

Digital Comprehensive Summaries of Uppsala Dissertations from the Faculty of Medicine 1880

Improving neonatal health care in Nepal

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ACTA UNIVERSITATIS UPSALIENSIS UPPSALA 2022

ISSN 1651-6206 ISBN 978-91-513-1636-9 URN urn:nbn:se:uu:diva-486589 Dissertation presented at Uppsala University to be publicly examined in Hall IV, Universitetshuset, Biskopsgatan 3, Uppsala, Friday, 9 December 2022 at 09:15 for the degree of Doctor of Philosophy (Faculty of Medicine). The examination will be conducted in English. Faculty examiner: Professor Debra Jackson (London School of Hygiene and Tropical Medicine, Department of Infectious Disease Epidemiology; MARCH- Centre for Maternal Adolescent Reproductive & Child Health).

Abstract

Brunell, O. 2022. Improving neonatal health care in Nepal. *Digital Comprehensive Summaries of Uppsala Dissertations from the Faculty of Medicine* 1880. 72 pp. Uppsala: Acta Universitatis Upsaliensis. ISBN 978-91-513-1636-9.

Every year, millions of newborns die globally due to poor quality of care around the time of birth. The overall aim of this thesis was to inform and test design of quality improvement (QI) interventions in Nepal. Contextual factors of importance for implementation of evidence-based newborn care practices were investigated, and the effect of a package of QI interventions on provision and experience of care was evaluated.

In Paper I, we used focus group discussions and key informant interviews with delivery care staff to identify barriers and enablers for delayed umbilical cord clamping (DCC). Results indicate that delivery care staff needed knowledge of the benefits of DCC to gain motivation for change. Training, supervision and evaluation were requested to be able to change old routines, and they wanted authorized guidelines to bring uniformity in clinical practice. In Paper II. individual interviews with staff working with newborn infants were used to explore factors affecting parent-infant closeness in hospitals. Informants thought that offering a comfortable environment, privacy and counselling would enhance parent-infant closeness, but hospital resources were insufficient to achieve this. They described routines in the hospitals, and traditions and cultural beliefs in the society, which separated parents and newborns. In Paper III. a stepped-wedge randomized control design was applied to evaluate the effect of a OI package including training, facilitation and feedback, on patient satisfaction. The likelihood of women being overall satisfied with care during childbirth increased (aOR 1.66 [CI: 1.59-1.73, ICC: 0.275]) but the overall proportion of satisfaction was low, increasing from 58% to 62%. In Paper IV, clinical observations of early essential newborn care (EENC) practices were done before and after the introduction of the QI package. Overall, the rate of initiation of breastfeeding within one hour increased from 5% to 12%, and DCC increased from 22% to 33%.

In conclusion, when designing interventions to improve quality of care, in Nepal or similar settings, it is important to use authorized guidelines and include education, training, supervision and evaluation. Hospital resources, routines and cultural beliefs need to be considered. The results indicate that a multi-pronged QI package can improve quality of newborn care in Nepal.

Keywords: global health, quality improvement, neonatal health care, Nepal, neonatal mortality, essential newborn care, delayed cord clamping, skin-to-skin contact, KMC, early initiation of breastfeeding, breastfeeding, parent-infant closeness, satisfaction with care, provision of care, experience of care

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ISSN 1651-6206 ISBN 978-91-513-1636-9

URN urn:nbn:se:uu:diva-486589 (http://urn.kb.se/resolve?urn=urn:nbn:se:uu:diva-486589)



List of Papers

This thesis is based on the following papers, which are referred to in the text by their Roman numerals.

- Rana, A., Brunell, O., Målqvist, M. (2019) Implementing delayed umbilical cord clamping in Nepal- Delivery care staff's perceptions and attitudes towards changes in practice. PLoS ONE, 14(6):e0218031.
- II. Brunell, O., Bergström, A., Gurung, R., Eriksson, L. Exploration of factors affecting parent-infant closeness and separation in hospitals in Nepal- a qualitative study. Manuscript.
- III. Brunell, O., Chaulagain, DR., KC, A., Bergström, A., Målqvist, M. (2022) Effect of a perinatal care quality improvement package on patient satisfaction: a secondary outcome analysis of a cluster-randomised controlled trial. BMJ Open, 2022;12:e054544.
- IV. Brunell, O., Chaulagain, DR., KC, A., Basnet, O., Målqvist, M. Effect of a quality improvement package on early essential newborn care in public hospitals of Nepal, a multi-center observational cohort study. Submitted.

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I have contributed in the following ways to the included papers:

Paper I: Data coding and analysis, reviewing and editing the manuscript

Paper II: Conceptualization, data coding and analysis, and manuscript preparation

Paper III: Conceptualization, preparation of data collection, data analysis, manuscript preparation, and review and journal correspondence

Paper IV: Conceptualization, preparation of data collection, data analysis, manuscript preparation, and review and journal correspondence

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Abbreviations

aOR adjusted Odds Ratio CI Confidence Interval

CSPro Census and Survey Processing System

DALYs Disability-Adjusted Life Years
DCC Delayed Cord Clamping
EENC Early Essential Newborn Care
EIBF Early Initiation of Breastfeeding

FGD Focus Group Discussion

GLMM Generalized Linear Mixed Models

HBB Helping Babies Breath

HBB-QIC Helping Babies Breath- Quality Improvement Circle

HCW Health Care Worker

HDI Human Development Index

ICC Intracluster Correlations Coefficients

KII Key Informant Interview KMC Kangaroo Mother Care

NePeriQIP Nepal Perinatal Quality Improvement Project

NICU Neonatal Intensive Care Unit NMR Neonatal Mortality Rate PDSA Plan-Do-Study-Act QI Quality Improvement SBA Skilled Birth Attendant

SDG Sustainable Development Goals

SNCU Sick Newborn Care Unit

SPSS Statistical Package for Social Sciences

SSC Skin-to-Skin Contact
U5MR Under-five Mortality Rate
WHO World Health Organization

Introduction

Neonatal mortality and morbidity - a global challenge

The time around birth is still a great risk for mother and child, and there are continuously unacceptably high numbers of maternal and newborn deaths globally. In 2020, an estimated 2.4 million newborn babies died within the neonatal period, i.e., the 28 first days, and about one-third of these newborns did not survive their first day of life [1, 2]. In addition to all these lives lost soon after birth, about 2 million stillbirths occur every year, with over 40 percent occurring during labor [3].

Despite a substantial decline in the global under-five mortality rate (U5MR) under the Millennium Development Goals era 1990-2015, neonatal mortality remains a challenge [4]. Due to less attention and investment, the reduction in neonatal mortality rate (NMR) has been slower [4], and newborn deaths now represent almost half of the total under-five deaths [1].

There are also large disparities in neonatal mortality across regions and countries and an overwhelming majority occur in low- and middle-income countries, with highest NMR in sub-Saharan Africa and South Asia [1, 2]. The worst affected region, West and Central Africa, has an NMR of 31/1,000 live births compared to European Union with 3/1,000 live births, while the global estimate is currently 17/1,000 live births [1, 5].

Besides mortality, neonatal disorders are also the top leading causes of global disability-adjusted life years (DALYs), constituting 7.3% of all DALYs [6]. Adult health and well-being are largely predicted by early growth and development, and human capital formation is influenced particularly by the time before and around birth [5, 7].

The time around birth

The three leading causes of neonatal disorders and deaths are preterm birth complications, intrapartum- related events and infections [8, 9]. A majority of neonatal deaths could be prevented or avoided through actions that are proven to be effective and affordable, but universal coverage is lacking. This was highlighted in the series *Every Newborn*, published in The Lancet in 2014, presenting the clearest picture so far of newborn survival [10-15]. The series advocated that a continuum of care is needed; from pre-pregnancy (family planning), through pregnancy (antenatal care) and childbirth to the postnatal

period. The most critical period, however, is the time right around birth. Care around this time, including skilled care at birth, emergency obstetric care, immediate care for every newborn and newborn resuscitation, has the potential to prevent stillbirths, avoid disabilities and save the most lives [13] [16].

A global commitment

The global challenge of neonatal mortality and morbidity is addressed in the United Nations Sustainable Development Goals (SDG), adopted in 2015 by all United Nations member states. In goal number 3, *Ensure healthy lives and promote well-being for all at all ages* [17], a specific target has been set to reduce the NMR to at least 12 per 1,000 live births in all countries by 2030. Beyond survival, all newborns should thrive and reach their full potential for health and life [18]. To provide a roadmap for countries to end preventable newborn mortality and stillbirth and reduce disability by 2030, the action plan Every Newborn Action Plan was endorsed by WHO [19]. The action plan is based on evidence presented in the Lancet *Every Newborn* series [10-15] and set out specific global and national milestones needed to reach the target.

Quality of care

In recent decades, increasing skilled birth attendance and shifting to facility delivery have been a central approach to improve neonatal health [20]. As a result, higher rates of births are taking place in health facilities in all regions, but it has not led to the expected improvements [21, 22]. A majority of avoidable neonatal morbidity and mortality are now occurring in health facilities, and the main reason has been identified as poor quality of care [13, 21-23]. Improvement in quality of care is therefore receiving increased attention, and the World Health Organization (WHO) has urged nations and researchers to focus on improving quality of perinatal care to meet SDG 3 [24, 25]. Quality of care is defined by WHO as "The extent to which health care services provided to individuals and patient populations improve desired health outcomes. *In order to achieve this, health care must be safe, effective, timely, efficient,* equitable and people-centered" [24] (see box below). This definition takes into consideration two important dimensions of care: the quality of the provision of care and the quality of care as experienced by women, newborns and their families.

Characteristics of quality of care

Safe - delivering health care that minimizes the risks and harm to service users, including avoiding preventable injuries and reducing medical errors

Effective - providing services based on scientific knowledge and evidence-based guidlines

Timely - reducing delays in providing and receiving health care

Efficient - delivering health care in a manner that maximizes resource use and avoid waste

Equitable - delivering health care that does not differ in quality according to personal characteristics such as gender, race, ethnicity, geographical location or socioeconomic status

People-centered - providing care that takes into account the preferences and aspirations of individual service users and the culture of their community

A framework and standards for the quality of care

To identify action points to improve the quality of care for maternal and newborn health, WHO has developed a conceptual framework (Figure 1). The framework includes eight domains (1-8) of quality of care within the health system, and highlights the two important and inter-linked dimensions Provision of care and patients' Experience of care [24]. For the provision of care, there should be (1) evidence-based practices for routine care and management of complications, (2) actionable information systems with record keeping, and (3) functional referral systems between levels of care, in place. Good quality within the dimension of the experience of care includes (4) effective communication between health care workers and women giving birth, (5) treatment given with respect and dignity and (6) access to emotional support. Both (7) competent and motivated human resources and (8) the availability of essential physical resources are required for the provision of care as well as the experience of care. By focusing on these eight domains to improve the quality of care, the likelihood of desired outcomes such as coverage of key practices and people-centered outcomes, will increase. Ultimately the improved quality of care leads to improved health outcomes.

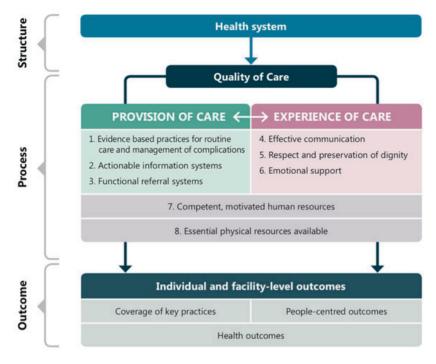


Figure 1. WHO framework for the quality of maternal and newborn health care. Reprinted from Standards for improving quality of maternal and newborn care in health facilities, page No 16. WHO (2016).

Evidence-based practices of quality care

Early essential newborn care

Based on the quality of care framework and on the evidence from the Lancet series *Every Newborn*, WHO has developed standards and measures for improving quality of newborn care in health facilities [26].

Among the WHO standards regarding the provision of care is early essential newborn care (EENC), a package of care that all newborns should receive immediately after birth, to help them adopt to the new environment and avoid complications leading to disability or death [13, 26]. The constituent basic components are (1) immediate and thorough drying, (2) skin-to-skin contact, (3) delayed cord clamping and (4) early initiation of breastfeeding.

Immediate and thorough drying

Immediately after birth, the newborn baby should be thoroughly dried with a clean, dry cloth, preferably while placed skin-to-skin on the mother's abdomen or chest [27]. This is an important measure to prevent hypothermia in the newborn, occurring from evaporation of amniotic fluid from the skin

[28]. Hypothermia contributes to neonatal mortality both directly, and indirectly as a comorbidity of other causes of death [29]. In addition to preventing hypothermia, drying helps stimulate breathing after birth for newborns who are not breathing spontaneously [30, 31].

