was 29.7% and expulsion rate was 7.5%. Among women who got their PPIUCD removed or had an expulsion, around half (45.4% and 50.8% respectively) had not switched over to any other modern contraceptive method at the time of their follow up. Of those who had switched, most had opted for condoms followed by female sterilization and oral contraceptive pills. The most common reason for discontinuing the method within one year were associated side effects such as bleeding, discharge and pain in abdomen.

Research Question 5: Does implementation of a package of post-partum family planning interventions through public health facilities of resource-constrained settings lead to an improvement in knowledge, attitude and practices of post-partum women and health service providers?

Main Findings: An improvement in knowledge about return to fertility and about the best time for counseling on postpartum family planning across all cadres of service providers. Among post-partum women, there was an improvement in knowledge about return to fertility as well as the three criteria of lactational amenorrhoea (LAM) from baseline to end line (0 vs 38.5%). The proportion of women who knew about three or more modern family planning methods also increased significantly (83.5% vs 96.1%). In addition, there was a statistically significant increase in the percentage of post-partum women receiving any contraceptive counseling. Proportion of post-

partum women who were offered at least three modern contraceptive methods at health facilities also significantly increased (31.6% vs 89.2%).

Research Question 6: Which key accelerators facilitate rapid scale up of public health innovations in low and middle-income countries?

Main Findings: We studied the strategies discussed in various published scale-up frameworks for low and middle income countries and mapped them against the strategies adopted by the Safe Childbirth Checklist program. This helped us identify key factors (accelerators) which facilitated rapid scale of the safe childbirth checklist program. The key factors identified as accelerators were: testing the intervention in real world, resource constrained settings; using an appropriate and time sensitive research design; testing the intervention at substantial scale and in diverse settings; using an adaptive and iterative prototyping approach for implementation; sharing data and evidence with key stakeholders on an ongoing basis; targeting bridge resources through strategic engagement of stakeholders and timely integration of scale-up plans with annual planning and budgeting cycles and systems.

Interpretation of the main findings

Outcomes of the WHO Safe childbirth checklist in improving quality of care

The World Health Organization (WHO) developed the checklist-based childbirth safety program in 2008 and the checklist was tested for usability in ten countries in Africa and Asia (5). However, there was an evidence gap in terms of the effectiveness of the checklist when implemented at scale in resource constrained settings. This gap was addressed by our study showing that implementation of the SCC program did lead to an increased adherence to 16 evidence based critical practices by health service providers during childbirth.

Increased adherence to evidence based practices, as observed in our study, has also been reported after implementation of SCC programs in Karnataka,

India, Namibia and Rwanda (6, 7, 8)). The pre-post intervention study in Rwanda found that SCC program lead to an increased adherence to 11 of the 29 identified evidence based practices in SCC (8). However, it is worth noting that both these studies were conducted in single hospital settings and lacked a comparison arm. After our study, a large cluster-randomized trial in Uttar Pradesh, India also found that implementation of SCC program did lead to an improved adherence to essential birth practices by health service providers of public health facilities (9). It is further worth noting that across the multiple studies, most of the practices that improved regarded problems related to either lack of knowledge or skills among providers and/or non-availability of essential commodities (6-9). However, the few practices which did not show an improvement or showed sub optimal improvement in either of these studies including ours, were common practice that were related to either provider behavior, e.g. handwashing and partograph filling, or cultural practices, e.g. skin to skin contact.

There is an additional question in the global health community. Does improvement in adherence to evidence based practices as a result of the use of the checklist result in reduction of neonatal and maternal mortality and morbidity. A few studies have traced the use of checklist to its anticipated outcomes like reduction in childbirth related complications, perinatal mortality and maternal mortality (9, 10). While Varghese et al (10) found that use of SCC was associated with 11 % reduction in stillbirths and very early neonatal deaths (deaths within first seven days of birth), the cluster –randomized controlled trial by Semaru et al (9) concluded that the use of SCC did not result in reduction of maternal and perinatal mortality as well as maternal morbidity. Semaru et al did however report significantly improved rate of birth attendants' adherence to essential practices in intervention facilities than in control facilities. This divergence in terms of impact of the SCC in different studies emphasizes the important role of the health systems and related contextual factors which ultimately determine the impact of innovative solutions like SCC on maternal and neonatal mortality.

To summarize, the WHO SCC is an effective innovative intervention in improving adherence to key clinical practices during childbirth in resource constrained settings. However, the SCC can only be optimally effective and produce impact on reduction of mortality and morbidity if the health system can enable provision of quality care. The extent of effectiveness is closely related to the health system's readiness shown by improvement of 'many but not all' clinical practices included in the WHO SCC. Some 'sticky' clinical practices, which are more dependent on elements of system readiness, like availability of competent human resources at all points of care, commodities and culture of accountability did not improve in the study. The determinants of adherence to those practices are not addressed just by the use of the WHO SCC. This inference is also validated by Semrau et al in their Better Birth Trial (9).

