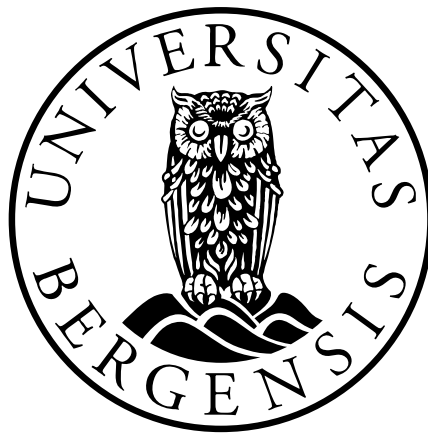


# End-of-life priorities in complex settings

*- An ethical analysis of decisions in Indian neonatal units*

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## **Contributors**

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ISF has administrated the project, employed the candidate and provided main supervision of the candidate through professor Ole Frithjof Norheim and has housed the candidate for most of the PhD programme.

### **Division of Medical Ethics, Department of Social Medicine, Harvard Medical School**

Provided co-supervision of the candidate through Sadath Ali Sayeed, MD, JD and housed the candidate for part of the PhD programme.



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## Summary

**Background:** In India, 1.2 million of the 26 million infants born annually die during the neonatal period. The National Neonatal Forum in India estimated that the need for intensive care beds in India is 72,000, but only 2,000 are currently in place. There is a lack of knowledge about how providers approach life-saving or life-ending decisions for potentially treatable newborns under conditions of obvious resource scarcity, and how socioeconomic factors affect these decisions. There are few studies exploring how different principles derived from general theories of distributive justice might be in conflict when applied to such decisions. The aim of this thesis is to describe and analyse end-of-life decisions for newborns in a context of resource constraints and non-Western culture.

**Method:** Doctors' experiences of ethical dilemmas, limits for treatment and reasons used in end-of-life decisions are explored by qualitative methods including in-depth interviews, observation and register data collected through several fieldworks in different neonatal units in India between 2000–2007. The analysis of the ethical acceptability of withholding life-saving treatment for children born between weeks 28 and 32 gestational age weeks (GAW) is done through a seven-step framework for impartial analysis of priority-setting dilemmas. Major effort is taken to analyse the outcome for neonates born between 28 and 32 GAW, by analysing their condition according to four accepted priority criteria: severity of disease, treatment effect, cost effectiveness and evidence of the former three.

**Results:** We found that all physicians experienced end-of-life decisions as the main ethical dilemma in their job. The providers operate under conditions of severe resource scarcity, and they employ a variety of non-standardized criteria for choosing which neonates will or will not receive treatment. Multiple outcomes external to the clinical welfare of the newborn influence our informants' decisions about treatment after preterm birth, and they had to adjust the gestational age limit for treatment thereafter. In these situations, they felt personally responsible for how their decisions

influenced the family's economy and future, other children's access to equipment in the unit, and the use of resources in an underprivileged population. In one unit, the limits set for treatment of premature neonates were no treatment to neonates <28 GAW, and treatment to all >32 GAW. These limits are almost inevitable and understandable due to the current conditions in India. However, in our ethical analysis, we question whether it is ethically ever permissible to limit treatment to neonates below 32 and above 28 GAW if we apply the two principles of health maximisation and overall health equality. Neonates score high on severity of disease, efficiency and cost effectiveness of treatment if one gives full weight to life years gained for a newborn. It is in the child's best interest to be treated. Lack of proper welfare policies for the poor and disabled in India are the main reasons for withholding treatment. This is not acceptable from a distribution-sensitive health- and welfare perspective.

**Conclusion:** End-of-life decisions for premature and sick neonates are experienced as difficult ethical dilemmas in neonatal units in India as documented in other countries, but our empirical study and ethical analysis showed that the limits and reasons behind decisions to withhold or withdraw treatment of premature neonates are context specific and highly dependent on cultural and socioeconomic factors. We found that in the settings studied, the dilemmas of setting priorities are more pressing than 'futility'-decisions, making end-of-life decisions a form of bedside rationing. We cannot generalise our results to all neonatal units in India or claim that our analysis captures all relevant aspects of such bedside rationing. The study was neither designed to provide results that can guide policy makers or clinicians in India on where to set fair limits. We can only hope that our efforts to make explicit choices made in some influential institutions in India, and describing and analysing the dilemmas, will be relevant to developing more informed decisions and priority setting processes.

There is an implicit denial of treatment for hundreds of thousands of premature neonates born in low-income countries, as others' needs are prioritised more. The

limited hospital care available for premature neonates in the low-income countries presents a major and unmet challenge in health care prioritisation schemes. If premature neonates are perceived as of less worth than older persons or other patient groups, this should be explicitly discussed and the reasons for supporting such views should be explored among a broad range of stakeholders. We hope our preliminary descriptions and analysis will inspire further research that will contribute to securing the rights of newborn and children born into the most disadvantaged circumstances, and to meet the real challenges that lie ahead if we truly intend to meet the MDG goals of reducing childhood, and specifically, newborn, mortality by two-thirds before 2015.



## Summary in Norwegian

### **Behandlingsavslutning i en kompleks verden. En etisk analyse av beslutninger i indisk nyfødtmedisin.**

**Bakgrunn:** Nesten 1,2 millioner av de 26 millioner barna som fødes årlig i India dør i løpet av nyfødt perioden. National Neonatal Forum i India har anslått at det trengs 72000 nyfødt intensiv-senger i India, mens det i dag bare finnes 2000 i hele landet. Vi vet lite om hvordan helsearbeidere forholder seg til liv-død beslutninger for nyfødte i land med ekstrem ressursmangel, og om hvordan ulike sosioøkonomiske faktorer påvirker beslutninger om å avslutte eller avstå fra å behandle. Det har i liten grad vært diskutert hvordan ulike rettferdighetsprinsipper kan komme i konflikt i denne type avgjørelser. Målet med denne avhandlingen er å beskrive og analysere liv-død beslutninger for nyfødte i en ikke-vestlig kontekst preget av ekstrem ressursmangel.

**Metode:** Legers erfaringer med etiske dilemma, grenser for behandling og grunner for beslutninger er studert ved hjelp av kvalitative metoder. Dybdeintervjuer, observasjon og registerdata ble samlet gjennom flere feltarbeid i ulike nyfødtavdelinger i India mellom 2000-2007. Etisk analyse av om grensen for behandling for barn født mellom 28.-32. svangerskapsuke er etisk akseptabel er basert på en 7-punkts upartisk analyse for prioriterings dilemma. Vi har lagt stor vekt på analysere følgene for barn født i uke 28 og uke 32 og vurderte tilstanden ut fra fire generelt aksepterte prioriterings kriterier; tilstandens alvorlighet, behandlings effekt, kostnadseffektivitet og evidens av de tre første.

**Resultater:** Alle legene vi intervjuet opplevde at liv-død beslutninger er det vanskeligste etiske dilemmaet de støter på i sitt arbeid. Vi fant at legene arbeidet i svært ressursfattige omgivelser og at de brukte en rekke ikke-standardiserte kriterier for å velge hvilke premature som skal få behandling eller ikke. En rekke andre hensyn enn den kliniske helsetilstanden til barnet påvirket informantenes beslutninger, og helsearbeiderne tilpasset grensene for behandling etter disse. I liv-

død beslutningene følte personalet seg personlig ansvarlig for hvordan deres valg påvirket hele familiens økonomi og videre fremtid, tilgangen til behandling og utstyr for andre barn, samt bruken av begrensede ressurser i en fattig befolkning. Ved en av avdelingene var det besluttet at ingen premature barn født før 28. svangerskaps uke fikk behandling, mens alle over uke 32 fikk. Under dagens forhold i India er denne grensen forståelig og nærmest uunngåelig. Men nyfødte født etter 28. svangerskapsuke har en alvorlig (dødelig) tilstand, har svært god effekt av behandlingen, og behandlingen er i tillegg kostnadseffektiv. Dette er vesentlige grunner til å hevde det er til barnets beste å få behandling. Vår etiske analyse konkluderer med at det ikke er etisk akseptabelt å begrense behandling mellom uke 28 og uke 32 hvis en vektlegger prinsippene helsemaksimering og helselikhet. Manglende velferdstilbud til fattige og funksjonshemmede er en av hovedgrunnene til at behandlingen blir begrenset og barnet dør. Dette er ikke akseptabelt fra et likhets motivert helse- og velferds-perspektiv.

**Konklusjon:** Behandlingsavslutning for premature nyfødte oppleves som et vanskelig etisk dilemma i India. Våre empiriske studier og etiske analyse avdekker at grensene for behandling og grunnene en legger vekt på i disse beslutningene er svært avhengig av konteksten og av en rekke kulturelle og sosioøkonomiske faktorer. Prioriterings dilemmaer var mer fremtredende enn dilemma knyttet til nytteløshet i behandlingen av premature, og valg av behandling må forstås som prioriteringsbeslutninger på et klinisk nivå. Vi kan ikke generalisere resultatene våre til å gjelde alle nyfødtavdelinger i India og heller ikke hevde at vi vurderer alle relevante aspekter av behandlingsgrensen i vår etiske analyse. Vi kan heller ikke rådgi klinikere eller retningslinjekomiteer om hvor en skal sette rettferdige grenser. Men vi håper at vårt forsøk på å åpent beskrive og analysere hva som foregår i enkelte velrenommerte institusjoner i India kan danne grunnlag for mer informerte beslutninger og prioriterings prosesser.



Hundre tusener av premature barns behov i verden neglisjeres fordi andres behov blir prioritert. Mangelen på tilgjengelig sykehusbehandling for nyfødte i fattige land er en stor og uløst utfordring for globale helseprioriteringer. Hvis premature blir tillagt mindre verdi enn voksne eller andre pasientgrupper bør dette argumenteres for åpent og grunnene for en slikt syn bør drøftes blant ulike høringsinstanser. Vi håper at våre foreløpige beskrivelser og analyse vil inspirere til videre forskning som kan bidra til å sikre rettighetene til nyfødte og barn som fødes under marginaliserte forhold, og dermed også til å møte de store utfordringene som ligger foran oss om vi skal nå FNs tusenårs mål om å redusere barnedødeligheten, og særlig nyføtdødeligheten, med 2/3 de neste årene.



## List of publications

1. Miljeteig I, Norheim OF. My job is to keep him alive, but what about his brother and sister? How Indian doctors experience ethical dilemmas in neonatal medicine. *Developing world bioethics* 2006;6(1):23-32.
2. Miljeteig I, Sayeed SA, Jesani A, Johansson KA, Norheim OF. Impact of ethics and economics on end-of-life decisions in an Indian neonatal unit. *Pediatrics* 2009;124(2): e322-328.
3. Miljeteig I, Johansson, KA, Sayeed, SA, Norheim, OF. End of life decisions as bedside rationing. An ethical analysis of life support restrictions in an Indian neonatal unit. Submitted 2010, *Journal of Medical Ethics*



## INTRODUCTION

The aim of this thesis is to describe and perform an ethical analysis of a much discussed ethical dilemma in modern medicine, end-of-life decisions for neonates, and to do so using data from an infrequently described and socioeconomically different context: neonatal units in India. What characterises end-of-life decisions in a setting with severe resource scarcity, and are the decisions fair? Through empirical findings and ethical analysis, I will highlight the decision to withhold and withdraw treatment of neonates within hospital units in several tertiary hospitals in different Indian states. As this work is carried out in the interface of several fields and disciplines, and the background is quite complex, an outline of what follows is given here. I start with a short introduction to the relevant fields of global neonatal health: medical consideration, outcomes and cost of treatment for premature neonates, and some background knowledge concerning newborn health issues and services in India. Next, I introduce limit settings in medicine viewed from two different angles, the end-of-life discourse and the priority setting in health care discourse. Central concepts such as the child's best interest, surrogate decision making, justice, fairness and legitimacy are presented.

