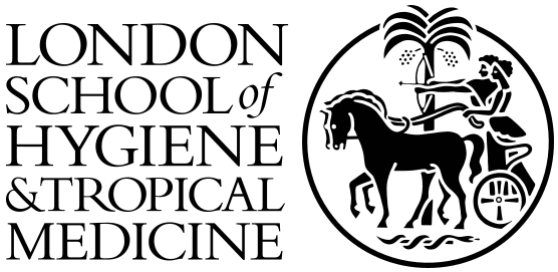

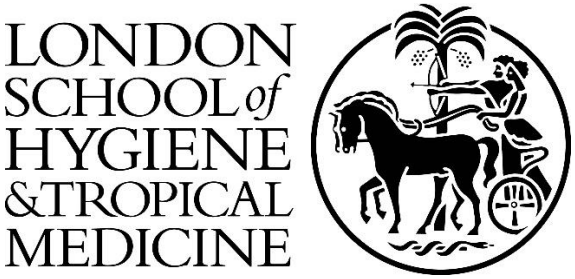

Improving quality of newborn care at scale through quality improvement: evaluation of the Safe Care Saving Lives programme in Telangana and Andhra Pradesh, India.

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Funded by the Medical Research Council

Declaration of own work

I, Karen Zamboni, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signed: 

Date: 1st July 2021

COVID-19 statement

All data collection was completed before the COVID-19 pandemic, between 2016 and 2019. The pandemic however had an important impact on my PhD: it delayed data analysis and write up, due to the challenge of juggling studies with childcare. It also impacted on our ability to disseminate results in country, given the limited bandwidth of participating hospitals in engaging with the project after its completion and during the pandemic.

Abstract

Background: Approximately 1 million newborn deaths could be prevented each year through high quality health systems. Quality improvement collaboratives, involving group problem-solving in health facilities and sharing of learning across teams, are a widely used strategy to improve quality. However, rigorous evaluations are scarce; contextual influences and mechanisms of change are poorly understood, and the feasibility of using this strategy at scale is underexplored.

Methods: I conducted a systematic review to understand how and under what circumstances quality improvement collaboratives may improve outcomes. I also evaluated the Safe Care Saving Lives programme, a quality improvement collaborative to reduce stillbirths and newborn mortality in 60 hospitals in Telangana and Andhra Pradesh, India. Using mixed methods, I evaluated impact on stillbirths and newborn mortality; contextual influences and mechanisms of change; and the feasibility of scaling up quality improvement through the state-level health insurance scheme which participating hospitals were part of.

Results: Quality improvement collaboratives may affect outcomes through the normalisation of new behaviours and ways of working among clinical teams, supported by leaders. The evaluation of Safe Care Saving Lives found no effect on stillbirths and newborn mortality; high attrition in programme implementation due to the challenge of engaging leaders in quality improvement, and diluted implementation of the quality improvement collaborative approach. Scaling up the collaborative quality improvement approach through the state health insurance scheme in Telangana was not feasible. Barriers included limited coherence between the approach and the quality policy framework, and the limited scope of leveraging health insurance payments as incentives for quality in newborn care.

Conclusion: this PhD highlights the limitations of quality improvement at facility level. Design of quality improvement should better consider strategies to engage leaders and respond to the needs of clinical teams, using formative research and theory of change. Greater coherence between quality improvement and other reform for quality in the health systems can aid improvement of newborn care at scale.

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"Dux femina facti" [Virgil, Aeneid]

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Abbreviations

ANCS: Ante-natal corticosteroids

ARR: Annual Reduction Rate

CHW: Community Health Worker

CI: Confidence Interval

CPAP: Continued Positive Airway Pressure

CS: Case Study

DALY: Disability-adjusted Life Years

DiD: Difference in difference

EBP: Evidence-based Practice

KMC: Kangaroo Mother Care

LAMA: Left against Medical Advice

LBW: Low Birthweight

LMIC: Low and Middle-Income Country

NHFS: National Family Health Survey

NICU: Newborn Care Unit

NMR: Newborn Mortality Rate

MES: Median Effect Size

OR: Odds ratio

PDSA: Plan, Do, Study, Act

PHFI: Public Health Foundation of India

QI: Quality Improvement

QIC: Quality Improvement Collaborative

QoC: Quality of Care

SCSL: Safe Care Saving Lives

SDG: Sustainable Development Goal

SNCU: Special Newborn Care Units

WHO: World Health Organization

Definitions of key terms[1]

Live birth: A baby born with any signs of life, irrespective of the duration of pregnancy

Low birthweight**:** A live birth with a weight at birth of less than 2500g

Maternal death: A death of a woman from any cause related to or aggravated by pregnancy or its management (excluding accidental or incidental causes) during pregnancy and childbirth or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy.

Preterm Birth: A live birth before 37 completed weeks of gestation, or fewer than 259 days since the first day of the women's Last Menstrual Period

Quality improvement: the systematic use of methods and tools to try to continuously improve quality of care and outcomes for patients (King's Fund)

Stillbirth: A fetal death at ≥1000g, or ≥28 weeks

[1] With the exception of the definition for quality improvement, all other definitions are from the World Health Organisation www.who.int

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Chapter 1: Background and Introduction to the thesis

Introduction

This PhD analyses the contribution of quality improvement collaboratives to address the challenge of improving newborn care quality at scale. This first chapter provides a background to the PhD work, situating it against the challenge of improving quality of care to prevent newborn deaths and stillbirths, globally and in India. The chapter presents the case for quality improvement in relation to newborn care and offers a review of quality improvement collaborative interventions in relation to maternal and newborn care in low- and middle-income settings. It then provides an overview on newborn mortality, and India's national response to this challenge. Against this background, this chapter then presents an overview of the Safe Care Saving Lives programme and evaluation, which was the study this PhD stemmed from. The chapter concludes with an outline of the problem statement, research questions and objectives, as well as the structure for the thesis.

It is important to flag that, while this chapter presents both stillbirths and newborn mortality as issues of relevance, greater emphasis is placed here and in the rest of the thesis on newborn care, and specifically intrapartum care and inpatient care for small and sick newborns, because this was the focus of the Safe Care Saving Lives programme.

1.1 The case for quality to prevent newborn deaths and stillbirths

1.1.1 The scale of the problem of newborn mortality and stillbirths globally

Newborn survival, including prevention of stillbirths, is a relatively new area of global concern, formally recognised as distinct from child survival in the Sustainable Development Goals era (1, 2). Under the Sustainable Development Goal 3 (to ensure healthy lives and promote wellbeing for all at all ages), target 3.2 calls for the reduction of neonatal mortality to at most 12 per 1000 live births by 2030. This target originates in the 2014 Every Newborn Action Plan through improving the coverage and quality of effective maternal and newborn care interventions (2). The inclusion of a specific target on neonatal deaths, defined as the death of a child aged 0 – 28 days, in the Sustainable Development Goals agenda is important for two reasons: first, it is the result of sustained evidence-based advocacy, highlighting the increasing share of neonatal mortality as a proportion of under-5 mortality; secondly, it galvanises global and national efforts towards that goal (3, 4). While previously neglected in the global agenda on maternal and newborn health, attention to the problem of stillbirths is increasing(5, 6). The Every Newborn action Plan commits countries to reducing stillbirth rate to 12 or less per 1000 births by 2030 (2), and stillbirths targets are included in the Global Strategy for Women, Children and Adolescent Health 2016 – 2030 (7), but not in the Sustainable Development Goals.

According to estimates developed by the UN Inter-agency Group for Child Mortality Estimation in 2020, about 6700 newborns died every day in 2019, or 2.4 million (90% uncertainty interval 2.3 – 2.7) a year globally (8). The newborn mortality rate was estimated at 17 deaths per 1,000 live births in 2019, pointing to the need to considerably accelerate progress on reducing it, if the SGD 3.2 target is to be met. Globally, the reduction in neonatal mortality has been slower than that for mortality for children aged 1 – 59 months. Neonatal disorders have remained the leading cause of DALYs loss over 1990-2019 for all age groups, albeit with a reducing proportion (9). Between 2000 – 2017, the global annual newborn mortality rate decreased by 51% (90% uncertainty interval 46-54), against a global annual under 5 mortality rate reduction of 58% (10). As a result, in 2019, newborn deaths represented 47% (45-49) of global deaths in children under 5, up from 40% (39-41) in 1990 (11). Projections by the

same study indicate that more than 60 countries are at risk of missing the neonatal mortality SDG target if they do not accelerate the annual rate of reduction, particularly in Sub-Saharan Africa and two in South Asia. Over 25 countries require an acceleration of at least 3 times the current levels of newborn mortality reduction, and for 10 countries, the acceleration required is 5 times higher. Without acceleration, it is estimated than 27.8 million neonates will die between 2018 and 2030, increasing the proportion of newborn deaths to 53% of all under-5 deaths (11).

According to estimates by WHO and the Maternal and Child Epidemiology Estimation group, the main causes of newborn deaths in 2017 are largely preventable conditions, including complications associated with prematurity (35%), intrapartum events, such as birth asphyxia (24%), and infections, such as sepsis and meningitis (14%) (10). The highest proportion of newborn deaths occur in the first hour after birth (37%)(12).

As for stillbirths, measurement of the global burdened has long been hampered by variability in definitions used at national level, and limited data availability in many low and middle income settings, particularly due to poor birth registration systems (13). For international comparison, WHO defines stillbirths as a baby born with no sign of life at 28 weeks or more of gestation (14), which corresponds to the International Classification of Disease 11 definition and adopts recommendations made by the Lancet Stillbirths series in 2016 (15). An estimated 2.6 million stillbirths occurred globally in 2015 (uncertainty range 2.4 – 3 million), of which 98% in low and middle-income countries (LMICs). About half of stillbirths, 1.3 million (uncertainty range 1.2 – 1.6 million) occurred during labour. With an annual reduction rate (ARR) of 2% between 2000 - 2015, the rate of decline of stillbirth rates since 2000 has been slower than that for maternal mortality (ARR 3%), neonatal mortality (ARR 3.1%), or post-neonatal mortality of under 5s (ARR 4.5%) over the same time period. At least 56 countries have to more than double their pace of stillbirth reduction in order to meet the international target. Sub-Saharan Africa and South Asia account for three-quarters of the global burden of stillbirths (15).

Contrary to prevalent myths, congenital anomalies are responsible for a median of only 7.4% of stillbirths, while an analysis of 38 maternal and fetal risk factors suggests that stillbirths are largely preventable. Key maternal risk factors include: maternal age above 35 years; maternal infections, specifically malaria in sub-Saharan Africa and syphilis in South Asia; and non-communicable diseases, such as obesity, pre-existing diabetes and hypertension. These risk factors often overlap in the same pregnancy (15).

1.1.2 The centrality of quality to prevent newborn mortality and stillbirths

A key strategy in the last two decades has been to increase utilization to skilled antenatal and delivery care (16). However, the Lancet Global Health Commission report on High Quality Health Systems reported that increasing access to skilled birth attendance does not necessarily equate to improved outcomes, pointing to differences in maternal and neonatal mortality rates across low- and middle-income countries (LMICs) with 80-90% skilled birth attendance coverage (17). A study in western Kenya reported that facility deliveries increased from 38% to 48% between 2009 and 2013, but there was no change in perinatal mortality during this period (18). Similar results were observed in an analysis of surveillance data of a cohort of over 100,000 pregnancies in central Ghana (19). A study in India testing the association between facility birth and neonatal mortality using data from the National Health Mission Survey 2015-16 in 8 Indian states found facility birth to be robustly associated with neonatal survival in 6 states, except in the two States (Uttar Pradesh and Bihar) together responsible for 43% of all Indian newborn deaths. The authors suggested this may have been due to gaps in the quality of care received by mothers in their contact with health facilities (20).

Over the last decade, landmark studies have highlighted the importance of improving quality of care to reduce maternal and newborn mortality (21-24) and stillbirths (5, 15, 25, 26). A study that compared case fatality rates in LMICs to those in best performing health systems estimated that approximately 1 million neonatal deaths each year could be averted by good quality health systems in LMICs, and of these, 50-60% are due to poor-quality care and the remainder due to underutilization (17). An analysis using the Lives Saved Tool in 81 countries that are the focus of Countdown to 2030, published in 2016, estimated that 520,000 stillbirths could have been averted by 2020 through adequate quality of care with current levels of use, and this may have been an underestimation, because quality was measured in terms of inputs and not processes of care (15, 27). Increasing coverage and quality of pre-conception, antenatal, intrapartum and post-natal interventions by 2025 could provide a triple return on investment, by preventing 71% of neonatal deaths, 33% of stillbirths, and 54% of maternal deaths per year (1, 15, 27, 28). This can also be thought of as a quadruple return of investment, as these interventions are also essential to enhance child development and build human capital (1, 15, 29-31).

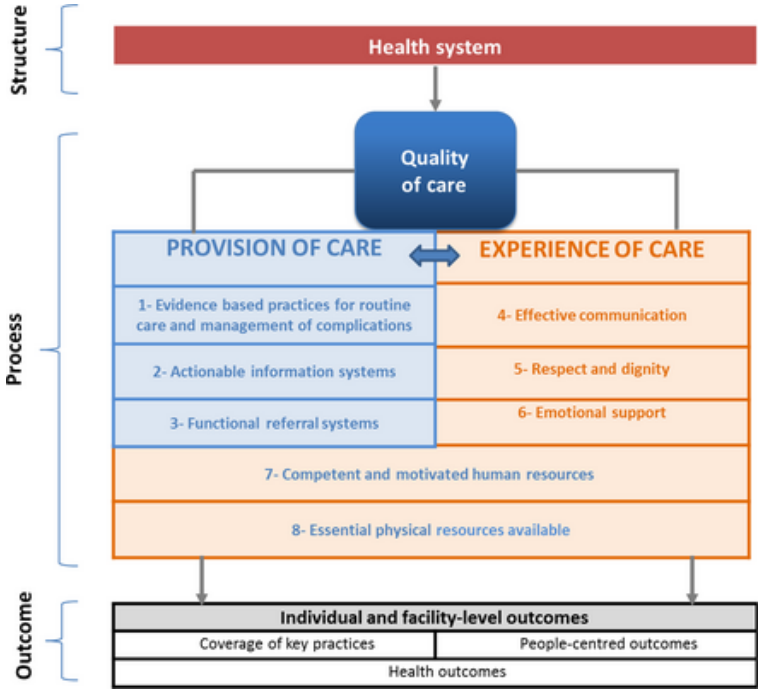
A health systems approach along the continuum of care should deliver routine and emergency care for all mothers and newborns at birth (32-35), and timely inpatient care for small and sick newborns (36), in addition to appropriate risk assessment and detection during ante-natal care and post-natal follow up. More specifically, stillbirths can be prevented through a comprehensive approach to quality intrapartum care and quality ante-natal care identifying and managing relevant risks (27, 37). The greatest effect on prevention of neonatal deaths is through high coverage and quality of interventions delivered during labour and birth, including for obstetric complications (41%) and care for small and sick newborns (30%) (27). Each of these packages require implementation of multiple evidence-based interventions (27, 38): for example, preterm infants, and those born small for gestational age, may require additional support to feed and maintain temperature, prevention and treatment of respiratory problems, jaundice and infection (39, 40). Access to an appropriate level of care in a timely fashion can prevent high mortality (35), as well as minimise the risk of developing future morbidities or disability (29, 39, 41). While inpatient care for small and sick newborn remains a major gap in service provision (36, 42), quality in maternal and newborn care suffers important quality gaps, and further research is needed on strategies to improve it (24, 38).

An assessment of the most recent Service Provision Assessment data available in nine LMICs, ranging from 2007 – 2015, reports that, on average, clinicians performed only about half of the required activities needed to make a correct diagnosis and provide appropriate management during antenatal, family planning and sick child visits (43). Studies in Uttar Pradesh, India also report that for a typical birth, health providers perform less than 40% of recommended practices for obstetric or newborn care (44, 45). Furthermore, providers do not seem to do more for sicker neonates—a basic failure of risk assessment and recognition of complications that is at the core of good quality care. In a review of 1200 under-5 deaths in Mali and Uganda, 84% of families were reported to have visited a health facility for the condition that led to death, but poor-quality care was demonstrated in at least half of these visits; this included failure of providers to identify danger signs, failure to provide essential treatment or to refer timely and in some cases provision of harmful treatment (46).

Improving quality of maternal and newborn care is a key priority of global maternal and child health strategies (2, 47, 48) and a key dimension of the universal health coverage agenda (49). Although there are multiple definitions (50-52), this research adopts World Health Organisation (WHO)'s definition of quality of care i.e. "*the extent to which health care service provided to individuals and patient populations improved desired health outcomes. In order to achieve this, health care needs to be safe, effective, timely, efficient, equitable and people-centred*"(22).

WHO's recent framework for understanding and improving quality of care (figure 1) (22) marries the Donabedian quality of care model at the provider level, with the rights-based definition from the client's perspective, and explicitly links the six health system building blocks with dimensions of the provision and experience of care (50, 52-54).

Figure 1-1: Quality of care for pregnant women and newborns—the WHO vision
Reproduced from Tuncalp et al. (22) [published Open Access under a CC-BY licence].



This framework also highlights the importance of improving care processes, as the improvement of inputs, such as better infrastructure or human resource allocation, on its own poorly correlates with health outcomes (55). Standards for improving quality of maternal and newborn care in health facilities were developed by the World Health Organization in 2016 (56) alongside updated clinical guidelines for maternal, newborn and child health and recommendations on respectful maternity care. Furthermore, the recent Standards for improving quality of care for small and sick newborns, published in 2020, help "*define, standardize and mainstream inpatient care of small and sick newborns, building on essential newborn care and ensuring consistency with the WHO quality of care framework*" (57). Meeting these standards implies that services deliver all the necessary practices and avoid unnecessary or harmful practices. The standards also imply that services are provided respectfully. Efforts are under way to develop global measures of effective coverage of reproductive, maternal, newborn, child health and nutrition, defined as the proportion of a population in need of a service that had a positive outcome from that service, which incorporate quality-adjusted coverage, or the proportion of a population in need of a service receiving a service according to a recommended standard, pointing to the need to improve health facility data (58, 59).

1.2 Quality improvement collaboratives in maternal and newborn health in LMICs

The WHO framework for quality of maternal and newborn care calls for the widespread adoption of continuous quality improvement, and in particular the Model for Improvement proposed by the Institute for Healthcare Improvement, which is at the heart of the quality improvement collaborative approach (22). Among the many strategies used to improve quality (60), quality improvement collaboratives (QICs), also known as learning collaboratives and collaborative improvement, have been used for several decades (61), including in maternal and newborn health. This approach will be described in detail later in this thesis. In short, the QIC approach entails team-based problem-solving, continuous cycles of goal setting, action and performance monitoring to improve adherence to evidence-based change packages, and lesson sharing with other teams (62).

The use of this approach has grown rapidly, despite the absence of rigorous evidence of its effectiveness. The most recent systematic review of effectiveness of QICs in LMICs, conducted by Garcia-Elorrio et al. in 2019, found large variations in the effectiveness of quality improvement collaboratives in low- and middle-income countries and that quality of studies was generally low (63). The next chapter will present a detailed literature review on QICs effectiveness and limitations of the evidence base.

While a large body of evidence demonstrates the growing use of the QIC approach in maternal and newborn health, this is mostly based on uncontrolled before and after studies, or interrupted time series analyses, and mostly uses self-reported outcomes (64-68). In order to illustrate the relevance of the QIC approach to the area of maternal and newborn care in LMICs, I will briefly outline findings from five selected studies with more rigorous designs. To select these, I identified all studies with a controlled design and which targeted maternal and newborn health outcomes in Garcia-Elorrio's systematic review. This consisted of 3 studies out of the 29 studies included in the review (69-71). I also conducted a non-systematic search in PubMed of studies using a QIC approach for maternal and newborn health in a LMIC setting and using a controlled design, published between 2019 and February 2021 (72-74). This yielded two additional studies. An overview of these five studies is provided in Table 1-1. In paragraph 1.2.1, I present each study individually, reporting on the key findings on primary outcomes and secondary outcomes relating to implementation of care practices at facility level, as well as key learnings from the related process evaluation, if available.

Table 1-1 – Overview of selected studies of quality improvement collaboratives focusing on maternal and newborn care outcomes in LMICs

Authors	Study title	Year published	Year conducted	Country	Study design	Identified through	Primary outcomes
Colbourn T. et al	MaiKhanda	2013	2007 – 2010	Malawi	Cluster randomised controlled study	Garcia-Elorrio's review	Maternal, perinatal and newborn mortality
Waiswa P. et al	Expanded Quality Management Using Information Power (EQUIP)	2017	2011 - 2014	Tanzania and Uganda	Quasi-experimental plausibility design	Garcia-Elorrio's review	Birth in health facilities; breastfeeding within 1 h after birth; oxytocin administration after birth; and knowledge of danger signs for mothers and babies.
Horwood C. et al	Effectiveness of an HIV-adapted IMCI Training and Supervision Programme for Community Health Workers	2017	2012 – 2014	South Africa	Cluster randomised controlled trial	Garcia-Elorrio's review	Care-seeking by mothers; frequency of visits by Community Health Workers; mothers' knowledge of maternal, newborn and child health; infant feeding practices.
Walker D. et al	East Africa Preterm Birth Initiative	2020	2016 - 2019	Uganda and Kenya	Cluster randomised controlled trial	Additional search	Fresh stillbirths and 28-day neonatal mortality
Borem P. et al	Parto Adequado Collaborative Project	2020	2015 – 2016	Brazil	Before and after study with comparison group	Additional search	Frequency of vaginal delivery

1.2.1 Five controlled studies using quality improvement collaboratives for maternal and newborn health in LMICs

1: The MaiKhanda Trial

The MaiKhanda study was a 2x2 factorial randomised controlled trial, comparing clusters comprising villages and health facilities in catchment areas of a comprehensive emergency obstetric care centre in 3 districts of Malawi. Clusters were randomly allocated to four study arms: a facility-based intervention based on the QIC approach (15 clusters); a community intervention with Participatory Learning and Action with women's groups (15 clusters); both the facility and community intervention (14 clusters); and no intervention (17 clusters) (69). Estimation of mortality used monthly community surveillance of all pregnant women and their infants until 2 months after delivery. Identified deaths were followed up by verbal autopsy.

The trial reported a newborn mortality reduction of 22% (OR = 0.78, 95% CI 0.60–1.01; p = 0.057) in the group receiving the combined facility and community intervention, which mostly comprised reductions in late newborn deaths at community level. No reduction was observed in maternal, perinatal or neonatal mortality in areas receiving only the facility quality improvement intervention. The study also reported no evidence of effect on clinical practices at facility level: for example, data on signal functions at health centres showed no changes over time in either the intervention or control health centres. The study reported major gaps in record keeping for clinical processes and that the implementation did not achieve the expected dose, due to staff shortages in health facilities and high workloads of available staff, which may explain the nil results. The process evaluation also suggested that collaborative mechanisms of change were not activated due to lack of a strong enough clinical network, and use of quality improvement methods was limited, possibly due to shortage of staff, limited competences, poor infrastructure, supply chain challenges and weak leadership (75).

2: The Expanded Quality Management Using Information Power (EQUIP) study

The Expanded Quality Management Using Information Power (EQUIP) study used a plausibility design to evaluate a quality improvement collaborative intervention at community, facility and district level in Uganda and Tanzania (70). The study compared changes over time in four primary outcomes (see Table 1-1) in one intervention district with those in a comparison district in each country. It used data from independent continuous household and health facility surveys from 2011 to 2014, and contextual data to interpret the analysis.

The intervention had a positive effect on the proportion of live births where mothers received uterotonics within 1 min after birth: the study reported an estimated difference-in-difference of 26 percentage points (95%CI 25-28) in Tanzania; and of 8 percentage points (95% CI 6–9) in Uganda. The other primary indicators showed no evidence of improvement. Secondary outcomes related to the implementation of care practices on topics selected by improvement teams. In Tanzania, positive changes for two locally identified improvement topics were observed: a 31 percentage points increase in preparation of clean birth kits for home deliveries (95% CI 2–60%) and 14 percentage point increase in health facility supervision by district staff (95% CI 0–28%). No change was observed in the other three selected topics in Tanzania, and in the four outcomes selected in Uganda.

The study suggests multiple reasons for the mixed results: the study was underpowered to detect small effects. There were challenges in implementing the QI intervention in both settings, due to limited data literacy and confidence in the use of data for decision making, long roll out timelines to engage the district and facility leadership, which meant that implementation at full strength may have been too short to produce an effect. This was a challenge particularly in Uganda, where the intervention was possibly diluted. The study and its related process evaluation highlight that there

were limitations in the types of decisions that could be made at the health facility level: systems bottlenecks such as shortage of staff, lack of clinical skills, equipment and drug stock outs constrained the type of changes that could be implemented. There may also have been a disconnect between focus care practices and the impact expectations as a result of a bottom up approach. On the other hand, health workers valued the problem-solving and mentoring approach, because they found a strong fit between the improvement topic and their own priorities. Finally, concurrent interventions aimed at improving quality of care in the same facilities, which may have diluted EQUIP's effect and made facility and district engagement harder (70, 76).

3: Trial on Effectiveness of an HIV-adapted IMCI Training and Supervision Programme for Community Health Workers

A cluster randomised controlled trial investigated the effect of a continuous quality improvement intervention among community health workers (CHWs) providing home education and support to pregnant women and mothers in a high HIV prevalence area in one district of KwaZulu-Natal, South Africa (71). The intervention group consisted of 15 randomly CHWs supervisors (out of a network of 32 supervisors) and 4 randomly selected CHWs per supervisor. These formed a quality improvement team, and received training in WHO Community Case Management and coaching on quality improvement for 12 months. Interviews were conducted with 736 and 606 eligible mothers supported by CHWs in the intervention and comparison group at baseline and follow-up 15 months later, respectively.

Mothers served by CHWs in the intervention group were more likely to have been visited by a CHW during pregnancy (76% vs 29%, $p < 0.0001$) and the postnatal period (73% vs 30%, $p < 0.0001$), and reported higher exclusive breastfeeding rates to 6 weeks (77% vs 65%, $p = 0.02$). Their maternal and child health knowledge scores were also reported to be higher than those of women supported by CHWs in the control group (49% vs 43%, $p = 0.02$), however this represented a very modest increase compared to baseline levels of 48% in both groups. There was no change in women's care seeking (attending a health clinic when needing to), the study reporting this was because health facility attendance was already high.

The study had important limitations: outcomes were self-reported and the study lacked a solid analysis of differences over time and details on clustering in relation to analysis. The approach was reported to be extremely resource intensive and hence unlikely to be scalable to the network of over 950 CHWs in the district, although it was highly acceptable among its participants. Furthermore, the study did not demonstrated that the quality improvement approach was superior to other forms of supervision to improve CHW performance.

4: The East Africa Preterm Birth Initiative

The East Africa Preterm Birth Initiative (PTBi-EA) implemented a cluster randomised controlled trial in eastern Uganda and western Kenya, to evaluate the effect of a quality improvement package for intrapartum and immediate newborn care on fresh stillbirths and 28-day neonatal mortality among preterm and low-birthweight babies (73). The study involved 20 out of 23 eligible facilities that provide 24-hour maternity care with at least 200 births per year. Eligible facilities were pair-matched and randomly assigned (1:1) into either the intervention group or the control group. All facilities received support to strengthen maternity register data and to use a modified WHO Safe Childbirth Checklist. Facilities in the intervention group additionally received provider mentoring using PRONTO simulation, which included basic emergency obstetrics and newborn care content, with a specific focus on complications of prematurity, as well as quality improvement collaboratives. Quality teams focused on improving three key practices: gestational age assessment, kangaroo mother care and ante-natal

corticosteroids administration. Analysis included liveborn or fresh stillborn babies who weighed between 1000 g and 2500 g, or less than 3000 g with a recorded gestational age of less than 37 weeks, and data were abstracted from maternity registers. Eligible births represented approximately 9% of all registered births. Follow-up was done by phone or in person to identify the status of the infant at 28 days.

The intervention had a large effect on prevention of fresh stillbirths and neonatal mortality among low birthweight and preterm babies: after accounting for matching and clustering, the intervention was associated with lower odds (OR 0·66, 95% CI 0·54–0·81) of fresh stillbirth or neonatal death (combined) among eligible births than the control; lower odds of fresh stillbirth (OR 0·69, 95% CI 0·57–0·83) and neonatal mortality (OR 0·72, 95% CI 0·58–0·90) in the intervention than in the control group. The intervention was also associated with lower odds of perinatal mortality (OR 0·67, 95% CI 0·56–0·81) and pre-discharge mortality (OR 0·57, 95% CI 0·48–0·68) in the intervention group compared to the control, and did not affect the proportion of women receiving caesarean section. Authors attributed the success of the intervention to the synergistic approach relying on a locally relevant package of strategies that targeted provider skills, knowledge and experience, combined with a problem-solving mechanism to tackle local bottlenecks for provision of essential care.

5. Parto Adequado Collaborative Project

In Brazil, Borem et al. evaluated the effect of a 20-month quality improvement collaborative intervention to increase the frequency of vaginal deliveries in a study of 28 hospitals (72). The collaborative worked on four innovations to increase vaginal delivery: 1) coalition building of stakeholders to promote "appropriate delivery"; 2) supporting pregnant women to choose their preferred mode of delivery; 3) implementation of care models favouring physiologic birth, and 4) improved information systems for continuous learning by health care providers. The comparison group consisted of eight hospitals in São Paulo that were similar to the five São Paulo hospitals included in the intervention group with respect to size, population characteristics, resources, insurance coverage, and health care provider mix. Data for intervention hospitals were collected based on monthly reports from hospitals and analysed using statistical process control. Data on vaginal delivery rates for the 8 hospitals in the comparison group was sourced from the Ministry of Health, however it was not granular enough to allow risk-stratification, so difference-in-difference analysis is only available for overall vaginal delivery rates, not specific to low risk deliveries.

Analysis was performed only on 13 hospitals in the intervention group that provided data for the entire baseline and intervention collection period, referred to as the intensive group. In this group, the study recorded a relative increase of 1.6 (95% CI 1.3–2 P<.001) in vaginal deliveries in target populations, from an average of 21% (95% CI 16% – 29%) in 2014 to 35% (95% CI 29% – 42%) in 2016. The difference-in-difference analysis comparing the 5 São Paolo hospitals in the intensive group with the 8 comparison groups suggested a relative rate increase of about 21% in vaginal births in the intensive intervention group (relative increase of 1.21, 1.05–1.41, P=0.01), representing an increase in overall vaginal delivery from 16% to 23% in the intervention group, compared with 11% to 13% in the comparison group.

This study has major limitations, including selection bias, as the 28 intervention hospitals were selected by implementers among 40 eligible facilities and of these, only 13 hospitals with complete datasets were included in the analysis. The comparison involved a very small sample of the participating hospitals (5 out of 28) and intervention hospitals having higher levels of vaginal deliveries at baseline. Furthermore, outcomes were self-reported by participating hospitals.

1.2.2 Brief synthesis of the evidence

Primary outcomes were mostly one or a few of the evidence-based practices for maternal and newborn health, with the exception of the MaiKhanda and the PTBi-EA trial which aimed to measure impact on newborn and maternal mortality (69, 73). QICs have been used both at health facility level and at community level, often in combination. Facility-based implementation of the collaborative quality improvement approach in maternal and newborn health has been mainly at primary health care level, including community health posts, district health centre or hospitals, although recent studies in East Africa and Brazil have involved hospitals (72, 73). Focus practices were mostly improving access to early and regular antenatal care, increasing institutional or skilled delivery rates, adherence to intrapartum and newborn care evidence-based care practices (partograph use, oxytocin administration protocol, active management of the third Stage of Labour, management of complications of pregnancies, or essential newborn care, management of complications of prematurity), or provision of education to pregnant women and mothers. While programmes rely heavily on the external support of academic partners, non-governmental organisations or consultancy companies, implementation suggests growing alignment with national health systems, for example by aligning with national data collection systems (67, 73), supporting local supervision structures (64, 66, 70), aligning with standard protocols or care packages (71, 73), where available. Finally, the most recent studies include the QIC approach in combination with other interventions, such as clinical training, leadership engagement, community mobilisation and other behaviour change strategies (64, 72, 73)[2], in line with the systematic review finding that QIC as a problem solving strategy may be more effective when accompanied by training (63).

Ambition for scale has grown, with recent experiences, such as those in Ghana (67, 77), Ethiopia (64) and Brazil (72), designed to rapidly achieve scale. It is important to note that the QIC approach is widely used by policy makers and implementers in programmes without formal evaluations, as illustrated by case studies collected by the Quality of Care Network coordinated by the World Health Organisation (http://qualityofcarenetwork.org/). Also, it is important to highlight that quality improvement methods are widely used in maternal and newborn health without the collaborative component as a problem-solving approach. For example, the highly influential Better Birth trial used quality-focused coaching to support implementation of the Safe Childbirth Checklist (45, 78, 79), and in a study in Nepal, used QI methods alongside training and leadership support (74).

1.3 Newborn mortality and the national response in India

With 522,000 annual newborn deaths in 2019 and a newborn mortality rate of 22 deaths per 1,000 births, India had the highest absolute number of newborn deaths globally in 2019 (8), representing 22% of the global burden (80). The contribution of neonatal deaths to under 5 mortality in India has increased from 41% in 1990 to 62% in 2019 (8). However, India has achieved sustained progress in reducing newborn deaths over the last decades: the annual reduction in NMR was 3.8% between 2000-18, higher than the global average ARR of 3.1%(11). Important inter-state differences remain (81, 82), as well as a marked urban-rural divide (83, 84). The major causes of newborn deaths in India are prematurity (44%); intra-partum related events (19%); sepsis (13%); and congenital malformations (11%). While these mostly mirror the leading causes of newborn deaths globally, deaths from complications of prematurity are higher in India than globally (80). In line with global trends, 40% of

[2] The ALERT study is also a relevant new study launched in 2020 using QIC as part of a wider quality improvement intervention. https://ki.se/en/gph/the-alert-intervention-research-project

neonatal deaths in India occur in the first 48 hours, and over three quarters in the first week of life, making improvements in facility-based newborn care an urgent priority (23).

With regard to stillbirths, India also had the highest burden of stillbirths globally in 2015 (15). However, India was also the first country to include a target to reduce stillbirths to less than 10 per live births by 2030 in its national Newborn Action Plan (83, 85), which is an important marker of the commitment to quality of care (15). In the last decade, the Indian government has invested heavily in demand-side programmes and community-based strategies, which have resulted in improvements in institutional deliveries and skilled birth attendance. The Janani Suraksha Yojana (JSY) cash transfer scheme was set up in 2005 to encourage women to deliver in health facilities (86-88)and, since 2011, the Janani Shishu Suraksha Karyakram (JSSK) scheme has provided free treatment, food and transport to access maternal care and sick newborn care services (89, 90). Partly due to these investments, women's access to health facilities for maternity services has improved dramatically: the National Family Health Survey (NFHS) 4 in 2015-16 estimated an institutional delivery rate of 79% nationwide, compared to only 15% in 1990-92 (NHFS-1). While urban-rural disparities remain, the change in rural areas has been particularly marked, with an increase from 29% and 68% in 2005–06 to 75% and 89% in 2015–16 in rural and urban areas respectively (91). However, this change has not translated in similar improvements in newborn mortality, and several studies have exposed a quality gap in care provision in Indian health facilities (92-97).

In line with global evidence on the importance of prioritising essential newborn care and care for small and newborns, India has intensified its investment in facility-based newborn care since 2014, driven by India Newborn Action Plan (83). Under the Facility-based Newborn Care, India has established Newborn Care Corners at all points of childbirth, providing essential newborn care at birth, including basic resuscitation and identification and referral of at risk and sick newborns. Three other levels of care for small and sick newborns have been established:

- Level I Newborn Stabilization Units at the level of health centres, providing management of newborns weighing 1800g to 2000g with no other complication, phototherapy for newborns with jaundice, management of newborn sepsis, stabilization and referral of sick newborns and those with very low birth weight
- Level II Special Newborn Care Units (SNCUs) at district and sub-district hospitals with an annual delivery load higher than 3000 births, providing care for very low birth weight infants, management of all sick newborns or those with complications from delivery, except assisted ventilation and major surgical interventions.
- Level III in Neonatal Intensive Care Units including assisted ventilation and surgery (83, 98, 99)

I will focus on level II SNCUs in this background, as these represent the key context of my study, as described in the next paragraph. The scale up of SNCUs has been very rapid. In 2014, over 14,000 Newborn Care Corners were reported to have been established at delivery points, as well as over 1,800 Newborn Stabilization Units and around 550 SNCUs (83), compared to only 18 in the first multi-state pilot in 2008-2010 (100). By 2019, SNCUs had been scaled up to 844, achieving a coverage of 82% of districts nationwide, with remaining gaps in the country North-East and Telangana state. This had been achieved through a sustained Government of India investment of nearly $500m since 2011, with nearly $100m in 2019 alone (100) at a cost of $111 per neonate admitted for the year 2010 (101). Annual admissions in SNCU have grown from 247,576 in 2014 to 1,165,020 in 2019, a number that

experts in 2020 expected to grow to an estimated 1.5m in 2022, as referral systems are strengthened (100)[3].

Several innovative strategies have been employed to deliver scale as well as quality. These include: standardisation of design and equipment; centralisation of equipment maintenance function across 3-4 districts; establishment of human resource standards; innovation in human resource policies, including decentralisation of recruitment, employment of contractual staff with attractive remuneration and benefit packages to incentivise working in remote areas, exemption of SNCU staff from rotations to promote specialisation and retainment of competences; tracking of bed-occupancy and human resource distribution, among other quality indicators, and development of a standardised online monitoring system which allows tracking of over 250 parameters, and has so far been rolled out to 100 private sector facilities as well (100), a number that is expected to increase.

However, key challenges remain, which underscore the need to focus on quality, in terms of inputs, practices, as well as linkages between SNCUs and the broader newborn care system. A review of the feasibility of setting up functional SNCUs in eight rural districts found major challenges related to admission overload, human resource recruitment and retention, maintenance of equipment and asepsis (102). A recent assessment conducted by UNICEF and based on monthly SNCU data suggests three broad priorities for improvement of newborn outcomes: first, optimising admissions by improving referral systems; second. Improving care practices; and, third, strengthening community linkages. In relation to the former, although kangaroo mother care rooms have recently been included in SNCUs to release pressure on SNCU beds and care for newborns on site as soon as they are stabilised, bed occupancy remains very high. In the first 6 months of 2019, 14 out of 27 reporting states reporting data for reported an average bed occupancy rate of 90% of higher, including the state of Andhra Pradesh with a bed occupancy of 104% and peak average state bed occupancy of 142% in Karnataka (100). Mortality in babies referred from another health facility between January 2017 and February 2020 was 1.8 times higher (13%) than mortality among babies born in the hospital where the SNCU is located (8%). Second, specific practices require improvement: case fatality rates for newborns with respiratory distress syndrome are very high, with SNCU data from January 2019 to February 2020 reporting 17% mortality in admissions due to respiratory distress syndrome compared to 8.8% mortality in total admissions, pointing to the need to further invest in continuous positive airway pressure (CPAP) therapy. Appropriate use of antibiotics is another major quality priority (100). Third: strengthening linkages with community care is necessary to enable optimal follow up to newborns. According to the same assessment, 1 in 4 newborns discharged by SNCUs in the last 3 years were below 2000g, requiring ongoing follow up for feeding, prevention of hypothermia, hygiene and support for optimal development in the community. SNCU have standard protocols for follow up care in the community, with an m-health system of notification to community facilities and health workers of a newborn discharge in some states, so that follow-up care can be provided in the community. This includes a weekly visit for the first 6 weeks in the community, followed by regular follow ups at the SNCU in the first year. However, these linkages need strengthening, the vision being that SNCUs will act as a specialist hub for newborn care with links with lower levels of the health system. For example, a retrospective cohort study of newborns discharged from SNCUs in 13 districts across four states of India found that mortality among babies discharged from SNCUs up to 6 weeks of follow up was 1.5%, and 2.2% in low birth weight babies, underscoring the importance of community follow-up. However, in this study, only 43% were reported to have been provided home visits at three time points as recommended (103), and this percentage was reported to be lower (26%) in the external evaluation

[3] This estimate was presented pre-COVID 19.

of the SNCU+ Programme, involving follow up in the community after SNCU admission, cited by the study (103).

In this context, moving towards institutionalisation of continuous quality improvement is essential (104, 105), as in-service training alone is likely to yield only limited returns (83, 106, 107). Programmes to improve quality of childbirth and newborn care are proliferating (45, 108, 109), including through the use of quality improvement methods (95, 105, 110, 111). A quality improvement collaborative network is also emerging, in collaboration with the National Neonatologist Federation (110, 112-114), addressing several relevant topics, such as care of pre-term babies(115), kangaroo mother care (116), breastfeeding (117) and emergency management of sick neonates (118).

1.4 An overview of Safe Care Saving Lives programme and evaluation

The Safe Care Saving Lives (SCSL) was a quality improvement collaborative programme implemented by ACCESS Health International (ACCESS), and funded by the Children's Investment Fund Foundation. The programme, designed in 2013-4 and implemented between 2015-18, aimed to reduce newborn mortality by 15% in neonatal care units in the two Indian states of Andhra Pradesh and Telangana, by improving intrapartum and newborn care in labour rooms and newborn care units of 86 hospitals that were part of state insurance schemes covering care for severely sick newborns (119).

The programme, described in detail in Chapter 4, targeted adherence to a package of 20 evidence-based newborn care practices, which are internationally recommended but not sufficiently implemented in most Indian hospitals. These evidence-based practices focused on birth asphyxia, complications of prematurity and newborn sepsis through interventions during the intrapartum and the early postnatal newborn care period in labour rooms and special newborn care units.

The programme adopted the Institute for Healthcare Improvement Breakthrough Collaborative approach (120, 121). This approach uses IHI's Model for Improvement, which hinges on a cycle of setting an aim for improvement; agreeing progress measures; identifying a suitable process; and using cycles of testing and refinement through continuous collection and review of data, to measure progress towards the desired aim, in cycles known as Plan-Do-Study-Act. ACCESS facilitated the formation of quality improvement (QI) teams in labour rooms and newborn care units and mentored them to (1) identify priority care practices through a gap analysis and innovative change ideas; to (2) study their effect on desired outcomes using facility data, and regular audits; and (3) to adapt such change ideas based on this evidence. In addition to mentoring, ACCESS also offered so-called "learning sessions", where teams from participating hospitals are oriented on quality improvement approaches, share experience and learn from each.

LSHTM was commissioned to undertake an external evaluation of the Safe Care Saving Lives programme, in partnership with the Public Health Foundation of India (PHFI), with three objectives:

1. To analyse the effect of the programme on key care practices, morbidity and neonatal mortality in delivery wards and among neonatal intensive care unit admissions.
2. To understand mechanisms of change of the intervention and their relationship to contextual factors.
3. To analyse the feasibility of using a government-sponsored health insurance network to drive quality improvement in network facilities

Chapter 3 describes the evaluation, study design and methods in detail. It is important to flag here that the second objective of the evaluation initially include a cost-effectiveness analysis of the

programme. This was renegotiated in February 2018 in consultation with the donor, and replaced instead with the in-depth process evaluation stemming from this PhD study.

1.5 Rationale of the PHD, research questions and objectives

This PhD aims to analyse the contribution of quality improvement collaboratives to addressing the challenge of improving newborn care quality at scale, through a mixed-method evaluation of the Safe Care Saving Lives programme.

There are two key research questions:

1. To what extent, how and under what circumstances did Safe Care Saving Lives improve adherence with evidence-based newborn care practices and reduce stillbirths and newborn mortality?
2. To what extent was the quality improvement collaborative approach operationalised by the Safe Care Saving Lives programme scalable?

As quality is a key priority for newborn care, there is a need for rigorous evaluation of strategies to improve quality. The quality improvement collaborative approach holds promise and has growing application in LMICs. However, there have been very few rigorous impact evaluations of this approach to date in LMICs, there is a dearth of literature on the study of processes of quality improvement, and limited understanding of the role of contextual factors in relation to quality improvement. Furthermore, there has been no systematic analysis of the potential for scale up of this approach, despite the growing experiences of implementation.

This PhD offers a rigorous impact and process evaluation which adds to the body of evidence on what works for newborn care quality improvement, and contributes to the development of future quality improvement programmes in three important ways. First, understanding what happens during implementation of a QIC intervention, and how changes in quality of newborn care are generated (research question 1) is essential to explain impact and to highlight which elements of the QI approach can be transferred or require adaptation (122-124). This can prevent scale-up through "*cargo cult quality improvement*", i.e. implementation of QI interventions by reproducing only their "*superficial outer appearance, rather than the mechanism (or set of mechanisms) that produced an outcome in the first instance*"(125), p.9. Second, understanding the role of context to activate intended mechanisms of change can help determine what additional investments may be necessary prior to deploying the quality improvement methodology, or concurrently in order to produce the expected results. Third, the PhD situates the QIC initiative in its health system and offers a systematic framework to evaluate its potential for scale up (research question 2) through a state-level health insurance platform. This contributes critical insights on the opportunities and challenges of linking quality improvement to strategic purchasing and the broader policy direction for quality in Telangana.

The overall aim is achieved through four objectives:

Objective 1: to develop a programme theory of change and, through this, describe the intervention

Objective 2: to evaluate the intervention effects on the implementation of essential evidence-based maternal and newborn care practices, on the stillbirth rate and neonatal mortality rate in labour wards and neonatal care units

Objective 3: to evaluate implementation, including challenges and adaptations to the context, and explore the mechanisms of change of the intervention.

Objective 4: to develop a framework to analyse "scalability" and analyse the feasibility of scaling up the QIC approach through the state-level health insurance scheme in Telangana.

1.6 Structure of the thesis

This thesis follows the book style, although some of the chapters have been published as articles in peer-reviewed journals. These include two papers that I have led as first author, both published in Implementation Science, which are included in the thesis in their entirety, and three papers I have contributed to as part of the LSHTM evaluation team (published in PLOS Med and Global Health Action) or through a separate project I have been involved with in my final study year (published as a methodological musing in Health Policy and Planning). I have adapted the material from the papers that I did not lead to fit in the thesis book style. One of the chapters is presented as a draft manuscript, prepared for publication.

The thesis is divided into 3 sections, outlined here and summarised in Table 1-2.

Section I comprises three chapters. The present chapter has provided a background to the PhD work and outlined the aims and objectives of the thesis. *Chapter 2* offers a systematic review on how and under what circumstances QICs can lead to better outcomes, which represents a critical review on the effectiveness of QIC and provides the evidence base on which to build the programme theory of change. This Chapter is the first of the two published papers included in this thesis in their entirety. *Chapter 3* describes the study setting and study design, including my role in the LSHTM evaluation research team. This chapter is based on two published papers (the evaluation protocol paper and a paper presenting findings from the evaluation baseline study) which I contributed to as second author.

Section II covers the results of this PhD work. *Chapter 4* addresses ***objective 1*** (to develop a programme theory of change and, through this, describe the intervention): it describes the intervention in detail and its theory of change, which is published as an annex to the protocol paper. Chapter 5 addresses ***objective 2 and objective 3*** (to evaluate impact and outcomes, and conduct the process evaluation) and presents findings of the mixed methods evaluation of the Safe Care Saving Lives programme. This chapter consists of the second published paper included in its entirety in this thesis. Together, Chapter 4 and 5 address ***research question 1***. *Chapter 6* addresses ***objective 4*** (to develop a framework to analyse "scalability" and analyse the feasibility of scaling up the QIC approach through the state-level health insurance scheme in Telangana) and responds to ***research question 2***: it presents a framework to evaluate scalability, adapting material I have published as first author in Health Policy and Planning, and presents the results of the analysis of the feasibility of scaling up the QIC approach used in Safe Care Saving Lives through the state-level health insurance scheme. This Chapter is presented in draft manuscript form.

Section III concludes this thesis and comprises two chapters. *Chapter 7* summarises the key findings, and critically discusses implications of these in relation to the challenge of improving quality of newborn care at scale. Chapter 8 provides an overall summary of the work including recommendations for policy, practice and research.

Table 1-2 – Overview of thesis structure, PhD objectives, research questions and related authored papers

Section and Chapter	PhD Objective	Research question	Authored papers contributing to the chapter
Section I – Chapter 1	Background	-	
Section I – Chapter 2	Literature review	-	**Zamboni, K.,** Baker, U., Tyagi, M. *et al*. (2020) How and under what circumstances do quality improvement collaboratives lead to better outcomes? A systematic review. *Implementation Sci* **15**, 27
Section I – Chapter 3	Study setting and methods	-	Hanson C, **Zamboni K**, Prabhakar V. *et al.* (2019) Evaluation of the Safe Care, Saving Lives (SCSL) quality improvement collaborative for neonatal health in Telangana and Andhra Pradesh, India: a study protocol. *Glob Health Action* **12**(1):1581466. Hanson C[#], Singh S[#], **Zamboni K**, Tyagi M, Chamarty S, Shukla R., et al. (2019) Care practices and neonatal survival in 52 neonatal intensive care units in Telangana and Andhra Pradesh, India: A cross-sectional study. *PLoS Med* **16**(7) [#] : joint first authors
Section II – Chapter 4	**Objective 1**: to develop a programme theory of change and, through this, describe the intervention	**Research question 1**: To what extent, how and under what circumstances did Safe Care Saving Lives improve adherence with evidence-based newborn care practices and reduce stillbirths and newborn mortality?	Webannex B – Safe Care Saving Lives implementation, in Hanson C, **Zamboni K**, Prabhakar V. *et al.* (2019) Evaluation of the Safe Care, Saving Lives (SCSL) quality improvement collaborative for neonatal health in Telangana and Andhra Pradesh, India: a study protocol. *Glob Health Action* **12**(1):1581466.
Section II – Chapter 5	**Objective 2**: to evaluate the intervention effects on the implementation of essential evidence-based maternal and newborn care practices, on the stillbirth rate and neonatal mortality rate in labour wards and neonatal care units		**Zamboni, K**., Singh, S., Tyagi, M. *et al*. (2021) Effect of collaborative quality improvement on stillbirths, neonatal mortality and newborn care practices in hospitals of Telangana and Andhra Pradesh, India: evidence from a quasi-experimental mixed-methods study. Implementation Sci 16, 4

	Objective 3: to evaluate implementation, including challenges and adaptations to the context, and explore the mechanisms of change of the intervention.		
Section II – Chapter 6	**Objective 4**: to develop a framework to analyse "scalability" and analyse the feasibility of scaling up the QIC approach through the state-level health insurance scheme in Telangana.	**Research question 2**: To what extent was the QIC approach operationalised by the Safe Care Saving Lives programme scalable?	**Zamboni K.,** Schellenberg J., Hanson C., Betran AP, Dumont A. Assessing scalability of an intervention: why, how and who?, *Health Policy and Planning*, 34:7, September 2019, Pages 544–552 **Zamboni K.,** Hanson C., Singh S., Shukla R., Schellenberg J. Leveraging health insurance for quality improvement: lessons on scale-up from a newborn care quality improvement programme in Telangana, India. [Manuscript, unpublished]
Section III – Chapter 7	Discussion	**PhD aim**: to analyse the contribution of quality improvement collaboratives to addressing the challenge of improving newborn care quality at scale, through a mixed-method evaluation of the Safe Care Saving Lives programme.	-
Section III – Chapter 8	Conclusion		-

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Chapter 2

Paper A – How and under what circumstances do quality improvement collaboratives lead to better outcomes? A systematic review

This chapter presents a critical review on the effectiveness of quality improvement collaboratives and contributes to the understanding of the contextual conditions for success and mechanisms of change of this intervention. It also provides the evidence basis on which the programme theory of change was developed in our study. This chapter was published on 4th May 2020 in Implementation Science 15, 27. The manuscript was published under Creative Commons License, (CC BY 4.0) and is included in full below. The Additional Files referenced in the paper are available at: https://implementationscience.biomedcentral.com/articles/10.1186/s13012-020-0978-z

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2-3 Citation

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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I led the conceptualisation of the paper, with input by Dr. Claudia Hanson, Prof. Joanna Schellenberg and Dr. Zelee Hill on the conceptual framework. I designed the search strategy and conducted the searches. I led data quality assessment, developing the tools for quality appraisal of papers and supervising Ms Mukta Tyagi, Research Assistant, to conduct quality appraisal. I developed data analysis tools and undertook data analysis, coordinating analysis of a sample of papers by Dr Ulrika Baker. I wrote the first draft of the manuscript and prepared the subsequent revisions with consideration of comments from co-authors.

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Implementation Science

SYSTEMATIC REVIEW Open Access

How and under what circumstances do quality improvement collaboratives lead to better outcomes? A systematic review

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Abstract

Background: Quality improvement collaboratives are widely used to improve health care in both high-income and low and middle-income settings. Teams from multiple health facilities share learning on a given topic and apply a structured cycle of change testing. Previous systematic reviews reported positive effects on target outcomes, but the role of context and mechanism of change is underexplored. This realist-inspired systematic review aims to analyse contextual factors influencing intended outcomes and to identify how quality improvement collaboratives may result in improved adherence to evidence-based practices.

Methods: We built an initial conceptual framework to drive our enquiry, focusing on three context domains: health facility setting; project-specific factors; wider organisational and external factors; and two further domains pertaining to mechanisms: intra-organisational and inter-organisational changes. We systematically searched five databases and grey literature for publications relating to quality improvement collaboratives in a healthcare setting and containing data on context or mechanisms. We analysed and reported findings thematically and refined the programme theory.

Results: We screened 962 abstracts of which 88 met the inclusion criteria, and we retained 32 for analysis. Adequacy and appropriateness of external support, functionality of quality improvement teams, leadership characteristics and alignment with national systems and priorities may influence outcomes of quality improvement collaboratives, but the strength and quality of the evidence is weak. Participation in quality improvement collaborative activities may improve health professionals' knowledge, problem-solving skills and attitude; teamwork; shared leadership and habits for improvement. Interaction across quality improvement teams may generate normative pressure and opportunities for capacity building and peer recognition.

