Evaluation of the Safe Childbirth Checklist Program in Rajasthan, India: The How and What of the Evaluation Efforts

Shwetanjali Kumari¹, Rajashree Panicker¹, Ashok Jayaram², Neha Dumka¹, Siyaram Sharma¹, Vivek Singhal¹, Tathagatha Chatterjee¹, Beena Varghese¹

¹Public Health Foundation of India, New Delhi, India (Current or Former)
²Independent Consultant, Bangalore, India

Correspondence to: Beena Varghese, Public Health Foundation of India, Plot 47, Sector 44, Gurgaon – 122002, New Delhi, India. Email: beena.varghese@phfi.org

ABSTRACT

Background: India has witnessed a dramatic increase in institutional deliveries in the public facilities over the past decade. The increased demand for services has put tremendous pressures on the health delivery systems and has serious implications on the quality of care. WHO-endorsed Safe Childbirth Checklist (SCC) is a facility-based reminder tool aimed at improving institutional care practices around delivery and newborn care. The Government of Rajasthan, India implemented an intervention based on the SCC tool during 2013-2015 with technical support from Jhpiego. The Public Health Foundation of India led the evaluation study.

Objectives: The evaluation study was designed to assess the effectiveness and cost-effectiveness of the SCC intervention in reducing stillbirths and very early neonatal deaths (within 3 days of birth). This paper describes the protocol of the evaluation study.

Methods: The evaluation employs a quasi-experimental design comparing public facilities that provide secondary level care and have specialized newborn care units in six intervention and four comparison districts of Rajasthan. Study sites include 19 facilities in the intervention districts, and 15 in the comparison districts. Evaluation data were collected from November 2013 to April 2015.

Conclusions: The protocol offers approaches that may be useful in planning and monitoring large-scale evaluation studies using information technology in other developing countries.

Trial Registration: ClinicalTrials.gov Identifier - NCT01994304
INTRODUCTION

Over the past decade, India has witnessed significant increase in institutional delivery rates from 40% in 2005/06 to 83% in 2012/13 [1,2]. Most of the increase has occurred in the public institutions. This increase in facility-based births, however, has put tremendous pressures on the health delivery systems and has affected the quality of institutional care. Global evidence indicates that access to and utilization of quality facility-based maternal care ensures better maternal outcomes [3,4]. Globally, and in India, various efforts and interventions are now underway to improve the quality of institutional care.

WHO-endorsed Safe Childbirth Checklist (SCC) [5] is a facility-based reminder tool aimed at improving institutional care practices around delivery and newborn care. The 29 items of the SCC tool address major causes of maternal and perinatal deaths (stillbirths and early neonatal deaths within 7 days after delivery) that include hemorrhage, infection, obstructed labor, hypertensive disorders, birth asphyxia, infection, and complications related to prematurity [6,7]. The checklist was developed following a rigorous methodology and is based on the findings from a pilot evaluation study conducted in Karnataka that indicated marked improvements in the delivery of essential safety practices by health workers [8]. However, evidence on the impact of SCC tool on mortality is not available as of date.

Implementation of SCC: Context and Rationale

The SCC has been implemented over a three-year period from 2013 to 2015 by Government of Rajasthan with technical support from Jhpiego in all district and sub-district facilities (101) across seven intervention districts. In India, these facilities provide secondary level of care to various populations within a district. The SCC tool was adapted to provide reminders and acts as a job-aid to health care providers during four important points of the delivery process: a) at admission; b) during delivery; c) after delivery; and, d) at discharge. As part of the implementation process, Jhpiego has undertaken a series of activities (inputs) that include:

1. Orientation of the providers of the identified facilities on the use of the SCC. The process was undertaken in two phases - May and October 2013
2. Enabling the facilities to implement the SCC through supportive supervision provided by Jhpiego and designated government staff from June 2013 until April 2015
3. Ensuring the availability of the essential supplies required for essential delivery care practices
4. Monitoring of activities through regular data collection

The activities outlined herein are expected to improve adherence to care practices before, during, and after delivery in the labor rooms, and are measured through process and output indicators as described in Figure 1. The changes in care practices are expected to have an impact on stillbirths (SB) and early neonatal mortality (ENM). SB and ENM are among the most sensitive indicators to measure effectiveness of facility-based interventions that are designed to improve intrapartum and postpartum clinical care practices [9-11].