Skin-to-skin contact

Immediately after birth, the newborn baby should be placed naked on their mother's (or other caregiver's) bare chest, in skin- to-skin contact (SSC), and the body should be covered with a clean, dry cloth [27]. All newborns, and especially preterm or low birth wight newborns, are at risk of developing hypothermia, as their thermoregulatory mechanisms are easily overwhelmed [32]. They are dependent of the surrounding temperature and drop quickly in body temperature by means of radiation and convection [33]. Hypothermia is an independent risk factor for newborn death and is associated with morbidities like hypoglycemia, respiratory complications and sepsis [33]. Placing the newborn in SSC prevents hypothermia [28, 32]. In addition to preventing hypothermia, SSC promotes breastfeeding [34] and is considered the natural, least stressful way of caring for the newborn after birth [35].

Delayed cord clamping

The umbilical cord should be clamped at 1-3 minutes after birth [27]. This practice is called delayed cord clamping (DCC), as opposed to early (or immediate) clamping which is carried out within one minute after birth. DCC allows time for placental transfusion of blood to the newborn, which contributes to up to one-third of total potential blood volume at birth [36]. There are multiple benefits of DCC, including increased hemoglobin levels, decreased risk of iron deficiency anemia, improved cardiopulmonary adaption and neurodevelopment [37-42]. Early cord clamping should only be performed if the baby needs to be moved immediately for resuscitation. However, several trials have investigated the feasibility of resuscitation with intact umbilical cord [43], and positive findings have been demonstrated [44].

Early initiation of breastfeeding

Breastfeeding should be initiated within one hour from birth, a practice referred to as early initiation of breastfeeding (EIBF). Breastfeeding is a cornerstone of child survival, nutrition and development, and exclusive breastfeeding is recommended for the first six months of life [45, 46]. There are multiple benefits of EIBF for newborn infants and mothers; it stimulates milk production, reduces the risk of heavy maternal bleeding, fosters mother-child bonding, increases rates of exclusive breastfeeding, and reduces neonatal deaths [47-49]. Colostrum, the first milk, is particular rich in factors that provide protection to the newborn from several pathogens, in addition to being a rich source of nutrients [50]. Also, newborns are at higher risk of developing symptomatic hypoglycemia compared to older children and adults. There are several reasons for this, including the abrupt disruption of

continuous transplacental glucose supply from the mother at birth [51]. Fine-tuned endocrine and metabolic responses are required to maintain appropriate blood glucose concentrations but can take some time to establish [52, 53]. However, for some newborns this adaption is dysfunctional and the risk for symptomatic hypoglycemia is increased in several conditions including prematurity, low birth weight, hypothermia, and maternal diabetes [54, 55]. One measure to prevent hypoglycemia is to initiate breastfeeding within the first hour after birth [56, 57].

Neonatal resuscitation

When EENC, as presented above, is provided to the newborn, breathing must be assessed simultaneously. If the newborn is not breathing, resuscitation should be initiated without delay to avoid morbidity and mortality from hypoxia. When a baby is born, a transition from intrauterine to extrauterine life must occur, and the first breaths start a rapid conversion from placental to pulmonary gas exchange [31]. Most newborns perform this transition spontaneously, but approximately 5-10% of babies require assistance to establish breathing at birth, and approximately 3-6% need basic resuscitation with bag-and-mask ventilation. Less than 1% require advanced resuscitation such as endotracheal intubation, chest compressions and drugs [58]. Although the percentage of newborns in need of resuscitation is low, the high number of births globally means that timely intervention to help the baby breath will prevent morbidity and save hundreds of thousands of newborn lives every year [58, 59]. Basic neonatal resuscitation, including bag-andmask ventilation is sufficient for most babies and such basic equipment and skills are adequate for effective resuscitation in low-resource settings [60]. Improving health care workers' competence in neonatal resuscitation could prevent 30% of deaths of full-term newborns with intra-partum related events [59].

Satisfaction with care

The WHO standards regarding experience of care reflect the interactions that patients have with the healthcare system [61]. These standards include effective communication with women and their families, who should be adequately informed and involved in all decision-making regarding treatment. Furthermore, women and newborns should receive care with respect and dignity, and their privacy should be respected at all times. Lastly, every woman should be provided with emotional support which strengthens her own capability during childbirth and should be offered to have a companion of her choice. Good quality leads to improved people-centered outcomes, such as satisfaction with care, which can be described as patients' evaluation of the care provided relative to their expectations [61]. The perspective of women and their families on the quality of services influences their care-seeking

behavior and creates demand for high quality care [62]. It is also positively associated with patient compliance, safety and clinical effectiveness [63]. Furthermore, it is useful to guide and evaluate quality improvement efforts.

Parent-infant closeness

Beyond survival, it is incorporated in the SDG 3 that all newborns should thrive and reach their full potential for health and life [17, 18, 64]. Thus, quality postnatal newborn care must not only address immediate health concerns with evidence-based medical care, but also help build parent-infant relationships, and establish behaviors that positively affect long-term infant development and health [65]. Promoting parent-infant closeness is important for achieving this [66]. It incorporates not only physical closeness, but also bonding and attachment between parent and newborn, and evidence points out several advantages for the newborn. Besides establishing the parent-infant relationship [67], the benefits of closeness range from avoiding hypothermia after birth [28, 68], increasing the rates of exclusive breastfeeding [34, 69]. and improving the cognitive development during childhood [70-72], to increasing survival [13]. The ultimate exercises for parent-infant closeness after birth are SSC and breastfeeding, the core components of kangaroomother-care (KMC), a recommended and life-saving method of care for preterm/low birth weight newborns [13, 73]. Though the benefits of SSC are proven for both stable and unstable newborns, separation remains standard in many hospitals, especially for small or sick newborns [74, 75].

Quality improvement interventions

Despite the availability of evidence-based practices to improve neonatal health and survival, as those described above, there are often difficulties in translating them into clinical practice [76]. This phenomenon, the so-called "know-do" gap, is known in many areas and has promoted a growing field of implementation science [77]. It is essential to strengthen implementation capacity and develop successful quality improvement (QI) interventions, to improve the quality of care [78, 79]. In designing such interventions, contextual factors need to be considered. Identification of local barriers and enablers, for example, is important to guide OI interventions [78]. Developing a culture of quality within the health facilities, using QI leaders, or facilitators, to promote quality improvement and establishing QI teams within the facilities has been successful approaches [80]. There are many different methods, or QI tools/activities, which can be incorporated into such interventions and the choice of tools depends on the healthcare system and available resources. Multifaceted QI interventions using a combination of QI strategies, such as involvement of local stakeholders, in-service training, and audit and feedback (for example weekly review-meetings, skill checks and self-evaluation) are more effective

in changing clinical practice than a single strategy [81-84]. Participation in an organized continuous QI process, for example plan-do-study-act (PDSA) cycles, has been found beneficial [80, 81, 85].

The Nepalese context

Nepal is situated in South Asia, bordering China (Tibet) in the north and India in the south, east and west. Its geography is diverse with mountains (the Himalayas), hills, flatlands and lowlands. The population is multiethnic, and Hinduism is by far the largest religion, followed by Buddhism, Islam and others. The population was 26.5 million in 2011 [86], and preliminary results from the latest national census from 2021 show 29.2 million with a declining annual growth rate. Nepal has long been classified as a low-income country, but according to the latest World Bank classification, it is now a lower-middleincome country. In 2019, the human development index (HDI) value, accounting for health, education and standard of living, was 0.587 for Nepal, which puts it in the medium human development category. Though continued progress in HDI has been made over the years, there are large differences between rural and urban areas, and Nepal is still behind most South Asian countries [87]. The country is facing several health challenges, including inequity in health care service availability and utilization and health status across different socio-economic groups. The complex geography further adds to this [88]. Health care is provided by both the public and private sectors. There are challenges in basic input for quality of care, such as lack of qualified health workers, stock out of drugs and commodities, non-functioning equipment, and inadequate physical infrastructure [89]. However, maternal and child health has long been a prioritized focus for the Government of Nepal, which has led to great progress. Nepal achieved the Millennium Development Goal on child survival - the U5MR fell from 142 deaths per 1,000 live births in 1990 to 38 in 2014 [90]. A range of different programs to increase skilled birth attendance and facility deliveries has been implemented, e.g. financial incentives for transportation of pregnant mothers to delivery facilities, increased availability of skilled attendance at birth and free antenatal and delivery care for all citizens [89]. However, as in many regions, the neonatal mortality did not decrease proportionately [90]. Despite a large increase in the number of women giving birth in health facilities in Nepal (a fourfold increase between 2001-2014) [91, 92], neonatal mortality remains a challenge. In 2020, the estimated NMR in Nepal was 17 per 1,000 live births and constituted 60% of the U5MR [1]. This exemplifies that simply increasing the number of hospitals births, without improving the quality of care, does not ensure improved health care outcomes [13, 21, 23]. A vision for the country is set in Nepal's Every Newborn Action Plan in which "there are no preventable deaths of newborns or stillbirths, where every pregnancy is wanted, every birth celebrated, and women, babies and children survive, thrive

and reach their full potential" [89]. Nepal is dedicated to improve quality of perinatal care as part of the national newborn care program [93] and has engaged to reduce NMR to 11 per 1,000 live births by 2035 [89].

Development of a quality improvement package

The Helping Babies Breathe (HBB) program of the American Academy of Pediatrics is a neonatal resuscitation training program aimed for implementation in resource-limited settings [94, 95]. In 2013, a study of a QI package for implementing the HBB resuscitation protocol was conducted in a tertiary hospital in Nepal. Besides clinical training, the package included other QI tools, aiming to continuously reinforce the HBB protocol throughout the intervention period and to motivate hospital management and individual health workers to be engaged in improvement. The study, Helping Babies Breath-Quality Improvement Cycle (HBB-QIC) showed improvement in health workers' performance and a reduction of intrapartum stillbirth and first-day neonatal mortality by 51 and 49 percent, respectively [96]. However, there was no significant change in overall in-hospital perinatal mortality, suggesting that improved continued postnatal care is needed to maintain the gains [97].

Based on the findings from HBB-QIC, and evidence-based QI interventions from other settings, a scale-up was developed by Ministry of Health and Population in Nepal in collaboration with our research group. The resulting QI package, Nepal Perinatal Quality Improvement Project (NePeriQIP) [98], focused on resuscitation and continued postnatal care. The WHO standards for improving quality of maternal and newborn care in health facilities [26] was used to incorporate EENC, KMC for low birth-weight newborns and infection prevention. The QI package was multifaceted, comprised of three major strategies; facilitation, training and audit and feedback (Table 1). Facilitators were recruited from within each hospital to facilitate implementation of the OI package and support health care workers (HCWs) in jointly sharing experience and expertise and to work together to improve quality of care. They mainly used Plan-Do-Study-Act (PDSA) cycles, a structured model for quality improvement recommended by WHO, aiming to identify and act upon local problems [99, 100]. Training for HCWs was carried out in each hospital, including resuscitation, EENC, KMC and infection prevention. Audit and feedback were incorporated through readiness assessments in each hospital, peer evaluation, self-evaluations and progress tracking.

NePeriQIP was rolled out in 12 referral hospitals for maternal and newborn care in Nepal, with the aim to improve quality of perinatal care through increased clinical skills and knowledge and establish a structure for continuous quality improvement. A stepped-wedged cluster randomized design was

used for evaluation, with intrapartum-related mortality as primary outcome [98]. Study III and IV were nested within NePeriQIP.

Table 1. Implementation strategies and corresponding quality improvement activities in NePeriQIP.

Implementation strategies	Strategy components	QI activities/QI tools
Facilitation	PDSA-cycles	Unit meetings
	Holistic and task-oriented facilitation	 Unit meetings Training sessions
	Regular supervision and support of facilitators	 Mentoring sessions for facilitators Supervision of facilitators performance by mentors
	Needs-based in-house training	Individual training of facilitators by mentors
	Experience sharing	Interaction sessions
Training	Training of trainers	Training of facilitators and mentors
	In-service training of health workers	 Initial basic training of health workers Refresher training after 6 months
Audit and feedback	Readiness assessment	Survey during preparatory faceDissemination of results
	Peer evaluation	Skill checks with peer evaluation Performance evaluation checklists to be discussed with peers
	Self-evaluation	Daily individual skill checks Individual assessment after delivery
	Progress tracking	Daily compilation of data displayed on progress boards

Rationale of the thesis

Successful interventions to improve the quality of newborn care are essential to meet the SDGs in reducing neonatal mortality and morbidity. There is an urgent need for implementation and research on the growing field of quality improvement, to inform design of interventions and evaluate the effect on newborn health outcomes [16, 76, 80, 101]. In Nepal, progress on newborn survival is clearly behind the trend seen in the post-neonatal period, despite initiatives that have increased access to and coverage of maternal and newborn care services [1, 89, 90]. Improving neonatal survival has a high priority in Nepal and concerns for the quality of services is growing [89, 93]. In this context, the search for ways to improve the quality of newborn care is crucial.