Conclusion: Our review offers a novel programme theory to unpack the complexity of quality improvement collaboratives by exploring the relationship between context, mechanisms and outcomes. There remains a need for greater use of behaviour change and organisational psychology theory to improve design, adaptation and evaluation of the collaborative quality improvement approach and to test its effectiveness. Further research is needed to determine whether certain contextual factors related to capacity should be a precondition to the quality improvement collaborative approach and to test the emerging programme theory using rigorous research designs.

Keywords: Quality improvement, Evaluation, Realist synthesis, Context, Mechanism of change

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Contribution to the literature

- Quality improvement collaboratives are a widely used approach. However, solid evidence of their effectiveness is limited and research suggests that achievement of results is highly contextual.
- Previous research on the role of context in quality improvement collaboratives has not explored the dynamic relationship between context, mechanisms and outcomes. We systematically explore these through a review of peer-reviewed and grey literature.
- Understanding contextual factors influencing intended quality improvement collaborative outcomes and the mechanisms of change can aid implementation design and evaluation. This systematic review offers a novel programme theory to unpack the complexity of quality improvement

Background

Improving quality of care is essential to achieve Universal Health Coverage [1]. One strategy for quality improve- ment is quality improvement collaboratives (QIC) defined by the Breakthrough Collaborative approach [2]. This en- tails teams from multiple health facilities working together to improve performance on a given topic supported by ex- perts who share evidence on best practices. Over a short period, usually 9–18 months, quality improvement coa- ches support teams to use rapid cycle tests of change to achieve a given improvement aim. Teams also attend "learning sessions" to share improvement ideas, experi- ence and data on performance [2–4]. Collaboration between teams is assumed to shorten the time required for teams to diagnose a problem and identify a solution and to provide an external stimulus for innovation [2, 3].

QICs are widely used in high-income countries and proliferating in low- and middle-income countries (LMICs), although solid evidence of their effectiveness is limited [5–11]. A systematic review on the effects of QICs, largely focused on high-income settings, found that three quarters of studies reported improvement in at least half of the primary outcomes [7]. A previous review suggested that evidence on QICs effectiveness is positive but highly con- textual [5], and a review of the effects of QICs in LMICs re- ported a positive and sustained effect on most indicators [12]. However, there are important limitations. First, with one exception [11], systematic reviews define QIC effective- ness on the basis of statistically significant improvement in at least one, or at least half of "primary" outcomes [7, 12] neglecting the heterogeneity of outcomes and the magni- tude of change. Second, studies included in the reviews are weak, most commonly before-after designs, while most randomised studies give insufficient detail of randomisation and concealment procedures [7], thus potentially overesti- mating the effects [13]. Third, most studies use self- reported clinical data, introducing reporting bias [8–10]. Fourth, studies generally draw conclusions based on facil- ities that completed the programme, introducing selection bias. Recent well-designed studies support a cautious as- sessment of QIC effectiveness: a stepped wedge randomised controlled trial of a QIC intervention aimed at reducing mortality after abdominal surgery in the UK found no evi- dence of a benefit on survival [14]. The most robust sys- tematic review of QICs to date reports little effect on patient health outcomes (median effect size (MES) less than 2 percentage points), large variability in effect sizes for dif- ferent types of outcomes, and a much larger effect if QICs are combined with training (MES 111.6 percentage points for patient health outcomes; and MES of 52.4 to 63.4 per- centage points for health worker practice outcomes) [11]. A review of group problem-solving including QIC strategies to improve healthcare provider performance in LMICs, although mainly based on low-quality studies, suggested that these may be more effective in moderate-resource than in low-resource settings and their effect smaller with higher baseline performance levels [6].

Critiques of quality improvement suggest that the mixed results can be partly explained by a tendency to reproduce QIC activities without attempting to modify the functioning, interactions or culture in a clinical team, thus overlooking the mechanisms of change [15]. QIC implementation reports generally do not discuss how changes were achieved, and lack explicit assump- tions on what contextual factors would enable them; the primary rationale for using a QIC often being that it has been used successfully elsewhere [7] . In view of the glo- bal interest in QICs, better understanding of the influ- ence of context and of mechanisms of change is needed to conceptualise and improve QIC design and evaluation [6, 7]. In relation to context, a previous systematic re- view explored determinants of QIC success, reporting whether an association was found between any single contextual factor and any effect parameter. The evidence was inconclusive, and the review lacked an explanatory framework on the role of context for QIC success [16]. Mechanisms have been documented in single case stud- ies [17] but not systematically reviewed.

In this review, we aim to analyse contextual factors in- fluencing intended outcomes and to identify how quality improvement collaboratives may result in improved ad- herence to evidence-based practices, i.e. the mechanisms of change.

Methods

This review is inspired by the realist review approach, which enables researchers to explore how, why and in

what contexts complex interventions may work (or not) by focusing on the relationships between context, mech- anisms and outcomes [18–20]. The realist review process consists of 5 methodological steps (Fig. 1). We broadly follow this methodological guidance with some important points of departure from it. We had limited expert engagement in developing our theory of change, and our preliminary conceptual framework was con- ceived as a programme theory [21] rather than as a set of context-mechanism-outcomes configurations (step 1) [22]. We followed a systematic search strategy driven by the intervention definition with few iterative searches [19], and we included a quality appraisal of the literature because the body of evidence on our questions is gener- ally limited by self-reporting of outcomes, selection and publication bias [7, 9, 15].

Clarifying scope of the review

We built an initial conceptual framework to drive our enquiry (Fig. 2) in the form of a preliminary programme theory [21, 23]. We adapted the Medical Research Coun- cil process evaluation framework [24] using findings from previous studies [8, 16, 25, 26] to conceptualise relationships between contextual factors, mechanisms of change and outcomes. We defined context as "factors external to the intervention which may influence its im- plementation" [24].We drew from Kaplan's framework to understand context for quality improvement (MUSIQ), which is widely used in high-income countries, and shows promise for LMIC settings [27, 28]. We identified three domains for analysis: the healthcare setting in which a quality improvement intervention is introduced; the project-specific context, e.g. characteristics of quality im- provement teams, leadership in the implementing unit, nature of external support; and the wider organisational context and external environment [29]. We defined mechanisms of change as the "underlying entities, processes, or structures which operate in particular contexts to generate outcomes of interest" [30]. Our definition implies that mechanisms are distinct from, but linked to, intervention activities: intervention ac- tivities are a *resource* offered by the programme to which participants respond through cognitive, emotional or or- ganisational processes, influenced by contextual factors [31]. We conceptualised the collaborative approach as a structured *intervention* or *resource* to embed innovative practices into healthcare organisations and accelerate dif- fusion of innovations based on seminal publications on QICs [2, 3]. Strategies described in relation to implemen- tation of a change, e.g. "making a change the normal way" that an activity is done [3], implicitly relate to normalisa- tion process theory [17, 32] . Spreading improvement is explicitly inspired by the diffusion of innovation theory, attributing to early adopters the role of assessing and adapting innovations to facilitate their spread, and the role of champions for innovation, exercising positive peer pressure in the collaborative [3, 17, 33]. Therefore, we identified two domains for analysis of mechanisms of change: we postulated that QIC outcomes may be gener- ated by mechanisms activated within each organisation (intra-organisational mechanisms) and through their collaboration (inter-organisational mechanisms). When we refer to QIC outcomes, we refer to measures which an intervention aimed to influence, including measures of clinical processes, perceptions of care, patient recovery, or other quality measures, e.g. self-reported patient safety climate.

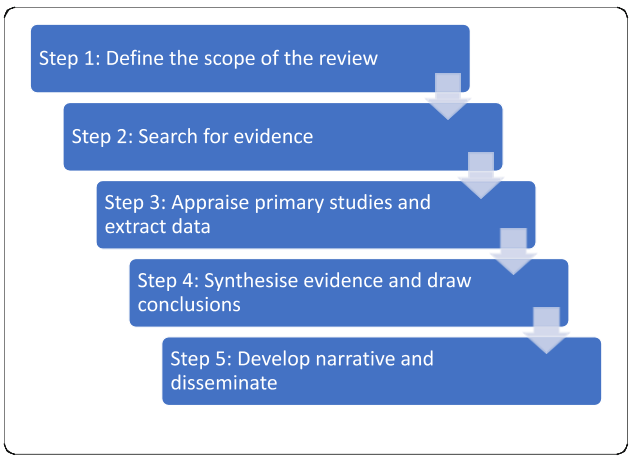
KZ and JS discussed the initial programme theory with two quality improvement experts acknowledged at the end of this paper. They suggested alignment with the MUSIQ framework and commented on the research questions, which were as follows:

Context

1. In what kind of health facility settings may QICs work (or not)? (focus on characteristics of the health facility setting)
2. What defines an enabling environment for QICs? (focus on proximate project-specific factors and on wider organisational context and external environment)

Mechanisms

3. How may engagement in QICs influence health workers and the organisational context to promote better adherence to evidence-based guidelines? (focus on intra-organisational mechanisms)
4. What is it about collaboration with other facilities that may lead to better outcomes? (focus on inter-organisational mechanisms)



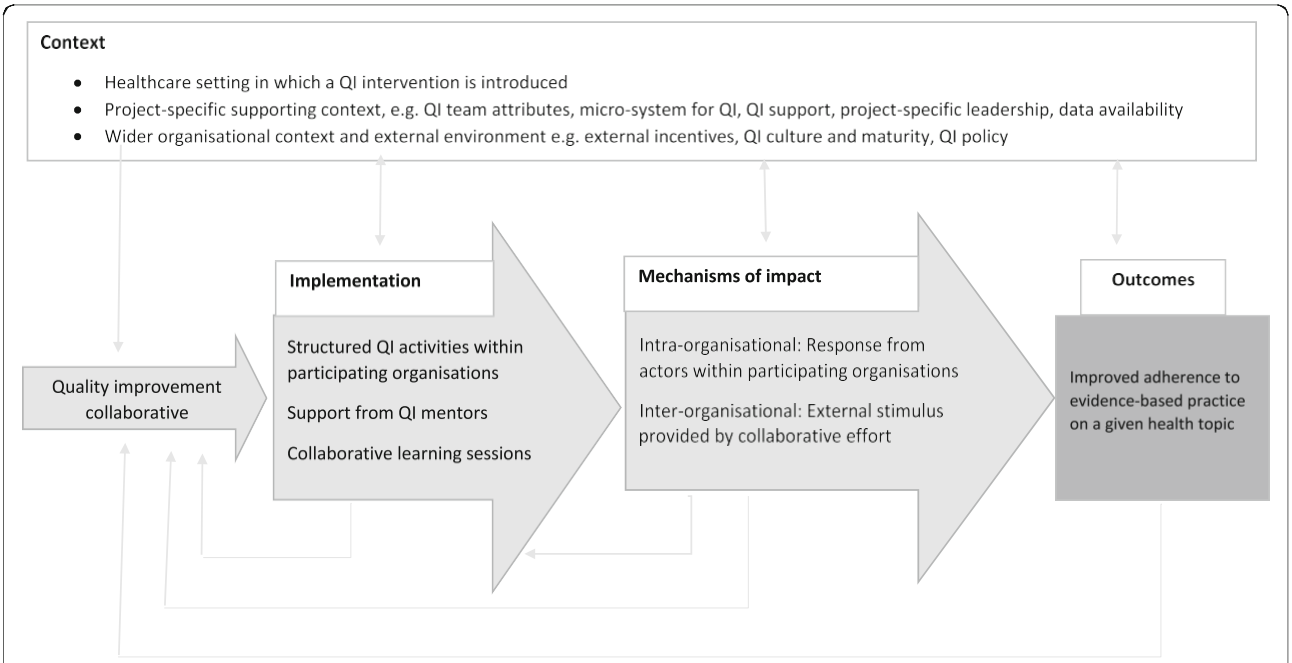


Fig. 2 Review conceptual framework (adapted from MRC process evaluation framework)

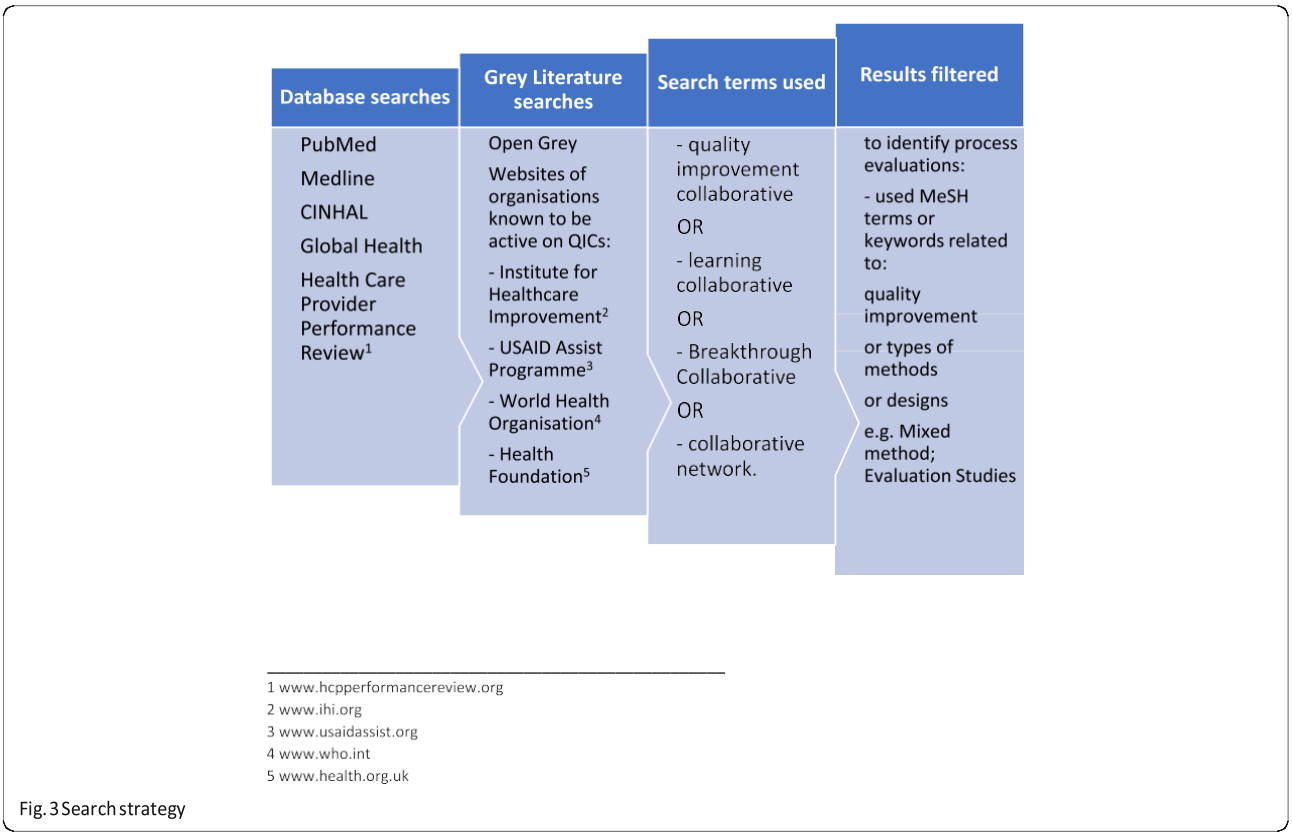


Fig. 3 Search strategy

Search strategy

The search strategy is outlined in Fig. 3 and detailed in Additional file 1. Studies were included if they (i) re- ferred to the quality improvement collaborative ap- proach [2, 5, 8, 16], defined in line with previous reviews as consisting of all the following elements: a specified topic; clinical and quality improvement experts working together; multi-professional quality improvement teams in multiple sites; using multiple rapid tests of change; and a series of structured collaborative activities in a given timeframe involving learning sessions and visits from mentors or facilitators (ii) were published in Eng- lish, French or Spanish, from 1997 to June 2018; and (iii) referred to a health facility setting, as opposed to com- munity, administrative or educational setting.

Studies were excluded if they focused on a chronic con- dition, palliative care, or administrative topics, and if they did not contain primary quantitative or qualitative data on process of implementation, i.e. the search excluded sys- tematic reviews; protocol papers, editorials, commentaries, methodological papers and studies reporting exclusively outcomes of QIC collaboratives or exclusively describing implementation without consideration of context or mechanisms of change.

Screening

We applied inclusion and exclusion criteria to titles and abstracts and subsequently to the full text. We identified additional studies through references of included publi- cations and backward and forward citation tracking.

Data collection

We developed and piloted data extraction forms in MS Excel. We classified studies based on whether they fo- cused on context or mechanisms of change and captured qualitative and quantitative data under each component. Data extraction also captured the interaction between implementation, context and mechanisms, anticipating that factors may not fit neatly into single categories [18, 19].

KZ and MT independently conducted a structured quality appraisal process using the STROBE checklist for quantitative observational studies, the Critical Appraisal Skills Programme checklist for qualitative studies and the Mixed Methods Appraisal Tool for mixed method studies [34–37] and resolving disagreement by consen- sus. To aid comparability, given the heterogeneity of study designs, a score of 1 was assigned to each item in the checklist, and a total score was calculated for each paper. Quality was rated low, medium or high for papers scoring in the bottom half, between 50 and 80%, or above 80% of the maximum score. We did not exclude studies because of low quality: in all such cases, both au- thors agreed on the study's relative contribution to the research questions [19, 38].

Synthesis and reporting of results

Analysis was informed by the preliminary conceptual framework (Fig. 2) and conducted thematically by frame- work domain by the lead author. We clustered studies into context and mechanism. Under context, we first analysed quantitative data to identify factors related to the framework and evidence of their associations with mechanisms and outcomes. Then, from the qualitative evidence, we extracted supportive or dissonant data on the same factors. Under mechanisms, we identified themes under the two framework domains using the- matic analysis. We generated a preliminary coding framework for context and mechanism data in MS Excel. UB reviewed a third of included studies, drawn ran- domly from the list stratified by study design, and inde- pendently coded data following the same process. Disagreements were resolved through discussion. We developed a final coding framework, which formed the basis of our narrative synthesis of qualitative and quanti- tative data.

We followed the RAMESES reporting checklist, which is modelled on the PRISMA statement [39] and tailored for reviews aiming to highlight relationships between context, mechanisms and outcomes [40] (Additional file 2). All included studies reported having received ethical clearance.

Results

Search results

Searches generated 1,332 results. After removal of dupli- cates (370), 962 abstracts were screened of which 88 met the inclusion criteria. During the eligibility review process, we identified 15 papers through bibliographies of eligible papers and authors' suggestions. Of the 103 papers reviewed in full, 32 met inclusion criteria and were retained for analysis (Table 1). Figure 4 summarises the search results.

Characteristics of included studies

Included studies comprised QIC process evaluations using quantitative, qualitative, and mixed methods de- signs, as well as case descriptions in the form of programme reviews by implementers or external evalua- tors, termed internal and independent programme re- views, respectively. While the application of QIC has grown in LMICs, evidence remains dominated by experi- ences from high-income settings: only 9 out of 32 stud- ies were from a LMIC setting of which 4 were in the grey literature (Table 2).

Most papers focused on mechanisms of change, either as a sole focus (38%) or in combination with implemen- tation or contextual factors (72%) and were explored mostly through qualitative studies or programme re- views. The relative paucity of evidence on the role of

Table 1 Overview of included studies

No.	Author (ref)	Year	Country	Collaborative name	Topic	Study aim	Health setting	No. facilities (individuals) in study	Study design	Published	Focus
1	Amarasingham et al.	2007	USA	Keystone Intensive Care Units Project	Central line associated bloodstream infection	Assess correlation between automation and usability of clinical information systems and clinical outcomes.	Intensive care unit	19 (19)	Uncontrolled before-after	Peer-reviewed	Context
2	Ament et al.	2014	Netherlands	ERAS (Enhanced Recovery after surgery)	Colonic surgery	Explore strategies for sustaining ERAS	Hospitals	10 (18)	Qualitative	Peer-reviewed	Mechanism
3	Baker et al.	2018	Tanzania	EQUIP (Expanded Quality Management using Information Power)	Maternal and newborn health	Investigate how different components of a QIC were understood and experienced by health workers, and contributed to its mechanisms of effect	District hospital, health centre and dispensaries	13(16)	Qualitative	Peer-reviewed	Mechanism
4	Benn et al.	2009	UK	Safer Patient Initiative	Patient safety	Understand participants' perception of impact of the pilot programme	NHS Health Trusts	4	Mixed methods: cross-sectional and qualitative	Peer-reviewed	Mechanism and implementation
5	Benn et al.	2012	UK	Safer Patient Initiative	Patient safety	Analyse impact of intervention of safety culture and climate and role of contextual and programme factors in changes.	NHS Health Trusts	19 [2 merged in 1] (284)	Uncontrolled before-after	Peer-reviewed	Context and implementation
6	Burnett et al.	2009	UK	Safer Patient Initiative	Patient safety	Analyse perceptions of organisational readiness and its relationship with intervention impact	NHS Health Trusts	4 (41)	Mixed methods: cross-sectional and qualitative	Peer-reviewed	Context
7	Carlhed et al.	2006	Sweden	Quality Improvement in Coronary Care	Acute myocardial infarction (AMI)	Evaluate effect of QIC on adherence to AMI guidelines	Hospitals	19 + 19 controls	Non-randomised controlled before and after	Peer-reviewed	Context
8	Carter et al.	2014	UK	Stroke 90:10	Stroke	Explain processes and outcomes of the QIC intervention	Hospitals	11(32)	Qualitative	Peer-reviewed	Mechanism
9	Colbourn et al.	2013	Malawi	MaiKhanda	Maternal and newborn health	Evaluate impact and processes of change	Hospitals and health centres	9 and 29	Mixed methods: cross-sectional and qualitative	Grey	Context, mechanism and implementation

Table 1 Overview of included studies *(Continued)*

No.	Author (ref)	Year	Country	Collaborative name	Topic	Study aim	Health setting	No. facilities (individuals) in study	Study design	Published	Focus
10	Catsambas et al.	2008	LMICs various	35 collaboratives funded by USAID between 2002 - 2007	Various: Maternal and newborn health, nutrition, HIV/AIDS	Document and evaluate the implementation and results of the Quality Assurance Project	Hospitals and health centres	N/A	External review - multiple projects	Grey	Context, mechanism & implementation
11	Dainty et al.	2013	Canada	Ontario Intensive Care Units Best Practice Project	Evidence-based care practices in Intensive Care Units	Understand staff perspectives on QIC and hypothesise theoretical constructs that might explain the effect of collaboration	Hospitals	12 (32)	Qualitative	Peer-reviewed	Mechanism
12	Dixon-Woods et al.	2011	USA	Keystone ICU Project	Central line associated bloodstream infection	Develop an ex-post theory of the project	Intensive Care Units	n/a	Case description	Peer-reviewed	Mechanism
13	Duckers et al.	2009	Netherlands	Better Faster	Patient safety	Test whether consensus on perceived leadership support among physicians influences the relation between physician's perception and participation.	Hospitals	8 (864)	Cross-sectional	Peer-reviewed	Context
14	Duckers M. et al.	2009	Netherlands	Better Faster	Patient safety	Assess relations between conditions for successful implementation, applied changes, perceived success and actual outcomes.	Hospitals	23 (237)	Cross-sectional	Peer-reviewed	Context, mechanism and implementation
15	Duckers M. et al.	2011	Netherlands	Better Faster	Patient safety	Describe how the first group of hospitals sustained and disseminated improvements	Hospitals	8 (8)	Qualitative	Peer-reviewed	Mechanism
16	Duckers M. et al.	2014	Netherlands	Better Faster	Patient safety	Test whether perceived average project success at QIC level explains dissemination of projects.	Hospitals	16 (84 out of 148)	Cross-sectional	Peer-reviewed	Mechanism
17	Feldman-Winter et al.	2016	USA	Best Fed Beginnings	Breastfeeding	Describe collaborative and present lessons learned from implementation.	Hospitals	89(89)	Case description	Peer-reviewed	Mechanism and implementation
18	Horbar et al.	2003	USA	Vermont Oxford Network Newborn Intensive Care Units /Q 2000	Quality and safety of neonatal intensive care	Describe collaborative and present implementation strategy.	Hospitals		Case description	Peer-reviewed	Context, mechanism and implementation
19	Jaribu et al.	2016	Tanzania	INSIST	Maternal and newborn health	Describe health workers' perceptions of a QIC	Health centres and dispensaries	11 (15)	Qualitative	Peer-reviewed	Mechanism

Table 1 Overview of included studies *(Continued)*

No.	Author (ref)	Year	Country	Collaborative name	Topic	Study aim	Health setting	No. facilities (individuals) in study	Study design	Published	Focus
						intervention					
20	Linnander et al.	2016	Ethiopia	Ethiopian Hospital Alliance for Quality	Patient satisfaction with hospital care	Analyse impact of QIC	Hospitals	68	Cross-sectional and uncontrolled before - after	Peer-reviewed	Context and implementation
21	Marquez et al.	2014	38 LMICs	Health Care Improvement Project	various	Document and evaluate the implementation and results of the Health Care Improvement project	various	N/A	External review - multiple projects	Grey	Context, mechanism and implementation
22	McInnes et al.	2007	USA	HIV collaborative under HRSA/ HAB	HIV/AIDS	Assess whether participation in QIC changes care processes, systems and organisation of outpatient HIV clinics	HIV clinics	52 (104) Intervention and 35 (90) Controls from non QIC sites.	Non-randomised controlled before and after	Peer-reviewed	Context
23	Mills and Weeks	2004	USA	5 Veteran Health Association collaboratives between 1999 - 2001	Various	To identify the organisational, interpersonal and systemic characteristics of successful improvement teams	Hospitals	134 medical QITs in 5 BTS collaboratives	Uncontrolled before–after	Peer-reviewed	Context and implementation
24	Nembhard	2008	USA	4 collaboratives supported by IHI	Efficiency in primary care; complications in ICUs; reducing adverse drug events; reducing surgical site infections	Understand participants' views of the relative helpfulness of various features of QICs	Hospitals	53 teams (217)	Mixed methods: cross-sectional and qualitative	Peer-reviewed	Mechanism
25	Nembhard	2012	USA	4 collaboratives supported by IHI	as above	Study the use of interorganizational learning activities as an explanation of mixed performance among collaborative participants	Hospitals	52 teams (48 hospitals)	Cross-sectional	Peer-reviewed	Mechanism
26	Osibo et al.	2017	Nigeria	Lafiyan Jikin Mata	HIV/AIDS	Discuss lessons learned from QIC implementation and analyse effect of QIC activities on process indicators.	Hospitals and PHC centres	32 (16 intervention + 16 controls)	Mixed methods: UBA and qualitative	Peer-reviewed	Mechanism and implementation
27	Parand et al.	2012	UK	Safer Patient Initiative	Patient safety	Identify strategies to facilitate the sustainability of the QIC	NHS Health Trusts	20 (35)	Qualitative	Peer-reviewed	Mechanism and implementation
28	Pinto et al.	2011	UK	Safer Patient Initiative	Patient safety	Evaluate influence of various factors on the	NHS Health Trusts	20 (635)	Cross-sectional	Peer-reviewed	Mechanism

Table 1 Overview of included studies *(Continued)*

No.	Author (ref)	Year	Country	Collaborative name	Topic	Study aim	Health setting	No. facilities (individuals) in study	Study design	Published	Focus
						perceived impact of QIC					
29	Rahimzai et al.	2014	Afghanistan	Maternal and Newborn Health Facility Demonstration Improvement Collaborative	Maternal and newborn health	Document implementation and describe results of a QIC project	Provincial hospitals, health centres and posts in provinces + large referral hospitals in Kabul	Participating facilities in "Demonstration wave": 25 in provinces and 6 in Kabul: Wave 1–2: additional 6 facilities.	Case description	Peer-reviewed	Mechanism and implementation
30	Schouten et al.	2008	Netherlands	Stroke Collaborative I	Stroke	Explore effects of QIC and determinants of success	Stroke services	23	Cross-sectional and before - after with reference group	Peer-reviewed	Context
31	Sodzi-Tettey et al.	2013	Ghana	Project Fives Alive!	Maternal and newborn health	Document implementation, describe results and lessons learned of a QIC project	Hospitals (district and regional) and health centres	N/A	Case description	Grey	Context, mechanism and implementation
32	Stone et al.	2016	USA	California Perinatal Quality Care Collaborative	Breastfeeding	Assess factors that that affect sustained improvement following participation.	NICUs	6 (n/s)	Qualitative	Peer-reviewed	Mechanism

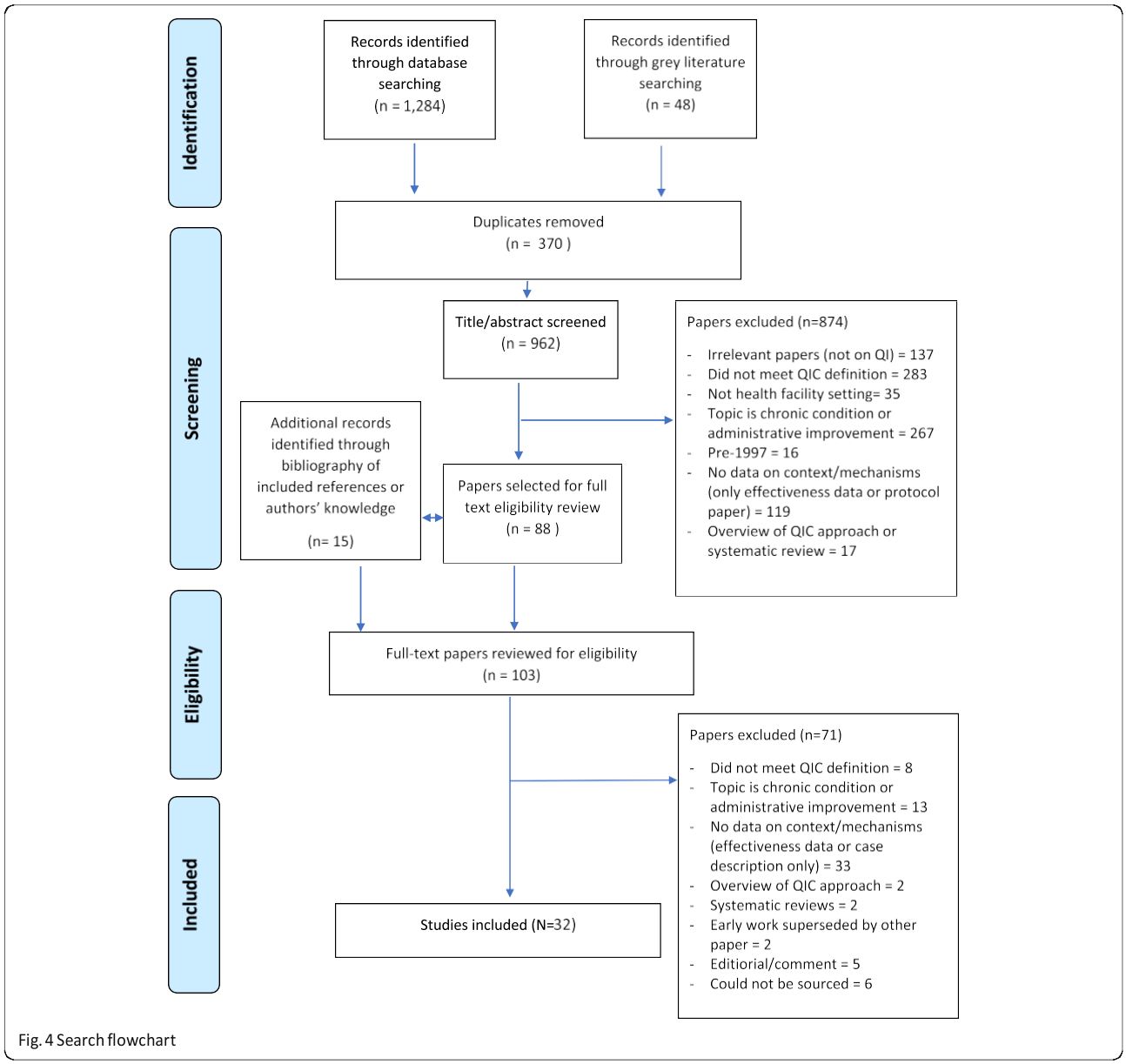


Fig. 4 Search flowchart

Table 2 Overview of study focus, by country setting and study type

Focus	Total	Country setting		Internal or independent programme review	Before and after (controlled or uncontrolled)	Qualitative	Cross-sectional	Mixed methods
		High-income	Low or middle income					
Mechanism	12	10	2	1	0	7	3	1
Context	6	6	0	0	3	0	2	1
Context and implementation	3	2	1	0	2	0	1	0
Implementation and mechanism	5	3	2	2	0	1	0	2
All	6	2	4	4	0	0	1	1
Total	**32**	**23**	**9**	**7**	**5**	**8**	**7**	**5**

context in relation to QIC reflects the gaps identified by other systematic reviews [7]. We identified 15 studies containing data on context of which 8 quantitatively tested the association between a single contextual factor and outcomes. Most studies were rated as medium qual- ity (53%) with low ratings attributed to all internal and external programme reviews (Additional file 3). How- ever, these were retained for analysis because of their rich accounts on the relationship between context, mechanisms and outcomes and the relative scarcity of higher quality evaluations taking into account this complexity [41].

Context

We present results by research question in line with the conceptual framework (Fig. 2). We identified two research questions to explore three types of contextual factors (Table 3).

In what kind of facility setting may QICs work (or not)?

The literature explored four healthcare setting characteristics: facility size, voluntary or compulsory participation in the QIC programme, baseline performance and factors related to health facility readiness. We found no conclusive evidence that facility size [42], voluntary or compulsory participation in the QIC programme [44], and baseline performance influence QIC outcomes [43]. For each of these aspects, we identified only one study, and those identified were not designed to demonstrate causality and lacked a pre-specified hypothesis on why the contextual factors studied would influence outcomes. As for heath fa- cility readiness, this encompassed multiple factors

Table 3 Contextual factors

Category	No. of studies	Evidence synthesis			Quality of evidence (ref.)	
		Relationship with outcome and mixed methods		Relationship with mechanism	Quantitative	Qualitative and review
1 Healthcare setting in which a QI intervention is introduced						
Facility size	*N* = 1	No	No evidence that hospital size is associated with improvement in outcome.	- Not discussed.	Medium [42]	
Base line performance	*N* = 1	Yes	Lower base line performance of hospitals is positively associated with magnitude of outcome improvement.	Yes Lower base line performance is positively associated with active participation in QIC.	Medium [43]	
Voluntary or compulsory participation	*N* = 1	No	No evidence of differences in outcomes.	- Not discussed.	High [44]	
Factors related to health facility readiness	*N* = 5	Yes/ No	Inconclusive evidence of association between programme pre-conditions (staff, resources, usability of health information system systems, measurement data availability and senior level commitment to target) and outcomes.	Yes Bottom up leadership style may foster more positive perceptions of organisational readiness for change. Limited clinical skills, poor staff morale and few resources negatively associated with outcomes.	Medium [42, 45, 46]; high [47]	Low [48]
2 Project-specific contextual factors						
External support	*N* = 6	Yes	Quality, appropriateness and intensity of quality improvement support positively associated with *perceived* improvement in outcomes.	Yes The number of ideas tested by quality improvement teams partly mediates the association between external support and *perceived* improvement.	Medium [42, 46]; high [49]	Low [48, 50, 51]
Quality improvement team characteristics	*N* = 4	Yes	Inclusion of opinion leader, team functionality and previous knowledge or experience of quality improvement is positively associated with outcome.	- Not discussed	Medium [52, 53]; high [49, 54]	
3 Wider organisational context and external environment						
Leadership characteristics	*N* = 5	Yes	Supportive leadership is positively associated with perceived improvement in outcomes.	Yes Supportive leadership may motivate physicians to implement quality improvement and may enable active testing of ideas by quality improvement teams. Lack of supportive leadership may demotivate and stall quality improvement team efforts.	High [49, 54, 55]	Low [51, 56]
Health system alignment	*N* = 4	-	Not discussed.	Yes Alignment with national priorities, national-level quality strategy, and incentives systems is essential to enable leadership support.	Medium [46]	Low [48, 50, 51]

perceived as programme preconditions, such as health information systems [42, 45, 47], human resources [42, 45, 46, 48] and senior level commitment to the target [42, 45]. There was inconclusive evidence on the relationships between these factors and QIC outcomes: the studies exploring this association quantitatively had mixed results and generally explored one factor each. A composite organisational readiness construct, combining the above- mentioned programme preconditions, was investigated in two cross-sectional studies from the same collaborative in a high-income setting. No evidence of an association with patient safety climate and capability was found, but this may have been due to limitations of the statistical model or of data collection on the composite construct and out- come measures [42, 45]. However, qualitative evidence from programme reviews and mixed-methods process evaluations of QIC programmes suggests that negative perceptions of the adequacy of available resources, low staff morale and limited availability of relevant clinical skills may contribute to negative perceptions of organisa- tional readiness, particularly in LMIC settings. High- intensity support and partnership with other programmes may be necessary to fill clinical knowledge gaps [46, 48]. Bottom-up leadership may foster positive perceptions of or- ganisational readiness for quality improvement [42, 46, 48].

What defines an enabling environment for QICs?

This question explored two categories in our conceptual framework: project-specific and wider organisational contextual factors. Project-specific contextual factors re- late to the immediate unit in which a QIC intervention is introduced, and the characteristics of the QIC inter- vention that may influence its implementation [29]. We found mixed evidence that adequacy and appropriate- ness of external support for QIC and functionality of quality improvement teams may influence outcomes.

Medium-high quality quantitative studies suggest that the quality, intensity and appropriateness of quality improve- ment support may contribute to perceived improvement of outcomes, but not, where measured, actual improvement [42, 46, 48–51]. This may be partly explained by the num- ber of ideas for improvement tested [49]. In other words, the more quality improvement teams perceive the approach to be relevant, credible and adequate, the more they may be willing to use the quality improvement approach, which in turn contributes to a positive perception of improvement. In relation to attributes of quality improvement teams, studies stress the importance of team stability, multi- disciplinary composition, involvement of opinion leaders and previous experience in quality improvement, but there is inconclusive evidence that these attributes are associated with better outcomes [49, 52–54]. Particularly in LMICs, alignment with existing supervisory structures may be the key to achieve a functional team [46, 48, 51, 57, 58].

Wider organisational contextual factors refer to characteristics of the organisation in which a QIC interven- tion is implemented, and the external system in which the facility operates [29]. Two factors emerge from the literature. Firstly, the nature of leadership has a key role in motivating health professionals to test and adopt new ideas and is crucial to develop "habits for improvement", such as evidence-based practice, systems thinking and team problem-solving [49, 51, 54–56]. Secondly, align- ment with national priorities, quality strategies, financial incentive systems or performance management targets may mobilise leadership and promote facility engage- ment in QIC programmes, particularly in LMIC settings [46, 48, 50, 51]; however, quality of this evidence is medium-low.

Mechanisms of change

In relation to mechanisms of change, we identified two research questions to explore one domain each.

How may engagement in QICs influence health workers and the organisational context to promote better adherence to evidence-based practices?

We identified six mechanisms of change *within* an organisation (Table 4). First, participation in QIC activities may increase their commitment to change by increasing confidence in using data to make decisions and identifying clinical challenges and their potential solutions within their reach [17, 49, 51, 55, 56, 60–62]. Second, it may improve accountability by making standards expli- cit, thus enabling constructive challenge among health workers when these are not met [17, 62, 64–66]. A rela- tively high number of qualitative and mixed-methods studies of medium–high quality support these two themes. Other mechanisms, supported by fewer and lower quality studies, include improving health workers' knowledge and problem-solving skills by providing op- portunities for peer reflection [46, 48, 64, 67]; improving organisational climate by promoting teamwork, shared responsibility and bottom up discussion [60–62, 67]; strengthening a culture of joint problem solving [48, 63]; and supporting an organisational cultural shift through the development of "habits for improvement" that pro- mote adherence to evidence-based practices [17, 56, 62]. The available literature highlights three key contextual enablers of these mechanisms: the appropriateness of mentoring and external support, leadership characteristics and adequacy of clinical skills. The literature suggests that external mentoring and support is appropriate if it in- cludes a mix of clinical and non-clinical coaching, which ensures the support is acceptable and valued by teams, and if it is highly intensive, particularly in low-income set- tings that are relatively new to using data for decision- making and may have low data literacy [46, 48, 51, 58].

Table 4 Intra-organisational mechanisms of change

Themes (No. studies)	Evidence synthesis				Quality of Evidence [ref.]	
	Description of relationship QIC component–mechanism–outcome			Contextual enablers of mechanism (or barriers)	Quantitative and mixed methods	Qualitative and review
	QIC component	Mechanism of change	Outcome			
Health professionals -knowledge, skills & problem solving (*N* = 4)	Use of continuous quality improvement approach	• Refreshed knowledge • Reinforced confidence and skills in improvement topic area • Facilitated a problem-solving approach	Change in clinical practice enabled	• Quality and appropriateness (mix of clinical and quality improvement expertise) of mentoring • Leadership and work culture open to bottom up discussion and reflection • Health workers participating in quality improvement interventions have adequate clinical competences (or a complementary clinical skills training programme is accessible)	Medium [46]	Low [48]; medium [57, 58]
Health professionals engagement, attitude and motivation (*N* = 8)	Formulating shared goals Alignment with national priorities and fit with existing practices Use of run-charts to visualise progress Dissemination of success stories Credibility of change package	• Increased motivation, by reframing improvement topic as desirable, urgent and achievable • Removed resistance to use of data • Increased Commitment to change	Increased engagement in QIC—may lead to increased success	• Intensity of mentoring to increase data literacy and use for decision-making, particularly in LMICs • Supportive leadership • Barrier: competing programmes and initiatives.	Medium [58, 59]; high [49, 57, 60]	Low [17, 51, 61]; high [57]
Organisational climate (*N* = 4)	General QIC approach	• Facilitated teamwork and multi-professional collaboration within and across departments • Facilitated bottom up dialogue and discussion		• Quality and intensity of mentoring • Wider use of improvement tools beyond unit of focus	High [60]	Low [61]; medium [62]; high [57]
Leadership (*N* = 2)	General QIC approach	• Enhanced leadership engagement • Decentralised/shared leadership promoted through encouraging bottom up problem solving	Staff morale boosted	• Previous success with quality improvement • Alignment with institutional responsibilities and participatory working culture	Low [48, 63]	
Organisational structures, processes and systems (*N* = 5)	Process mapping	• Definition of standard care processes facilitated	New expectations on performance generated	• Previous success with quality improvement • Alignment with institutional responsibilities and priorities • Complementary approach (beyond QIC activities) to institutionalise new ways of working e.g. incorporation in induction or staff training; performance management frameworks for accountability at the level of health workers and/or organisation		Low [17]; medium [62, 64, 65]; high [66]
Organisational culture (*N* = 3)	General QIC approach	• Development of habits for improvement facilitated	Normalisation of new practices	• Leadership open to new practices • Health system enabling decentralised innovation		Low [17, 56]; medium [62]

For example, in Nigeria, Osibo et al. suggests that redu- cing resistance to use of data for decision-making may be an intervention in itself and a pre-condition for use of quality improvement methods [58]. As for leader- ship characteristics, the literature stresses the role of hospital leadership in fostering a culture of perform- ance improvement, promoting open dialogue, bottom- up problem solving, which may facilitate a collective sense of responsibility and engagement in quality im- provement. Alignment with broader strategic priorities

and previous success in quality improvement may fur- ther motivate leadership engagement [46, 48, 50, 51]. Adequacy of clinical skills emerges as an enabler par- ticularly in LMICs, where implementation reports ob- served limited scope for problem-solving given the low competences of health workers [46] and the need for partnership with training programmes to comple- ment clinical skills gaps [48].

What is it about collaboration with other hospitals that may lead to better outcomes?

This question explored inter-organisational mechanisms of change. Four themes emerged from the literature (Table 5). Firstly, collaboration may create or reinforce a community of practice, which exerts a normative pres- sure on hospitals to engage in quality improvement, [17, 46, 50, 63, 67–69]. Secondly, it may promote friendly competition and create *isomorphic pressures* on hospital leaders, i.e. pressure to imitate other facilities' success because they would find it damaging not to. In reverse, sharing performance data with other hospitals offers a potential reputational gain for well-performing hospitals and for individual clinicians seeking peer recognition [17, 46, 63, 68, 69, 72] . A relatively high number of medium-high quality studies support these two themes. Thirdly, collaboration may provide a platform for cap- acity building by disseminating success stories and methodologies for improvement [51, 67–70]. Finally, collaboration with other hospitals may demonstrate the feasibility of improvement to both hospital leaders and health workers. This, in turn, may galvanise action within each hospital by reinforcing intra-organisational change mechanisms outlined above [51, 63, 71]. However, evidence for this comes from low-quality studies.

Table 5 Inter-organisational mechanisms of change

Themes (No. studies)	Evidence synthesis				Quality of Evidence [ref.]	
	Description of relationship QIC component–mechanism–outcome			Contextual enablers of mechanism (or barriers)	Quantitative and mixed methods	Qualitative and review
QIC component	Mechanism of change		Outcome			
Shared community of practice (*N* = 7)	Collaboration with other hospitals	• Sense of community reinforced or created • Increased motivation, by supporting reframing of improvement topic as desirable, urgent and achievable	Health workers motivated and empowered to take action towards common goal	• Settings where a *community of practice* amongst clinicians exists or can be developed • Barrier: external pressures on hospitals incentivising competition v. collaboration.	Medium [46, 67–69]	Low [17, 50, 63]; medium [67, 69]
Platform for capacity building (*N* = 5)	Collaboration with other hospitals	• Platform to refine skills for improvement provided • Definition of standard care processes facilitated		• Settings with quality-focused HR systems, e.g. incorporating quality objectives in professional devel- opment and performance appraisals • Barrier: high performing hospitals have less to gain from collaboration • Barrier: Collaboration can be undermined by free-riding (not all facilities contribute equally) and social loafing (leaving it to others to support low performing hospitals)	Medium [51, 67–70]	Low [51]; medium [67, 69, 70]
Demonstration role (*N* = 3)	Collaboration with other hospitals	• Feasibility of improving outcome of focus is demonstrated	Increased engagement in QIC	• Supportive leadership • External support to disseminate success stories • Barrier: Large hospitals may have less to gain from collaboration	Medium [71]	Low [51, 63]

Friendly competition (*N* = 6)	Collaboration with other hospitals	• Reputational gain from improvement (or conversely risk of non-improvement) at individual and organisational level achieved. • Access to others' data and benchmarking for internal gains enabled.	Normative pressures to conform (change practice and improve) created.	• Open sharing of data on mutual performance • Alignment with institutional priorities (lack of which contributes to perception that collaboration is stressful and time-consuming) • Geographically dense professional network • Non-hierarchical teams facilitating decentralised decision making • Barrier: competition for financial incentives linked to quality criteria	Medium [47, 66]	Low [17, 63]; medium [69]; high [72]

Key contextual enablers for these inter-organisational mechanisms include adequate external support to facili- tate sharing of success stories in contextually appropri- ate ways and alignment with systemic pressures on hospital leadership. For example, a study on a Canadian QIC in intensive care units found that pressure to cen- tralise services undermined collaboration because hospi- tals' primary goal and hidden agenda for collaboration were to access information on their potential competi- tors [72]. The activation of isomorphic pressures also as- sumes that a community of practice exists or can be created. This may not necessarily be the case, particu- larly in LMICs where isolated working is common: a study in Malawi attributed the disappointing QIC out- comes partly to the intervention's inability to activate friendly competition mechanisms due the weakness of clinical networks [46].

The relative benefit of collaboration was questioned in both high and low-income settings: less importance was at- tached to learning sessions than mentoring by participants in a study in Tanzania [57]. Hospitals may fear exposure and reputational risks [68], and high-performing hospitals may see little advantage in their participation in a collabora- tive [68, 72]. Hospitals may also make less effort when working collaboratively or use collaboration for self-interest as opposed to for sharing their learning [69].

Figure 5 offers a visual representation of the identified intra- and inter-organisational mechanisms of change and their relationship to the intervention strategy and expected outcomes.

Discussion

To the best of our knowledge, this is the first review to systematically explore the role of context and the mech- anisms of change in QICs, which can aid their imple- mentation design and evaluation. This is particularly important for a complex intervention, such as QICs, whose effectiveness remains to be demonstrated [6, 7, 11]. We offer an initial programme theory to understand whose behaviours ought to change, at what level, and how this might support the creation of social norms pro- moting adherence to evidence-based practice. Crucially, we also link intra- organisational change to the position that organisations have in a health system [33].

The growing number of publications on mechanisms of change highlights interest in the process of change. We found that participation in quality improvement collaborative activities may improve health professionals' knowledge, problem-solving skills and attitude; team- work; shared leadership and habits for improvement. Interaction across quality improvement teams may gen- erate normative pressure and opportunities for capacity

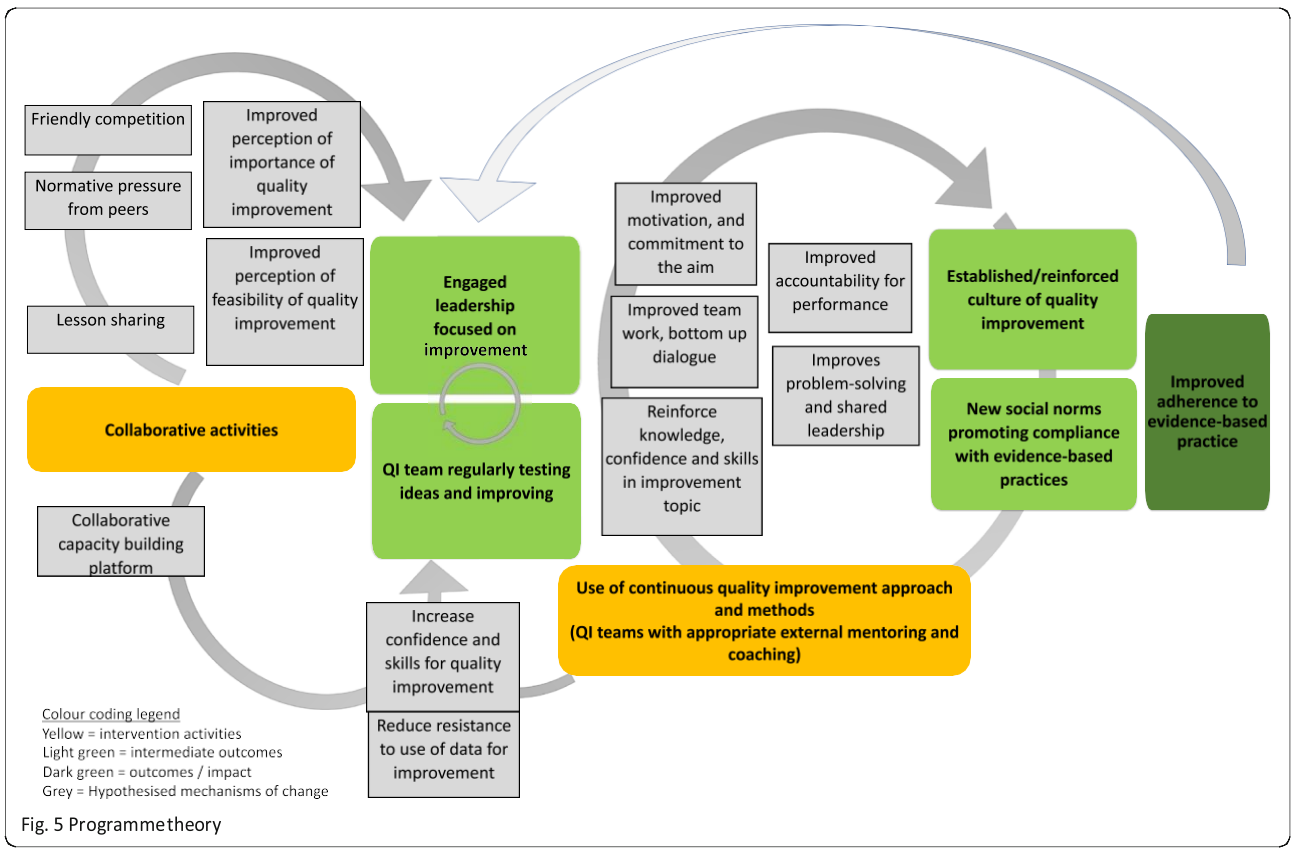


Fig. 5 Programme theory

building and peer recognition. However, the literature generally lacks reference to any theory in the conceptu- alisation and description of mechanisms of change [7]. This is surprising given the clear theoretical underpin- nings of the QIC approach, including normalisation process theory in relation to changes within each organ- isation, and diffusion of innovation theory in relation to changes arising from collaborative activities [32, 33]. We see three key opportunities to fill this theoretical gap. First, more systematic application of the Theoretical Do- mains Framework in design and evaluation of QICs and in future reviews. This is a synthesis of over 120 con- structs from 33 behaviour change theories and is highly relevant because the emerging mechanisms of change pertain to seven of its domains: knowledge, skills, reinforcement, intentions, behaviour regulation, social influences and environmental context and resources [73, 74]. Its use would allow specification of target behav- iours to change, i.e. who should do what differently, where, how and with whom, to consider the influences on those behaviours, and to prioritise targeting behav- iours that are modifiable as well as central to achieving change in clinical practice [75]. Second, we recognise that emphasis on individual behaviour change theories may mask the complexity of change [76]. Organisational and social psychology offer important perspectives for theory building, for example, postulating that motivation is the product of intrinsic and extrinsic factors [77, 78], or that group norms that discourage dissent, for ex- ample, by not encouraging or not rewarding constructive criticism act as a key barrier to individual behaviour change [79]. This warrants further exploration. Third, engaging with the broader literature on learning collabo- ratives may also help develop the programme theory fur- ther and widen its application.

Our findings on contextual enablers complement pre- vious reviews [16, 80]. We highlight that activating mechanisms of change may be influenced by the appro- priateness of external support, leadership characteristics, quality improvement capacity and alignment with sys- temic pressures and incentives. This has important im- plications for QIC implementation. For example, for external support to be of high intensity, the balance of clinical and non-clinical support to quality improve- ment teams will need contextual adaptation, since different skills mixes will be acceptable and relevant in different clinical contexts. Particularly in LMICs, align- ment with existing supervisory structures may be the key to achieve a functional quality improvement team [46, 48, 51, 57, 58].

