Development of a quality improvement package for reducing sight-threatening retinopathy of prematurity

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Purpose: With improving survival of preterm neonates, retinopathy of prematurity (ROP) is emerging as a major cause of childhood blindness. Incidence of sight-threatening ROP can be reduced by improving the quality of care provided to preterm neonates. 

Methods: This before-and-after study was designed to develop a need-based intervention package to improve knowledge, skills, and practices of those providing care for preterm neonates, and to evaluate the effectiveness of this package when combined with point-of-care quality improvement (POCQI) in improving survival of preterm neonates without sight-threatening ROP. The study had a formative component to assess baseline knowledge, skills, practices and attitudes, and to assess the needs of the healthcare staff to improve the care of preterm neonates. It was conducted in four special care neonatal units (SCNU) in the state of Madhya Pradesh in India. 

Results: A theory of change was developed to guide the development of study tools including needs assessment and educational package development. The educational package thus developed has been tested at the study sites in combination with POCQI projects driven by local teams of healthcare providers. The effectiveness of the interventions has been evaluated by collection of individual-level data on neonates admitted at the study sites. 

Conclusion: A multidimensional educational package integrated with system changes in the form of quality improvement (QI) endeavours driven by local context and needs were developed and evaluated in the project.

Key words: Quality improvement, retinopathy of prematurity, theory of change

With improving access to facility-based neonatal care (FBNC), an increasing number of preterm neonates are surviving in India and new challenges are emerging about their ongoing care.\cite{1} Such a major challenge is ensuring the survival of preterm neonates with intact and optimal neurosensory abilities. Retinopathy of prematurity (ROP) is one of the important conditions which endangers intact survival, and which needs to be detected in a timely manner and treated promptly, if severe. ROP is also amenable to primary prevention by improving adherence to evidence-based clinical care practices in hospitalized sick preterm neonates.\cite{2,3} Improved access to FBNC does not, however, ensure adherence to best practices, and thus a quality-improvement and assurance system needs to be put in place to prevent the consequences of suboptimal clinical care. The recent expansion of neonatal care services in many low- and middle-income countries, coupled with suboptimal care is leading to an increasing number of infants with stage 4 and 5 ROP being seen by ophthalmologists, including India.\cite{4,5}

ROP is not only among the commonest causes of acquired blindness in children but is also an excellent indicator of the quality of care provided to preterm neonates in a healthcare facility. Risk factors for ROP include unmonitored and unnecessary oxygen administration, sepsis, poor nutrition, and exposure to blood products.\cite{3} Therefore, interventions aimed at reducing ROP are likely to impact many aspects of neonatal healthcare resulting in improved rates of intact survival without abnormal neurological outcomes. The hypothesis of the Madhya Pradesh-quality improvement (MP-QI) project is that among preterm neonates admitted in SCNUs (population), implementation of a need-based intervention package comprising evidence-informed practices targeting healthcare providers (nurses, doctors, coordinators) to improve their capacity and skills for providing clinical care as well as undertaking QI activities (intervention), would improve neonatal survival without severe ROP (outcome) compared with current quality of care and competencies (control). To test this hypothesis, we developed a theory of change [Fig. 1] which formed the basis of the package of interventions. The current article presents the development of the theory of change and the study protocol to test this theory of change.

Methods

This before-and-after study is being undertaken in three district hospitals and a medical college in the state of Madhya Pradesh, India. The study had a formative component to assess baseline knowledge, skills, practices and attitudes of healthcare workers and to assess the needs of the healthcare staff to improve the care of preterm neonates. It was conducted in four special care neonatal units (SCNU) in the state of Madhya Pradesh in India. The effectiveness of the interventions has been evaluated by collection of individual-level data on neonates admitted at the study sites. The hypothesis of the Madhya Pradesh-quality improvement (MP-QI) project is that among preterm neonates admitted in SCNUs (population), implementation of a need-based intervention package comprising evidence-informed practices targeting healthcare providers (nurses, doctors, coordinators) to improve their capacity and skills for providing clinical care as well as undertaking QI activities (intervention), would improve neonatal survival without severe ROP (outcome) compared with current quality of care and competencies (control). To test this hypothesis, we developed a theory of change [Fig. 1] which formed the basis of the package of interventions. The current article presents the development of the theory of change and the study protocol to test this theory of change.

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India. Madhya Pradesh was one of the four states selected for the ROP project supported by Queen Elizabeth Diamond Jubilee Trust (2013–2019) following a situational analysis.

