

**EVALUATION OF THE SAFE CARE, SAVING LIVES (SCSL) QUALITY
IMPROVEMENT COLLABORATIVE FOR NEONATAL HEALTH IN INDIA:A
STUDY PROTOCOL**

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ABSTRACT

Background: Evidence-based mother and newborn health practices may be more widely used if the Institute for Healthcare Improvement's collaborative quality improvement strategy is implemented. In 87 public and commercial hospitals in India, the Safe Care, Saving Lives initiative supported the implementation of 20 evidence-based maternal and newborn care practices with a focus on neonatal care units and labor wards.

Objective: We offer a protocol for assessing this program, with the objectives being to: (a) calculate the impact of the initiative on mortality and evidence-based care practices; (b) assess the mechanisms influencing shifts in adherence to evidence-based practices and how they relate to contextual factors; and (c) investigate the viability of expanding the approach.

Methods: A phased implementation nested within a plausibility design forms the basis of the mixed-method evaluation. The 48 remaining hospitals, where the quality improvement strategy was implemented subsequently, were contrasted with the 39 non-randomly selected institutions that made up wave II of the program. With the use of abstraction from registers, checklists, observations, and interviews conducted at intervention and comparison hospitals, we evaluated mortality and compliance with evidence-based practices at baseline and conclude. We also looked at factors that influence and propel changes in the use of evidence-based procedures. Qualitative approaches examined the mechanisms of transformation in hospitals chosen specifically to serve as case studies.

Discussion: In a middle-income nation connected to a public health insurance program, this is the first quality improvement collaboration focusing on newborn health in secondary and tertiary institutions. We will refine assumptions regarding how this quality improvement method leads to the institutionalization of evidence-based practices through our theory-driven process evaluation.

KEYWORD

Collaborative quality improvement; perinatal health; India; evidence- based practices; neonatal mortality; stillbirth; implementation science

BACKGROUND

In India, neonatal mortality was predicted to be high in 2020 at 24 fatalities per 1000 live births [1], with broad regional variations. An estimated 760,000 babies in India pass away in the first 28 days of life each year. In response to the issue of newborn mortality, the Indian government has recently undertaken significant investments aimed at improving access to care during childbirth and the initial days of life. In order to encourage women to give birth in medical facilities, the Janani Suraksha Yojana (JSY) cash transfer scheme was established in 2005 [2]. Meanwhile, the Janani Shishu Suraksha Karyakram (JSSK) scheme offers free treatment, food, and transportation for women seeking care for sick newborns or for childbirth [3].

Three levels of neonatal care have been established since 2014:

- (1) resuscitation and essential care at birth provided by Newborn Care Corners at all points of childbirth;
- (2) Level-I Newborn Stabilization Units that manage low birthweight babies not requiring intensive care and stabilize sick newborns before further referral;
- (3) Level-II care in Special Newborn Care Units at district and sub-district hospitals that provide all types of care to sick newborns, except assisted ventilation and surgeries;
- and (4) Level-III Neonatal Intensive Care Units [4,5].

The significance of enhancing care quality and following best practices is underscored by the recent investments made in health infrastructure and access to care. Studies conducted in India have revealed deficiencies in healthcare quality that go beyond inadequate infrastructure [6–8]. In-service training is a crucial intervention for delivering high-quality care, but if done alone, it is likely to have limited effects. As a result, methods to quality management and improvement are becoming more and more necessary to support high-quality services. In order to improve the quality of newborn care and lower neonatal mortality and stillbirths, ACCESS Health International (ACCESS) launched the Safe Care, Saving Lives (SCSL) initiative India, in 2016. The initiative was based on the Institute of Healthcare Improvement's Breakthrough Series Quality Improvement Collaborative (QIC) approach. [6].

Utilizing structured quality improvement techniques and teamwork with other participating teams tackling related problems, the QIC approach seeks to increase adherence to evidence-based practices (EBP) in healthcare settings [6, 7]. Teams in health facilities are encouraged to use a problem-solving approach and are provided with coaching and mentorship from external staff, as well as training or sensitization in quality improvement approaches. Additionally, teams are encouraged to attend "learning sessions" where they can observe and learn from other active teams. This strategy is being used more often in low-resource environments to raise the standard of care[8].

Although the QIC technique is being used more often, there is scant and conflicting data regarding its efficacy [20]. There aren't many reliable studies from low- or middle-income countries that evaluate QIC [14, 17]. Furthermore, the Safe Care, Saving Lives project employed a creative strategy by embedding the QIC into a Health Care Trust platform, which may serve as an outside force for quality improvement. In response to the necessity of supplying additional proof on the efficacy of the QIC approach and its impact on results, we seek to evaluate:

- (1) The impact of the Safe Care, Saving Lives campaign on critical evidence-based care practices for mothers and newborns, the rate of stillbirths, and the neonatal mortality in intensive care units and labor rooms.
- (2) The viability of expanding the QIC method via a platform supported by the government for health insurance.
- (3) The processes influencing modifications in the adherence to evidence-based care practices and how they interact with environmental factors

METHODS

Study sites

The health care trusts pay for the costs of treating septicemia in mothers and newborns who require third-line antibiotics, stabilization, care for malformed neonates, and ventilation [11–13]. About 70%

of people are qualified for health insurance coverage. To be eligible for service reimbursement from the Health Care Trust, hospitals must meet specific the rapeutic and infrastructure requirement[28].