The studies included in this thesis aim to contribute to advancing quality of care. Two of the studies investigates the context, assessing practices in hospitals and attitudes among health care workers in Nepal. The remaining two evaluates the effect of NePeriQIP on outcomes of provision of care and experience of care, respectively (Figure 2).

The findings could help inform the design and implementation of interventions aimed at improving the quality of care to increase newborn health and survival, especially in Nepal and similar settings.

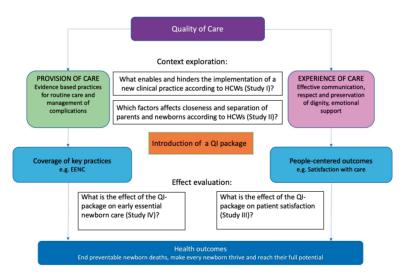


Figure 2. Research questions responding to the rationale of the thesis and their relation to the WHO framework for quality improvement of maternal and newborn care. HCW= health care worker, QI= quality improvement

Aim and objectives

The overall aim of this thesis was to inform and test the design of QI interventions in Nepal, by exploring contextual factors and evaluating a package of QI interventions. The specific objectives for each paper were:

- I. To explore barriers and enablers for implementation of delayed cord clamping in Nepal.
- II. To explore factors affecting closeness and separation of parents and newborns in hospitals in Nepal.
- III. To investigate the effect of a QI-package on patient satisfaction with perinatal care in hospitals in Nepal.
- IV. To evaluate the impact of a QI-package on early essential newborn care practices in hospitals in Nepal.

Methods

Study design

The studies included in this thesis used different study designs. An overview of methods for each study is outlined in Table 2.

Table 2. Overview of methods for each study. FGD=focus group discussion, KII= key informant interview

Study	Study design	Participants	Analysis	Outcome
I	Qualitative	FGDs with 34 nurse-midwifes KIIs with 12 skilled birth at- tendant-trainers and ward in- charges	Qualitative content analy- sis	Categories and sub-categories
п	Qualitative	Individual in- terviews with 10 health care workers in- volved in new- born care	Inductive the- matic analysis	Themes and sub-themes
III	Stepped-wedge randomized control design (secondary analysis)	Exit interviews with 54,919 women who gave birth in 7 of 12 hospitals included in Ne- PeriQIP	Chi-square test, General- ized Linear Mixed Models (GLMM)	Overall satis- faction, Experi- ence of care
IV	Observational before and after	Clinical observations of 27,009 newborns in the 4 high-volume hospitals included in Ne-PeriQIP	Chi-square test, multilevel logistic regres- sion	Immediate and thorough dry- ing, immediate skin to skin contact, de- layed cord clamping, early initiation of breastfeeding

Study I and II are qualitative and build upon interviews with a purposive sample. Study III and IV are quantitative and were nested within the larger NePeriQIP trial (ISRCTN30829654), which used a stepped-wedged

randomized controlled design [102]. Each wedge included one high-volume (>8,000 deliveries a year), one medium-volume (>3,000 deliveries a year) and one low-volume (>1,000 deliveries a year) hospital. Each cluster had a control and an intervention period. During the first three months of the study period, no intervention activities took place at any of the hospitals (baseline period). The QI package of NePeriQIP was then introduced to one wedge with three hospitals at a time, with a three-month delay between wedges (Figure 3). The stepped-wedge randomized control design was used to evaluate the effect of the NePeriQIP QI package on patient satisfaction and experience of care. An observational before and after study design was used to evaluate the impact of the NePeriQIP QI package on immediate newborn care.

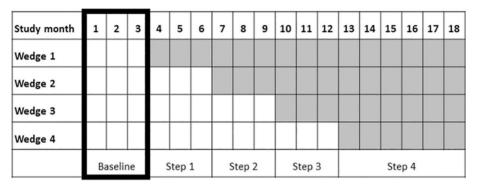


Figure 3. Stepped-wedge design and time line of the NePeriQIP trial. The period within bold lines represents the baseline period. The shaded period constitutes the intervention period. Each wedge contains three hospitals (clusters).

Study settings

The investigation of delivery staff's perceptions of the implementation of delayed cord clamping (Study I), was carried out at two referral teaching hospitals for maternal services in the capital city Kathmandu, with 20,000 and 7,500 deliveries per year. The three remaining studies (Study II-IV) were conducted in hospitals included in NePeriQIP, which were selected by Ministry of Health and Population based on the criteria of having more than 1,000 deliveries a year and being public referral hospitals for maternal and newborn care. All hospitals provided vaginal and cesarian delivery and all had access to neonatal resuscitation services at birth. Skilled birth-attendants led the labor units. In the low-volume hospitals there were no specialized sick newborn care services; sick newborns were managed at the pediatric unit, led by medical doctors. In medium and high-volume hospitals, sick newborn care units (SNCU) or neonatal intensive care units (NICU) were led by pediatricians. The hospitals were located mainly in the flatlands but

provided care to patients of diverse ethnicity, language, and religion. The intrapartum-related mortality rate ranged from 9 to 31 per 1,000 births at the hospitals (mean 13/1,000 births) during the baseline period [102]. Factors affecting parent-infant closeness and separation (Study II) were explored at five hospitals (one low-volume, two medium-volume, and two high-volume). The effect of NePeriQIP QI package on patient satisfaction and experience of care (Study III) was investigated at all 12 hospitals. Evaluation of the effect of the QI package on EENC practices (Study IV) was done at the four high-volume hospitals, one from each wedge.

The intervention step-by-step (Study III and IV)

The QI package included a series of activities initiated at different time points in the different hospitals according to the stepped wedge study design of NePeriQIP, and was introduced in the following steps:

Orientation: First, the hospital management of each hospital was oriented on the QI intervention package.

Selection and training of facilitators: Hospital management then appointed in-hospital QI facilitators from among pediatricians, medical officers and nurses. The number of facilitators depended on the size of the hospital: two from low-volume, three from medium-volume and four from high-volume-hospitals. All facilitators participated in seven days of training on the facilitator's role and the QI package, organized per wedge and conducted by members of the study team. The in-hospital QI facilitators were supported in implementing the QI package by external mentors recruited by the study team.

Assessment of perinatal care: The in-hospital QI facilitators assessed service readiness and availability of perinatal care in their respective hospitals using a checklist developed by the team. Based on the assessment, a two-day bottleneck analysis workshop was organized at each hospital.

On-site training: After the initial steps presented above, all health care workers involved in perinatal care in the hospitals received a three-day on-site basic training organized by the in-hospital QI facilitators and the study team. The training consisted of theoretical education and skills training on resuscitation, EENC, KMC, infection prevention and a set of QI tools. HBB training manual version 1.0 [94] was used for resuscitation training. The QI tools included daily bag-and-mask ventilation skill check on a mannequin (the low-cost simulator Laerdal NeoNatalie), a checklist for preparations before each birth, a self-assessment checklist of performed resuscitation, the use of score-

boards comprising major indicators on neonatal resuscitation and weekly Plan-Do-Study-Act (PDSA) meetings.

Post training QI practice: Each hospital was provided with the HBB job aid, mannequin set for skill check, birth preparation checklists, self-assessment checklists, score-boards and weekly PDSA review meeting notes. After the basic education, the health care workers started to perform daily skill checks on mannequins and use checklists before delivery and after performing resuscitation. The in-hospital QI facilitators started updating the score-board installed in delivery rooms and initiated weekly PDSA meetings as part of routine work in all units, involving health care workers related to perinatal care.

Refresher training: About six months after the basic education, the health care workers received a one-day refresher training in HBB.

Study population and sample size

Study I All nursing staff working in delivery units, skilled birth attendants (SBA)-trainers and ward in-charges from the two hospitals were invited to participate. The duty schedules were arranged to enable everyone's participation. A number of eight group discussions were carried out, four at each of the two participating hospitals. Each group consisted of 3-5 health care workers involved in deliveries, resulting in a total number of 34 participants. The number of participants needed to be large enough to generate a meaningful group discussion but also depended on duty schedules. Separate interviews were conducted with 12 ward in-charges and SBA trainers from the hospitals.

Study II A purposive sample of health care workers involved in delivery and postnatal care working in different sizes of hospitals, were invited to participate. The criteria for inclusion were HCWs with varying experience and of different professions posted in the selected hospitals' labor rooms, postnatal wards, or SNCUs/NICUs. In total, 10 HCWs were available during the data collection dates and consented to participate.

Study III All women who gave birth at any of the 12 hospitals after the baseline period, at a gestational age of 22 weeks or more, who had fetal heart sound at admission and consented to participate were eligible for inclusion. Women who experienced stillbirths, neonatal deaths, malformations and complications during childbirth were excluded as these events could affect the primary outcome. A total number of 65,895 women were eligible for inclusion, 946 women were excluded based on exclusion criteria, and due to data incompleteness from one of the hospitals, another 5,366 women were excluded, leaving 59,583 women available for analysis. Initial analysis revealed that low-volume hospitals showed large heterogeneity and differed

from the medium and high-volume hospitals. As a consequence of this finding, the final analysis was performed on the medium and high-volume hospitals only, where 92% of deliveries took place (n= 54,919).

Study IV All newborns born vaginally in any of the four hospitals after the baseline period, at a gestational age of 22 weeks or more, who had fetal heart sound at admission and whose mother consented to participate were eligible for inclusion. Stillbirths, twins, newborns with malformations, newborns with a very low birthweight (<1500grams), and those receiving bag and mask ventilation were excluded as those might not be subject to standard care. A total of 27,009 newborns were finally included for analysis.

Power calculation for NePeriQIP was calculated for the main outcome, intrapartum-related mortality [102], and there was no a priori estimation of sample size for study III and IV.

Data Collection

Study I To explore enablers and barriers for implementing DCC both focus group discussions (FGDs) and individual key informant interviews (KIIs) were carried out. Data were collected in April and May 2018 on the topic *Delivery care staff's perceptions and attitudes towards changes in the practice of umbilical cord clamping*, using an interview guide with open-ended questions developed by the authors. Ward in-charges and SBA-trainers who were supervisors for the units were explicitly asked not to patriciate in focus group discussions, to allow the participants to speak more freely. To include perceptions at the managerial level and increase variation of data, they were instead invited to separate interviews. The first author moderated all focus group discussions and individual interviews, which lasted between 20-40 minutes and were voice recorded. They were then transcribed verbatim in Nepali and translated into English.

Study II To explore factors affecting closeness and separation of parents and newborns in hospitals in Nepal individual interviews with HCWs were carried out during the intervention period of NePeriQIP. The interviews were conducted by two trained public health professionals who were not part of the NePeriQIP interventions, on the topic *Closeness and separation between parents and newborns during the hospital stay*, using a pre-developed question guide. The interviews lasted from 10 to 30 minutes, were voice recorded and then transcribed verbatim in Nepali and translated into English.

Study III To investigate the effect of the NePeriQIP QI package on patient satisfaction, quantitative data were collected through structured interviews with all included mothers upon discharge throughout the intervention period of NePeriQIP (June 2017 to October 2018). An independent data collection

team was established at each hospital, and a structured questionnaire based on WHO's "Standards for improving quality of maternal and newborn care in health facilities" [26] was developed by the study team and used to collect the data in paper format. Patient satisfaction was measured through overall satisfaction and the three dimensions of experience of care (effective communication, respect and dignity and emotional support) in the WHO Quality of Care framework for maternal and newborn health [24]. Overall satisfaction was measured as an aggregate score of two questions: *Overall, how satisfied are you with the services?* and *Would you recommend a friend to deliver at this hospital?* The experience of care was investigated through a set of questions suggested in WHO's "Standards for improving quality of maternal and newborn care in health facilities" [103].

Study IV To evaluate the impact of the NePeriQIP QI package on early essential newborn care practices, direct clinical observations were conducted by a team of eight trained nurses in each high-volume hospital. The study period for this study was July 2017 to October 2018. The team members received a seven-day training on the data collection process prior to placement to the respective hospitals, and then worked on 24/7 hours rotation to ensure observations at all times during the study period. Data were collected in paper format, and the data collection forms were pre-tested in a tertiary level maternity hospital in Kathmandu. The outcome variables were the four elements of EENC; (1) immediate and thorough drying, (2) immediate skin to skin contact, (3) delayed cord clamping, and (4) early initiation of breastfeeding, based on WHO's "Standards for improving quality of maternal and newborn care in health facilities" [103].