### Status of newborn health

Four million neonates die globally during the first four weeks of life (the neonatal period). Ninety-nine percent of them are born in South and Central Asia and in sub-Saharan Africa (1). Perinatal and neonatal conditions account for 5.3–5.5% of the causes of death in the world and is thereby the seventh leading cause of death (2). Mortality in the neonatal period is an important health indicator for mother and child, and is strongly correlated to the country's investments in health. Awareness of this has led to an increased global focus on child and maternal mortality during the last decade. The UN developed Millennium Development Goals (MDGs), and one of the

goals, labelled MDG 4, aims at reducing child mortality by two-thirds by 2015 (3). Several interventions are recommended to reach this goal(4). As much as 30–60% of the neonatal deaths worldwide could probably be prevented by implementing basic, cost-effective proven interventions, and the scale-up of interventions is promising (5-8).

## Premature neonates

Worldwide, it is estimated that 12.9 million of the 136 million born yearly are born premature (birth before gestational age week 37) (9), and about one-third of them are very or extremely premature (born before 32 and 28 gestational age weeks, respectively) (8). Low birth weight can be a result of intrauterine growth restrictions or prematurity, and it results in a 13 times higher neonatal mortality rate (NMR) and increased vulnerability for malnutrition, infections, neurodevelopmental disabilities and death after the neonatal period. Although prematurity of birth accounts for less than one-third of NMR, it is the underlying cause of several other causes of death (10). Bang et al. sought to determine if the single primary cause for death really holds, or if death is due to the effect of the multiplicity of morbidities (10). They conclude from their Indian data that prematurity and intrauterine growth restriction (IUGR) are ubiquitous components of NMR, but are usually not sufficient to cause death in and of themselves. Most deaths occur due to a combination of preterm or IUGR with other co-morbidities. Prematurity and IUGR are therefore also a special group where interventions to prevent infections, etc., are highly important.

Although there has been an increased awareness of the need to reduce neonatal mortality in low-income countries (LIC), interventions specifically aimed at reducing deaths among premature neonates are few or nonexistent. In a new report from March of Dimes, the researchers note that:

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*“The relative neglect of preterm birth is linked to data gaps on the global toll of prematurity, including the extent of associated death and disability....Widely held perceptions that effective care of the preterm baby requires costly interventions well beyond the health budgets of most LMIC, couples with concern that greater attention to preterm birth will draw needed funding away from other devastating maternal and perinatal health problems, have also contributed to the reluctance of policy makers to make the problem of preterm delivery a global priority.”(11)*

Many of the most premature will need resuscitation or other medical interventions in hospital to survive. To date, the premature in need of emergency neonatal care have nearly been left out of guidelines, research and interventions focus. The Lancet Neonatal Survival Steering Team recommended 15 interventions to reduce NMR in LMIC, but advanced hospital care for premature infants is not one of them, attributed to the high cost (8). The WHO guide for essential practice for pregnancy, childbirth, postpartum and neonatal care offers only general guidance for those in need, recommending urgent transport to a hospital facility for advanced care (12). It is not explicit on what to do in the hospital if there are insufficient resources for optimal treatment or what to do if transport is not available. The WHO guide ‘Managing newborn problems. A guide for doctors, nurses and midwives’ gives advice on comfort for grieving mothers if the baby dies, but is silent on what to do if death could have been prevented, but treatment was withheld or withdrawn due to resource constraints (13). It seems to be a grey area who to treat or not. In such gray areas, cost constraints often seem to affect decision making for the marginal patients (14).

## **Neonates in need of resuscitation/advanced medical care**

About 6 million of the 136 million born yearly need basic resuscitation (bag and mask ventilation), while above 1.3 million need advanced resuscitation (intubation, chest compression and drugs) at birth (15). More than one-third of all neonatal deaths occur during the first 24 hours, nearly half within the first three days and nearly

three-quarters within the first week (1). There are approximately 0.9 million intrapartum stillbirths<sup>1</sup> and 1.3 million neonatal deaths related to intrapartum circumstances<sup>2</sup>(16). Evidence from several observational studies show how facility-based, basic neonatal resuscitation could avert 30% of the intrapartum related neonatal deaths (17). According to expert opinion, resuscitation performed by trained community health workers could reduce the mortality rate as much as 20% (18).

The WHO guide recommends that resuscitation should not occur in the following cases: stillbirths that are not fresh; newborns who have a ‘severe malformation’ (hydrocephaly, anencephaly, trisomy 13 or 18, short-limbed dwarfism, multiple defects) and ‘extremely low gestational age’, determined by local policy and probability of survival(19).

The current International Liaison Committee on Resuscitation (ILCOR) guidelines recommend that after 10 minutes of continuous and adequate resuscitative efforts, neonatal resuscitation may be discontinued if there are no signs of life (no heartbeat and no respiratory effort) (20). Wall et al. report that some experts advocate that if there are no facilities for intubation and ventilation, then resuscitation should be stopped, unless there are clear indications that there is a modifiable factor involved, such as opioid administration to the mother during labor (16). We can assume that there are limited facilities for intubation and ventilation in most LIC settings. It’s important to note that when defining intrapartum-related neonatal death, premature infants younger than 34 GA weeks are excluded, and the recommended interventions do not focus on the premature neonate in need of resuscitation (16, 21).

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<sup>1</sup> A stillborn baby heavier than 500 grams or older than 22 gestational age weeks, where the death is assumed to have occurred in the 12 hours before delivery, and most likely due to an intrapartum hypoxic event.

<sup>2</sup> Intrapartum-related neonatal deaths (previously called birth asphyxia): neonatal death of term babies with encephalopathy or who cannot be resuscitated. Other causes should be excluded such as lethal congenital malformations or preterm birth complications (younger than 34 gestational age weeks or a birth weight <2000 grams)16. Wall SN, Lee ACC, Niermeyer S, English M, Keenan WJ, Carlo W, et al. Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale up? *International Journal of Gynecology & Obstetrics*. 2009 Oct;107:S47-S64.



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## The premature neonate in need of resuscitation/advanced medical care

The Lancet neonatal steering group committee focuses on the premature neonate not in need for advanced care (8), and the increased focus on the neonate in need of emergency care and resuscitation excludes the neonates born before 34 weeks in their recommendations (16). So what about the moderate/severe premature neonate in need of resuscitation and hospital medical care? Wall et al. conclude that the question, ‘When should resuscitation not be initiated, and when should it be stopped?’ is a difficult ethical question, particularly regarding resuscitation of babies with malformations or extreme prematurity (16). Their review of the literature on the subject primarily explores studies of settings with neonatal intensive care. They found only one paper concerning care in low-income countries (22), which was old and of variable quality. They concluded that a detailed discussion of the ethical question was beyond the scope of their paper, although they tried to sketch out a resuscitation protocol for peripheral levels of the health system.

International guidelines have for decades recommended that countries should develop local limits for gestational age. Some (high-income) countries have made national recommendations, but empirical studies show large differences in actual limits (23-28). The procedures for limit setting and the actual limits in low-income countries seem not to be discussed in the literature (17, 29).

## Outcome of premature birth

Studies concerning survival and long term consequences of premature birth show how mortality and morbidity increase with decreasing gestational age (30-34). The ‘MOSAIC-study’ from ten European regions showed that mortality varied between 7-20% for neonates born between 24-32 GAW, depending on the region they were born (35). A cohort study of neonates born before 26 GAW from United Kingdom and

Ireland, the 'EPICure-study', showed that one third of the survivors developed normally, half demonstrated minor impairments and one fourth were left with serious impairments at 30 months of age (36). A study of 903,402 neonates born in Norway between 1967 and 1983 showed that among those with no medical disability the gestational age at birth was associated with the education level attained, income, receipt of Social Security benefits, and the establishment of a family, but not with rates of unemployment or criminal activity. But the study also suggests that, although very premature infants have poorer medical and economic outcomes than their peers, most function well as adults (37). The family's education and socio-economic status on neonatal mortality and morbidity rates have high impact on the neonates' development (38, 39). There are more preterm deliveries among women from deprived parts of the population (40-42), and the family status seems to be the major influencing factor on the performance of the neonates without severe disabilities (43, 44).

Mortality and morbidity data from low income countries are most often referring to birth weight instead of gestational age (45), and the rate of neonates born small for gestational age (SGA) are higher than in high income countries (46). In the Pune low birth weight study (India), follow up at 12 years of age of 180 children discharged from a NICU after being born at a weight less than 2000 grams showed that the intelligence and academic performance of the children were significantly lower than that of controls, though within normal limits (47). They also had poor visuo-motor perception, motor incompetence, reading and mathematics learning disability. The preterm SGA and VLBW children had the poorest cognitive abilities (47). Khan et al measured neurodevelopmental outcomes of preterm infants in Bangladesh (48). They found one third of the survivors developed normally, half demonstrated minor impairments and one fourth were left with serious impairments at 30 months of age. That is similar to the outcome as the EPICure study (36), but the gestational age groups they studied were below 33 weeks, not below 26 weeks. They also found that 65% survived, 16% died and 19% were lost to follow-up. The deaths were mainly due to infections within the first month of life. Parental education and family income

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had significant influence on post discharge mortality (48). There has been little research focus on childhood disabilities in low and middle income countries, and major research gaps found in the areas of interventions, service utilization, and legislation (49). In their review of childhood disabilities in low- and middle-income countries, Maulik and Darmstadt found few studies providing data on outcome of morbidities, especially morbidity due to delivery complications and neonatal and early childhood illnesses (49). Several authors recommend an increased global capacity to assess and provide services for children at risk of disability (50, 51).

## The cost and cost-effectiveness of treating premature neonates

Cost increases as gestational age decreases (52-56). The cost per child is correlated to factors such as respiratory distress syndrome (RDS), gender, need for artificial ventilation and length of stay in the neonatal unit (57, 58). In addition, rehospitalisation, need for special care and rehabilitation is inversely proportional among the lowest gestational age groups (52, 55, 59-65). Among those with no disability, there is a lower level of income and a higher use of Social Security as the gestational age decreases (37). The cost for families with a neonate in the NICU is also acknowledged (66). Mangham et al. constructed a decision-analytic model to estimate the costs to the public sector over the first 18 years after birth, stratified by week of gestational age at birth (31). They found that despite concerns about ongoing costs after discharge from perinatal services, the largest contribution to the economic implications of preterm birth are hospital inpatient costs after birth, which are responsible for 92% of the incremental costs per preterm survivor (31). This was quite new knowledge, as other authors have argued that the actual cost of treating premature neonates would be much higher if future costs for follow-up were included (65). Although there are several studies showing the cost of hospital stays and later health and social needs of the neonate, a proper cost-effectiveness analysis has not been done using recent morbidity and mortality data. There is a common assumption

that it will be cost-effective in the long run to treat the premature neonates(67), due to the sickest dying within few days, the small number of survivors with disability and the long-term healthy life expectancy of the majority, but his assumption has not been documented (68).

Interestingly, the argument that NIC treatment is cost-effective is only used in discussions in Western countries. In a different discourse in neonatology, intensive care is in disfavour when it comes to cost-effectiveness. In a low-income setting with high NMR, the cost is perceived to be too high to even do an efficiency analysis (8, 69). But as former low-income countries develop and the economy improves, NICUs are built and advanced care is available for at least parts of the population (70). We do not know much about the costs or cost-effectiveness of neonatal intensive care treatment in these countries, though some preliminary studies exist (71-73) .

## State of newborn health in India

India accounts for about 30% of the global NMR; among the 26 million born in India yearly, 1–1.2 million die during the first four weeks of life (74). There has been great improvement since the eighties, when the NMR was as high as 69 out of 1,000 live births. The improvement is partly due to the reduced incidences of tetanus as a result of vaccination programs, the gradual increase of institutionalised deliveries, female education, and family planning that indirectly led to increased neonatal survival (75). The latest update on NMR is 40 out of 1,000 live births, ranging from as low as 10 out of 1,000 in Kerala to as high as 61 out of 1,000 in Orissa (76). Wealth, development and other relevant social determinants of health differ between the states and can account for these differences. Within the states, there are differences in NMR, due to such factors as infrastructure, health care availability, urban-rural locations, socioeconomic status of the families, caste, female literacy and control of income (76).

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The highest proportion of low birth weight children in the world are born in India, where one-third of the 26 million newborns born yearly weigh less than 2500 grams (the standard definition of low birth weight) and 14% are born premature (before 37 gestational age weeks)(76).