As referred in the framework of my theses, the health system readiness determines the extent of effectiveness of the checklist in improvement in adherence to evidence based practices as observed in our findings above. Health System readiness can be broadly categorized into three domains: competencies of providers, availability of essential commodities and culture of accountability. Our interpretation from the observations related to variability in outcomes as a result of introduction of the WHO SCC in different settings is that the theory of change through which the WHO SCC influences improvement in quality of care is context-specific (different in different settings with different levels of system readiness). In high income countries where competencies, commodities and accountability are consistently present, the checklist improves quality through minimizing errors by acting as a ready reckoner or memory tool. However, in resource-constrained contexts, like India, the SCC can help focus the efforts by acting as a framework for improving the availability of competencies, commodities and accountability. Hence it is critical for the scientific and program community to appreciate the role of context and system readiness in assessing not just 'if' an intervention is effective in a setting but also 'how' an intervention is effective in different settings.

This is the reason for the title of this thesis 'Context appropriate innovative solutions for improving access to quality intra- and immediate postpartum care in India'. We would also want to share an additional interpretation and perspective based on the discordance in findings related to neonatal mortality reduction in our program in Rajasthan state of India, which showed 11% reduction in neonatal mortality (10) and the large Randomized Controlled Trial conducted in the neighboring state of Uttar Pradesh of India that did not show any reduction in neonatal mortality (9), though both these studies did show improvement in adherence to clinical practices. Given the fact that each of the clinical practices included in the SCC have an evidence base on effectiveness with regard to improving maternal and neonatal outcomes (11), in an ideal world, if the SCC improves adherence to the clinical practices, the maternal and neonatal outcomes should improve. However, it is not always so. This points towards the complex interplay between many health systems related factors responsible for non-translation of improved adherence to better maternal and neonatal outcomes.

Effectiveness of using virtual classrooms in strengthening competencies of nursing-midwifery students

Recognizing the importance of a competent nursing-midwifery workforce in provision of quality care to mothers and newborns, the government of Bihar state of India, in the year 2012, launched the virtual training program in its general nurse midwifery (GNM) training institutes. This initiative was launched to mitigate the shortage of quality faculty in the state by linking the premier nursing institution in the state capital through satellites and other internet technology with all other nursing institutions in the state. The objective was to beam live classes on important midwifery competencies from the premier nursing institution in the state capital to all peripheral institutions to strengthen the quality of trainings being rendered to nursing students of these institutes. This decision of introduction of technology innovations to strengthen quality of education was backed by evidence from other similar contexts, which

showed that use of information technology such as virtual learning platforms do have the potential of imparting quality education (12-14).

Our study showed that use of technology of virtual classroom training, in addition to regular traditional classroom teaching, does lead to improved knowledge and skills. Literature on this subject is vast and varied. There are a number of studies and reviews, which have evaluated the effect of virtual learning platforms on knowledge, attitude and skills of students belonging to different health related streams like medicine, nursing and dentistry. While some studies have compared the traditional lecture method with virtual platforms of teaching (15-17), other studies have compared the traditional method with the blended approach – which is a combination of both traditional lectures and virtual classroom teaching (18, 19). Blended learning approach is considered more suitable for healthcare training because of the need to combine hands-on skills-based training at a practical level with self-directed learning (20 - 22).

The group of studies that compare blended and traditional training approaches have shown either the blended learning approach to be superior (19) or equivalent to the traditional learning method (18, 23, 24) in terms of improving the knowledge or skills of students. While the contexts for moving towards a blended learning approach in these cited studies were very different from that of our study, the findings do support the effectiveness of blended learning approach and are in line with the findings of our study. A number of studies (18, 25) do also report a higher level of satisfaction among students with the blended learning approach than with the traditional approach. Studies have also shown that over time, blended learning approaches can be more cost-effective than the traditional face to face trainings (26).).

Our interpretation of the findings is that the poor baseline scores of students in our study validate the findings of the various studies, including the important

study conducted by the National Health System Resource Centre of India, that had assessed the quality of education in nursing schools of Bihar and found it to be grossly sub optimal (27). The report had cited a number of probable reasons including unavailability of adequate numbers of staff, sub-optimal training infrastructure, and inadequate academic and clinical training of students. In this context, a technological innovation like virtual classroom training can be effective in mitigating the shortage of faculty and infrastructure by leveraging technology to link the well-resourced nursing institutions of the states to the remote institutions. This linkage enables beaming of live classes of essential midwifery competencies from the well-resourced nursing institutions to the under-resourced institutions. These technological innovations can thus play a key role in ensuring that the nursing-midwifery students of all nursing institutions of the state, irrespective of the shortage of faculty and infrastructure, have the requisite clinical competence when they pass out of the schools. This is another example of how an innovative solution, contextualized to the local context, is able to mitigate some of the innate system barriers in a resource constrained setting and thereby contribute to improvement in quality of maternal and newborn care. Competent and confident nurse midwives are an important pre-requisite to provision of quality care to mothers and newborns.