An evaluation study was thus designed to assess the effectiveness and cost-effectiveness of SCC program in reducing SB and very early neonatal deaths (vENDs, defined as deaths within 3-days of birth) in Rajasthan. Rajasthan is reported to have an early neonatal mortality rate of 27 per 1,000 births; 31 in rural and 13 in urban areas [12]. This paper describes the ‘how and what’ of setting-up a large-scale evaluation using an electronic platform for all aspects of the study - from data collection to validation to creation of a database. This paper is expected to be useful to researchers across the world, especially in resource-constrained settings, to support their efforts in planning and implementing evaluation studies.

OBJECTIVES OF EVALUATION

The evaluation is led by the Public Health Foundation of India (PHFI) with support from the Government of Rajasthan, and the implementing partner, Jhpiego. The goal of the evaluation is to measure the effectiveness and cost-effectiveness of SCC in reducing facility-based
SCC, a reminder tool and job-aid, aims to support health-care workers to improve maternal and newborn care practices

### Inputs

- **Stakeholders consultation**
- **Introduction & Orientation for use of SCC**
- **Supportive supervision**

#### Activities

1. Orientation: Providers are oriented on SCC during one-and-a-half day session covering 4 stages of delivery care defined in the checklist
2. Supportive Supervision
   - SCC adherence
   - Assess facility
   - Facilitate achievement & identify gaps
   - Debrief stakeholders
3. Facilitating availability of essential supplies
4. Monitoring of the intervention
   - Monthly periodic report (MPR) – for supplies
   - Periodic assessment (PA) – SCC adherence & changes in provider behavior

#### Outputs

1. Percentage of facilities where SCC implemented (from MPR)
2. Percentage of provider oriented (Training tracking sheet)
3. Availability of essential drugs, supplies and equipment (MPR)
4. Periodic assessment at facility level
   - Partograph use
   - Recording mother's BP at admission
   - Recording mothers temperature at admission
   - Oxytocin/misoprostol use for AMTSL
   - New born dried with a clean dry cloth
   - Recording baby birth weight
   - Initiation of breastfeeding within 1 hour of birth
   - Recording baby temperature at discharge

### Impact / Outcomes

Reduction in:

- Still births
- Very early neonatal deaths (within 3-days of birth)

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**Figure 1: Safe Childbirth Checklist: Monitoring and Evaluation Framework, Rajasthan, India**

SBs and vENDs. The specific objectives are to:

1) Estimate the effectiveness of SCC in the reduction of facility-based SB and vENDs.
2) Analyze the cost-effectiveness of the intervention in terms of costs per death averted.

Learning from the implementation of the SCC and the results of the impact evaluation will be documented and shared with the government, and will be disseminated in a timely manner at various forums to inform scale-up strategies.

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**MATERIALS AND METHODS**

**Study Design**

The SCC evaluation uses a quasi-experimental cluster design - ‘post only with concurrent control’ [13] using a mixed-methods approach [14] to determine whether SCC implementation in public health facilities has led to improved adherence to safe care practices for childbirth and subsequent reduction in mortality. Intervention and control districts were randomly selected and do not reflect any preferences and were only selected based on primary criteria of comparability in terms of delivery load, neonatal mortality rates and SB rate. District selection process is done in consultation with Government of Rajasthan and this ensured that there were no other maternal and newborn health interventions introduced during the study period (Figure 2).