Weight has been the major indicator for both prematurity and intrauterine growth restriction, as a confirmed gestational age is difficult to get without ultrasound and adequate antenatal care. The statistics concerning prematurity in the Indian neonatal population are therefore uncertain, and the relevant numbers are few and from tertiary hospital settings or some smaller rural intervention studies (10, 46, 77, 78). The National Neonatal Forum found that in 18 well equipped institutions, the premature rate was 14.5%, low birth weight was 31.5%, very low birth weight 3.4% (<1500 grams) and extremely low birth weight was 0.7% (<1000 grams)(77).

Several interventions have been put into effect, and one of them is the 'The National Rural Health Mission', launched by the government in 2005 to tackle deepening disparities in the country, with the reduction of the infant mortality rate as a primary goal (79). Other interventions, such as cash transfers for expectant mothers living below the poverty line, neonatal services, and the Integrated Management of Neonatal and Childhood Illness, are gradually being rolled out (80, 81).

There are many obstacles before all neonates in India will be able to get proper care and treatment. First, there is the lack of adequate facilities and competent personnel to handle their special needs. Another major factor is the care-seeking behaviour among large parts of the population. The lack of response to serious illness and provision for relevant and correct handling of symptoms and diseases of the newborn is a serious problem in India(76, 82, 83). One reason is that the symptoms in neonates are often subtle and evolve rapidly. Also, there is a lack of awareness of serious symptoms and/or adequate response to symptoms within the family, leading to delayed contact with qualified health personnel (82). Local, unqualified persons are frequently relied upon instead of a primary health care facility, because the parents do not trust the primary health care facility and because sick newborns are viewed in

terms of tradition and mysticism (84). The distance to a health facility is an important factor that prevents newborns from receiving medical assistance, especially since many find the primary health care facility inappropriate and untrustworthy and would prefer a referral institution farther away. The availability of affordable and available transport, the fees for transport and hospital and additional obstacles, such as the inability to find someone to accompany the mother and neonate, play major roles in the failure to receive appropriate treatment (85). There are studies showing that primary health care facilities are not prepared to treat newborns adequately, as they lack equipment and competent providers (86); they are more comfortable treating older children and refer neonates to a higher level of the health system (87). This increases the costs and distance for the families, and few pursue the referrals elsewhere (85). In a study from two urban slums in Delhi, 13% of the consultations ended in recommending hospital admission, but only 25% of the families followed the recommendations (88).

### **Service for premature or sick neonates in India**

Studies show that through community interventions, the NMR can decrease substantially in the rural and slum areas in India (78, 89, 90). But the effect on the severely or extreme premature neonates has not been specifically described (91). These premature neonates would require hospital treatment, either at a sick neonatal care unit (SNCU<sup>3</sup>)/level 2 or at a NICU (76). So far, few hospitals have a neonatal intensive care unit in India. In some of the larger cities, there are hospitals with level 2 neonatal units, most of them in private institutions. Very few of the approximately 160 medical colleges in India have a NICU/level 2 unit, and in some states there is

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<sup>3</sup> Sick neonatal unit is defined by the National Neonatal Forum in India. There are norms for physical facilities, staff, neonatal resuscitation, neonatal transport, thermoregulation, nutrition, infection control, monitoring and therapeutic facilities, investigative facilities, neonatal follow-up, teaching and administration 92. National Neonatal Forum NNPD Network India. Norms For Accreditation Of Level II Special Care Neonatal Units. <http://www.nnfi.org/normslevel2.htm>. 1991. Access date 10.01.2010.

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only one unit covering the whole state<sup>4</sup>. A study from a neonatal unit in Delhi showed that it was almost always at 100% occupancy and that the unit was highly pressured throughout the year(76).

National Neonatal Forum India and Save the Children/Us estimated that there is a need for 72,000 NICU beds in India, based on estimations of incidence of very low birth weight neonates (0.9 million annually) and average length of stay for this patient group (3 weeks)(76). Fewer than 2,000 beds were in place in 2005<sup>5</sup>, which is less than 3% of the estimated need (76). The scale-up of advanced hospital treatment for neonates has not been encouraged by researchers or policymakers, who use such arguments as the high costs, that the families could not afford it and the obstacles to getting qualified personnel (7).

However, there are now studies showing that providing hospital treatment to neonates in India has a positive effect on the NMR (75, 93-96). Sen et al. developed a 12-bed, state-of-the-art SNCU (based on level-II criteria from the National Neonatology Forum, India) and trained the staff in a district hospital in West Bengal (96). The unit included a controlled environment, individual warming and monitoring devices, an infusion pump, central oxygen and oxygen concentrators, resuscitation and exchange transfusion equipment, a portable X-ray and an in-house laboratory. Baseline data for ten months were compared with two years' data of SNCU operation. The effect on the NMR for the district was tremendous; a 14% and 21% reduction in a one- and two-year follow-up respectively. No single other intervention could be expected to reduce the NMR to that extent at such a rapid rate (8, 76, 93). So far it is unknown to what extent the infant mortality or under-5 mortality has been influenced by the SNCU set-up, or how much further the NMR could decrease if the SNCU also had intensive care services provided for the sickest neonates.

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<sup>4</sup> The number is estimated in "State of Indias newborns" made by Save the Children/US and National Neonatal Forum India. They did not describe how they found this number, and we were not able to find any up dated numbers.76. Save the Children/US. National Neonatal Forum. State of India's Newborns. Washington: Save the Children 2004.

## Cost of hospital treatment for neonates in India

There is scarce data on cost or cost-effectiveness of hospital treatment for sick or severely premature neonates in India. Unfortunately, the available data are old, and the cost of NICU treatment varies widely between different institutions, depending on the level of care (76). A study from a NICU in Chennai estimated average costs per day for surviving patients and those who did not survive (97). The study did not include salaries in the measurement, which usually has a high impact on cost estimations. Costs were inversely proportional to birth weight and were highly dependent on the neonate's need for artificial ventilation, and were higher among the non-survivors. They found that care for the neonates weighting more than 1,250 grams were cost beneficial. However, they do not explain how they measured the benefit ratio. Thirty-five fathers were interviewed, and 55% of them had depended on a loan for their financial support and 14% used their savings to pay the hospital bill. A similar study from AIIMS (government owned teaching hospital) in Delhi showed that the families paid \$5 per day for medicines and other needs (and probably had to pay more for a family member to stay in the hospital lodge), while the treatment costs for the hospital was \$33 per day. Treatment of a very low birth weight VLBW neonate costed \$870 on average, a high price in an Indian setting, but as the authors point out, that's 'less than half the charges of an adult coronary bypass surgery in the same institution, with 6–8 times more life years gained'(76).

Narang et al. presented cost data from their neonatal department at PGIMER Chandigarh in Punjab(a governmentowned teaching institution) (73). In their unit, the families had to bear 25% of the expenses; the rest was subsidized. The biggest proportion of establishment and running costs were equipment and personnel salary. Costs were inversely proportional to birth weight and were highly dependent on the neonate's need for artificial ventilation. They recommend comparing the costs with

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<sup>5</sup> The number is estimated in "State of Indias newborns" made by Save the Children/US and National Neonatal Forum India. They did not describe how they found this number, and we were not able to find any up dated numbers.76. Ibid.



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other critical care interventions that currently are funded through the government (73).

In India, 82% of health expenses are out of pocket. The expenditures for health are only 5% of the GDP; government expenditures on health are only \$4 per capita (74). Although the poorest of the poor are more frequently using public health facilities, the most common health providers are unqualified local people who require money for their services or private institutions. For most families, this has a significant impact on their finances: 28% are living below the national poverty line in India (less than \$0.25 per day), 42% are living on less than \$1.25 and 76% are living on less than \$2 per day (98). Studies show that among families who have a member admitted to hospital, about 40% have to borrow money or acquire debt, most often with extremely high interest rates (99). This can lead to future familial economic burdens and obviously increases the risk of falling further into poverty (100). In the worst case, indebtedness can push families into acute nutritional crises, and play a causal role in the death of siblings or other family members (101). If the child survives with a disability and needs special care, this will bring extra expenses in terms of hospital visits, medication and loss of income for the person taking care of the child (85).

### **Special concern: the female neonate in India**

The female neonates are in a particularly vulnerable position. Neglect of girls, infanticides and feticides are responsible for a sex ratio favouring males (102). Gender bias results in about 44 million missing women in India (103, 104). The sex ratio differs among states; it's highest in some of the northern states (105). The influence of mothers' education, the families' socioeconomic status and income influence the sex-selection practice, but the nature of that influence is not entirely clear (105). There are also studies showing that neglect of girls' health needs is more common among women in high-income strata of the population(106) The sex ratio at birth (i.e., the number of boys per 100 girls) increases with increasing birth order and from the second birth onward (107).

Amartya Sen describes how gender inequity has shifted from ‘mortality inequity’ to ‘natality inequity’ after the facilities for antenatal sex determination became available(104). The activist and researcher George states that, ‘This holocaust of unborn girls is unprecedented in human history’(105). Although antenatal sex determination is illegal in India, sex-selective abortion still has a major effect on the sex ratio(108). Prenatal discrimination has not totally replaced post-natal discrimination; however, when and how this is happening is difficult to assess. Infanticide in the first days of life is often reported as a ‘stillbirth’ or not reported to the birth registry system at all (107). There are currently no studies documenting gender selection of neonates during delivery and the immediate post-partum period within hospitals. Neglect of the female neonate’s health needs in a rural setting is documented by Willis et al. (109). They found that the perception of illness was significantly lower in incidence among households with female versus male newborns, and that the expenditures for healthcare was four times higher in households with male newborns (109). Bhan et al. found that girls were less likely to be taken to hospital, even if they had a higher mortality in the study population (106). Verbal reports indicate higher fatality rates and more ‘unexplained deaths’ occur in neonatal girls(110). Higher morbidity for girl infants and children could be a result of neglect of nutritional and medical needs (111). Girls with disabilities are in a special vulnerable position, and their medical, nutritional and social/educational needs are neglected (112). Being female, disabled and poor is considered the major reasons for discrimination by the National Centre for Promotion of Employment for Disabled People in India (113). Martha Nussbaum’s work explores equity and gender in India and clarifies the problems faced by Indian girls and women (114). It is beyond the scope of this introduction to try to explain the reasons and structures behind the disadvantaged position of some of the girls and women in India.

## THEORETICAL PERSPECTIVES

### End-of-life decisions in neonatology

In 1973, Duff and Campbell wrote a groundbreaking article describing the ethical dilemmas raised by neonatal intensive care (115). Since then, an extensive number of papers have been written on the ethics of neonatal decision making (116-118). Orfali and Gordon note that:

‘Neonatology has become perhaps the banner field for technology, miracles, and ethical dilemmas, offering a unique site of study for philosophers, ethicists, lawyers, and social scientists, as well as physicians and epidemiologists... Neonatal intensive care provides extensive case studies for the life and death decision making that have become central ethical challenges of contemporary medicine.’(119)

Some of the challenges in neonatal medicine have been related to the uncertainty and variation of outcome data, the difficulties of predicting prognosis of the individual child, and the restricted transfer-value of data from one study setting to another. As the lower limits for viability have continued to decrease and has varied among countries, the need for updated and local relevant facts has been considerable. The problems of transferring and comparing data are partly due to lack of standards for reporting NMR: some researchers have included all infants born, some only live births and others have included only those admitted to NICU after decisions in the resuscitation room have been made (116, 118, 120). The definition and reporting of gestational age has also differed. Another key factor is the policy or ‘medical culture’ in the unit reporting survival rates; if the unit is liberal in withholding treatment of infants who are over 24 gestational age weeks, the survival rate will be low, as compared to a unit that put effort toward saving this group (121).