The study has three main objectives. Firstly, to assess baseline levels of knowledge, skills, attitudes, and practices of SCNU healthcare personnel, state SCNU coordinators, and child health consultants about clinical care pathways which are likely to reduce the risk of severe ROP, to assess their problem solving and QI skills, and the awareness of parents regarding the need for ROP screening and potential therapy. Secondly, to formulate pilot test and finalize a package of interventions (consisting of educational materials [webinars and videos], protocols/guidelines, simulation-based training, standard operating procedures, advocacy tools for policy change, collaborative quality-improvement network) to improve knowledge, skills, attitudes and practices of SCNU coordinators, child health consultants, and SCNU healthcare workers in abovementioned domains. Lastly, to evaluate the effectiveness of this package of interventions in improving knowledge, skills, attitudes and practices of the health care professionals identified above; increasing awareness of parents regarding the need for ROP screening and potential therapy; improving clinical practices related to risk of ROP and ultimately, increasing the survival of preterm infants without severe ROP.

For objective 1, the needs assessment was undertaken by the coordinating centers (PGIMER, Chandigarh, GMCH Chandigarh, and AIIMS New Delhi) in the four facilities outlined above. For objective 2, a learning package was developed by the coordinating centers which was tested in the SCNUs used for objective 1. (website for free access to the learning package: https://www.pretermcare-eliminatingrop.com.) For the development of QI collaborative, network data were collected from the participating SCNUs and coordinating centers through an app developed specifically for this purpose. POCQI tool developed in collaboration with World Health Organization South-East Asia Regional Office (WHO-SEARO) was used for imparting training for QI projects (www.pocqi.org and http://workbook.pocqi.org/) For objective 3, the study unit consisted of a teaching institution as the hub and three SCNUs as the spokes, with the intention that the teaching institution would mentor the SCNUs and help implement the educational and QI packages.

For objectives 1 and 2, participants included medical officers or consultants employed in the state child health program with responsibilities pertaining to SCNU; pediatricians, medical officers, and nurses working in SCNUs. For objective 3, data were collected from neonates who fulfilled criteria for ROP screening as per guidelines of the Government of India.

Figure 1: Theory of change
Table 1: Method of information collection for the formative phase (objective 1)

| Participants                        | Information to be collected                                                                 | Methods                      |
|-------------------------------------|---------------------------------------------------------------------------------------------|------------------------------|
| State Ministry; NHM                  | Priorities in newborn health                                                                | Key informant interviews     |
|                                     | Mechanisms or processes for QI                                                              |                              |
|                                     | New policies on the horizon                                                                 |                              |
| State SCNU coordinator/ child health consultants | Role in/approaches to QI in the state                                                      | One to one in-depth interview|
|                                     | Main challenges                                                                             | Web-based questionnaire      |
|                                     | Limitations in current training of SCNU staff                                              |                              |
|                                     | Priorities for training and capacity building                                               |                              |
|                                     | Attitude towards creating a QI nurse in each SCNU                                          |                              |
|                                     | Potential role of a QI nurse                                                                |                              |
|                                     | Characteristics of an ideal QI nurse                                                        |                              |
|                                     | Knowledge assessment in leadership and QI methodology                                        |                              |
| Senior nurses in SCNU               | The support they receive from state SCNU coordinator and hospital administration              | One to one in-depth interview|
|                                     | Training nurses have received                                                               |                              |
|                                     | In-service training for themselves and other nurses                                          |                              |
|                                     | Staff turnover/attrition                                                                    |                              |
|                                     | Main challenges in the SCNU                                                                 |                              |
|                                     | Approaches currently followed to improving quality                                          |                              |
|                                     | Roles of nurses and doctors and how they complement each other                              |                              |
|                                     | Equipment and whether it is functioning                                                     |                              |
|                                     | Attitude towards creating a QI nurse in this SCNU                                          |                              |
|                                     | Potential role of a QI nurse                                                                |                              |
|                                     | Willingness for staff to be trained                                                        |                              |
|                                     | Priorities for capacity building among staff                                                |                              |
|                                     | Knowledge assessment in leadership and QI methodology                                        |                              |
| Nurses                              | Pre-service and in-service training                                                         | Questionnaire; case studies  |
|                                     | Current knowledge about the care of preterm infants                                         |                              |
|                                     | How long they have worked on the SCNU                                                      |                              |
|                                     | How they access information to improve their work                                           |                              |
|                                     | Access to the internet and on-line materials and attitudes towards online learning          |                              |
|                                     | Satisfaction with their work                                                                | Focussed group discussions   |
|                                     | Challenges they face in their work                                                          |                              |
|                                     | Freedom to make decisions and act on them                                                    |                              |
|                                     | Use of clinical care protocols                                                              |                              |
|                                     | How they currently gain knowledge and skills                                                |                              |
|                                     | How problems are managed in the SCNU                                                        |                              |
|                                     | Attitudes concerning knowledge and skills of the doctors                                    |                              |
|                                     | Response to the idea of a QI nurse                                                          |                              |
|                                     | Attitudes towards mothers                                                                  |                              |
|                                     | Areas they would like training in                                                           |                              |
|                                     | Current skills and practices e.g., handwashing, setting alarms                              | OSCE and observation         |
| Doctors                             | Satisfaction with their work                                                                | One to one in-depth interview; case studies|
|                                     | Challenges they face in their work                                                          |                              |
|                                     | Who makes decisions about patient care                                                       |                              |
|                                     | How problems are managed in the SCNU                                                        |                              |
|                                     | Their role in training nurses                                                               |                              |
|                                     | Attitudes concerning knowledge and skills of the nurses                                     |                              |
|                                     | Attitudes towards mothers                                                                  |                              |
|                                     | Attitude towards creating a QI nurse in this SCNU                                          |                              |
|                                     | Potential role of a QI nurse                                                                |                              |
|                                     | Current knowledge in various domains of preterm neonatal care                                | Questionnaire                |
|                                     | Current skills and practices e.g., handwashing, wearing gloves, use of antibiotics          | OSCE and observation         |
| Parents                             | What they know about ROP                                                                   | Questionnaire                |
|                                     | Their attitudes towards helping to provide care for their infant                            |                              |
|                                     | Barriers they face in spending time in the NICU                                             |                              |