Our review offers a more nuanced understanding of the role of leadership in QICs compared to previous concepts [8, 25]. We suggest that the activation of the mechanisms of change, and therefore potentially QIC success, rests on the ability to engage leaders, and there- fore leadership engagement can be viewed as a key part of the QIC intervention package. In line with organisa- tional learning theory, the leaders' role is to facilitate a data-informed analysis of practice and act as "designers, teachers and stewards" to move closer to a shared vision [81]. This requires considerable new skills and a shift away from traditional authoritarian leadership models [81]. This may be more easily achieved where some of the "habits for improvement" already exist (13), or where organisa- tional structures, for example, decentralised decision- making or non-hierarchical teams, allow bottom-up prob- lem solving. Leadership engagement in QIC programmes can be developed through alignment with national prior- ities or quality strategies, alignment with financial incen- tive systems or facility performance management targets, particularly as external pressures may compete with QIC aims. Therefore, QICs design and evaluation would bene- fit from situating these interventions in the health system in which they occur.

Improving skills and competencies in using quality im- provement methods is integral to the implementation of QIC interventions; however, the analysis of contextual factors suggests that efforts to strengthen quality im- provement capacity may need to consider other factors as well as the following: firstly, the availability and us- ability of health information systems. Secondly, health workers' data literacy, i.e. their confidence, skills and at- titudes towards the use of data for decision-making. Thirdly, adequacy of health workers' clinical compe- tences. Fourth, leaders' attitudes to team problem solv- ing and open debate, particularly in settings where organisational culture may be a barrier to individual re- flection and initiative. The specific contextual challenges emerging from studies from LMICs, such as low staffing levels and low competence of health workers, poor data systems, and lack of leadership echo findings on the lim- itations of quality improvement approaches at facility-level in resource constrained health systems [1, 82]. These may explain why group-problem solving strat- egies, including QICs, may be more effective in moderate-resource than in low-resource settings, and their effect larger when combined with training [11]. The analysis on the role of context in activating mecha- nisms for change suggests the need for more explicit assumptions about context-mechanism-outcome rela- tionships in QIC intervention design and evaluation [15, 83]. Further analysis is needed to determine whether certain contextual factors related to capacity should be a precondition to justify the QIC approach (an "invest- ment viability threshold") [84], and what aspects of qual- ity improvement capacity a QIC intervention can realistically modify in the relatively short implementa- tion timeframes available.

While we do not suggest that our programme theory is relevant to all QIC interventions, in realist terms, this may be generalizable at the level of theory [18, 20] offering context-mechanism-outcome hypotheses that can inform QIC design and be tested through rigorous evaluations, for example, through realist trials [85, 86]. In particular, there is a need for quantitative analysis of hypothesised mechanisms of change of QICs, since the available evi- dence is primarily from qualitative or cross-sectional designs.

Our review balances principles of systematic reviews, including a comprehensive literature search, double abstraction, and quality appraisal, with the reflective realist review approach [19]. The realist-inspired search methodology allowed us to identify a higher number of pa- pers compared to a previous review with similar inclusion criteria [16] through active search of qualita- tive studies and grey literature and inclusion of low qual- ity literature that would have otherwise been excluded [41]. This also allowed us to interrogate what did *not* work, as much as what did work [19, 22]. By reviewing literature with a wide range of designs against a prelim- inary conceptual framework, by including literature spanning both high- and low-resource settings and by exploring dissonant experiences, we contribute to understanding QICs as "disruptive events within systems" [87]. Our review may have missed some papers, particularly because QIC programme descriptions are often limited [7]; however, we used a stringent QIC definition aligned with previous reviews, and we are confident that the- matic saturation was achieved with the available studies. We encountered a challenge in categorising data as "context" or "mechanism". This is not unique and was anticipated [88]. Double review of papers in our research team minimised subjectivity of interpretation and allowed a deep reflection on the role of the factors that
appeared under both dimensions.

Conclusion

We found some evidence that appropriateness of exter- nal support, functionality of quality improvement teams, leadership characteristics and alignment with national systems and priorities may influence QIC outcomes, but the strength and quality of the evidence is weak. We ex- plored how QIC outcomes may be generated and found that health professionals' participation in QIC activities may improve their knowledge, problem-solving skills and attitude; team work; shared leadership and the de- velopment of habits for improvement. Interaction across quality improvement teams may generate normative pressure and opportunities for capacity building and peer recognition. Activation of mechanisms of change may be influenced by the appropriateness of external support, leadership characteristics, the adequacy of clinical skills and alignment with systemic pressure and incentives.

There is a need for explicit assumptions about context-mechanism-outcome relationships in QIC design and evaluation. Our review offers an initial programme theory to aid this. Further research should explore whether certain contextual factors related to capacity should be a precondition to justify the QIC approach, test the emerging programme theory through empirical studies and refine it through greater use of individual behaviour change and organisational theory in intervention design and evaluation.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s13012-020-0978-z.

Additional file 1. Search terms used.

Additional file 2. Systematic review alignment with RAMESES publication standards checklist.

Additional file 3. Quality appraisal of included studies.

Abbreviations

IQR: Inter-quartile range; LMIC: Low and middle-income country; MES: Median effect size; MUSIQ: Model for understanding success in improving quality; QIC: Quality improvement collaborative; STROBE: Strengthening the reporting of observational studies in epidemiology

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Data availability statement

The datasets analysed during the current study are available in the LSHTM repository, Data Compass.

Authors' contributions

KZ, CH, ZH and JS conceived and designed the study. KZ performed the searches. KZ, UB and MT analysed data. MT and KZ completed quality assessment of included papers. KZ, UB, CH, MT, ZH and JS wrote the paper. All authors read and approved the final manuscript.

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N/A

Consent for publication

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Publisher's Note

Chapter 3: Methods

Introduction

This chapter outlines the methods used in this PhD work. First, it presents the setting in which the evaluation of Safe Care Saving Lives was undertaken. Then, it presents an overview of the study design of the impact evaluation, followed by the design of the process evaluation. A description of the methods accompanies each results chapter in this thesis, either in the form of a published paper or manuscript (see Section II: Results). This chapter expands on methods used to describe the intervention and its theory of change, which were not included in the published evaluation protocol paper, the results of which are presented in Chapter 4 (1). This chapter also expands on the methods for case study selection, as these could not be fully included in the mixed-methods results paper (Chapter 5) (2). Finally, this chapter outlines my role in the evaluation team and offers a self-reflection on positionality, or how my identity and background may have affected my work in this project.

3.1 Study setting

The study was conducted in the two Southern Indian states of Andhra Pradesh and Telangana, a new state formed in 2014 when Andhra Pradesh was divided in two. They are characterized by slightly better demographic and socio-economic development indicators than the Indian average, as summarised in Table 3-1, including a much lower proportion of the population living beyond the poverty line and lower total fertility rate. Indicators on maternal, infant and newborn mortality, reproductive, maternal and newborn care are also better in Telangana and Andhra Pradesh compared to the Indian average (3). For example, these States have a lower newborn mortality rate, albeit with a more marked urban-rural disparity, a higher coverage of ante-natal care, institutional delivery and post-natal care, and higher coverage of some positive newborn care practices, such as exclusive breastfeeding in the first 6 months of life, than the Indian average. While the institutional delivery rate is near universal both in Telangana and Andhra Pradesh, the private sector plays a critical role in providing maternal and newborn care services: more childbirths are delivered in private health facilities than public facilities, and the private sector admits about a quarter of newborns in need of intensive care. The baseline study, which compared adherence to newborn health practices in public versus private facilities, did not find a difference between these settings, which is in line with other evidence globally and from India (4). Specific quality of care challenges exist in these settings, related to the use of potentially unnecessary practices (5): for example, in Telangana and Andhra Pradesh, 75% and 57% births happening in a private facility are delivered through a c-section, a higher proportion than c-sections in births happening in public health facilities (41% and 26% in Telangana and Andhra Pradesh, respectively), and higher than the India average (41%) (3).

The study population consisted of hospitals that were part of the government-sponsored health insurance scheme: the Aarogyasri Health Care Trust in Telangana and the Dr Nandamuri Taraka Rama Rao Vaidya Seva in Andhra Pradesh. These schemes, covering approximately 70% of the target population, provide poor families with access to secondary and tertiary care, including, in relation to newborn care, cover for septicaemia with need for third line antibiotic treatment, stabilization and care for babies with malformations and ventilation. They also provide cover for major surgical and medical conditions, including cancer care, cardiac treatment, neurological diseases and trauma. Care through these schemes is provided in selected public and private facilities that meet specific infrastructure and treatment

conditions, called “empanelled” facilities (6-10). The rationale for recruiting hospitals empanelled in the health insurance scheme in the programme design was to test the feasibility of scaling up quality improvement through the health insurance platform (11). At the time of design of the Safe Care Saving Lives programme and evaluation in 2014, 85 facilities were part of these schemes.

Table 3- 1: Demographic, socio-economic and health indicators in Telangana and Andhra Pradesh

Demographic indicators									
	India			**Andhra Pradesh**			**Telangana**		
Population 2019[#]	1,210,854,977			84,580,777					
Projected life expectancy at birth 2016-2020 (years) [#]	*Male*	*Female*		*Male*			*Female*		
	68.8	71.1		64.8			72.1		
Total fertility rate 2016	*Total*	*Rural*	*Urban*	*Total*	*Rural*	*Urban*	*Total*	*Rural*	*Urban*
	2.3	2.5	1.8	1.7	1.7	1.5	1.7	1.8	1.6
Socio-economic indicators									
Population below the poverty line 2011-12 (%)	*Total*	*Rural*	*Urban*	*Total*		*Rural*		*Urban*	
	21.9	25.7	13.7	9.2		11		5.8	
Female literacy rate 2011	*Total*	*Rural*	*Urban*	*Total*		*Rural*		*Urban*	
	65	58	79	59		52		74	
Households without toilet connectivity and no access to public latrine -2011 (%)[#]	50			48					
Maternal and newborn health care indicators									
Maternal mortality ratio 2014-16 (per 100,000 deaths)	130			74					
Infant mortality rate 2017 (per 1,000 live births)	*Total*	*Rural*	*Urban*	*Total*	*Rural*	*Urban*	*Total*	*Rural*	*Urban*
	33	37	23	32	36	23	29	33	23
Newborn mortality rate 2017 (per 1,000 live births)^	25	33	16	24	33	12	23	n/a	n/a
Women receiving four ante-natal care visits* (%)~	51			76			75		
Women receiving a post-natal care visit within 2 days from birth from any skilled attendant* (%)~	62			80			82		
Women delivering in a health facility* (%)~	79			92			92		
Childbirths delivered in a public health facility * (%)~	52			38			31		
Childbirths delivered in a private health facility	27			61			53		
Private Newborn Intensive Care Unit admissions out of total NICU admissions (%)~	n/a			24			25		
Breastfeeding within 1 hour from birth* (%)~	42			40			37		
Exclusive breastfeeding	55			70			67		

The table presents data extracted from the Government of India Central Bureau of Health Intelligence National Health Profile 2019 (3), which collates data from various official sources. The most recent data are presented for each indicator.

[#] : Data only available for Andhra Pradesh as based on Indian Census 2011 conducted prior to division

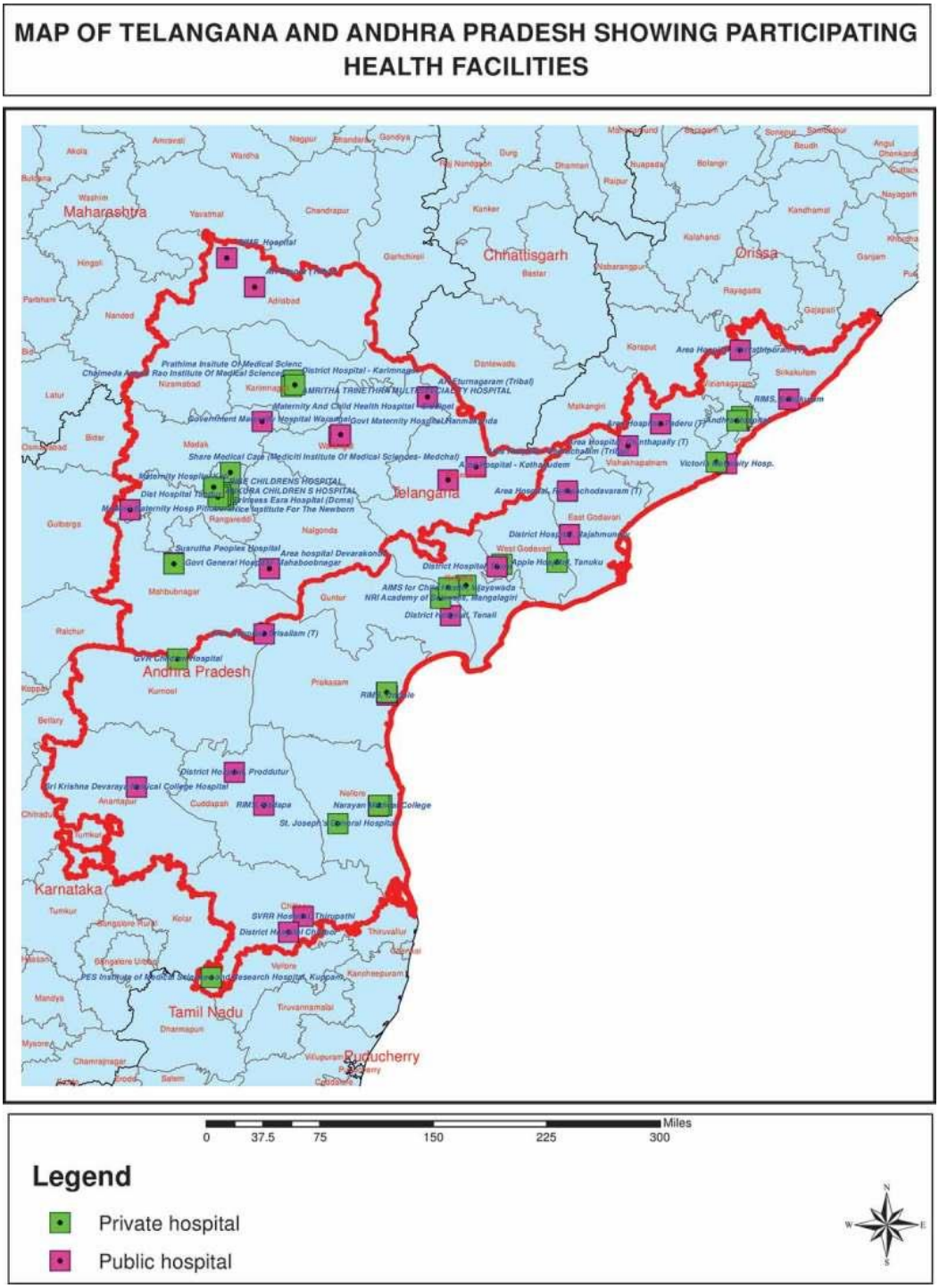
^ Data from Sample Registration System Statistical Report 2012, reported in India Newborn Action Plan 2017 (12)

*Data refers to last birth in the five years before the survey; ~ Data from NHFS-4 2015-16

Implementation of the programme was in 3 waves: wave I comprised 25 facilities (10 private and 15 public) across Andhra Pradesh (10) and Telangana (15), where the approach was piloted and refined between 2015-2017, and implementation continued through to 2018. These 25 were excluded from this study. Wave II and III targeted 29 and 31 facilities respectively More details on allocation are provided in the next section on study design. These 60 hospitals comprised 35 hospitals in Andhra Pradesh and 25 in Telangana, and 26 and 34 private and public facilities, respectively (1). Detailed analysis of care practices in participating hospitals was published in PLOS Med based on the baseline study conducted in 52 of the 60 study facilities which consented to the evaluation (Figure 3-1) (4). A summary of salient contextual features is presented here (Table 3-2).

Figure 3- 1: Study area with hospitals consenting to the study

Reproduced from: Hanson C, Zamboni K, Prabhakar V, et al. Evaluation of the Safe Care, Saving Lives (SCSL) quality improvement collaborative for neonatal health in Telangana and Andhra Pradesh, India: a study protocol. Glob Health Action. 2019;12(1):1581466., p. 4 [published Open Access under a CC-BY licence].



https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6419630/figure/F0001/

Table 3- 2: General information by type of hospital

Reproduced from: Hanson C, Singh S, **Zamboni K**, Tyagi M, Chamarty S, Shukla R., et al. (2019) Care practices and neonatal survival in 52 neonatal intensive care units in Telangana and Andhra Pradesh, India: A cross-sectional study. *PLoS Med* **16**(7), p. 8. [published Open Access under a CC-BY licence]

	Public secondary		Public medical college		Private tertiary		Private medical college		Explanation of those missing
	N = 28		*N* = 6		*N* = 20		*N* = 6		
	N or mean/ median	% or IQR	*N* or mean/ median	% or IQR	*N* or mean/ median	% or IQR	N or mean /median	% or IQR	
Agreed participation in baseline assessment (full or partial)	26		5		15		6		
Labour room assessment	26		4		3		6		12 private hospitals had no labour ward, 1 public secondary hospital refused data collection, and 1 public medical college missing
No. of deliveries per month	282/200	99–382	584/472	324–845	24/29	11–32	136/167	39/195	
Neonatal care unit assessment	25		5		14		5		
Breastfeeding room	21	87%	4	80%	11	85%	5	100%	1 public secondary and 1 private tertiary
Kangaroo Mother care room[#]	14	70%	3	60%	7	50%	2	40%	5 public secondary
No. of admissions per month	91/82	55–138	143/148	110–176	31/30	21–45	47/47	38–53	3 public secondary, 1 public medical college, 1 private tertiary, and 1 private medical college
Beds in neonatal care unit	18/18	14–20	18/18	18–20	17/18	12–20	12/12	10–14	1 public secondary, 1 private tertiary
Monthly admission to bed ratio	5.5 /4.4	3.4–5.9	8.8/8.4	5.4–12.2	1.9/1.4	1.2–2.5	4/3.9	2.6–5.3	3 public secondary, 1 public medical college, 2 private tertiary, 1 private medical college
No. of paediatricians	3/2	1–3	4/4	2–6	6/4	2–6	7/7	6–7	1 public secondary, 1 private tertiary
No. of nurses	10/11	6–13	15/14	14–18	8/8	3–12	14/11	10–14	
Paediatricians per 10 beds	1/1	1–2	2/2	1–3	4/3	1–3	6/6	5–7	
Nurses per 10 beds	6/6	4–7	9/8	7–10	6/6	2–8	13/10	7–14	

[#]A Kangaroo Mother Care room allows the mother to have a bed or comfortable chair to keep her baby on the chest.

Abbreviation: IQR, interquartile range

https://doi.org/10.1371/journal.pmed.1002860.t001

The 34 public hospitals included 28 secondary hospitals at district or sub-district level, and 6 medical colleges, reporting to the Commissioner, Vaidya Vidhana Parishad under the Ministry of Health and Family Welfare and the Directorate of Medical Education, respectively. All public hospitals offered Level II newborn care (Special Newborn Care Units or SNCUs), in addition to delivery care. The 25 private facilities included 20 tertiary hospitals and 6 medical colleges, also under the Directorate of Medical Education. These offered both Level II and Level III newborn care with Newborn Intensive Care Units (NICUs), and 12 did not have a labour room (1, 4). SNCUs and NICUs will be referred to jointly at newborn care units throughout the rest of this thesis.

The study setting included large referral hospitals with a high caseload: the mean number of deliveries in public medical colleges was 584 per month, with a median of 487 and interquartile range [IQR] 324-845. Mean deliveries in the 6 private medical colleges were over 4 times lower than in public medical colleges (a mean of 136, IQR 39 – 195). In total, the newborn care units had just over 3,000 admissions per month. The median number of monthly admissions to newborn care units was also lower in the private than in

the public sector: 30 (IQR 21–45) and 47 (IQR 38–53) in private tertiary hospitals, and private medical colleges compared to 82 (IQR 55–138), and 148 (IQR 110–176 in public secondary hospitals and public medical colleges, respectively. Private facilities also had a lower median number of monthly admissions per available bed in the newborn care units: 1.4 and 3.9 in private tertiary hospitals and private medical colleges, against 4.4 and 8.4, in public secondary hospital and public medical colleges, respectively (4).

The higher caseload in public facilities was compounded by lower staffing availability. The median number of paediatricians per hospital was 2, 4, 4, and 7 in public secondary, public medical colleges, private tertiary, and private medical colleges, respectively, with differences becoming more marked when expressed as the ratio of paediatricians per 10 beds: a median of 6 paediatricians for 10 beds in the private medical colleges compared with a median of 1 paediatrician in public secondary hospital. A similar comparison applies to nurses per 10 beds. While nurse availability corresponded to the staffing norms laid down in the India Newborn Action Plan (12), staffing ratios for paediatricians were only met in public medical colleges and private hospitals. Furthermore, we can not conclude that staff availability was adequate, given the overcrowding of facilities indicated by the admissions per bed indicator, particularly in public facilities, and the lack of global human resource norms in relation to caseload (4).

Most hospitals had a breastfeeding room: 87%, 80%, 85%, and 100% of public secondary, public medical colleges, private tertiary, and private medical colleges, respectively. However, availability of a kangaroo mother care room was higher in public than private facilities(4), perhaps reflecting the Government investments in standardising public sector Special Newborn Care Units infrastructure (13).

Based on observations of 126 admissions to a sample of newborn care units, we estimated adherence to essential care practices at admission to be low, particularly in public sector facilities, but with important quality gaps in private sector facilities as well (Table 3-3). For example, temperature was taken on admission in only 30%, 27% and 59% of admissions in public secondary hospitals, public medical colleges, and private tertiary hospitals, against 100% in private medical colleges. Hand hygiene when handling the baby was practiced in only 40% and 31% of admissions in public secondary hospitals and medical colleges. The practice was not universal in private medical colleges either (76%)(4). Beyond admission, a greater proportion of newborn contacts complied with all steps of hand hygiene in private than public facilities (44% vs 12%, $p < 0.001$), however there was no difference by facility caseload (14).

Based on data from newborn care unit registers, the most common admission diagnosis in the study setting was prematurity or low birth weight (24% of admissions), followed by jaundice (23%), asphyxia (16%), and sepsis (5%). Of note, admission diagnosis was missing in 26% of admissions in private tertiary facilities. (Figure 3-2) (4). Medical colleges admitted proportionately more pre-term and low birth weight babies than other hospital types, in line with referral patterns and other studies in Indian newborn care units (15, 16).

Table 3- 3: Care at admission to newborn care unit by type of hospital

Reproduced from: Hanson C, Singh S, **Zamboni K**, Tyagi M, Chamarty S, Shukla R., et al. (2019) Care practices and neonatal survival in 52 neonatal intensive care units in Telangana and Andhra Pradesh, India: A cross-sectional study. *PLoS Med* **16**(7) , p. 9 with permission from lead authors. [published Open Access under a CC-BY licence]

		Public secondary[a] % (95% CI)	Public medical college[b] % (95% CI)	Private tertiary[c] % (95% CI)	Private medical college[d] % (95% CI)	P value (chi-squared test) adjusted for clustering
Admission staff[e]	Paediatrician	21 (10–39)	14 (5–35)	45 (29–61)	100	0.045
	Medical doctor	48 (25–73)	78 (47–93)	6 (1–40)	0	
	Nurse	31 (17–48)	8 (1–38)	49 (32–67)	0	
History taken[f]		92 (77–98)	92 (67–99)	89 (44–99)	100	0.953
Auscultation done[g]		42 (25–62)	47 (13–84)	100	100	0.361
Temperature taken[h]		30 (12–56)	27 (9–57)	59 (14–93)	100	0.218
Neonate weighed		87 (75–94)	97 (83–99)	100	100	0.500
Hand hygiene before examination[i]		40 (29–52)	31 (15–52)	100	76 (26–97)	0.056
Sent back or referred[j]		9 (3–26)	0	0	0	0.593

All estimates weighted according to average case load in neonatal care unit in the 3 months before the observations.

[a]21 hospitals; 81 observations included

[b]5 hospitals; 26 observations included

[c]6 hospitals; 12 observations included

[d]3 hospitals; 7 observations included

[e]2 missing values from 1 public secondary

[f]3 missing values from 1 public secondary

[g]1 missing from 1 public secondary

[h]1 missing from public secondary, 1 public medical college

[i]1 missing from public secondary and 1 from private tertiary

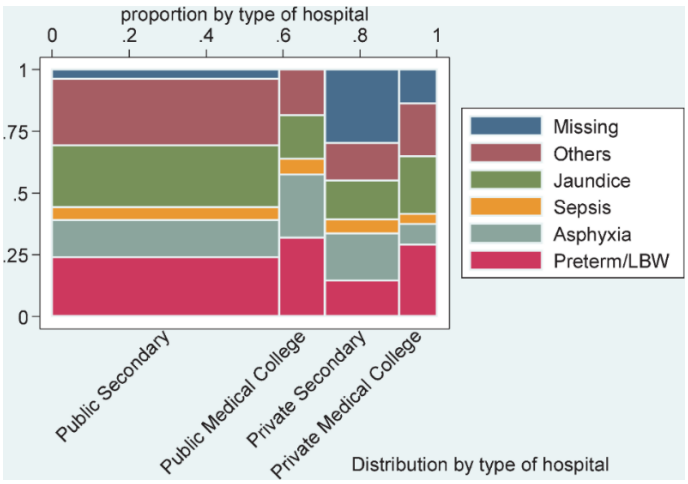
[j]1 missing from public secondary

Abbreviation: CI, confidence interval

https://doi.org/10.1371/journal.pmed.1002860.t002

Figure 3- 2: Admission diagnosis by type of hospital based on register data

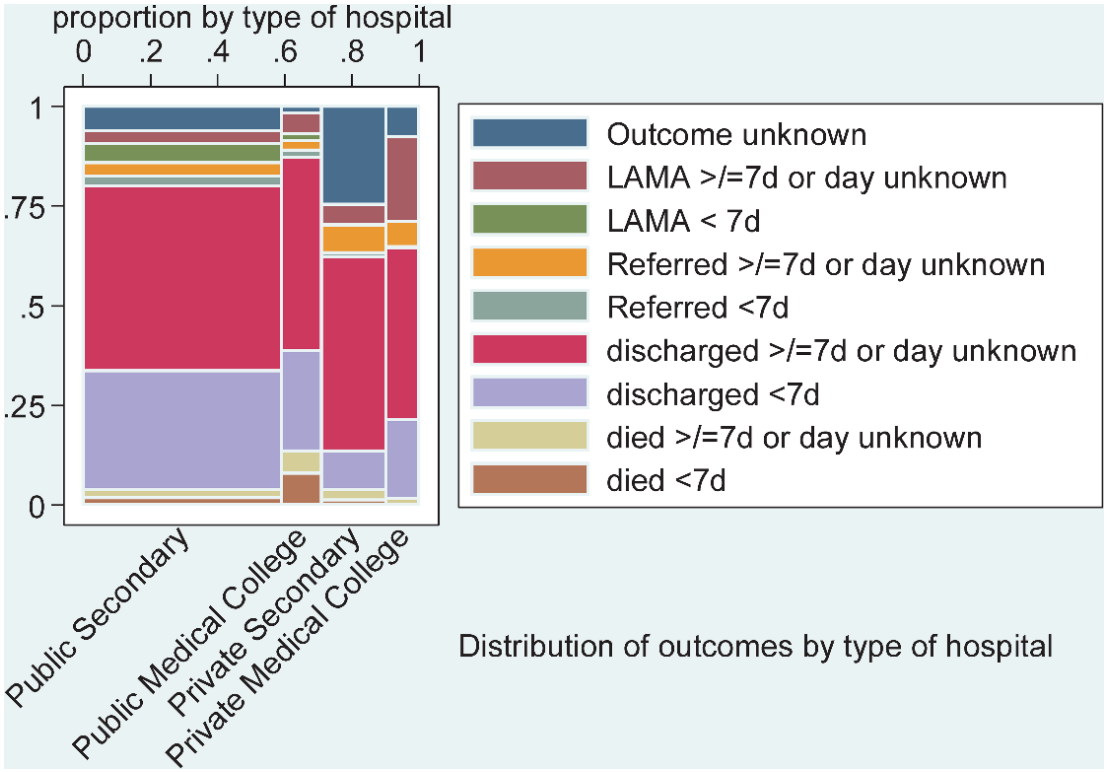
Reproduced from: Hanson C, Singh S, **Zamboni K**, Tyagi M, Chamarty S, Shukla R., et al. (2019) Care practices and neonatal survival in 52 neonatal intensive care units in Telangana and Andhra Pradesh, India: A cross-sectional study. *PLoS Med* **16**(7), p. 10 [published Open Access under a CC-BY licence] https://doi.org/10.1371/journal.pmed.1002860.g002



In terms of outcomes after admission, three-quarters of neonates admitted to newborn care units in the study hospitals were either discharged within the first 7 days of life (28%) or 7 to 28 days after birth (45%), and almost 6% of neonates were referred to other facilities, particularly from private facilities, although information on the place of referral was not available. In private hospitals, the outcome was not documented for 20% of admitted neonates (Figure 3-4). Overall, newborn case fatality was 5.9%: 3.1% within the first 7 days and an additional 2.8% during days 7–28 (4). 7-day case fatality was highest in neonates admitted due to prematurity or low birth weight (7.2%; 95% CI 4.0-12.8) compared to other birth asphyxia (4.1%; 95% CI 1.8-9.0) and sepsis (2.4%; 95% CI 0.7-8.1). In terms of facility type, 7-day case fatality was highest in public medical colleges (17.3%; 95% CI 3.7%–53.2%, p < 0.001). Public medical colleges also reported a high case fatality of 31.3% (95% CI 13.4%–47.4%) in neonates of 32 to 36 weeks of gestational age. In line with evidence at national level(12), mortality was higher in newborns born in other facilities and referred in, than in newborns born in the same hospital (4).

Figure 3- 3: Babies' outcome after admission to neonatal care unit by type of hospital based on register data

Reproduced from: Hanson C, Singh S, **Zamboni K**, Tyagi M, Chamarty S, Shukla R., et al. (2019) Care practices and neonatal survival in 52 neonatal intensive care units in Telangana and Andhra Pradesh, India: A cross-sectional study. *PLoS Med* **16**(7), p. 12 [published Open Access under a CC-BY licence]



LAMA, left against medical advice. LBW: low birth weight
https://doi.org/10.1371/journal.pmed.1002860.g004

3.2 Design, data collection and analysis for impact evaluation

The impact evaluation aimed to assess the effect of Safe Care Saving Lives on facility-based newborn mortality and stillbirths, and adherence to evidence-based newborn care practices. Its design and methods are described in detail in the protocol paper (1) as well as in Chapter 5, which presents the results. In brief, the evaluation used a quasi-experimental design comparing 29 intervention hospitals allocated to receive the intervention in wave II with 31 comparison hospitals, which were expected to receive the intervention in wave III. Facility allocation was originally designed to be randomised. However shortly before implementation started the implementing NGO, ACCESS, decided not to adhere to randomised allocation due to the programmatic decision to implement the intervention in clusters of hospitals around a main tertiary referral facility. This was approved by the donor and the evaluation became a non-randomised study. Details on the allocation procedure were published in the protocol paper (1).

The primary outcomes were: (1) the stillbirth rate (number of foetuses born without any signs of life and weighing 1000 g or more, of all births) which should reflect the evidence-based practices for reliable intra-partum care and newborn resuscitation; (2) 7-day; and (3) 28-day neonatal mortality after admission to a neonatal care unit (the number of babies who died before completing 7 or 28 days of life divided by the number of babies admitted to a neonatal care unit) which should primarily reflect the effect of preventing complications from prematurity and neonatal sepsis. The study was powered to detect a 35% reduction of stillbirths and 20% reduction in neonatal mortality with 80% power (1).

Secondary indicators included the 20 evidence-based practices targeted by the Safe Care Saving Lives programme, and outlined in Table 3-4 on the following page. For secondary outcomes, the study was powered to detect a 16% improvement in flagging high risk admission, a 32% improvement in using a delivery checklist and a 50% improvement in hand hygiene with 80% power (1).

To collect data to assess the primary and secondary outcomes, we conducted a survey of participating hospitals at baseline and endline using 18 data collection tools including (i) labour room and newborn care unit checklists to investigate infrastructure, supplies and human resources; (ii) abstraction of case notes and observations to investigate implementation of the 20 evidence-based practices; and (iii) abstraction of registers in labour wards and newborn care units complemented by on-site interviews with mothers and telephonic follow-up of mothers to estimate mortality after discharge for babies from labour rooms and newborn care units (1).

We used a difference-in-difference (DiD) approach to assess the effect of the intervention on stillbirths and newborn mortality as well as secondary outcomes (17), adjusting for clustering at hospital level (18). Analysis was conducted using Stata version 15.1.

Table 3- 4: List of indicators, data sources and number of observations

Reproduced from: **Zamboni, K.**, Singh, S., Tyagi, M. et al. Effect of collaborative quality improvement on stillbirths, neonatal mortality and newborn care practices in hospitals of Telangana and Andhra Pradesh, India: evidence from a quasi-experimental mixed-methods study. Implementation Sci 16, 4 (2021) – [published Open Access under a CC-BY licence]

Indicator	Data source	N baseline	N endline
Outcome indicators			
% of stillbirth of all hospital deliveries	Labour room register	6466	12054
% of neonates dying before the age of 7-days among those admitted to the newborn care unit	Telephonic Interviews with mothers after discharge	866	1067
% of neonates dying before the age of 28-days among those admitted to the newborn care unit			
Output indicators (denominators)			
% of high-risk admissions correctly flagged (Number of women who were high risk i.e. risk_any)	Case note abstraction	709	1603
% of admissions where essential information was documented in partograph and attached to case notes (total no. of observations)	Case note abstraction	1125	2034
% of admissions where safe childbirth checklist was used and attached to case notes (total no. of observations)	Case note abstraction	1125	2034
% of vaginal examinations where hygiene standards are met (Number of women who were examined through PV)	Observations	142	272
% of deliveries where the six cleans were adhered to (total no. of observations)	Observations	234	392
% of all induced deliveries where use of oxytocin protocol was indicated on case notes	Case note abstraction	Insufficient power to measure indicator at baseline. Data collection not repeated at endline	
% of high-risk deliveries where personnel trained in resuscitation were present	Observation of delivery		
% of asphyxiated babies for which resuscitation was initiated within 1 minute	Observations of delivery		
% of mothers with risk of sepsis where antibiotics were given	Case note abstraction	Not assessed at baseline _ because of very poor documentation of risk of sepsis such as fever, foul smelling discharge etc.	
% of babies seen in the neonatal care admission ward for whom temperature was measured within 15 minutes (total no. of observations)	Observations of admissions	109	217
% of patient contacts where hygiene standards are met (total no. of observations)	Observations of patient contact in newborn care unit	2499	4652
% of cannulations where hygiene standards are met (total no. of observations)	Observations of IV line	188	202
% of babies discharged from newborn care unit who were exclusively breastfed at first interview after discharge (total no. of observations)	Telephonic Interviews with mothers after discharge	866	1067
% of mothers in NCUs that reported being assisted for kangaroo mother care by a health worker or a relative (total no. of observations)	Telephonic Interviews with mothers after discharge	378	534

Additional file 1: https://static-content.springer.com/esm/art%3A10.1186%2Fs13012-020-01058-z/MediaObjects/13012_2020_1058_MOESM1_ESM.docx

3.3 Design of process evaluation

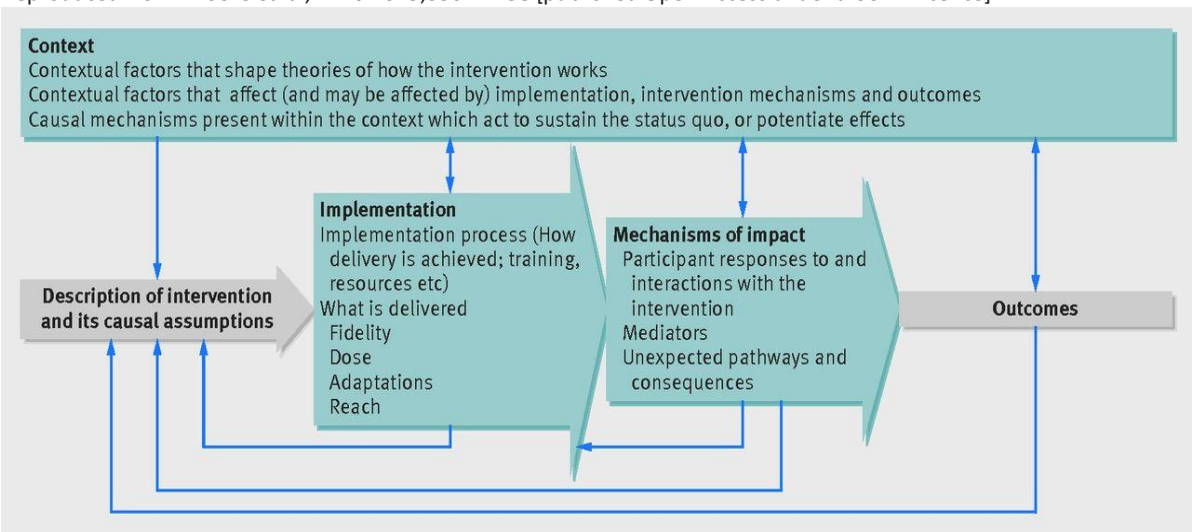
The process evaluation was added to the initial study through this PhD. Nested in the impact evaluation, it aimed to answer two questions:

1. How, for whom, under what circumstances did Safe Care Saving Lives improve adherence to evidence-based obstetric and newborn care practices in the participating hospitals?
2. What is the feasibility of scaling-up the quality improvement collaborative approach using a health insurance platform?

The process evaluation was informed by the Medical Research Council's framework for process evaluation of complex public health interventions (Figure 3-4) (19, 20) and the theory-driven approach to evaluation (21).

Figure 3- 4: The Medical Research Council process evaluation framework

Reproduced from: Moore et. al, BMJ 2015;350:h1258 [published Open Access under a CC-BY licence]



Safe Care Saving Lives was considered a "complex intervention", as it aimed to address multiple outcomes through non-linear pathways, requiring a wide range of behavioural, organisational and systemic changes at different levels (e.g. QI team, hospital department, hospital as a whole, district, network of providers empanelled in a health insurance scheme, state). There was a high degree of flexibility and tailoring of intervention: hospitals could select which evidence-based practices and innovations (or change ideas) to focus on, and such flexibility was crucial to secure hospitals engagement in wave 1 (1, 20) . In line with the Medical Research Council's process evaluation framework, the process evaluation had 4 conceptual domains.

First, the description of the intervention. Given the complexity of the intervention, an in-depth description of the implementation strategy was necessary, both to enable adequate reporting with a view to replicate the intervention, if successful (22), and to understand its causal assumptions, which are critical to understand mechanisms of impact (20, 23) but were poorly articulated in intervention design documents. Methods for this work are described in section 3.4 below and the implementation strategy is presented in Chapter 4.

Second, a study of implementation. I aimed to describe the implementation process in wave II, using monitoring data from mentors' engagement with target facilities provided by ACCESS, to evaluate the programme's dose i.e. the intensity of implementation, and reach, i.e. the extent to which the target hospitals came into contact with the intervention, and for how long (20). Together with the notion of fidelity, or the extent to which an intervention is delivered as intended (24), these elements represent the traditional domains of process evaluations, which have been advocated for inclusion in randomised controlled trials over the last decade. For example, Oakley A. and others argued on the importance of conducting process evaluations addressing dose, reach and fidelity to avoid Type III error in statistical analysis of trial results, by failing to distinguish between intervention failure due to a faulty intervention or poor delivery (25, 26). I aimed to evaluate "fidelity" not in relation to a set of pre-specified activities, but in relation to the Breakthrough Collaborative quality improvement approach to which the intervention strategy was explicitly aligned. This is because complex health interventions are rarely delivered as per their ideal protocols; because participants respond to interventions in unpredictable ways; and because adaptations to the local context of implementation and responsiveness to participants' inputs are key features of a successful intervention (20, 24). Therefore, I aimed to highlight the key adaptations made by Safe Care Saving Lives to fit the context.

Third, the study of mechanisms of change. I defined these as the "underlying entities, processes, or structures which operate in particular contexts to generate outcomes of interest" (27). I viewed the intervention as a set of resources offered to participants, and aimed to explore their engagement and response to it (28), to understand how and why the intervention would (or would not) affect the intended outcomes, inspired by realist evaluation (29, 30) and the possibility of realist trials (31, 32).

Finally, the study of context. In addition to describing the context of implementation at baseline, I aimed to explore contextual influences on implementation and mechanisms of change. To address question 2, I situated the intervention in the policy and health system context and conducted a qualitative study to analyse the feasibility of scale-up through the state health insurance platform.

Table 3-5 summarises the process evaluation design.

Table 3- 5: Process evaluation design

Process evaluation domain	Process evaluation question	Specific questions	Focus	Approach	Methods	Timeline
1 - Intervention description	Q1	How might Safe Care Saving Lives achieve improved adherence to evidence-based practices?	Theory of change	Qualitative	Interviews with Senior staff at ACCESS Participatory workshop with ACCESS staff, and donor	August - September 2017 October 2017
2 - Implementation in context	Q1	What was the intervention package delivered? How was implementation influenced by contextual factors?	Dose Reach Fidelity Adaptations	Descriptive analysis of implementation data Qualitative: case studies	Review of monthly programme implementation data collected and provided by ACCESS Interviews with ACCESS mentor, Hospital managers, Unit Managers, QI team members	Quarterly starting in September 2017 November – December 2017 May 2018
3 - Mechanism of change in context	Q1	How did participants interact with the intervention? How were observed changes generated? How were mechanisms of change influenced by contextual factors?	Perceived appropriateness and relevance Participants' understanding of change	Qualitative: case studies	As above	As above

4 -Context (health system)	Q2	What was the programme's scale-up strategy? To what extent did the programme align with the policy framework for newborn care improvement in Telangana? What was the feasibility of using the state health insurance scheme to scale-up the quality improvement collaborative approach?	Programme scale-up strategy and its implementation Relevance of the programme to the quality improvement landscape Incentives for quality improvement	Qualitative	Interviews with ACCESS staff, participatory workshop (see domain 1) and review of programme documents Mapping of key quality-focused initiatives in Telangana Interviews with key stakeholders in Telangana (Hospital leaders in case study hospitals, representatives of health authorities and insurance scheme, other major health programmes on quality of maternal and newborn care)	October – December 2017 July 2018 Updated: November 2020 July 2018

3.4 Evaluation timeline

Table 3-6 presents the timeline for the various components of the evaluation, against the programme implementation timeline.

Table 3- 6: Evaluation timeline

	Year										
	2015	2016	2017				2018				2019
			Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	
Safe Care Saving Lives implementation											
Wave I (25 hospitals)											
Wave II (29 hospitals)*											
Wave III (31 hospitals)**											
External evaluation											
Impact evaluation											
Baseline data collection		Jun-Aug									
Endline data collection									Aug-Sep	Oct	March
Process evaluation											
Review of programme implementation reports											
Interviews (case studies)							Mar	Apr-May		Nov-Dec	
Interviews (Scalability study)									Jul		

T= Telangana State; AP= Andhra Pradesh

*: 2 hospitals did not engage in the intervention; the number of hospitals involved declined to 24 in Q3, and 9 in Q4.

**: wave III was not implemented

3.5 Data collection and analysis for chapter 4

We used a theory of change to describe the intervention and its causal assumptions, following the approach outlined by Da Silva et al. and incorporated in the Medical Research Council's process evaluation framework (21). Here, I describe the methods used to develop the theory of change for Safe Care Saving Lives, following the reporting format proposed by Breuer et al. (33). Our working definition of a theory of change was a "theory of how and why an intervention works" (21): we aimed for the theory of change to provide a visual representation of the link between inputs (programme activities) and desired outcomes, i.e. improved adhered to evidence based practices, and impact i.e. reduction in facility-based newborn mortality and stillbirths. This approach was best suited to our evaluation for 4 key reasons: first, the intervention was complex, as explained above, involving several programme sites, participants and activities. When we started the evaluation, there had been high staff turnover within the implementing team, including in the programme leadership, and seemingly different understanding of intervention implementation by different members of the implementation team. The development of a theory of change was intended to shape a common understanding of the intervention between the

evaluation and the implementation team, and in turn build a good working relationship (21). Second, in the preliminary meetings with the donor and the implementing organisation, the intervention was presented through a very linear programme diagram, outlining the expected change through the well-established link between newborn care practices and newborn mortality reduction (Figure 3-5). This did not adequately articulate how the planned activities could improve adherence to newborn care practices. Safe Care Saving Lives also had a process diagram (Figure 3-6), however this did not articulate the connections between the drivers of change and the aim. Third, while the quality improvement collaboration approach used by Safe Care Saving Lives has a strong theoretical basis in the Breakthrough Collaborative approach (34), this was not explicit in the intervention narrative at first. Fourth, we believed the development of a theory of change would enable a deeper qualitative process evaluation, by helping identify missing links in the programme results chain or weak programme assumptions (35, 36).

Figure 3- 5: Safe Care Saving Lives original programme diagram

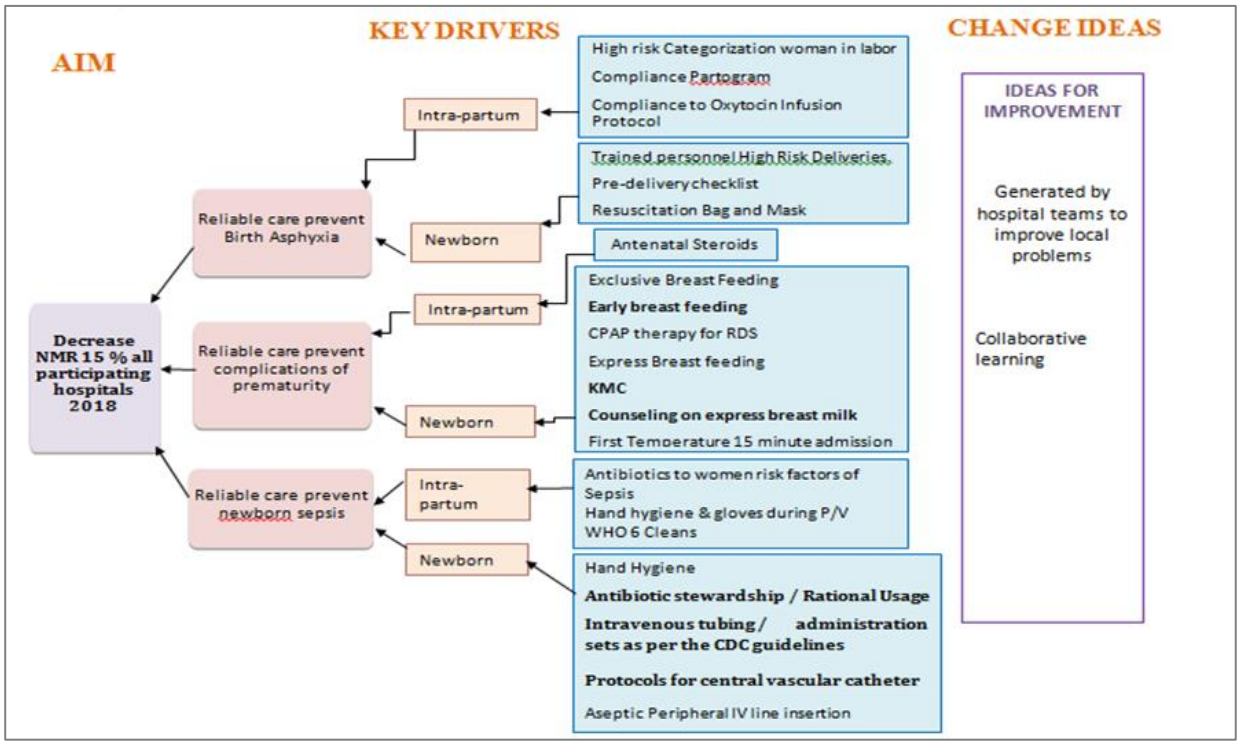
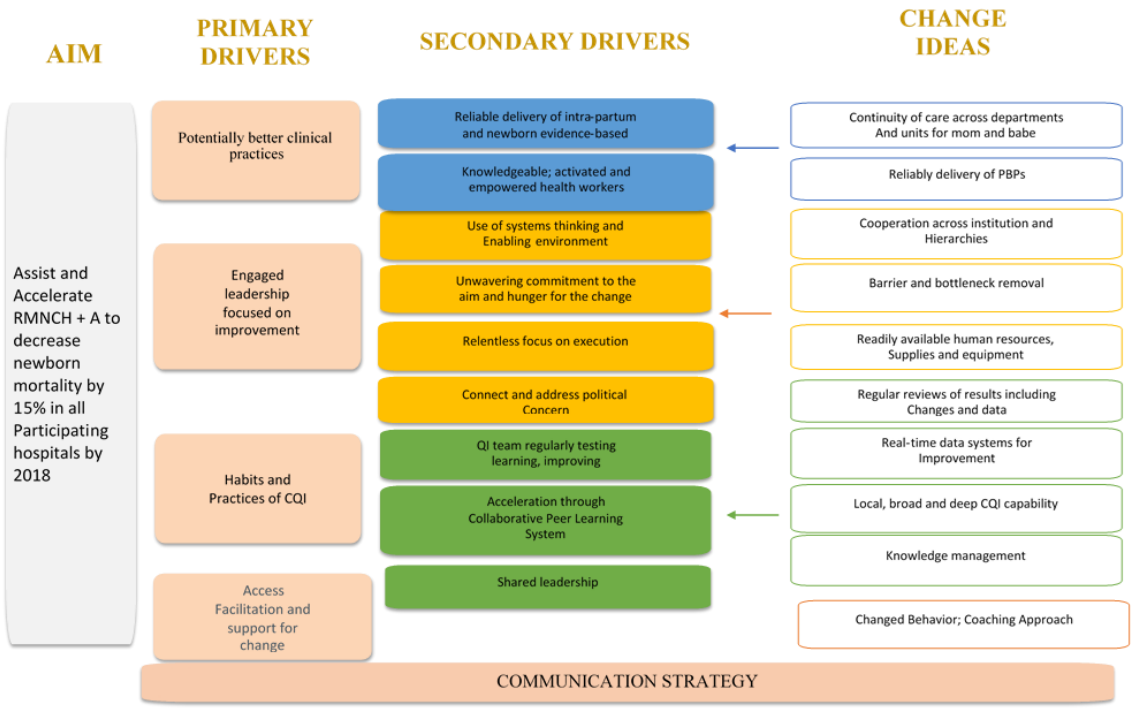


Figure 3- 6: Safe Care Saving Lives original process diagram



The process for developing the programme theory of change consisted of 6 steps.

Step 1 – literature review: between January and June 2017, I conducted a literature review on determinants of quality improvement collaborative success and mechanisms of change. The review, which was later updated and published as a systematic review (Chapter 2), was important to identify potential pathways through which the quality improvement collaborative intervention might influence the intermediate outcomes, and to surface important contextual assumptions for implementation of Safe Care Saving Lives, based on experience from other quality improvement collaboratives. Importantly, the review was not confined to low and middle-income settings, because while LMICs do present unique challenges for implementation, QICs are presented as an approach applicable universally (34), which originates and is widely used in high income settings. The literature review also helped to identify relevant social theories underpinning implementation of the QIC intervention.

***Step 2 – preliminary development of a theory of change*:** I reviewed the Safe Care Saving Lives programme drivers diagram (Figure 3-5) and process diagram (Figure 3-6) provided by ACCESS against the evidence emerging from the literature on contextual factors relevant to success and mechanisms of change. Through informal Skype discussions with the ACCESS leadership between July – October 2017, I developed a preliminary theory of change, offering a visual representation of our joint understanding of the intervention at that time.

Step 3 – participatory workshop: I organised a workshop in Hyderabad in October 2017, involving 25 participants, including all 19 staff of the ACCESS implementation team (including mentors, area supervisors, monitoring and evaluation staff, and the programme senior leadership) and the evaluation team. The workshop, which I co-facilitated with a Senior Researcher from the Public Health Foundation of India (PHFI), had three objectives: 1) to describe the intervention in detail; 2) to identify intended

changes and link planned activities to these; and 3) to identify and discuss programme assumptions. Participants worked in small groups, comprising of ACCESS staff of different seniority and evaluation team members. At that point in time, the intervention had been implemented for 6 months in wave II, therefore participants were encouraged to share their own views and experience of what the intervention was delivering, and contrast these with those of other colleagues or facilities. Participants were first asked to list activities conducted in individual hospitals in wave II, mini-collaboratives activities, and activities targeted at or involving the insurance schemes and health authorities responsible for quality of newborn care at district and state level. Then, they were asked to map the pathways of change from these activities to newborn care practice improvement, with prompts asking them to reflect on what changes were needed, by whom and how these changes were being supported. Finally, through individual reflections followed by a facilitated plenary discussion, participants discussed key contextual enablers and barriers to change; challenges to the way implementation was structured or resourced; the programme internal synergies (e.g. whether change at one level depended on change elsewhere in the results map), and the extent to which these were targeted coherently.

Step 4 – analysis and refinement: The workshop was recorded and all group work was documented through flip charts. I completed a write up of these shortly after the workshop, complemented by notes taken during the workshop. I used these notes to refine the preliminary theory of change: I developed a diagram for each of the levels of intervention (individual health facility, collaborative, and health system), and included all activities and anticipated mechanisms of change as described by programme implementers. This meant dropping some of the mechanisms of change that had emerged from the literature which did not appear relevant in this context, for example interprofessional collaboration and accountability.

Step 5 – validation and finalisation: validation involved follow-up discussions with ACCESS Director and Programme Team Lead over 2 months, and included 3 iterations on the theory of change diagram. Co-authorship of the protocol paper with members of the ACCESS implementation team helped strengthen ownership of the jointly developed theory of change, by ensuring consensus on the final product and accompanying narrative (1).

Step 6 - use of the theory of change: I used the final theory of change as an analytical framework for the process evaluation. It helped identify 4 theory-driven questions for the qualitative study, structure the analysis and present results (see Chapter 5).