Data management study III and IV: To ensure the effectiveness of the data collection process, a coordinator was assigned from among the data collectors, who had weekly online meetings with the study team in Kathmandu. To ensure the quality of data, the study team monitored the data collection process using a pre-developed standard operating procedure. The study team also visited the data collection sites frequently. The completed data collection forms were sent weekly to the central research office in Kathmandu, where the data were transferred into the electronic database Census and Survey Processing System (CSPro) by a team of independent data entry officers. The data entry officers indexed the forms for respective hospitals before entering them into CSPro software, and the forms have been stored safely at the research office.

Data analysis

Study I Data were analyzed with an inductive approach using qualitative content analysis (QCA) as outlined by Graneheim and Lundman [104]. The

transcripts were coded manually, and codes were collated in Microsoft Excel and condensed into sub-categories, which were then sorted into categories in a back-and-forth process between the authors. Quotes that were representative of each category were selected from the transcripts.

Study II Data were analyzed with inductive thematic analysis as outlined by Braun and Clarke [105]. The translated transcripts were coded manually, codes with associated extracts were then collated together in Microsoft Excel, and the codes were sorted into potential themes. This was a back-and-forth process between the authors, which resulted in the formation of themes and sub-themes. The list of themes and subthemes was then reviewed and refined at the level of coded extracts and in relation to the dataset. The final themes and sub-themes were analyzed, expressed in text, and discussed among all authors.

Study III Pearson's Chi-Squared test of proportion was used to analyze background characteristics of participants in the control and intervention groups, performed with Statistical Package for Social Sciences (SPSS) version 25.0. Change in satisfaction and experiences of care between the control and intervention groups were analyzed by generalized linear mixed models (GLMM) using the software R (version 3.4.0). Analyses were performed with R package lme4. Adjustments were made for structural discrimination factors (cast/ethnicity and educational level). Intra-cluster correlations coefficients (ICC) for each outcome were calculated. Initial analyses showed high ICC for all outcome variables, making the results inconclusive. Further analysis of the data by hospital displayed that the low-volume hospitals showed large heterogeneity. As a consequence, the final GLMM analysis was performed on the medium and high-volume hospitals. Analysis of change before and after intervention at each hospital was performed with binary logistic regression of satisfaction and experience of care (adjusted for caste/ethnicity and education level) with SPSS version 25.0.

Study IV Pearson's Chi-Squared test of proportion was performed to analyze the background characteristics of participants during the control and intervention period. Pearson's Chi-Squared test was used for the comparison of outcome variables between the pre-intervention and intervention period. Multilevel logistic regression was performed to display crude and adjusted odds ratios with 95% confidence intervals (CI) for each outcome variable. In the first model socio-demographic variables were adjusted for, and in the second model maternal and neonatal characteristics were included. In the final model, adjustments were also made for hospitals. SPSS version 25.0 was used for all analyses. Missing data were excluded from all analyses.

Ethical consideration

All research involving newborn infants needs careful ethical consideration, mainly since they cannot agree to whether they want to participate in the study or not. Ethical approval was obtained from Nepal Health Research Council (study I: ref 17-2018, study II-IV ref 26-2017) and the Regional Research Ethics Committee, Uppsala, Sweden (study I: ref 2013/271, study II-IV: ref 2017/240). The QI package was developed in close collaboration with the Ministry of Health and Population in Nepal. The hospital management of all hospitals consented to their involvement in the studies.

Participation in all studies was voluntary, and a signed written informed consent form in Nepali or English was obtained from all participants or caregivers before data collection. In case of illiteracy, the consent form was read to them. Withdrawal from a study was possible at any point. Interviews took place in secluded areas, or in separate rooms, to maintain privacy.

The identity of all participants was coded before electronic data storage, analysis and reporting of results, and the code key was stored in a safe environment that only the project management had access to. Audio records and paper forms were kept in a locked room at the central research office in Kathmandu.

Results

Contextual factors affecting quality of newborn care

In study I and II we explored contextual factors which can impact the quality of care (Figure 2), and be of importance when planning QI interventions. We researched this by interviewing HCWs to get their perspective on the provision of two key practices, DCC (Study I) and parent-infant closeness (Study II).

Enablers and barriers for the implementation of delayed cord clamping (Study I)

The analysis generated six categories and 18 sub-categories (Table 3).

Medical and physical barriers

Maternal or fetal medical conditions and physical settings were discussed as barriers to DCC. For example, the HCWs disclosed that if there was a post-partum hemorrhage or a newborn in bad condition, the umbilical cord must be cut immediately. Occasionally they needed to cut the umbilical cord immediately because the mother opposed to keep the baby on her abdomen, or because the delivery bed was too small to keep them together. Sometimes there was simply no time to wait to cut the umbilical cord due to lack of manpower and heavy workload.

"Some mothers would get afraid and say don't keep it on my abdomen. . .they would say "I don't want to hold the baby"."
(Birthing center in-charge)

Habitual practice

To change a habitual practice that one has been carrying out for a long time was perceived difficult, especially without reminders in the hectic everyday work. Also, motivation for change was lacking if the benefits of the new practice was unknown.

"Very senior sisters, they themselves don't want to change, they want to do what they have been practicing." (SBA trainer/supervisor)

Forced to informal learning

HCWs felt hesitant to adopt a new clinical practice if they are forced to rely on informal learning like hearsay, self-education or peer-learning. They would rather have formal information, training and continuous supervision.

"There should be simulation and at the beginning they should have supervisors with them, that will help them to learn it gradually" (*Nurse midwife*)

Table 3. Categories and corresponding subcategories from both focus group discussions and key informant interviews.

Categories	Sub-categories		
Medical and physical barriers	Maternal medical condition		
	Fetal medical condition		
	Physical setting		
Habitual practice	Routine work		
	Need for reminders		
	Need to have knowledge about benefits		
	Change through practice		
Forced to informal learning	Lack of refresher training		
	Peer learning, and informal information		
Lack of coherence	Lack of team work		
	Lack of trust among team		
Need to bring uniformity	Knowledge update through coaching and orientation		
	Request for authorized protocol		
	Supervision, monitoring and evaluation		
	Use flex chart, poster and pamphlet to raise awareness		
Opportunities for change	The will to do good		
	Research as authority		
	Trust in hierarchical system		

Lack of coherence

A sense of lack of coherence within the work team was revealed. Without proper teamwork and trust among the team members, it is difficult to bring uniformity in practice. For example, it was thought that medical doctors regard themselves as superior and won't listen to what nurses say or suggest, even though it is about the latest evidence or guidelines, that doctors might be unaware of

"Yes, they feel superior. . . 'we are doctors and you are just a nurse. Why should we listen to nurses'? We feel it, we have the same value as they have but they feel that, 'nurses are our assistants'."

(SBA trainer/supervisor)

Need to bring uniformity

To bring about change, the participants emphasized a need to bring uniformity to clinical practice. To achieve this, it was suggested that there should be official protocols with instructions from higher authorities, like the hospital management and the government. They requested knowledge updates, clinical training and supervision and efforts to increase awareness among the public.

"Those who are exposed to conducting delivery should formally know about it. Small orientations or one- or two-day packages as per content volume." (*Nurse midwife*)

"We can do advocacy, it will be effective to do it through television or radio, now everyone has Facebook."

(Matron)

Opportunities for change

The participants had positive attitudes towards delayed umbilical cord clamping in general, as it was perceived uncomplicated and beneficial for the mother and child. The inherent will to do good among health-care staff along with a high level of trust in scientific evidence and the hierarchical system were identified as opportunities for change in clinical practice.

"We conduct delivery with the good health of mother and baby in mind, therefore, if delayed cord clamping helps the baby, then we will do it for the benefits it provides. This is how I get motivated. "
(Nurse midwife)

Factors affecting parent-infant closeness and separation in hospitals in Nepal (Study II)

The analysis generated three main themes and 11 sub-themes (Table 4).

Table 4. The main themes and corresponding sub-themes from interviews with health care workers about factors affecting parent-infant closeness and separation in hospitals in Nepal.

Themes	Sub-themes
Hospital resources	Spatial conditions
	Comfortable environment
	Privacy
	Workforce and workload
In-hospital practices and attitudes	Rules in the hospitals
	Routines in the hospitals
	Health care workers attitudes
	Health care workers' actions beyond rou-
	tines
Parental-newborn relationships and social fac-	Parental involvement
tors	The role of cast, education, and poverty
	Gender discrimination

Hospital resources

Keeping the newborns spatially close to their mothers, offering a comfortable environment, and privacy were thought to enhance closeness. However, maternity ward and SNCU/NICU were often located far apart, and beds or chairs for parents were often lacking as well as a separate area to enable privacy while breastfeeding or practicing KMC. Heavy workload and lack of workforce hampered HCWs efforts to enhance closeness.

"We must keep mothers and babies close to each other. The baby's weight and breastfeeding get better if the baby gets proper care staying close to the mother. Staying together also helps in increasing the attachment of the mother and baby."

(P9)

In hospital practices and attitudes

There were routines and rules which separated parents and newborns and hindered closeness. Fathers were usually not allowed in the delivery room and sometimes not even in the maternity ward, but were often involved to a greater extent after caesarian sections when the newborn was routinely separated from the mother. Admitted newborns were often cared for by nurses rather than parents, and parents were not allowed to stay with their newborns in SNCU/NICU. Visiting procedures could be very restricted.

"Parents cannot touch and see their babies inside [the ward]. They can only visit once, wearing a gown, and cannot touch their babies." (P5)

Attitudes towards closeness among HCWs and actions which strengthened closeness were described. For example, they transferred beds from other wards to make it possible for mothers to stay close to their newborns admitted to the SNCU/NICU. They tried to create an environment where mothers could be accompanied by a family member, and ensured that the babies got to be with their mothers as much as possible by not keeping them for treatment or examinations more than necessary. HCWs believed that their professional role in promoting closeness was important for health outcomes, and it was perceived easier to provide treatment to the newborn if it was kept together with the mother.

"Service providers behavior plays a huge role, undoubtedly. While treatment, medicines, and proper care are essential, the service providers response to the visitors and parents is also crucial in building child bonding. For example, when the child is brought here for treatment, the parents are usually very nervous and tempered. So, proper counseling from service providers is essential, and health care workers should always take responsibility for these things. We are here to treat patients, and taking responsibility seriously significantly impacts the overall condition of patients and visitors".

Parental-newborn relationships and social factors

Parental involvement, and the influence of various social aspects such as education, cultural beliefs and gender discrimination were brought up as factors affecting closeness. It was frequently mentioned that all parents loved their babies and showed loving behavior by trying to be close to their newborns, carry them and provide care for them. In some communities, it was common for the father to work abroad, making him unavailable. Sometimes, the mothers did not appreciate close physical contact.

"If we put the baby in skin-to-skin contact, the mother asks us to take the baby away from her. Some call their mothers and sisters, complain that their baby is placed on their chest, and request them to take the baby away... we don't know why they say so. We don't ask them."

(P1)

It was mentioned that mothers with a higher level of knowledge tended to provide more care to the baby by themselves and that fathers and other family members acted more loving and caring if they were knowledgeable, while on the other hand, illiterate people listened more to HCWs and complied with their counseling.

Discrimination against newborn girls was brought up as an issue relating to closeness in two hospitals. It was described that baby girls were less cared for by parents and sometimes necessary treatment was withheld from them.

"There was a case where a mother gave birth to two preterm baby girls. Their condition at birth was not good. They could have been saved if the parents had

taken them to a hospital that had a NICU. Although we counseled them about this, they refused to go there because the newborns were daughters. Eventually, both babies died here. The mother couldn't do anything about it; it was the decision of her husband and his family members."

(P3)

The effect of a QI intervention package on quality of newborn care

In study III and IV we evaluated the effect of the QI package of NePeriQIP on both dimesons of quality care; experience and provision of care (Figure 2). Patient satisfaction was measured as the outcome for experience of care (Study III) and the key practice EENC was measured for the provision of care (Study IV).

Effect of a QI package on patient satisfaction (Study III)

Overall satisfaction

The likelihood of women being overall satisfied with care during childbirth increased after the intervention (adjusted Odds Ratio (aOR) 1.66 [CI: 1.59-1.73, ICC: 0.275]). The results varied between hospitals (aOR 0.39-3.57) and the overall proportion of satisfaction was low (control 58%, intervention 62%) (Table 5).