There are empirical studies on the limits for, guidelines for, attitudes toward and parental involvement in treatment of premature from various Western countries (23, 122, 123). Studies have also been conducted to explore how, where and when treatment is limited or not (124-130). Although clinicians manage to predict the risk of dying in the neonatal period to a higher degree now than some years back, there is still prognostic uncertainty. There are anecdotes about extremely premature babies judged to be hopeless who miraculously survive and live a normal life; of course, there are anecdotes that concern the opposite results: severely disabled and brain-damaged children who are dependent on artificial ventilation and nutrition. And the uncertainty concerning future morbidity and life course of the premature is still there; predicting who will suffer feeding problems, increased risk of respiratory problems and learning difficulties is hard in the first days of life when life or death decisions must be made (131). Studies show that although the doctors may correctly predict a prognosis, they will not necessarily withdraw treatment to hasten death or continue care in cases where the child will probably survive. It depends on the setting and on the policy (23). Most of these studies are from high-income countries, primarily the US or Western European countries. There are major knowledge gaps on how these decisions are made in middle- and low-income countries (132, 133). A few studies from such settings exist, but a lack of contextual information and the varied quality of the methodology make it hard to extract reliable facts (134-140).

The ethical debate has concerned the ethical permissibility of the limits for decision making, discussions about futility and the best interests of the child, the sanctity and quality of life, surrogate decision making, autonomy and parents' involvement and, to a small extent, the fair distribution of resources (68, 141). The latter has only been mentioned as one relevant issue, but so far no one has really discussed neonatal end-of-life decisions as an ethical dilemma concerning priority of resources (68). The opposite is more commonly discussed: there is a perception of overuse of resources in the ICU (142). When futility of or limits for treatment are discussed, authors have

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different acceptances of the risk of future morbidity and mortality. Some argue that it is in the best interest of the child to limit the risk of disability as much as possible, as a life with a predicted poor quality of life is worse than dying due to the limiting of advanced intensive care interventions. Others argue that by providing these interventions, one might be denying some potential normal babies the chance to live, or that quality of life is not possible to predict in the individual cases. The concept of 'best interest' is highly debated, and spawns arguments about paternalistic medicine, personal attitudes, religion and emotions involved (118, 143). Empirical studies show that the understanding of best interest can differ between health providers and parents, and the issue has been discussed in ethical forums as a part of the controversies in surrogate decision making and autonomy among parents. Most ethicists hold that parents should be involved in the decision, but they differ to what extent. Some hold that the decisions should be made solely by health personnel, because parents are not qualified to understand the choices they are making, or because they should be protected emotionally. Others argue that the family should be involved, as they are the ones to live with the child (119). Maharaban Singh has argued for giving priority to the family, instead of to the child's best interest, in the Indian setting (144) .

The current state of this research is diverse and continues along the empirical and theoretical lines described above. In addition there are publications describing and arguing for defined policies and standardisation of the decision-making processes (25, 145-147). What is interesting is that many of them are based in countries that allow neonatal euthanasia in special circumstances, such as the Netherlands, Switzerland and Belgium (146, 148-150). The authors of these papers all argue for transparency in these decisions, and for acknowledging that these decisions are influenced by personal beliefs and perceptions. There is clearly a need for an open discussion among colleagues and an active involvement of parents and others, such as the hospital's clinical ethical committee, if there is a disagreement or conflict. Several authors recommend promoting a public debate and discussion within the medical community. As a response to the public debate that emerged in England, the Nuffield

Council on Bioethics issued a report, 'Critical care decisions in fetal and neonatal medicine: ethical issues', aimed at exploring the diversity of dilemmas, knowledge gaps and opinions about the issue (68). The working group proposed concrete limits for gestational age and offered relevant questions for the decision makers to consider when planning to withhold or withdraw treatment of a neonate. Other countries have made similar recommendations (23, 151).

## Priority setting

So far, I have described limit setting as an ethical dilemma concerning the futility of treatment. But during the last few decades, there has been an emerging focus on the dilemma of limiting medical treatment due to resource constraints. Below, I present the concepts involved as well as relevant studies and theories in the discourse of priority setting in health care.

### **Priority setting and rationing**

Priority setting occurs whenever medical or public health services are withheld from individuals who could benefit from them, whether or not that is an intended consequence of a decision to set priorities(14, 152). Beneficial care can be defined in terms of what a fully informed person would want when faced with disease and in the absence of resource constraints (14). Many consider the term priority setting as synonymous with rationing (152) . The latter is defined by Ubel as 'any implicit or explicit mechanisms that allow people to go without beneficial services'(153). A distinction used is that priority setting refers to setting limits at a macro- or population level, and 'rationing' refers to micro-level selection or exclusion of individual patients (154). I use the concepts interchangeably and see both as forms of limit setting due to resource constraints.

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Health care priority setting can take the form of denial, dilution, deflection, delay, deterrence or termination (155) at a macro, meso- or micro-level of the health care system. Calabresi and Bobbitt distinguish between first- and second-order decisions (156). First-order decisions are political decisions concerning the size and capacity of the health care service ('How much of a good should be produced or provided?'). Second-order decisions concern the selection or ranking of patients ('Who is to get the scarce good in question?'). Second-order decisions can occur at an overarching clinical level intended to decide best practise for a patient population, or at a practical level where treatment choices for individual patients are made.

In this study we assess second-order rationing at the bedside level within Indian neonatal units. Bedside rationing is defined by Ubel as:

'the withholding by a physician of a medically beneficial service because of that service's cost to someone other than the patient. Three conditions must be met...before a physician's action qualifies as bedside rationing. The physician must 1) withhold, withdraw, or fail to recommend a service that, in the physician's best clinical judgment, is in the patient's best medical interests; 2) act primarily to promote the financial interests of someone other than the patient (including an organization, society at large, and the physician himself or herself); and 3) have control over the use of the medically beneficial service'(157).

There have been controversies about the physician's role in rationing care at this level (158). Some question the dual role of physicians in being both the patient's advocate and society's gatekeeper of the resource (159). They typically emphasize the importance of trust in the doctor-patient relationship and that doctors are obliged to always do what is best for their patients. Lauridsen argues that bedside rationing is an illegitimate form of distribution of health resources (160). Others assert that bedside rationing is an unavoidable part of clinical practise and that we should focus on developing acceptable thresholds and processes. Empirical studies show that bedside rationing is common in daily practice, that physicians' rationing behaviour is highly

variable and strongly influenced by context-related factors, and that implicit rationing strategies occur most frequently (161-167).

Troug et al. describes three different forms of bedside rationing: 1) in accordance with external constraints 2) by rules of medical practise and 3) by exercising clinical judgement where the first two mechanisms do not apply (168). Hurst and Danis divide rationing by clinical judgement into three sub-forms: 1) triage for such instances as limited time, hospital beds or staff; 2) comparisons of potential patients; 3) use of thresholds for individual benefits and costs (169). When they were questioning physicians faced with resource constraints about the underlying reasons in their decisions, only some mentioned concerns about justice (166). The researchers found this 'alarming', as it could be a sign of the weak link between general concerns for fairness and the clinical practise of bedside rationing (169).

## **Justice and fairness**

In the literature, fairness is often used to describe justice or equity in distribution. Although we acknowledge the accuracy and the distinct use of the three concepts of justice, fairness and equity in a philosophical debate, we are less precise when we use these concepts descriptively within the documentation of this thesis. Our informants used the concepts (in-)justice and (un-)fairness interchangeably when talking about their daily clinical life. In the normative analysis, we try to use clearly defined terms.

Advocates of utilitarianism hold that we should prefer the act, policy or principle which produces the greatest happiness for the members of society (170). There are several versions of utilitarianism, all partially differing from Kant, who concluded that the expected consequences of an act are themselves morally neutral, and therefore irrelevant to moral deliberation (171). The only objective basis for moral value would be the rationality of the good will, expressed in the recognition of moral duty. Kantian theories of justice focus on the importance of respect for the individual, to treat the person as a goal in himself, not only as a means to an end. In egalitarian theories, the interests of each member of the community matter, and matter equally;



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each citizen is entitled to equal concern and respect. Dworkin held that this is the heart of all plausible political theories (170, 172). In ‘Justice as Fairness’, Rawls asserted that there should be a ‘hypothetical’ agreement from all involved partners (173). Scanlon continued this line of argument and added that an action is right if no one has a reasonable ground to reject it (174). Rawls also argued for the protection of the worst off. His most important principle is known as ‘the difference principle’: ‘[s]ocial and economic inequalities are...to be to the greatest benefit of the least advantaged members of society’(175). Habermas goes further, claiming an actual consent when he describes the principle of discourse: the legitimacy of an action depends on actual consensus among all affected stakeholders. He also presents the principle of universalism, that a norm is valid if all affected parties give their approval. To achieve the norms with more than hypothetical acceptance, there is a need for procedural arrangements (176).

In this thesis, I define inequalities in health as those distributions or practises that are deemed to be unfair or resulting from some form of injustice (177). But what kinds of inequities are unjust? My understanding of that in this thesis is similar to what’s expressed in a recent paper by Norheim and Asada (178). They transform Whitehead and Dahlgren’s much-used statement that ‘health inequalities that are avoidable, unnecessary, and unfair are unjust’(179) into a pluralistic alternative (178). By describing two principles they make a definition that is compatible with several theories of distributive justice:

‘The weak principle of equality states that every person or group should have equal health except when: (a) health equality is only possible by making someone less healthy, or (b) there are technological limitations on further health improvement. In short, health inequalities that are amenable to positive human intervention are unfair. The principle of fair trade-offs states that weak equality of health is morally objectionable if and only if: (c) further reduction of weak inequality leads to unacceptable sacrifices of average or overall health of the population, or (d) further reduction in weak health inequality would

result in unacceptable sacrifices of other important goods, such as education, employment, and social security' (178).

The challenge in health policy and at a clinical level is to make fair procedures for balancing the different concerns.

## **Legitimacy**

### **Acceptable rationing criteria**

By what criteria can we legitimately select (and exclude) patients for service?

Kapiriri and Norheim divide priority criteria into acceptable, unacceptable and contested criteria (180). In Norway, the national health priority-setting guidelines are identical to the acceptable criteria, which are: 1) severity of disease, which is prognosis without intervention; 2) effectiveness, which is prognosis with intervention; 3) cost-effectiveness, which is often measured in cost per Disability-Adjusted Life Year (DALY) and 4) the quality of evidence of criteria 1–3 (181).

Unacceptable criteria are those that fair-minded people would agree are unacceptable when giving all persons equal moral weight: gender, sexual orientation, religion, race, tribe, social status and educational level (180). There are theoretical discussions about the acceptability of the contested criteria, and in practice they often influence judgments, both in first- and second-order decisions (163). The contested criteria are age; prioritizing the young before the older, economic status (whether it's fair to prioritize the poorest); responsibility for one's own disease and the importance of the individual's productivity for the family or the society (180). Examples are the denial of organs for alcoholic liver failure (formulated in guidelines) and prioritization of VIPs for access to ART treatment (informal clinical decision) (182). Although there is generally agreement on the acceptable criteria<sup>6</sup>, the balancing of the different

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<sup>6</sup> There are exceptions from this agreement, for instance shown through the perspectives presented by Persad, Wertheim and Emanuel 183. Persad G, Wertheimer A, Emanuel EJ. Principles for allocation of scarce medical interventions. *The Lancet*. 2009 2009/2/6/:373(9661):423-31.

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criteria remains to be solved theoretically, and in practical life depends on a fair process. Unfortunately, empirical studies show that in most cases there is no fair process (161-163, 167, 184).

### **Fair process**

Norman Daniels' response to the dispute about what is a fair distribution of resources is that there will be legitimate alternative answers and reasonable disagreements on what are the most fair rationing decisions. Instead of theoretical arguments about what is a 'fair' limit or a substantial understanding of fairness, we should focus on a fair process when limiting treatment (185). People with different preferences and different theoretical background can agree on the relevance of a fair process when the following four conditions are met: relevance, publicity, revisions and enforcement (186). Daniels' and Sabin's 'Accountability for reasonableness' (A4R) has become a well-known framework for securing a fair process at macro- or meso-health care levels (152).