A key strength of this evaluation approach was its participatory nature: the session was designed as a programme reflection opportunity using the principles of natural group discussions (37). Discussion in small groups during the workshop enabled constructive dialogue and reflection among intervention implementers, which helped shape a common understanding of what the intervention was actually delivering as opposed to what it ought to have delivered. For example, it became clear that remote coaching via Whatsapp was a more frequent activity than in-person mentoring, given the high number of hospitals and wide geographical areas covered by each mentor. It also became clear that activities to engage participating hospitals, such as meetings, correspondence and relationship building, were a key part of implementation, which mentors had spent considerable time on, but had not been captured in previous descriptions of the intervention.

Harnessing the interaction between team members highlighted conflicting or under-conceptualised change mechanisms or assumptions, as expected (38). For example, discussion on the planned activities

at the level of the health system was particularly important to bring clarity to the implementation strategy in relation to scale-up of quality improvement. From an evaluation perspective, it was important to let these discrepancies surface, because they helped identify untested assumptions, for example the expectation that the health insurance platform would play an active role in facilitating collaborative activities and sharing learning across participating hospitals. From the implementers' perspective, such group discussion can help clarify the programme direction, expectations and possible barriers – hence refine implementation strategies (39).

This approach also had limitations: first, it was time consuming and resource-intensive (40). We would have wanted to hold a final group discussion with the implementing team to present the refined theory of change, incorporating lessons learnt up to that point on the intervention, its implementation and the mechanisms of change. However, this conflicted with other implementation priorities. The lack of final feedback to the whole implementation team somewhat limited the value of the theory of change to implementers. The validation exercise only included two key senior members of the implementation team, which potentially closed off opportunities for further critical reflection. The process of developing a theory of change also did not include other stakeholders in the system. Emerging practice on this approach suggests that it is beneficial to triangulate views on what an intervention can and should attempt to change, validate assumptions and co-create an intervention that can suited to its context (41). In the case of Safe Care Saving Lives, this would have entailed engagement of those that were part of the programme design, as well as hospitals participating in wave I. This was not possible due to staff turnover, limited resources, and, crucially, the fact that the theory of change development was initiated by the evaluation team and not the implementation team.

3.6 Case study design

Case study selection was theory-driven: the hospitals were selected to test predictions of different results based on explicit hypothesis, in line with the *theoretical replication* proposition of case study research (42). Our theory of change hypothesised that improvement in adherence to evidence-based practices could be achieved through active engagement by QI teams, who would regularly test new ideas, learn and adapt, supported by an engaged leadership focused on improvement. Leadership engagement was also identified as a key determinant of QIC success in previous reviews (43). We further hypothesised that such engagement would be facilitated or constrained by external contextual factors, including, among others, staff workload. This was supported by our review of the programme in wave I, which identified time constraints as a key barrier to QI teams' engagement (44).

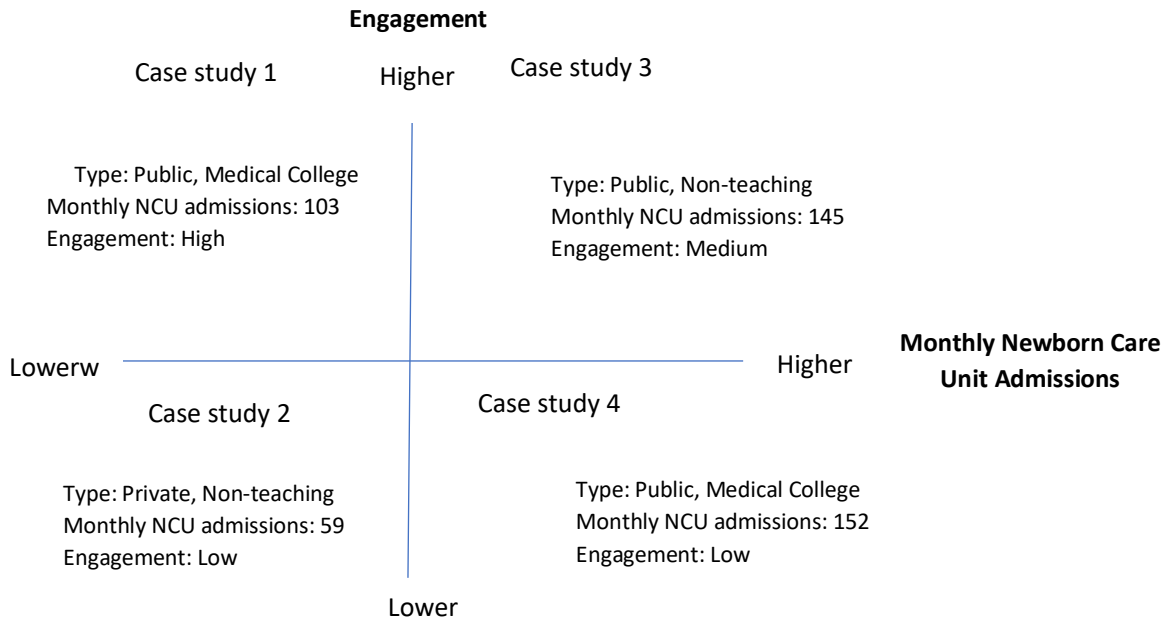
Therefore, two primary criteria were used to identify case study sites: (i) Admission load in newborn care units; and (ii) Facility engagement. We also wanted to achieve a balanced sample by facility type (public or private, and teaching status).

i. **Admission load** in newborn care units was chosen over admission in Labour room because all 23 consenting wave II facilities had a newborn care unit, while only 19 had a labour room. Admission load was determined based on the number of newborn care unit admissions per month, using data from the baseline facility assessments, with exceptions of 3 hospitals, for which baseline data was missing and monthly data from the Government Special Newborn Care Units database November 2016 – April 2017 was used instead.

ii. **Facility engagement** was a categorical indicator reported by mentors and used by ACCESS for programme monitoring. A category of high, medium or low engagement was assigned by mentors to each intervention hospital in late 2017, to inform strategic prioritisation of support following an Annual Review with the donor.

After this review, implementation was halted in 15 facilities, including all those in Andhra Pradesh, and only 9 wave II facilities in Telangana remained in our sampling frame, of which 2 had not consented to the evaluation. We selected the only private hospital and the only non-teaching public hospital remaining in the sampling frame; then the only hospital marked as high engagement, and out of the remaining 4 hospitals with low engagement, we selected the facility with highest caseload. Figure 3-7 provides an overview of the selected case studies.

Figure 3- 7: Case study matrix



3.7 Student's role in evaluation team and reflections on positionality

I joined the evaluation team as a PhD student in September 2016 when the team had just completed baseline data collection for the impact evaluation and a small review of implementation in wave I. I supported data analysis and reporting for the baseline report, later reworked as a paper (4). I led the design and implementation of the process evaluation throughout 2016-2018, with the support of the Principal Investigator and Lead Researcher from LSHTM (my two Supervisors) and the Research Lead from PHFI (my in-country Supervisor). I also led data analysis for both the impact and process evaluation in 2019-20. The research team also comprised a Research Coordinator based in PHFI for the entire duration of the project, and Research Assistants recruited by PHFI for quantitative and/or qualitative data collection. In terms of relationships with the implementing NGO, ACCESS, my main relationships were with the Programme Director, the Programme Lead and the M&E Officer through monthly calls as well as ad hoc meetings, such as in relation to the theory of change development. The Research Lead

and Coordinator from PHFI maintained day-to-day relationships with the ACCESS team, including mentors supporting the case study hospitals.

Positionality refers to the notion that a researcher's characteristics (including age, gender, socio-economic status, ethnicity, cultural and ideological background) can influence how research is framed, access to informants, quality of data collection and the way data is analysed (45-47). Reflecting on the researcher's standpoint is critical to promote decolonisation of health research(48), particularly in implementation research, by acknowledging the power imbalances that often exist within research teams, and between researchers and participants (49). It is also important to establish effective working relationships with implementation teams as external evaluators of an intervention, to achieve a quality evaluation (20); to ensure quality in qualitative research (46, 50), and to balance different epistemological traditions and disciplines to effectively integrate different evaluation components in mixed methods research (51, 52).

My being white, with a high level of education and my affiliation with a highly respected institution carried significant privilege and expectations. On the other hand, my lack of clinical training and my relatively junior position in the evaluation team hierarchy as a research degree student diminished my legitimacy as a credible interlocutor on technical matters of newborn care, particularly when interacting with senior hospital staff and hospital leaders. While at the time of fieldwork I had over 10 years' experience in implementing maternal and newborn care programmes, I had no prior experience of working in India. I was (and to some extent still are!) a complete outsider in this research context, with a major language barrier, not speaking either Hindi or Telugu, and I only had the opportunity to travel to the research sites over 3 short trips. Based on my experience elsewhere, I was conscious that these would be significant barriers in engaging research participants. My position is an external evaluation team, independent from programme implementers, further compounded these barriers.

For all these reasons, I have strongly felt that the most appropriate and effective approach to conducting this research, as well as the ethical and equitable way of doing it, was to build a strong relationship with research colleagues in PHFI, learn from and incorporate their perspectives throughout data collection, analysis and write up of the research, and support professional development of team members to the best of my ability, whenever relevant. I will further reflect on the implications of my position as a researcher in relation to the strengths and weaknesses of my work, in Chapter 7.

Quantitative data collection was undertaken entirely by Research Assistants recruited by PHFI. Their training at baseline was undertaken by my Supervisors from LSHTM and my in-country Supervisor. At the time of this, I was not part of the team. At endline, the training was held by PHFI, with minimal remote supervision. We shared results findings with participating hospitals: we developed summary fact sheets pertaining to each hospital capturing baseline data on infrastructure and human resources, as well as compliance with the focus newborn care practices, including comparisons with the State average. These were led by PHFI and very well received by hospital leaders. Final results unfortunately could not be disseminated as intended: analysis was completed in early 2020, when COVID-19 prevented dissemination and most importantly absorbed the bandwidth of the stakeholders we would have engaged in India. Therefore, dissemination was limited to an international online conference and a blog, which was circulated via PHFI and relevant professional networks, but it was not feasible or appropriate to conduct in-country events.

As for qualitative data collection, I planned interviews to be delivered by the most appropriate research team members, depending on the seniority of respondents. For example, interviews for the study on scalability were undertaken by the LSHTM Principal Investigator, and the LSHTM and PHFI Research Leads (i.e. my LSTHM Supervisors and in-country Supervisor). I was present for interviews in 2 hospitals in November 2018, during the second round of data collection. Although this was a small number of interviews, I believe this has enhanced, rather than reduced, the quality of data collection, because it may have helped interviewers create a stronger rapport with interviewees than would have been possible with a complete outsider like me, as well as enable the use of languages other than English to support their comfortable participation. I did however invest considerable time in building Research Assistants' skills, confidence and understanding of the qualitative data collection process, through a 3-day training in October 2017; use of daily diaries and reflection tools; weekly debriefing calls, and analysis discussions through the use of case study memos, all conducted remotely. The latter were particularly important to bring their perspective in the analytical process, thus neutralising the potential bias that may have come from my limited outsider's understanding of interactions in clinical teams in Indian hospitals. Finally, as well as using self-reflexivity and open dialogue as a strategy to equalise any power imbalance between myself, the research team and the respondents, the research approach stressed openness about the research agenda and activities undertaken, working around participants' work schedules and time constraints and explicit recognition of research participants' expertise and status (53).

Finally, my training prior to my PhD is in Public Health, and my background in social sciences. My field experience makes me very comfortable with perceiving and navigating complexity. The research team on the ground were mainly quantitative researchers, used to administering structured surveys and less versed in qualitative work. Explaining why Safe Care Saving Lives was and needed to be conceived and evaluated as a *complex public health intervention* required considerable effort. In this effort, I had huge support from my PhD Supervisors, both epidemiologists, who genuinely valued inter-disciplinary research and soon realised that the value of this study would have come not just from the results of the trial, but also (and perhaps more so) from its nested process evaluation, embracing the possibility of realist randomised controlled trials (32, 54-56). My professional experience in programme design and implementation in LMICs also meant I took a very pragmatic approach to the design, conduct and reporting of the process evaluation: for example, I engaged with theory, including realist evaluation principles, insofar as this was helpful to understand and improve implementation. The effective multi-disciplinary collaboration in our research team helped interpret quantitative and quantitative research findings in a truly complementary way (52).

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Chapter 4

Paper B – Safe Care Saving Lives Implementation strategy and theory of change

Webannex B from: Evaluation of the Safe Care, Saving Lives (SCSL) quality improvement collaborative for neonatal health in Telangana and Andhra Pradesh, India: a study protocol

This chapter addresses objective 1 of the study i.e. to develop a programme theory of change and, through this, describe the intervention. It presents results from the participatory development of the programme theory of change and outlines Safe Care Saving Lives implementation strategy. This chapter was published on 8th March 2019 in Global Health Action 12(1), as a webannex to the evaluation protocol paper. The manuscript was published under a Creative Commons License (CC BY 4.0) and the published webannex is included in full below. This is available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6419630/ (Annex B).

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4-3 Citation

Hanson C, Zamboni K, Prabhakar V, et al. Evaluation of the Safe Care, Saving Lives (SCSL) quality improvement collaborative for neonatal health in Telangana and Andhra Pradesh, India: a study protocol. Glob Health Action. 2019;12(1):1581466. doi:10.1080/16549716.2019.1581466

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed <u>for each</u> research paper included within a thesis.

SECTION A – Student Details

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First Name(s)	Karen		
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Thesis Title	Improving quality of newborn care at scale through quality improvement: evaluation of the Safe Care Saving Lives programme in Telangana and Andhra Pradesh, India.		
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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I led the conceptualisation of the process evaluation described in this paper, under the supervision of Dr. Claudia Hanson and the study PI, Prof. Joanna Schellenberg. I led the systematisation of the intervention description and the conceptualisation of the theory of change described in this paper, facilitating and coordinating input from all other authors. I co-facilitated the workshop on the theory of change with Dr Rajan Shukla, which the webannex presents in detail. I wrote the first draft of the manuscript with Dr Claudia Hanson, and contributed to the subsequent revision. I wrote webannex B (implementation strategy and theory of change) in its entirety after the participatory theory of change development workshop, with input from other authors.

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Webannex B - Safe Care Saving Lives Implementation strategy and theory of change

1. Background

Programme design and partnership arrangements

The Safe Care Saving Lives programme intervention was designed by Access Health International (hereafter ACCESS) in partnership with the Institute for Health Care improvement, modelled on the Project *5 Alive* in Ghana (2).

The programme was designed to respond to the need to improve quality of care and processes in special newborn care units, identified through an assessment of fourteen newborn care units in the former state of Andhra Pradesh, undertaken by the National Rural Health Mission Andhra Pradesh, UNICEF and the Commissioner Health and Family Welfare in 2011-12, with participation from ACCESS. The programme was designed following a previous collaborative quality improvement experience: in August 2014, ACCESS Health India, together with the Institute of Healthcare Improvement, brought together representatives from six of the best public and private neonatal intensive care units in India to develop and pilot a standard set of hospital processes to reduce the number of care driven infections among newborns. In this early "Indian Neonatal Collaborative", practitioners worked together to learn, implement, and scale up practices that reduce newborn deaths caused by infection (Unpublished).

The Safe Care Saving Lives programme was developed in partnership with the Rajiv Aarogyasri Health Care Trust. The Aarogyasri Health Insurance scheme is a unique community health insurance scheme that provides financial protection to families living below the poverty line for the treatment of serious ailments requiring hospitalization and surgery, including treatment of small and sick newborns. The scheme reimburses empanelled hospitals for the provision of services to eligible groups, and hospitals must meet six empanelment criteria relating to infrastructural setting in order to benefit from the scheme (3).

ACCESS signed a memorandum of understanding with the Rajiv Aarogyasri Health Care Trust in June 2014 with the aim to reduce perinatal and neonatal mortality by fifteen percent over a four-year period (2014-2018) in the 85 public and private sector neonatal care units empanelled with the Rajiv Aarogyasri Health Care Trust. Following the bifurcation of the former state of Andhra Pradesh in 2014, the Rajiv Aarogyasri Health Care Trust was split into the Aarogyasri Health Care Trust in Telangana and the Dr. Nandamuri Taraka Rama Rao (NTR) Vaidya Seva Trust in Andhra Pradesh in August 2015. This triggered the need to renegotiate partnership arrangements in the two states.

All public health facilities are directly managed and governed by the office of the Commissioner Health and Family Welfare and are supported under the national health mission, so a tripartite memorandum of understanding involving Aarogyasri Health Care Trust, ACCESS Health International, and the Commissioner Health and Family Welfare was signed in January 2017 in Telangana. In Andhra Pradesh, a memorandum of understanding was being developed at the time of writing.

Programme timeline and overview

Implementation was designed in 3 waves or phases including 85 hospitals in two states, jointly identified by Aarogyasri Health Care Trust (before the split) and ACCESS Health International:

- Wave I (2014 – 2016) involved two components: the identification of focus evidence-based practices by an Expert Faculty Group and development of the Quality Improvement Toolkit for participating hospitals (details under section 1 below), followed by implementation in 25 hospitals that volunteered to participate in the intervention. Hospitals were invited to attend a high-level project launch in August

2014, where leading clinicians in the field of Neonatology and Paediatrics from the Safe Care Saving Lives Expert Faculty Group presented evidence on the main drivers of newborn mortality and morbidity and potential improvements in care practices and processes to address them. Participating hospitals were also introduced to the quality improvement approach through success stories and invited to apply to participate in the Safe Care Saving Lives programme. The 25 initial hospitals were selected among 29 applicants following visits from the programme team to discuss the hospitals' motivation and review available care facilities based, on a self-assessment form (4). Wave I was a phase of programme refinement and adaptation, as is typical in phased implementation of quality improvement programmes (5). In 2016, the programme design was substantially revised to incorporate lessons learned and to allow renegotiation of institutional partnership agreements after the state bifurcation.

- Wave II, originally planned to start in December 2015, began in February 2017, involving 29 of the remaining 60 eligible hospitals, identified in partnership with State governments. However, two of the identified hospitals refused to participate, thus the intervention initiated in only 27. Wave II is the focus of this paper.
- Given delays on the original timetable for implementation, wave III, originally planned for 2017 and involving 31 hospitals, was planned for the second half of 2018.

The Safe Care Saving Lives initiative was based on the collaborative quality improvement approach developed by the Institute for Health Care Improvement in the Breakthrough Series Model (6). The approach is called a "collaborative" because teams from several hospitals work together in a structured way to improve a specific practice related to newborn care, and is defined by the following features (6-9):

a) A focused clinical subject (evidence-based practices for newborn mortality reduction)
b) Learning from experts in field of Obstetrics, Neonatology and Quality Improvement
c) Multi-professional teams from multiple hospitals participate
d) Teams use a structured approach for quality improvement (setting targets, collecting data and testing changes).
e) A series of learning sessions between hospitals

In its second wave (wave II), the programme was implemented at three interconnected levels:

1. At the level of individual participating hospitals, where hospitals implemented quality improvement activities in newborn care units and, if available, labour rooms (for details on hospital recruitment, see study population and randomisation sections of the protocol paper).
2. At the collaborative level, where groups of hospitals shared learning and experience of quality improvement
3. At the state health system level, where the programme engaged institutional stakeholders to promote and prioritise quality improvement.

The implementation strategy at each of these levels is described in detail below, followed by the programme support structure and theory of change. Although the programme approach at its core entailed a collaboration between different facilities, the implementation strategy is described starting from the individual hospital level, because this best represents the hospital engagement approach used by ACCESS Health International in wave II. While the original Breakthrough Collaborative model and the model used in wave I were top down (hospitals joining a collaborative, attending an initial group learning session and then beginning their own quality improvement activities), the approach used in wave II was bottom-up (hospitals engaged in quality improvement individually and then linked in collaborative efforts). Also the system-level component was added

after the wave I review, to complement and aid feasibility, effectiveness and sustainability of direct and collaborative quality improvement activities.

2. Improvement work – hospital level

The Model for Improvement approach

The intervention quality improvement approach is based on health facility teams working towards improved adherence to evidence-based practices (EBPs), that if optimally implemented have the potential to reduce newborn mortality and stillbirths. These practices targeted key drivers of newborn mortality and stillbirths (namely: complications of prematurity; newborn sepsis and birth asphyxia) through interventions during intra-partum and the early newborn care period. These were identified in early 2014 by an Expert Faculty Group, including over 35 local, national and international technical and clinical experts, and were collated into a guide for participating hospitals, referred to as a "Safe Care Saving Lives Quality Improvement Toolkit"(10). This Toolkit described the focus evidence-based practices, measurement indicators and audit tools, and included possible change ideas to test, based on successful experience elsewhere. The Safe Care Saving Lives Quality Improvement Toolkit was revisited at the end of wave I. The original Safe Care Saving Lives Quality Improvement Toolkit used in wave I hospitals detailed 15 evidence-based practices; another six practices were added and 1 dropped in March 2017, incorporating new evidence and experiences in implementing and testing the changes. The Safe Care Saving Lives Quality Improvement Toolkit used in wave II included 20 EBPs, organised in "bundles", each of which was a combination of two or more EBPs to address a focus area such as sepsis, prematurity and birth asphyxia.

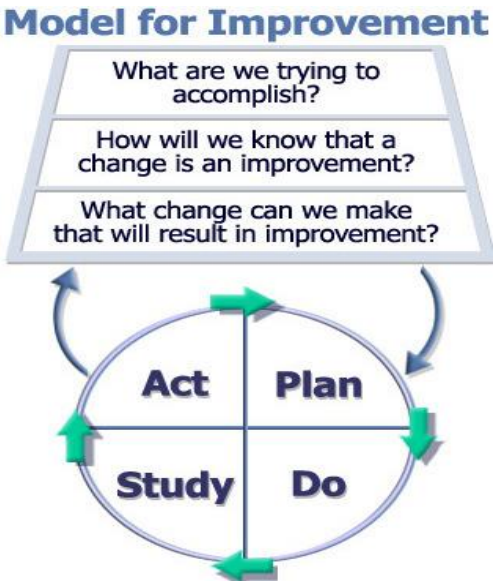
Table 1 provides an overview of the evidence-based practices targeted by the intervention.

Table 1 – Description of evidence-based practices by bundle

	Sepsis bundle	**Prematurity bundle**	**Asphyxia bundle**
Practices promoted in labour rooms	• Antibiotics to women at risk of sepsis • Hand hygiene & gloves during per-vaginal examination • WHO 6 cleans	• Ante-natal steroids • Early breastfeeding	• High risk categorization of woman in labour • Trained personnel for high risk delivery • Compliance with partogram • Pre-delivery checklist • Compliance with oxytocin infusion protocol • Resuscitation with bag and mask
Practices promoted in neonatal care units	• Hand hygiene • Rational usage of antibiotics • Intravenous tubing • Protocol for central vascular catheter • Aseptic Peripheral IV line insertion	• First temperature in 15 minutes from admission • Exclusive breastfeeding • Kangaroo Mother Care	• CPAP in preterm neonates with respiratory distress
Total no. practices	**8**	**5**	**7**

The intervention involved the formation of Quality Improvement (QI) teams in labour / delivery rooms and Special Newborn Care Units / Neonatal Intensive Care Units of participating hospitals. QI teams were formed of health care workers from the target units, supported by ACCESS staff (see section 2 below) to implement quality improvement activities, and develop a problem-solving approach towards the adoption of selected evidence-based practices.

Figure 1. Model for Improvement (1)



The programme used the continuous quality improvement approach developed by Langley et al. and adapted from the automobile industry to health care organisations, known as the "Model for Improvement", shown in Figure 1 (1). The approach hinges on a cycle of setting an aim for improvement; agreeing progress measures; identifying a suitable innovation (change); and continuous testing and refinement of changes through collection and review of data, to measure progress towards the desired aim, in cycles known as Plan-Do-Study-Act (1, 6).

The Model for Improvement shares with other quality improvement approaches the focus on continuous quality improvement, but it has a distinctive theoretical underpinning in Deming's system of profound knowledge, or the interplay of theories of systems, knowledge, variation and psychology (1).

- In line with systems theory, the approach assumes interdependence in a system, and therefore emphasises the monitoring of unintended consequences of change through so-called "balancing measures". Importantly, the approach also posits that "every system is perfectly designed to deliver the results it produces" (1)(p.79), therefore fundamental change is required to improve performance in the long-term.
- The approach emphasises that knowledge is built through an iterative deductive and inductive approach. The identification of change ideas (Plan phase) is based on a prediction on the effect of the introduction of the change. The better the knowledge of the system in which the change is being introduced, the more accurate the prediction can be. The planning phase is essentially about articulating a theory about how change will happen, and putting it to the test through the Do phase (deductive knowledge building). Once the test on a small scale is completed, in the Study and Act phases, data is used to either refine, discard or adopt the idea, and refine hypotheses about the system's response to change (inductive knowledge building) (6).
- The approach is data-driven, and relies on longitudinal analysis to detect variation over time. Quality improvement efforts are supported by collection of data against relevant measures, and these are regularly plotted in run-charts, and analysed to estimate the effect of introduced changes, and to determine the necessary course of action.
- The approach emphasises that specific strategies altering permanent support structures are required to promote the implementation (adoption) of a change idea that has proven effective in the testing phase, for example redesigning job descriptions, or providing in-service training systematically. This will mean that the change gradually involves larger groups of people, hence the need to focus on both individual and collective psychology when introducing changes. The approach draws from theories of behaviour change, and stresses the importance of understanding team members' intrinsic and extrinsic motivation, and of anticipating and dealing with resistance with appropriate communication strategies.

It is important to note that, although this quality improvement approach has explicit key principles, one of its distinctive feature is adaptability. The Model for Improvement is rather a problem-solving approach, a mindset more than a set of tools (11).

The use of the Model for Improvement in a collaborative programme also has another important distinctive feature. In a continuous quality improvement approach used in individual health settings, teams choose their own issues of focus, and spend time identifying problems, causes, and solutions, which may or may not draw on evidence about effective interventions in the focus area (6). In a collaborative approach, this evidence is already condensed in the "Safe Care Saving Lives Quality Improvement Toolkit", and topics for improvement are identified from a pre-identified set of practices that are known to reduce a specific driver of newborn mortality. As a result, the diagnosis time is shortened, and hospitals are encouraged, though not obliged, to test innovation and ideas that have already proven effective in a similar context (7, 12).

Engagement of participating hospitals

Prior to starting implementation of improvement activities, ACCESS staff (mentors) raised awareness of the hospital leadership on the importance and opportunities for quality improvement in newborn care, and actively sought their engagement and buy-in to the programme. This was described as a "sensitisation" phase, consisting of multiple face-to-face visits and communications, primarily with the Medical Superintendent and Head of Departments (newborn care unit and Labour Room). In this phase, the hospital leadership was introduced to the programme, the expected outcomes, and given an overview of the quality improvement approach. This phase lasted 1 – 4 months, or longer, depending on the leadership's interest and response.

Quality Improvement teams and their composition

Following a positive response from hospital leadership, mentors facilitated the formation QI teams in the target departments, generally 2 teams per hospital. Doctors, nurses, and data entry operator were invited for the first orientation / sensitization session, during which the department leadership nominates specific health workers to be part of the QI Team, based on their involvement in the newborn care unit or labour room, and his or her interest in the quality improvement initiative.

The teams generally comprised 4-5 clinical and administrative staff from each Department. These could include: 2 doctors (Paediatrician/Obstetricians), 1-2 resident doctors (in case of teaching hospitals) and 2-3 nurses per department. Where feasible, the Head of Hospital Administration and a data entry operator from the newborn care unit were also included. The structure of the QI teams was not fixed, but flexible depending on the availability and interest of the staff.

Quality improvement activities implemented by Quality Improvement teams

Gap analysis

ACCESS mentors conducted gap analysis using two checklists (for labour room and SNCU) to assess infrastructure, equipment, human resources, protocols and processes, and records maintenance. They summarised the identified gaps, and the level at which these could be solved. Access mentors shared the results with the hospital leadership and discussed major gaps and clinical priorities. ACCESS mentors worked with the hospital QI team on further problem analysis and identification of priority areas.

Identification of priority areas of focus

Mentors facilitated the initial baseline data collection from clinical data in order to build a historical trend on admission rates, newborn mortality, and respective causes, based on the previous 12 months. Mentors undertook the initial analysis and presented it back to QI teams, as well as provided an initial introduction to

the Model for Improvement for the QI teams. Based on this, a priority issue for improvement was selected among the main drivers of mortality (sepsis, prematurity or asphyxia), and 1 or 2 EBPs contributing to reduction of that driver of mortality are prioritised per hospital. Targets for improvement were set at >80% coverage, based on the expectation that coverage of EBPs at scale be required to impact on mortality.

Once the focus area (sepsis, asphyxia, prematurity) was identified and the team had decided on which EBPs they wanted to start, mentors provided training and coaching to QI team members to use the Model for Improvement approach. They facilitated QI teams' analysis of causes of poor adherence to the focus practice, using tools such as process mapping, root cause analysis and bottleneck analysis.

Generation of change ideas

The QI team brainstormed on "change ideas", or innovative practices that could potentially improve the adherence to the identified evidence-based practice. Change ideas were identified by the team themselves or the team used one of the change ideas already used in other hospitals. Based on the learning from the quality improvement work in wave I, ACCESS developed a change package which included a list of change ideas that were tested and adopted. As explained above, the rationale for introducing change ideas selected from the "change package" was that it may shorten the time required by teams to identify solutions, promoting diffusion of innovation among hospitals, and therefore accelerating the achievement of results.

Table 2 describes examples of change ideas relevant to each EBP.

Table 2: Change ideas for evidence-based practices

EBP	Change idea
MANAGEMENT OF SEPSIS	
Ensure appropriate use of Antibiotics	− Follow a unit level policy on antibiotic use − Adopt the All India Institute of Medical Sciences sepsis management algorithm for antibiotic administration − Every SNCU/NICU must have its own antibiotic policy based on the culture and antibiotic sensitivity report from a reliable laboratory − Multidisciplinary team − Assess the baseline adherence to appropriate antibiotic administration − Audit of case sheets/drug consumption − Ensure supply of antibiotics is in consonance with the unit's antibiotic policy − Antibiotic stewardship – permission of consultant if deviations from policy are necessary
Ensure Per Vaginal examination is conducted correctly in the Labor room	− Ensure continuous availability of running water and gloves of all sizes − Train all the labor room staff on sterile Per Vaginal examination − Assign responsibility to specific nurses to perform the Per Vaginal examination − Limit the number of Per Vaginal examinations to three for women in labor − Display 'Steps of sterile Per Vaginal examination' poster in the Labor Room
WHO 6 cleans	− Protocol dissemination − Audit
Ensure compliance with optimal hand hygiene practices among all staff in the SNCU / NICU	− Install elbow operated taps in front of the NICU AND Install hand dryers to wipe wet hands − Introduce alcohol based hand rub at every bed − Reorient and train the staff on correct steps for hand washing − Use autoclaved newspaper to wipe wet hands − Keep 'Hand washing register' at the entry of NICU − Stick 'Hand wash reminder' poster on warmer

	– Floor taping in red color at the entrance of newborn area – Conduct regular audits using video recordings at NICU
Ensure compliance to Aseptic Non Touch Technique (ANTT) during Peripheral Intravenous line insertion	– Delegate two nurses to perform the intravenous cannulation procedure – Keep a dedicated autoclaved trolley set for intravenous Cannulation procedure – Ensure adequate availability of peripheral intravenous insertion kits in the crash carts. – Sensitize the staff – Modify step four of Aseptic Non Touch Technique from cleaning of the trolley surface to spreading the autoclaved cloth of sterile set on trolley surface – Flip the cover of the kidney tray to place the equipment used for intravenous cannulation. – Display 'Nine steps of Aseptic Non Touch Technique' poster in the unit – Conduct of cross audit by the medical officer apart from nurses
Antibiotics to neonates born to mother with risk factors for sepsis	– Protocol dissemination – Audit
Prevent ventilator associated Pneumonia	– Protocol dissemination – Audit
MANAGEMENT OF PREMATURITY COMPLICATION	
Ante-natal steroids	– New format to capture details of administration of Ante-natal corticosteroids – Use ultrasound scan to assess the gestational age of pregnant women arriving with complaints of labor pains – Protocol dissemination – Audit
Early breastfeeding Exclusive breastfeeding Counselling on expressing breast milk	– New format for recording Expressed Breast Milk – Ensure counseling is given properly – Distribute the work among the team instead of relying on one person. – Protocol dissemination – Audit – Ensure privacy – Demonstration (milk expression and feeding)
Take the first temperature of all babies in the Neonatal Care Units within fifteen minutes of admission	– New format for recording the baby's temperature – Designated triage in the Casualty – Monitor the temperature of the Labor Room – Record temperature and time of measurement of the newborn inside Labor Room on the case sheet – Leave warmer switched on for ten to fifteen minutes before shifting the baby – Note first temperature within fifteen minutes in the designated triage area of Neonatal Intensive Care Unit – Record temperature at first point of contact-ambulance/casualty. Note the referral point and mode of transportation of babies coming to Neonatal Intensive-Care Unit in outborn cases; Use transport incubator – Ensure correct temperature in preparation for resuscitation/before transport – Cover baby – Protocol dissemination – Audit

Continuous Positive Airway Pressure (CPAP) therapy for Respiratory Distress Syndrome	– Policy for early initiation of CPAP (preferably in the labor room) and continuation of the same (depending on the clinical indications) – Ensure availability of CPAP with tubings – Protocol for referral of babies who have deteriorated on CPAP/for those who need advanced ventilation. – Protocol dissemination – Audit
Kangaroo Mother Care	– Protocol dissemination – Ensure privacy of mother by creating a dedicated clean and private area Provision of gowns or KMC bags in the unit – Proper demonstration of the correct method of KMC – Videos & Posters as reminders – Frequent assessment of the knowledge and skills of the care givers (e.g. nursing staff) pertaining to KMC – Encourage mothers to interact/counsel one another – Encouraging fathers to provide KMC in the hospital – Establish dedicated phone line at the facility for answering the queries of the mothers post discharge – Home visits by the nursing staff/ care givers to ensure the practice of domiciliary KMC
Management of Birth Asphyxia	
High risk categorization of woman in labour	– Protocol dissemination – Audit – Use Government of India, Dakshata, Maternal and Newborn Health checklist for categorizing high risk cases. – Sensitize Labor Room nurses on categorization of high risk mothers – Use a "flower" sign / High risk stamp / 'High risk' label with red pen to mark all the high risk women case sheets. – Reorient the staff periodically on Maternal and Fetal risk factors – Write the high risk cases on a black board inside the Obstetrics & Gynaecology department. – Arrange an alarm bell in Labor Room & Operation Theatre to 'connect' Sick Newborn Care Unit. – Establish a communication linkage between both Obs (Labor Room) and Sick Newborn Care Unit (Pediatrics). Use a mobile phone to call the Duty medical officer. – Track the outcome of women till delivery, to determine if delivery is normal or Caesarean section, and the condition of baby – Keep separate register for noting High risk cases with their condition. – Put up a chart to capture data on High risk Cases on a daily basis. – Stick high risk conditions poster in the Labor Room for reminding the nurses
Compliance with partogram	– Protocol dissemination – Audit – Ensure availability of partograph sheets in the Labor Room. – Conduct a training session for post graduate trainees on filling/documenting partograph. – Delegate training responsibility to two Skilled Birth Assistants to train the other staff. – Train all nurses on partograph sheet at the beginning of every month. – Periodic retraining schedule for the new staff on rotation to Labor Room.

	− Fill the essential components of partograph − Attach the Partograph sheet within the case sheet to ensure it is filled during the course of labor − Post Dakshata trained staff nurses in the morning and afternoon shift. − Post at least one nurse trained in Skilled Birth Assistance in each shift or post senior most staff on duty. − Create a WhatsApp group with the staff to ensure that partograph data is captured real time. − Include the partograph data in the daily duty statistics of Labor Room Medical Officer register. − Ensure that a gynecologist is present at all times and that surprise visits are conducted by the Head of Department. − Ensure partograph sheet is filled by duty Doctors. − Monthly review by Head of the unit.
Compliance with oxytocin infusion protocol	− Protocol dissemination − Training − Audit
Trained personnel for high risk delivery	− Protocol dissemination − Audit − Stick the contact details of the Duty Medical Officer in NICU. Use mobile for calling. − Ensure that all resuscitation equipment are available when the SNCU staff attend the case. − Retrain all the SNCU staff in Newborn Resuscitation Protocol protocols if sufficient staff available, else, train Labor Room staff. − Train more staff in Newborn Resuscitation Protocol. − Swap one staff between the Gynecology and Pediatrics department − Nurses trained in Newborn Resuscitation Protocol are resourceful during high risk deliveries. − Swap the staff for a limited period of a time for on job training of Labor Room staff. − Post SNCU staff in labor wards on a rotation basis. − Fix Labor Room postings of Newborn Resuscitation Protocol trained staff. − Note the time difference between call by nurse and arrival of pediatrician in high risk register. − Capture the number of high risk cases attended in the pediatric department.
Pre-delivery checklist	− Checklist adaptation/tailoring − Training − Test preferred mode of checklist dissemination (paper-based, laminated, visual in labour room) − Audit availability of items in the checklist − Audit checklist use
Resuscitation with bag and mask	− Protocol dissemination − Training − Improve team work through teamwork assessment scales

Use of Plan-Do-Study-Act cycles

QI teams were supported to use a structured cycle for quality improvement activities, or Plan-Do-Study-Act (PDSA) cycle, (as suggested by the Model for Improvement outlined above), to understand whether change ideas result in improvement. Each cycle includes four stages:

Plan - planning the introduction of a change idea in the QI team, and gaining support for it from the head of Department and hospital leadership.

Do – implementing the change. Specific QI team members were tasked with the introduction of the change idea, and other clinical staff from the Department could be asked to support this improvement work on an ad hoc basis.

Study – regular audit and review of results to study whether the change had resulted in improvement in a given context. This was led by members of the QI team, and involved tracking selected indicators on a regular basis (daily / weekly/ fortnightly).

Act–taking a decision on the basis of the "study" results. This could include adoption of the change idea, i.e. a decision to continue with it and integrate it in clinical practice; adaptation of the change idea, for example modifying some aspects to ensure a better fit with the hospital setting; discard or abandon the change idea.

It should be noted that the approach was not necessarily sequential, but was logically structured. For example, the cycle could start from the Study component, or the planning phase could be shortened if change ideas are simple. Decisions (under the Act part of the cycle) could entail further testing (adaptation) in which case the cycle was repeated. Multiple cycles were generally required, both to refine and adapt the change idea to the individual setting, and to ensure change ideas build on each other, and over time to address the multiple root causes identified.

Mentors coached QI teams to use the Model for Improvement approach, without using jargon such as PDSA cycles. The programme aimed for QI teams to become competent in using a structured method for identifying and responding to barriers to the adoption of an EBP.

Table 3 provides an overview of wave II progress in implementing QI activities in the first three quarters of the intervention.

Table 3 – Implementation description

	Quarter 1 (April – June 2017)	Quarter 2 (July – Sept 2017)	Quarter3 (Oct- Dec 2017)
Uptake of EBPs			
Total no. EBPs started (across all hospitals)	17	50	23
– Sepsis package	5	17	4
– Prematurity package	8	24	17
– Asphyxia package	3	9	2
– Vitamin K administration	1	0	0
Implementation of QI activities			
Total no. change ideas tested	27	132	52
– Sepsis package	8	56	9
– Prematurity package	12	56	32
– Asphyxia package	7	20	11
Average no. PDSA cycles used for change idea by package			
– Sepsis package	1.0 (8/8)	1.2 (68/56)	1.3 (12/9)
– Prematurity package	1.4 (17/12)	1.4 (79/56)	1.1 (36/32)
– Asphyxia package	1.0 (7/7)	1.0 (20/20)	1.3 (14/11)
Support to QI teams			
Total no. mentor-facility contact	72	142	105
Average no. of mentor-facility contact per hospital	4.2 (72/17)	5.9 (142/24)	5.8 (105/18)
No. hospitals with at least one quarterly contact with mentor	15	23	16
Focus of mentor-QI team contact			
No. hospitals receiving QI-related training	15	21	17
No. of hospitals receiving clinical or protocol-related training relevant to EBP of focus	4	11	10
No. of hospitals receiving other type of support/facilitation (e.g. equipment or infrastructure related or posters)	3	10	10
Remarks	2 hospitals dropped early not included in this data. Info not recorded for 10 hospitals. Info available for N=17	2 hospitals dropped early not included in this data. Info not recorded for 3 hospitals. Info available for N=24	2 hospitals dropped early not included in this data. Additional 3 hospitals dropped. Info not recorded for 6 hospitals. Info available for N=18

3. Support structure and delivery

ACCESS supported participating hospitals through mentors, who were generally public health professionals specifically recruited for this role, trained on the quality improvement methodology. At the beginning of wave I, nine ACCESS mentors attended a 2-day training on the Model for Improvement approach, delivered by the Institute for Healthcare Improvement (IHI), of which, at the end of 2017 three were working as mentors, other staff having been lost due to attrition. Team members recruited later in the programme life attended online training on the Model for Improvement through the IHI Open School (13), complemented by in-house training delivered by the Programme Manager.

Each hospital was supported by a Quality Improvement (QI) Mentor and a Senior Associate or Quality Improvement (QI) Lead. Mentors mostly had 2-5 years experience after post-graduate studies, and generally less than two years of experience in quality improvement. Senior Associates or QI Leads were more experienced mentors, as summarised in table 4 below. A programme organogram is provided in figure 2.

Table 4 – Overview of ACCESS team

Function	Role	No. staff	No. staff with clinical background	No. staff trained in QI	No. staff trained in QI by IHI	Years of experience (mean)	Years of experience in QI (mean)
Hospital mentors	Quality Associate	6	0	5	5	2-4 (2.5)	≤ 2 years (1.1)
	Quality Lead/Senior Quality Associate	6	1	5	3	4 - 9.5 (6)	0.75 - 9.5 (4)
QI Cell staff	Quality Advisor/Data Analyst	2	1	1	1	12-14 (13)	0 - 0.5 (0.25)
AHI Management	Director QPI/Program Manager/M&E Lead	3	2	2	1	9 -15 (12)	1-5 (2.7)
Other	Other consultants	3	0	2	0	2.5 - 4 (3)	0 - 3 (1.8)

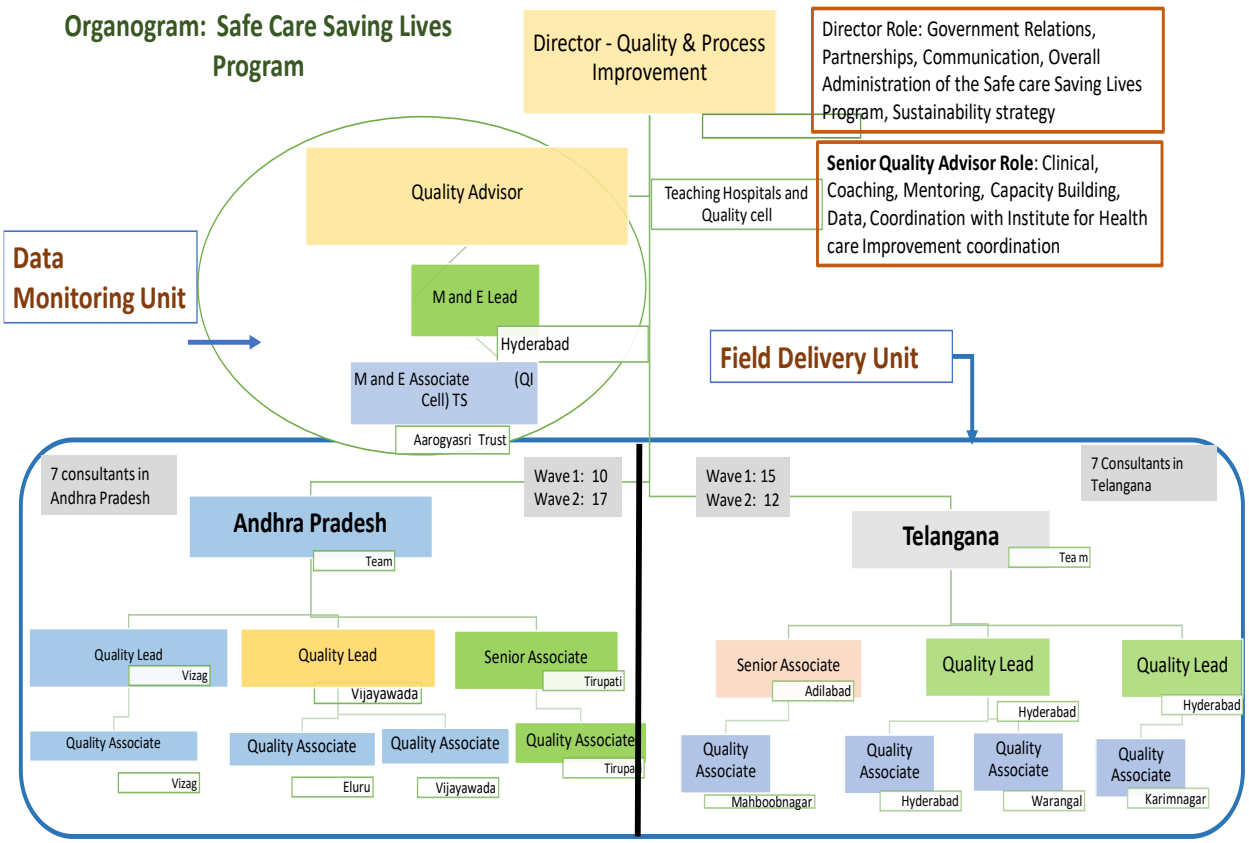
The Quality Improvement (QI) Associate was primarily responsible for capacity building, technical support, coaching and follow up to QI teams, and the senior member (Senior QI Associate or QI Lead) complemented the technical support provided by the QI Associate, and worked with the hospital leadership to facilitate the removal of bottlenecks to quality improvement and the adoption of EBPs. QI Leads were responsible for 1-3 QI Associates who in turn mentored 3-5 hospitals. In addition to supporting activities with individual hospitals, they conducted baseline and regular aggregate data analysis to identify common challenges, and opportunities for collaborative learning. They facilitated learning sessions, with support from the relevant QI Associate, and were responsible for disseminating success stories and lessons learnt.

An indicative list of mentors' activities with participating hospitals is below:

- Sensitisation and engagement of hospital leadership
- Identify and nurture QI champions
- Facilitate formation of QI teams
- Facilitation of gap analysis and identification of aim for improvement

- Capacity building on quality improvement methodology (planning and conducting trainings, sharing knowledge)
- Support to ongoing data management and analysis
- Mentoring and coaching through regular visits to hospital
- Regular contact and follow up with QI teams and leadership (whatsapp, phone)
- Support to implementation of change ideas, for example:
  - Support to resource mobilization (facilitating infrastructural changes)
  - Facilitation of clinical training (if requested by the QI team as one of their change ideas)
  - Facilitating internal coordination (e.g. between various cadres; between frontline, physicians and administration; between labour Room and neonatal care units) and externally (e.g. with district health authorities)
- Organize, support and follow up from mini-collaborative learning sessions
- Disseminate success stories and lessons learnt.

Figure 2: Organogram



In addition to the facility QI teams and hospital leadership, the programme engaged with the Aarogyasri Health Care Trust, with a QI Advisor and Data Analyst seconded to the Aarogyasri Health Care Trust QI Cell, and ongoing interaction between ACCESS mentors/Leads and the hospital Medco (a medical doctor responsible for the implementation of the Aarogyasri scheme in the facility).

At senior level, the team also included ACCESS Quality and Process Improvement Director, who led on activities at state level and reported to ACCESS headquarters. The programme engaged the formal structure for Quality

Assurance under the National Health Mission at state and district level. It comprised of the State Quality Assurance Committee (where ACCESS is represented by the Quality and Process Improvement Director) and District Quality Assurance Committees, where ACCESS – represented by Senior QI Associates – interfaced with District Quality Assurance Managers. ACCESS core team also included a Program Manager and Monitoring and Evaluation Advisor.

4. Collaborative platform

In addition to mentoring and coaching of individual hospitals, the "Breakthrough collaborative approach" entails collaborative activities between hospitals working on similar evidence-based practices (6). In the Safe Care Saving Lives programme, the quality improvement collaborative was based on the Government-sponsored health insurance platform (i.e. the Aarogyasri Health Care Trust in Telangana and Dr NTR Vaidya Sewa in Andhra Pradesh), engaging hospitals that were empanelled in this scheme and that shared a common aim for improvement of newborn care. Hence, unlike other collaboratives, participation was not voluntary (6, 12). The health insurance platform was used to justify the engagement phase (sensitisation) described above, as well as the strategies to promote hospital leadership's engagement through system-level interventions.

In the Breakthrough Collaborative approach, QI teams from participating hospitals work together over a specific timeframe (often 9-12 months) to learn about quality improvement methods, and exchange ideas and success stories during so-called learning sessions. Participating hospitals usually attend 3-4 face-to-face or virtual sessions over the course of the collaborative timeframe. Between these learning sessions, each hospital introduces and tests changes in their own setting (using the Model for Improvement approach described in sections 1), supported through regular coaching and mentoring.

The Safe Care Saving Lives programme promoted open ended collaboration between participating hospitals, initially facilitating linkages and communication for the duration of the programme implementation. ACCESS organised collaborative learning sessions, by identifying common challenges or priorities for improvement based on baseline and regular data collection; by nurturing champions and QI teams to share their work and be open to learning from other participating hospitals; and by documenting and disseminating success stories and lessons learned through the Aarogyasri Health Care Trust website. The Breakthrough Collaborative model entailing large learning sessions was used in wave I and found to be ineffective given logistic challenges and time requirements to convene large gathering across two States. Therefore, in wave II, the programme formed regional (mini-) collaborative jointly with wave I facilities, mostly consisting of a main referral hospital with its referring facilities. Mini-collaborative learning sessions involved hospitals in each regional collaborative that were working on the same evidence-based practice, and a good performing wave I hospital also participated as a model. These learning sessions could be held face-to-face or virtually. The programme envisaged the health insurance network taking over the facilitation and coordination of collaborative learning sessions at the end of the intervention in each State. Table 5 summarises the implementation of mini-collaborative activities in the first 3 quarters of the wave II.

Table 5 – Implementation of mini-collaborative activities

	Quarter 1 (April – June 2017)	Quarter 2 (July – Sept 2017)	Quarter3 (Oct- Dec 2017)
Support to mini-collaborative			
No. mini-collaborative learning sessions conducted	4	3	4
No. wave II hospitals attending a mini-collaborative learning session	4	3	2

5. Intervention at the health system level

The Safe Care Saving Lives programme also aimed to strengthen capabilities and the policy framework for scale up of continuous quality improvement at state level. There were two streams of support:

- Support to government sponsored health insurance trusts
- Support to state and district level health authorities

Engagement with the Aarogyasri Health Care Trust originated from the assumption that a health insurance trust would be interested in improving quality of care to reduce costs.

The tripartite agreement between ACCESS, the Aarogyasri Health Care Trust and Ministry of Health and Family Welfare in Telangana, mentioned in the background, committed Aarogyasri Health Care Trust to institutionalising a Quality Improvement (QI) Cell, as a technical and advocacy unit for quality improvement within the Aarogyasri Health Care Trust. The QI Cell was meant to strengthen Aarogyasri Health Care Trust's capacity for quality control to support empanelled hospitals' quality improvement efforts. It also provided a data analysis function to stress the case for investment in quality improvement as a strategy for effective and efficient care. ACCESS supported the formation of a QI Cell in Aarogyasri Health Care Trust through the secondment of a Data Analyst and a Quality Improvement (QI) Technical Advisor, on the understanding that these positions will be absorbed into the Aarogyasri Health Care Trust structure at the end of the programme. ACCESS staff in the QI Cell worked towards strengthening Aarogyasri Health Care Trust capacity, and towards developing an incentive system to link Aarogyasri Health Care Trust payments to quality improvement measures. The QI Cell planned to meet monthly, with attendance at senior level in the signatory parties, thus providing a regular quality control function. ACCESS conducted data analysis on claims filed with Aarogyasri Health Care Trust; provided capacity building to Aarogyasri Health Care Trust counterparts for quality improvement mentoring and monitoring; disseminated success stories and lessons learned through the Aarogyasri Health Care Trust website; and provided technical support to the development of the quality improvement incentive package. The support provided to Aarogyasri Health Care Trust focused on building capacity for quality improvement broadly, not restricted to newborn care, and the development of incentives incorporated all the insurance packages of Aarogyasri Health Care Trust, where newborn care is a very small component.