The virtual classroom program in Bihar was supported by technical agencies that had dedicated funding for the program. Considering that setting up of the infrastructure required for operationalizing the virtual classroom program and thereafter sustaining it did require additional investments, there is a need to study the cost effectiveness of this intervention which would be key to informing the government and policy makers and would determine its uptake in different regions as well as scale up. In addition, as this intervention is technology driven, there is also a need to study the feasibility of operationalizing it in different contexts as well as perceptions of end users (teachers and students) towards using it.

Outcomes of post-partum intra uterine contraceptive device services in India

The Government of India introduced Post-partum intra uterine contraceptive device (PPIUCD) services at public health facilities in 2010-2011. We conducted two studies around this intervention – one to know the profile of women who opt for this method, their satisfaction levels with the method as well as outcomes at six weeks post insertion and the second to know the one-year continuation rate of the method, as achieved under a large scale national program.

In our studies, we observed that more than 3 out of 4 women had no complaints with the post-partum IUCD insertions six weeks after insertion and more than 3 out of 5 women retained the IUCDs at the end of 12 months after insertion. Our interpretation of the findings of the first study is that most women accepting PPIUCD are fully satisfied with the method - both at the time of insertion as well as at six weeks after insertion. This corroborates with findings of a number of studies from both India as well as globally (28 - 30) which have shown high levels of satisfaction with the method among women who accept PPIUCD. This is particularly encouraging given that higher level of satisfaction with the method is known to result in better continuation rates, which in turn decreases the probability of unwanted pregnancies (31). In the context of India, higher levels of satisfaction with the method is also important to ensure wider acceptance across the community as ‘word of mouth’ is one of the most common sources of information about contraceptive methods among women in rural India (32).

We also infer that given that the vast majority of women chose the PPIUCD because it was long acting reversible method as well as a non-hormonal one, this points to a felt need for expansion of the basket of contraceptive choices in the public health sector of India, which otherwise is heavily skewed towards female sterilization (33). This is a very important consideration for the government of India as the basket of contraceptives in India is still very limited and many methods like sub-cutaneous injectable contraceptives

as well as implants, which are available in other LMICs, are still not available in the public health system.

In contradiction to the widely held apprehension among the gynecologists in India, the post-insertion outcomes, especially the expulsion rates, of PPIUCD insertion, both at six weeks post insertion and one-year post insertion, were low and very comparable to interval IUCD insertions. This was in consonance to findings from various studies across the globe as well as in India (34, 35). These low expulsion rates, which are very much dependent on competency levels of providers, demonstrate that the PPIUCD program in India was effective in being able to ensure required skills and competency among service providers for inserting PPIUCDs, even when they were scaled-up.

The post-insertion removal rates reported at six weeks of around 5% and at one year of 29.7%, indicate that an over-whelming majority of women were satisfied by the method. These rates of discontinuation are much lower than some of the other reversible contraceptives like injectables (36), which indicate that PPIUCDs are an effective long term reversible method for preventing unintended pregnancies. Additionally, since the majority of the removals, both at six weeks and at one year, were reported to be because of perceived side effects like abdominal pain, increased bleeding and discharge, which is in line with the findings of various other studies (37, 38), this emphasizes the need to strengthen pre and post insertion counselling of women for these side effects. These side effects are expected side effects of the method and there is a need to ensure that women accepting PPIUCDs are made aware of them through counseling during the various contacts of the women during pregnancy through antenatal care, during childbirth and after childbirth through postnatal care. This is in alignment with studies which have shown that counselling on the method improves continuation rates of the method (39, 40).

The one-year continuation rate of PPIUCD of 62.8% as found in our study is much higher than the continuation rate of some of the other reversible contraceptives like injectables (36). Since findings from our study are more

representative of the ‘real world settings’, i.e. the data was collected from multiple states of India, PPIUCD can be considered to be an effective long-acting reversible contraceptive method for preventing unintended pregnancies. PPIUCD services can be provided when women are already in the health facilities for childbirth. Therefore, this method, like other PPFP methods, has a strong potential to address the disproportionately high unmet need for PPFP in LMICs and thereby contributes to spacing pregnancies and improving the maternal and neonatal health outcomes.

Effectiveness of a package of interventions to improve knowledge and practices of healthcare providers and women in their postpartum period

Multiple studies evaluate single interventions for improving access to PPFP services, but this research is the first of its kind which provides evidence on the effectiveness of a package of interventions, implemented at scale, for improvement of knowledge and practices of healthcare providers and women in their postpartum period. Findings from this research indicate that a package of scalable capacity building initiatives for the health care provider, along with creating an enabling environment for integration of PPFP messages and services in maternal health platforms can be effective in increasing the awareness about key concepts of PPFP among post-partum women and their communities.