The Safe Care, Saving Lives intervention

The strategy contains the following characteristics:

- a. A targeted clinical topic
- b. Gaining knowledge from professionals in the domains of quality improvement, neonatology, and obstetrics
- c. Making use of several Plan-Do-Study-Act (PDSA) cycles and the Model for Improvement
- d. Enhancement of Quality Teams gather information to assess their effectiveness. e. Hospitals work together to share knowledge and best practices.

Method of implementation

The initiative envisaged the government- sponsored health care trusts taking over the organizing and coordination of collaborative learning sessions and dissemination of success stories at the end of the inter- vention in each State.

In order to provide an ongoing quality control function for hospitals that have been accredited, the Safe Care, Saving Lives program at the State level offered technical assistance for the establishment of a Quality Improvement Unit within the Aarogyasri Health Care Trust. Additionally, the program developed an incentive system that connected insurance payments to quality improvement measures. Furthermore, the programme provided capacity building and technical support to the State Quality Assurance Committee and District Quality Assurance Managers, to improve operationalization of quality improvement methods recommended in the National Quality Assurance System [9], and greater prioritization of quality improvement during quality assurance monitoring.

EVALUATION

Using metrics such as the number of EBP promoted in labor and delivery rooms and neonatal intensive care units, the number of change ideas tested, the quantity and frequency of mentoring interactions, training sessions offered, and learning sessions conducted, the ACCESS team tracked the implementation strength and reported it to the evaluation team on a quarterly basis.

Through monthly consultations with ACCESS staff and mentors, the assessment team documented contextual factors, such as changes in infrastructure, supplies, trainings given, or ongoing programs to improve the quality of care for mothers and newborns in target hospitals.

Using the Medical Research Council Process evaluation framework, a mixed methods process assessment investigated how, for whom, and under what conditions the intervention enhanced compliance with EBP [10].

Using semi-structured interviews with Quality Improvement Teams, Hospital Leaders, Health Workers Not Involved in Quality Improvement Activities, and Non-Participant Observation of Program Activities, a qualitative study employing a theory-driven multiple case study design investigated how the approach was tailored to the context and how participants engaged with the quality improvement intervention.

Estimates of the stillbirth and newborn mortality rates from our baseline assessment were combined with estimates of the EBP's application in the comparator group. Using our baseline data for four

indicators—stillbirth rate, high-risk admission (derived from abstraction of case notes), infant death, and handwashing (derived from observations)—we calculated the k factor.

DISCUSSION

To the best of our knowledge, this is the first QIC connected to a health insurance plan that focuses on newborn health at secondary and tertiary hospitals in a middle-income nation.

Impact, outcome, and output indicators are all included in our evaluation, allowing for the measurement of changes at various points along the implementation pathway. Using this method, we demonstrate learning that goes beyond the intervention's impact.

Our theory-driven process evaluation aims to refine hypotheses on the potential contribution of a structured quality improvement strategy to the institutionalization of evidence-based practice (EBP) and the potential value addition of inter-hospital collaboration in this regard. At a time when scaling up structured quality improvement is being advocated internationally to accelerate reductions in newborn mortality [21], the process evaluation will add to the growing body of evidence on mechanisms of change in relation to quality improvement [15,16] and challenge presumptions about the engagement of healthcare professionals and hospital administrators in quality improvement in a middle-income country setting.

The evaluation will test the program's premise that institutionalization of quality improvement in both private and public hospitals can be promoted through external levers by examining the interaction between the intervention and its health system. It will also evaluate the viability of government-sponsored health insurance schemes in fostering and maintaining quality improvement.

Approach-related issues for the impact evaluation, we had originally intended to utilize a randomized research design, but this was not practical because of the programmatic choice to enroll hospitals in order to facilitate the quick establishment of regional mini- collaboratives around referral networks. However, the distribution of public and private facilities, workload, and baseline newborn mortality were among the important hospital parameters that the non-randomized allocation managed to reach a decent balance with.

The outcomes of hospital quality improvement initiatives are likely to be influenced by contextual factors, such as state funding for maternity and newborn care. In light of this, we will examine and discuss the findings of our evaluation and record any adjustments made during the evaluation period as advised [18].

Assessing neonatal mortality in hospitals is particularly difficult since parents of extremely unwell newborns may decide to forego medical advice and leave their baby in the event that they do not have a chance of life. According to our baseline report, the risk profiles of kids who were released, those who departed against medical advice, and those who were referred vary, with the group of babies who left against medical advice having the highest chance of dying [22]. Prior to comparing overall hospital-based mortality, differences in risk must be taken into account. Hospital-based mortality is intrinsically biased towards higher mortality in hospitals caring for sicker neonates when it disregards various risk groups [19].

In the lack of records of intrapartum or recent stillbirths, we used the general stillbirth rate as a measure of progress in the labor ward. However, as prenatal treatments also affect this indication, the findings will need to be carefully interpreted.

The power to identify any changes is constrained by the small number of clusters and observations per cluster, even if we plan to conduct stratified analysis in respect to State, hospital ownership, and other characteristics, such as caseload.

We are confident that our thorough assessment, which combines qualitative and quantitative methodologies, will yield crucial insights into the operation and outcomes of quality improvement in the demanding environments of both public and private institutions, such as colleges and specialty hospitals.

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