For decisions to be considered legitimate, they must be well grounded and perceived as acceptable in the population (187, 188). There are especially some dilemmas in priority setting that invoke legitimate disagreement among ethicists, policy makers and clinicians. Daniels describes four of them: 1) the fair chance vs. best outcome problem; 2) the priorities problem (how much priority to the worst off and who is worst off?); 3) the aggregation problem (modest benefit to many vs. large effect for few) and 4) the democracy problem (when is a fair process the only chance to reach fairness?) (189). Daniels used a population perspective when describing these unsolved problems, but they could also be illustrated at the bedside level (186). Another dilemma leading to legitimate disagreement is the equity/efficiency trade-off, the trade-off between weak equal health and maximizing concerns (178). Anand frames the question in this way: 'what amount of healthy life years, if enjoyed equally by everybody, would have equivalent value to a greater average health life expectancy?' (190). 'Equal health' refers to equality of health that can be influenced by positive human intervention. Until recently, it has been difficult to illustrate this

trade-off properly, as there have been few examples in which measurements of equity are compared with efficiency rates. A promising effort is the use of Atkinson's index, suggested by Anand, and the Achievement index proposed by Wagstaff (178).

In these 'unsolved' legitimate disagreements, there can be different outcomes even if there has been a fair procedure. But Daniels and Sabin hold that as more decisions are made through fair procedures, there will be consensus on what is fair in the population and the implementation of A4R will educate the population on justice concerns (186).

## **METHOD**

### **Qualitative studies of experiences and decision making**

We used a qualitative approach to collect and analyse empirical data. A qualitative method is used to explore the meaning of social phenomena as experienced by individuals in their natural context (191). Qualitative methods can register aspects of complex behaviour, attitudes and interactions, which quantitative methods are unable to reflect (192). Contextual issues are more appropriately studied with qualitative methods (193). This is particularly so in those environments that have not been studied in the past. Those were our main reasons for using individual in-depth interviews and observations to explore underlying reasons and values and to get the subjective views of the decision makers in three neonatal units in India. Due to the sensitive topic and the hierarchical structure within the medical system in India, we decided to use individual interviews instead of focus group interviews. This was also partly the reason for our efforts toward systematic observations in the second fieldwork. In the first fieldwork, we found that some of the informants were trying to pass on the 'correct' view when discussing end-of-life and resource considerations among their colleagues. When discussing real, ongoing cases in a private room in the first and second fieldwork we believe we registered genuine opinions.

#### **Paper 1**

To explore the ethical dilemmas experienced by health personnel working in NICUs in India, we conducted in-depth interviews and observations in two government-owned hospitals in one of the largest cities in India during a two-month period in 2000. During that period, we triangulated information by visiting three other neonatal departments and one department of community medicine. We did unstructured observations and informal interviews within the hospitals, but also visited several

rural neonatal projects that were part of the public health community programmes. In the rural areas, we joined workshops for teaching traditional birth attendants (dais), mobile antenatal and children's clinics, anganwadi and health care centres and hospitals at lower levels in the government system.

The interviews and observations were transcribed and coded according to Malterud's modified version of Giorgi's phenomenological approach. This approach is recommended for development of new descriptions and concepts, and has its roots in phenomenological theory (194). The aim is to develop new knowledge about the informant's experiences and lifeworld. The analysis of the written text is done in four major steps: 1) getting a total impression; 2) identifying meaningful units; 3) abstracting the contents of individual meaning units and 4) summarising their importance (194).<sup>7</sup>

Further details of the study design, setting and sample are provided in paper 1.

### **Method used in paper 2 and 3**

The next fieldwork was designed to find concrete treatment limits for gestational age and explore regulations and the underlying reasons for the limits in a neonatal unit in India. It was conducted by undertaking several fieldtrips to different neonatal units in India. In 2002, we (Miljeteig and Johansson) did a study at St. Johns Medical Hospital, Bangalore, where we also did informal interviews and observations in the NICU and in the paediatric community department to extend our understanding of decision making in neonatology. During our fieldwork in 2002, we visited two other NICUs in Mumbai and interviewed doctors there about their ethical dilemmas and decision making. In 2005, I performed two sets of fieldwork in Mumbai, conducting several interviews of doctors to find a proper site for embarking upon the final fieldwork in an Indian NICU. I wanted to study decision making in a large hospital

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<sup>7</sup> All formal interviews were conducted by Miljeteig. Norheim joined the data analysis.

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with a NICU that covered all social groups and where it would be possible to follow the referral chain from home to the NICU.

The fieldwork for papers two and three was conducted in a private, nonprofit, large teaching hospital in a smaller Indian city during the period from January to March 2007. The interview guide for the formal in-depth interviews was originally developed to explore the decision-making process and the regulations that governed it; however, it soon became evident that formal regulations played only a minor role in the process, and we changed the interview guide and study focus to capture the nuances and reasoning behind decisions and the decision-making strategies. (See appendix 1 for the attached interview guide.) In addition to formal interviews of doctors and nurses in the neonatal and obstetric departments, we tried to get as broad a picture as possible of the decision making involving the treatment of premature neonates in the surrounding districts, hospitals and units.<sup>8</sup>

In the neonatal and obstetric departments in the hospital where the study was performed, I used all opportunities to explore end-of-life decision making and priority setting in general. The number of cases was extensive, and the personnel were exceptionally willing to explain and share their understanding and reasons. The material was transcribed and initial coding was done when still in the field.<sup>9</sup>

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<sup>8</sup> I stayed in the hospital campus for three months and joined the daily life in the NICU and other departments. I did not intervene in the treatment of the neonates, but followed the rounds, meetings, consultations, paper work and breaks. I got very familiar with both the doctors and nurses, and also spent some time with the mothers, although I did not do any formal interviews with them. Some days were spent in the four other intensive care units in the hospital to explore the way end-of-life decision were done when the patients were older, and to look for similarities or differences in reasons and policies. I visited the children and maternity wards, the outpatient and high risk clinics and the casualties to talk with people that handle pregnant mothers and neonates. I joined the doctors working in the delivery rooms and resuscitation room when neonates were born and resuscitated to get the impression of “real life” decision making and to be able to debrief the decision immediately after decisions were taken. I also tried to follow the referral chain from the villages to local health clinic or local hospital and for those when this was not sufficient; the referral further to the main hospital and NICU. A couple of days were spent in the different departments in two local affiliated hospitals (belonging to the same organisation). To get an impression of the government system that provided treatment for the poorest of the poor, we spent some time in the main government hospital nearby, and talked with health personnel in the neonatal unit

<sup>9</sup> All formal interviews were conducted by Miljeteig, while Johansson joined in some of the informal interviews, data registry, and field observations, coded several interviews and joined the analysis. Norheim joined the data analysis.

The modified Giorgi's phenomenological method recommends that the number of meaningful units should not extend more than 6–7(194). We found this low number of meaningful units to limit our first categorisation of the rich and diverse material. Therefore we used elements of coding and conceptualisation from grounded theory instead. The initial step is coding of the material, with no limitations in numbers of codes (195). We had 75 initial codes, but the numbers decreased as we worked on finding overlapping content. Codes that were similar or contained information about the same issues were grouped together in categories. Finally, the categories were grouped in themes, and the three themes were; decisions, reasons and process. We used NVivo version 7 to assist in the analysis.

The registry-data on gender, details of deaths and gestational age in the delivery room and neonatal department were collected manually. The data were transcribed and plotted in a spreadsheet. Combined statistics from the obstetric and the neonatal departments were presented monthly at the hospital and we got hold of the datasets from 2006 and the three first months of 2007.

Further details of the study design, setting and sample is provided in paper two and three.

## **Ethical considerations**

The project was reviewed and approved by the Norwegian Social Science Data Service according to the privacy and licence requirements of the Personal Data Registers Act and the guidelines for research ethics in the social sciences, law and humanities according to the National Committee for Research Ethics in Medicine. All informants were informed about anonymity issues and the purpose of the study, and gave informed consent to participate. For the fieldwork in 2000, research permission



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was given by the head of the relevant departments<sup>10</sup> while in the fieldwork in 2007, we applied for a research permit and the project was approved by the local hospital ethics committee.

## Ethical analysis

There are no standard forms for evaluating a case or dilemma, but different approaches suggest different starting points and structures for evaluation. The legitimate interests and goals that must be considered when studying the impact of a decision on various stakeholders can be identified by some guiding principles. There are several similarities between different methods of case analysis in clinical ethics. Below, I present some of them.

The applied ethics approach addresses ethical issues that arise in practise through the application of particular ethical theories or concepts to concrete clinical or research cases. The focus is not to make a procedure for reaching a decision, but to develop a theoretical framework which would, for instance, help define what makes an action good (196). Approaches that seek to give ethical guidance in clinical cases through specified moral principles can be referred to as ‘principlism’. Beauchamp’s and Childress’ often described and globally used ‘Four principle approach’, describes and identify principles in biomedical ethics (197). The four principles are autonomy, beneficence, non-malificence and justice. By applying general principles to ethical problems, the authors argue that the principles help finding the answers to what to do in a concrete case. The model starts at a high level of abstraction and ‘gradually zooms into the specific’ for the case (198). Gordon et al. points out that ‘it is rather unclear what exactly people do when they apply this approach. Ranking, specification, and balancing vary greatly among different people regarding a

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<sup>10</sup> At that time I was a medical student and student projects not involving patients does not need research approval by the Norwegian National Committee for Research Ethics in Medicine. The hospitals in India did not have any formal regulations for small scale data collections not involving patients.

particular case' (199). The method has been criticised as insensitive and narrow because it employs only four principles on all kinds of complex and incompatible problems, and that the weighting among the principles—i.e., what principles to weight the most heavily when they are in conflict—is imperfect (200).

In comparison with the first two theory-laden approaches, a case-based approach is a bottom-up approach. Several authors argue for referring to analogue cases previously discussed among ethicists when discussing a concrete case, while the most well-known approach is the 'four quadrant approach' presented in 'Clinical Ethics' by Jonsen et al., a book that is frequently a part of medical curricula (201). Sokol calls the approach 'an ethical stethoscope increasing the clinician/ethicist's ability to see what is morally relevant while revealing, at the bedside, the moral dynamics of the case'(198). The 'four quadrant approach' for clinical and ethical decision making describes four broad topics to be discussed: medical indications, preferences of the patient, quality of life and contextual features. Within each topic there are more specific questions (201). The model is probably functional for identifying the important ethical questions and dilemmas in daily clinical life. But as Sokol points out after using the method on a concrete case, the judgement and justification needed to resolve the specific problems, such as the scope of a prior refusal of treatment, are not included in the model. This is why the approach could be fruitfully combined with a theory such as principlism and the associated methods of specification (i.e., 'filling in' principles to increase their relevance to a given situation) and balancing (i.e., determining the moral weight of competing principles and assessing which takes priority) (198).

We reviewed the literature to find the most appropriate analytical framework for our evaluation of a case that illustrates a normative dilemma of fair distribution of resources. Our aim was to analyse the acceptability of the limit in the concrete case, relating it to the substantial analysis of setting limits fairly. We wanted a standardized analysis which could be a transparent tool for analysing complex dilemmas, with a special emphasis on impartiality. But during our review of the literature, we could not

find any previously described framework that captured all relevant considerations. The considerations for others that are affected by the decision are only sparsely described in the ‘four quadrant approach’, which made it hard to capture the complex decision making we were about to analyse. The four principle approach by Beauchamp and Childress has also its limitations in providing an overall ethical analysis (197), and we found that it had to be extended to systematize the case in an explicit manner. We also evaluated and acknowledged ideas from decision tree approaches to make the dilemma, with its different alternatives and consequences, as distinct as possible (202). We therefore suggest our own seven-point normative analysis to reach this goal, building on ideas from several previously described frameworks.

The starting point of the framework is a modified version of Kymlicka’s ethical case analysis, first described to analyse new reproductive technologies without depending on a moral philosophical theory (203). Kymlicka claims that ‘[t]aking morality seriously, ... requires taking people seriously—showing concern for people’s lives and interests.’ And this is done by 1) identifying which people are affected by the decision/policy and 2) ensuring that health care is used in such a way as to promote, or at any rate, not harm, its legitimate interest (203). In addition to separating Kymlicka’s two points in more detail, we needed more information about the case and its outcome.