The dimensions of experience of care

All three domains of experience of care (effective communication between health care workers and women giving birth, treatment given with respect and dignity and access to emotional support, Figure 1) were affected in a positive direction by the intervention. Women were more likely to be satisfied with education and information from health workers after intervention (aOR 1.34 [CI: 1.29-1.40, ICC: 0.167]) as well as more likely to state that they had been treated with dignity and respect (aOR: 1.81 [CI: 1.52-2.16, ICC: 0.063]). The likelihood of having experienced abuse during the hospital stay decreased (aOR: 0.42 [CI: 0.34-.051, ICC: 0.082]) and of being satisfied with the level of privacy increased (aOR 1.14 [CI: 1.09-1.18, ICC: 0.136]). Two measures were affected in a negative direction after the intervention, but displayed relatively high ICC in the GLMM model, rendering the adjusted odds ratios to be inconclusive; the likelihood of being adequately informed about examinations, actions and decisions taken for their care (aOR 0.55 [CI: 0.53-0.58, ICC: 0.507]) and having a companion of choice during labor (aOR 0.27 [CI:0.25-0.29, ICC: 0.687]) (Table 5).

Table 5. Binary logistic regression for full sample and GLMM analysis correcting for clustering (by hospital) displaying adjusted odds ratios. Chi2-test for group differences. (n=54,919).

		Control n (%)	Intervention n (%)	aOR (95% CI)**	ICC
Patient satisfaction					
Are you satisfied with services and would you recommend a friend to deliver at this hospital?	No	9,070 (42.1)	12,694 (38.0)	Ref	
	Yes	12,485 (57.9)	20,670 (62.0)	1.66 (1.59-1.73)	0.275
Patient experience					
Were you adequately informed by the care provider about examina- tions, actions and decisions taken for your care?	No	5,021 (23.4)	6,437 (19.3)	Ref	
	Yes	16,439 (76.6)	26,882 (80.7)	0.55 (0.53-0.58)	0.507
Are you satisfied with education/information?	No	12,227 (56.7)	16,922 (50.7)	Ref	
	Yes	9,328 (43.3)	16,422 (49.3)	1.34 (1.29-1.40)	0.167
Are you satisfied with level of privacy?	No	10,433 (48.4)	16,350 (49.0)	Ref	
	Yes	11,122 (51.6)	17,014 (51.0)	1.14 (1.09-1.18)	0.136
Were you or your newborn physically, verbally or sexually abused during labor or childbirth or after birth?	No	21,308 (98.9)	33,149 (99.4)	Ref	
	Yes	247 (1.1)	215 (0.6)	0.42 (0.34-0.51)	0.082
Were you treated with respect and was your dignity preserved during your stay at the hospital?	No	275 (1.3)	290 (0.9)	Ref	
	Yes	21,280 (98.7)	33,074 (99.1)	1.81 (1.52-2.16)	0.063
Did you have a companion of your choice during labor and child birth?	No	17,837 (83.1)	26,991 (81.0)	Ref	
	Yes	3,623 (16.9)	6,328 (19.0)	0.27 (0.25-0.29)	0.687

aOR= adjusted odds ratios, GLMM= generalized linear mixed models, ICC= intra class correlation

^{*}Binary logistic regression models adjusted for caste/ethnicity and education level

^{**} GLMM models adjusted for clustering (by hospital) and caste/ethnicity and education level

Effect of a QI package on early essential newborn care practices (Study IV)

Only a small proportion of newborns received all four EENC practices both pre-intervention and during intervention (1.4% and 3.8%, respectively). Results for the different components of EENC are presented below (Figure 4).

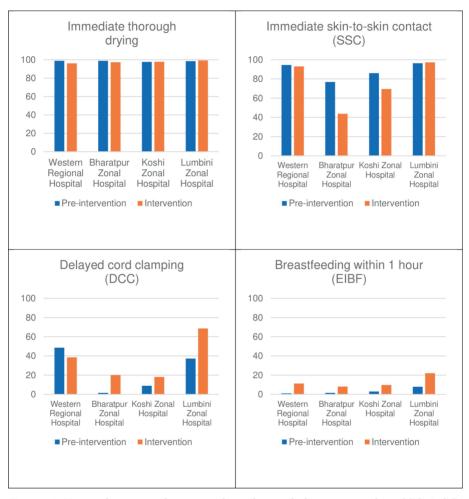


Figure 4. Hospital wise trends in immediate thorough drying, immediate SSC, DCC and EIBF.

Immediate and thorough drying

Immediate drying was widely performed both pre-intervention and during intervention, with a slight overall decrease from 98%-97% (Table 6), and was less likely to be practiced during intervention period compared to pre-intervention (aOR 0.73, 95% CI 0.58-0.93) (Table 7).

Table 6. Early essential newborn care. Chi2-test for group differences in the total sample, four hospitals combined.

EENC practices		Total n (%)	Pre-inter- vention n (%)	Intervention n (%)	p- value n (%)
Immediate thorough drying	Yes	26,405 (97.8)	9,592 (98.4)	16,813 (97.4)	
	No	604 (2.2)	158 (1.6)	446 (2.6)	< 0.001
Immediate skin to skin contact (SSC)	Yes	20,710 (76.7)	8,681 (89.0)	12,029 (69.7)	
	No	6,299 (23,3)	1,069 (11.0)	5,230 (30.3)	< 0.001
Delayed cord clamping (DCC)	Yes	7,277 (28.7)	2,112 (22.1)	5,165 (32.6)	
	No	18,118 (71.3)	7,435 (77.9)	10,683 (67.4)	< 0.001
Early initiation of breastfeeding (EIBF)	Yes	2,486 (9.2)	480 (4.9)	2,006 (11.6)	
	No	24,523 (90.8)	9,270 (95.1)	15,253 (88.4)	< 0.001

Immediate skin-to-skin contact (SSC)

Immediate skin-to-skin contact dropped in two of the included hospitals during intervention, and remained on a similar level in the other two (Figure 4). The proportion of SSC decreased from 89% to 70% overall (Table 6), and the likelihood for immediate SSC to be practiced decreased (aOR 0.35, 95% CI 0.32-0.38) (Table 7). No neonates were continuously kept skin-to-skin for at least 1 hour as per the WHO guidelines.

Delayed cord clamping (DCC)

Delayed cord clamping increased during intervention in three of the four study hospitals (Figure 4), from 22% to 33% overall (Table 6). The likelihood for DCC also increased (aOR 3.40, 95% CI: 3.15-3.67) (Table 7).

Early initiation of breastfeeding

The rate of initiation of breastfeeding within one hour increased in all hospitals in the intervention period (Figure 4), from 5% to 12% overall (Table 6), compared to pre-intervention and so did the likelihood for EIBF (aOR 3.93, 95% CI: 3.49-4.43) (Table 7).

Table 7. Logistic regression displaying crude and adjusted odds ratios with 95% confidence intervals for pre-intervention compared to intervention.

EENC practices		Crude Odds ratios (CI 95%)	Adjusted Odds ratios (CI 95%) ¹	Adjusted Odds ratios (CI 95%) ²	Adjusted Odds ratios (CI 95%) ³
Immediate thorough drying	Yes	0.62 (0.52-0.75)	0.51 (0.41-0.64)	0.53 (0.43-0.66)	0.73 (0.58-0.93)
	No	Ref	Ref	Ref	Ref
Immediate skin to skin contact (SSC)	Yes	0.28 (0.26-0.30)	0.24 (0.22-0.26)	0.23 (0.22-0.25)	0.35 (0.32-0.38)
	No	Ref	Ref	Ref	Ref
Delayed Cord Clamping (DCC)	Yes	1.70 (1.61-1.81)	1.63 (1.54-1.74)	1.63 (1.53-1.73)	3.40 (3.15-3.67)
	No	Ref	Ref	Ref	Ref
Early initiation of breastfeeding (EIBF)	Yes	2.54 (2.29-2.82)	2.84 (2.54-3.18)	2.77 (2.47-3.10)	3.93 (3.49-4.43)
	No	Ref	Ref	Ref	Ref

¹Adjusted for sociodemographic factors (caste and education)
² Adjusted for sociodemographic factors, maternal and child characteristics (teenage mother, primiparity, preterm birth and low birth weight)
³Adjusted for sociodemographic factors, maternal and child characteristics and hospital

Discussion

Quality of newborn care in health facilities must improve to reduce neonatal mortality and morbidity. Therefore, it is essential to implement effective QI interventions. The studies included in this thesis aimed to inform and test the design and implementation of QI interventions in Nepal, by exploring contextual factors and evaluating a OI package.

The results of the contextual exploration indicate that delivery care staff needs knowledge of the benefits of evidence-based newborn care to gain motivation to change clinical practices. Training, supervision and evaluation are needed to change old routines, and authorized guidelines are important to bring uniformity in clinical practice. Parent-infant closeness can be enhanced in hospitals by involving parents more in care and by offering a comfortable environment, privacy and counselling, but hospital resources are currently insufficient to achieve this. Routines in the hospitals, and traditions and cultural beliefs in the society, separate parents and newborns. After introducing the QI package consisting of facilitation, training and audit and feedback, we saw that women giving birth were more likely to be satisfied with care. We also saw changes in EENC practices, with improvements in DCC and EIBF.

Contextual challenges and opportunities

To target and tailor QI interventions, it is important to investigate the context [78]. In study I, we investigated delivery care staff's perceptions of enablers and barriers to DCC, and in study II, HCWs perspectives on factors affecting parent-infant closeness and separation in the hospitals.

In most settings it has long been the norm to clamp the umbilical cord immediately, mainly to reduce the risk of postpartum hemorrhage [106]. However, recent studies have shown no clear benefits [42], while evidence of multiple benefits of DCC has emerged. Therefore, the WHO and the International federation of Gynecology and Obstetrics now recommend DCC [106, 107]. Despite the recommendations, DCC is not yet commonly practiced in Nepal and other places [108, 109]. The results of study I highlight several barriers that HCWs face when trying to implement DCC, which also appear to recur in other settings. Similar to our findings, a systematic review of 18 studies in 2018 found that common barriers to DCC include concerns regardpostpartum hemorrhage and neonatal medical conditions, ing

environmental factors, and lack of staff awareness [110]. Key strategies to facilitate DCC were found to include protocol development, education, and effective teamwork, like in study I. Likewise, a study in India found that simulation in combination with institutional policy achieved change in DCC practice [111]. The need to achieve uniformity in practice through authorized guidelines, clearly communicated to HCWs, has been described in several previous studies [108, 112, 113]. We found an inherent will to do good among HCWs, which can motivate DCC if they are educated about its benefits. The HCWs' request for regular training, supervision and reminders to avoid falling back into practice as usual, reflect that change is something that occurs gradually over time, an evolution which needs continuous efforts to take place [112].

Physical and emotional closeness should be encouraged in hospital settings as part of quality care to increase survival, health, and well-being for all [66], but separation remains standard in many settings [35]. In study II we found that available resources in the hospitals were insufficient to promote and maintain closeness; maternity ward and SNCU/NICU were often far apart, limited space was provided inside SNCU/NICU for the parents, privacy to breastfeed and keep the newborn in SSC was lacking and the workload was too heavy. It is increasingly recognized that the architecture of the SNCU/NICU is essential to enhance closeness [66]. Providing space for parents at their newborn's side may increase their presence in SNCU/NICU [66, 114], but this is lacking in many settings [115, 116]. Challenges to maintain privacy is also a common problem [116, 117], as well as low nurse-baby ratios in low- and middle-income countries, which makes it difficult to provide quality care [118-121]. In India, the introduction of Mother-Newborn Care Units, with mothers present 24 hours a day, increased SSC and breastfeeding rates and lessened the workload for HCWs [122]. Introducing these kinds of units in Nepal would probably improve closeness, but it is complex and costly. A feasible measure could be to introduce small, low-cost changes in the wards, like having comfortable chairs at the bedsides and screens for privacy, to help keep the parents close and lessen the workload for HCWs. Rules and routines in the hospitals were found to increase separation. For example, parents were only allowed to spend minimal time with their admitted newborns, as in many SNCU/NICUS around the world [74]. Despite many benefits of paternal involvement for both mother and newborn [123-126], fathers were mostly not seen as an integrated part of care and were restricted from being present, like in other settings [126, 127]. HCWs perceived that parents accepted to be separated from their newborn and did not interfere with care. While this can be expected in a hierarchical society where one obeys authorities, separation itself might also lead to less confidence in the parental role, and the stress of having a small or sick infant can lead to withdrawal physically and emotionally [128]. Parental education and cultural beliefs also impact closeness; for example, some mothers did not want to keep the newborn in skin-to-skin contact, which was also found in study I. The practice of postpartum seclusion, restricting husbands and family members from touching the newly delivered mother and child, was mentioned and has been reported on earlier by Lewis et al. [124]. Occurrence of discrimination against girls was considered to influence the care provided by the parents. Though Nepal's constitution is committed to eliminate all forms of discrimination and achieve gender equality by 2030, gender inequalities and discrimination remain in the country [129].