Our interpretation to this finding is that the key to getting optimum results from implementation of these initiatives is carefully bundling the different interventions for ensuring implementation of concerted and holistic programs for strengthening PPFP services. The important interventions that should be included in the package of PPFP interventions include effective capacity building of all cadres of workers involved in these services,, effective integration of PPFP messages and services in the maternal health platforms as well as developing an ecosystem of enablers and serviced delivery tools for health care workers. The bundling of interventions brings about synergies between the various interventions, which

thus produce population level outcomes. The bundling of interventions also simplifies the process for scale up of the interventions in resource constrained settings as it brings about efficiencies between the various inputs required for different components of the package. Our study was the first of its kind that demonstrated on ground implementation of the global guidance on comprehensive programming for strengthening PPFP services (41) which provided recommendations on bundling of key interventions for PPFP to produce population level impact.

Accelerators to enable rapid scale-up of promising innovations to save precious lives of women and children

Multiple frameworks in literature provide guidance on the optimum pathway for scale-up of successful interventions (42 – 47). They recommend adherence to the key principles laid out in these scale-up frameworks such as contextualizing the intervention, rigorous evaluation of the intervention before scale-up, engaging important stakeholders through evidence-based advocacy, and mobilization of resources for scale-up lead to innovation uptake and expansion.

However, this research provides guidance on ensuring that the pathway to scale up is time-sensitive and suggests actionable steps to minimize the time lag between providing evidence that an intervention really works and its scale-up, thereby responding to the political urgency faced in LMICs where preventable deaths of mothers and newborns are happening every minute. The inference from the findings of my research is that it is possible to strike a balance between the needs of scientific rigor for testing of innovations before scale up and the political urgency faced by governments of LMICs which puts pressure on them to rapidly expand coverage of promising interventions by scaling up of the interventions. While most existing frameworks speak of a sequential series of steps (pilot test, advocate, scale-up), this research suggests that it is possible to initiate these streams of work in parallel and save considerable time. The seven accelerators identified in this research for facilitating rapid scale-up

of proven interventions provide pragmatic guidance to policy makers and program managers to design their pathway to scale-up to respond to their urgent needs for saving precious lives of mothers and newborns.

Methodological considerations

Quality of samples

Five of the six studies in my thesis involved primary data collection. Three of these studies (Chapter 3, 4 and 5) were conducted in program implementation settings or ‘real world settings’ as compared to corresponding similar studies which were conducted within controlled environments of single or a couple of health facilities. By virtue of coming from the real world settings, findings of these studies are more relevant and valid for program implementers as well as policy makers for informing their decision making.

However, the health facilities where the follow up studies on PPIUCD acceptors were conducted (Chapter 3 & 4) were selected purposively based on the feasibility of carrying out the study and hence are liable to selection bias. In addition, the study participants were those PPIUCD acceptors who owned a telephone and this too might have led to selection bias, probably providing a sample of somewhat more than averagely motivated participants. This may imply that we overestimated effects somewhat.

Quality of Information

For each study which involved primary data collection, the interviewers (Chapter 3, 4 & 5) and observers (Chapter 1 & 2) who collected data for respective studies were trained on using data collection instruments, study methodology and the standard operating procedures through standardized trainings. Chapter 1 employed observations of clinical practices as the mode of measurement of quality of care – which is one of the better ways of measuring the same (48, 49). Many similar studies rely on documents or self-reported data for measuring quality of care and hence are liable to biases (49). Chapter 2 employed a validated tool - the OSCE methodology – for measuring

the skills of general nurse midwifery students. Chapter 4 utilized a prospective cohort design for knowing the outcomes at 6 weeks post PPIUCD insertion and hence averted potential recall bias. We thus expect to have prevented large information biases regarding these sources of information.

However, studies that carried out observation of practices or skills (Chapter 1 & 2) were liable to Hawthorne effect. In addition, the set of observers were different for the baseline and end line data collection rounds and therefore inter-observer variations may have had an influence on the findings. In Chapter 5, some of the parameters were compared (baseline –end line) with less power than remaining parameters due to smaller sample at baseline.

Potential for causal inferences and confounding

Two (Chapter 1 & 2) of the three studies which looked at effects of interventions did collect information on potential confounding factors and adjust for them in the analyses. The studies evaluating the effects of virtual classroom training and the PFP package did not have a comparison arm and therefore secular changes, which may have influenced the outcomes, could not be accounted for. Moreover, due to this lack of a comparison group in these two studies, we cannot fully infer all pre-post differences to only the intervention as study.

Implications for Policy and Practice

- **Prioritize investments for improving quality of care and clinical education, using innovative solutions to leapfrog the system barriers:** Our research on the outcomes from the use of the WHO SCC and virtual training demonstrate that at least these innovations are an effective way to strengthen quality of education and care in resource constrained settings. These improvements in quality are necessary: significant improvements in the access to essential care have been realized in low and middle income countries

(LMICs), but this increase in access has not resulted in proportionate reduction of maternal and neonatal mortality. The Lancet commission report on quality of health clearly states that larger number of deaths are happening due to sub-optimal quality of care rather than lack of access to care (50).

However, improving the quality of care is also dependent on the readiness of the health system (9), which includes human resources for health, infrastructure and commodities. Some of these innate barriers of health system cannot be fixed overnight due to system constraints and hence there is a need to test and use innovative solutions to strengthen quality of care in resource constrained settings. Use of innovations to strengthen quality of care has also been found to be effective in other studies in similar settings (51).