The first point in our ethical case analysis is to make explicit the ethical dilemma and the alternative arguments in the decision (Table 1). It is important to specify the alternatives to ensure consistency of further analysis. The rest of the analysis evaluates the various implications of the alternatives. In our analysis, we put much effort on the outcome analysis. Relevant evidence depends on the dilemma analysed, and we explain the outcome analysis in detail below, according to the severity of the disease, efficiency, cost-effectiveness and evidence of the first three criteria. Third, we ask for an overview of formal and informal, national and local guidelines, policies and regulations. One reason why this is important is to clarify the duty and rights of

the different parties involved. Fourth, affected parties should be identified. These could be ranked after how the issue at stake affects them. For instance, the patient is more affected than the hospital management in individual end-of-life decisions. In addition, their benefits and burdens should be identified. Benefits for the patient could include a longer life if there is an intervention, but treatment could also be a burden if it prolongs a very painful condition that ultimately leads to death. The next step is to analyse the interests of the different parties. In our analysis concerning justice, we use overarching interests such as the desire to live a healthy life and the patient's overall welfare. In the final steps, the principles that are identified and discussed, depend on the issue at hand. For instance, they could concern health- and welfare maximisation and distribution.

<b>Ethical case analysis</b>
<ol style="list-style-type: none"><li>1. Statement of the problem and alternative actions/rules</li><li>2. What is the evidence concerning the outcomes of the different alternatives?</li><li>3. Are there guidelines or legal acts that regulate the issue at hand?</li><li>4. Who are the affected parties?</li><li>5. What are the benefits and burdens for the affected parties?</li><li>6. Are substantial interests in conflict?</li><li>7. Are fundamental principles in conflict?</li></ol>

**Table 1. Seven steps in ethical case analysis**

## Outcome analysis including cost and QALY estimates

In our second fieldwork, we found that the gestational age limit for treatment was as follows: no treatment to neonates born below 28 GAW, treatment to all above 32 GAW and between 28–32 GAW, decision making depended on medical and non-medical reasons. We wanted to make explicit the trade-offs made in these decisions, so in the third paper, we did an outcome analysis on relevant priority criteria for providing treatment to neonates born in week 28 and in week 32 in an Indian setting.

When evaluating the outcomes, we use four criteria that are discussed in the literature on rationing and about which we make an open assumption that fair-minded people will agree they are of central relevance: the severity of disease if untreated, effectiveness of the intervention, cost-effectiveness and strength of evidence concerning the first three criteria (204). Outcomes were estimated by a decision tree developed with the software ‘Treeage’.

Estimates regarding the severity of disease refer to the prognosis without treatment in the two GA groups. We could not find any studies on this outcome and relied on expert opinions from independent neonatologists, three working in India and three working in the US/Norway to arrive at the estimates. We report effectiveness both as a survival rate of live births in a hospital that provides neonatal intensive care until discharge, and the 5-year survival rate from live births at a hospital with a NICU. We estimate the mean effect per child who is admitted to hospital with a NICU in QALYs (Quality Adjusted Life Years). The survival rates are from the study hospital in our second fieldwork (registry-data). We validated the data against expert opinions from doctors at relevant institutions in India. The survival rates up to 5 years were given by the informants at the hospital and verified by external experts.

We wanted to calculate the effect of treatment and therefore we needed the prevalence of disability in the different gestational age groups. But there exist no published studies from India on the probability of developing disabilities for the

survivors in different gestational age groups. We therefore relied on a published study by Mangham et al. that relied on data from Wales and England (31). Their study presents absolute risk for death and disability up to 18 years of age under ‘optimal’ treatment conditions, and is among few studies that provide information about all gestational age groups. Disabilities in the Mangham study are defined as the presence of motor disability, which includes cerebral palsy, visual and hearing disabilities, and developmental delays/cognitive disabilities. Severity is graded according to no, mild, moderate and severe. The UK data indicate the risk of ending up in one of the four severity states. We combined these data with a Canadian study providing data on health-related quality of life for adolescents with cerebral palsy rated severe, moderate or minor (205, 206). For those with no disabilities, we used health-related quality of life data for a general population in Sweden younger than 30 years of age (207). We relied on data from other countries because of the lack of Indian data, but used a life expectancy in India of 62.8 years (208).

We applied a health system perspective on costs and include only the expenditures of the first hospital visit. Costs in the model were based on published empirical cost data from a large tertiary care hospital in India (73). In the cost analysis, costs were reported according to birth weight and we converted this to GA groups. Since Narang did not report costs for the 32- and 31-week-old neonates, we assumed costs were respectively 88% and 90% of the cost for the 30-week-olds, which is in accordance with the Mangham study.

Since we were not intending to deliver a full cost-effectiveness analysis, we did not provide any sensitivity analysis of expected high and low values of the included variables. To validate our findings, we compared our results with a health economic evaluation that looked at the cost-effectiveness of 15 different interventions to reduce neonatal mortality in infants from low-income families (8).

## **AIMS**

**General:** To describe and analyse end-of-life decisions for newborns in a context with resource constraints and non-Western culture.

### **Specific aims:**

**Paper 1:** To explore and describe how doctors in two neonatal units in India experience ethical dilemmas concerning the withdrawal of treatment among critically sick and/or premature neonates.

**Paper 2:** To describe how providers in an Indian NICU reach life-or-death treatment decisions.

**Paper 3:** To do an ethical analysis of two alternative answers to whether it is ever permissible to withhold or withdraw treatment of neonates older than 28 and younger than 32 gestational age weeks in India.





## **RESULTS (synopsis of papers)**

### Paper 1

#### **My job is to keep him alive, but what about his brother and sister? How Indian doctors experience ethical dilemmas in neonatal medicine**

In this paper, we explore and describe the nature of ethical dilemmas and how they are experienced in two state-owned neonatal units in India. We interviewed 14 doctors working in the neonatal department on their experiences of ethical dilemmas concerning the withdrawal of treatment among critically sick and/or premature neonates. In this study we used Giorgi's phenomenological approach in the analysis.

All doctors reported situations where the question of withdrawal of treatment was experienced as the worst part of their job. They felt that they lacked training in how to handle such dilemmas, and some had never talked about ethics before. They were especially concerned about non-medical considerations that do not feature in current treatment guidelines. In describing their personal experiences, the informants mentioned their sense of responsibility in situations where they were aware that their decisions would influence a family's economy and reputation, availability of food and education for siblings, other children's access to equipment in the unit and the use of resources in an underprivileged population. Sometimes lack of resources, usually ventilators, forced them to make decisions about which babies should get the chance to live. Other reported dilemmas included difficulties co-operating with uneducated and poor parents.

Working in a NICU in India is experienced as challenging and difficult, due to economic, medical and communication constraints. Relevant legal approaches seem

to be adapted from settings that are remote from the Indian context of scarce resources, high patient numbers and variety of cultures/religions. The informants refer to consequences for other children, for parents and society. They asked for context-specific guidelines that could protect them from the whole burden of being responsible for the decision to withhold treatment.

Our findings indicate that there is a need of increased awareness of well-known and context-specific ethical dilemmas when neonatal intensive care is implemented in a resource-poor context. We find that our informants experience different dilemmas when treating premature neonates than previously described dilemmas in Western countries. This illustrates the importance of studying dilemmas in local contexts and the value of empirical data in the philosophical debate.

## Paper 2

### **Impact of ethics and economics on end-of-life decisions in an Indian neonatal unit**

In paper 1, we found that end-of-life decisions were perceived as the most difficult ethical dilemmas by doctors working in two neonatal units in India. Little is known about how poverty and social values influence specific clinical decision making about life-sustaining treatment for premature neonates. The aim of the second paper is to describe in depth how life-or-death treatment decisions are reached in another neonatal unit in India. We did this by qualitative in-depth interviews, field observations, and document analysis at an Indian non-profit private tertiary institution providing advanced neonatal care under conditions of resource scarcity.

Compared to American and European units with similar technical capabilities, the unit studied maintained a much higher threshold for treatment initiation and continuation (ranging from 28–32 completed gestational age weeks). We observed complex, interrelated socioeconomic reasons influencing specific treatment decisions. Providers desired to protect families and avoid a broad range of perceived harms: they were reluctant to risk outcomes with chronic disability; they openly factored scarcity of institutional resources; they were sensitive to local, culturally entrenched intra-familial dynamics; they placed a higher regard on ‘precious’ babies and they felt relatively powerless to prevent gender discrimination. Formal or regulatory guidelines were either lacking or were not a controlling factor.

In a tertiary-level academic Indian neonatal intensive care unit, multiple factors external to predicted clinical survival of a premature newborn influence treatment decisions. Providers adjust their decisions about withdrawing or withholding treatment based on pragmatic considerations. Numerous issues related to resource scarcity are relevant and providers prioritise outcomes affecting stakeholders other

than the newborn. These findings may have implications for initiatives seeking to improve global neonatal health.

## Paper 3

### **End-of-life decisions as bedside rationing: an ethical analysis of life support restrictions in an Indian neonatal unit**

In our last paper, we did an ethical analysis of one key result described in paper 2.

We had found that that even for neonates born at 32 gestational age weeks (GAW), treatment is rationed, and multiple external factors influence treatment decisions. We question whether withholding life-saving treatment for children born between week 28 and 32 GAW is acceptable from an ethical perspective.

We do a seven-step impartial ethical analysis that includes an outcome analysis where we evaluated the treatment of neonates born at 28 and 32 GAW by using four accepted priority criteria: severity of disease, treatment effect, cost-effectiveness and evidence. The ethical analysis sketches two alternative answers. The first alternative is that it is not ethically permissible to limit treatment to neonates born between 28 and 32 GAW if we assign high weight to health maximisation and overall health equality. Neonates below 32 GAW score high on severity of disease, efficiency and cost-effectiveness of treatment if one gives full weight to life years gained for a newborn. It is in the child's best interest to be treated. The second alternative is that it may be acceptable to limit treatment for this gestational age group if we assign high weight to reduce welfare-inequality and maximising overall welfare, and/or if not assigning full weight to life years gained for a premature newborn. From a distribution-sensitive health- and welfare perspective, we would not accept the second alternative, as it relies on accepting the lack of proper welfare policies for the poor and disabled in India.

Our analysis indicates that an explicit priority process in India for financing neonatal care is needed. If premature neonates are perceived as being of less worth than other

patient groups, these reasons should be explored among a broad range of stakeholders.

## **DISCUSSION**

This PhD project has described and analysed ethically neonatal real-world end-of-life decisions in an Indian context. Main findings are: 1) End-of-life decisions are experienced as difficult ethical dilemmas. 2) Limits and reasons behind decisions to withhold or withdraw treatment of premature neonates are context specific and highly dependent on cultural and socio-economic factors. 3) The dilemmas of priority setting are more pressing than futility of treatment. 4) We question whether the limits drawn in one of the NICU we studied are ethically acceptable from a distribution-sensitive health- and welfare perspective. Two major limitations are present: 1) Findings are not easily generalisable to other settings. 2) No substantial ethical answers are provided; findings are only useful for policy makers and clinicians as background information for a fair deliberative priority setting process. In the next sessions follows in-depth discussions of methodological considerations and key findings of this thesis.

### **Methodological considerations**

#### **Fieldworks and qualitative analysis**

We find qualitative methods to be most appropriate for our study purpose due to the complexity of the phenomena we aim to describe and evaluate, our interest in the participants own categories of meaning and personal experiences, our emphasis on embedding decisions into a local context, and the importance of identifying contextual factors and how they relate to decision making. We also wanted to identify the dynamic process of how a broad spectre of reasons might influence end-of life decisions. However, several methodological considerations need further comments.

**Sample**

Our sampling strategy was a combination of purposeful and “snowballing” sampling strategy. One limitation is that the researcher might miss out important voices or get many with similar opinions. By spending time in the wards and observing concrete cases, we managed to sort out who was involved and tried to talk with them within a short time after decisions were made to get their immediate response. We thereby also bypassed recall bias (209). A major limitation of the sampling is the lack of interviews from the parents and other family members involved in decision making. That would have added valuable and important information to the study. The reason for excluding interviews with parents and family members was that the amount of data was already very large, and in this previously almost undescribed field, we wanted first to focus on health providers’ decision making.

**Registry-data**

Fortunately, the hospital in the second study had adequate registration of relevant data, which I had access to. This provided important contextual information, the triangulation of limits for treatment as reported by the informants and valuable quantitative data for the outcome analysis. One problem was that only certain factors were registered, and that different factors were registered in different registers in the hospital. The data in the register could itself be uncertain, as it depended on such factors as proper registration and accuracy as well as proper measurement and reporting of various facts, including gestational age and correct diagnosis.