Effects of a QI package

In the WHO framework for quality of care (Figure 1) the two important and inter-linked dimensions *Provision of care* and patients' *Experience of care* are highlighted [24]. In study III and IV we evaluated the effect of the QI package of NePeriQIP on these dimesons. Patient satisfaction was measured as the outcome for experience of care (Study III) and the key-practice EENC was measured for the provision of care (Study IV).

Experience of care

The quality of interpersonal care and patient experience are rarely measured [130]. Yet, patient satisfaction is important in several aspects to improve quality of care; it can reveal gaps in the health system to address, it creates accountability among health care providers and stakeholders, it is useful to guide and evaluate QI efforts, and in addition, satisfaction is known to affects patients care-seeking behavior and compliance [61, 131-133]. The likelihood that women were satisfied with perinatal care increased after the introduction of the QI package of NePeriQIP, and the quality measures of experience of care suggested by WHO [26] were affected in a positive direction. The exact mechanisms behind our results are unclear, as the intervention did not specifically focus on people-centered skills. However, self-evaluation, insight in the ongoing QI process and involvement in problem-solving can create a deeper understanding among health workers and make them pay more attention to what they are doing and why [134]. This might increase their engagement and capacity to attend to interpersonal interactions with patients. Similar to our result, a recent study conducted in India which also adopted the PDSA approach and facilitation to improve quality of care, showed improvement in satisfaction among women who had recently given birth [135].

Satisfaction is a complex phenomenon influenced by several determinants, not only the measures of experience of care that we have studied. Other known determinants are structural elements (i.e., cleanliness of the health facility and availability of human recourses, medicines and supplies) and outcome related determinants such as health status of the mother and newborn [136]. Nevertheless, it is previously shown that the inter-personal components of experience of care dominate satisfaction with maternity care in Nepal and

other low-income countries [136, 137]. The proportion of satisfied women both before and after the introduction of the intervention was lower than in previous studies from Nepal and India [135, 138, 139]. We do not know why the women were not more satisfied with care but some factors can be considered. First, as women tend to report more satisfied with care if interviewed early after childbirth, biased by social desirability and the joy of having a healthy baby [140], we sought to reduce the influence of social desirability by our definition of satisfaction (overall satisfaction combined with whether to recommend the facility to a friend). Second, determinants mentioned above which were not included in our study, could play a role. For example, both limited hospital recourses and heavy workload were identified in study I and II. Subsequent overcrowding and long waiting times have been shown to increase the likelihood of dissatisfaction in Nepal [137, 139]. Third, satisfaction with care depends on patients' expectations [141].

Provision of care

The WHO recommends EENC (immediate thorough drying, immediate SSC, EIBF, and DCC) for all newborns to reduce neonatal mortality and morbidity [13, 19, 142]. In addition, newborns who are not breathing should be resuscitated. A substantial part of NePeriQIP dealt with newborn resuscitation with bag-and-mask ventilation (BMV). Previous results from NePeriQIP have shown increased use of BMV and reduced intrapartum-related mortality (intrapartum stillbirth and first day mortality) in the intervention period [102]. The uptake and retention of neonatal resuscitation knowledge and skills among HCWs also improved [143, 144]. However, in this thesis we focused on provision of EENC in uncomplicated births and in situations where additional emergency care was not needed.

In study IV, only a small proportion received all four EENC practices both pre-intervention and during intervention, though they should ideally be delivered as a package to improve survival [145]. Thorough drying and immediate SSC which, among other things, are essential for thermal care after birth [146] both decreased during intervention. Immediate thorough drying was however at a satisfactory level both pre-intervention and intervention, similar to a previous multi-country study [147], and the decrease from 98.4%-97.4% might not be clinically relevant. Immediate SSC was not at a satisfactory level, and has been reported to be practiced at a sub-optimum level in several other low and middle-income countries [148, 149]. In many settings, including Nepal, it is common practice to wrap the baby before placing it with the mother, or putting it in a cot. In study I difficulties to change old habits were highlighted and can be assumed to be an issue also for immediate SSC. In addition, we found in both studies I and II that women sometimes objected to having their baby skin-to-skin. Further, the proportion of immediate SSC dropped dramatically in two of the participating hospitals during the intervention period, and it remained almost the same in the remaining two

hospitals. This was a surprising finding, which is difficult to understand. To some extent, it might be explained by the fact that less emphasis was placed on these practices during the basic training for health workers, compared to bag and mask ventilation, DCC and EIBF, which may have led to a crowding out effect.

Both DCC and EIBF improved after the introduction of the QI package. The recommendation to delay umbilical cord clamping is not yet commonly practiced in Nepal and other settings [109, 150] though continuous efforts are being made to increase this practice [111, 150, 151]. Our findings suggest that a OI package including facilitation, training and audit and feedback can improve the practice of DCC, which cohere with the findings from study I. Rates of EIBF are globally low (only 42% in 2017), with large variation between regions, and the demand to improve this practice is escalating [152, 153]. The proportion of EIBF in our study was low both in pre-intervention and intervention periods, at similar levels reported in a multi-country study in 2021 [147]. Still, it was higher than reported by Reema et al. in South India (1.39%), and by LC Mullany et al. in Southern Nepal (3.4%) [154, 155]. Though we could demonstrate that EIBF practices improved in all participating hospitals during intervention, the rate of EIBF during the intervention period is still lower than the national rate of EIBF in India (44.5%) reported by VM Aguayo et al. [156]. It has been found that EIBF correlates with SSC [69, 157]. In our study the rates of SSC were much higher than EIBF and the drop in SSC in some hospitals did not result in a drop in EIBF.

We observed an influence of local context in general in study IV. The participating hospitals differed widely in some EENC practices preintervention and there was a significant influence on the results at the level of hospital. Specific contextual factors are likely to contribute to this, and further investigation regarding this is warranted.

Methodological considerations

Qualitative methods (Study I and II)

Qualitative methods were chosen for the purpose of study I and II, as they can be used to understand why people act in the way they do, or why things are the way they are. When analyzing and reporting qualitative data, measures should be taken to enhance the trustworthiness of the findings [158]. This typically involves the criteria credibility, transferability, dependability and confirmability [159]. There are different ways to meet these criteria [160].

Credibility concerns the level of truth in the findings. The participant in both studies had experience of the phenomenon under study and were able to comment on it. There was a limited number of HCWs available for interviews during data collection in both studies, but especially in study II. By inter-

viewing additional HCWs, we might have gained more insight into factors affecting parent-infant closeness and separation in the hospitals, and even more by including parents. Still, we succeeded in interviewing HCWs from different professions, with varying work experience, and from different hospitals. There is a risk that we did not reach what is sometimes referred to as saturation, which itself is complex and debated for its controversies and contradictions [161, 162]. The interview guides for study I and II contained open-ended questions to allow for different views from the participants and interviews/discussions were continued until all the topics in the guide were covered and all participants had been able to state their thoughts. Despite the limited number of participants, a variety of opinions and information was provided. All statements from the interviewees were given equal consideration. Social desirability bias should be taken in consideration in these types of studies, especially in hierarchical systems and contexts. In study I, the potential problem of hierarchy hindering participants to share their opinions openly, was reduced by not including the ward in-charges and SBA supervisors in the FGDs. In study II, the data collectors were not members of the larger study team of NePeriQIP and had no relation to the participants. In both studies participants were guaranteed anonymity to limit the influence of social desirability bias. During analysis individuals with different background and varying familiarity with the context were involved, providing both an inside and an outside perspective on the final results. It is a limitation that we did not undertake any member-checks of our findings.

Transferability concerns the extent to which the findings are applicable in other contexts. It is often argued that it is impossible to demonstrate that the findings and conclusions from a qualitative study are applicable to other situations and populations, as the findings are specific to a small number of particular environments and individuals. In addition, the researcher cannot assess the transferability to another context as he or she knows only the 'sending context' [160]. We tried to describe the context and methods as thoroughly as possible to enable the reader to judge whether our findings are transferable to their own settings, as purposed by Lincoln and Guba [158]. Several of our findings have been described in others studies. For example, the finding in study II, that HCWs undertook various actions to facilitate closeness, but balanced them with medical needs and perceived risks for the newborn, is similar to a study by Feeley et al. in Canada and Finland [163]. Another example is the systematic review mentioned earlier, which found that common barriers to DCC include medical concerns, environmental factors, and lack of staff awareness, and that key strategies to facilitate DCC include protocol development, education and effective teamwork [110]. These results are similar to our findings in study I.

Dependability deals with if the findings are consistent and repeatable, with the same methods, in the same context and with the same participants. It is accepted in qualitative research that we can never measure the same thing twice, as the context is always changing. However, the context and processes undertaken within the study should be reported as well as changes to standard procedures. The number of 3-5 participants in the FGDs were lower than the ideal of 5-10 [164]. Though we had to adapt our groups to suit work schedules and staffing in the wards, the discussions were perceived to be rich. We defined our sampling as purposive (the wards in study I and hospitals in study II) but the availability of HCWs during data collection created a limitation in the selection of participants.

Confirmability concerns the aspect of neutrality and describes how other researchers can find similar results with the same data. When analyzing qualitative data, there will always be some level of interpretation during analysis and researchers might influence the results through their personal history and pre-understanding. Effort should be made to stay as neutral as possible. We tried to achieve this by adhering to the chosen methods for analysis as outlined by Graneheim and Lundman, and Braun and Clarke, respectively [104, 105]. To reduce the risk, a rigorous back-and-forth process between several authors with different backgrounds was applied when coding and determining categories and themes. Having good contextual knowledge is valuable in qualitative research and in study I the first author (NR) was familiar with the health-care settings where the research was conducted, and in study II the third author (RG) was. The other authors provided an outside perspective and all authors were involved in creating a consensus of the findings.

Quantitative methods (Study III and IV)

Roll-out and effect of individual QI-activities

Though the QI intervention package was rolled out in the same manner in all hospitals, and internal QI facilitators was engaged, adherence to the continuous QI activities like for example running PDSA-cycles and perform self-evaluating skill checks, might have differed between hospitals. The QI package was multi-faceted and as we could not unbundle it, we could not analyze the effect of individual QI activities on the outcomes.

Stepped wedge design

Study III and IV were nested within the stepped-wedged randomized controlled design of NePeriQIP [102]. This design allows for roll out of expected advantageous intervention at all sites, while mimicking a randomized-controlled trial. It is also a pragmatic way to introduce interventions that would be very resource-consuming if carried out at the same time in all hospitals [165]. The high-, medium-, and low-volume hospitals were randomly allocated into one of the four wedges.

In study III we had to exclude one high-volume hospital due to data incompleteness and the four low-volume hospitals due to initial analysis showing high ICC. This deviates from the original design and should be considered when interpreting the results.

In study IV we adopted an observational before and after design, including the four high-volume hospitals. This design can only describe the associations between the QI package and its desired outcomes, not the actual causality. Due to the stepped-wedge design of the main study each hospital contributed with an unequal number of participants in study IV, which should be considered as we observed a significant role of local context on the results.

Power calculation

Power calculation was calculated for the main outcome of NePeriQIP, intra-partum related mortality [102], and there was no a priori estimation of sample size for study III and IV. Given that this is a rare outcome, enough power can be expected for the outcomes under study in paper III and IV.

Statistical analysis

Given the complexity of the stepped-wedge design, no further multi-level analyses were performed for study III. Using Odds Ratios as the measure of association is at risk of overinflation. However, we believe logistic regression is sufficient for the purpose of the studies, as we are not primarily searching for more precision. Secular trends were not analyzed in any of the studies, which is a limitation.

Generalizability

Both studies III and IV included a large number of participants and covered diverse settings. In study III we excluded all low-volume hospitals, and in study IV only high-volume hospitals were included, which reduces generalizability to different sizes of hospitals. In study IV around 17% of births were not observed, but were missing at random. Data collectors could only observe one birth at a time, resulting in unobserved births when there were multiple deliveries happening simultaneously. Though we tried to have data collectors at all times, the data collector might have been absent for unforeseen reasons. The QI package was introduced in the existing set-up of hospitals, without modification in structure or management. The participating hospitals were of different sizes (Study III) and differed in terms of geography, ethnicity, and languages of the catchment population (Study III and IV).

Clinical observations

In study IV we used observations by trained data collectors. This is gold standard for measuring a clinical practice, rather than using interviews or patient records [130]. However, the results might have been subject to a degree of the Hawthorne effect; there is a possibility of influence of the direct observation on the behaviors of the health workers, making them perform better than usual especially during the initial period of data collection. This might have affected our results on the effect of the QI package [166].