Based on our findings and the supporting global literature, we make two recommendations, closely related to each other. First, governments must prioritize investments for strengthening quality of care being provided, as that will greatly improve the maternal and neonatal health outcomes and will help governments in getting bang for the buck with regards to the investments made for improving access. Secondly, recognizing the fact that the innate health system barriers cannot be overcome overnight, we strongly recommend the governments and other stakeholders to consider using innovative solutions to leapfrog the system barriers, thereby improving quality of care in the short term and thus averting preventable deaths of mothers and newborns.

- **Contextualize the use of innovations like WHO Safe Childbirth Checklist and use of technology for training for improving quality of Care:** Our findings from the study on WHO SCC, as well as other studies on WHO SCC, indicate the variability in improvement in adherence to practices as well as variability in the maternal and neonatal outcomes as a result

of the introduction of the SCC. This variability in the outcomes emphasizes the importance of the context when designing or adopting innovations for solving any problem. It is critical for policy makers and program managers to appreciate the fact that an innovation should not just be ‘imported’ from a different context and used ‘as it is’. Just as any other technology or product, when imported from high income settings, it is contextualized based on local requirements (automobile industry is a great example).

The use of innovations such as the WHO SCC needs to be contextualized for the local settings. The need for contextualization of the SCC as a tool and of the way it is implemented as well as the way it influences change has been observed in other studies as well (9, 52). While the SCC strengthens quality of care in high income countries through minimizing errors by acting as a memory tool, in resource constrained contexts, the SCC can help focus by acting as a framework for improving the availability of competencies, commodities and accountability, thereby improving quality of services. The Government of India, based on the results of the WHO SCC project, designed the national Quality Improvement program called ‘Dakshata’, meaning competence, wherein the practices included in the WHO SCC were used as a framework for strengthening competencies of providers, ensuring uninterrupted availability of commodities and supplies and improving accountability by measuring adherence to the practices included in the SCC. Based on the findings of this research, it is recommended that countries using the WHO SCC for improving quality of care should use it as a framework for prioritizing and focusing efforts to strengthen competencies, commodities and culture of accountability (the 3 C model). Additionally, the governments should always prioritize contextualization of any solution being ‘imported’ from any other setting, to solve the context specific problems of the country concerned.

- **Leverage the ‘contacts’ of clients for SBA to increase access to quality post-partum family planning services, including postpartum IUCD services:** Recognizing the fact closely spaced pregnancies lead to adverse maternal and neonatal outcomes (53, 54). The associations of parity and maternal age with small-for-gestational-age, preterm, and neonatal and infant mortality: a meta-analysis. BMC Public Health] and that there is disproportionately high unmet need for family planning among women in their postpartum period, the governments in LMICs should use the increase in SBA contacts to provide counselling and FP services to these women. This increase in contacts of clients with the health system for maternal health services affords an unprecedented opportunity to the governments for increasing access to Family Planning services. This recommendation is based on the findings regarding research questions 3,4 and 5, that indicate that women who receive Postpartum IUCD services as a package of the PPFP services, were highly satisfied with the method. Additionally, women who received counseling of these services during the Antenatal period during the antenatal care contacts were more likely to accept PPIUCD as well as continue the use of PPIUCD one year after insertion.

This integration of PPFP services in the Maternal and Neonatal health platforms was also found to be a best practice in other studies globally (55). . Integration of FP counseling and services during all contacts of the women with the health system during pregnancy, childbirth and postnatal period, not only optimizes the use of scarce resources to improve access, it also positively influences the quality of PPFP services being provided and as experienced by the clients, thus increasing the adoption of methods like PPIUCD during childbirth as well as continued use of PPIUCDs at one year postpartum due to continued counseling during ante- and postnatal periods. This recommendation aligns with the WHO recommendation which encourages women receiving information on family planning

during antenatal care, immediately after birth, and during postpartum period (56).

More specifically, immediate PPFP services, like PPIUCD services, offered during the period of childbirth, are recommended for adoption by LMICs, because women have more contraceptive options to choose from just after childbirth. FP counselling just before and after childbirth increases awareness of the importance of birth spacing and PPFP options and finally a large number of women and their partners and families can be reached during institutional deliveries.

- **Address the asymmetry of information among clients through targeted counseling efforts through community and facility based interventions for increasing access and strengthening quality of PPFP services:** There is lack of awareness for family planning, especially the importance of birth spacing and PPFP services, among women and their communities. This asymmetry of information among women plays an important role not only in low utilization of PPFP services as well as in lack of satisfaction and discontinuation of usage of these methods after initial acceptance. Additionally, given the fact that FP is not just a matter of spacing of pregnancies but also concerns the reproductive rights of the women, the women and their partners should have timely access to complete information regarding importance of the different methods of FP and their expected adverse effects, so that the principles of volunteerism and informed choice, essential elements for family planning services, is not compromised.

