Improving neonatal resuscitation: ethical aspects

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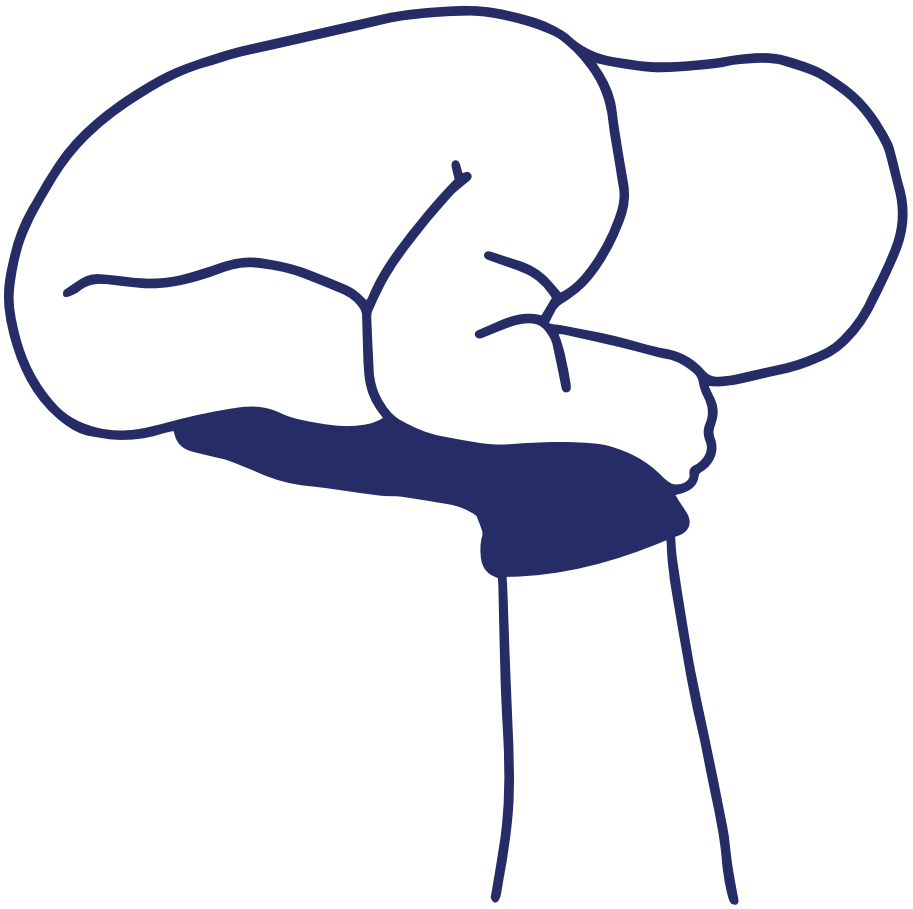
PART 1

PREFACE AND GENERAL INTRODUCTION



PREFACE

Virginia and Anthony[1] are expecting their first child. After 24 weeks of pregnancy, Virginias waters break. Virginias midwife refers Virginia to the hospital, where an obstetrician examines her and diagnoses preterm prelabour rupture of membranes (PPROM). Virginia is advised to stay in the hospital to closely monitor her and her baby for signs of infection. Subsequently, Virginia and Anthony are counselled by a neonatologist. Counselling includes detailed information about extreme prematurity, neonatal resuscitation, and the period that their baby might have to be in the hospital. Virginia and Anthony are then asked whether they want neonatal care providers to provide neonatal resuscitation or palliative comfort care in case Virginia will go into labour before 27 weeks of pregnancy.

During neonatal resuscitation, neonatal care providers evidently strive to provide the best possible care during neonatal resuscitation. The best possible care can be assured through conducting research and quality evaluation and improvement activities. However, as neonatal resuscitation oftentimes occurs in emergency situations and involves both very ill infants and physically and emotionally distressed parents, conducting these activities can be ethically challenging. This thesis discusses some of the ethical challenges that neonatal care providers of the neonatal intensive care unit (NICU) of the Leiden University Medical Center (LUMC) encounter in their endeavour to provide and study the best possible care during neonatal resuscitation[2].