Using clinical observations also creates an ethical dilemma. First, being observed in one's professional practice can be sensitive, as it may create a

feeling of being personally judged and possibly blamed. Before initiating data collection, the hospital management and HCWs were well informed about the presence of observers and the HCWs were ensured about the confidentiality of the observed behaviors. Secondly, our observers were trained nurses because we assumed having data collectors with prior knowledge and skills in the field would make the data collection process effective and smooth. In some instances, this created an expectation that they would support HCWs in providing care for the newborns. This was against the instructions given to our data collectors as they were not allowed to interfere with the routine work of the hospital. This was resolved to some extent by clarifying the role of our data collectors to hospital management and HCWs. Third, not allowing our trained nurses to intervene if the newborns were not given proper care can be argued to be unethical. If there was an imminent threat to a child's life, however, they were instructed to intervene, and if harmful practices were used, they were to be corrected immediately.

Measurements

Our outcome measures were guided by the WHO framework for the quality of maternal and newborn health care and Standards for improving quality of maternal and newborn care in health facilities [103], which strengthens external validity. However, satisfaction, measured in study III, is a complex phenomenon influenced by several determinants besides the inter-personal measures of experience of care that we have studied. Using other tools for measuring this might have given us a better understanding of the determinants of satisfaction [167, 168]. Nevertheless, it is previously shown that the inter-personal components of experience of care dominate satisfaction with maternity care in Nepal and other low-income countries [136, 137].

Conclusions

In this thesis we have researched ways to improve neonatal health care in Nepal, by exploring contextual factors of importance for implementation of evidence based newborn care practices, and by evaluating the effect of a QI package on provision and experience of care. In summary, when designing interventions to improve quality of care, in Nepal or similar settings, it is important to use authorized guidelines and include education, training, supervision and evaluation. Likewise, hospital resources, routines and cultural beliefs need to be considered. QI interventions have the potential to improve experience of care and bring changes in EENC practices, but further studies are required to assess the predictors and avoid unexpected negative impact.

These findings can be helpful in the development of future interventions aimed at improving quality of neonatal care.

- I. Delivery staff are hesitant to apply delayed cord clamping as they lack education and knowledge of its benefits and have to rely on their own decision making. To change umbilical cord clamping practices, support by the governance structures of the health system, with clear and approved guidelines and coherent training and clinical support, is needed.
- II. Though closeness is considered important among health care workers, separation is common due to limited resources and existing rules and routines in the hospitals. Introducing small, low-cost changes in the wards, like offering a comfortable place to sit, can help keep the parents close and lessen the workload for health care workers. To avoid separation, hospital rules and practices should be changed, and the parents should be supported to take on the role of primary caregivers, with medical support from health care workers. There are traditions and cultural beliefs in society that hampers parental-infant closeness.
- III. Women giving birth in health facilities were more likely to be satisfied with care after the introduction of the QI package, but the overall proportions of satisfaction were low. Given the large sample size and the modest increase in the proportion of satisfaction, the results should be interpreted with caution.

IV. Implementing QI interventions can bring changes in the EENC practices in public hospitals of Nepal, however further studies are required to assess the predictors, especially the role of the local context, to avoid unexpected negative impact.

Future perspectives

Our study results revealed a need for further research to better inform and design future QI interventions for newborn care in Nepal. We recommend focusing on the following areas listed below:

- Exploring which aspects of care that are of most importance to improve patient satisfaction in Nepal.
- Qualitative studies to understand the role of local context in varying levels of adherence to EENC practices in different hospitals.
- Studies to understand why rates of EIBF is on such a low level generally.
- Conducting a qualitative study to analyze the unexpected negative impact on SSC in some hospitals.
- Process evaluation of the implementation process of QI packages to add important information on the role of individual QI activities.
- The sustainability of the QI package should be evaluated.

Summary

In 2020, 2.4 million newborns died worldwide before reaching the age of one month. One million did not even survive their first day. The leading causes of neonatal deaths are preterm birth, intrapartum-related complications and infections, many of which are entirely avoidable by the provision of basic care around the time of birth. Firstly, immediately after delivery, drying the newborn baby with a cloth will both avert hypothermia and stimulate breathing. Secondly, breathing should be assessed and assisted if not occurring spontaneously within the first minute. Thirdly, the child should be placed in skin-to-skin with its mother (or other available person) as soon as possible to keep warm and to facilitate breastfeeding and attachment. Fourthly, umbilical cord clamping should be delayed until at least one minute, as it allows for passive transfusion of blood to the newborn, enhances circulatory adaptation and prevents iron deficiency. Finally, breastfeeding should be initiated within one hour of birth, to prevent newborn hypoglycemia, stimulate milk production and start psychological bonding. Throughout the hospital stay, parents and newborns should be kept close to each other, both physically and emotionally. This helps build parent-infant relationship and positively affects long-term infant development and health. In addition, a priority of the process is to give the mother a positive birth-experience. If she is satisfied with care, she is more likely to follow advice given by health professionals and more likely to return for future care. As this type of basic newborn care is inadequate in many settings, there is a need for interventions to improve the quality of care at each stage of the

The overall aim of this thesis was to research ways to improve the quality of newborn care in Nepal.

In paper I, delivery care staff at two hospitals were interviewed about the introduction of delayed umbilical cord clamping in their hospitals. Results indicate that they need more knowledge of the benefits of delayed cord clamping to get motivated and confident. They hesitated to place the baby in skin-to-skin with the mother while delaying clamping as it felt unsafe and because some mothers opposed to it. Training and supervision were requested to enable change of old routines, and they wanted authorized guidelines to bring uniformity in clinical practice.

In paper II, staff working with newborn infants in five different hospitals were interviewed about factors affecting parent-infant closeness in the

hospitals. Although breastfeeding and skin-to-skin contact are fundamental, separation of parents and newborns were common. Fathers were often not allowed in the neonatal wards at all and visiting hours were very limited even for mothers. The staff did not have time to support the mothers in breastfeeding and skin-to-skin contact and due to crowding of the wards it was difficult to maintain mothers' privacy during breastfeeding. The parents were described as passive observers, and staff were worried that the medical condition of the child would worsen if parent were allowed to handle their sick children. The efforts to increase parent-infant closeness was hampered when mothers did not want to have their baby skin-to-skin or breastfeed.

In paper III, we investigated if the introduction of a large quality improvement project involving training, facilitation and audit and feedback in 12 hospitals affected the mothers' satisfaction with care. Though the mothers were not very satisfied with care in general, they were more likely to be satisfied after the introduction.

In paper IV, we evaluated the effect of the quality improvement project on immediate newborn care. The proportion of newborns who received delayed cord clamping and early initiation of breastfeeding increased, while the proportion of newborns who were placed skin-to-skin decreased. Almost all newborns were dried immediately after birth, both before and after the introduction of the quality improvement project.

In conclusion, the results highlight local conditions that are important to take into account when designing quality improvement interventions in Nepal and similar settings. Hospital resources and routines need to be considered, as well as cultural beliefs and traditions in society. Authorized guidelines on newborn care, education, training and supervision are important to implement new routines. The results indicate that a multi-pronged quality improvement intervention package can improve quality of newborn care in Nepal.

Populärvetenskaplig sammanfattning

Under 2020 dog 2,4 miljoner nyfödda barn runt om i världen innan de hunnit bli en månad gamla. Nästan en miljon av dessa barn överlevde inte ens sitt första dygn. De främsta dödsorsakerna under nyföddhetsperioden är att barn föds för tidigt, och att det uppstår förlossningskomplikationer och infektioner som man inte kan eller vet hur man ska klara av. Störst risk för att dö har barnet under tiden kring förlossningen, men det är också då det finns möjlighet att rädda flest barn. Grundläggande nyföddhetsvård innefattar enkla och effektiva insatser som kan rädda liv om de används. När ett barn föds ska det till exempel genast torkas av, dels för att förhindra avkylning och dels för att stimulera andningen att komma igång. Barnets andning ska sedan utvärderas och om barnet inte andas tillfredsställande inom en minut måste det få hjälp. Vidare ska barnet snarast möjligt läggas hud mot hud med sin mamma (eller annan tillgänglig person) för att hålla värmen och för att underlätta amning och anknytning. Flödet i navelsträngen ska inte stoppas förrän tidigast efter en minut, eftersom det möjliggör en blodtransfusion till det nyfödda barnet och förhindrar järnbrist. Mamman bör sedan försöka amma barnet inom en timme efter förlossningen för att initiera den livsviktiga amningen och för att undvika skadligt lågt blodsocker hos barnet. Det är också viktigt att föräldrar och barn får fortsätta vara nära varandra efter förlossningen, både fysiskt och emotionellt. Detta påverkar barnets fortsatta utveckling och lägger grunden för ett hälsosamt liv. Förlossningsvården bör sträva efter att mamman får en positiv upplevelse av förlossning och eftervård. Om mamman är nöjd kommer hon vara mer benägen att följa de råd som ges från vårdpersonal, och hon kommer vara mer benägen att söka vård igen. På många platser i världen brister vårdkvaliteten för nyfödda barn då ovan beskrivna metoder inte används eller används på fel sätt.

Det övergripande syftet med denna avhandling är att bättre förstå vilka åtgärder som kan förbättra vårdkvaliteten för nyfödda i Nepal.

I delarbete I intervjuades förlossningspersonal på två sjukhus om införandet av sen avnavling, d.v.s. att vänta mer än en minut efter förlossningen innan blodflödet i navelsträngen stoppas. Resultatet visade att förlossningspersonalen behöver utbildas mer om fördelarna med sen avnavling för att motiveras och känna sig trygga att använda metoden. Att införa sen avnavling skulle innebära nya rutiner och personalen efterfrågade träning och handledning för att lyckas med det. Personalen vågade inte lägga barnet hud mot

hud på mamma i väntan på avnavling då patientsängarna upplevdes för små och beskrev även att mammorna inte ville ha det nyfödda barnet liggandes på sig. Officiella riktlinjer med tydliga direktiv från högre ort ansågs nödvändigt för att få alla att arbeta enligt de nya rutinerna.

I delarbete II intervjuades personal som arbetar med nyfödda på sjukhus om möjligheterna att stimulera och upprätthålla fysisk och emotionell närhet mellan föräldrarna och barnet. Trots att amning och hud-mot-hudkontakt lägger grunden för denna närhet vårdades barn och föräldrar ofta på skilda platser inom sjukhusen. Pappor var ofta inte tillåtna inne på barnavdelningarna och besökstiderna var mycket begränsade även för mammor. Personalen hade inte tid att stötta mammorna med amning och hud-mot-hudkontakt och det var svårt att upprätthålla mammornas integritet vid amning på grund av trängseln på avdelningarna. Föräldrarna beskrevs som passiva betraktare när barnen var inlagda och det fanns en rädsla för medicinska komplikationer om de tilläts hantera sina sjuka barn. Personalens ansträngningar hindrades ibland av att en del mammor inte ville ha sina barn hud mot hud eller amma. Förekomst av diskriminering mot flickor ansågs ibland påverka omvårdnaden från föräldrarna.

I delarbete III undersöktes hur mammornas nöjdhet med vården förändrades i och med införandet av ett stort kvalitetsförbättringsprojekt på 12 olika sjukhus, som innefattade utbildning, klinisk träning och återkoppling . Även om mammorna inte var särskilt nöjda med förlossningsvården generellt, så ökade sannolikheten att de var nöjda efter införandet.

I delarbete IV utvärderades hur kvalitetsförbättringsprojektet påverkade den grundläggande nyföddhetsvården. Andelen barn som fick sen avnavling och amning inom en timme ökade, medan andelen barn som lades hud mot hud minskade. Andelen som torkades av omedelbart efter födelsen var generellt hög och i det närmaste oförändrad efter införandet av kvalitetsförbättringsprojektet.

Sammanfattningsvis visar resultaten på lokala förutsättningar som det är viktigt att ta hänsyn till när man designar kvalitetförbättringsprojekt i Nepal och liknande miljöer. Sjukhusens resurser och rutiner behöver ses över och föräldrarna bör inkluderas mer i vården. Även kulturella föreställningar och traditioner i samhället behöver vägas in. Vårdpersonalen i Nepal efterfrågar tydliga officiella riktlinjer kring omhändertagandet av nyfödda, samt utbildning, träning och utvärdering av nya rutiner. Resultaten tyder på att kvaliteten på nyföddhetsvården i Nepal kan förbättras genom fortsatt arbete med kvalitetsförbättringsprojektet.