Initially the study outcome was planned to be perinatal mortality to be measured through facility records and phone tracking of all births at all the intervention and control facilities (101 intervention and 99 control facilities). However, from the pilot study during 2012, we learned that phone tracking of all births was not feasible because of lack of tracking information. Thus, facility records would be the primary source of information for mortality. SB records were readily available from labor room registers, and the special newborn care unit (SNCUs) registers provided valid information on vENDs. SNCUs are facility-based specialized units placed at district hospitals and are high delivery load community health centers (CHCs) to provide specialized care for newborns with complications. Given that the literature indicates that 70-80% [15,16] of ENM happens within three days after birth, we decided that changing the outcome to vENDs will have minimal impact on the objectives of the evaluation study. This was endorsed by the project technical advisory...
Ethical Considerations

The institutional ethics committee of PHFI approved the study protocol on September 28, 2012 (TRC-IEC-141/12). The study has also received permission from the Department of Health and Family Welfare, Government of Rajasthan, to access the facilities and records to be used for the study. The study is registered at the Clinical Trials website of the U.S. Government with ClinicalTrials.gov identifier: NCT01994304.

Study Sites

Our study sites include 34 facilities that had SNCUs across six intervention and four comparison districts: 19 from the intervention (6 district hospitals) districts and 15 from the comparison (4 district hospitals) districts. The intervention districts included Alwar, Churu, Dausa, Jalore, Sikar and Sirohi, and comparison districts include Bharatpur, Jhunjhunu, Nagaur, and Pali. Furthermore, comparison of socio-demographic and key maternal and newborn indicators confirmed comparability between the intervention and comparison districts and facilities as shown in Supplementary Table (available on journal’s website). This comparability was additionally strengthened by findings from a rapid assessment of facilities done by Jhpiego in 2012, which showed similarity in infrastructure, human resources, and equipment and supplies between the intervention and comparison facilities.

Sample Size

The sample size was computed for a quasi-experimental facility-level cluster design based on the hypothesis that the introduction of the SCC would result in at least a 15% reduction in the facility-based perinatal (SB and vENDs) mortality. We assumed the prevailing proportion of facility-based perinatal mortality to be 30 deaths per 1000 births and used a level of significance of 5% and 80% power to estimate the sample size. In addition, to adjust for the clustering at facility level we estimated the coefficient of variation (CV - defined as the ratio...
of the standard deviation of cluster sizes to the mean cluster size) using available mortality data for the study facilities and also adjusted for the in-tri-class correlation (ICC). SB data obtained from the government records from the pre-evaluation period provided an estimate of CV as 0.849. For the ICC (defined as the proportion of variance accounted for by within the cluster and between the cluster variations), we reviewed estimates from studies within the Indian context. Based on the ICC estimates provided by Pagel et al [17], we chose the Ekjut study from rural India as it had very similar conditions to our study.

Our study had 34 facility clusters with SNCUs with an average cluster size of 3,183 annual births catering to a wide heterogeneous population (with varied risks of SB) coming from various villages within the districts. This was similar to Ekjut study where 8-10 villages formed a cluster, with average cluster population of 6,338 individuals, and a reported SB rate of 29.7 per 1000 births. For the Ekjut study, Pagel et al estimated ICC of 0.00012 for SBs. For our sample size estimation, we used a slightly higher ICC at 0.0002 and CV of 0.849 (design effect of 2.043) using Hemming et al formula [18]. Thus, the study is powered at 88% to detect the targeted reduction. The effective sample size from the 19 intervention and 15 comparison sites will be 60,477 and 47,745 births, respectively.

**Evaluation Timeline**

The evaluation timeline is in tandem with phased-in implementation design with a six month gap between introduction of SCC tool and start of evaluation. In the first phase, evaluation data is collected from November 2013 to December 2014. For the remaining facilities SCC orientation happened in October 2013, and evaluation data is collected from April 2014 to April 2015. The evaluation data is thus collected for each study facility for fourteen months capturing the cyclical pattern of deliveries found in this State.

**Data Sources**

The main source of data is the labor room (LR) register that provides obstetric and newborn details of all deliveries. LR register data is available from all the facilities, and this forms the study base for this evaluation. LR registers provide information on the main outcomes of interest for this evaluation, including SBs, as newborn status at birth is recorded here as live birth, referred, SB or intrauterine death (IUD). Newborns with complications get referred to the SNCUs. Newborns referred from the LR are termed as inborn cases whereas newborns referred from outside are identified as outborn cases.