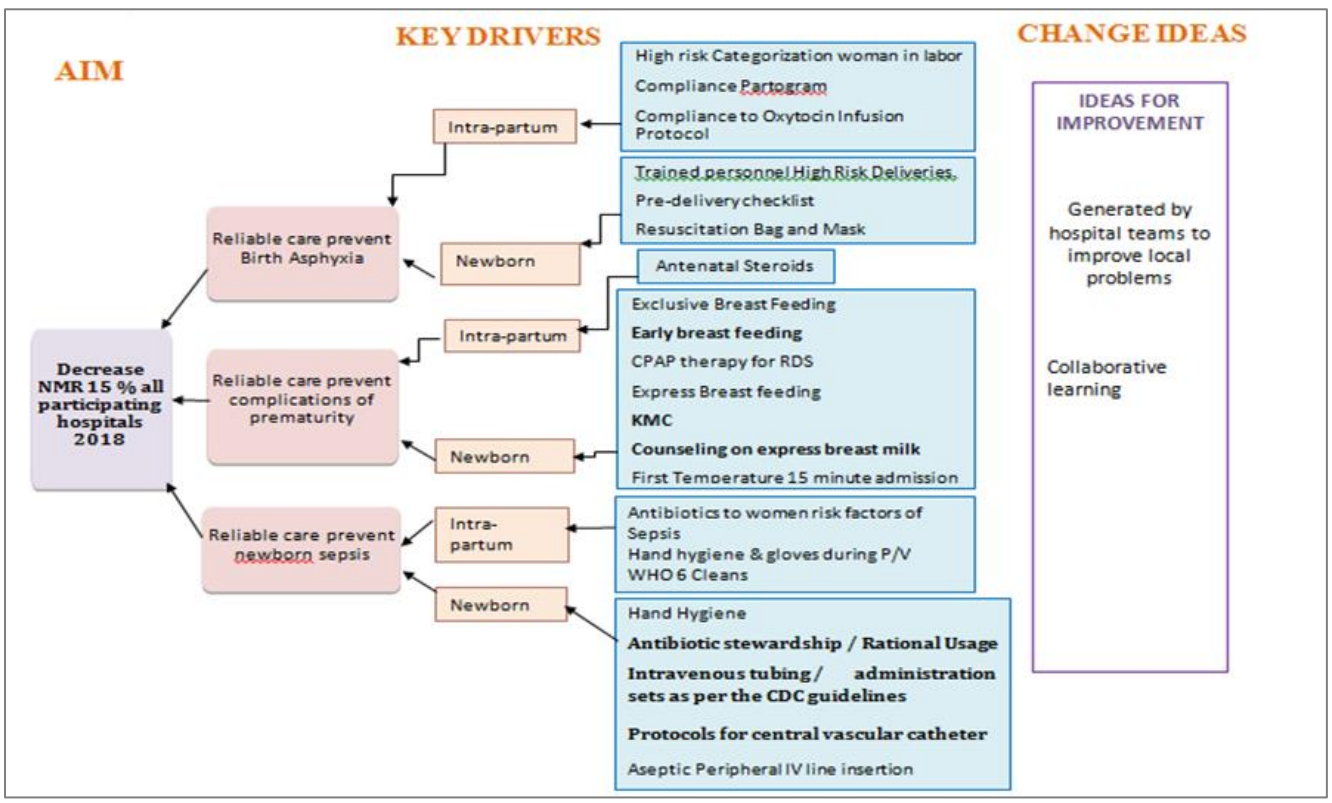
In relation to government health authorities, the programme aimed to build capacity in the State Quality Assurance Committee (SQAC) and district-level Quality Assurance staff. The programme aligned with the National Quality Assurance framework and standards (14), and aimed to integrate quality improvement processes into the Quality Assurance system. Specifically, through engagement in the State Quality Assurance

Committee, it aimed to influence capacities for operationalisation of quality improvement methods recommended in the National Quality Assurance framework, and greater prioritisation of quality improvement during regular Quality Assurance monitoring and accreditation visits conducted by District Quality Assurance Managers. ACCESS participated in the recruitment of District Quality Assurance Managers and supported their quality improvement training through enrolment in the IHI Open School. It conducted analysis using data from hospitals participating in the collaborative programme, to differentiate process and infrastructure gaps required to achieve accreditation, and used this analysis to advocate for greater focus on process changes through continuous quality improvement efforts over infrastructure. ACCESS also participated in joint monitoring visits with District Quality Assurance Managers, and undertook external assessments during the accreditation process.

6. Theory of change

The Safe Care Saving Lives programme assumed that the reliable delivery of 20 evidence-based practices for intrapartum, early newborn care and care of small and sick newborns to prevent key drivers of newborn mortality, (i.e. birth asphyxia, complications of prematurity and newborn sepsis) would contribute to a reduction in newborn mortality at hospital level (see figure 3). This was in line with analysis indicating that increased coverage and quality of a package of interventions along the continuum of pre-conception, maternal and newborn care by 2025 could avert 71% of newborn deaths, and that the maximum effect on neonatal deaths is through interventions during labour and birth, followed by care of small and ill newborn babies (15).

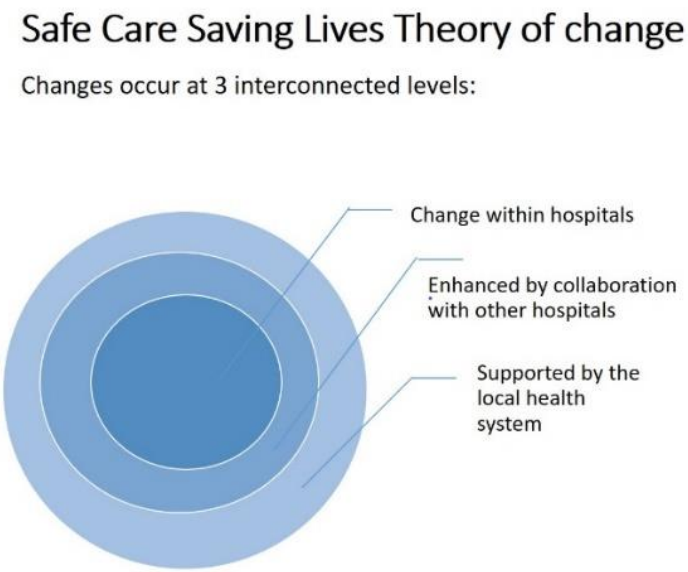
Figure 3: Safe Care Saving Lives Drivers Diagram



The programme aimed to improve the adoption of EBPs by supporting the establishment of a culture of quality improvement; the creation of new social norms promoting compliance with EBPs; and by improving cooperation across departments and cadres. It aimed to achieve capacity, behavioural and organisational level changes

within each hospital, and it assumed that these would be enhanced by collaborative work, and supported by the local health system (Figure 4).

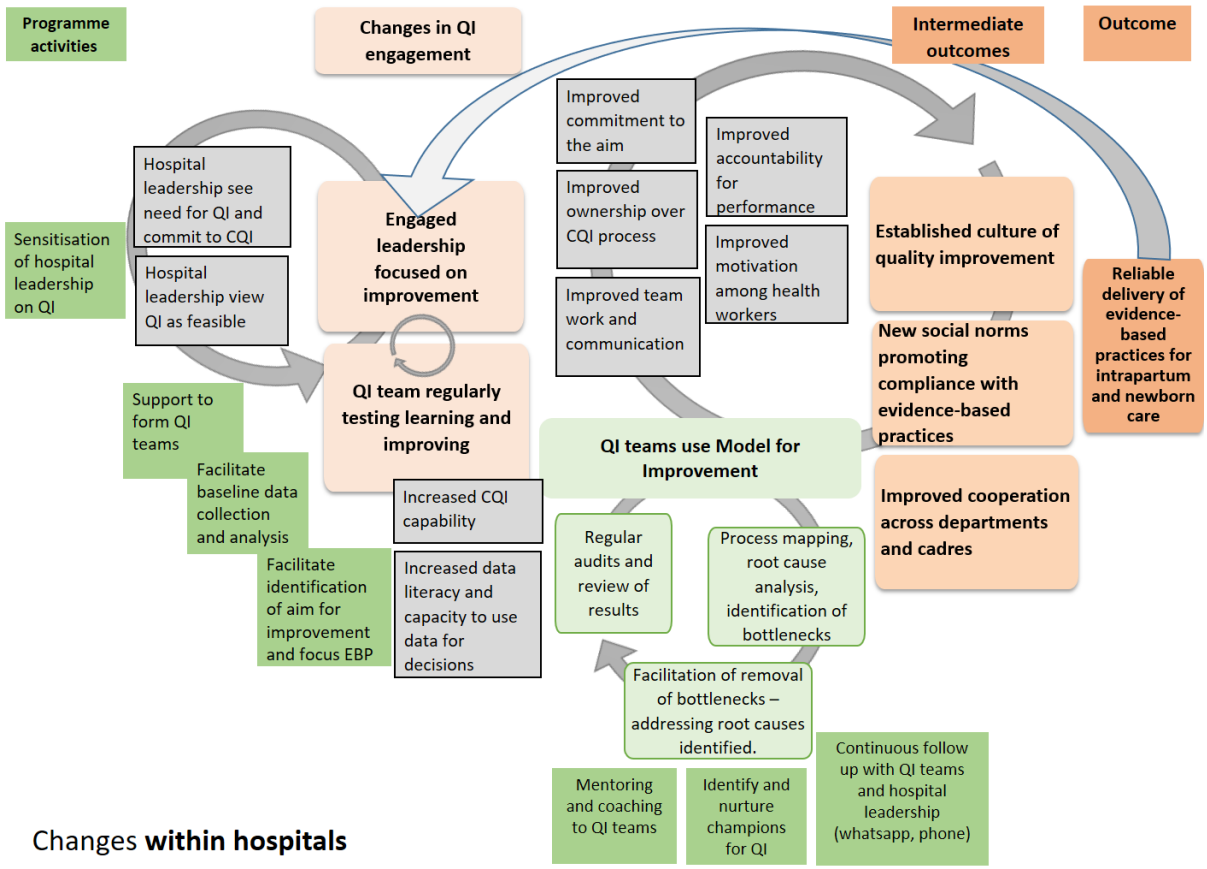
Figure 4: Theory of change – Diagram 1: Levels of change



5.1 Changes within each hospital

At the core of the programme theory of change were active QI teams, regularly testing innovation, learning and improving, and supported by an engaged leadership focused on improvement. Therefore, the programme focused on formation of QI teams, capacity building, mentoring and support, to increase capability for continuous quality improvement, and to increase data literacy and capacity to use data in decisions, in both QI teams and hospital leaders. It also focused on sensitisation and continuous engagement of hospital leaders, to increase understanding on the need for quality improvement in relation to clinical outcomes and hospital strategic priorities, and to foster a perception that quality improvement is a feasible strategy, thus increasing their readiness to engage in quality improvement and commitment to the aim and methodology. These are illustrated in figure 5.

Figure 5: Theory of change diagram 2 – Changes within hospitals



In line with evidence from published literature on quality improvement, engagement of leaders and active QI teams were thought of as a mutually reinforcing engine for change: the more QI teams demonstrated results through their work, the more leaders would increase their interest and engagement in quality improvement. An open leadership, focused on results and problem-solving, and providing the necessary motivation and resources for quality improvement was essential for effective quality improvement efforts (7, 16-18).

The combination of active QI teams, supported by engaged leaders, was assumed to be able to activate a variety of mechanisms leading to the establishment of a culture of improvement, the creation of new social norms and improved collaboration across teams and departments(19-21). The programme did not make explicit reference to theory, but its design echoed the behaviour change model at individual level, and social learning theory and normalisation process theory at organisational level (22-24).

It should be noted that the identified mechanisms were also assumed to be mutually reinforcing, for example improved team work and communication would improve motivation among health workers, and vice versa. The programme assumed a plurality of pathways, given that each hospital could be considered a micro-cosmos of its own. Hence, the diagram in figure 5 represents potential conceptual avenues and not a sequential series of expected outcomes.

5.2 Changes at Quality Improvement collaborative level

The programme also assumed that changes within hospitals be enhanced by collaboration with other hospitals. The expectation was that the QI collaborative activities would generate rapid improvements in the clinical area of focus, by shortening the time for diagnosing problems and developing changes, and by providing an external stimulus to make large improvements by spreading of ideas across sites (1, 25, 26).

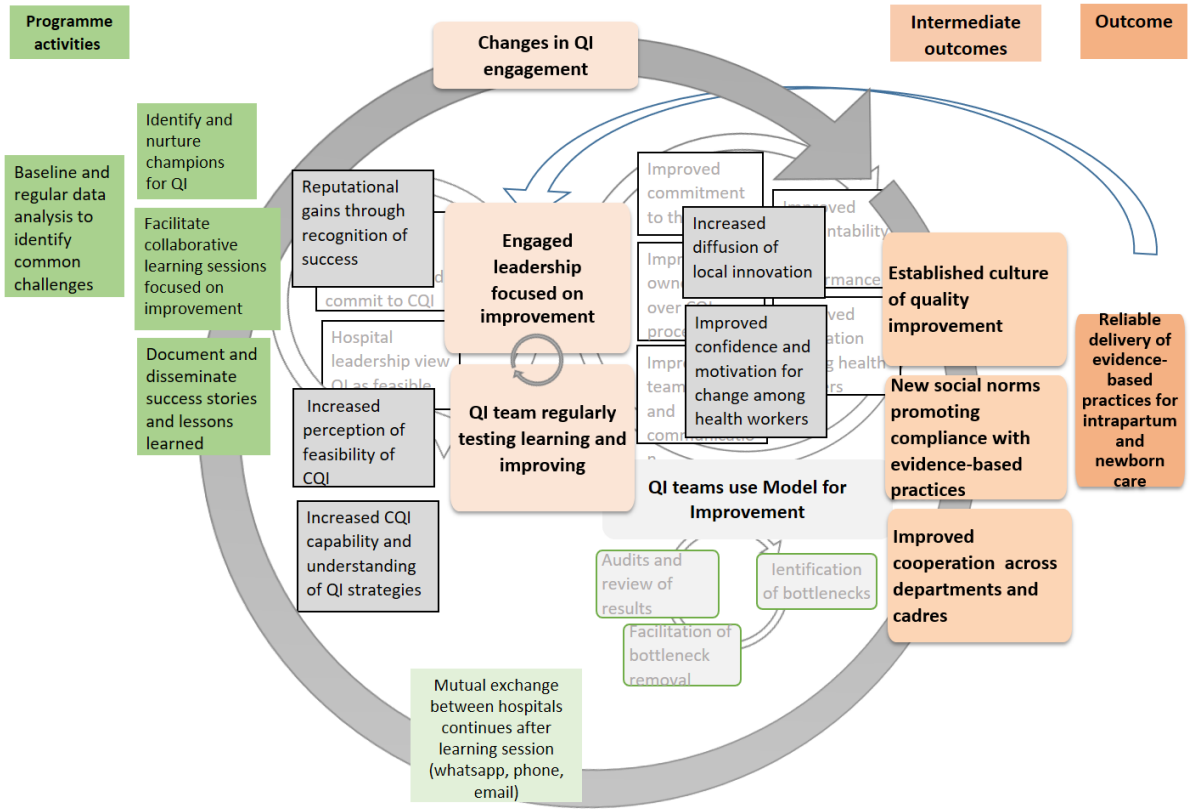
The approach borrowed from Rogers' diffusion of innovation theory, assuming that adoption of an innovation (a change idea for improvement) would be greater depending on *attributes of the idea itself*: the relative advantage over the status quo or other ideas that have been proposed; the *degree of compatibility with existing values*, experiences and needs; the *complexity of the idea*; its *trialability*, or the extent to which the idea had been tested; and its *observability*, i.e. the opportunity for people to observe the success of the change for others(27). This framework explained the focus on early adopters to showcase innovation and act as hubs for learning and improvement in mini-collaboratives.

The QI collaborative approach intended to enhance quality improvement efforts in various ways (see figure 6):

- For early adopter hospitals, it may provide reputational gains through recognition among peers, and further enhances team motivation and commitment to quality improvement (19).
- For other hospitals participating in the QI collaborative, the collaborative approach may enhance leadership and frontline health workers' engagement in quality improvement, by increasing perceptions of its feasibility (thus activating the observability mechanism, demonstrating the compatibility of the change with existing needs) and by favouring the diffusion of local innovation (thus activating the *trialability* mechanism)(12, 28).

It also may reinforce the establishment of new social norms promoting compliance with EBPs, specifically by supporting the development of a culture of improvement across hospitals, which was assumed to generate normative pressures on other hospitals to adopt the quality improvement process and the focus practices, as in the long run they would find it damaging not to (19, 29, 30).

Figure 6: Theory of change diagram 3 – Changes at QI collaborative level



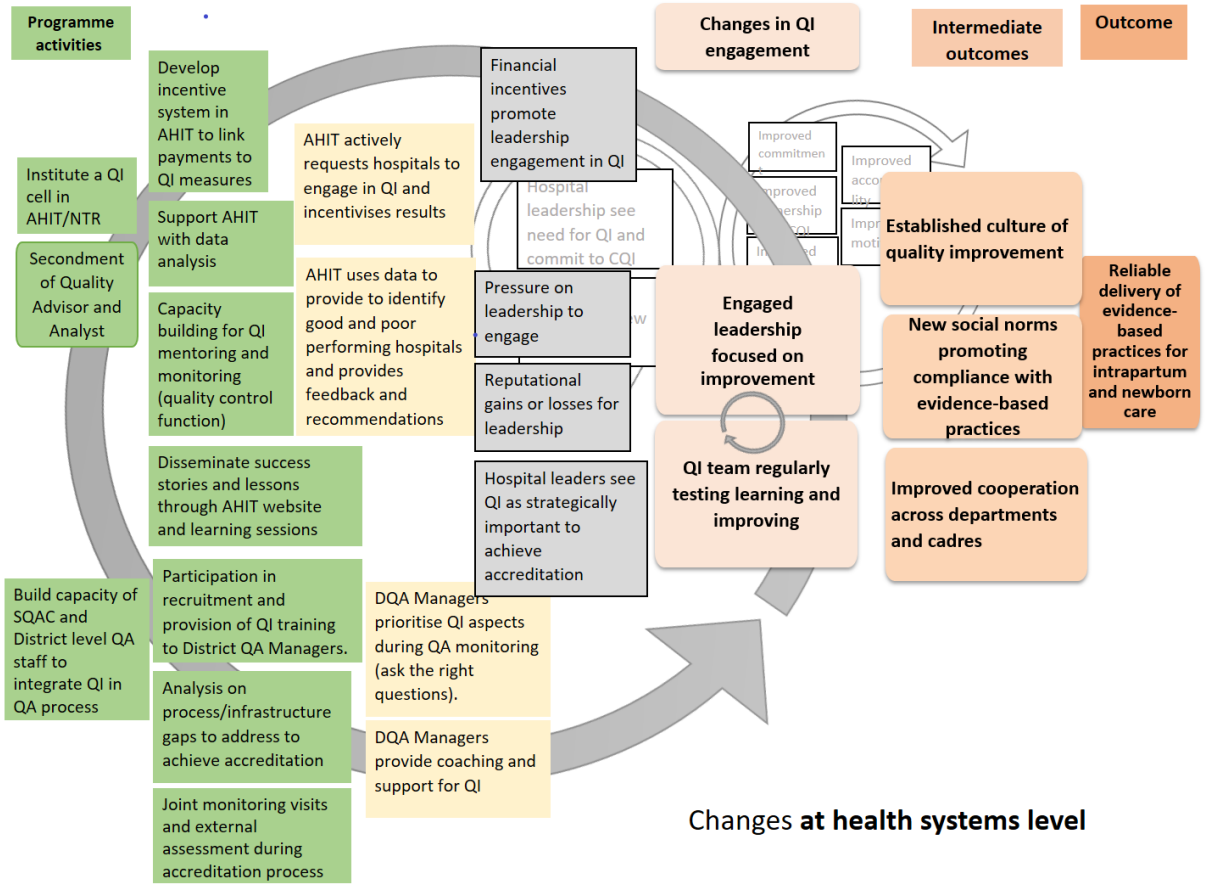
Changes **at collaborative level**

5.3 Changes at health system level

The programme embodied health systems theory in its core assumption that "every system is perfectly designed to achieve the results it obtains"(1), p. 79. The programme scale up strategy rested on the assumption that if a shift in prioritisation of quality improvement occurred among stakeholders that had a regulatory and governance function in the health system, this would trickle down to individual hospital leaders, and act as a facilitator of greater adoption of quality improvement processes and improved newborn care practices.

Although not explicitly articulated in its design, the programme's positioning in the health system, and its activities with government-health insurance companies and with state and district level authorities emerged organically from programme experience in wave I, and in response to challenges in engaging hospital leadership. The intervention at health systems level focused on activating pressure on hospital leaders through mechanisms that the health systems literature describes as carrot, stick and sermon approaches, referring respectively to a system of financial or other types of incentives, coercive pressure, and normative or motivational pressures (31) (see figure 7).

Figure 7: Theory of change diagram 4 – Changes at the level of the health system



In the Safe Care Saving Lives programme, efforts to strengthen the incentive system included support to the development of a financial incentive system for quality improvement, linked to health insurance payments. When the programme started, Aarogyasri Health Care Trust gave incentives to hospitals that were accredited with the National Accreditation Board of Hospitals. ACCESS planned to work with the Aarogyasri Health Care Trust to expand the incentive system to link payments to hospitals adopting and continuing quality improvement, in addition to achieving accreditation, assuming that this would increase hospital leaders' commitment and engagement in quality improvement.

Incentive-related pressure (carrot mechanisms) related to ACCESS advocating at state and district level for increased prioritisation of quality improvement in the quality assurance system. The programme assumed that if relevant Quality Assurance authorities in charge of monitoring, verification and accreditation "asked the right questions of leaders", (that is, if they focused on process of care as opposed to inputs in their ongoing monitoring and assessments), hospital leaders would increasingly prioritise improvements in clinical practice within available resources, as these would be seen as strategically important towards accreditation. Accreditation would in turn increase clinicians' professional recognition, hospital status, and potentially revenues.

Coercive pressures (also referred to as stick mechanisms) related to regulation, statutory powers, licencing, and in the case of health insurance companies, empanelment criteria. The assumed pathway by which Safe Care Saving Lives intended to activate coercive pressure was by strengthening health insurance companies' capacity to directly request engagement in quality improvement activities by those empanelled, or to provide direct

feedback or recommendation to hospitals. Essentially, the programme assumed that the health insurance companies would exert a quality control function in the system, which would activate coercive pressures on empanelled hospitals to conform to Aarogyasri Health Care Trust's Standard Treatment Guidelines. This pathway rested on the ongoing analysis of hospital data to identify good and poor performing hospitals, on the regular discussion at the level of QI Cell on these data, and fundamentally, on the health insurance companies seeing quality improvement as a strategy for efficiency as well as effectiveness.

Normative and motivational pressures (also referred to as sermon mechanisms) related to promoting leadership engagement by nurturing personal commitment to the reduction of newborn mortality, the adoption of EBPs and a culture of quality improvement. The programme aimed to foster a networked community of leaders, committed to the programme aim and relentlessly focused on improvement. Relevant strategies included providing hospitals and clinicians with opportunities for reputational gains by sharing success stories, and cultivating a network of champions of quality improvement at all levels, through collaborative work.

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Chapter 5

Paper C – Effect of collaborative quality improvement on stillbirths, neonatal mortality and newborn care practices in hospitals of Telangana and Andhra Pradesh, India: evidence from a quasi-experimental mixed-methods study.

This chapter presents the findings of the evaluation of the Safe Care Saving Lives programme described in detail in Chapter 4. It includes the results from the impact and outcome evaluation, responding to Objective 2 of the PhD (to evaluate the intervention effects on the implementation of essential evidence-based maternal and newborn care practices, on the stillbirth rate and neonatal mortality rate in labour wards and neonatal care units). It also includes results from the nested process evaluation, addressing Objective 3 of the PhD (to evaluate implementation, including challenges and adaptations to the context, and explore the mechanisms of change of the intervention). This chapter was published on 7th January 2021 in Implementation Science 16, 4. The manuscript was published under Creative Commons License, (CC BY 4.0) and is included in full below. The paper and annexed files are available at:

https://implementationscience.biomedcentral.com/articles/10.1186/s13012-020-01058-z

Please note the erratum included before the full paper.

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Zamboni, K., Singh, S., Tyagi, M. et al. Effect of collaborative quality improvement on stillbirths, neonatal mortality and newborn care practices in hospitals of Telangana and Andhra Pradesh, India: evidence from a quasi-experimental mixed-methods study. Implementation Sci 16, 4 (2021). https://doi.org/10.1186/s13012-020-01058-z

RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	LSH1603470	Title	Ms
First Name(s)	Karen		
Surname/Family Name	Zamboni		
Thesis Title	Improving quality of newborn care at scale through quality improvement: evaluation of the Safe Care Saving Lives programme in Telangana and Andhra Pradesh, India.		
Primary Supervisor	Dr. Claudia Hanson		

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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I led the design and implementation of the process evaluation nested in the study, under the supervision of Dr. Claudia Hanson and Prof. Joanna Schellenberg and with in-country oversight from Dr. Samiksha Singh, and coordination from Ms Mukta Tyagi. I conducted interviews in 2 hospitals in the second round of interviews and supervised data collection teams during the qualitative study remotely. I conducted quantitative and qualitative analysis for the paper, with input from Ms Muka Tyagi, and led a data analysis workshop involving Dr C. Hanson and Dr S Singh, to review and finalise the analysis. I wrote the first draft of the manuscript and prepared the subsequent revisions with consideration of comments from co-authors.

SECTION E

Student Signature	**Karen Zamboni**
Date	**30th May 2021**

Supervisor Signature	**Claudia Hanson**
Date	**30th May 2021**

Erratum – Chapter 5 Table 5

The following errors to Table 5 were found in the article after publication. An erratum will be submitted to the journal as well.

The correct estimates of the difference-in-difference effect for the primary outcomes are included under the published version in bold.

Indicator	Baseline		Endline		Difference in difference (DiD) effect (95% CI)	p-value of DiD
	Intervention N = 18	Comparison N= 21	Intervention N = 18	Comparison N= 21		
	Mean (95% CI)		Mean (95% CI)			
Primary outcomes (impact indicators)						
1. % of stillbirth of all hospital deliveries	2.8 (2.1-3.6)	1.4 (0.5-2.3)	0.9 (0.4-1.4)	0.5 (0.2 – 0.9)	-1.3 (-2.6-0.1) **-1.1 (-2.4 – 0.2)**	0.073 **0.105**
2. % of neonates dying before the age of 7-days among those admitted to the newborn care unit	4.9 (1.1-8.8)	6.0 (1-11)	1.2 (0.1-2.4)	0.5 (-0.5-1.5)	-1.6 (-9-6.2) **0.02 (-5 – 8)**	0.689 **p: 0.56**
3. % of neonates dying before the age of 28-days among those admitted to the newborn care unit	7.6 (1.8-13.5)	8.0 (0.8-15.1)	1.4 (0.1-2.6)	1.7 (-0.7-4.3)	-3.0 (-12.9-6.9) **-0.01 (-9.6– 9.6)**	0.546 **0.99**

For secondary outcomes, data presented for baseline and endline status and the DiD were correct.

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Implementation Science

RESEARCH Open Access

Effect of collaborative quality improvement on stillbirths, neonatal mortality and newborn care practices in hospitals of Telangana and Andhra Pradesh, India: evidence from a quasi-experimental mixed-methods study

Karen Zamboni[1*], Samiksha Singh[2], Mukta Tyagi[2], Zelee Hill[3], Claudia Hanson[1,4†] and Joanna Schellenberg[1†]

Abstract

Background: Improving quality of care is a key priority to reduce neonatal mortality and stillbirths. The Safe Care, Saving Lives programme aimed to improve care in newborn care units and labour wards of 60 public and private hospitals in Telangana and Andhra Pradesh, India, using a collaborative quality improvement approach. Our external evaluation of this programme aimed to evaluate programme effects on implementation of maternal and newborn care practices, and impact on stillbirths, 7- and 28-day neonatal mortality rate in labour wards and neonatal care units. We also aimed to evaluate programme implementation and mechanisms of change.

Methods: We used a quasi-experimental plausibility design with a nested process evaluation. We evaluated effects on stillbirths, mortality and secondary outcomes relating to adherence to 20 evidence-based intrapartum and newborn care practices, comparing survey data from 29 hospitals receiving the intervention to 31 hospitals expected to receive the intervention later, using a difference-in-difference analysis. We analysed programme implementation data and conducted 42 semi-structured interviews in four case studies to describe implementation and address four theory-driven questions to explain the quantitative results.

(Continued on next page)

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(Continued from previous page)

Results: Only 7 of the 29 intervention hospitals were engaged in the intervention for its entire duration. There was no evidence of an effect of the intervention on stillbirths [DiD − 1.3 percentage points, 95% CI − 2.6–0.1], on neonatal mortality at age 7 days [DiD − 1.6, 95% CI − 9–6.2] or 28 days [DiD − 3.0, 95% CI − 12.9—6.9] or on adherence to target evidence-based intrapartum and newborn care practices. The process evaluation identified challenges in engaging leaders; challenges in developing capacity for quality improvement; and challenges in activating mechanisms of change at the unit level, rather than for a few individuals, and in sustaining these through the creation of new social norms.

Conclusion: Despite careful planning and substantial resources, the intervention was not feasible for implementation on a large scale. Greater focus is required on strategies to engage leadership. Quality improvement may need to be accompanied by clinical training. Further research is also needed on quality improvement using a health systems perspective.

Keywords: Quality improvement, Evidence-based practices, Neonatal mortality, Newborn care, India, Sick newborn

Contributions to the literature

- Quality improvement collaboratives are a widely used approach, but evidence of their effectiveness is mixed. We conducted an evaluation of a quality improvement collaborative aiming to reduce newborn mortality and stillbirths, targeting labour rooms and newborn care units of 60 hospitals in two Indian states.
- We found no evidence that the intervention reduced stillbirths or neonatal mortality, nor that it improved targeted intrapartum and newborn care practices in labour rooms and newborn care units.
- Implementation of the intervention was challenging, and there was high attrition from participating hospitals.
- This study contributes to an emerging body of evidence suggesting caution in considering quality improvement collaboratives an effective short-term intervention. Much attention is needed on engaging leadership and building capacity to enable quality improvement at scale.

Introduction

Globally, poor quality care contributes to over 1 million newborn deaths each year [1]. India is a high-burden country, with around 760,000 yearly newborn deaths, and an estimated neonatal mortality rate of 24 deaths per 1000 live births, with variations across states, wealth quintiles and urban-rural settings [2]. In the last decade, the Indian government has invested heavily in demand- side programmes, which resulted in improvements in institutional deliveries and skilled birth attendance [3]. In line with the Indian Every Newborn Action Plan [4], four levels of neonatal care have been established: Newborn Care Corners at all places offering childbirth care, providing essential care at birth and newborn re- suscitation; Level I Newborn Stabilisation Units provid- ing management of low birthweight babies not requiring intensive care and stabilisation of sick newborns before referral; Level II Special Newborn Care Units at district and subdistrict hospitals, providing care to sick new- borns except ventilation and surgery; and Level III Neo- natal Intensive Care Units [5]. Considerable progress has been made in operationalising these structures through standardised infrastructure guidelines, human resource standards and a system for reporting data on facility- based newborn care [5, 6]. However, quality in newborn care remains suboptimal due to limited adherence to care protocols, a weak referral system and admission overload [5, 7–9]. National quality improvement initia- tives and quality assurance schemes, such as that of the National Neonatology Federation, have recently been in- troduced (see Fig. 1). A nationwide quality of care net- work has been established, spreading the adoption of quality improvement (QI) strategies [10].

The Safe Care, Saving Lives programme (SCSL), implemented by ACCESS Health International (ACCESS), an international NGO, used a collaborative quality improvement approach, adapted from the Institute of Healthcare Improvement [11] to reduce neonatal mor- tality. In this approach, teams from multiple hospitals work together to improve implementation of evidence- based practices (EBPs), in this case EBPs for intrapartum and newborn care. Twenty EBPs were identified by neonatologists and obstetricians, addressing the three main drivers of neonatal survival through: (1) neonatal sepsis prevention and management, (2) prevention and management of complications from prematurity and (3) reli- able intrapartum care and newborn resuscitation [12]. Teams were supported by quality improvement coaches

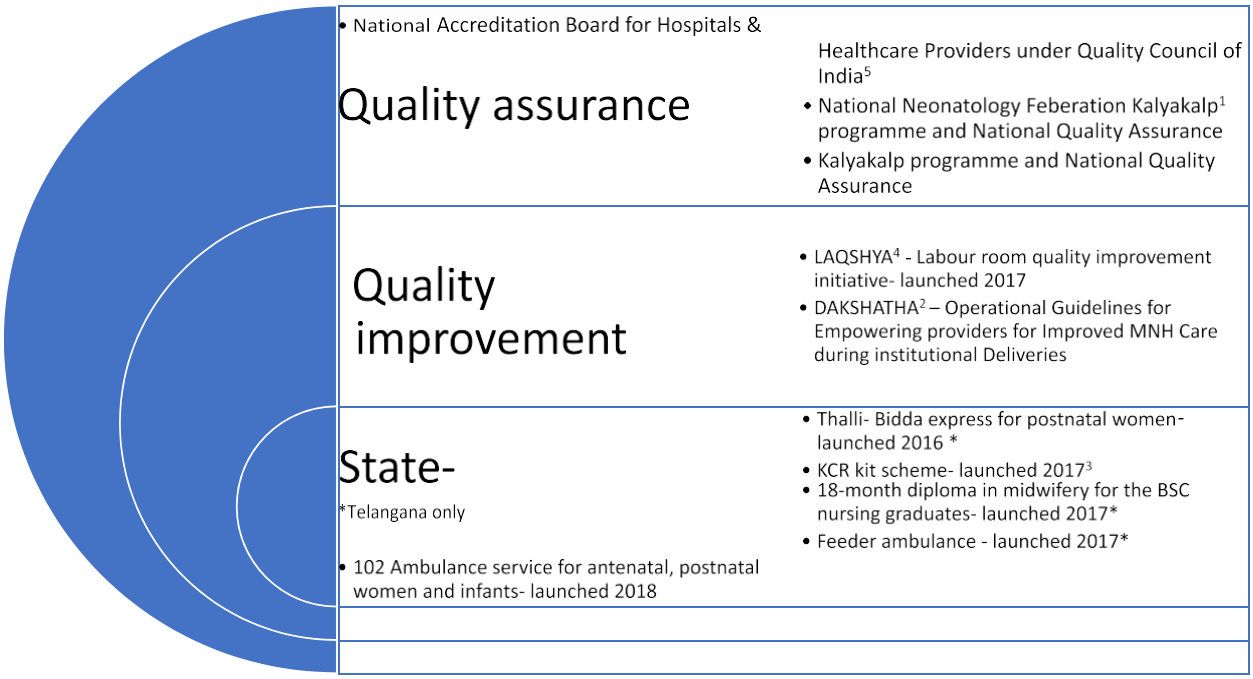

Fig. 1 Context panel. Maternal and newborn health initiatives affecting labour room and newborn care units in Andhra Pradesh and Telangana

to use rapid cycle tests of change to achieve a given improvement aim and attend "learning sessions" to share improvement ideas, experience and data on performance [11]. Quality improvement collaboratives (QICs) are a widely used approach. Collaboration between teams can shorten the time required to identify challenges to EBP implementation and can provide an external stimulus for innovative problem-solving [13]. Evidence on QICs effectiveness is mixed [14, 15] and of variable quality [14, 16], but recent robust studies reported positive results for newborn health outcomes [17]. SCSL developed a collaborative of all hospitals empanelled into a government-sponsored health insurance scheme covering care for severely sick newborns: the Aarogyasri Health Care Trust [18] and the Dr Nandamuri Taraka Rama Rao Vaidya Seva in Telangana and Andhra Pradesh, respectively. The schemes provide the poor with access to secondary and tertiary newborn care in both private and public facilities. SCSL targeted Level II Special Newborn Care Units and Level III Neonatal Intensive Care Units, which we refer to together as "newborn care units" (NCUs), and labour wards in 60 public and private hospitals in Telangana and Andhra Pradesh.

We conducted an external mixed-methods evaluation of the SCSL programme. Here we report on the following: (i) effects on the implementation of essential evidence-based maternal and newborn care practices; (ii) the impact on the stillbirth rate and neonatal mortality rate in labour wards and neonatal care units; (iii) programme implementation including challenges and adaptations to the context and (iv) observed mechanisms of change and their relationship to contextual factors.

Methods

Study design, allocation and setting

We used a quasi-experimental plausibility design with a nested process evaluation, details of which are presented elsewhere [12]. The intervention targeted all 85 hospitals that were empanelled in the health insurance schemes, through a phased intervention roll-out organised in three waves (see Table 1). Wave 1, where the intervention was piloted and refined [12], involved 25 hospitals that volunteered to participate after a programme

Table 1 Implementation and evaluation timeline

	Safe Care Saving Lives Programme timeline											
	Year											
	2014	2015	2016	2017				2018				2019
				Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct – Dec[#]	
Implementation milestones												
Programme design phase												
Wave 1 (25 hospitals)												
Programme review and adaptation of design												
Wave 2 (29 hospitals)*					TS-12 AP-15	TS-12 AP-15	TS-10 AP-14	TS- 9 AP-0	TS- 7 AP-0	TS-7 AP-0		
Wave 3 (31 hospitals)**												
Evaluation milestones												
Survey of consenting hospitals for quantitative evaluation												
Baseline data collection			Jun-Aug									
Endline data collection										Aug-Sep	Oct	March
Process evaluation												
Programme implementation reporting from ACCESS												
Qualitative data collection (case studies)								Mar	Apr-May		Nov-Dec	

TS= Telangana State; AP= Andhra Pradesh

*: 2 hospitals did not engage in the intervention; the number of hospitals involved declined to 24 in Q3, and 9 in Q4.

**: wave 3 was not implemented

Data collection only. No mentoring support and programme wind-down.

launch. These were excluded from our study. The 60 remaining hospitals represented the study sample. The allocation of the 60 eligible hospitals to waves 2 and 3 was initially planned using randomisation. However, be- fore implementation, ACCESS purposely reallocated 5 facilities to enable collaboration between hospitals in the same newborn referral cluster and relative geographical proximity. This created a non-randomised, quasi- experimental study. In the study sample, 29 hospitals re- ceived the intervention in wave 2 between April 2017 and July 2018, and 31 represented the comparison group, where wave 3 roll out was planned from July 2018. How- ever, the wave 3 group did not receive the intervention be- cause permission for the programme was withdrawn in Andhra Pradesh in late 2017, and a programme review by the donor recommended that ACCESS intensified support to waves 1 and 2 hospitals, instead of expanding into new sites. Hospital characteristics are reported in Table 2.

For the qualitative component, we used a two-round multiple case study design to evaluate intervention adapta- tion, contextual factors, and mechanisms of change. We purposely selected four case study hospitals in Telangana. We aimed to include a private and public hospital and a medical college and to balance high and medium admis- sion caseloads, hypothesising that these characteristics would influence their engagement in the programme.

Participants

The study site was two Indian states of Telangana and Andhra Pradesh, which have a slightly better socio- economic situation than India's average [12]. The 60 par- ticipating hospitals included 28 public secondary hospitals, 6 public medical colleges, 20 private tertiary hospitals and 6 private medical colleges with high neonatal mortality rates as described elsewhere [19]. We included women seeking childbirth care and neonates admitted to NCUs.

Intervention

Figure 2 summarises intervention implementation, de- scribed elsewhere in detail [12]. To evaluate intervention delivery, we used quarterly programme data reported by ACCESS on EBP implementation in each hospital, re- ported under programme implementation.

ACCESS also planned to facilitate learning sessions among participating hospitals. However, only one mini- collaborative was set up which, upon request of

Table 2 Infrastructure and human resources in included hospitals

	Baseline		Endline	
	Intervention	Comparison	Intervention	Comparison
Agreed participation in baseline and endline assessment	25	27	18	21
Facility assessment done in labour room	20	19	14	17
Public secondary/college	15/1	11/3	12/1	11/2
Private secondary/college	1/3	2/3	1/1	1/2
Mean no. of deliveries per month	369	171	459	317
Median (IQR)	315 (157–500)	166 (32–247)	426 (253–636)	233 (85–516)
Mean no. beds	8	6	6	4
Median (IQR)	5 (3–11)	2 (2–10)	4 (3–8)	3 (2–7)
Hospital has an operating theatre	18 (90%)	16 (84%)	13 (87%)	13 (81%)
Mean no. of obstetricians per 10 beds	4	9	10	10
Median (IQR)	3 (2–7)	5 (3–10)	5 (3–8)	8 (5–15)
Facility assessment done in NCU	24	25	15	20
Public secondary/college	15/2	10/3	11/1	11/2
Private secondary/college	4/3	10/2	3/0	5/2
Have a breastfeeding room*	21 (88%)	20 (80%)	11 (85%)	14 (82%)
Have a Kangaroo Mother Care room	16 (67%)	10 (40%)	11 (79%)	13 (72%)
Mean no. of admission per month	77	72	91	69
Median (IQR)	67 (28–86)	51 (28–106)	65 (53–153)	53 (18–96)
Mean no. beds in NCU	19	16	19	20
Median (IQR)	18 (14–20)	16 (10–20)	20 (12–20)	20 (13–22)
Mean monthly admission to bed ratio	5	4	5	4
Median (IQR)	4 (3–5)	4 (2–6)	4 (3–8)	3 (1–6)
Mean no. of paediatricians	4	4	3	3
Median (IQR)	3 (2–7)	3 (1–6)	2 (1–4)	3 (1–5)
Mean no. of nurses	5	4	9	9
Median (IQR)	5 (3–6)	4 (2–5)	7 (6–14)	8 (3–13)
Mean no. of paediatricians per 10 beds	2	3	1	2
Median (IQR)	2 (1–3)	2 (1–3)	1 (0–3)	2 (1–3)
Mean no. of nurses per 10 beds	6	8	5	5
Median (IQR)	6 (3–8)	7 (5–8)	5 (4–7)	5 (3–7)

Note: *5 missing at endline (2 intervention, 3 comparison)

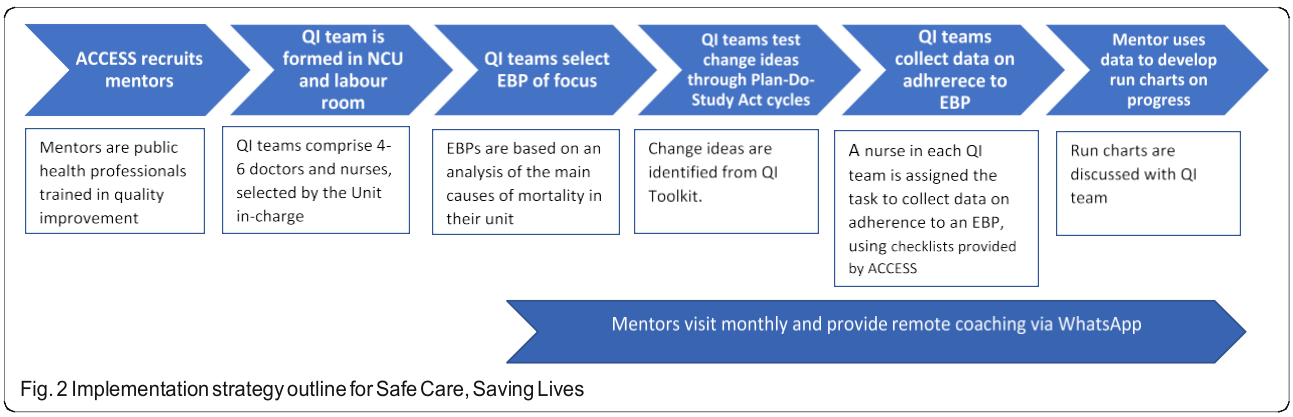

Fig. 2 Implementation strategy outline for Safe Care, Saving Lives

participating hospitals, focused on newborn referral pathways instead of EBPs. Therefore, this component was not included in the evaluation.

Outcomes

Primary outcomes were as follows: (1) the stillbirth rate, defined as number of foetuses born without any signs of life and weighing 1000 g or more, as a proportion of all births; (2) 7-day and (3) 28-day neonatal mortality rate after admission to a neonatal care unit, defined as babies who died before they completed 7 or 28 days of life, as a proportion of all babies admitted to the neonatal care unit. Deaths post-discharge but before 7 or 28 days of life were included. Secondary outcomes related to an improvement in the 20 intrapartum and newborn care practices targeted by the programme. Indicator definitions were mostly con- sistent with those used by the programme and aligned to international standards (Additional file 1).

Sample size

We based our sample size on the 3 primary impact indica- tors of the stillbirth rate in the labour ward and the 7-day and 28-day neonatal mortality rate after admission to the newborn care unit. We used the formula proposed by Hayes and Moulton for unmatched clusters [20] and esti- mates of the k-factor, output and impact indicators from our baseline assessment. In each hospital, we aimed to in- clude 260 observations from birth registers in the previous month and 190 phone interviews and newborn register data combined to be able to detect a 35% reduction of stillbirths and 20% reduction in mortality with 80% power [12].

Quantitative data collection

Our baseline and endline surveys assessing primary and secondary outcomes were independent from the internal programme monitoring and included (i) labour room and newborn care unit readiness checklists, (ii) case note ab- straction and observations of admissions and (iii) register abstraction in labour wards and newborn care units and (iv) face-to-face and telephonic interviews with mothers to estimate neonatal mortality after discharge from labour rooms and newborn care units [21]. We used android- based tablets (Lenovo) with an SQLite application with in- built skips and ranges to improve quality of data. Data were saved daily and uploaded on a safe server weekly.

Researchers from the Public Health Foundation of India (PHFI) collected data at baseline and endline over a period of 6 days per hospital. We employed six teams at baseline and three teams at endline, due to its smaller scope. To minimise inter-observer bias, one third of team members worked on both baseline and endline surveys.

Baseline data collection ran from June to August 2016. The majority of endline data collection was conducted from August to October 2018, after the programme end. However, due to delays in receiving permissions from the hospitals and suspension of PHFI's license to receive foreign funding under the Foreign Contribution (Regulation) Act, data collection in 12 hospitals took place in March 2019 [22].

Statistical analysis

Data were clustered at hospital level, so we computed cluster (hospital) summary estimates and tabulated pri- mary and secondary outcome indicators, by intervention and comparison groups. We used a difference-in- difference (DiD) approach to assess the effect of the intervention on primary and secondary outcomes [23] using Stata version 15.1. In view of major investments in maternal and newborn care in the two states over the course of this study, we also conducted a post hoc ana- lysis of all indicators in the study population to describe changes in primary and secondary outcomes over time.

Case study design, data collection and analysis

For the nested qualitative study, we first developed a theory of change through a participatory workshop with programme implementers [12], then refined it integrating relevant theory, informed by a systematic review [24, 25]. We developed four theory-based questions for the enquiry of context and mech- anisms of change (Fig. 3) and conducted semi-structured in- terviews to explore participants' understanding of the intervention, their perception of the priorities, barriers and enablers to newborn care quality improvement and their views of positive and negative changes occurring in their units. In the four case studies, we interviewed hospital leaders, 4–5 QI team members and ACCESS mentors. We drew the sample purposively from a list provided by ACCE SS, balancing seniority and cadres. Interviews were con- ducted in English or Telugu after translation, back- translation and piloting of interview guides, and undertaken in two rounds in March–April and November 2018. In round two, we also interviewed 1–2 health workers not in- volved in the QI teams to understand the changes occurring in the unit and explore sustainability. In the three public hos- pitals, we completed 11–13 interviews, while in the private hospital we conducted 5 interviews in the NCU only. Overall, we conducted 31 interviews in round 1 and 11 in round 2.

Data quality assurance included (i) debriefing after each interview and on a weekly basis, (ii) production and review of transcripts while in the field or shortly after and (iii) discussion of a draft case study summary ahead of the final interview with the facility mentor. We used thematic content analysis using NViVO 12.1 based on a preliminary coding framework for the broad domains of implementation, context and mechanisms of change. Two researchers independently coded data using a deductive-inductive approach. We first applied the cod- ing framework to the data and gradually refined it through discussion as interviews were coded. A final

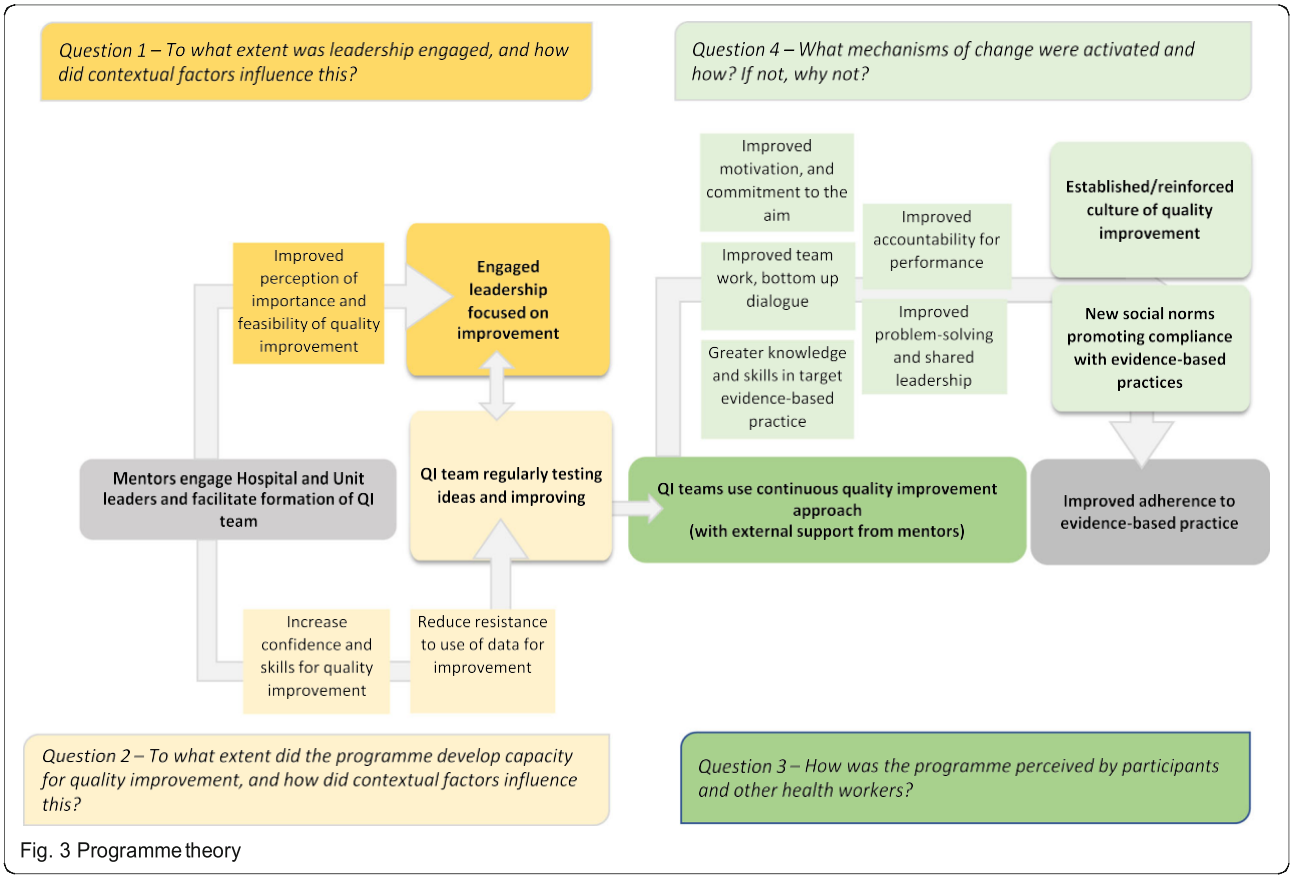

Fig. 3 Programme theory

coding framework was agreed by both researchers. We completed analysis of single case studies first, then contrasted and synthesised key themes across case studies, to answer the theory-driven questions [26].

Ethics

Ethical approval was granted from LSHTM (LSHTM Ethics Ref 10358) and PHFI's Institutional Ethics Com- mittee (IIPHH/TRCIEC/064/2015). Consent was ob- tained from each participating hospital prior to starting data collection and from each participant health worker and mother, after reading out an information sheet. Par- ticipants could withdraw or request to stop recording in- terviews at any time. Confidentiality was assured, as per institutional guidelines of research institutions.

Results

Programme implementation

Only 9 of the 29 hospitals recruited in wave 2 continued implementation for 12 months, and only 7 for 16 months (Fig. 4). Although the intervention promoted 20 EBP, a subset of 14 was implemented by any of these 9 hospi- tals (a mean of 5 per hospital), the commonest being hand hygiene, kangaroo mother care and anti-septic non-touch technique in NCUs and early breastfeeding in labour rooms (Table 3). Most EBP involving clinical protocol implementation were not adopted by any of the hospitals (Table 4).

Outcome and impact results

Before-after data is available from 39 hospitals because 8 at baseline and further 13 at endline did not grant consent (Fig. 5). We completed 12,054 register abstrac- tions in labour rooms and 1067 telephonic interviews at endline, a substantial increase from the 6466 and 866 completed at baseline respectively. At baseline, stillbirths represented 2.8% (95% CI 2.1–3.6) and 1.4% (95% CI 0.5– 2.3) of hospital births in the intervention and comparison group, respectively. The 7-day and 28-day mortality rates were estimated at 4.9% (95% CI 1.1–8.8) and 7.6% (95% CI 1.8–13.5) of newborns admitted in NCUs in the interven- tion group and 6.0% (95% CI 1–11) and 8.0% (95% CI 0.8–15.1) in the comparison group respectively.

There was no evidence of an effect of the interven- tion on stillbirths [DiD − 1.3 percentage points, 95% CI − 2.6–0.1, p = 0.073]; on neonatal mortality at age 7 days [DiD − 1.6 percentage points, 95% CI − 9–6.2, p = 0.689] or 28 days [DiD − 3 percentage points,

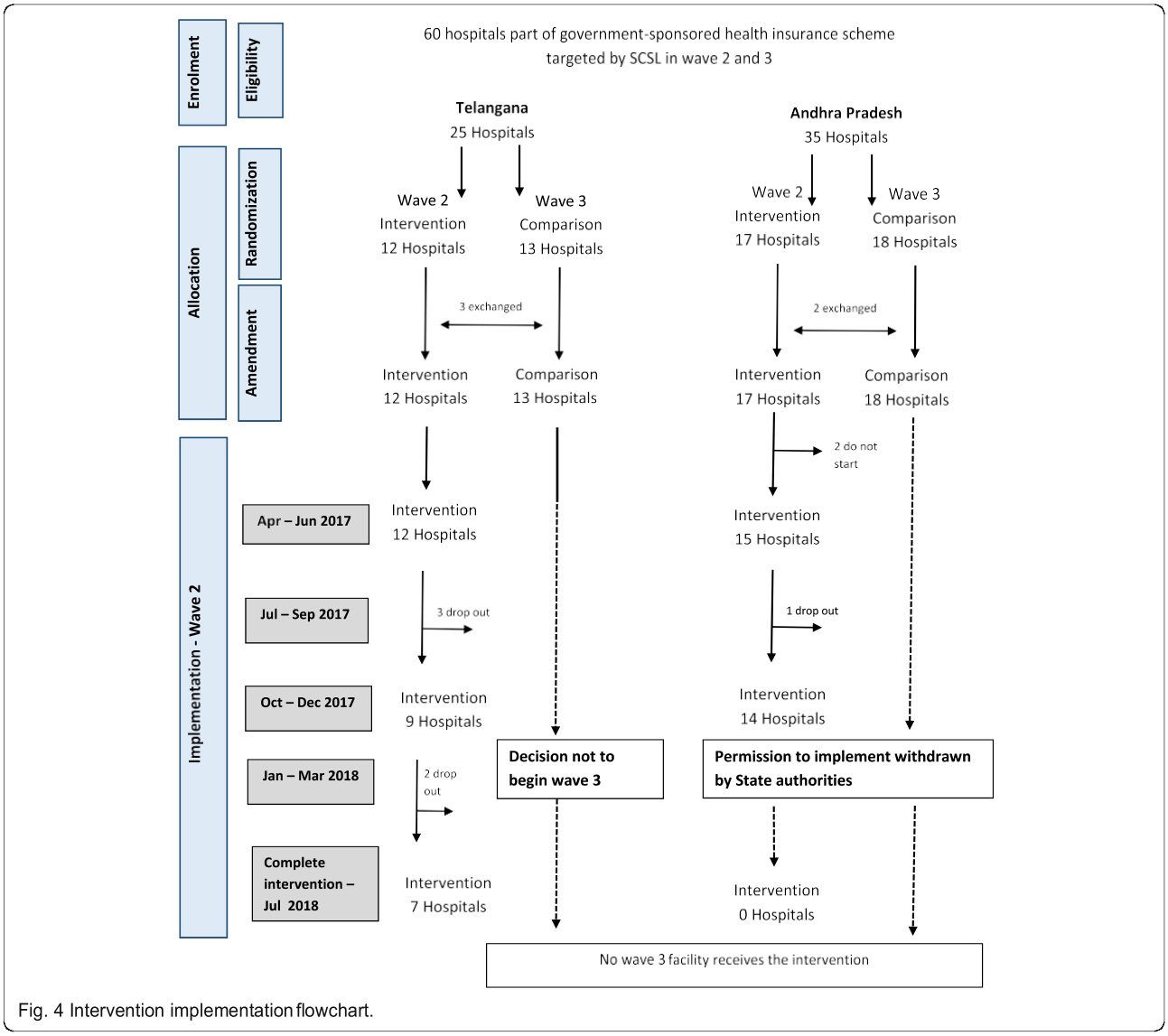

Fig. 4 Intervention implementation flowchart.