Summary in Nepali

सन् २०२० मा विश्वभर २४ लाख नवजात शिशुको एक महिनाको उमेर नपुर्प्दै मृत्यु भएको थियो। एक लाख आफ्नो पहिलो दिन पिन बाँच्न सकेन। नवजात शिशुको मृत्युको प्रमुख कारणहरू समय नपुर्गी जन्मेको, जन्म-सम्बन्धित जिटलताहरू र संक्रमणहरू हुन् जसमध्ये धेरै जसो जन्मको समयमा आधारभूत हेरचाहको प्रावधानद्वारा पूर्ण रूपमा जोगिन सिकन्छ। सबैभन्दा पहिले, प्रसव पिछ तुरुन्तै, नवजात शिशुलाई कपडाले सुकाउँदा शिताङ्गबाट बच्न र सास फेर्न सहयोग हुन्छ। दोस्रो, श्वासप्रश्वासको मूल्याङ्कन र सहयोग गरिनुपर्छ यदि पिहलो मिनेट भित्र सहज रूपमा देखा पदैंन भेने। तेस्रो, बच्चालाई सकेसम्म चाँडो आमा (वा अन्य उपलब्ध व्यक्ति) सँग न्यानो राख्न र स्तनपान र संलग्नताको सुविधाको लागि छाला-देखि-छालामा राख्नुपर्छ। चौथो, नाभिको नली काट्न कम्तिमा एक मिनेटसम्म ढिलो गर्नुपर्छ, किनिक यसले नवजात शिशुलाई रगतको निष्क्रिय सन्चालन हुन्छ, रक्तसञ्चार अनुकूलनलाई बढाउँछ र आइरनको कमीलाई रोक्छ। अन्त्यमा, नवजात शिशुलाई हाइपोग्लाइसेमियाबाट बच्न, दूध उत्पादनलाई उत्प्रेरित गर्न र आत्मियता सुरु गर्न जन्मेको एक घण्टाभित्र स्तनपान गराउनु पर्छ। अस्पतालमा रहँदा, आमाबाबु र नवजात शिशुहरूलाई शारीरिक र भावनात्मक रूपमा एकअर्काको नजिक राख्नुपर्छ। यसले अभिभावक-शिशु सम्बन्ध निर्माण गर्न मद्दत गर्दछ र दीर्घकालीन शिशु विकास र स्वास्थ्यमा सकारात्मक प्रभाव पार्छ। यसको साथै, यस प्रक्रियाको प्राथमिकता आमालाई सकारात्मक जन्म-अनुभव दिनु पिन हो। यदि उनी हेरचाहबाट सन्तुष्ट छिन् भने, उनले स्वास्थ्यकर्मीहरूले दिएको सल्लाह पालन गर्ने र भविष्यमा हेरचाहको लागि फर्कने सम्भावना बढी हुन्छ। यस प्रकारको आधारभूत नवजात शिशु हरचाह धेरै सेटिङहरूमा अपर्याप्त भएकोले, प्रक्रियाको प्रत्येक चरणमा हेरचाहको गुणस्तर सुधार गर्न परिचय प्रोग्रामहरूको आवश्यकता छ।

यस थीसिसको समग्र उद्देश्य नेपालमा नवजात शिशु स्याहारको गुणस्तर सुधार गर्ने तरिकाहरू अनुसन्धान गर्नु थियो।

पेपर I मा, दुई अस्पतालहरूमा प्रसूति हेरचाह कर्मचारीहरूलाई उनीहरूको अस्पतालहरूमा ढिलो नाभिको नली काट्ने प्रोग्राम सुरुभएको बारेमा अन्तर्वार्ता गरिएको थियो। नितजाहरूले संकेत गर्दछ कि उनीहरूलाई उत्प्रेरित र आत्मविश्वास प्राप्त गर्न ढिलो नाभिको नली काट्नेको फाइदाहरूको बारेमा थप ज्ञान चाहिन्छ। उनीहरूले बच्चालाई आमाको छातीमा राख्न हिचकिचाउँदै नाभिको नली ढिलो काट्न असुरक्षित महसुस गरे र केही आमाहरूले यसको विरोध गरे। पुरानो दैनिक क्रियाकलापहरू परिवर्तन गर्न प्रशिक्षण र पर्यवेक्षणलाई सक्षम बनाउन अनुरोध गरिएको थियो, र उनीहरू क्लिनिकल अभ्यासमा एकरूपता ल्याउन आधिकारिक दिशानिर्देशहरू चाहन्थे।

पेपर II मा, पाँच अलग-अलग अस्पतालहरूमा नवजात शिशुहरूसँग काम गर्ने कर्मचारीहरूलाई अस्पतालहरूमा अभिभावक-शिशुको निकटतालाई असर गर्ने कारकहरूको बारेमा अन्तर्वार्ता गरिएको थियो। यद्यपि स्तनपान र छाला-देखि-छालाको सम्पर्क आधारभूत हो, आमाबाबु र नवजात शिशुहरू बीचको अलिगनु सामान्य थियो। नवजात शिशु वार्डहरूमा बुबाहरूलाई प्रायः अनुमित दिइँदैनथ्यो र आमाहरूका लागि पिन भेट्ने समय धेरै सीमित थियो। आमाहरूलाई स्तनपान गराउने र छाला-छालाको सम्पर्कमा सहयोग गर्ने कर्मचारीसँग समय थिएन र वार्डहरूमा भीडभाडका कारण स्तनपान गराउँदा आमाको गोपनीयता कायम राख्न गाहो भएको थियो। आमाबाबुलाई निष्क्रिय पर्यवेक्षकको रूपमा वर्णन गरिएको थियो, र कर्मचारीहरू चिन्तित थिए कि यदि आमाबाबुले आफ्ना बिरामी बच्चाहरूलाई सम्भाल्न दिएमा बच्चाको स्वास्थ्य अवस्था बिग्रन्छ। आमाहरूले आफ्नो बच्चालाई छाला-देखि-छाला वा स्तनपान गराउन नचाहँदा आमाबाबु-शिशुको घनिष्ठता बढाउने प्रयासहरूमा बाधा परेको थियो।

पेपर III मा, हामीले 12 अस्पतालहरूमा गुणस्तर सुधारको ठूलो परियोजनाको परिचयले हेरचाहमा आमाहरूको सन्तुष्टिलाई असर गरेको छ कि छैन भनेर अनुसन्धान गऱ्यौं। यद्यपि आमाहरू सामान्य रूपमा हेरचाहबाट धेरै सन्तुष्ट थिएनन्, तर उनीहरू परिचय प्रोग्रामपछि सन्तुष्ट हुने सम्भावना बढी थियो।

पेपर IV मा, हामीले तत्काल नवजात शिशुको हेरचाहमा गुणस्तर सुधार परियोजनाको प्रभावको मूल्याङ्कन गर्यौ। नाभिको नली ढिलो काट्न र स्तनपानको प्रारम्भिक शुरुवात गर्ने नवजात शिशुहरूको अनुपात बढ्यो, जबिक छाला-देखि-छाला राखिएको नवजात शिशुहरूको अनुपात घट्यो। लगभग सबै नवजात शिशुहरू जन्म पिछ तुरुन्तै सुख्खा राखियो, गुणस्तर सुधार परियोजनाको परिचय अघि र पिछ दुवै।

निष्कर्षमा, परिणामहरूले नेपालमा गुणस्तर सुधार प्रोग्रामहरू र यस्तै स्थलहरू डिजाइन गर्दा स्थानीय अवस्थाहरूलाई ध्यानमा राख्नु पर्ने मा प्रकाश पार्दछ। अस्पतालका स्रोतहरू र दैनिक क्रियाकलापहरु साथै समाजका सांस्कृतिक विश्वास र परम्पराहरू विचार गर्न आवश्यक छ। नवजात शिशुको हेरचाह, शिक्षा, तालिम र सुपरिवेक्षणमा आधिकारिक दिशानिर्देशहरू र नयाँ दैनिक क्रियाकलापहरु लागू गर्न महत्त्वपूर्ण छन्। परिणामले नेपालमा बहु-आयामी गुणस्तर सुधार प्रोग्राम प्याकेजले नवजात शिशुको हेरचाहको गुणस्तर सुधार गर्ने देखाउँछ।

Acknowledgements

Before becoming a medical doctor, I used to travel to Guinea in west Africa to dance and live life. I started at the age of 15 and returned 10 years in a row. This is how my interest in medicine, pediatrics and global health grew. Every time I returned, I found that at least one young child I had met the previous year, had passed away. This was of course heartbreaking, and the situation for the children of the world dawned on me. I wanted to contribute to a brighter future, and being naive and idealistic I figured becoming a medical doctor to save all the children would be appropriate. I did become a medical doctor, and a pediatric resident, but have not yet managed to save all the children. However, I got the great opportunity to learn more and take on a PhD with focus on global child health when I met my main supervisor Mats Målqvist. I am so grateful that I met you Mats, and that you took me on this journey! Without your confidence in me and your patient guidance, this would never have happened. Thank you for being a great supervisor and such a warmhearted and funny friend of mine, and for all good times spent together with both our families. Mats introduced me to my co-supervisor **Anna Bergström**. and I could not be happier with that! After our "honeymoon" in Nepal, I was mesmerized. Your energetic engagement and positivity are contagious. You, as a non-apologizing woman and female researcher is an inspiration to me. I'm very grateful to **Uwe Ewald** for agreeing to be my second co-supervisor. You are a legend within neonatology in Sweden and your work and research have contributed to advancements in quality of neonatal care. If it wasn't for you, my application to register as PhD candidate would not have been accepted.

To my fellow PhD candidate within the same project, **Dipak Raj Chaulagain**, thank you for completing me in my work. Without you, many questions would have been unanswered. I am so glad I always had you by my side (in spirit if not in person) and I highly appreciate our friendship.

Thank you, **Leif Eriksson**, for excellent guiding and co-working on the parent-infant closeness study. I am grateful to my other co-authors, **Nisha Rana**, **Rejina Gurung**, **Ashish KC and Omkar Basnet**. You all provided invaluable insight in the Nepalese context. Ashish was the principal investigator of NePeriQIP and the engine who made the whole project possible. Thank you, Nisha, for the time spent together in Uppsala, working

intensely with the qualitative analysis. Thank you, Rejina, Ashish and Omkar for taking good care of me in Kathmandu and Rejina also for translating the summary in Nepali.

I would like to acknowledge the whole team of NePeriQIP in Nepal and the members of the data collector teams for all their work. Special thanks to **Kanchan Thapa** and **Madhu Sudhan Subedi** for conducting the interviews for the parent-infant closeness study.

I am deeply grateful to all mothers who agreed to participate in our studies and gave us the opportunity to collect data on their newborns.

I've met so many nice and helpful people over the years at the Department of Women's and Children's Health in Uppsala. Thanks to all staff, researchers and fellow PhD candidates, past and present.

Thank you **Arja Harila-Saari, Tryggve Nevéus** and **Fredrik Ahlsson** for engaging me in teaching and at the same time giving me the opportunity to work on my PhD. Thank you, **Nick Brown**, for being such a nice person and offering your expertise.

I'm happy to have many inspiring colleagues and friends in the clinic at the children's hospital in Uppsala. Special thanks to my fellow residents and the pediatric specialists in the emergency department, for always cheering me up and supporting me! I would like to thank **Klas Ekström**, Head of Department, and **Ulrika Bäckman**, Head of Section, for having a research-friendly attitude and for enabling me to take leave from the clinic to work on this.

I'm truly blessed with many good friends and a large family. Thank you, mum **Gunilla** and dad **Labbe**, for encouraging me in everything that I do and for always believing in me. Thank you also for providing me a stable foundation through my sisters **Alice** and **Sonja**, my step-parents **Lisa** and **Per** and for the tribe surrounding me in life; thank you for your solid support and love **Kanka**, **Chrille and Uggla-family**, **Mesay**, **Tina**, **Jordi**, **Eva**, **Lasse** and the **Brunell-family**. Chrille, thank you for taking me to Guinea, imagine life without that experience! I would also like to send my appreciation and love to the **Dogan/Petterson-family**.

Thanks to my dance community for sharing the passion of my life and many ups and downs through the years, and special thanks to my dance-sister **Bea** for never letting me stop dancing (and for spoiling me with massage)! **Ulrika**, thank you for introducing me to Mats.

"Världens bästa fantastiska supermammagrupp (för att uttrycka det ödmjukt)", what a superpower to have shared that time with you all and have

you as friends. **Clara** and **Katja** - thank you for helping me improve my work both for half-time and for the thesis. **Linus** thanks for being the best ex-neighbor ever.

"A Tribe called BLISS", I'm truly grateful for moving to Rosendal and get to know you. Being surrounded by loving and supporting women is the best.

Cyndie, thank you for letting me use the picture of your child for my cover.

And to all my other friends; thank you for dinners, wine, fika, sparkles, walks, workouts, deep and not so deep conversations, tears and laughter.

Love lifts us up where we belong! My beloved husband **Erkan**, there is no one like you, you are my greatest support and I cherish every moment I spend with you.

And to my sons Daouda and Malkolm, I love you beyond words.

Uppsala Oktober 2022 *Olivia Brunell*

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