Virginia and Anthony are very saddened and distressed about the imminent extremely premature birth of their baby. After deliberation among each other and with some family members, they request to provide neonatal resuscitation to their baby. In order to reduce the chance of complications in the infant from being born prematurely, Virginia is treated with magnesium sulfate and two courses of corticosteroids. A few days later, Virginia goes into labour. As the hospital where she is admitted has no NICU beds available, Virginia is transferred to the LUMC by ambulance. Soon after her arrival at the LUMC, Virginia gives birth to a boy: Peter. As time to approach Virginia and Anthony was lacking, the neonatal care providers decide to include Peter in the delivery room studies that are currently being performed at the NICU. For both studies, Peter is randomized into the experimental arm.

Conducting delivery room (DR) studies is much needed, but can be ethically challenging, as obtaining valid (proxy) informed consent for time critical studies from

[1] The presented case reflects a real case with fictive names.
[2] If people think about ethics and neonatal resuscitation, one of the first questions that might come to mind is 'should we provide neonatal resuscitation or palliative comfort care'? With the limits of viability decreasing, this question continues being relevant and actual. Although pressing, this thesis will not discuss the question whether or not to provide neonatal resuscitation, but discusses ethical challenges that are raised after the decision to provide neonatal resuscitation.

parents faced with an imminent premature birth can be arduous. In concordance with (inter)national guidelines, the ethics review committee of the LUMC allows participants to be included into specific studies without prior informed consent in emergency situations. Various DR studies have been conducted using this so-called deferred consent approach. When using a deferred consent approach, neonates can be included in a DR study without prior parental consent. As soon as possible, parents are then informed and asked for permission to continue their child's study participation and to use already obtained data.

Peter is born at a gestational age of 25 + 1 weeks with a birth weight of 800 gram. As Peter is not breathing, the neonatologist starts respiratory support. After sustained inflations and a few minutes of positive pressure ventilation, Peter starts breathing by himself. Peter is further stabilized on continuous positive airway pressure and subsequently transferred to the NICU. During the whole neonatal resuscitation, Anthony was standing nearby Peter, holding his little hand whenever possible.

International guidelines on neonatal resuscitation recommend parental presence during neonatal resuscitation where possible. At the NICU of the LUMC parents are therefore encouraged to be present during neonatal resuscitation. However, mothers often cannot be present as resuscitation normally is not performed in the DR itself, but in an adjacent room.

When Peter has been admitted to the NICU for three weeks, Virginia and Anthony meet with their primary neonatal care provider, doctor Hoch, for their weekly appointment. During this appointment, Virginia mentions she has some questions about the resuscitation of Peter. Doctor Hoch therefore asks Virginia and Anthony whether they would like to review the recordings that were made during the neonatal resuscitation of Peter. One week later, doctor Hoch reviews the recordings with Virginia and Anthony and answers all their questions.

Virginia and Anthony are not the only ones reviewing the recordings of the resuscitation of Peter. Also, the neonatal care providers review the recordings during their weekly plenary audit of neonatal resuscitation. Doing so teaches them that in specific cases, pressures provided during respiratory support needs to be increased a lot in order to overcome obstruction.

For over ten years, both video and vital parameters of neonatal resuscitations performed at the NICU of the LUMC are recorded. Initially, these recordings were used for research purposes. Studies evaluating these recordings revealed that providers often diverge from the guideline for neonatal resuscitation and that documentation about the resuscitation in the infants medical record is often inaccurate or incomplete. In order to improve this, recordings are reviewed in weekly plenary audits since 2014. Furthermore, parents are offered the possibility to review the recording of their infant together with their primary neonatal care provider. Recording and reviewing neonatal resuscitation is now considered standard of care at the NICU of the LUMC, but implementation at other NICUs is impeded by various ethical concerns, including concerns about privacy, consent, medicolegal consequences and negative impact on providers.

The case presented above reveals some of the ethical challenges of improving neonatal resuscitation that will be addressed in this thesis. This thesis will discuss ethical challenges of consent for DR studies and recording and reviewing neonatal resuscitation in-depth. By combining empirical research with ethical reasoning, this thesis aims to provide guidance for the ethical conduct of activities that aim to improve neonatal resuscitation.