95% CI − 12.9–6.9, $p = 0.546$], or on adherence to evidence-based practices (Table 5).

The post hoc analysis of changes in primary and secondary outcomes over time indicated marked improvements in both implementation and comparison groups combined in: stillbirths [from 1.9 to 0.7%, − 1.2 percentage points, 95%CI − 1.8 to − 0.7, $p < 0.001$]; 7-day mortality [from 5.4 to 0.9%, − 4.5 per- centage points, 95%CI − 7.6 to − 1.4, $p = 0.009$]; 28- day mortality [from 7.7 to 1.5%, − 6.2 percentage points, 95% CI − 10.3 to − 2.1, $p = 0.007$). A few tar- get EBPs also improved in both groups combined: hand hygiene in NCUs [from 6 to 43%, 37 percentage points, 95% CI 25–48, $p < 0.001$]; use of safe birth checklists in labour room [from 11 to 41%, 30 percentage points, 95% CI 14–47, $p = 0.0008$]; and assist- ance for kangaroo mother care in NCUs [from 34 to 58%, 24 percentage points, 95% CI 3–45, $p = 0.0257$]. There was no evidence that this increase was stronger in the intervention compared to the comparison group (Table 5), and no evidence of a change in the other secondary outcomes (see Additional file 2).

Case study (CS) analysis

This section presents findings against the 4 theory- driven process evaluation questions outlined in Fig. 3. Table 6 describes the case study setting and implemen- tation. Additional file 3 provides detailed qualitative results.

To what extent was leadership engaged, and how did contextual factors influence this?

Participants saw leaders' role as essential to champion and model new behaviour and to provide

Table 3 Implementation of evidence-based practices in wave 2 facilities (Telangana state only)

Hospital N.	Type	Level	No. EBPs implemented[#]	Sepsis				Prematurity					Birth Asphyxia				
				Labour room		NCU		Labour		NCU			Labour room				NCU
				Six cleans	Hand hygiene in vaginal exam	ANTT	Hand hygiene in NCU	Early BF	ANCS	TMA	KMC	Exclusive BF	High risk categorisation	NRP in high risk delivery	Parto-graph	Pre-delivery checklist	CPAP
1*	Public	Secondary	6	x	X	x	x	x			x						
2	Public	Medical college	9					x	x	x	x	x	x	x		x	x
3	Public	Secondary	5				x		x	x	x		x				
4	Public	Secondary	5			x	x	x			x	x					
5	Public	Secondary	8		X	x	x	x			x	x	x		x		
6	Public	Secondary	8			x	x	x	x	x	x		x	x			
7	Private	Secondary	2			x	x										
8*	Private	Secondary	5			x	x				x	x			x		
9*	Private	Secondary	1				x										
Number of hospitals implementing EBP				1	2	6	8	5	3	3	7	4	4	2	2	1	1

Based on data provided by implementing partner to donor in July 2018

ANTT anti-septic non-touch technique for IV line insertion, *ANCS* ante-natal corticosteroid administration, *BF* breastfeeding, *High risk* high risk categorisation at admission, *KMC* Kangaroo Mother Care, *NCU* newborn care unit, *NRP* neonatal resuscitation trained personnel, *CPAP* continuous positive air pressure, *TMA* temperature monitoring at admission

[#]EBP implementation defined as EBP a hospital is working on at the time of report

*Facility for which we have no data due to non-consent to study

Table 4 Evidence-based practices not implemented

Setting	PBPs not implemented	No.
	Sepsis package	4
Labour room	Antibiotics for women at risk of sepsis	
NCU	Protocol for central vascular catheter	
NCU	Prevent ventilator associated pneumonia	
NCU	Antibiotics for neonates born to mothers with risk of sepsis	
	Prematurity package	0
	Birth Asphyxia package	2
Labour room	Compliance with oxytocin infusion protocol	
Labour room	Resuscitation with bag and mask	
	Total	6

administrative support and resources. The case stud- ies offered mixed views about the extent to which leadership had the skills to motivate staff, were en- gaged in the initiative and were driving new behav- iours. Three key contextual challenges to proactive leadership emerged. First, professional hierarchies and boundaries did not allow the creation of shared lead- ership across doctors and nurses, resulting in limited multi-professional collaboration. Second, top-down management styles hindered junior doctors' active

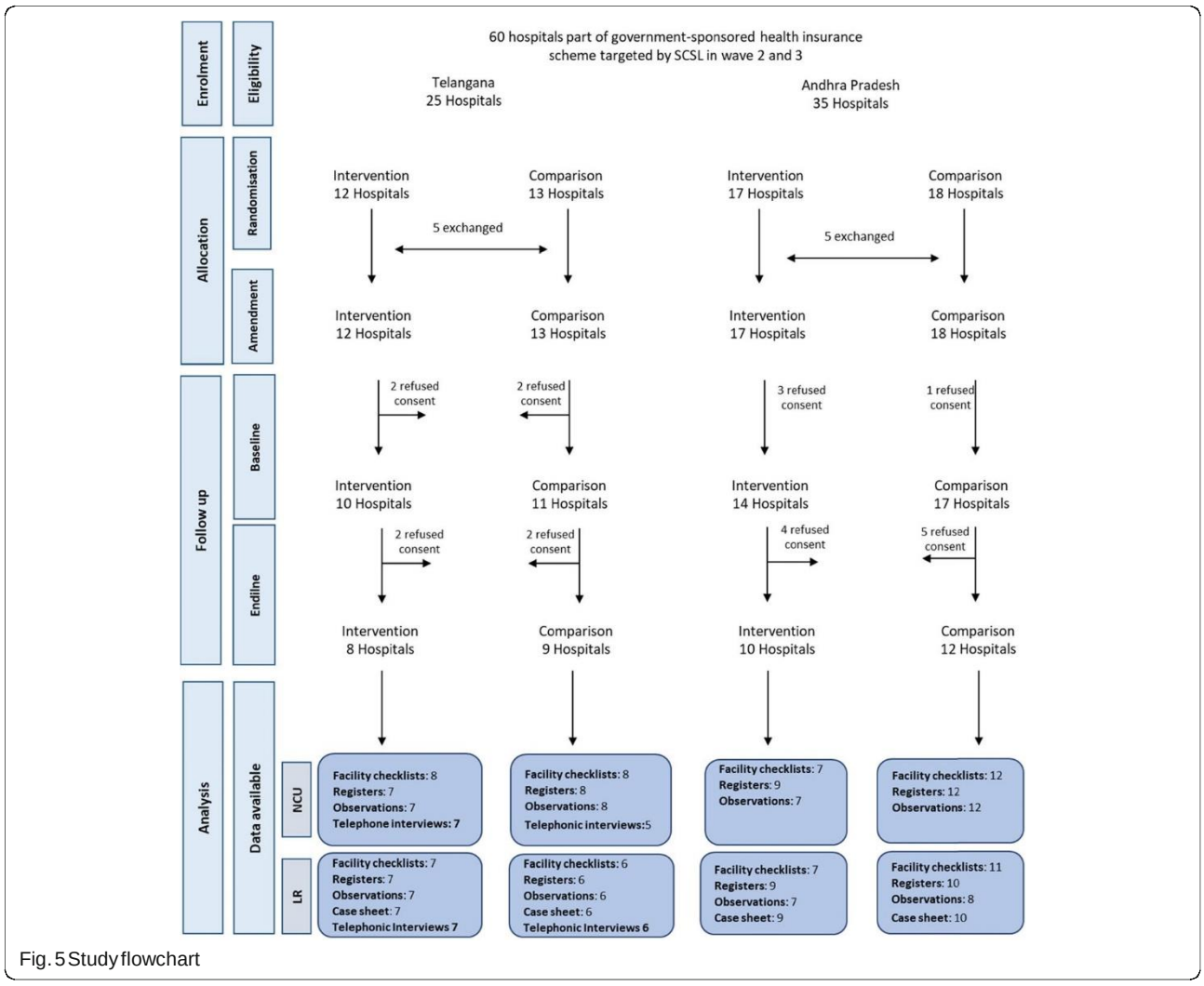

Fig. 5 Study flowchart

Table 5 Endline indicator summary

Indicator	Baseline		Endline		Difference in difference (DiD) effect (95% CI)	*p* value of DiD
	Intervention *N* = 18	Comparison *N* = 21	Intervention *N* = 18	Comparison *N* = 21		
	Mean (95% CI)		Mean (95% CI)			
Primary outcomes (impact indicators)						
1. % of stillbirth of all hospital deliveries	2.8 (2.1–3.6)	1.4 (0.5–2.3)	0.9 (0.4–1.4)	0.5 (0.2–0.9)	− 1.3 (− 2.6–0.1)	0.073
2. % of neonates dying before the age of 7 days among those admitted to the newborn care unit	4.9 (1.1–8.8)	6.0 (1–11)	1.2 (0.1–2.4)	0.5 (− 0.5–1.5)	− 1.6 (− 9–6.2)	0.689
3. % of neonates dying before the age of 28 days among those admitted to the newborn care unit	7.6 (1.8–13.5)	8.0 (0.8–15.1)	1.4 (0.1–2.6)	1.7 (− 0.7–4.3)	− 3.0 (− 12.9–6.9)	0.546
Secondary outcomes (EBP indicators)						
Delivery care practices in labour rooms						
1. Percentage of high-risk assessments correctly flagged	37 (27–46)	35 (23–48)	19 (12–27)	20 (8–31)	− 2 (− 23–19)	0.841
2. Percentage of admissions where essential information was documented in partograph and attached to case notes	8 (0–16)	10 (0–23)	17 (8–26)	13 (3–22)	6 (− 14–26)	0.545
3. Percentage of admissions where safe childbirth checklist used and attached to case notes	12 (1–26)	9 (0–21)	53 (31–75)	29 (10–49)	21 (− 14–55)	0.232
4. Percentage of vaginal examinations where hygiene standards are met	17 (− 6–39)	29 (0–66)	20 (3–37)	17 (1–33)	15 (− 29–59)	0.495
5. Percentage of deliveries where the six cleans were adhered to	0 (− 0.4–1.3)	5 (0–15)	11 (0.2–22)	8 (0–26)	8 (− 11–26)	0.419
Newborn care practices in Newborn Care Units						
6. Percentage of babies seen in the neonatal care admission ward for whom temperature was measured within 15 min	49 (24–73)	52 (23–81)	22 (0–44)	51 (33–70)	− 26 (− 76–23)	0.285
7. Percentage of patient contacts where hygiene standards are met	6 (1–12)	7 (2–13)	49 (34–65)	38 (22–53)	12 (− 11–36)	0.292
8. Percentage of cannulations where hygiene standards are met	13 (0–32)	7 (0–21)	32 (9–54)	18 (1–35)	7 (− 29–44)	0.692
9. Percentage of babies discharged from newborn care unit who were exclusively breastfed at first interview after discharge	93 (86–99)	94 (89–99)	70 (59–82)	73 (56–89)	− 1 (− 19–16)	0.870
10. Percentage of mothers in SNCU that reported being assisted for kangaroo mother care	22 (5–39)	39 (22–57)	59 (40–78)	56 (38–63)	20 (− 15–56)	0.260

participation in quality improvement as they did not feel empowered to make suggestions to their superiors.

As an obstetrician… if new initiatives are to be followed… we have to change behavior of doctors and nurses. We don't think about it; as junior sub- ordinates we don't give any suggestions. It will be good if they (seniors) will take suggestions from us… it will be good for patients. CS1_Medical Offi- cer Labour Room

Third, leaders lacked higher level pressure to prioritise quality improvement, resulting in limited engagement.

Generally there will be a resistance because […] quality is not compulsion to any Government hospital and it is their choice to implement it or not. If the leadership wants it strongly then the staff obviously do it… but they do it forcibly. If the staff wants to develop their own unit, they do it. CS1_Mentor

To what extent did the programme develop capacity for quality improvement, and how did contextual factors influence this?

The case studies provided little evidence that the intervention developed capacity for QI in a sustainable way. Selection of focus EBP was mostly based on consultation with the Unit Manager in the NCU or labour room, based on a gap analysis conducted by the mentor. Prac- tices were prioritised based on ease of implementation, as opposed to a team reflection on the gap analysis, for

Table 6 Case study characteristics and programme implementation details

	Case study 1	Case study 2	Case study 3	Case study 4
Key characteristics				
Type and level	Public—medical college**	Private— secondary	Public—medical college**	Public— secondary
Area	Urban	Urban	Urban	Rural/tribal
Monthly admissions to NCU	103	59	152	145
No. beds in NCU	11	18	18	Missing
Paediatricians per 10 beds in NCU [state average 2]	2.7	1.7	1.1	n/a
Nurse per 10 bed in NCU [state average 7]	11.8	6.7	6.1	n/a
Monthly deliveries	1153	n/a	375	325
Baseline performance in NCU (selected indicators)				
% of occasions when hand hygiene was followed in NCU [state average 16%]	15	42	0	0
% observed babies on exclusive breastfeeding [state average 72%]	91	100	96	75
Implementation				
Duration of implementation (months)	April 2017 January 2018 (10)	June–December 2017 (6)	July 2017 July 2018 (13)	July 2017 July 2018 (13)
Total no. EBPs at programme end (based on interview)	2	0	6	9
Total no. EBP^ (based on programme reports)	5	2	5	8
NCU				
QI team	Active	No QI team	Active	Active
Focus EBP (based on participants' interviews)	Hand hygiene ANTT	0 TMA KMC	Hand-hygiene	Hand hygiene ANTT Exclusive BF KMC TMA
Labour room				
QI team	Not formed	No labour room	Formed but unstructured	Active
QI work				
Focus EBP (based on participants' interviews)	None	n/a	ANCS	NRP at delivery HRC Early BF ANCS
HRC				
[Vitamin K administration]				

ANTT anti-septic non-touch technique for IV line insertion, *ANCS* ante-natal corticosteroid administration, *BF* breastfeeding, *HRC* high risk categorisation at admission, *KMC* Kangaroo Mother Care, *NCU* newborn care unit, *NRP* neonatal resuscitation trained personnel, *TMA* temperature monitoring at admission #At baseline

*These were public secondary facilities at baselines, then accredited as medical colleges while the programme was ongoing

^Discrepancies are as follows:

- Case study 1: qualitative interviews did not confirm QI activities on 3 practices in the labour room. Participants referred to additional practices, but suggested they had been working on these before this programme and were supported by concurrent programmes
- Case study 2: programme reports include practices for which the facility provided monthly data; however, use of the QI approach was not confirmed by qualitative interviews
- Case study 3: vitamin K was not in the SCSL change package. It was introduced in LR to rationalise over-admission in NCU where the only reason for referral to NCU was vitamin K administration
- Case study 4: interview participants also referred to exclusive breastfeeding, for which the facility did not collect data

example prioritising practices that the hospital was already working on, such as kangaroo mother care. Functionality of QI teams varied across the case studies (Table 6). Implementation of PDSA cycles was unstruc- tured and mostly limited to the *do* and *study* part of the cycle [11]. In three cases (CS1, CS3 and CS4), interviewees reported limited understanding of the change package, and that new initiatives were imple- mented based on mentors' suggestions, while in the fourth case study (CS2) respondents were not clear about the concept of testing ideas for improvement. The limited understanding of the QI approach is evidenced

also by the discrepancy between what interviewees understood the EBP of focus to be and what emerged from process monitoring data (Table 6). Health workers involved in the QI interventions reported being tasked with collecting data for ACCESS to analyse, although they were largely unaware of the purpose of this exercise. In two cases (CS3 and CS4), interviewees reported discussing results with ACCESS, but not sharing findings with others in the unit. Contextual factors that challenged implementation and capacity building, according to respondents, included staff shortages and high staff turnover, perceptions of inadequate resources and resistance from staff due to low motivation and limited focus on outcomes.

I: Did she (mentor) discuss anything about improvement?
R: No she did not because there is no staff. […] Most of us are busy, whenever she visited us. You may have noticed it too. One sister has to look after 20 babies. It's very difficult. CS3_Nurse NCU
It is difficult nobody wants to work. We take salaries and we don't work. That is attitude of the people. Every sister wants to sit daily. CS4_NCU Manager

How was the programme perceived by participants and other health workers?

Participants did not engage in the programme in the way it was intended. In the private hospital and one medical college (CS1 and CS2), the intervention did not generate involvement beyond 1–2 committed individuals, and very few other interviewees were aware of the programme activities. The intervention appears to have been better received in the other two case study facilities, based on the detail with which implementation was explained and examples of change provided by respondents. In all case studies, the programme was perceived as an external assessment. Participants mostly described the process of quality improvement as compiling a checklist to audit compliance with a certain EBP and reporting to ACCESS.

R: They assess whether we are practicing hand wash or using hand rub. They observe us and if we are free, they come and also ask us.
I: What they do with assessment?
R: I think they tell unit-manager and medical officers CS1_Nurse NCU

Participants directly involved in programme activities suggested that the programme increased their workload because of the burden of documentation.

I: Why has the use of the checklist stopped?
R: We are busy and there is nobody to ask about it. We monitor but not document. We guide each other orally CS1_Round 2_ Nurse NCU

Respondents articulated other more pressing priorities for QI, for example increasing staff numbers. Also, they could not fully differentiate this intervention from other ongoing initiatives. Nevertheless, in the three public facilities, participants welcomed the training received (e.g. on handwashing), lamented the short-term duration of the programme, and suggested that further monitoring by ACCESS would have been welcomed to keep focus on EBPs.

What mechanisms of change were activated and how? If not, why not?

Given the challenges with implementation and the lack of an effect of the intervention, the analysis of mechanisms of change could not be conducted as intended. We report instead on the themes emerging from participants' responses when asked about changes they were seeing in their practice, in their team or in their unit, recognising that these represent the view of a few highly involved staff rather than prevalent views in the target units. We also report on contextual challenges emerging from the case studies which may explain why these changes failed to involve the wider team and thus why the expected change did not occur.

In terms of positive changes, five themes emerged. First, interaction with mentors helped bring focus on the aim for improvement and new ideas. Second, participation in the intervention improved motivation and commitment to improving the target EBP. Interaction with mentors reinforced the importance of complying with the practice and helped expose gaps and challenge complacency and reframe the issue as a problem with a solution over which staff had control. Seeing results further reinforced motivation. Third, the intervention enhanced staff knowledge and capacity to perform a certain practice. Fourth, participation in the intervention increased the sense of personal responsibility of the QI champions involved, who saw themselves as leading change by example. Fifth, a few respondents conveyed that the intervention created a climate in which behavioural expectations, for example for handwashing, were clear, and where staff could challenge each other if they observed non-adherence to those behaviours.

Previously they used to not do that. But now after the quality improvement people have come they do

compulsorily hand wash and use hand rub in be- tween. If they forget also, we remind them. They don't feel [bad] because we are seniors they know why we are saying. Now everyone is aware that they should do hands wash. CS4_Round 2_Staff Nurse NCU

However, only in case study 4 did it appear that these mechanisms were sustained to the end of the programme. In the others, as soon as external scrutiny from mentors waned, the use of QI tools was discontinued.

If you give us some work and ask us to do, we will perform that activity only if we know that you are going to come back tomorrow to verify the same. If you come once in a blue moon day and ask us to do something, then they will not do it. The staff needs to have fear that people are coming back to ask us again. CS3_Staff Nurse NCU

The change in a few individuals did not translate in a shared sense of responsibility for QI. Contextual factors mentioned above, including high workloads, team work regulated by professional hierarchies and top-down management styles, as well as limited systems for holding staff to account and rewarding performance, were mentioned as key challenges. Nevertheless, interviews in round two suggested that adherence to target practices that had received sustained effort, e.g. handwashing in NCUs, was con- tinuing and was well-understood by all, even if moni- toring of compliance had ended.

Discussion

Our study adds robust and substantive evidence, com- bining impact and theory-driven process evaluation on a large-scale quality improvement programme in second- ary and tertiary Indian hospitals [27–29].The interven- tion was not implemented as intended, and only 7 of the planned 60 hospitals implemented QI activities for 16 months: two thirds of the intervention group dropped out, and none of the comparison group started activities, contrary to the initial plans. We found no effect of the intervention on facility-based neonatal mortality and stillbirths, or on the adherence to evidence-based intra- partum and newborn care practices in labour rooms and newborn care units. However, we found evidence of im- provements over time in both groups with regard to stillbirths, 7- and 28-day neonatal mortality, use of checklists at birth, assistance with kangaroo mother care and hand hygiene: it seems likely that these were due to other interventions.

We used a theory of change to understand how con- textual factors influenced implementation and the hypothesised mechanisms of change. We found key bot- tlenecks to the pathways identified in the theory of change, namely challenges in engaging leaders and main- taining commitment; challenges in developing capacity for QI; and challenges in activating mechanisms of change at the unit level, rather than for a few individ- uals, and in sustaining these through the creation of new social norms for all target practices.

High attrition of participating hospitals reflects the challenge of sustaining institutional stakeholders' buy-in in Andhra Pradesh, and of engaging hospital leaders, in- cluding hospital administrators and the Unit Incharge, particularly in private hospitals and medical colleges. The model for QIC was modified during implementation to respond to the challenge of generating and sustaining commitment. These included a fluid QI team, selection of EBPs based on feasibility rather than driven by the gap analysis, and an unstructured cycle for innovation testing, relying on external advice and data analysis, ra- ther than facilitation of team reflection. As a result, the quality improvement approach was diluted and per- ceived mostly as a data collection and auditing exercise by some participants, as opposed to a bottom-up problem-solving opportunity. The lack of collaborative learning sessions, a key feature of the QIC approach, may have compounded the limited opportunity for QI capacity building, since the approach was extremely new for the context.

This evaluation supports the body of evidence emer- ging from rigorous studies of QIC which has mixed re- sults [30–32] and suggests caution in concluding that QIC interventions are effective [15, 16]. In particular, our study is consistent with the findings of the most re- cent systematic review, which found that QICs are more effective in moderate and opposed to low-resource set- ting, and when combined with training [14]. In our study, staffing constraints severely impacted on health workers' ability to engage in quality improvement. Al- though mentors delivered training on quality improve- ment and on non-clinical practices, e.g. hand washing techniques, the programme did not envisage training on new clinical practices, such as antenatal corticosteroid administration. Recent evaluations of QICs for newborn outcome improvement point to the importance of com- bining QI with problem analysis and clinical training [17]. The limited coherence between analysis of drivers of hospital mortality and selection of EBPs, the limited focus on EBPs requiring clinical practice changes and the emphasis on single EBPs as opposed to a whole change package of clinical and non-clinical interventions for the key driver of mortality in each hospital may partly explain the nil results.

A recent review on how and why QICs may improve outcomes highlights the need to contextualise QIC implementation and test mechanisms of change through greater use of theory in design and evaluation [24]. Our results confirm that QIC effectiveness is highly sensitive to context. Limited fidelity in application of PDSA ap- proaches has been found in high-income settings as well [33], and high attrition is a common implementation challenge [34]. While some process evaluations have re- ported positive perceptions from participation in quality improvement [35], other studies have reported similar challenges in engaging leadership [34, 36]. This high- lights the need to consider leadership engagement as part of the intervention, because this cannot be taken for granted. Therefore, QICs should not be considered a short-term intervention. The SCSL programme was ini- tiated concurrently with other government initiatives, including quality assurance schemes, and was not, at least initially, aligned to these. This may explain the challenge of engaging hospital leaders. Our findings on leadership also suggest that in a context with strong professional hierarchies and boundaries, greater attention needs to be placed on ensuring that implementers have the profes- sional credentials, the networks and status required to generate traction across all the health worker cadres whose behaviour is targeted. Developing strategies for leadership engagement may require greater understand- ing of health system factors and pressures and incentives for hospital leadership.

Similarly, building systems and skills for continuous use of data for decision-making and reducing resistance to this has been described elsewhere as "an intervention in itself", requiring longer timeframes than expected [33]. Our findings are consistent with these. In our con- text, the challenges of building QI capacity were compounded by systemic constraints, such as high staff-patient ratios, high workloads and infrastructural challenges. This echoes the limitations of point of care interventions reported elsewhere [1, 9, 37–39], and that further attention to the enabling environment, or readiness for quality improvement, is necessary to improve intervention design and effectiveness [40].

Our qualitative results confirm the complexity of QIC interventions: more than a set of tools and approaches, QICs need to be designed and evaluated as social innovations, requiring change at multiple levels and adaptation to the context. Our qualitative analysis aimed to explore the cognitive, social and organisational changes brought about by participants' engagement with the QIC intervention and how these could explain outcomes [28, 41, 42]. Our theory of change appears valid, as case studies confirmed most of the themes that had been hypothesised as mechanisms of change. In addition, case studies highlighted that the mentoring received brought new focus and new attention to a specific issue. This is consistent with quality improvement principles [13] and has been described elsewhere as a process of reframing [43]. In the theory of change, this could be conceptualised as the first key mechanism on the pathway to further changes (individuals need to perceive the severity and urgency of a problem in order to prioritise doing something about it) [44]. However, in our evaluation, we found that the changes reported by a few individuals involved in the intervention did not translate in a sustained shift to a culture of quality improvement at the level of units and hospitals, and there was no change in intended outcomes, therefore we cannot conclude that these acted as mechanisms of change. In addition to limited leadership engagement, this may have been due to three contextual factors: (i) staff workload and low motivation, preventing adequate implementation and active engagement in QI approaches; (ii) the challenge of mobilising a professionally diverse QI team for bottom-up gap analysis and discussion, due to professional boundaries and hierarchical processes for decision-making; and (iii) the prevailing working culture encouraging compliance to external requests, as opposed to self-reflection and problem-solving. At the root of our theory of change is normalisation process theory [25]. In line with this theory, our findings suggest that the contextual challenges did not enable participants to find the intervention coherent with their concerns, capabilities and priorities, resulting in limited ownership of the QI approach. This in turn hampered collective action and reflective monitoring [45]. Greater focus on organisational change mechanisms, as opposed to individual behaviour change, and on developing strategies that modify key contextual bottlenecks is necessary to improve intervention design [46, 47].

Our impact and outcome evaluation used a quasi-experimental design with externally assessed as opposed to self-reported outcomes, which is a strength. The integration of a rigorous process evaluation enables us to explain observed results. The theory-driven approach adds depth to our analysis and enables us to capture learning that is relevant to the wider debate on how to improve quality of maternal and newborn care, which is the major frontier for the achievement of universal health coverage.

We could not test whether outcomes relate to the intensity of the mentoring and coaching approach, due to challenge of capturing process data to define implementation strength reliably. Improved standardisation of process monitoring, for example standardising definitions on when an EBP is considered adopted may be useful in future evaluations of QIC. Because of the high attrition, we also lacked the statistical power to conduct such secondary analysis. We couldnot test mechanisms of change through a mediation analysis, due to the small sample in which the inter- vention was implemented. However, the qualitative work has contributed to a theory of change that may allow quantitative testing in future studies. Finally, groups

could have differed in important ways at base- line because of lack of randomisation. However, im- plementation would have been even weaker had facilities been randomly allocated.

Conclusion

Our evaluation of a QIC intervention in 60 secondary and tertiary hospitals with newborn care units in Telangana and Andhra Pradesh, India, found that the intervention did not improve adherence to target EBP or result in a measurable impact on neonatal mortality or stillbirths. Moreover, of the initial 29 hospitals intended to be included in the intervention, only 7 implemented the intervention for 16 months, suggesting that the intervention was not feasible in this context. The nested process evaluation highlights the need to consider the contextual challenge of engaging leaders: greater involve- ment of technical experts and alignment with national quality strategies may aid this. Building capacity for QI requires timely and consistent support. Using a theory of change can help to conceptualise individual and organ- isational changes and potential bottlenecks. Quality im- provement may need to be accompanied by clinical training if target EBPs require changes in clinical prac- tice. We highlight the need for further research on strat- egies for positioning quality improvement efforts within health systems, on quantitative testing of our QIC theory of change and on the optimal combination and intensity of training and QI.

Supplementary Information

The online version contains supplementary material available at https://doi. org/10.1186/s13012-020-01058-z.

Additional file 1: Annex 1: List of indicators, data sources and number of observations.

Additional file 2: Annex 2: Post-hoc before and after comparison (intervention and comparison groups combined)

Additional file 3: Annex 3: Table 5 – Leadership, Table 6 – Contextual challenges for QI team mobilisation and capacity building, Table 7 - Perceptions of programme by health workers, Table 8 – mechanisms of change

Abbreviations

ACCESS: Access Health International; CS: Case study; DiD: Difference-in-difference; EBP: Evidence-based practice; NCU: Newborn care unit; QI: Quality improvement; QIC: Quality improvement collaborative; PDSA: Plan, Do, Study, Act; SCSL: Safe Care Saving Lives

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Authors' contributions

SS, CH and JS conceived the impact and outcome study. KZ, JS, CH and ZH conceived the process evaluation. SS coordinated quantitative data collection, with support from MT, and supervised by CH and JS. KZ and MT coordinated process evaluation data collection, supervised by CH and SS. MT and KZ conducted field interviews. KZ and MT conducted quantitative and qualitative data analysis, reviewed by SS and CH prior to drafting the manuscript. KZ wrote the first draft of the paper, with contributions from all authors. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets analysed during the current study are available in the LSHTM repository, Data Compass.

Ethics approval and consent to participate

See manuscript—Methods section.

Consent for publication

Consent for publication was received from all individuals mentioned in the acknowledgement section.

Competing interests

The authors declare that they have no competing interests

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Publisher's Note

Chapter 6

Paper D – Leveraging health insurance for quality improvement: lessons on scale-up from a newborn care quality improvement programme in Telangana, India.

This chapter presents the analysis from the qualitative study exploring the the potential for scaling the quality improvement collaborative approach used by Safe Care Saving Lives in Telangana. It addresses objective 4 of the PhD (to develop a framework to analyse "scalability" and analyse the feasibility of scaling up the QIC approach through the state-level health insurance scheme in Telangana).

This chapter is presented as a draft manuscript, which I plan to submit to Health Policy and Planning.

The manuscript references a methodological musing I published in Health Policy and Planning on 31st July 2019[4] which contains the scalability framework used for the analysis. The methodological musing was published under Creative Commons License, (CC BY 4.0) and is included as Annex 1 to this thesis. It is also available at: https://academic.oup.com/heapol/article/34/7/544/5542084 .

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[4] **Zamboni K.,** Schellenberg J., Hanson C., Betran AP, Dumont A. Assessing scalability of an intervention: why, how and who?, *Health Policy and Planning*, 34:7, September 2019, Pages 544–552

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Student ID Number	1603470	**Title**	Ms
First Name(s)	Karen		
Surname/Family Name	Zamboni		
Thesis Title	Improving quality of newborn care at scale through quality improvement: evaluation of the Safe Care Saving Lives programme in Telangana and Andhra Pradesh, India.		
Primary Supervisor	Dr. Claudia Hanson		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

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Please list the paper's authors in the intended authorship order:	Zamboni K., Singh S., Hanson C., Shukla R. and Schellenberg J
Stage of publication	Not yet submitted.

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I led the design of the study including the conceptual framework, data collection tools and plan, under the supervision of Dr. Claudia Hanson and Prof. Joanna Schellenberg. I analysed data, with input from Dr C Hanson and wrote the first draft of the manuscript

SECTION E

Student Signature	Karen Zamboni
Date	30th June 2021

Supervisor Signature	Claudia Hanson
Date	30th June 2021

Leveraging health insurance for quality improvement: lessons on scale-up from a newborn care quality improvement programme in Telangana, India.

Background

Improving quality of newborn care is a key priority for the reduction of newborn mortality, including care at birth and inpatient care of small and sick newborns (1, 2). This is generally provided in secondary and tertiary care facilities, offering special newborn care or newborn intensive care units (3-5). Health financing is a major barrier to scale-up inpatient newborn care, as specialised care is costly and often lacks designated funding. Prohibitive user fees and inadequate financial protection for families requiring access to specialist care for babies born too soon or small are also part of this challenge (6). In India, impoverishment as a result of healthcare costs is common for patients and their families and the cost of specialist care results in major inequities in access to specialist care (7).

Purchasing services from the private sector is one of the strategies used to expand access to quality healthcare(8), although limited evidence exists on the success of this approach (9, 10). The Government of India has made major investments in the last decade to increase the number of special newborn care units in public secondary hospitals, which provide specialist care to small and sick newborns except surgery and ventilation (11-14). It also supports private sector participation to extend such provision to the urban poor(11), given the large market share of the private sector (15, 16). Structured collaboration with the private sector is emerging, for example by extending the obligation of reporting through the national newborn admission database to private providers (12). Another example of public-private partnerships are government-sponsored health insurance schemes providing financial protection to the poor when accessing specialist services provided by public and private providers. One such scheme is the Aarogyasri Health Insurance scheme in the state of Telangana, which is one of the few LMIC examples s of insurance schemes including care for small and sick neonates requiring hospitalisation and surgery (17-20). The scheme was originally formed as the Rajiv Aarogyasri Community Health Insurance scheme in the unified state of Andhra Pradesh in 2007, and continued in Telangana once this state was formed from the split of Andhra Pradesh in 2015. The Aarogyasri Health Care Trust was formed to implement and monitor the scheme, which was administered by an insurance company. The scheme covers care delivered through an existing network of public and private sector hospitals, which must meet six criteria relating to infrastructural setting in order to join, and are reimbursed for the provision of services to eligible groups, up to a cover of $4500 per family each year (17, 19-21). Approximately 70m individuals were reported to be covered by the scheme in 2012, representing 85% of the Andhra Pradesh population (22). The scheme is not specific to maternal and newborn care and includes all specialised care including (for example) cardiology and nephrology.

Despite the growing role of the private sector in the provision of newborn care, there is little evidence in the peer-reviewed literature about the contribution of private providers to inpatient newborn care in terms of numbers, skills, human resources and available infrastructure (11, 23). While perceptions of higher quality of care in the private sector prevail, the very few studies that have compared care practices in private and public providers reported quality gaps in private as well as public facilities (24-27). So, the challenge of improving financial protection for equitable access to inpatient care for small and sick newborns goes hand in hand with the challenge of improving quality of care among both public and private care providers.

The Safe Care Saving Lives programme, implemented by ACCESS Health International between 2015 – 2018, aimed to reduce newborn mortality and stillbirths by improving quality of intrapartum and newborn care through the use of the collaborative quality improvement approach, inspired by the Institute for Healthcare Improvement (28) and described in detail elsewhere(29). The programme was

developed in partnership with the Aarogyasri Health Care Trust, on the assumption that health insurance payments could provide financial incentives for quality improvement at scale (29). The newborn care quality improvement collaborative was set up to include all 85 public and private special newborn care units that were part of the Aarogyasri network (29), which was important as the private sector represents 25% of newborn admissions in Telangana (30). We conducted a mixed methods evaluation of the Safe Care Saving Lives programme, assessing the effect on newborn mortality and stillbirths, and evaluating contextual factors and mechanisms of change. This is reported elsewhere: in brief, the evaluation found no evidence of effect on primary or secondary outcomes; high attrition from participating hospitals, and diluted implementation of the quality improvement approach (31). Here we analyse the feasibility of scaling-up the collaborative approach leveraging the Aarogyasri Health Care insurance platform in Telangana.

Methods

We conducted a qualitative study consisting of 3 components: i) in depth description of the strategy for scale developed by Safe Care Saving Lives; ii) development of a framework for analysis of "scalability"; and iii) qualitative primary data collection and analysis.

Description of scale-up strategy

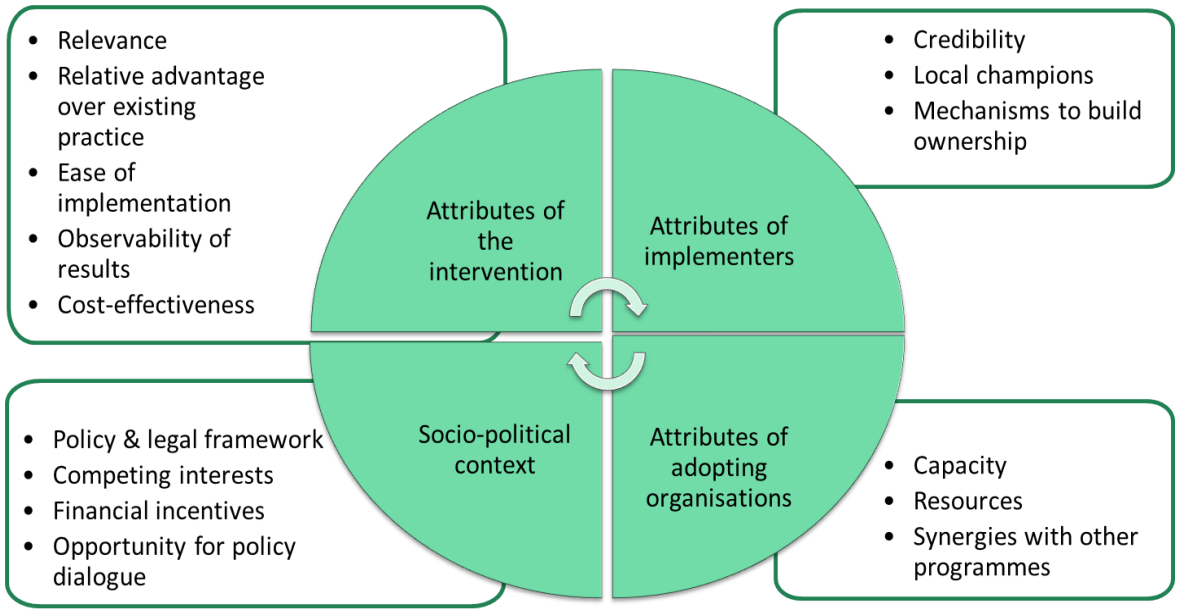
We reviewed programme design documents and the scale-up strategy developed by the implementing organisation for the programme donor. Based on this, we identified a preliminary set of assumptions on the role envisaged for the Aarogyasri Health Care Trust in scaling up quality improvement at the collaborative level and in the state health system. We discussed and validated these in a participatory workshop held in Hyderabad in July 2017, involving ACCESS staff who had been involved in designing the programme, the programme donor and the ACCESS team implementing the programme. In the workshop, we elicited participants' understanding of the activities implemented or planned to facilitate quality improvement scale-up through the Aarogyasri Health Care Trust; we facilitated identification of intermediate outcomes for this work, and their link to programme impact; we probed participants to articulate the preconditions leading to these outcomes and the necessary contextual conditions, resources required, and how the programme would have gained support for mobilisation of those resources. We consolidated these into a theory of change at the level of the collaborative and the health system to map intended changes and the key assumptions (32).

Development of a framework for analysis of scalability

We defined scale-up in line with the World Health Organization ExpandNet definition, as 'deliberate efforts to increase the impact of successfully tested health innovations, so as to benefit more people and to foster policy and programme development on a lasting basis'(33). The core tenet of this definition is that scale-up is broader than expansion of coverage, and it entails institutionalisation and sustainability of innovations into a health system, as well as maintaining their effectiveness. The definition emphasises that scale-up can be facilitated and guided through an intentional process of stakeholder engagement, as opposed to happening through spontaneous diffusion (34).

We developed a framework to identify key factors that require consideration for intervention scale-up, and can aid the evaluation of an intervention's 'scalability', or 'the ability of a health intervention shown to be efficacious on a small scale or under controlled conditions to be expanded under real-world conditions to reach a greater proportion of the eligible population, while retaining effectiveness' (35). Methods for this are published elsewhere (36). In short, we conducted a rapid review of scale-up frameworks and tools in the peer-reviewed and grey literature to identify critical factors that require consideration when thinking about scale-up. We identified four factors: attributes of the innovation; attributes of the implementers; attributes of the adopting community; and socio-political context (Figure 1). Considering these factors at the start of an intervention design and implementation can inform the development of a scale-up strategy and maximise the opportunity for scale-up (37-41), whilst recognising the dynamic and inherently political nature of scale-up processes (42, 43).

Figure 1: Framework for analysis of scalability



Primary data collection and analysis

We conducted 18 semi-structured interviews with government health authorities, representatives of organisations supporting quality improvement in partnership with the government of Telangana, which we refer to as technical partners, and representatives of the Aarogyasri Health Care Trust. We also interviewed a senior representative from ACCESS, and hospital leaders (Medical Superintendents) and managers of Special Newborn Care Units in 4 case study hospitals selected for the Safe Care Saving Lives process evaluation (31). Sampling of interviewees was done purposively: stakeholders in the health system were selected based on the analysis of context and technical networks of our evaluation partner, the Public Health Foundation of India (PHFI). Selection of case study hospitals aimed to include the types of hospitals involved in the programme, including a private facility, a public secondary hospital and two public medical colleges, details of which are reported elsewhere (31). Within each case study, participants were selected for their role in implementing quality improvement (Unit Managers) as well as interfacing with the Aarogyasri Health Care Trust (Medical Superintendents). None of the sampled interviewees refused to participate. Interview guides explored stakeholders' understanding of the Safe Care Saving Lives programme and its links with the Aarogyasri Health Care Trust, their perceptions on the role of the Aarogyasri Health Care Trust for newborn care quality improvement, the policy priorities around quality of newborn care and quality improvement in Telangana, and the relevance of Safe Care Saving Lives to these.

Interviews were conducted in English by three senior researchers from our evaluation team (two international academics, and an Indian academic regularly participating in technical dialogue on newborn care at the state level), to match the level of seniority of selected interviewees, as previous experience in conducting qualitative research in this context suggested this is important to build good rapport during the interview(44). Prior to the interviews, we mapped quality improvement initiatives in Telangana based on their technical engagement in the maternal and newborn care sector, to situate the intervention in context and later enable interpretation of responses. This contextual map was shared with all interviewers ahead of fieldwork. Drawing on their experience and understanding of the programme in context, interviewers used prompts flexibly during the discussion. Debriefing in the field team occurred daily, and a set of field notes was collated by one of the interviewers, capturing observations on the context of interviews and preliminary reflections of the field team. Interviews

were recorded and transcribed by Research Assistants, the transcripts reviewed by the Lead Researchers, and clarification sought from interviewers where appropriate.

We analysed data through framework analysis: we coded data against the four key domains in our scalability framework (attributes of the intervention, of implementers, of the adopting organisation and socio-political context) and we identified key themes under each (44), using NVIVO 11.

Ethical approval

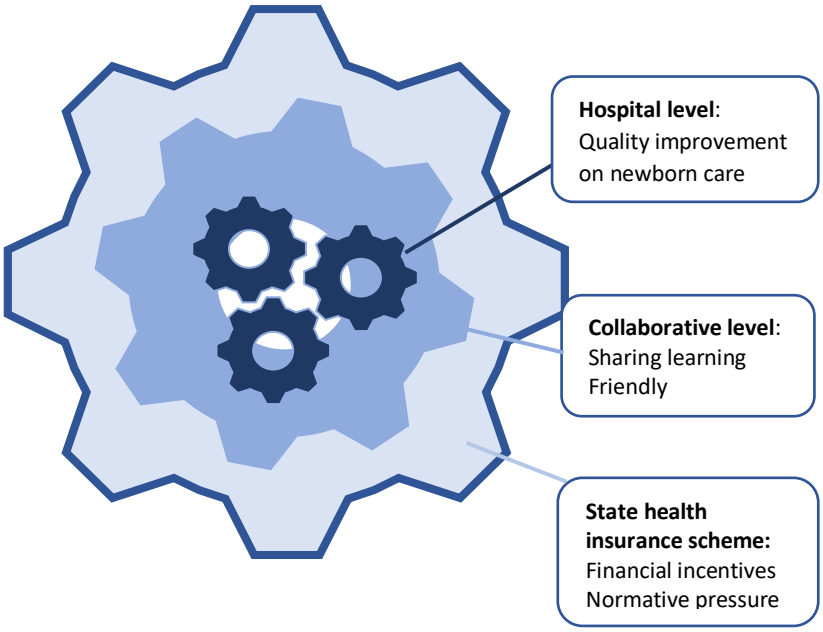
Ethical approval was granted from LSHTM (LSHTM Ethics Ref: 10358) and PHFI's Institutional Ethics Committee (IIPHH/TRCIEC/064/2015). Informed consent was obtained from each participant after reading out an information sheet. Participants could withdraw or request to stop recording interviews at any time. Consent for interviews in hospital settings was obtained from the hospital prior to starting data collection, and from each participating respondent. Confidentiality was assured, as per institutional guidelines of each research institution.

Results

Strategy for scaling newborn care quality improvement through state health insurance platform

As discussed elsewhere (29)[Annex B], Safe Care Saving Lives activities related to scale-up complemented the intervention at the level of individual hospitals and collaborative activities (Figure 2). In each hospital, quality improvement teams were trained and mentored to introduce and test innovations to improve adherence to newborn care practices through Plan-Do-Study-Act cycles (28). At the collaborative level, teams from different hospitals shared ideas and lessons learned through so-called learning sessions, intended to promote diffusion of innovation and generate friendly competition to motivate improvement. The scale-up strategy and related activities in Safe Care Saving Lives rested on the assumption that the Aarogyasri Health Care Trust may play a role in improving quality of newborn care in public and private providers in three ways: first, by sustaining collaborative activities for newborn care quality improvement in the Aarogyasri network after the end of the programme; second, by providing financial incentives for healthcare providers delivering quality services; and third, by exerting normative pressure on hospitals to improve quality.

Figure 2: Complementarity between levels of intervention in Safe Care Saving Lives



Therefore, activities related to the Aarogyasri Health Care Trust were three-pronged. First, ACCESS Health International aimed to build the Aarogyasri Health Care Trust's capacity to take over coordination of the collaborative platform: to this end, ACCESS developed a webpage and other communication products to profile and disseminate the activities of empanelled hospitals in relation to newborn care quality improvement. Second, ACCESS seconded a Quality Improvement Adviser in a newly established Quality Cell in the Aarogyasri Health Care Trust to support the development of a mechanism linking Aarogyasri payments to hospitals with the adoption of quality improvement methods in newborn care units. Third, ACCESS aimed to strengthen Aarogyasri's quality assurance function: to be part of the Aarogyasri network, hospitals already had to be accredited with the National Accreditation Board for Hospitals and Health Care providers under the Quality Council of India, a hospital wide accreditation scheme, with standards on care of patients, human resource management, patients' rights and infection control, among others (45). ACCESS aimed to include quality improvement teams and performance on newborn care outcomes as new criteria for continuous empanelment of public and private healthcare providers in the network.

Feasibility of scale-up through state health insurance platform

Qualitative study results

Table 1 summarises key themes emerging under each domain of the scalability framework (Table 1).

Table 1: key themes under scalability framework domain

Domain	Key themes
Attributes of the intervention	• Intervention responds to a pressing problem • No clear advantage over existing practice • Results are not demonstrated
Attributes of implementers	• Limited credibility • Loss of local champions • Weak coordination and duplication
Attributes of adopting organisations	• Limited fit with contextual challenges and key needs • Limited synergies with other programmes
Socio-political context	• Complex framework around quality, focused on quality assurance • Limited scope for leveraging financial incentives through health insurance

Attributes of the intervention

Three themes emerged in relation to characteristics of the intervention. Stakeholders found the intervention broadly relevant to the context, as they reported that improving quality of maternal and newborn care is a pressing concern and a priority for policy-makers. However, interviewees' understanding of the intervention approach, focused on quality improvement through team problem-solving, was limited and, as a result, they could not articulate the advantage of this approach over quality improvement through quality assurance and standardisation of facilities. Finally, stakeholders were not aware of progress with implementation of evidence-based interventions, nor of evaluation results. Although ACCESS did monitor progress of the implementation of evidence-based interventions, this data was only available to the hospitals providing it, and not disseminated through the Aarogyasri network.

Attributes of the implementers

Three key themes emerged in relation to characteristics of the implementers that may facilitate scale-up. First, the implementing organisation, an international NGO, was a relatively new player in the context, and quality improvement mentors were mainly public health professionals rather than clinical specialists. This created a credibility challenge for the implementers.

> *"If I am a non-medical person, the first block comes there, if I* […] *am trying to talk to a nurse who's from the medical side"* – Technical partner 1

> *"We had some very senior professors, associate professors and assistant professors over there* [in the participating hospitals]*, and some young people trained on quality coming in, and trying to tell them* [about quality improvement]*. Many people really did not take it very positively"* – ACCESS representative

Second, during the design phase of the programme, the programme worked closely with an Expert Faculty Group including leading neonatologists and paediatricians to identify the package of promising evidence-based practices to introduce at scale in intrapartum and newborn care (46). It also worked closely with state health insurance authorities and the Ministry of Health and Family Welfare at state level. However, the relationship with the Expert Group was not formalised or extended to provision of technical support through mentoring of hospitals during the implementation phase, due to both budget constraints and challenges in reaching hospitals in a wide geographic area. This compounded the credibility challenge and resulted in loss of high-level champions for sustained implementation. Finally, there were limited structures for coordination of players on the quality improvement agenda,

at least at the beginning of the intervention, as quality improvement was only then emerging as a policy priority.

> *"When the project of ACCESS started there was no clear understanding even at the national level of improving quality. It was very broad and even accreditation was never on mind"* – Technical partner 1

So, implementation was not coordinated with other quality-focused programmes, and some efforts, for example the development of software to routinely collect newborn care performance data, were duplicative of other more established efforts.

> *"The only limitation for Safe Care Saving Lives programme* [is that] *it's not actually embedded into the government programme. So it's like a parallel programme done by ACCESS Health International"* – Technical partner 2

> *"They have developed a software for integrating the information or to get the data. […] but somehow there is no support from the Government, because the Government is thinking that there is another software of National Health Mission under Commissioner of Family welfare […]. Many software will ultimately lead to duplication and unnecessary confusion in the information or data*" – Aarogyasri Health Care Trust representative

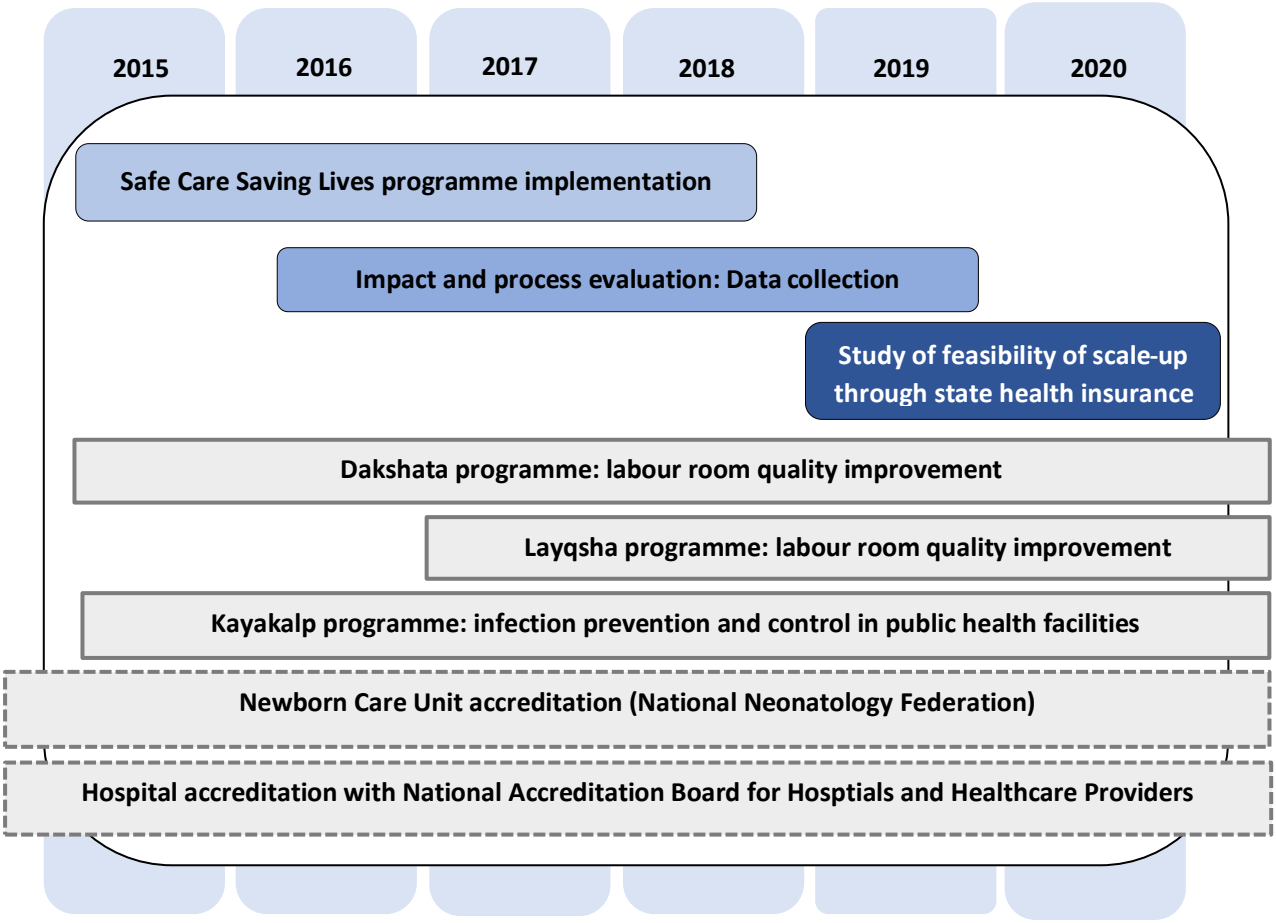
Attributes of the adopting organisation

Two themes emerged from interviews. First, stakeholders pointed to challenges in implementation due to high workload in facilities and poor consideration of other contextual challenges such as skills and specific needs of clinical teams, resulting in limited engagement.