This research clearly found that women who are counseled for PPFP services during ante-, intra- or postpartum period were more likely to accept these methods and continue usage of these methods for longer periods of time. They experience more satisfaction and lower anxiety due to the expected adverse effects of methods like PPIUCD. It was also observed that concerted demand sided interventions, both at community

level through community health workers as well as at facility level through nurses, counselors and doctors, results in overall improvement in awareness levels for PPFP among women and communities. These findings are consistent with other studies in LMICs (57).

Based on these findings, governments are recommended to invest in efforts for targeted counseling for women, using all cadres of health workers, including community health workers, and using integration of FP counseling during maternal and neonatal care contacts. This recommendation is consistent with WHO recommendations (41, 58)..

- **Adopt time sensitive processes and pathway for scale-up of promising innovations to avert preventable deaths of precious lives:** Rapid scale-up of promising innovative interventions in LMICs to achieve population level benefits in a time-sensitive manner is a key challenge due to constant tension between the need for scientific rigor and the need to rapidly expand coverage of promising interventions. This research investigated how an innovation was robustly evaluated and scaled up nationally in a time sensitive manner. Specifically, the SCC program in Rajasthan illustrated that it is possible to prove an innovation in a robust manner and secure government commitment and readiness for national scale-up within a reasonably short time span, 3 years in this case.

Based on these findings, the adoption of the following accelerators which facilitates rapid scale up of promising innovations is recommended: testing the intervention in real world, resource constrained settings; using an appropriate and time sensitive research design; testing the intervention at substantial scale and in diverse settings; using an adaptive and iterative prototyping approach for implementation; sharing data and evidence with key stakeholders on an ongoing basis; targeting

bridge resources through strategic engagement of stakeholders and timely integration of scale-up plans with annual planning and budgeting cycles and systems. These seven accelerators should be incorporated into the existing global scale-up frameworks, to guide future testing and scale-up of innovations in a time-sensitive manner. With the unacceptable burden of preventable maternal and newborn deaths, it is imperative that more attention is given to how progress can be made quickly but without necessarily compromising scientific rigor.

Implications for future Research

- The variability in findings related to neonatal mortality reduction in our program in the state of Rajasthan and the Randomized Controlled Trial conducted in the state of Uttar Pradesh of India (9) indicates that there may be many health systems related factors responsible for non-translation of improved adherence to better maternal and neonatal outcomes. There is therefore a need for high quality research for understanding these factors, which would benefit the SCC program as well as similar other large-scale quality improvement initiatives
- As observed in the multiple studies related to WHO SCC, most of the practices that improved as a result of introduction were related to either lack of knowledge or skill gap among providers and/or non-availability of essential commodities (6 – 10). However, the practices that were related to either provider behavior, example handwashing and partograph filling, or cultural practices, example skin to skin contact, did not improve significantly. There is therefore a need to conduct focused research on these ‘sticky’ practices in order to better understand the barriers to changing the adherence to these important practices.
- Our findings on the outcomes from the introduction of PPIUCD services indicate that more than 3 out of 5 women continue the usage of IUCD at 12 months after the insertion. However, this also

means that about 2 out of every 5 women who accepted PPIUCD services discontinued the usage of OIUCD before completion of 1 year. While we have analyzed the reasons as given by the women for the discontinuation of PPIUCD, there is a need for further research on the potential solutions to address these reasons of discontinuation as well as a better understanding of the interplay of other behavioral as well socio-cultural factors which influence the continued use of IUCDs.

- Based on the study conducted for introduction of the WHO SCC and its subsequent rapid national scale-up in India, we have identified seven accelerators for facilitating the scale-up of promising innovations in resource constrained settings. However, there is a need for further research on understanding the role as well as interplay of each of these accelerators as they relate to different health systems and different levels of health needs and political urgency.
- We observed the outcomes from the use of technologies like Virtual Classrooms for improving learning outcomes for the nursing students in India. However, the improvement in learning outcomes do not necessarily translate to the
- We have investigated the outcomes from the introduction of various interventions related to postpartum family planning, including postpartum IUCD services. However, our outcomes are related to experiences of clients and client outcomes as well community level awareness about postpartum family planning services. There is however a need to understand the impact of increased availability of postpartum family planning services on the overall unmet need and contraceptive prevalence rates of women in their reproductive age. This will inform the prioritization of investments of governments in postpartum family planning services as it relates to overall availability and utilization of family planning services.

Conclusion

The central aim of this thesis was to investigate the outcomes of innovations to improve access to quality intra- and postpartum care among women in India and on the optimal pathways for rapid scale-up of these innovations. The findings from the studies conducted emphasize the need for governments and other stakeholders to invest in innovative solutions to strengthen the quality of and access to essential maternal, newborn and family planning services. The key to successful investments in these areas include the focus on openness to innovations that help to solve the long standing problems related to access and quality and customizing the innovations to suit the context specific challenges of the health system. Leveraging the increased contacts of the women with the health system during pregnancy and childbirth provides an unprecedented opportunity to expand access to postpartum family planning services to these women, thereby helping to reach a healthy timing and spacing of pregnancies. And finally, all stakeholders involved in introduction of innovations should be sensitive to the seriousness of large number of preventable deaths of women and children every day and hence adopt approaches that have demonstrated the successful rapid scale –up of promising innovations to people who need them the most. The approaches adopted for testing and scale-up of promising innovations should be based on the intellectual curiosity and intention to achieve perfection but on the moral imperative and political urgency of saving human lives. This is essential to basic value of global health that all lives are of equal value and chances of survival of any mother and newborn should not be dependent on where they live.