**Reflexivity**

The effect of a researcher’s perspective and position is acknowledged in contemporary theories of knowledge (210) and there are disputes about the influence



of the beliefs of a neutral observer even within laboratory science. Subjectivity arises when the effect of the researcher is ignored (191, 194), and we have tried to provide insight into our backgrounds and preconceptions in all papers. Being a medical doctor could lead to preconceptions about how clinical decisions and reasoning are done, but I have never been in a neonatal decision-maker role, and we did not find this to be a major problem. To be a medical doctor seemed an advantage in securing the necessary trust and interest in involving the researcher in decisions and everyday routines. Being young and female seemed to partly bypass the hieratical barriers when relating to non-medical professionals, but on the other hand, provided less authority in formal situations. Two of the other authors (KJA and OFN) also visited the units and joined in some informal interviews and observations to validate the findings for the second paper. All authors are medical doctors with medical ethics as their academic field. We are especially concerned with priority setting in global health, and are working within a deliberative democracy tradition. This could bias our focus when in the field and influence our analysis. We have tried to assess these effects and share our understanding of them with the readers, a recommended strategy when committing to reflexivity (191).

We acknowledge the methodological challenges following from studying a complex, foreign setting, where, for instance, parents' consultations in the local languages had to be translated for me. There were, of course, a dilution of details and nuances I could not capture because English is not my first language, either. However, we found that the length of the stays in each setting gave me the opportunity to revisit things I found unclear when transcribing the interviews and looking through the field notes, reducing the number of misunderstandings and gaps in knowledge. The rigorous data gathering with respect to the context was another way of limiting misinterpretations.

We had developed questions to guide the individual interviews. One limitation of this might be that the questions do not manage to capture what we were interested in, were not understood or made the interviewees respond according to what they

thought the interviewer wanted to hear (209). Ideally, the process of data gathering continues until ‘theoretical saturation’ is reached (195); that is, until nothing new is revealed. We found that the length of stay in the second fieldwork provided enough time to explore the limits of treatment, but the nuances of the reasoning has still been insufficiently studied. To fully understand these nuances, we would have needed more time in the field and extensive background knowledge on the Indian setting, neonatology and decision theory.

We did not use a specific theoretical framework to analyse our results, comparing the main results with other empirical studies and themes discussed in the ethical discourse. But again, our theoretical background and the ‘reading glasses’ of priority-setting issues in the analysis should be openly acknowledged.

### **Validity**

Establishing external validity in qualitative research involves ascertaining if the results could be applied in other settings, by providing descriptions, notions or theories applicable within a specified setting (191). A discussion on who and what the findings actually relate to is a key component of external validation in an qualitative study (191). Description of the context and setting is important so the reader can determine what part of the information provides validity. We have described how a sample of doctors and nurses experience ethical dilemmas and make decision in neonatal units in India. We used the phrase ‘Indian doctors’ in the first paper, but we should have used the term ‘some doctors in India’ so that it could not be interpreted as an attempt to generalise. We have tried to emphasise the special context in which we conducted our studies, acknowledging that the diverse reality in India is unfamiliar for most readers. We would have liked to add more details on the study settings, but space limitations in the papers prohibited presentation of the richness and diversity in the material. We would have liked to visit the fields again and up-dated our findings. There has been overall development in India and increased health- investments focusing at neonatal health since we did our first fieldwork. Still,

according to our Indian collaborators there is a long way before NICU treatment is available for more than a small privileged group of neonates and hard choices continues to be made.

In addition, in our second study, we addressed the validity of our findings in four ways. First, we triangulated data from three different sources (documents, interviews, and observations) to maximise comprehensiveness and diversity. Second, the data analysis was reviewed and commented on by two groups: one group of professors and PhD students studying the qualitative method used in health research and one independent, interdisciplinary group of professors and PhD students (including physicians, anthropologists, bioethicists, health economists and health policy scholars) working on the ethics of priority setting in global healthcare. The role of prior assumptions and experience, which can influence any inquiry, were discussed and acknowledged. Third, all research activities were rigorously recorded to permit a critical appraisal of the methods. Fourth, a draft of the findings was distributed to some participants for comments on accuracy and reasonableness in the findings.

## **Ethical analysis**

We wanted to do a thorough ethical analysis of some of our empirical data concerning the gestational age treatment limit for neonates in one of the neonatal units in this study. To discuss all factors which we find relevant for an ethical analysis, we found no ethical analysis template to be sufficient for our purpose. As a consequence, we used elements from a broad spectre of analytical approaches, and identified evaluative criteria which aided in exploring the dilemmas from an impartial perspective. We found our analytical approach to be appropriate, making explicit the issues at stake and the consequences and ethical considerations involved, but acknowledge that there are several limitations to our approach. The conclusion in our ethical analysis depends on the validity of our preliminary outcome analysis. There

are several limitations in the level of evidence and availability of data to make a robust analysis, and our aim was not to make a full health economic evaluation.

As in the analysis of our qualitative data, the results and interpretations depend on the researchers' position and perspectives. Our medical background and theoretical affiliations frame our analysis. Our view on age weighting is an example on how our standpoint has a strong impact on the outcome of the analysis. We have tried to be transparent about our position and to reflect on the possible impact our background has on the results.

We analysed data that were collected in a foreign country, an unfamiliar setting for us. In one way this could be positive, preventing us from reaching a common understanding of what interests and principles to give the most weight to. On the other hand, the Indian subcontinent is a multicultural, value-pluralistic society, and we analysed the limit for gestational age through our Western, individual-focused, egalitarian 'lenses'. We also share a common understanding of a welfare state being responsible for its inhabitants, democratic traditions and a judicial system that functions adequate and can be trusted. Kopelman and Kopelman note the importance of discussing the role of 'cultural and value imperialism' in ethical dilemmas involving stakeholders with a different cultural background (211). They point out the need to acknowledge cultural diversity and different value sets in addition to sticking to some standards that are universal. They note how the United Nations puts respect for human rights at a higher value than respect for cultural diversity (211). According to Sen and Nussbaum, every human being has certain capabilities or real opportunities based on personal and social circumstance (114, 212). Nussbaum describe ten capabilities that all democracies should support, where life (that is being able to live a life at normal length, not dying prematurely) and bodily health is another (213). Poverty is understood as a capability deprivation (214). We are not in a position to say that our analysis is 'right'. We have tried to be explicit about our position and set of values. We acknowledge that the providers handled their dilemmas according to their set of values and their limited resources. We do not

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intend to criticise them for making ‘unethical’ decisions. However, we believe such decisions are so important that they need to be identified and discussed as ethical dilemmas.

Our analytical framework is not a procedural framework. Fair procedures are required to balance the different interests and principles and come to a conclusion that could be accepted as legitimate among a broad range of stakeholders. Our aim was to identify relevant factors in a limit-setting decision for further ethical scrutiny. If the framework is used in concrete dilemmas where a decision must be made, these factors may not be sufficient, and we argue that the fairness of decision-making process must also be evaluated.

## **Outcome analysis**

In general, most studies from low- and high-income countries seem to be limited to the extreme premature neonatal group, or report data for wider ranges of gestational age weeks or use birth weight instead of gestational age (32, 60, 215, 216). In the absence of any relevant, reliable published studies, the outcome data used in paper 3 had to be estimated and modelled. The empirical data on treatment and costs was gathered from different settings and years (and we did not discount them). We acknowledge that, for example, to use quality-of-life living with disability data from a Canadian setting is not directly transferrable to a person living with the same disability in an Indian village. The risks of disabilities among premature neonates are probably also higher in the Indian setting, due to suboptimal intrauterine and intrapartum conditions. The data used from England, Canada and Sweden were drawn from the most relevant studies we could find, and there is a general consensus in health economic practise that second-best solutions are needed in the absence of optimal data(217). We hope that the transparency and explicitness of the method used is sufficient to set forth our central concerns and promote further discussion. A

sensitivity analysis would have compensated for some of the uncertainty, but it was beyond the scope of the ethical analysis presented in the paper. We find that perhaps the most thought-provoking issue in our preliminary outcome analysis is its illustration of the scarcity of evidence relevant for policy makers and clinicians who make their judgements and decisions.

We recommend more follow-up studies concerning outcomes and costs neonates, families, communities, and hospitals in low income countries. Clinicians that are currently forced to practice bed-side rationing and policymakers that might consider population –level priority setting decisions ought to have better data to help rationally informed future decisions.

## Discussion of the results

In the first study we describe major ethical dilemmas in two tertiary neonatal units in India. We found that decisions to withhold and withdraw neonatal treatment were experienced as the most difficult dilemma by our informants. Our later field visits and second fieldwork confirmed this. That end-of-life decisions are perceived as a difficult ethical dilemma in neonatology is neither new nor unexpected. Previous studies have documented that physicians involved in life-or-death decision-making find this both professionally and personally challenging (28, 116). To our knowledge, our studies are the first documenting that physicians in India experience many of the same challenges as documented in other parts of the world. This similarity is important to acknowledge and explore further. Our study contributes to the existing literature: a better understanding of which factors made the decisions difficult and how these factors influenced the decision making in two Indian neonatal units. Previous studies from Europe and North-America show that decision makers in neonatology report that quality of life/sanctity of life, over-treatment, and the child's future and suffering are the most pressing ethical issues in neonatology (28, 128,

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131). Our informants gave little weight to these issues when encouraged to talk about the ethical challenges they have faced in neonatology. The ethical topics that were of most concern were: the perceived responsibility for the entire family's future and economy, priority setting, and the negotiation with poor and uneducated parents/families. Treatment restrictions for neonates in selected hospital units seemed to be left solely to the doctors without any procedural regulations. There were no appropriate national guidelines or legal regulations, and when asked, our respondents called for guidelines tailored to their situation and level of resource scarcity.

Poverty and socio-cultural challenges are more pressing in the setting studied than what previous end-of-life studies have described. Our study indicates that the context influences the experience of ethical dilemmas and the ethical reasoning concerning the child's versus the family's best interest. The special problem concerning the influence of gender on parental involvement illustrates the importance of providing in-depth studies of the dilemmas where they arise. Further studies are needed to confirm our reported variations in type of dilemmas, as well as how and to what extent the scarcity of resources, culture, religion, and education affect decisions.

In the second study we assessed the treatment-limits used and the underlying reasons for withholding or withdrawing treatment. We found that the gestational age limit for treatment ranged between 28 – 32 GAW in the unit we studied. This threshold is higher than typically described elsewhere (123, 218). Most obstetric and neonatal providers in US and Europe not resuscitate below 22 weeks gestation and many will object treatment below 23 weeks (23, 25, 129, 219). But after 25-26 weeks, most providers in these countries would agree that resuscitation and treatment should be given, even if the parents disagree. If so, the parents surrogate decision maker role can be set aside by law (123, 220, 221). In these situations, the core argument is to do what is in the best interest of the child (119, 124, 211, 222). Our informants found the family's surrogate decision maker role especially challenging in situations where they suspected that the gender of the neonate influenced the family's opinion on treatment. In the absence of a generous system of compensated health care delivery, individual,

social, and legal security, they could not solely adhere to an individualised, ethical commitment to the child and set the family's will aside. Additionally, moral commitment to family welfare above the good of individuals is having deep socio-cultural-religious roots across Indian society (134, 138, 223).

The dilemmas of priority setting were more pressing than futility of treatment in the settings we studied, which makes the end-of-life decision a form of bedside rationing. Our informants kept reminding us that with more resources, their limits would have been at lower gestational ages. In the Indian setting we visited, complex and intertwined social and economic reasons influence treatment decisions. Our informants aimed to protect families and avoid a broad range of perceived harms, and they had a high standard for "intact survival". We do not know the extent of these reasons in end-of-life decisions in India. Mani et al say about this: 'With little or no debate, so far, on the sensitive issues surrounding unwanted treatments, the ethical and legal implications of forgoing life support have remained unexplored in the Indian context'(224). Our study is too small to generalize how entrenched contextual factors influence decisions. Still, our findings suggest that such factors may have a larger impact on health outcomes for infants and children in the developing world than previously realized.