> *"Suppose you are trying to teach me something, and you are trying to teach five things. Out these, three already I know, my interest from the remaining two also comes down. […] I felt the concept was nice but taking into consideration […] pre-existing or the baseline skills, attitudes […]…. that's very important when you devise a package" – Technical partner 1*

Second, hospitals reported that other concurrent programmes were being implemented, and could not distinguish the Safe Care Saving Lives programme approach from these interventions. Three concurrent interventions were referred to as the core quality improvement activities in the state (Figure 3): the Dakshata programme in labour wards, implemented by JHPIEGO since 2015 and focusing on implementation of the safe birth checklist, in-service training on maternal health complications and support to improvement of the labour room environment (47); the Laqshya programme, launched in 2017, incorporating the Dakshata approach into a broader maternity care quality improvement initiative, focusing on structural and process improvement (48); and the newborn care unit accreditation programme by the National Neonatology Forum, developed jointly with UNICEF (49).

Figure 3: Timeline of implementation of Safe Care Saving Lives programme and evaluation, and selected quality-focussed programmes in Telangana



Socio-political context

The analysis on the socio-political context domain looked specifically at the fit between the intervention and the policy and regulatory framework around the intervention and the institutional set up. Two themes emerged: first, a policy framework that focused more on quality assurance than on quality improvement, through a complex set of initiatives and standards at state level. Second, there was limited scope for leveraging financial incentives through health insurance.

With regard to the policy framework, this was characterised by a wide range of standards and guidelines for both labour rooms and newborn care units and a focus on quality assurance rather than quality improvement. Hospital level schemes included accreditation with the National Accreditation Board for Hospital and Healthcare Providers, mentioned above(45), and quality assurance through the Kayakalp programme, launched in 2015 and focusing on hygiene and infection prevention and control in public health facilities(50). Both programmes were linked to financial incentives for hospitals. Other relevant schemes included accreditation for Labour rooms under the Laqshya programme and accreditation of newborn care units with the National Neonatology Federation (48, 49). Achieving accreditation emerged as the most pressing concern of the hospital leaders that we interviewed. Institutional stakeholders also confirmed that progress on implementation of these schemes was the key priority.

> *"Currently, accreditation by the National Neonatology Forum is the ultimate measure of the quality of care. Apart from the outcomes and apart from the process also which we can also measure"* – Technical partner 1

"Previously we have done standardization pertaining to labour rooms. But now we have wards and operation theatres also. Now we have to form coaching teams at district level and labour room quality circles at the facility level" – Ministry of Health and Family Welfare representative, discussing the Laqshya programme.

The Laqshya programme had an explicit focus on process improvement, through the establishment of quality improvement teams called quality circles, and the use of rapid improvement cycles, supported by district quality mentors. This "improvement phase" followed an assessment phase focused on identifying and addressing structural gaps. However, there was limited clarity amongst stakeholders on the link between the quality improvement activities and the quality assurance schemes, possibly because it was still early in the programme implementation.

I - Right now, in your opinion in terms of quality are we just talking about infrastructure or we are also talking about practices in Laqshya?

R - Standardization I think we have done. We have reached about 65-70% standardization. Regarding this you want to know…? What else…?

I - Regarding protocols and practices…?

R - Practices, most of the institutions they are practicing.

R2 - It is a continuous process. It is not a new one where somebody is helping us. It's there. It is in government hand, it's going on. – Ministry of Health and Family Welfare representatives

The ACCESS team did highlight the conceptual complementarity between quality improvement and quality assurance: for example, accreditation with National Neonatology Federation specifies thresholds for newborn mortality and stillbirths below which performance is deemed unsatisfactory, and requires self-reports on availability and implementation of protocols for key newborn care practices. Use of quality improvement can support the achievement of these performance levels. However, this link was not clear to other stakeholders we interviewed.

In relation to the scope to leverage financial incentives for quality improvement through the Aarogyasri Health Insurance scheme, interviewees reported three key barriers: first, hospital leaders saw Aarogyasri's role on quality as providing equipment, for example for ventilation of sick neonates. Second, they reported delayed flow of funds from Aarogyasri, and that the administrative burden required to process the claims was not commensurate to the financial return. Third, the strategy to incentivise quality improvement through Aarogyasri payments was perceived not to be coherent with the institutional set-up for newborn care. Stakeholders highlighted the authority of the Ministry of Health and Family Welfare for public secondary facilities, and of the Directorate of Medical Education for public medical colleges, and stressed that the Aarogyasri HealthCare Trust had limited interest in improving newborn care, since this represented only a very small part of eligible procedures.

Aarogyasri is not dealing much with mother and child health because it [maternal and child health] *is being funded by Govt. of India, dual funding should not be there* […]*. That's why there is not much initiative from the Aarogyasri side to this quality cell point of view* – Aarogyasri Health Care trust representative

"The entire health department runs through the mission director National Health Mission and Commissioner of Health and Family Welfare. There is an alternative hierarchy created only for the purpose of Aarogyasri claims. And this hierarchy cannot dictate the performance, cannot dictate attendance or anything to people who are primarily engaged by the Commissioner. […] *Maybe this organization* [ACCESS] *should have focused efforts on improvement of the quality of empanelment and approvals"* – Technical partner 1

"Then some new CEO [of Aarogyasri Health Care Trust] *who came, first of all, had a big question. Why is Aarogyasri even working on newborn health? Newborn health is something, which the commissioner of health and family welfare has to do. […] Because for Aarogyasri Healthcare Trust, the newborn piece of the package is just a drop in the ocean. They are more concerned about cardiology, nephrology, and all those things" – ACCESS representative*

Discussion

Our study explored the feasibility of scaling up quality improvement for newborn care through the Aarogyasri Health Care Trust in Telangana. The ambition of the Safe Care Saving Lives programme was to strengthen the strategic purchasing power of this government-sponsored health insurance scheme by leveraging financial incentives linked to reimbursements, and by creating normative pressure for improved quality within the network of service providers. This would have allowed reach into private as well as public service providers, a key priority for newborn care in a context where the private sector has a large market share. We used a novel scalability assessment framework to examine factors aiding scale-up, and found that the approach proposed by the Safe Care Saving Lives programme was not scalable. The *intervention* did not represent a clear advantage over existing practice, and lack of data sharing in the network did not enable demonstration of results. The evaluation later concluded the intervention had not improved newborn care outcomes (31). *Implementers* had limited credibility and some strategies to engage leadership were ineffective. The programme faced implementation challenges due to the limited fit with the context, and operated in parallel with other initiatives which were a priority for *adopting organisations*. In terms of the *socio-political context*, there was limited coherence with the prevailing quality approach at state level, focusing on quality assurance, and limited scope to leverage financial incentives through health insurance. Neonatal care was not a priority area for the Aarogyasri Health Care Trust; and the design lacked the appropriate institutional set up.

As argued by the Lancet Global Health Commission report on high-quality health systems, isolated interventions at the level of health facilities are unlikely to result in large-scale improvements, as they do not alter the performance of health systems (51). Conversely, alignment with national systems and quality priorities may influence the success of quality improvement collaboratives (52). Greater synergy is needed between initiatives at the point of care and macro-level programmes and policies aiming to improve quality, including financing for quality through strategic purchasing (51). The Safe Care Saving Lives programme's ambition to work with the state-level health insurance platform was to embed incentives for quality in the system, as thus promote leaders' engagement in quality improvement in both public and private hospitals. Incorporating a quality improvement collaborative in a state health insurance scheme was an extremely innovative approach for the Telangana context at the time of our study and to some extent this remains true. When Safe Care Saving Lives was introduced in Telangana, the quality agenda for newborn care was still largely focused on setting up special newborn care units, as opposed to improving processes of care, which is the key contribution of the quality improvement approach (28, 53). The policy framework rapidly evolved, with quality assurance schemes for labour rooms and newborn care units placing increasing emphasis on process improvement; however the limited credibility of the implementers and the weak alignment of the programme with large government initiatives led to limited opportunity for scale. It is important also to stress that the Safe Care Saving Lives intervention ultimately did not achieve the intended outcomes, fundamentally undermining the potential for scale-up (31).

Learning lessons from this experience is extremely timely in the context of strategic purchasing for quality. In March 2018, the Government of India launched the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) programme, which aimed to provide publicly funded health insurance cover of up to 500,000 Indian rupees (over US$7,000) per family per year to about 100 million families, or 40% of India's poor and marginalised population, identified based on deprivation criteria measured in the 2011 Socio-Economic Caste Census (54-56). In addition to expanding primary healthcare provision, AB-PMJAY introduced a National Health Protection Scheme, covering primary, secondary

and tertiary care, including for newborn care, provided by public and private providers. In states which already had government-sponsored health insurance schemes, details of how these schemes will be integrated are under development. While the primary aim of the scheme is financial protection for the poor, the scale of AB-PMJAY presents an opportunity to consider the potential to leverage health insurance for improving quality of maternal and newborn care.

Although Safe Care Saving Lives could not effectively activate collaboration between hospitals and could not leverage financial incentives for quality through the Aarogyasri platform in Telangana, four important lessons can be gathered from this experience. First, given that data is a fundamental driver of quality improvement, improvement collaboratives require a common data platform (57, 58), with the assumption that this would generate friendly competition among hospitals(28, 52). Lack of routine data on newborn care unit performance for comparison purposes was a key barrier to activating normative pressure in the Aarogyasri network. However, the introduction of a separate newborn care database to measure performance of Aarogyasri hospitals was not acceptable to users, and duplicative of other government efforts, even though these did not involve the private sector at the time of Safe Care Saving Lives implementation. Use of routine data which is now available from public and, increasingly, from private newborn care units could be strengthened for the purposes of exposing and addressing quality gaps.

Second, in our study, institutional structures did not recognise the role of health insurance in improving quality of newborn care, and the programme implementation partnership lacked a major centre of authority, the Ministry of Health and Family Welfare, which was responsible for delivery of quality newborn care. Also, newborn admissions comprised a small part of eligible payments, of negligible relevance to hospital leaders. Leveraging health insurance payments for quality should carefully consider the institutional set up and political economy of relationships between relevant institutional actors, and the relative role of insurance payments for maternal and newborn care services compared to other financial flows. This may determine not only the most appropriate institutional set up but also the extent to which incentives through insurance payments represent an attractive “carrot” to generate process changes (59-63). This is particularly important for engagement of private sector providers in contexts such as India, as payments from private health insurance may be more attractive for providers than government sponsored health insurance schemes (64).

Third, in our study, an external NGO implementer, tried to initiate major reform including introduction of new criteria for payment of insurance claims; new criteria for quality control for provider participation in the network; and capacity-building for the health insurance provider to maintain collaboration in the network focusing on quality. While each may have had merit, any external player would have needed extraordinary credibility to drive reform of this scale and complexity. A more specific approach, co-designed with authorities, may have been needed: the literature on performance-based financing highlights the adverse consequences of schemes driven by donors and external agencies (65).

Finally, accreditation is a key mechanism to drive quality through strategic purchasing by health insurance. Successful reforms have linked strategic purchasing to accreditation not only based on outcomes, but on a sustained quality improvement system (66, 67). In our study, empanelment in Aarogyasri was based on hospital-wide accreditation focusing on structural aspects of quality, and there was no link with emerging newborn care unit accreditation schemes which promoted process improvement, because of the limited role of health insurance for newborn care. In summary, there was limited overlap between roles, interests and priorities for newborn care quality improvement among institutions relevant to Safe Care Saving Lives.

A key strength of this study is situating a hospital-level quality improvement intervention , the Safe Care Saving Lives quality improvement collaborative programme, as part of a broader set of institutional actors and reforms to improve quality of care. This exposes critical challenges in achieving coherence between quality improvement intervention at the point of care and macro-level financing

strategies for quality. While results are not generalisable to other contexts, our study highlights the need to carefully consider alignment of initiatives at design stage, for example the kind of institutional arrangements or data systems that are required to facilitate such coherence. We also use a structured approach to understand barriers to scale-up, which allows us to explore the complementarity of factors aiding scale-up, including features of the intervention, the implementers, adopting organisation and the socio-political context (36).

Our study has limitations: we conducted a relatively small number of interviews, and could not interview Aarogyasri officials at the district level or ACCESS staff seconded into Aarogyasri. These might have provided more insights on the relevance and bottlenecks to Aarogyasri reimbursements for newborn care conditions; the health insurance scheme approach to quality control and assurance, and the challenges of linking payments to quality criteria. In-depth policy analysis of the Laqshya programme and the National Neonatology Forum scheme for accreditation of newborn care units, including standards and indicators to measure process improvement, was beyond the scope our study, but this could have further exposed challenges in achieving coherence between quality assurance schemes and quality improvement. This study was nested in the broader impact and process evaluation of the Safe Care Saving Lives programme. As researchers, we were aware of the Safe Care Saving Lives implementation challenges during data collection, and of the evaluation results during the analysis, which may have influenced our perception of the feasibility of the scale-up approach (68).

Conclusion

Our study of the feasibility of scaling up newborn care quality improvement through a government-sponsored health insurance scheme in Telangana found important barriers relating to both design and implementation of the approach. These include: limited evidence of effectiveness of the quality improvement intervention; limited credibility of the implementing agency; poor coordination with other quality-focused maternal and newborn care initiatives; limited coherence with the quality assurance policy framework, and a limited role for health insurance payments as incentives for quality in newborn care. Strengthening the role of health insurance for newborn care quality improvement through strategic purchasing should consider performance data requirements and availability; institutional roles and relationships, and approaches should be co-designed with health authorities. Further implementation research from other LMICs is needed to identify models to define newborn care quality standards for strategic purchasing and to link quality improvement objectives with quality assurance schemes.

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Chapter 7: Discussion

Introduction

The aim of this PhD was to analyse the contribution of quality improvement collaboratives to improving quality of newborn care by exploring their potential to scale-up.

The research has focused on a mixed-methods evaluation of the Safe Care Saving Lives quality improvement collaborative (QIC) programme in Telangana and Andhra Pradesh, with two specific research questions:

1. To what extent, how and under what circumstances did Safe Care Saving Lives improve adherence to evidence-based newborn care practices and reduce stillbirths and newborn mortality?
2. To what extent was the QIC approach operationalised by the Safe Care Saving Lives programme scalable?

The PhD aim required me to explore various interrelated themes: the intervention effectiveness; the feasibility and challenges of implementation; the relevance and acceptability of this intervention for participants and relevant stakeholders; the way in which the intervention generates changes (mechanisms of change); the influence of contextual factors on implementation, mechanisms of change and outcomes; and the coherence between quality improvement efforts at facility and collaborative level with broader quality initiatives at the level of the health system.

In Section I of this thesis I have outlined the quality challenge in relation to newborn mortality and stillbirths; reviewed the application of QICs to the area of maternal and newborn health and described the study setting and the study design. In Section II, I have presented the results of the study, including: a theory-driven description of the QIC programme; the findings of the mixed-methods evaluation; and results of a qualitative study to analyse the feasibility of scale-up through the state health insurance platform. In this discussion chapter, I first synthesise the findings of my work; second, I discuss their implications in relation to the challenge of scaling quality improvement for newborn care, and implications for research; third, I reflect on strengths and weakness of my study, including methodological considerations. In the next Chapter, the study conclusion, I will outline recommendations for intervention design and evaluation, and for research.

7.1 Synthesis of findings

In this synthesis, I first summarise the key points highlighted in the Background section, then present key findings in relation to the research questions.

7.1.1 Key points from Background section

In Chapter 1, I described the global burden of newborn mortality and stillbirths, and how this is largely preventable through the implementation at scale of an evidence-based package of interventions along the continuum of care (1). The greatest impact on preventing neonatal deaths is through high coverage and quality of interventions delivered during labour and birth, including for obstetric complications, followed by care for small and sick newborns (1). The latter is a particular gap in newborn care service provision: its components have only recently been defined systematically, and coverage of special newborn care units is still low globally, representing a large service readiness gap (2-4). The service readiness gap is compounded by a quality gap (1, 2, 5-7). This calls for investment in

improving coverage and quality of services that have the highest potential to impact on newborn deaths. These considerations are equally relevant to the context of my research, the states of Andhra Pradesh and Telangana in India: here, the quality challenge for newborn care entails scaling the implementation of intrapartum and special newborn care practices that are known to prevent newborn deaths, and improving linkages in the continuum of care, between birth care and special newborn care, and inpatient and outpatient care (8-12).

Quality improvement programmes, including QICs, are proliferating. In Chapter 1, I briefly reviewed recent randomised controlled trials of QICs in the field of maternal and newborn care in low-income settings. I concluded that results were mixed, and evaluations documented important challenges, which prevented implementation with the intended reach, duration or intensity. This echoed conclusions from the available systematic reviews (13-15). In engaging with the literature on QIC effectiveness, I noted that the very definition of QIC effectiveness used in the literature presents limitations. As discussed in Chapter 2, with the exception of Garcia-Elorrio's systematic review (16), previous reviews define QIC effectiveness on the basis of statistically significant improvement in at least one primary outcome, or at least half of primary outcomes (15, 17). This definition does not consider the heterogeneity of outcomes; the magnitude of change; the need for concurrent changes to improve patient outcomes, or the plausibility of linkages between clinical processes and patient outcomes. The challenges of achieving high fidelity in implementation (18) and high attrition (15, 17, 19) support the need for caution when drawing conclusions on QIC effectiveness, and contextual influences on effectiveness are poorly understood(20, 21). In summary, while there may be evidence that some QICs have brought about a change in a few evidence-based practices at facility level, what has not been shown rigorously is that this change can be sustained, augmented and integrated into routine clinical practice and into standard systems (16, 22).

These considerations prompted me to undertake a systematic review, inspired by realist synthesis (23-25), to better understand how and under what circumstances QICs may lead to better outcomes (Paper A, Chapter 2)(26). In relation to mechanisms of change(27, 28), I found that participation in quality improvement collaborative activities may improve health professionals' knowledge, problem-solving skills and attitude; teamwork; shared leadership and habits for improvement. I also found that collaboration between quality improvement teams may generate normative pressure and opportunities for capacity building and peer recognition. I identified four contextual enablers to activate mechanisms of change: the appropriateness of external support, leadership characteristics, quality improvement capacity, and alignment with systemic pressures and incentives. The findings on contextual enablers complemented previous reviews (20, 29): however, instead of focusing on the association between single contextual factors and outcomes, I offered a more dynamic understanding of contextual influences, by discussing how the combination of critical contextual enablers influences implementation and in turn mechanisms and outcomes. For example, in LMICs alignment with existing supervisory structures appeared not only necessary to achieve a functional quality improvement team but also to generate sufficient ownership of the intervention by hospital leaderships, which is in itself a critical determinant of success (30-34).

The contribution of the systematic review to this PhD is two-fold. Firstly, at a pragmatic level, it allowed the development of a theory of change for the evaluation of Safe Care Saving Lives, drawing on relevant social theory. Secondly, at a conceptual level, it contributed to an understanding of QICs as a complex public health intervention, complementing the evidence on effectiveness and offering a framework (the theory of change) to understand pathways of change and the role of context on implementation. I will return to this point in the discussion on implications of my findings in paragraph 7.2.1 below.

7.1.2 Research question 1: To what extent, how and under what circumstances did Safe Care Saving Lives improve adherence with evidence-based newborn care practices and reduce stillbirths and newborn mortality?

The external evaluation of the Safe Care Saving Lives programmes aimed to evaluate the effectiveness of a quality improvement collaborative intervention in 60 public and private, secondary and tertiary hospitals in the two Indian states of Andhra Pradesh and Telangana. Specifically, we aimed to evaluate the impact on the stillbirth rate and neonatal mortality at 7 days and 28 days in labour wards and neonatal care units, and the effects on the implementation of 20 essential evidence-based maternal and newborn care practices targeted by the quality improvement package. These included intrapartum care practices in labour rooms, such as correct high risk assessment of mothers at admission; use of safe birth checklists at admission; adherence to WHO six cleans (35); and newborn care practices in newborn care units, such as compliance with hand hygiene during contacts with the baby; temperature checking at admission, and assistance to mothers for kangaroo mother care. We compared two groups of hospitals: 29 hospitals participating in wave 2, and 31 hospitals that did not participate in the intervention. At baseline, in 2016, the two groups were broadly comparable. Through a nested process evaluation, we also evaluated programme implementation including adaptations to the context and challenges, the observed mechanisms of change and their relationship to contextual factors.

(To what extent) did it work?

At endline, in 2018, we found no evidence that the intervention had an effect on stillbirths or on neonatal deaths. The mean number of stillbirths reduced in both intervention and comparison hospitals by very similar amounts: from 2.8% to 0.9% in the intervention group, and from 1.4% to 0.5% in the comparison group. The observed difference-in-differences (DiD) was -1% (95% confidence interval CI -2, 0). Neonatal deaths also reduced over time, by the same amount in both intervention and comparison hospitals: from a mean of 4.9% to 1.2% in the intervention group, and 6% to 0.5% in the comparison group at 7 days; and from a mean of 7.6% to 1.4% in the intervention group, and 8% to 1.7% in the comparison group at 28 days. The DiD was 0% for both neonatal mortality at 7 days (95% confidence interval -5, 8) and for neonatal mortality at 28 days (95% CI -10, 10).

There was no evidence of an effect on any of the evidence-based practices. For example, hand hygiene in newborn care units changed from 6% to 49% in the intervention group, and from 7% to 38% in the comparison group. The estimated DiD was 12% (95% CI -11,36). For kangaroo mother care, the estimated DiD was 20% (95% CI: -15,56); and for use of safe birth checklists in labour rooms it was 21% (95% CI -14,55).

Therefore, the relevant question to answer through the nested process evaluation turned to “why did it not work?”. The answer considers i) what was implemented and why, and iii) why were mechanisms of change not activated?

What was implemented and why?

Findings in this area relate to the fidelity of the intervention, the reach and the dose.

Intervention fidelity

In Chapter 3, I mentioned I would explore fidelity in relation to consistency with the Institute of Healthcare Improvement’s Breakthrough Collaborative approach. Chapter 4 (Paper B) offered a

description of the intervention as originally intended by implementers (36). Here, I highlight the key adaptations from the original model (Table 7-1).

Table 7- 1: Intervention adaptation in Safe Care Saving Lives

Intervention feature	IHI Breakthrough Collaborative Approach (37-39)	Adaptation in Safe Care Saving Lives (36)	Contextual factors influencing the implementation approach (36)
Collaborative learning	A series of collaborative learning sessions, involving quality improvement teams from each participating site. Focus on quality improvement approach and lessons learned through implementation of PDSA cycles.	Mini-collaboratives, including 4-5 secondary hospitals clustered around a tertiary care hospital with a newborn intensive care unit (hub and spoke model). Focus on strengthening referral of small and sick newborns	Logistics (distance between participating hospitals) Cost Staff time constraints preventing participation Learning from wave I suggesting focus on referrals
Quality improvement team composition	QI teams including health professionals from multiple professions are set up in each participating facility	Fluid QI teams. Mentors mainly interacted with the Unit Manager and 1-2 doctors or nurses assigned to the quality improvement activity, with responsibility to reach other colleagues in the Unit	High staff turnover in labour rooms Staff time constraints due to high workload
Quality improvement focus	Top down selection of priorities: Hospital join a collaborative, together select an aim for improvement and implement PDSAs towards that aim. Common measures to assess performance and drive improvement, including sharing of data in the collaborative Bottom up problem solving to identify change idea on selected area for improvement	Bottom up selection of priorities: Hospitals were engaged individually and then linked in mini-collaboratives. Each hospital could select which evidence-based practice to work on Once priority practice selected, change idea selected from QI change package.	Challenge in engaging leadership and securing hospital consent to form QI team required individualised approach.
External support for quality improvement	Two mentors per facility: a subject-matter expert (clinical expertise) and a quality improvement expert	One mentor with a public health background and 2-5 years' experience, with training in quality improvement, supported by a Senior mentor.	Resource constraints Involvement of Expert Faculty Group involving Neonatologists and Paediatricians that had participated in programme design and pilot phase (wave I) was not sustained.

Limited fidelity is not the major reason for the nil results. Complex public health interventions are by definition flexible and should be tailored to the implementing context (40-43). Adaptations in Safe Care Saving Lives stemmed from lessons learned during the pilot phase (wave I) and they are an example of adaptive management required of programme implementers (44). Low fidelity of implementation of quality improvement interventions using PDSA cycles has also been reported in high-income settings(18). The nil results can be better explained by the analysis of implementation reach and dose.

Why were mechanisms of change not activated?

Intervention reach

Intervention reach can be defined as the extent to which the target groups who should be participating in or receiving the benefits of an intervention actually do so (41, 45, 46). As described in Chapter 4, 29 hospitals were supposed to participate in the QIC intervention in wave II, over 16 months, from February 2016 to July 2018. Thirty-one hospitals should have begun implementation thereafter in wave III. In Chapter 5 (Paper C), I reported that only 7 of the planned 29 hospitals implemented QI activities for the intended duration, and none of the comparison group started activities. There were several reasons for this. First, the state of Andhra Pradesh withdrew permission as the intervention was not perceived as priority. Second, it was challenging to engage tertiary hospitals and particularly medical colleges, probably as they felt that the project had limited clinical content and its public health orientation was of limited relevance. Third, it was challenging to engage hospitals in the private sector, many of which were also medical colleges: reasons overlap with those mentioned above. In addition, private hospitals had limited incentives to review and improve quality of care.

Intervention dose

Intervention dose broadly refers to "the amount of an intervention received by participants" (43) and is best evaluated by looking at the interface between dose delivered (the amount of intervention offered to participants) and dose received (the amount of intervention that was received, based on participants' engagement with and response to the intervention)(45-47).

In terms of dose delivered, the Quality Improvement toolkit, described in Chapter 4, included 20 evidence-based practices which are known to contribute to reduction of newborn deaths but are not sufficiently implemented. The toolkit was organised in three packages for each of main drivers of newborn mortality: prematurity, sepsis and birth asphyxia. Each hospital selected a few evidence-based practices of focus, with a mean of 5 practices per hospital. Also, there was limited implementation of the full package of evidence-based practices: for example, while all 5 practices in the prematurity package were implemented by at least one hospital, only 1 hospital included all 5 practices. The collaborative element through the hub and spoke model was only set up in one hub-and-spoke cluster from March 2018, and this was excluded from the study. Furthermore, implementation did not make use of the structured cycle of testing innovations (or change ideas) known as PDSA cycles: health workers' workload and time constraints prevented this. Introduction of change ideas relied mostly on external advice from the mentors based on the QI change package, rather than bottom up problem-solving initiated by QI teams based on data analysis (48).

In terms of dose received: first, while welcomed, the intervention was perceived as an assessment, as opposed to an opportunity for reflection. Second, it did not generate ownership, with analysis on compliance with target practices not conducted with QI teams and not shared beyond Unit Managers. Third, it did not respond to participants' concerns, who saw structural barriers, such as the lack of equipment, infrastructure or the excessive workloads, as a fundamental barrier to improving quality.

Furthermore, medical colleges lamented the limited clinical content of interventions, for example the emphasis on practices such as hand hygiene and KMC (48).

Therefore, in Chapter 5, I concluded that the intervention was *diluted*, and as a result, it failed to activate the mechanisms of change required to generate and sustain the fundamental changes in individual and collective behaviour required to improve adherence to evidence-based practices, and achieve impact (48). Using terminology proposed by realist evaluation, it appears that in our study the QIC approach was a "resource" which participants could not or chose not to use (27).

7.1.3 Research question 2: To what extent was the QIC approach operationalised by the Safe Care Saving Lives programme scalable?

In Chapter 6, I first defined the concepts of "scale-up" (49, 50) and "scalability" (51, 52) and presented a scalability assessment framework (52)(reproduced in Annex A). Then, I described the scale-up strategy used by ACCESS Health International; and finally, I reported on the findings of a qualitative study on the feasibility of scaling up the QIC approach through the state health insurance scheme in Telangana.

The scale-up strategy and related activities in Safe Care Saving Lives rested on the assumption that the Aarogyasri Health Care Trust may play a role in improving quality of newborn care in public and private providers in three ways: first, by sustaining collaborative activities for newborn care quality improvement in the Aarogyasri network after the end of the programme; second, by providing financial incentives for healthcare providers delivering quality services; and third, by exerting normative pressure on hospitals to improve quality. The hope was also that this would allow engagement of private hospitals in quality improvement, since both private and public hospitals are part of the insurance scheme (36).

Using the scalability assessment framework, I identified barriers to scale-up through this approach in all four relevant domains: the *intervention* did not represent a clear advantage over existing practice, and most importantly, it did not demonstrate results. *Implementers* had limited credibility and the design did not have the appropriate institutional partnerships. *Adopting organisations* faced major structural barriers, which the programme could not meet, and there was poor coordination with other quality-focused maternal and newborn care initiatives programmes which were the key priority for hospital leaders. In terms of the *socio-political context*, there was limited coherence with the quality assurance policy framework the prevailing quality approach at state level, and limited scope to leverage health insurance payments for newborn care.

It is important to note that the analysis of feasibility of scale-up was conducted alongside the evaluation of the intervention effectiveness. The concept of scale-up assumes that an intervention's effectiveness is demonstrated: this was not the case for Safe Care Saving Lives, and as I have discussed above, it may not be the case for the quality improvement approach overall. Nevertheless, the literature on scale-up supports the case for thinking about scale early on, or to plan with scale in mind, and I have elsewhere argued that considering "scalability" as a focus of analysis may be useful for implementation research to maximise the fit between an intervention and the health system in which it is introduced (52-55). This is particularly important for complex public health interventions, because by definition these target different levels of the system(41, 56), need to engage multiple stakeholders (57) and because interventions are only one of the concurrent forces at play in health systems(58). I discuss implications of the findings on the (non) feasibility of scale-up in section 7.2.4. below.

7.2 Implications for design and implementation of quality improvement interventions

Throughout this thesis, I have pointed to the limitations of the evidence on QIC effectiveness and to the mixed results from previous rigorous studies, and I have reported on the findings of our study in South India, which had nil results. Our study had limitations (described in Chapter 5 and in paragraph 7.5 below), and programme implementation was also severely constrained by limited resources and a short time frame. It is possible that with a different skills mix in the implementation team, or a different implementing organisation with greater support from state-level health authorities, or more time to implement, the programme may have led to positive results. However, in Chapter 5, I discussed that the limitations of quality improvement interventions at the facility-level which we observed in our study echo those found in other studies and are now well documented in the literature. So what, then, is the role of quality improvement for the global challenge of improving quality of newborn care?

In teasing out the implications of my study, it is important to point out that these do not stem from the assumption that the findings are generalisable to other settings, but rather from the learning that has emerged through the theory-driven process evaluation and our realist-inspired conceptualisation of the relationship between context, mechanisms of change and intended outcomes.

7.2.1 Quality improvement is more than the application of its methods

Through the systematic review of contextual and mechanisms of change I have articulated the complexity of change that quality improvement seeks to achieve. Regardless of which evidence-based practice is targeted, this is essentially a change in individual health workers' perceptions of a problem and self-efficacy to tackle that problem; a change in individual and collective behaviour of health workers, and often a change in the way clinical care is organised (26). My systematic review highlights that achieving adherence to evidence-based practice in routine clinical practice is essentially about normalising a new behaviour in a team: therefore, change is needed not only at individual health worker level, but at organisational level as well (26, 59, 60). The original literature on healthcare quality improvement also implicitly addresses behaviour change: it identifies resistance to change as a key challenge for quality improvement and discusses management strategies to deal with it, resting on clear communication, proactive leadership, and open reflection (61).

If quality improvement is fundamentally about changing behaviour of health workers as individuals and as teams, then emphasis should be placed in understanding whose behaviour needs to change, what influences and hinders it, and how this change can be supported. Our evaluation used a theory of change approach to conceptualise this change (40, 62). In Chapter 2, I suggest that frameworks such as the Theorical Domains Framework can also help anticipate the multiple drivers of individual behaviour change (63-65). Greater use of these approaches during the design of interventions may be helpful, although they are time consuming (66). Intervention designers will have variable resources available to conduct or consult formative research to inform behaviour change strategies during intervention design. However, some degree of rigorous formative research should be a priority for future quality improvement efforts. Replicating the use of quality improvement methods, without understanding the change that that approach is expected to trigger and without tailoring the approach to the needs of those whose behaviour ought to change will simply not work, as old and recent studies have highlighted (19, 20, 67-70). Instead, assumptions must be made explicit in the design phase and updated regularly during implementation. For example, the quality improvement approach assumes

that bottom up problem solving in QI teams is feasible and supported by leaders. Instead, our evaluation demonstrates that in this context, engagement of leadership needed an intervention in its own right and that bottom up problem solving was not compatible with hierarchical team structures.

7.2.2 Focus on a whole set of practices for the most pressing problem

In Chapter 5, I have discussed that implementation of the quality improvement collaborative approach in Safe Care Saving Lives was diluted. Implementation aimed to demonstrate results quickly, and through these galvanise greater support for quality improvement (61): this resulted in prioritising practices that were perceived as easiest to change (the "low hanging fruits"), but were not fully coherent with the problem identified through gap analysis. For example, in participating hospitals, prematurity was the leading cause of newborn deaths (71), however only one hospital focused on implementing all the five practices included in the prematurity package. While I cannot prove the counterfactual (that implementation of all 5 components of the prematurity package would have achieved a better result), focusing on low hanging fruits was not sufficient to reduce newborn mortality: the level of acceleration of newborn mortality needed to achieve global targets calls for a bolder approach to scaling up what works, where it is needed the most.

There is consensus on the set of interventions that are needed to tackle the leading causes of newborn death, and increasing evidence on the bottlenecks to implement these at scale. The recent definition of levels of newborn care and standards for inpatient care of small and sick newborns is a further opportunity for targeting quality improvement approaches to a whole package of processes (4). Supporting clinical teams to engage with and determine priorities based on data they themselves generate is an important contribution of the quality improvement approach. The diagnosis of a problem can bring visibility and create ownership and accountability for problem resolution (38, 61): our evaluation findings underscore the importance of a solid gap analysis to identify priority issues. Several tools exist to identify root causes of poor implementation[5], but ownership is key. Previous studies in LMICs have suggested that health workers welcomed and valued support to engage with their own facility data to identify and monitor changes on a particular issue (31, 33), but our systematic review also highlighted that strengthening the use of data for improvement may require high-intensity support to develop competences for data analysis and attitudes for evidence-driven implementation, and to harness and strengthen existing data systems (26, 34).

It is also possible that the Safe Care Saving Lives programme tried to achieve too much in too short a time frame, and that greater emphasis on fewer practices may have achieved stronger results. Defining impact of quality improvement as reduction of mortality and trying to improve 20 care practices at once was possibly too ambitious, given the implementation strategy and available resources. Structural challenges still represent major bottlenecks to the implementation of evidence-based practices for newborn care, such as lack of appropriate equipment or human resource constraints, in terms of both skills and specialisms as well as excessive caseload (2, 72). The Safe Care Saving Lives programme only focused on quality improvement, and this prevented it from intervening on some of root causes of the problem or tackling some of the necessary evidence-based practices, such as providing respiratory support through CPAP. Recent systematic reviews suggest that quality improvement approaches based on group problem-solving may be more effective if accompanied by clinical training, and in moderately resourced compared to low resource settings (13, 16). More recently designed quality improvement initiatives have incorporated quality improvement alongside training and provision of essential equipment (73, 74), thus complementing quality improvement with

[5] http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx

quality planning efforts, in line with the so-called Juran trilogy (75): this appears a more promising approach to address the root causes of poor adherence to evidence-based practices and contribute to their scale-up in LMICs. I will discuss this further under 7.2.4 below.

7.2.3 Beyond the micro-level: focus on referral systems

In Chapter 5, I discussed that Safe Care Saving Lives intervened solely at the level of individual health facilities and this contributed to the disappointing impact of the programme. This limitation has been highlighted by other QI experiences (68, 76, 77), despite early QI literature highlighting that several healthcare challenges cannot be resolved by individual organisations, because they require whole-sector coordination and action (78). Two implications for improved design of QI interventions can be drawn from this: i) that problem analysis in QI needs to look beyond individual facilities, and interventions developed at a broader level, such as referral systems or district health systems; and ii) that point of care interventions need to complement upstream efforts to improve quality – which I will discuss below, in paragraph 7.2.4.

In Chapter 4, I outlined that Safe care Saving Lives aimed to complement quality improvement in single hospitals with collaborative work in clusters of facilities: this was intended to enhance capacity for QI and reinforce changes occurring in health facilities through sharing of learning (36). In table 7-1, I described that this approach was not feasible and not entirely relevant for participating hospitals: responding to a request by some tertiary hospitals, Safe Care Saving Lives attempted instead to use the collaborative approach to strengthen the referral system for inpatient care of small and sick newborns through a hub-and-spoke model, involving a tertiary hospital (hub) and secondary hospitals referring into it (spokes). As outlined in Chapter 5, the collaborative component was not fully implemented, and we did not evaluate it. However, from a design perspective, this approach had merit: it responded to the key concerns of clinical teams participating in the intervention and it would have been coherent with the drivers of newborn mortality in participating hospitals. Indeed, in Chapter 3, I reported that mortality was primarily in public tertiary hospitals, which offer the highest level of referral, and that mortality was higher among newborns referred in from other facilities than in-born (71), a picture that is in line with other studies and with the emerging national analysis (9, 11). Understanding the contribution of referrals to newborn mortality, diagnosing the specific challenges to a functional referral system, and implementing quality improvement approaches focused specifically on referral pathways appears a highly relevant focus for future QI programmes.

The need to optimise referral pathways to provide timely access to care at the appropriate level of the system is a cornerstone of strategies to improve quality (7, 22). However, strengthening referral systems is complex, and there are multiple barriers to functional referral systems, which have been well documented in relation to obstetric referral systems in India and other LMICs (79-87). Care for small and sick newborns requires specific considerations for referral systems: obstetric emergency care and newborn care signal functions do not fully overlap, so while at lower levels of the systems, facilities offering childbirth services would be expected to deliver routine newborn care and newborn resuscitation, at higher levels of the system, facilities offering special and intensive newborn care are not the same as those offering comprehensive obstetric care (2, 4, 83, 88). They may be co-located, but referral pathways are distinct. Also, effective referral of newborns requires specialist skills and equipment. Few studies have focused specifically on newborn care referral pathways for pre-term, low-birthweight and sick newborns, possibly because this is an emerging area for research and implementation. For example, a qualitative study by Teklu et al in Ethiopia identified structural barriers to effective referrals, including distance from newborn referral centres, limited transport options; barriers related to providers, such as unavailability or non-adherence to referral protocols,

poor communication and lack of coordination; and patient-related barriers, including cost of referrals to families, fatalistic attitudes, and fear of the unknown (89). These barriers are not entirely different from challenges with referral systems for mothers or older children, however the need for timely specialist care to prevent mortality in sick newborns is even more pressing.

While quality improvement, on its own, may not address structural barriers such as lack of ambulances equipped for newborns, in conducive contexts where such barriers are addressed by complementary reforms, quality improvement may have a role to play in improving referral processes which contribute to slow or ineffective referral. Implementing QI at the level of referral systems may also help address the challenge of inadequate stabilisation of newborns before referral, and reduce admission overload at tertiary care level, by ensuring quality delivery of special newborn care in all secondary hospitals feeding into a tertiary care service (2, 12). Hub and spoke models aligned to newborn referral systems appear promising, and these have been feasible in India with health authority involvement and participation (90).

7.2.4 Link quality improvement with quality planning and assurance

As argued by the Lancet Global Health Commission report on high-quality health systems, isolated interventions at the micro-level are unlikely to result in large-scale improvements, because health systems are complex adaptive systems. Many parts interact in unpredictable ways, produce unanticipated results, and systems are resistant to change (22, 91-93). This consideration is not specific to quality improvement: Moore et al. have recently argued that public health interventions aim to fundamentally disrupt the status quo in health systems, and therefore evaluation should focus on their functioning within the social system (58). This concept is also not new in the quality improvement literature: in fact, a key underpinning of the quality improvement approach is that "every system is perfectly designed to get the result that it does."(Edwards Deming, quoted by G.L. Langley) (61). The literature on quality management considers *quality improvement* as one of three approaches, the other two being *quality planning* and *quality control*. This is often referred to as the Juran trilogy (75, 94). Quality planning refers to "a systematic process for developing services and processes that ensure customer needs are met" (95), while quality control refers to the internal process required to ensure that services delivered remain stable, or within acceptable variation, using statistical process control analysis (61, 94). *Quality assurance* complements quality control, by providing an external assessment at regular intervals to determine how the system is performing. So the findings of the Lancet Global Health Commission reiterate a key principle of the quality management approach, which had been lost in the search for simple solutions (19): improving quality at scale requires synergy between quality planning, quality improvement and quality assurance (22).

Taking a health system approach to interpret the results of the Safe Care Saving Lives study allows a reflection on the missing links between the three elements of the trilogy. In Chapter 6, I discussed that the programme was not adequately integrated in the *quality planning* architecture at district and state level – for example it did not use the state-level database of admissions in newborn care units, which is standardised across Special Newborn Care Units in public facilities, and gradually being introduced in private hospitals (9). It also could not directly respond to quality challenges arising from the way services are configured, such as the high staff workloads and lack of specialist. The programme did not succeed in building capacity for internal *quality contro*l, which would have required longer engagement and different strategies to motivate and build capacity of clinical teams for analysis of their own data. Furthermore, Safe Care Saving Lives did not sufficiently align to emerging *quality assurance* schemes at state level. While timing of the Safe Care Saving Lives, which preceded some of these quality assurance mechanisms, may partly explain this pitfall, my thesis underscores the

importance of greater coherence between quality improvement interventions in facilities and the wider strategies to improve quality.

Quality planning for quality improvement

The World Health Organization has recently published guidelines for Quality Planning in LMICs, which outline the actions required at national, district and facility levels to create an environment where efforts to improve quality of care can succeed (96). Another important debate that underpins strategies to improve quality relates to redesign of health systems to promote centralisation of maternity services. The core argument for this approach is that centralisation would prevent de-skilling of health workers due to isolated working; enable better recruitment and retention of a scarce health workforce; and allow access to the range of specialisms required to manage the increasing complexities of cases (22, 97). Risks related to this approach have also been highlighted, with key concerns relating to equity, women's autonomy of decision-making, cost-effectiveness and the risk that a focus on service redesign will inadvertently emphasise structure over process in national debates on quality of care (98, 99). The argument of greater centralisation of specialist care aligns with the high-income trajectory of regionalisation of newborn care through an integrated network of facilities (100-103). However, the appropriateness of regionalised care models in resource-constrained settings is still contested (104).

Discussing service design for quality planning is beyond the scope of this thesis. However, four considerations emerge from the Safe Care Saving Lives study that appear essential to improve quality of newborn care: first, staffing needs; second, integration of care; third, data systems; fourth, leadership skills. These are also presented in figure 7-1 below. These building blocks are not an exhaustive list, as other health systems building blocks such as medicines and equipment, and financing, have been recognised as major barriers to quality service delivery in the wider literature (105). In relation to the first, staff workload was a major barrier to the implementation of quality improvement approaches, and may be a key driver of poor adherence to evidence-based practices (72). Although newborn care units met the staffing norms stipulated by relevant national guidance, nurse to bed ratios were high, and high workload was a key concern of programme participants and prevented adequate implementation of QI activities (48, 71). Safe staffing is increasingly recognised as being dependant on caseload rather than population served, and this is critically important in relation to inpatient care for small and sick newborns (106, 107). Workload specific staffing norms are increasingly applied to human resource planning in LMICs (108-111), and these should be extended to design of newborn care services. In addition to safe staffing, effective delivery of quality improvement activities requires understanding and responding to health workers' preferences and needs, so that quality improvement is not perceived as an additional burden for stretched staff.

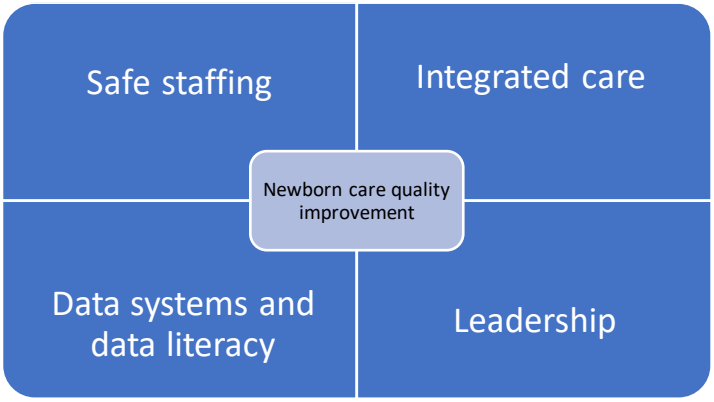
Second, integration of care in our study setting was a major challenge: a weak referral system contributed to the high facility-based mortality observed in our study setting and potentially inappropriate admissions, for example the high admissions due to neonatal jaundice; limited integration between antenatal and delivery care prevented appropriate implementation of evidence-based practices, for example correct high risk categorisation during pregnancy. Limited integration of inpatient and postnatal care may have also contributed to the high newborn mortality after admission (48, 71). Implementing quality improvement at the level of referral systems, as discussed above, requires integrated quality planning across levels of care, to allow for appropriate risk detection, management and follow up of mothers and newborns. However, this poses new institutional challenges and requires strong leadership, appropriate governance and data systems (112). If implementation of quality improvement at the referral level is not feasible, then a realistic set of goals

ought to be set, for example focusing on improvement of a specific practice instead of health impacts such as newborn mortality.

Third, quality improvement requires data (113). Our study found that a key implementation barrier was that clinical teams perceived quality improvement as creating additional burden (48). Using existing data systems may help mitigate this challenge, particularly in contexts where improving coverage and quality of routine newborn care units data is a priority, such as India (9). Using existing data platforms for improving quality of care may also contribute to strengthening data quality (114). Third, quality improvement requires data (112). Our study found that a key implementation barrier was that clinical teams perceived quality improvement as creating additional burden, because they had to collect additional data, for example to audit implementation of practices they had selected to improve (48). Using existing data systems may help mitigate this challenge, particularly in contexts where improving coverage and quality of routine newborn care units data is a priority, such as India (9). Using existing data platforms for improving quality of care may also contribute to strengthening data quality (113). Importantly, building confidence in engaging with data, and using data to improve performance is a key habit for improvement and requires a shift in working culture, that can be better enabled by long-term investments in the health workforce, such as making quality improvement part of pre-service training.

Fourth, quality improvement requires leadership. In Chapter 2, I have discussed that effective implementation of quality improvement requires engagement of those in a leadership position who can enable the initiation of quality improvement activities and support staff involved in these. I have discussed that such engagement should be considered part of the intervention implementation, not an assumption, particularly where quality improvement is a relatively new concept (26). The results from the Safe Care Saving Lives evaluation also suggest that failure to activate a mechanism of joint problem-solving may explain the nil results – this underscores that building leaderships skills ought be as much as about engagement of formally recognised leaders as well as building shared leadership in champions of quality improvement, who may or may not be those in a position of responsibility, and often, instead more junior doctors. Reflecting on the profile of "improvers" in the NHS, Lucas describes clinicians who can ask better questions, manage change, be facilitative in their approach to problem solving and generation of ideas, and tolerate uncertainty (115). These characteristics echo those identified by Senge as defining leaders in learning organisations (116). Building skills for reflective practice through exposure to quality improvement in pre-service training, as well as building these competences among established leaders appears critical to create a culture for improan enabling environment for quality improvement.

Figure 7- 1– Building blocks for newborn care quality improvement



The quality improvement – assurance continuum

In Chapter 2 I have discussed that aligning quality improvement efforts with local priorities is necessary to gain buy-in of decision makers at all levels (26, 48), and in Chapter 6 I have discussed how limited coherence with the broader quality assurance framework was a challenge for scaling quality improvement in our study.

At least conceptually, quality assurance can provide the motivation for improving quality or, using health systems terminology, represent the "carrot" for change (117). However, this was not feasible in our study, because the initiatives were not sufficiently aligned. Design of future quality improvement interventions may need to consider how quality improvement can support facilities achieve quality assurance, if this is the major driver of change. Vice versa, policy-makers at national and district level, as well as leaders at facility level should ensure design and implementation of quality assurance programmes emphasises relevant processes of newborn care at the appropriate level, thus building an opportunity for quality improvement, given that a focus on structures on its own will not deliver the necessary improvement (118). Such links should be articulated in national directions for quality, for which guidance has recently emerged (119).

7.3 Implications for research

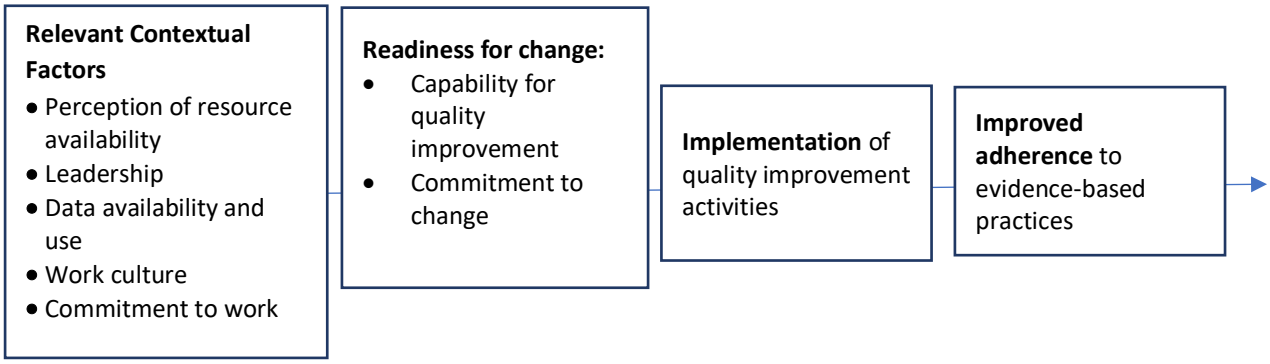
7.3.1 Organisational readiness as a precondition for quality improvement

In Chapter 2, I highlighted the need for further research to determine whether certain contextual factors related to capacity should be a precondition to the quality improvement collaborative approach. Originally, as an additional objective of this PhD, I planned to explore the association between organisational readiness for quality improvement and adherence to evidence-based practices in Safe Care Saving Lives. This was inspired by the MRC process evaluation guidance on understanding contextual influences on observed outcomes, and intended to contribute to the identification of a minimal threshold for investment in quality improvement. However, this analysis did not prove feasible: the high attrition in implementation resulted in a very limited sample size, which prevented any moderation analysis. More fundamentally, developing a valid measure for organisational readiness proved very challenging.

The literature on service readiness in relation to newborn care generally focuses on structural inputs, such as staffing, infrastructure and equipment (72), however there is poor correlation between these and process outcomes (118). So, although we collected data on structural inputs through facility checklists, describing their association with evidence-based practices would not have added much to the literature. A relevant framework, proposed by Weiner et al., defines organisational readiness for change as the product of organisations' motivation and capability for quality improvement, which are in turn affected by organisational-level contextual factors (120). It also acknowledges the role of "soft" elements of the context, such as leadership, team work, work culture, in relation to performance, which is confirmed by other literature (77, 121). However, tools for measuring organisational readiness for change are relatively new and not tested in LMICs (122).

I attempted to operationalise the construct of "organisational readiness for change" as the combination of 5 contextual factors operating at organisational level: perception of resource availability; leadership; use of data; work culture and commitment to work (Figure 7-2). This construct married Weiner's organisational readiness for change framework (120) with the "soft" elements of the context, which the quality improvement literature identified as critical to understand the success of quality improvement (26, 123).

Figure 7- 2: organisational readiness for change framework



I used the Context Assessment for Community Health (COACH) tool to measure these contextual factors, because this tool had been specifically developed to understand contextual influences on the uptake of evidence-based practices in LMICs, and had strong psychometric properties, having been tested in LMICs (124). Using this tool, I conducted a survey in 29 hospitals participating in Safe Care Saving Lives wave II in Andhra Pradesh and Telangana, and generated a composite readiness score for each facility using Principal Component Analysis. In the pilot phase, I encountered important problems with the tool: the most important one was high social desirability bias. Despite training data collectors, rewording questions to translate appropriately in Telugu, and ensuring that interview settings protected confidentiality, responses on leadership, work culture and commitment to work were mostly positive and there was very limited variability. I also used Conrad and Blair's taxonomy of problems related to questionnaire items (125) to categorise problems encountered, and found some prominent logical problems (the item had more than one focus), and few inclusion/exclusion problems (i.e. difficulty in determining what to include or exclude when responding to the item). Similar problems had emerged in other studies using the tool since its initial testing (126, 127).

An important assumption for the analysis of the association of organisational readiness for change and evidence-based practices was that the readiness score would not change over time, so would not be affected by the intervention. However, when I compared readiness scores at baseline and endline, I found the opposite: the score had changed over time in the same facilities, and there was no distinct pattern to explain such change, pointing to the low reliability of the COACH tool.