Registers at the SNCUs provide additional information on status of newborn, which is recorded as alive, left against medical advice (LAMA), referred to a higher care facility, or dead. Most of the deaths occur within first two days of birth, and thus form an important source of information for our primary outcome—vENDs. The cases from SNCUs when linked to study births from LR thus provide information on vENDs among the study births. The referred and LAMA cases are further tracked through phone calls to ascertain the newborn status (live or dead) as described in Figure 3. Thus, facilities with SNCUs would provide information on SBs and vENDs through full record of SBs recorded in the LRs and almost complete information on vENDs recorded at the SNCUs. As the data were collected from facility registers, no informed consent was taken for from the mothers for participation in the study.

**Planning for the Evaluation: Electronic Data Capture and Data Management**

The preparatory period (June 2012 - October 2013) was used to plan the workload and manpower requirements and to test the feasibility of tracking birth outcomes for all live births seven days after delivery through phone calls to community health workers. Based on the findings from the preparatory period, data collection, storage, and management using paper-based format was replaced with electronic data capture method that uses software developed by Handheld Solutions & Research Labs (HANDSREL) in Bangalore, India. This software was designed to create an electronic portal for data collection, monitoring, tracking and linking SNCU cases to LR birth records. The electronic data capture framework included five modules as shown in Figure 4. LR and SNCU records are collected through electronic forms
Figure 3: Case Ascertainment and Tracking Logic Model

<table>
<thead>
<tr>
<th>Mobile data capture module</th>
<th>Data validation module</th>
<th>Phone tracking module</th>
<th>Data mapper module</th>
<th>Reports module</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consists of preloaded mobile forms to capture labor room and sick newborn care center records using dedicated mobile handset (mobile Nokia Asha 205)</td>
<td>Facilitates the supervisors in verifying the data entered by the data collectors by cross-validating a sub-set of labor room and sick newborn care center records during the supervisory field visits</td>
<td>Provides newborn outcome information for referred cases. Also provides information on cases with no place of delivery recorded</td>
<td>Matches a sick newborn care center case to a birth record from labor room and updates newborn status information</td>
<td>Facilitates real-time monitoring and generates report</td>
</tr>
</tbody>
</table>

Figure 4: The Electronic Data Capture Framework

using dedicated mobile handset (Nokia ASHA 4 and 5) or desktop preloaded with data collection software. The phone-tracking process is limited to cases that were referred out or left from SNCUs (within three days of birth), so that the final outcome for such cases (alive or dead) may be ascertained.

Quality Control

A robust quality control system has been developed with the aim to minimize errors during the two-year long data collection and management phase. The steps include:

- Soft and hard checks within expected range of values during data entry to minimize logical errors;
- Re-entry of key variables during data entry, if mismatched, the software prompts the data collector to take corrective action;
- Supervisory level monthly validation checks using e-forms with a subset of variables for up to 2 to 10 percent of all data collected and for all deaths recorded.
• All mismatches or missing data are highlighted and supervisors can correct the same through reentry of data using appropriate forms. All changes made are recorded in the respective databases to enable tracking of error rate in data collection;

• Performance based monetary rewards/incentives to data collectors, based on points scored on important parameters, to ensure complete data entry and correctness.

In addition, the supervisors also review and recommend improvement in the type and accuracy of data recorded in the LR and SNCU registers. As a result, the quality and quantity of information on birth-weight, gestational age in LR registers, phone numbers for referrals, place of delivery for outborn in SNCU registers have improved.