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Summary

Women in many low and middle income countries, including India, still lack access to quality care during and after childbirth. While systems have invested to improve access to essential care during intra- and immediate postpartum care, quality of care is grossly sub-optimal due to innate system barriers which include shortage of human resources, infrastructure and information systems. This has resulted in sub-optimal access to quality intra- and immediate post-partum services for women and the newborns. Contextually appropriate innovative solutions, if tested and scaled-up in time sensitive manner, can help in improving access to intra- and immediate postpartum care for women and their newborns.

The aim of this thesis is the extent to which context appropriate innovations have been effective in improving access to quality intrapartum and immediate postpartum care for mothers and newborns India. The thesis also investigates the processes which can drive the rapid scale up of these innovations in a time-sensitive manner, in a complex resource limited setting. Finally, this thesis gives recommendations on ‘what to do’ and ‘how to do’ with respect to innovations for increasing access to quality intra- and immediate postpartum care. The innovative solutions that have been included in this thesis were tested and scaled up in the complex and large health system of India. These innovative solutions include the Safe Child Birth Check List by the World Health Organization (WHO-SCC), a simple paper based tool which acted as a framework for strengthening competency, commodities and accountability of the health system to deliver quality childbirth care and resulted in >11 percent reduction in very early neonatal mortality in India. Similarly, use of innovative technology solution like virtual training systems to mitigate the shortage of quality training institutions was proven to be effective in improvement

of competencies of nurse-midwives produced at the nursing institutions in India. The importance of postpartum family planning (PPFP) services and its delivery during and just after the childbirth cannot be overemphasized in countries like India where there is limited contact of women with the health systems. India introduced PPFP services, including the postpartum IUCD services, in a staggered manner from 2013/14 to leverage the increase in facility based childbirths. It was observed that if concerted technical intervention are executed to integrate postpartum contraceptive services, especially the postpartum IUCD services, during childbirth, this results in >60% women showing continued usage of these contraceptive services at the end of one year after childbirth, and complication rates among women accepting these services are comparable to other contraceptive services, demonstrating the fact that introduction of PPFP services during and after childbirth is an effective way to increase access to Family Planning services among women. And finally, this thesis shares strategies through which a promising innovation can be robustly evaluated and scaled in a time sensitive manner. Based on the investigation of the factors which contributed to rapid scale up most of the interventions that we tested and have included in the thesis, especially the WHO SCC, the adoption of the seven accelerators which facilitates rapid scale-up of promising innovations is recommended. These accelerators include testing the intervention in real world settings; using an appropriate and time sensitive research design; sharing data and evidence with key stakeholders on an ongoing basis and continued engagement of all stakeholders for sharing of data and mobilization of resources. With the unacceptable burden of preventable maternal, newborn deaths, it is imperative that more attention is given to how progress can be made quickly but without necessarily compromising scientific rigor.

The findings and recommendations from this thesis is intended to provide actionable guidance to policy makers and program managers in India and other resource constrained settings on strategies that can help to leapfrog the innate system barriers in these

health systems to ensure provision of quality care during intra- and immediate postpartum period, thus contributing to preventing needless and avoidable deaths of women and newborns around the world.

Samenvatting

Vrouwen in veel lage en middeninkomenslanden, waaronder India, hebben nog steeds geen toegang tot kwaliteitszorg tijdens en na de bevalling. Hoewel er fors is geïnvesteerd om de toegang tot essentiële zorg tijdens de bevalling en direct daarna te verbeteren, is de kwaliteit van zorg vaak nog steeds suboptimaal omdat gezondheidszorgsystemen niet goed functioneren. Er is vaak een tekort aan personeel, voorzieningen, infrastructuur en informatiesystemen. Goede, bewezen effectieve en context-specifieke innovaties kunnen helpen bij het verbeteren van de toegang tot goede intra- en postpartumzorg voor vrouwen en hun pasgeborenen.

Het doel van dit proefschrift is te onderzoeken in hoeverre in India gebruikte innovaties effectief zijn geweest. Ook werd onderzocht hoe bewezen effectieve innovaties snel kunnen worden opgeschaald in een complexe resource beperkte setting. Tenslotte, geeft dit proefschrift aanbevelingen over ‘wat te doen’ en ‘hoe te doen’ met betrekking tot innovaties om de toegang tot kwaliteitsvolle intra- en onmiddellijke postpartumzorg te verbeteren.