Given the important limitations in the data, in discussion with my Supervisors I decided not to present the analysis. In hindsight, further validation of the COACH tool would have been needed in my setting, however this was beyond the scope of my PhD.

While this attempt did not work, other studies have recognised the need for measures of organisational readiness for quality improvement, which go beyond assessing structural inputs (77). Facility-level, regional and national criteria for readiness to implement quality improvement programmes would be useful to tailor implementation strategies to local actors and contexts, and remain a key gap for implementation research.

7.3.2 Other evidence gaps

Our study confirms the need for more robust evaluations of quality improvement collaboratives, ideally through randomised controlled trials or other robust designs that allow comparison with a counterfactual, for example through plausibility designs or interrupted time series (13).

Compounding the limited robust evidence on effectiveness of quality improvement collaboratives, the pathways through which these interventions produce results is highly variable and subject to contextual factors (26). I have discussed above the need to apply systems thinking to the evaluation of strategies to improve quality of newborn care, which calls for mixed-methods research, including policy analysis. Theory-driven or realist randomised controlled trials have the potential to unpack the complexity of change (62, 128). The need for piloting and adaptation cannot be underestimated, since there is uncertainty that this type of intervention can be feasibly implemented, and that implementation will activate the intended mechanisms of change (129). During implementation, timely process and outcome evaluation can aid refinement of implementation strategies.

Learnings from the Safe Care Saving Lives study point to the importance of equitable and timely collaboration between evaluators and health system actors responsible for improving quality, since externally generated and driven interventions may have limited feasibility and effectiveness. Such collaborations require time to mature, and must accompany broader strategies for co-design for quality (99). Since the success of quality improvement can be explained in the context of the broader quality strategy (or lack of it) at district and national level, taking a scalability perspective at the start of an evaluation is critical: the scalability framework I have used for the ex-post analysis of the potential to scale-up can be used prospectively, integrated with formative research to inform the design of interventions (52, 130). Engaging with a scalability assessment is also an opportunity for researchers to reflect on the types of partnerships needed to maximise the contextual fit of new interventions and promote co-design of feasible and acceptable "disruptions to the health system"(58).

Quality improvement studies in maternal and newborn care may also need to focus on implementation of whole bundles of evidence-based practices, aligned with the relevant level of care, thus advancing the implementation of global Standards of Care (131, 132). The potential to focus on referral systems as the scalable unit for implementation of bundles of evidence-based practices requires further evaluation: as discussed above, reduction of mortality through improvement in quality of care relates not just to improved adherence to evidence-based practices at facility level, but also to the organisation and coordination of a continuum of care. Referral systems for obstetric care and for care of small and sick newborns require separate but coordinated focus. The quality improvement collaborative approach has potential because collaboration among facilities can unearth context-specific barriers that sit in the interface between each facility micro-cosmos. However, the collaborative approach would depart from the Breakthrough Collaborative model, since it would not seek to promote friendly competition among facilities, but rather closer collaboration and better coordination through normative pressure for performance accountability at the referral level. Investment in data systems that allow tracking patients across the referral system, as well as leadership that promotes shared accountability would be necessary to take this approach. As mentioned above, such research could not meaningfully happen without close partnerships between implementation researchers and district-level decision makers and frontline workers.

Cost-effectiveness is a critical dimension for decisions on scaling interventions, and the cost-effectiveness of quality improvement collaboratives remains a major research gap (133). The Safe Care Saving Lives evaluation initially included a cost-effectiveness component (Chapter 3): a key reason why this was dropped was the challenge of defining and quantifying the intervention inputs.

7.4 Strengths

The strengths and limitations of each of the studies included in this thesis are mentioned under each chapter. Here I will include broader reflections about the work overall.

A key strength of this study is the integration of impact and outcome evaluation with process evaluation, which allows us to explain the nil results of the study and draw lessons for future implementation of quality improvement interventions in newborn care (41). This was made possible by a balanced relationship between the external evaluation and implementation teams: communication was close enough to allow us to understand implementation but distanced enough to allow critical questions to emerge (41). The success of this relationship is largely due to a close partnership with the Public Health Foundation of India, which prevented the external evaluation being perceived as a threat, and ensured the relationship was culturally appropriate and responsive.

Another key strength of this study is the use of a systematic review on context and mechanism of change to inform the programme theory of change: this added depth to the qualitative process evaluation nested in the study, and enabled it to respond to the most relevant questions by identifying missing links in the intervention causal pathway and its position in the context (134).

We collected data independently from project implementers, basing our estimates of baseline and endline primary and secondary indicators on the most accurate and complete available source when a choice was possible: for example, for newborn mortality estimates we used interviews with mothers post discharge and the project used facility records (see 7.5.1 below for rationale). Our estimates of mortality did differ from those reported by the project at baseline and endline and reflected a more accurate assessment of the context and effect of the intervention. This minimised the bias that may have been introduced by the non-blinding of intervention participants and researchers.

Finally, evaluating the intervention relationship with broader strategies for quality planning and assurance a state level allowed us to explore the health systems perspective, thus making our study more relevant to policy-makers and implementers.

7.5 Limitations

7.5.1 Methodological issues

In addition to the challenge of measuring organisational readiness for quality improvement, discussed above, two additional methodological issues warrant discussion: measuring adherence to evidence-based practices and estimates of newborn mortality.

Measuring evidence-based practices

We planned to measure the 20 evidence-based practices targeted by the project as secondary outcomes. We collected data independently from project implementers using case note abstractions and observations in labour rooms and special newborn care units. However, we could only measure 10 of the 20 targeted evidence-based practices, summarised in Table 7-2.

Table 7- 2: Secondary outcomes not measured in the study

Care bundle	No. practices included	No. practices measured	Practices not measured	Reason
Prematurity	5	3	Administration of ante-natal corticosteroid	Poor documentation in case notes
			Early breastfeeding	
Birth asphyxia	7	3	CPAP	Insufficient power at baseline
			Trained personnel at high risk delivery	
			Compliance with oxytocin protocol	Poor documentation in case notes and EBP not implemented
			Newborn resuscitation with bad and mask	
Sepsis	8	4	Intravenous tubing	EBP not implemented
			Central vascular catheter	
			Rational use of antibiotics	
			Antibiotics for women at risk	

In addition to limited EBP implementation, two key challenges constrained measurement of these secondary outcomes: poor completeness of case notes and observation of rare events.

With regard to the former, our analysis was limited by relatively low levels of completeness of facility data. At baseline, facility checklist data indicated that case sheets were in use in 96% of facilities in Andhra Pradesh and 91% of those in Telangana. However they were complete in only 74% of facilities in Andhra Pradesh and 71% in Telangana. Completeness was similar for labour rooms registers (73% and 79% in Andhra Pradesh and Telangana facilities respectively), and slightly higher for newborn care registers in Andhra Pradesh (83%) but not in Telangana (71%)(135). Important risk information was not consistently available: for example, we could not measure compliance with oxytocin protocols in induced deliveries in labour room, because registers did not include indication for induction of labour, and we could not measure administration of ante-natal corticosteroid, because of lack of data on risk identification and poor gestational age metrics (136).

Another challenge related to observation was observing relatively rare events, constraining the achievement of adequate sample sizes to measure the indicator: while we were able to complete 4652 observations of patient contacts to measure hand hygiene compliance, we could only observe 202 cannulation procedures, and we had insufficient observations to assess resuscitation of babies with bag and mask. We also had relatively small samples for observation of deliveries (e.g. 392 in endline) and admissions in newborn care units (202 at endline): even though we increased the number of observations at endline since we had fewer facilities to cover, this still represented a very small sample compared to the admission load of these facilities. These challenges arose partly from the fact that

our study was under-resourced, and partly from the challenge of securing consent for evaluation, particularly in labour rooms.

With regard to observations, we trained data collectors and implemented rigorous processes for ensuring data quality (36). However, adherence was measured during non-random observations. While the relatively long duration of the observation period in each hospital (6 days) may have reduced the Hawthorne effect, we cannot completely exclude it. This limitation is common in similar studies (68), and observation is preferable to self-reports. Compared to similar studies, our study also included night-time observations in each hospital, and weekend observations in hospitals that could not complete the 6-day observation period at weekdays: this partially mitigates the limitation.

Finally, our measurement of kangaroo mother care, a key practice targeted by the prematurity bundle of the programme, had to be adapted from the initial definition: we could not measure the percentage of babies admitted for prematurity that received correct kangaroo mother care, because could not link delivery room registers with newborn care unit register to identify babies born prematurely. We measured instead the percentage of babies in newborn care units that were assisted for KMC. We also could not measure *correct* duration of KMC, since our measure was derived from mothers' interviews and not facility registers, and duration of KMC would have been prone to recall bias (137).

In the future, measuring process indicators such as those referring to key evidence-based practices requires investments in facility-based data completeness and accuracy. Indeed, recent effective quality improvement programmes in LMICs, such as the East Africa Preterm Birth Initiative define strengthening data systems including facility registers as a key component of the intervention package, including annual workshops to review and standardise indicator definitions, regular data audits to check completeness and correctedness, use of data dashboards to aid interpretation by health workers, and provision of training and equipment to aid measurement where needed, for example assessment of gestational age (73). The new WHO Standards for quality of maternal and newborn care stress the importance of strengthening facility data systems that allow gathering and analysis of process indicators (131, 132).

Mortality estimates

At baseline, we measured newborn case fatality using two data sources: newborn registers and telephone interviews with mothers post-discharge. We could only follow up 50% of mothers, because our study used telephone numbers reported in newborn care unit registers, which were prone to missing data and errors, unlike other studies that had a prospective data collection system(68). Despite this, case fatality was much lower when constructing the indicator from data from neonatal care registers (see Table 7-2)(135).

Table 7- 3: 7-day newborn case fatality of babies admitted to newborn care units: two data sources

Data source	No. observations and missing	Telangana (N hospitals =19)	Andhra Pradesh (N hospitals =28)
Newborn care unit registers	7,128 register observations.	2.1% 0.2-3.9%	6.6% 3.3-10.0%
Telephonic interviews	1,118 cases enrolled for telephonic interviews, 1 missing answer	6.5% 3.2-9.8%	9.8% 5.5-14.2%

Some difference between estimates derived from registers and through telephonic follow-up is expected because register data often do not capture the full 7-day period due to early discharge.

However, register-derived mortality was over four percentage points lower than that from telephonic interviews in Telangana. Babies discharged against medical advice make a major contribution to mortality. For example, at baseline in our study setting, 3.5% of parents left with their neonates against medical advice during the first 7 days, and a further 4.3% left between 7 and 28 days of life. The telephone interviews suggested that over one-third (37%) of the neonates discharged against medical advice died (71). 7-day mortality after admission to newborn care units was lowest in babies who were discharged, but the higher level of mortality reported through telephonic interviews indicates that some babies might have been discharged too early or might have developed new problems and parents did not come back, or there was inadequate follow-up post-discharge.

Given this finding, we used estimates derived from telephonic interviews in our analysis of the effect of the intervention reported in Chapter 5 (48), and we increased the sample size of interviews per hospital to mitigate for inaccurate or missing phone numbers. In total, we increased the number of telephonic interviews with mothers post-discharge from 866 at baseline to 1,067 at endline. The underestimation of mortality using facility registers remains a key challenge for quality improvement programmes that use facility-based data to monitor progress, as this may lead to an overestimation of the intervention effect.

Our analysis of newborn mortality was constrained by low completeness of facility registers: the cause of death was not mentioned in any of the facility registers, so the analysis of mortality presented in Chapter 3 is based only on cause of admission. Missing data on risk factors also constrained the ability to conduct risk-adjusted mortality estimates. There was a large number of missing outcome data, for example 20% of register extracted data from private facilities lacked a newborn care outcome. This limited the opportunity for comparisons across type of facilities, and in Chapter 3, I reported only descriptive statistics. Date of birth was also missing, so we could not always calculate 7-day and 7–28-day case fatality (71).

7.5.2 Positionality

In Chapter 3, I reflected on my position within the research team and in relation to programme implementers and research participants: these led to both strengths and limitations of my study. Because of childcare responsibilities, I was not able to fully immerse myself in the research context and I only travelled to the project sites on 3 occasions. This, coupled with my inability to speak Hindi or Telugu, prevented me from fully appreciating health workers' perspectives in relation to quality improvement as well as their working and cultural context. My lack of a clinical background may have contributed to participants' perception of limited credibility of the research, as this dynamic was also observed in relation to quality improvement specialists implementing the intervention. My status as a PhD student within an external evaluation team, independent of programme implementation, possibly created further barriers to deep engagement of research participants, as there was limited time to create rapport, and the research may have been perceived as extractive.

On the other hand, I invested strongly in building a solid and equitable research partnership with my colleagues in the Public Health Foundation of India, who played a critical role in the delivery of the external evaluation project commissioned to the London School of Hygiene and Tropical Medicine, and to the extent this was possible given the programme structure, I also invested in building a positive working relationship with the NGO implementing the quality improvement intervention. For example, I took time in the early research days to understand my colleagues' backgrounds, expectations and ways of working. Together, we took stock of collective resources and expertise in the research team, striving to maximise the contribution of each of us. We established roles and ways of working, for example deciding that PHFI would have lead maintaining and development relationships with the

implementing NGO and participating hospitals, and I would have joined monthly donor-NGO calls together with them to remain informed of programme developments. I worked hard in the early days of my PhD to achieve consensus on the process evaluation protocol, as well as the design of research components that may have presented reputational risks for them or the implementing NGO, for example the qualitative study on the feasibility of scale up. I strived to capture their perspectives and contributions during data collection and analysis through regular dialogue and frequent calls, and strived to ensure these were valued and recognised through joint authorship of published papers, including with programme implementers whose reflections enabled the articulation of the intervention strategy published in the evaluation protocol paper. Before and during data collection, I committed to sharing relevant skills to promote others' professional development, striving to and hopefully managing to make our collaboration an equal mutual learning opportunity and capacity exchange. Throughout the work, their insights and cultural interpretations allowed me to access deep meaning of the social fabrics, such as to better appreciate the challenges of interdisciplinary working in clinical teams, due to the power imbalances between different clinical cadres.

While this does not fully alleviate the limitations linked to my positionality and the lack of direct partnerships with research participants, it does represent a strength of the work, in that the work was the product of an equitable partnership, and allowed me to develop strong transferrable skills in research partnership management.

7.5.3 Other limitations

Although we collected data on various dimensions of quality of care, including structural inputs, processes of care and outcomes such as newborn case fatality and stillbirths, the study was not powered to allow for stratified analysis to look at correlation between inputs, processes and outcomes. Also, the lack of overall results prevented this analysis. In a way, this was a missed opportunity for a study that collected large amounts of data which could not be fully utilised, particularly in relation to facility checklist data.

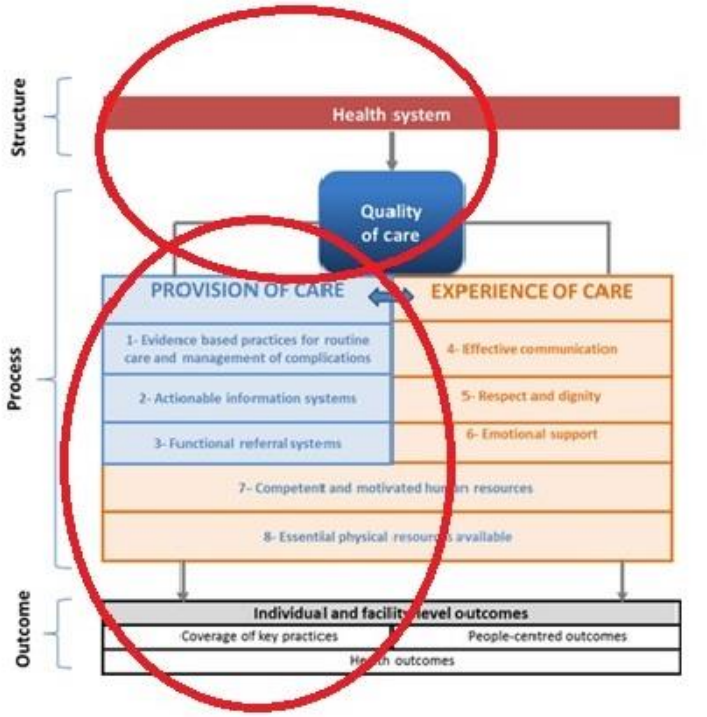
Similarly, we could not conduct the dose-response analysis mentioned in the evaluation protocol (36), because we did not observe variable results following the intervention. Another key methodological issue that prevented the dose-response analysis was the challenge of quantifying the intervention strength. This is not unique to quality improvement (138), however in quality improvement a critical challenge is to determine at what point an evidence-based practice is classified as adopted. Quality improvement approaches do have standard ways of categorising this, although these were not used in Safe Care Saving Lives, and they rely on self-reports (34).

A key limitation of the qualitative study is that it relied only on interviews. Although we planned to observe mentoring sessions and collaborative meetings, we could not do it, because most of the mentoring happened on social media, face-to-face meetings in teams were not scheduled regularly, and collaborative meetings did not happen as planned. While observation of meetings may have helped triangulate our understanding on mechanisms of change, it is also possible that observation by external evaluators would have affected interaction between mentors and clinical teams, and exacerbated the perception of quality improvement as an externally imposed activity (139).

Finally, our study did not consider the patient-related dimension of quality of care, focusing exclusively on provision of care, including structure, processes and outcomes (Figure 7-3)(140).

Figure 7- 3: Quality of care dimensions explored by Safe Care Saving Lives study

Adapted from Tuncalp et al. (140)



Exploring experiences of care from the perspective of mothers and families whose newborns had been admitted to newborn care units would have helped our understanding of newborn mortality in this context. As noted earlier, those with early discharge without adequate follow up or parents' decisions to leave against medical advice were a sizeable proportion of the caseload (71): analysing patients' perspectives of quality of care and reasons for leaving against medical advice could have helped understand the extent to which care provided in newborn care units was respectful and acceptable, and other family-related barriers to inpatient newborn care, yielding important lessons to inform strategies for community follow up post-discharge (141).

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Chapter 8: Conclusion

Increasing coverage and quality of evidence-based interventions is a key priority to prevent newborn deaths globally. Care of small and sick newborns and care at birth have the highest potential to reduce newborn deaths. In India, major investments in the last decade have resulted in a substantial increase in facility births, without corresponding improvements in newborn mortality, thus exposing the quality gap. Among strategies to improve quality of care, quality improvement collaboratives are increasingly used. In this PhD, I have examined the contribution of quality improvement collaboratives to improve newborn care at scale, through the evaluation of the Safe Care Saving Lives programme in the two Indian states of Telangana and Andhra Pradesh.

The programme which my study focused on did not achieve its intended results: as outlined in Section II and discussed in Chapter 7, there was no evidence of an effect of the intervention of newborn mortality, stillbirths, and on any of the evidence-based practices targeted by the intervention. Intervention implementation had low fidelity, which was both expected and encouraged by programme implementers to maximise the contextual fit of the approach. More importantly, implementation was diluted, achieving limited reach and dose and, as a result, it did not activate the mechanisms of change hypothesised in the intervention theory of change. My study also concluded that the intervention was not scalable for multiple reasons, related to the intervention itself, the implementers and the adopting organisations. Most importantly the intervention was not scalable because it was not coherent with the quality assurance policy framework, and because of flawed assumptions on the scope to leverage health insurance payments for newborn care health insurance payments for newborn care.

Having discussed the findings in detail in Chapter 7, I offer here four key recommendations for policy and programme design.

Recommendation 1: Policy-makers and actors responsible for programme design should consider quality improvement as a behavioural and organisational change intervention, underpinned by effective leadership, and entailing more than the application of its method.

Rationale: My systematic review contributed to an understanding of quality improvement collaboratives as complex public health interventions. Achieved desired adherence to evidence-based practices essentially entails a change in individual health workers' perceptions of a problem and self-efficacy to tackle that problem; a change in individual and collective behaviour of health workers, and often a change in the way clinical care is organised. The theory of change mapping these changes, which I have offered based on a systematic review of experiences of implementing quality improvement collaboratives in diverse hospital settings, is far from linear. Other systematic reviews suggest that quality improvement collaborative results are highly context dependent. Challenges with intervention implementation, including high attrition and poor fidelity documented in our study and elsewhere suggest that quality improvement collaboratives are not a quick fix or a magic bullet. Moreover, engagement of leadership is a pre-condition, both for the set-up of functional quality improvement teams, and to drive the changes quality improvement intends to achieve.

Specifically, policy-makers and programme designers should:

- Promote and support the use of a theory-based approach in the design of quality improvement collaborative interventions, unpacking the necessary behaviour and organisational changes

- Question the relevance and appropriateness of the quality improvement collaborative approach to the specific behaviour and organisational change challenge it is intended to address
- Ensure consultation with stakeholders and, where possible, robust formative research on barriers to implementation of target evidence-based practices informs the implementation strategy, and use it to challenge assumptions on how change would occur.
- Develop an intervention theory of change, and use it to validate assumptions during implementation and to refine implementation.
- Consider complementary strategies to build leadership support for quality improvement and for end results.

Recommendation 2: Focus on a whole set of evidence-based practices that address the biggest problem

Rationale: The quality improvement collaborative approach implemented in Safe Care Saving Lives was diluted, and the programme did not achieve the intended reduction in newborn mortality and stillbirths. However, there is strong evidence on the set of evidence-based practices that require scaling up to address the leading causes of these deaths. The quality improvement approach in Safe Care Saving Lives prioritised "low hanging fruits" deemed more achievable – the intention being to demonstrate results quickly, galvanise support and build capacity for quality improvement. In this respect, the programme adopted an intervention-centric approach rather than a context-centric approach where the intervention responded coherently to the problem analysis. For example, it focused mostly on practices, such as handwashing, which, while important, did not directly affect the leading cause of mortality i.e. prematurity. This limitation is not generalisable, and rarely do QIC projects have mortality reduction as their end goal. However, as I have discussed in my critique of the evidence on QIC effectiveness in Chapter 2, QIC effectiveness has generally been defined on the basis of statistically significant improvement in at least one primary outcome, regardless of the magnitude of that change, or the plausibility of causal pathways on results chains, suggesting that a focus on few practices may not be the exception. Given the level of acceleration required to meet newborn mortality and stillbirths targets, focusing on a few low-hanging fruits is simply not enough. The recent definition of levels of newborn care and standards for inpatient care of small and sick newborns provide an important opportunity to further focus quality improvement approaches to whole set of practices that define a certain level of care and/or specific standards of care, not all of which quality improvement interventions may be best placed to meet.

Therefore, policy makers and programme designers should:

- Conduct rigorous analysis of the leading causes of mortality in target facilities – the quality improvement approach of using facility data and involving clinical teams in analysing their own data is an important step to generate ownership around the problem diagnosis
- Ensure rigorous use and documentation of root cause analysis to identify gaps in implementation of key evidence-based practices known to address the leading causes of mortality, using available tools from the quality improvement toolbox
- Ensure such analysis of implementation gaps considers the entire set of practices or standards that are to be expected at a specific level of newborn care, in line with service packages defined at national or international level.
- Design the quality improvement intervention package to target the whole set of practices required at the specific level of care and to address the leading cause of mortality

- Consider the complementary approaches to quality improvement that are necessary to enable or achieve implementation of priority evidence-based practices, and either build these components into the package of support, or build the necessary partnerships to provide the complementary support.

Recommendation 3: Plan beyond the micro-level. Focus on systems that include referrals

Rationale: The Safe Care Saving Lives evaluation highlighted the limitation of intervening with quality improvement only at health facility level. A key implication discussed in Chapter 7 is the need to consider the contribution of delayed or ineffective referral to facility based newborn mortality in the design of quality improvement initiatives. In fact, the highest mortality in the study Special Newborn Care Units was observed in babies born in other facilities, which mirrors national data. Although the Safe Care Saving Lives programme explored a collaborative linking Newborn Care Units in secondary hospitals with their tertiary referral centre for small and sick newborns, this started too late into the programme to represent a model case and to have an impact.

Therefore, policy makers and programme designers should:

- Integrate analysis on the role of referrals in relation to newborn mortality observed at facility level in programme design
- Based on such analysis, question whether targeting individual health facilities are the optimal intervention strategy.
- Consider the relevance and opportunity to adopt a referral cluster approach to operationalise the coordination between different established levels of newborn care, both for effective risk detection during antenatal care, as well as optimal intrapartum and post-natal care
- Exploit the concept of collaborative working between facilities to focus on improving definition, coordination and implementation of established referral pathways linking the various facilities in the clusters
- Consider the institutional incentives and bottlenecks for effective collaboration among facilities, and appropriate strategies to facilitate such collaboration.

Recommendation 4: Link quality improvement with quality planning and assurance

Rationale: One of the foundational tenets of quality improvement is that “every system is perfectly designed to get the result that it does” and the literature on quality management considers *quality improvement* as one of three approaches, the other two being *quality planning* and *quality control*. The findings of the Lancet Global Health Commission on quality Health Systems reiterate that improving quality at scale requires synergy between these three components, and isolated quality improvement interventions are unlikely to yield major results. The Safe Care Saving Lives evaluation illustrated the limited impact and potential for scale as the quality improvement intervention was not implemented adequately and was not sufficiently aligned with system-level efforts on quality planning and assurance.

Policy makers and programme designers should, therefore, implement strategies to better link quality improvement with quality planning and assurance. Specifically, in relation to quality planning, key recommendations include:

- Promote and support application of WHO quality planning guidelines, by ensuring that quality improvement structures align with actions implemented at national, district and facility level to create an environment conducive to quality.
- Embed quality improvement in pre-service training, for example through training on quality improvement and exposure to quality improvement projects

- Embed quality improvement in health workforce management, for instance introducing quality improvement objectives in job descriptions, making discussions on evidence-based practice a core part of performance appraisals, or incentivising quality improvement projects in continuous professional development.
- Consider quality improvement as complementary to investments in service planning and delivery that allow quality and equitable implementation of newborn levels of care, and their interconnections through referral systems. Consider, in particular:
    - Definition and application of context-specific staffing norms based on caseload, which allow safe service provision as well as the opportunity to engage in quality improvement effectively
    - Opportunities for integration of care through referral systems or networks of care, applying quality improvement at the level of the cluster, as discussed above
    - Design monitoring systems for quality improvement relying on routinely collected data that feed into established reporting systems, as opposed to creating parallel systems. This can help generate ownership on facility data as well as strengthen routine data collection systems.

In relation to quality assurance linkages, specific recommendations include:

- Consider whether, in the implementation context, quality assurance schemes are or have potential to be important drivers of performance change for newborn care in health facilities If so, consider appropriate strategies to link quality improvement performance with milestones or targets that resonate with quality assurance schemes
- Also, policy-makers at national and district level should seek to ensure design and implementation of quality assurance programmes emphasises relevant processes of newborn care at the appropriate level, and not merely focus on structures

Recommendations for research

This PhD has contributed a rigorous evaluation of a quality improvement collaborative for newborn care in India, adding to the relatively limited, but growing, body of evidence that questions the effectiveness of this intervention in the field of maternal and newborn health using a solid research design. The inclusion of a systems-level perspective in the evaluation of the intervention scalability has complemented the understanding of the opportunities and challenges of scaling up QICs. While results are highly contextual and not generalisable to other settings, the scalability assessment framework presented in this PhD offers a structured lens for future research on the topic of intervention scale up. Furthermore, my systematic review has contributed to the understanding of the mechanisms of change and contextual factors including QIC results, and offered a programme theory which can be used for future programme design and evaluation.

Based on this contribution, five key recommendations can be made for further research:

1. Future evaluation of QICs should adopt robust designs, especially randomised controlled trials if feasible. One of the challenges to take QICs to scale is to find out through rigorous evaluation whether the approach can work in facilities that do not self-select to participate.
2. Further evaluation should also adopt a theory driven evaluation approach to question contextual assumptions and mechanisms of change from the early stages of evaluation. Incorporating a theory of change approach can support implementers to question their assumptions during implementation, tailor the intervention to the context as well as explain QIC results after the study.

3. Cost-effectiveness of QICs also remains a research gap, which requires interventions being more specific on programmatic inputs: the challenge of defining the intervention detail was one of the reasons why our originally planned cost-effectiveness analysis could not be undertaken.
4. Linking to the recommendations for programme design and implementation, further research is also needed on optimal implementation strategies for QIC implementation, including:
    - further work on understanding the challenges practitioners experience in engaging with quality improvement, and how these may be overcome in different contexts.
    - Further work on understanding practitioners' perceptions of quality improvement approaches, so that suitable approaches can be tailored to their work environment
    - strategies for implementation of QICs at the level of referral systems;
    - optimal combination of quality improvement and complementary interventions for improving performance, such as leadership engagement and skills building, clinical training, capacity building on using data for practice improvement, and structural inputs needed for the delivery of bundles of evidence-based practices.
    - Further work on effective approaches to foster a quality improvement culture through pre-service training in quality improvement and other strategies related to health workforce management, such as embedding quality improvement in job descriptions performance appraisals, and incentives for continuous professional development.
5. At systems level, there is a need to design and evaluate innovative approaches to align quality improvement with national directions and reforms for quality, where emerging, including strategic purchasing as well as newborn care quality assurance schemes.

Annex 1

Paper E – Assessing scalability of an intervention: why, how and who?

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Methodological Musings

OXFORD

Assessing scalability of an intervention: why, how and who?

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Abstract

Public health interventions should be designed with scale in mind, and researchers and implementers must plan for scale-up at an early stage. Yet, there is limited awareness among researchers of the critical value of considering scalability and relatively limited empirical evidence on assessing scalability, despite emerging methodological guidance. We aimed to integrate scalability considerations in the design of a study to evaluate a multi-component intervention to reduce unnecessary caesarean sections in low- and middle-income countries. First, we reviewed and synthesized existing scale up frameworks to identify relevant dimensions and available scalability assessment tools. Based on these, we defined our scalability assessment process and adapted existing tools for our study. Here, we document our experience and the methodological challenges we encountered in integrating a scalability assessment in our study protocol. These include: achieving consensus on the purpose of a scalability assessment; and identifying the optimal timing of such an assessment, moving away from the concept of a one-off assessment at the start of a project. We also encoun- tered tensions between the need to establish the proof of principle, and the need to design an innovation that would be fit-for-scale. Particularly for complex interventions, scaling up may warrant rigorous research to determine an efficient and effective scaling-up strategy. We call for researchers to better incorporate scalability considerations in pragmatic trials through greater inte- gration of impact and process evaluation, more stringent definition and measurement of scale-up objectives and outcome evaluation plans that allow for comparison of effects at different stages of scale-up.

Keywords: Scale-up, scalability, evaluation

Key Messages

- We developed a scalability assessment during the design of a multi-component intervention to reduce unnecessary caesarean sections in low- and middle-income countries, adapting available scale-up frameworks and tools.
- We documented the methodological challenges we encountered. These include: achieving consensus on the purpose of a scalability assessment; identifying the optimal timing of such an assessment; and resolving tensions between the need to establish the proof of principle, and the need to design an innovation that would be fit-for-scale.
- As scale-up is a relatively new focus for implementation research, we found little evidence that these methodological challenges have been fully addressed. We call for researchers to better incorporate scalability considerations in pragmatic trialsthrough greater integration of impact and process evaluation, more stringent definition and measurement of scale-up objectives and outcome evaluation plans that allow for comparison of effects at different stages of scale-up.

Introduction

Planning for scale is increasingly important to increase impact and achieve health goals (Implementing Best Practices Consortium, 2007), and there is growing recognition that publications, policy reform and training alone are insufficient to achieve scale (ExpandNet WHO, 2009; Edwards, 2010; Barker *et al.*, 2016; Wright *et al.*, 2018). For complex interventions, understanding conditions that may facilitate their implementation at scale is increasingly important.

Concurrently with the growing focus on scale-up in global health, the body of literature on scale-up has expanded in the last decade. Previous research helped distinguish the concept of scale-up from rep-lication and expansion, and made theoretical assumptions aroundscale-up explicit, borrowing largely from Roger's diffusion of innov- ation theory and Glaser's formulation of factors related to knowledge transfer (Glaser *et al.*, 1983; Mangham and Hanson, 2010; Fixsen, 2013; Rogers, 2013). More recently, empirical research has focused on the process of scale-up, and on identifying factors facilitating or hindering it, with evidence emerging from diverse fields, including re-productive health, malaria and HIV/AIDS, and diverse settings, including both low-middle income (Wall *et al.*, 2009; Bradley *et al.*, 2012; Spicer *et al.*, 2014; Dickson *et al.*, 2015; Smith *et al.*, 2015; Perez-Escamilla and Moran, 2016) and high-income countries (McCannon and Perla, 2008; Milat *et al.*, 2015; Aldbury *et al.*, 2018;January 2018). Generic models and frameworks to plan scale-upefforts during intervention delivery are available in the literature, often accompanied by case studies of projects or initiatives thatreached scale (ExpandNet WHO, 2009, 2010; Yamey, 2011; Cooley and Kohl, 2012; Barker *et al.*, 2016; Milat *et al.*, 2016). These have mostly emerged from experiences in low- and middle-income coun- tries, with one exception (Milat *et al.*, 2016).

We define scale-up in line with the WHO ExpandNet definition,as 'deliberate efforts to increase the impact of successfully tested health innovations, so as to benefit more people and to foster policy and programme development on a lasting basis' (ExpandNet WHO,2009). This definition assumes that scale-up can be an intentionally guided process, as opposed to spontaneous diffusion, and empha- sizes institutionalization and sustainability of innovations into a health system, as opposed to just expansion of coverage.

The literature on scale-up has also referred to failures (Glassman, 2016; Jordan *et al.*, 2016)—although negative experiences are not as widely documented—and attributed these, at least in part, to untimely consideration of the scale-up process and priorities: in other words, scale-up has often been an afterthought (Cooley and Kohl, 2006; ExpandNet WHO, 2011). Implementers are now encouraged to 'design for scale' or to consider intervention 'scalability' during pilot phases.

We defined 'scalability' as 'the ability of a health intervention shown to be efficacious on a small scale or under controlled conditions to be expanded under real-world conditions to reach a greater proportion of the eligible population, while retaining effectiveness', in line with Milat (Milat *et al.*, 2013). This definition, emerging from the health promotion field, encompasses three themes: (1) expansion of coverage, the potential reach of an intervention varying in relation to the problem being addressed, characteristics of the intervention, the target group, and the context; (2) transferring control for delivery from initial implementers or innovators to local actors or institutions; and (3) retaining the effectiveness demonstrated in proofof principle studies (Milat *et al.*, 2013). These themes differentiate the concept of 'scalability' from the related concepts of transferability, replicability and sustainability (Supplementary Annex S1) (Bonell, 2006).

The concept of scalability is still relatively new, and in practice it is often confused with ability to widen the reach of an intervention,without much attention to continued robust performance under rou- tine conditions, or to the extent to which it is embedded in a local delivery system.

This article discusses methodological lessons learned in incorpo-rating scalability considerations during the design of a proof of prin-ciple trial to evaluate a multifaceted intervention to reduce unnecessary caesarean section rates in low- and middle-income countries (QUALI-DEC[1], see Supplementary Box). We agreed that incorporating a scalability assessment into the QUALI-DEC proto-col would help tailor the intervention and implementation approachand may increase the likelihood of success at scale. Our scalability assessment process is outlined in Figure 1. Here, we describe our ex- perience in the preparatory and initial planning stages. We antici- pate that further learning will occur as we conduct the assessment and begin implementation. We believe that such reflection is valu- able to other researchers, given the limited application of the con- cept of scalability in research and the relative scarcity of bibliography in this area.

Methods

First, we conducted a review and synthesis of scale-up frameworks,to identify the dimensions to explore through a scalability assess- ment and available tools. Based on this, we agreed on the assessment purpose and process for QUALI-DEC (Figure 1). Finally, we identi- fied relevant tools, selected the most appropriate for our purpose and adapted it for our study.

Review of scale-up frameworks and tools

Through a literature search in PubMed, Google (for grey literature) and references of previous reviews on similar topics, we identified 10 models or scale-up frameworks presented as a generic tool to aid

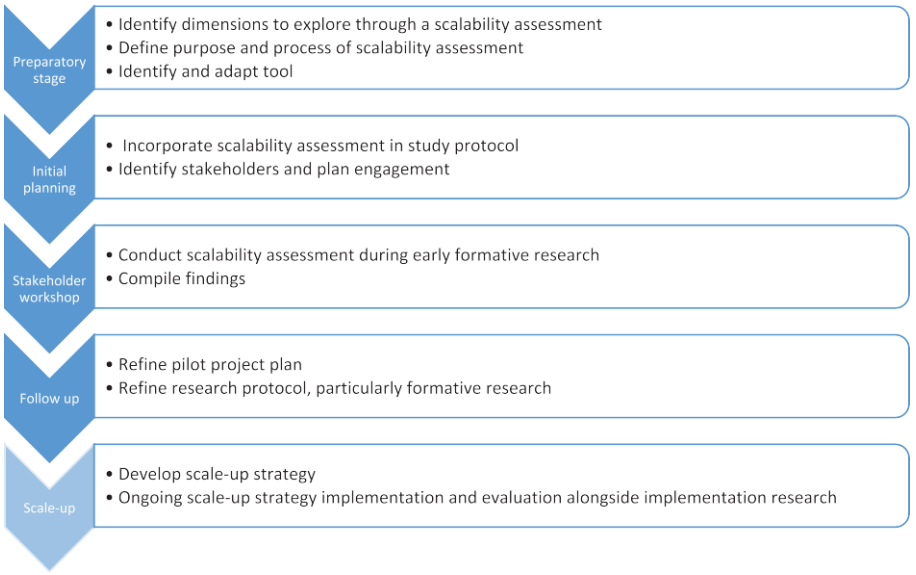

Figure 1 Scalability assessment process in QUALI-DEC.

scale-up beyond a specific health intervention (Table 1), of which 5 were based on implementers' experiences, and 5 originated from theresearch community, mostly as literature reviews supported by qualitative interviews with stakeholders in a given health system ora Delphi process. Most were framed against Rogers' diffusion of in-novation theory (Rogers, 2013), although this was only explicitly referred to in four frameworks.

We analysed frameworks to identify critical factors that require consideration when planning scale-up, and found five common themes: (1) attributes of the innovation; (2) attributes of the imple-menters (actors introducing an innovation or actively supporting their scale-up); (3) attributes of the adopting community; (4) socio-political context and (5) scale-up strategy (Table 2).

The different emphasis in focus between frameworks appeared to stem from the context and stakeholders contributing to their de-velopment. For example, the academic work was more focused on explaining how scale-up occurs and what facilitates it, while frame-works emerging from implementation were presented as practical guides to drive the process of scale-up, with a more marked focus on strategic planning. As our purpose was to identify relevant dimen-sions for scalability assessment, rather than to conduct a systematic review, we concluded the search once thematic saturation was achieved.

Four of the frameworks were accompanied by a tool or checklistto assess scalability during an early phase of intervention design or implementation; however, one of these (Cambon *et al.*, 2013) focused on transferability as opposed to scale-up.

Designing a scalability assessment process

We intended to conduct an initial assessment during the pilot phaseof the research, with the aims to (1) refine the intervention design to enhance scalability and (2) inform a future scale-up strategy, includ-ing advocacy and ongoing communication with key stakeholders.

The assessment was designed as qualitative and participatory, involving researchers developing and evaluating the multifaceted intervention to reduce unnecessary caesarean sections; clinicians and hospital managers in participating hospitals and Ministry of Health representatives. A stakeholder consultation workshop was proposed to be the main avenue for the assessment, after identifying a relevant scalability assessment tool.

Tool selection and adaptation

Of the scalability tools identified in the literature, we selected Cooley and Kohl's (2012) for our study: it was consistent with our scalability definition and developed with a LMIC setting in mind, therefore pre-ferred to Cambon *et al.*'s, (2013) and Milat *et al.*'s, (2016) tools. Like the ExpandNet tool (ExpandNet WHO, 2011), it covered all concep- tual dimensions identified in our review, and we preferred it because of its structure guiding systematic analysis of each dimension, and the specificity of its items enabling analytical depth.

We made three key adaptations to the tool: (1) we structured it infour sections, corresponding to the critical factors that require consid-eration to aid scale-up emerging from the evidence review: attributesof the innovation; attributes of the implementers; attributes of the po-tential adopting organizations or communities; and socio-political context. The fifth broad theme emerging from the review (scale-upstrategy) was not included, because the findings from the scalabilityassessment would have been used precisely to develop a tailored scale-up strategy. (2) We omitted items that were not relevant to our intervention, for example items related to technological innovation. (3) We integrated it with dimensions from other tools: for example, from Cambon *et al.* (2013), we added items related to understanding users' needs, to allow stronger segmentation of the project target group and a deeper understanding of the incentives and barriers to their behaviour change; and from ExpandNet WHO (2011), we added items related to attributes of the adopting organizations and community and socio-political context, for example the extent to which service delivery points in which the intervention is tested are different from those in which it would be implemented at scale.

The assessment tool was developed as a checklist, with 34 items,to be scored on a three-point scale (scale-up is easier, neutral, harder)based on participants' perceptions and knowledge. Rather than pro- viding a yes or no answer on whether scale-up would be possible, theassessment tool and process was designed to aid reflection on chal-lenges and opportunities for scale-up and identify areas to be furtherresearched or developed in later phase of the programme.

Table 1 Scale-up frameworks

Framework	Theoretical framing	Basis of framework	Practical application		
			Scale-up strategy tools	Scalability assessment	Purpose of scalability assessment
Massoud (2004)	Not explicit	Practice	No (QI methods)	No	
Implementing Best Practices Consortium (2007)	Explicit (diffusion of innovation theory)	Practice, supported by literature	No	No	
ExpandNet/WHO (2007 – 2012) (Simmons *et al.*, 2007; McCannon and Perla, 2008; ExpandNet WHO, 2009, 2010)	Explicit (diffusion of innovation theory and Glaser's CORRECT attributes)	Practice, supported by literature	Yes	Yes	Ensure relevance of innovation and tailor to setting; generate political commitment; reach consensus on expectations for scale-up.
Yamey (2011)	Explicit (diffusion of innovation and socialnetwork theory)	Literature review and interviews	No	No	
Cooley/Management Systems International (Cooley and Kohl, 2006, 2012)	Not explicit, but present (diffusion of innov- ation theory and Glaser's CORRECTattributes)	Practice, supported by literature	Yes	Yes	Anticipate likely challenges to maximize feasibility of scale-up through adaptation.
Bradley *et al.* (2012)	Not explicit, but present (diffusion of innov- ation theory; social cognitive theory and social networks)	Literature review and interviews	No	No	
Cambon *et al.* (2013)	Not explicit	Practice	Yes	Yes	Concerned primarily with transferability/replicability.
Spicer *et al.* (2014)	Not explicit	Interviews	No	No	
Barker *et al.* (2016)	Explicit (diffusion of innovation theory)	Literature review, supported by practice	No (QI methods)	No	
Milat *et al.* (2016)	Not explicit	Literature review, tion can realistically be scaled up. Emphasizes evi-dence of effectiveness as precondition for scale-up.	Yes	Yes	Determine whether interven-

QI ¼ quality improvement.

Lessons learned

Incorporating a scalability assessment in the QUALI-DEC trial protocol raised methodological and practical challenges for the research team.

Firstly, a scalability assessment can serve both a formative pur-pose, i.e. to refine an intervention, and a predictive purpose, i.e. to determine the extent to which scale-up is possible. These two purposes can coexist, as donors, implementers and stakeholders in the adopting community may have an interest to identify interventions with low scalability potential early on, as this can save resources and funds. From a research perspective, achieving consensus on the purpose of a scalability assessment is necessary to improve methodological rigour. For example, emphasizing the predictive function of the scalability assessment requires further research for tool development and validation, while emphasizing the formative nature of the assessment calls for rigorous standards in participatory qualitative research to minimize bias, manage power dynamics and aid open dialogue on scalability challenges. In QUALI-DEC we defined the purpose as formative rather than predictive, interpreting scalability as an effort to maximize the intervention's contextual fit.

Secondly, there is a need to reflect on the optimal timing. Scale-up considerations are necessary at all stages of project management, but a scalability assessment should, by definition, be integrated into early stages of intervention design and planning. In the context of QUALI-DEC, although the multiple components of the intervention were proven effective in other contexts, the lack of evidence of their effectiveness as a package in a low- or middle-income setting (which the research is designed to generate) may have led to limited the engagement from decision-makers in an early assessment. However, we also noted that greater exposure to the intervention, including understanding its components, the credibility of the evidence underpinning them, and the urgency of the problem being addressed, may have changed perceptions of its scalability over time. From a methodological point of view, a scalability assessment adds value not only early into implementation but throughout implementation, to enable ongoing analysis of scale-up barriers and opportunities. This is consistent with methodological guidance on scale-up (Cooley and Kohl, 2006; ExpandNet WHO, 2009; ExpandNet WHO, 2010) and suggests the need for scalability-focused formative research to be nested in a study to measure to effects of the intervention. In our study, we considered key dimensions of the scalability assessment to design the intervention theory of change—thus identifying potential barriers to feasibility and acceptability, and we plan to use the scal- ability assessment during pilot evaluation and at multiple points

Table 2 Factors considered in scale-up frameworks

Features	ExpandNet (Simmons *et al.*, 2007; McCannon and Perla, 2009, 2010)	ExpandNet WHO, 2008;	Management Systems International	Yamey and Kohl, 2006,	Cooley (2011) 2012)	Implementing Best Practices Consortium (2007)	Massoud (2004)	Barker *et al.* (2016)	Bradley *et al.* (2012)	Cambon *et al.* (2013)	Spicer *et al.* (2014), Massoud (2004)	Milat *et al.* (2016)
Attributes of the innovation/intervention												
Credibility of model (evidence base for innovation)												
Observability of results (impact or effectiveness)												
Relevance to concern of potential adopters												
Relative advantage over existing practice												
Simplicity or ease of adoption												
Model testable and adaptable												
Affordability or cost-effectiveness												
Acceptability												
Aligned and harmonized with existing government health system or programme												
Attributes of implementers												
Leadership and credibility												
Use of champions												
Networking, collaboration and partnership (to foster buy-in)												
Capacity to support scale-up (skills, size, resources and experience) Stability or grant size and length Culture of urgency and persistence												
Provision of capacity building for adopting stakeholders												
Attributes of adopting community												
Clarity on who user organizations are, their needs and concerns												
Capacity for scale-up (staffing, skills, logistic system and other)												
Supportive organizational culture and leadership												
Capacities for data collection and reporting systems												
Timing or window of opportunity												
Learning systems												
Engaged, activated community and institutional buy-in												
Extent to which decision-making is data-driven												

(continued)

Table 2 (continued)

Features (Simmons *et al.*, 2007; McCannon and Perla, 2008; ExpandNet WHO, 2009, 2010)	ExpandNet	Management Systems International (Cooley (2011) and Kohl, 2006, 2012)	Yamey	Implementing Best Practices Consortium (2007)	Massoud (2004)	Barker *et al.* (2016)	Bradley *et al.* (2012)	Cambon *et al.* (2013)	Spicer *et al.* (2014), Massoud (2004)	Milat *et al.* (2016)
Socio-political context										
Political will										
Country ownership and institutional support										
Stakeholder analysis										
Assessment of policy priorities, government systems and political climate										
Analysis of inter-sectoral collaboration (if relevant)										
Policy-legal environment (financial, economic or procedural incentives)										
Attitudes, values, priorities and motivations of health workers and communities										
Scale-up strategy										
Create a vision for scale-up										
Define scalable unit										
Tailoring scale-up to context										
Strategic choices inform scale-up plan										
Phased approaches to scale-up or ongoing refinement for sustainability										
Alignment or integration in system or service										
Advocacy and communication Resource mobilization and alignment										
Scale-up plan										
Ongoing M&E and dissemination of learning										

during the study, to refine our understanding of the optimal fit between intervention, implementation team, adopting organizations and socio-political context.

Thirdly, there was a tension between demonstrating proof of principle through a randomized controlled trial, and adapting the intervention to maximize its fit with the health system so as to aid scale-up, if proven effective. Waiting for the results of a multi-yeartrial before considering scale-up strategies, on the ground that proofof principle must be established first, is not a departure from com- mon practice and leaves the scalability question unaddressed. Complex interventions are context-specific and therefore researchers and practitioners must consider attributes of the intervention, avail-able capacities and resources required to produce impact at scale, once controlled study conditions end and adapt implementation over time. This may fit better with evaluation designs that allow forpotential modification of the intervention during implementation, and may be hard to reconcile with randomized controlled trials, which often require fixed implementation protocols over multiple years, and monitor fidelity (or adherence to implementation proto- cols) to explain observed effects.

Discussion

The limited literature on scalability suggests integrating scalability assessments into pilot projects. However, implementation does not always proceed linearly from pilot to scale-up (Craig *et al.*, 2008). Implementers are required to use 'adaptive management' approaches, that is to refine interventions to improve relevance and effectiveness as they are being implemented, while concurrently expanding coverage.In some settings, political pressure is such that small scale pilots arenot encouraged (Spicer *et al.*, 2014). Evaluation is increasingly required in real time, and there are often pressures to scale-up promis- ing interventions without conducting pragmatic trials or waiting forresults of the pilot project evaluation (Indig *et al.*, 2017). For complex interventions, the distinction between proof of principle trial and implementation research is also more blurred. For example in our study, while each intervention component is underpinned by evidence derived from proof of principle RCTs (Chen *et al.*, 2018), it is also true that proof of principle is needed on whether the multi-component intervention would have the expected effects, and that it can be feasibly implemented (with opportunities for scale-up) in a LMIC setting.

The challenges presented above are not unique to QUALIDEC,and resonate with evaluation literature that has contrasted intervention-centric with context-centric approaches. There is a recog- nized methodological gap in methods and approaches to understandcontexts in relation to effectiveness, and this also has implications forscalability, which can ultimately be thought of as an effort to maxi-mize contextual fit (Craig *et al.*, 2008; Davey *et al.*, 2017).

Scale-up is a relatively new concept, often still conflated with replication and expansion. The body of literature on scale-up in implementation research is growing, but we found little evidence that the methodological challenges we have documented here have been fully addressed. Of the four scalability assessment tools we reviewed, two emerged from communities of practice (Cooley andKohl, 2006; ExpandNet WHO, 2011), and experiences of moving from projects to programmes using the ExpandNet scalability as- sessment tool are increasingly being documented (Ghiron *et al.*, 2014; Keyonzo *et al.*, 2015; Omimo *et al.*, 2018). Implementation research has also documented intervention adaptation to aid scale- up of quality improvement interventions using the Institute for Healthcare Improvement's approach (Twum-Danso *et al.*, 2014; Barker *et al.*, 2016). These demonstrate the feasibility of using a scalability tool and framework to aid adaptive management, but do not provide evidence on whether an intervention that is gradually adapted to a context to aid scalability is more or less effective. In the research sphere, we found few studies that used the scalability tools identified in the peer-reviewed literature (Cambon *et al.*, 2013; Milat *et al.*, 2016) to consider the question of scalability of an inter-vention. Such studies were either retrospective case studies using the tool as an analytical framework (Trompette *et al.*, 2014; Vidgen*et al.*, 2018), or trial protocols proposing a qualitative implementa-tion study or process evaluation focused on scale-up, running in par-allel or at the end of the study (Kabore *et al.*, 2016; Lonsdale *et al.*,2016). However, these are yet to generate evidence on the success of scaling-up strategies, as advocated by previous reviews (Ben Charif*et al.*, 2017).

Assessing and enhancing scalability compels researchers to en-gage with the concept of scalability from the start and undertake substantial formative research at baseline to design implementation protocols that maximize the potential for implementation at scale by considering the key scalability dimensions (attributes of the inter- vention design, the adopting community, the implementers and a fit with the socio-political context). It compels researchers to go be- yond a one-off assessment during a pilot project (assuming there isone) (Cooley and Kohl, 2006; ExpandNet WHO, 2010; Barker*et al.*, 2016), and instead thoroughly document how the interventionor the way it was delivered evolved to enhance its scalability, for ex- ample through theory-driven and scale-up focused implementation studies running alongside a trial (Lund *et al.*, 2012). That is, to usemore context-driven intervention and evaluation designs, with greater integration of impact and process evaluation, for which methods are advancing (Davey *et al.*, 2017).

An explicit focus on scalability also compels researchers to develop outcome analysis plans that take into account this evolution and compare interventions effects across phases of implementation, looking in these subgroups for evidence of whether the effects changed accordingto the phase, if adequate power can be reached.

We are fairly confident that the dimensions explored by our scal- ability assessment tool are comprehensive, because they incorpo- rated all facilitating factors for scale-up emerging from our rapid review of scale-up frameworks. To our knowledge, none of the existing scalability tools have been validated, and content validity testing is beyond the scope of our study. However, we anticipate fur- ther refinement, including abbreviation of our tool as we begin using it, and later research may also test the tool's predictive value.

Conclusion

Achieving impact at scale is essential for the achievement of Sustainable Development Goals. The successful delivery of complex health interventions at scale requires a close fit between interventions, the socio-political contexts and the health systems inwhich they are implemented, which can be aided by early scalabilityassessments and ongoing scalability-focused implementation research. In this methodological musing, we described the process of incorpo-rating scalability considerations in the design of study to evaluate an intervention to reduce unnecessary caesarean sections in low- and middle-income countries. We identified three key methodological challenges: achieving consensus on the purpose; identifying optimal timing; and resolving tensions between the need to establish proof of principle and the need to design an innovation that is fit-for-scale.

Partnerships between researchers and stakeholders are necessary to achieve sound contextual framing of a new intervention and to aid

scale-up. The quality of these partnerships will determine both the extent to which health systems bottlenecks that may hinder scale-up canbe debated in an open way during scalability assessments, and the ex-tent to which interventions can be adapted to suit contexts.

We could not find evidence of studies that have fully resolved the methodological challenges we have documented; however, recently published study protocols are increasingly explicit about scalability considerations. We call for researchers to better incorporate scalability considerations in pragmatic trials through greater integrationof impact and process evaluation, more stringent definition and measurement of scale-up objectives, and outcome evaluation plans that allow for comparison of effects at different stages of scale-up.

Ethical approval

No ethical approval was required for this study.

Note

1. The QUALI-DEC study is still under development and not yet registered.

Supplementary Data

Supplementary data are available at *Health Policy and Planning* online.

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