Paper three is an ethical analysis of the limits that were applied, which were presented in detail in paper two. We ask if it is ever permissible to withhold or withdraw treatment of neonates >28 and <32 gestational age weeks. Through our analysis, we try to make outcomes and the conflicting interests and principles explicit. We assign higher weight to the principles of health maximisation and overall health equality than overall welfare maximisation<sup>11</sup> and equality of welfare. We conclude that it is not ethically permissible to withhold treatment to neonates with

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<sup>11</sup> Withdrawal of life support can be used as a means to limit reduction in welfare for others if expected welfare loss for the whole family is in aggregate greater by letting the neonate live.



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such a severe condition, high effect of treatment, and probably of high cost effectiveness. However, we acknowledge that the weighting of the principles is dependent on our egalitarian standpoint, as well as the fact that we assign equal weight to all age groups. Stakeholders could legitimately disagree with us on: 1) The relative high weight we give to the principles of improving health and reducing health inequalities; 2) The relatively low weight we give to increasing overall welfare and reducing welfare inequalities; and 3) The high weight we give to life years gained for a newborn.

However, it would be challenging to legitimately disagree on the principle of gender or disability non-discrimination. In most cases, neonates that had a 20-30% risk of future disability were denied treatment. The informants' reasoned that these neonates have a poor prospect of being taken care of by their respective families or the society. Such reasons for not treating persons were found to be undescribed in the literature. In the ethics literature concerning late abortion of a fetus with anomalies or potential of disease, the arguments supporting abortion are that the condition is unbearable for the child itself, or for the parents (225). We found no support of late abortion by referring to the concern that the conditions will make the child's life miserable because the parents will not take proper care of him/her, and therefore it is better that the child dies. One could argue that poor neonates in India are victims of a triple-burden: 1) The burden of being born prematurely with the severe prognosis that follows; 2) The burden of being born in a society that can not take proper care of them if disabled; 3) The burden of not being offered NICU-treatment due to 1+2. Many of them also experience the burden of stigmatisation and all of the consequences that follow from being a victim of stigmatisation (50). It is beyond the scope of this thesis to pinpoint the discriminators; the international society, the Indian society, the hospital, the neonatal ward, the physicians, or the parents/family.

We accept the argument of giving high weight to improving/increasing overall welfare and equality of welfare within a society or family, and that this sometimes involves decisions resulting in neonatal deaths. However, our informants reason in a

slightly different manner when they let children die in order to increase the overall welfare of the family. In the first line of argument, the consequence is that the children die and in the second the consequence is that the welfare increases. The moral question here is: What are permissible means and consequences (226)? Stakeholders could legitimately disagree with us on this issue.

The recent load of evidence-based information on the effects and costs of interventions is necessary for policy makers in their scale up of interventions aimed at disadvantaged/at-risk groups. However, such information does not solve underlying value conflicts like the value of a newborn life versus an older child. The value conflicts we have highlighted and explored should be explicitly argued for, and the reasons should be explored among a broad range of stakeholders. The literature on fair political processes in health care policy development suggests that different theories of justice also deviate with regards to what they consider to be the fair and just course of action (185). For this reason, large health care institutes like NICE are attempting to implement fair processes in health policy decision making. They acknowledge that people disagree and that a fair conclusion can not be separated from a fair development process (227). Few resource-constrained settings have actual experiences with implementing fair processes (162). More debate, both theoretically and empirically, is needed on fair process in policy decision making in low-income countries. As our study indicates, a large patient group is at risk of being neglected in the priority debate because evidence and reasons have not been adequately subjected to reasoned scrutiny. Considering the current situation in India, with high burden of disease and significant resource scarcity, implementation of open and evidence-based processes is one possible way to go in policy making. Arguably, more, not less, is at stake in this setting compared to high income countries.

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## Lesson learned: The need for context-specific and resource-sensitive clinical guidance

In this study we found that concrete, yet controversial, decisions seem to be left to the unit, and in some instances, to the individual doctor on call. When asked, our informants suggested that context-specific, tailored clinical guidelines would help them to make better decisions.

The absence of nationally tailored guidelines, combined with a need for exploring the contested nature of reasons used, bring up two important fairness-questions: 1) Is it possible to sketch a fair and legitimate development process of clinical guidelines in this area?; 2) Are there procedural fairness criteria that can guide clinical decision making at a bedside level when legitimate macro priorities are absent?

The common understanding of clinical guidelines is that they are recommendations for best practise, through the use of criteria for evidence-based medicine, and in some instances, cost-effectiveness analysis. Several studies show that clinical guidelines implicitly function as a method to ration health care resources (228). Guidelines as a rationing tool are getting more attention among people dealing with priority setting in Europe and North-America (228-231). Norheim holds that ‘Economic or political decisions should not be disguised as clinical decisions’, and that rationing decisions based on guidelines could be acceptable if guidelines are developed through open and fair procedures (232). He argues that a fair guideline development process require one set of demands for the development procedure and another for the information available in the guidelines. Key criteria for an acceptable and fair development procedure are by Norheim considered to be: 1) available information about the development procedure; 2) involvement of a broad range of stakeholders; 3) influence on recommendations from economic or political decisions should be recognised and discussed; 4) decisions should rely on acceptable rationing criteria like effect of treatment, severity of disease, cost-effectiveness and level of evidence; and 5) information should be available and accessible to the public. These criteria

should be included in the development process of guidelines together with additional well established requirements of evidence-based medicine(233). If the guideline development process can be said to be fair and legitimate, the chances that the recommendations per-se are fair and just increases. Hence, guidelines can then more easily be directly applied as legitimate and concrete rationing tools aiding clinicians in handling tragic and conflicting dilemmas (232).

Whether it is possible to create clinical guidelines with concrete limits for gestational age or weight, and whether the clinicians will adhere to recommendations, remains important empirical questions. India has huge cultural, religious and economical variations. If guidelines are to be used in all settings, they need to be context specific in order to be implemented successfully, and to ensure that the values supporting the recommendations represent the stakeholders' actual values(234). That would imply that the specific resource constraint or patients' ability to pay should also be included. If guidelines are developed at a national level, they will need to be subdivided into a broad spectre of recommendations that considers the resource situation in the health institution. Alternatively, the general national priority setting guidelines could be developed, and one could leave the specific clinical guideline development to take place at a hospital level. Both versions could result in different limits between public hospitals even on the same level of care in the same city. Hospitals have varied budgets and patients differ in socio-economic status and their ability to pay – also in public hospitals – and stakeholders will disagree regarding which reasons should be given priority. Today, this seems to take place through implicit muddling-through processes. Would priority decisions differ if they were made through a fair process?

An alternative normative political framework for handling priority setting is Accountability for Reasonableness. Daniels and Sabin suggested that their framework, Accountability for Reasonableness, could be used to ensure that priority settings at the institutional level are fair and legitimate. The conditions set out for this framework are supposed to be acceptable to all reasonable fair-minded persons.

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According to Daniels, the fair conditions for legitimate outcomes in resource allocations are (185):

1. **Publicity Condition:** Decisions regarding both direct and indirect limits to meet health needs and their rationales must be publicly accessible.
2. **Relevance Condition:** The rationales for limit-setting decisions should aim to provide a reasonable explanation of how the organization seeks to provide “value for money” in meeting the varied health needs of a defined population under reasonable resource constraints. Specifically, a rationale will be “reasonable” if it appeals to evidence, reasons, and principles that are accepted as relevant by (“fair minded”) people who are disposed to finding mutually justifiable terms of cooperation. Where possible, the relevance of reasons should be vetted by stakeholders in these decisions – a constraint easier to implement in public than in private institutions.
3. **Revision and Appeals Condition:** There must be mechanisms for challenge and dispute resolution regarding limit-setting decisions, and, more broadly, opportunities for revision and policy improvement in the light of new evidence or arguments.
4. **Regulative Condition:** There is either voluntary or public regulation of the process to ensure that conditions 1–3 are met.

The crucial idea underlying this framework is that fair-minded people will accept that the basis of allocation decisions is relevant reasons when health care needs are to be met fairly under the constraint of scarcity. The goal for this kind of procedural decision-making would be to have all relevant information considered, and broadening the range of participating stakeholders. However, Daniels and Sabin stress that the framework should not be considered a substitute for democratic processes enacting the will of the people. Rather, the framework should be taken to

*facilitate* democracy in that '[t]he four conditions connect decisions at any institutional level to a broader educative and deliberative democratic process'(185).

If the guideline development is recommended to be on a local level, how can this be done? Hurst and Danis have specified criteria for fair bedside-rationing when there are no fair guiding macro decisions available for physicians (169). They hold that there are six minimal requisites in order to facilitate fair bedside rationing: (1) a closed system that offers reciprocity; (2) attention to general concerns of justice; (3) respect for individual variations, (4) application of a consistent process; (5) explicitness; and (6) review of decisions. These issues need to be respected to develop a legitimate process, as well as acceptable decisions by the clinicians. Hurst and Danis find that their framework is sensitive to the different versions of bedside rationing, and that the process could be monitored for its applicability and appropriateness(169). In addition, other writers highlight the need for exploring, developing, and regulating the decision making process at the clinical level, and to make doctors more aware of their role as distributors of limited resources, and the normative consequences of their decisions (133, 166, 235-237). Interestingly, there has been the same call for procedural guidance for making legitimate end-of-life decisions when there is a question of futility (238-240). To date, there are only few empirical studies describing the use of procedures for limit setting at the clinical level, either to prioritise or reduce futile treatment. We find that this will be an important area of research in both fields. We hope that our studies can inspire others to do this in contexts where the consequences of such decisions are particularly serious.

## CONCLUSION

Our empirical study and ethical analysis of end-of-life decisions in selected neonatal units in India provide new knowledge on health professionals' experience of ethical dilemmas, actual treatment limits and reasons behind decisions to withhold or withdraw treatment for premature neonates. Our perception of treatment restriction as a form of bedside rationing brings a novel perspective to the ethical discourses on surrogate decision making and futility. From a priority-setting perspective, I have asked if the limits set for premature neonates in the Indian context are fair. By using ethical method and theories on justice, I analysed this issue in detail. Understanding the relative weight given to meeting health needs for the worst off (the sick premature) versus improved overall welfare for the many (the family and other children in the hospital), and the reasoning underlying these priorities have been crucial. We cannot generalise our results to all neonatal units in India, but we believe our findings are relevant in all these contexts. We are not in a position to guide policy makers or clinicians in India on where to set the limits. We can only hope that our effort to make explicit what is going on in some influential institutions in India, by describing and analysing the dilemma, will be relevant for more informed decisions and priority setting processes.

There is an implicit denial of treatment for hundreds of thousands of neonates born every year. Many of the premature neonates who are born in resource-limited settings could have benefited from hospital treatment and would have survived if their needs were given priority. But in these settings, other patient groups' needs are viewed as more pressing, and scarce resources are distributed to other interventions. Severely premature and sick newborns are among the worst off in society in terms of severity of disease without treatment. Except, perhaps, for the extremely premature neonates (<28 gestational age weeks), treatment is efficient and cost-effective, even in a resource-limited setting. Although only a small fraction of the neonates born in India will be referred to a neonatal unit that can care properly for them, the services are

being increasingly provided and there is a growing awareness among people about newborns' health needs. My research provides a window into a future that policymakers and donors may soon face -- when basic care is available for all. I therefore argue that the cases from neonatal intensive care units in India provide insightful knowledge about the decisions to limit treatment for newborns in a context where treatment is scarce, but available, and the population is poor.

Our results will be of interest for people working with newborn health and global health challenges, but also for ethicists dealing with the ethical dilemmas of priority setting. A priority perspective on end-of-life decisions in neonatology will bring new aspects to a debate that traditionally focuses on the futility of treatment for patients. We hope our preliminary descriptions and analysis will inspire further research that will contribute to securing newborn and child rights born into the most disadvantaged circumstances, and to meet the real challenges that lie ahead for those of us seriously interested in meeting the MDG goals of reducing childhood, and specifically, newborn, mortality by two-thirds before 2015.



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