**Linking SNCU Data to Births in Labor Rooms**

Data collected from the SNCUs (newborns with complications) have to be linked to their respective labor room records to provide full information of all study births. However, in Rajasthan and most of India, health facilities do not use a common unique identification number for an individual across all health facilities. Thus, for inborn cases (coming from the respective LR), data collectors manually match each inborn case in the SNCU to the labor room register in that facility and record the respective unique labor room registration number in the SNCU data forms. For outborn cases (coming from other facilities), the place of delivery recorded in the SNCU register is the only variable that provides information as to whether the newborn was delivered at a study facility or not. The actual linking of the two databases (SNCU and LR) is done electronically by matching five to six variables which then creates a single record for a given birth record. This complete record is then entered in the composite database. Two levels of matching are done:

• Level 1 match requires exact match between chosen variables - LR registration number; mother’s and father’s name, address, date of birth, and sex of child. Some flexibility in spelling of names is allowed.

• Level 2 match allows a difference of plus or minus one for date of birth, LR registration number, and more flexibility with names is allowed. Supervisory field teams provide further clarifications as required to improve the matching process.

Figure 5 describes the process of the creation of the composite database that includes all data from the LR database including the birth records with matched additional information from SNCU database.

**Primary Outcome Measures**

The primary outcomes of the study are the facility-based SBs and vENDs. SB is defined as a baby born with no signs of life at or after 28 weeks’ gestation [19]. For our study, we have considered SB as late fetal death occurring at or beyond 28 weeks of gestation or with a birth weight of at least 1,000 grams [20]. SBs included both the macerated and fresh SBs, as such level of distinction is not available in the facility records. Facility-based vENDs is defined as newborn death within three days after birth. This is calculated using recorded dates of birth and death.

**Secondary Outcomes Measures**

The main secondary outcome is the in-depth understanding of intervention and factors leading to change obtained from the analysis of qualitative interviews with health care providers. These are expected to provide further understanding of the reasons for (or lack of) acceptance and use of SCC, and to understand the impact of SCC on provider behavior, which may have impacted perinatal mortality. These interviews will be done after informed consent is obtained from all health care providers. In addition, we may review the proportion of referrals from facilities for various maternal and newborn complications to understand the impact of the SCC intervention on referral patterns.

**DATA ANALYSES PLAN**

**Quantitative Analyses**

A technical advisory group comprising of international and national health research
experts from various domains - epidemiologists, social scientists, maternal newborn experts, and biostatisticians will guide the data analysis process and will approve the study findings.

In this quasi-experimental study, univariate and multivariate regression methods are used to evaluate the impact of SCC on mortality reduction. Descriptive statistics using cross-classified tables and exploratory univariate analyses are employed to understand the pattern and nature of the data.

A marginal modeling approach with a poisson link using generalized estimating equations (GEE) is employed to estimate the impact of this intervention. Such a modeling enables to bypass the correlation structure of the data and can assume any general working correlation structure and the parameter estimates would still be consistent. The model is of the following form (adjusting for the total number of births per facility per month, type of facility and for the linear trend):

\[ \log(\text{death rate}) = \beta_0 + \beta_1 \text{Intervention} + \beta_2 \text{DH} + \beta_3 \text{month} \]

Where,
- \( \beta_0 \): Expected log death rate for a comparison CHC
- \( \beta_1 \): Log Relative Risk due to Intervention
- \( \beta_2 \): Log Relative Risk due to DH
- \( \beta_3 \): Log linear trend of time (months)

All quantitative data analyses are performed using R 3.1.2 software [21].

**Qualitative Analyses:**

Qualitative data collected through in-depth interviews is analyzed to gain a nuanced understanding of the acceptability, applicability and utilization of the SCC amongst the providers. The interviews try to explore reasons for changes, or lack thereof, in provider behavior and mother and newborn care delivery. The interviews are analyzed by developing a coding scheme based on the specific questions used in the interview guide. The modality of the analysis follows the model proposed by Taylor [22], and includes use of themes obtained by examining

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Figure 5: Framework for Composite Database
the data followed by coding and analyzing data by topics. Interpretations relate to the objectives within the context in which data were collected.