De innovaties die in dit proefschrift zijn opgenomen, zijn getest en opgeschaald in het complexe en grote gezondheidssysteem van India. De Safe Child Birth Check List van de Wereldgezondheidsorganisatie (WHO-SCC) is een eenvoudig papieren hulpmiddel. Implementatie van deze checklist resulteerde in > 11 procent reductie van zeer vroege neonatale sterfte in India. Een andere innovatieve technologische oplossing die in dit proefschrift werd onderzocht, virtuele opleidingssystemen, hebben als doel om het tekort aan goede opleidingsinstellingen te verminderen. Deze vorm van opleiden is effectief gebleken bij het verbeteren van de competenties van verpleegkundigen/verloskundigen die worden

opgeleid in India. Het belang van postpartum-gezinsplanning (PPFP) tijdens en vlak na de bevalling kan niet genoeg worden benadrukt in landen als India, waar vrouwen maar beperkt in contact komen met de gezondheidszorg. India introduceerde PPFP, inclusief het direct postpartum inbrengen van een spiraaltje, vanaf 2013/2014. Het bleek dat > 60% van de vrouwen een jaar na de bevalling hetzelfde contraceptivum nog steeds gebruiken en er tevreden over zijn. Aangetoond werd dat het inbrengen van een spiraaltje direct na de bevalling een effectieve manier is om de toegang tot gezinsplanning te verbeteren.

Tenslotte werd onderzocht hoe bewezen effectieve interventies sneller maar toch robuust kunnen worden geëvalueerd en opgeschaald. Zeven factoren die implementatie en opschalen kunnen versnellen werden geïdentificeerd. Deze factoren zijn o.a.: uittesten van de interventie in ‘real life setting’, een geschikt onderzoeksdesign gebruiken en doorlopend gegevens en bewijsmateriaal delen met belangrijke belanghebbenden. In de onaanvaardbare werkelijkheid van vermijdbare sterfgevallen bij moeders en pasgeborenen, is het noodzakelijk dat er snel vooruitgang wordt geboekt, zonder dat dit afbreuk doet aan de wetenschappelijke kwaliteit van het bewijs dat geleverd moet worden over de effectiviteit en veiligheid van een interventie voordat deze kan worden opgeschaald.

De bevindingen en aanbevelingen uit dit proefschrift zijn bedoeld om bruikbare richtlijnen te bieden aan beleidsmakers en programma managers in India. Dit zal helpen om het gezondheidssysteem beter te laten werken. Daarmee wordt bijgedragen aan het voorkomen van onnodige en vermijdbare sterfgevallen van vrouwen en pasgeborenen in India en over de hele wereld.

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CV of the Author

Dr. Somesh Kumar is a public health physician with two decades of experience in policy formulation, advocacy, planning, and implementation for Global Health programs, including RMNCH and Women's Cancer Control (Cervical Cancer and Breast Cancer) programs. His experience has been focused around increasing access to and strengthening the quality of essential public health services in underserved regions of the world. He currently serves as senior director of new initiatives and innovations at Jhpiego. He provides the vision and strategic direction to identify, conceptualize, design, and support the development and accelerate the implementation of transformative programmatic, policy, process, and technology solutions and innovations. He also leads the efforts for Jhpiego's foray into newer technical areas like Immunization, Women's Cancers, Primary Health Care/UHC and engagement with private sector. Before this position, Dr. Somesh served as the Country Head of Programs and Deputy Country Director of

Jhpiego India. He led the design, implementation, and evaluation of global health programs implemented at large scales. Dr. Kumar supported the Government of India in development of their national programs on non-communicable diseases, including the national program for prevention of Cervical Cancer. He played a pivotal advocacy and technical support role in many key policy decisions taken by the government of India in the area of RMNCH. He has published peer reviewed papers on FP, MNH, and HRH in international peer-reviewed journals. Dr. Kumar was worked with the Norwegian government as senior technical advisor for Global Health and deputy head of section for Health and Development Cooperation in the Ministry of Foreign Affairs. He worked with PATH to introduce Japanese encephalitis vaccination in India. In his tenure with and WHO-AFRO region, he worked for Nigeria's National Programme on Immunization. He also worked with WHO in routine immunization and polio eradication activities in India.

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The Safe Motherhood Series

The Dutch Working Party 'International Safe Motherhood and Reproductive Health' aims to contribute to improvement of the reproductive health status of women around the globe, in particular by collaborating with local health workers (<http://www.safemotherhood.nl>). The Working Party is part of both the Dutch Society of Obstetrics and Gynaecology (NVOG) and the Dutch Society for International Health and Tropical Medicine (NVTG). The activities that are undertaken under the umbrella of the Working Party can be grouped into four pillars: education, patient care, research and advocacy.

Research activities are undertaken by (medical) students, Medical Doctors International Health and Tropical Medicine and many others. Some research activities develop into PhD-trajectories. PhD- candidates all over the world, Dutch and non-Dutch, work on finding locally acceptable and achievable ways to improve the quality of maternal health services, supervised by different members of the Working Party. Professor Jos van Roosmalen initiated the Safe Motherhood Series, which started in 1995.

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