OSCE=Objective structured clinical examination, QI=Quality improvement
Table 1 presents the methods of data collection for the formative component of the study. Table 2 presents the outcomes relevant to each specific objective of the study.

Approval was obtained from the ethics committees of the respective institutions and written informed consent was obtained from healthcare providers (for objective 1 and 2) and either parent of preterm neonates (for objective 3).

**Results**

Five main target clinical areas were identified in the theory of change for improvement which could impact preterm survival without severe ROP. These areas included good control of oxygen, less exposure to blood products, good nutritional status, less systemic infections, and good developmentally supportive care. Good control of oxygen included steps to improve methods of oxygen administration and monitoring and optimizing the use of continuous airway pressure (CPAP) and surfactant. Strategies to reduce exposure to blood products included less blood sampling, policy to restrict the use of blood products and effective use of phototherapy. Strategies to improve nutritional status included early initiation and rapid advancement of enteral feeding with breastmilk. Various strategies were planned to improve aseptic techniques at the time of birth and during hospital admission to reduce systemic infections. Prevention of hypothermia, kangaroo mother care, pain control and less noise, and light exposure were strategies to improve developmental care, with greater involvement of parents in the care of their preterm baby during the hospital stay.

Table 3 enlists the QI projects conducted in the SNCUs during the study. Fig. 2 presents an example of a successful QI project. At present, data collected during the project are being analyzed to evaluate the effectiveness of the intervention package on the study outcomes.

**Discussion**

This study was planned to improve the survival of preterm neonates without sight-threatening ROP. The interventions used in the study are based on two important evidence-based approaches. Firstly, it has been recognized that although healthcare workers in resource-limited settings have suboptimal knowledge and skills about preterm care, the latter cannot be improved by continuing medical education or skill training alone. System barriers which preclude the application of evidence-based practices need to be overcome along with improvement in knowledge and skills. Therefore, the interventions in this study have components of improving the capacity of healthcare workers and their teams in both clinical and QI domains. Secondly, it has been recognized that risk factors for ROP in preterm neonates cared for resource-limited settings are different from those in reported from well-resourced...
countries. Unmonitored and unnecessary use of oxygen therapy and a high incidence of infection are two important risk factors identified in low- and middle-income countries. As a result, ROP is often observed in heavier and relatively mature preterm neonates. Therefore, improvement strategies to decrease the incidence of ROP need to focus on improving context-specific risk factors and health systems.

We have used both in-person contact and e-learning approaches to reach many healthcare providers in the target hospitals. While in-person two-way interaction is an important component of adult learning, e-learning has advantages as it can reach a large number of learners in a shorter time, there are opportunities of repeated synchronous (web-meetings and chat session) and asynchronous (discussion boards and group emails) interactions and standardization of learning material. We believe that in a vast country like India with tens of thousands of healthcare providers involved in neonatal care, it is important to use e-learning platforms. We have previously demonstrated the effectiveness of the e-learning approach in improving knowledge and skills of healthcare providers.

**Conclusion**

Due to weak and fragmented health systems, even skilled and knowledgeable healthcare providers may face challenges in using evidence-based practices. Some of the health system-related challenges are due to poor infrastructure (e.g., lack of an adequate number of pulse oximeters) but many are related to lack of point-of-care policies or standard operating procedures (e.g., identifying neonates needing oxygen therapy). A QI approach managed by local teams of doctors and nurses can overcome these contextual issues. The success of such an approach in improving clinical practices has been demonstrated in both resource-rich and resource-limited settings. Therefore, we planned to integrate the QI approach with knowledge and skill-building.

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**Conflicts of interest**

There are no conflicts of interest.

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