Cost-effectiveness Analyses

A costing analysis is done from a program’s perspective and includes the additional costs of the SCC program. Costs of all inputs and resources (paid and unpaid) - labor and material resources towards training, supervision, support for commodities/supplies and other inputs that are part of the intervention are collected from Jhpiego using a standardized cost data collection format. The effectiveness of SCC program measured in terms of total deaths averted and total cost per life years saved in the intervention facilities compared to comparison facilities is used and cost-effectiveness of the intervention is expressed as cost per death averted and cost per life year saved.

DISCUSSION

The increase in demand for institutional deliveries at the public facilities in India over the past decade has not always been matched with appropriate supply side strengthening in terms of the availability of skilled human resources and essential supplies. This has affected the quality of institutional delivery care and efforts are now underway to improve the care at these facilities. The SCC, a reminder tool and job-aid is designed to provide support for health care providers to deliver essential routine and emergency care before, during and immediately after delivery [6,7]. This improved provision of routine and emergency care is expected to decrease maternal and newborn morbidity and mortality. SBs and early neonatal deaths are one of the most sensitive indicators to measure effectiveness of facility-based maternal and newborn care interventions [9-11].

The study protocol described herein aims to evaluate the effectiveness and cost-effectiveness of the SCC in preventing SB and vENDs. The costing component of the study will inform policy makers about the additional costs required for integrating the checklist into the existing public health system. Moreover, insights will be gained from the health workers on the acceptance and adherence of standards of care prescribed in the checklist and barriers if any that may affect the usage of the checklist.

The quasi-experimental study design is expected to provide an estimate of the impact of the SCC intervention on newborn mortality. The pre-intervention phase of the study enabled the team to adopt an efficient electronic data capture and management system (through HANDSREL software) that improved efficiency and accuracy of the data collection and management processes. In addition, rigorous quality control measures have been introduced through soft and hard check during data entry, blinded validation process by supervisors, and incentives to data collectors for error-free entries. For the evaluation study, facility registers from the LRs and SNCUs remain the main sources of mortality data, and these two sources are linked electronically through a two-level matching process as described in the previous section.

Rigorous quantitative and qualitative methods are employed to triangulate study findings. Quantitative methods are vetted by a technical advisory group to ensure internal validity of the study findings. The study births include women delivering in 34 facilities across 10 districts within a large state of India. These births are representative of births across the country, thus ensuring external validity, too. In addition, qualitative methods will help understand any potential concerns regarding internal and external validity of the quantitative findings.

One of the main limitations is the quasi-experimental design which is limited in its scope for strong causal inferences. However, the district selection process does not reflect any preferences and we ensure comparability between intervention and comparison districts (in terms of delivery load, neonatal mortality rates and stillbirth rates). The study uses information as recorded in the facility registers therefore encompasses all limitations of using such records. Finally, our study only includes facilities with SNCUs, impacting the generalizability of our results across all health facilities. However, this was required to ensure accuracy in the counts of vENDs as they are only reported in facilities with SNCUs.
CONCLUSIONS

The protocol described here summarizes the careful and elaborate planning, continuous supervision, and the efficient use of e-platforms to evaluate the use of the SCC to improve maternal and newborn outcomes. This protocol thus offers approaches that may be useful in planning and monitoring other large-scale evaluation studies using information technology in similar settings. The evaluation study of the checklist program, if found to be cost-effective, is expected to provide the evidence base required for the potential scale up of the SCC program nationally and internationally.

AUTHORS’ CONTRIBUTIONS

SK contributed to the design of the evaluation and drafted the manuscript. RP, AJ wrote various sections of the protocol (while they were working on the project in 2012 and 2013) that was used for drafting the manuscript. ND, SS, VS and TC provided intellectual input to the design and drafting of the protocol. BV is the principal investigator of the study and led the conception, design and coordination of the study. She provided assistance in drafting and editing the manuscript. All authors read and approved the final manuscript.

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CONFLICT OF INTEREST

Authors have declared that no competing interests exist.

REFERENCES


Additional Material on Journal’s Website

Supplementary Table - Comparison of Intervention and Control Districts Selected for SCC Evaluation Study, Rajasthan, India