Extreme Prematurity

PRACTICES, BIOETHICS, AND THE LAW

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EXTREME PREMATURITY

Extreme Prematurity: Practices, Bioethics, and the Law examines the controversial issues surrounding the clinical management of this group of neonates through the intervention of modern neonatal intensive care. The forgoing of life-sustaining treatment is of particular importance. The subject matter is very relevant because of the alarming increase in multiple and preterm births, caused by the increase in women undergoing assisted reproductive procedures, and the large increase in premature labor. No recent book covers the subject in such comparable breadth.

The first section of this very timely monograph covers the epidemiology and practices in different parts of the world; the second section covers bioethics considerations, including ethical theories, moral principles, and quality-of-life issues; the third section covers national and international guidelines; and the last section covers medical law aspects in the United States and around the world.

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EXTREME PREMATURITY

Practices, Bioethics, and the Law

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FOR TRICIA

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PART 1

THE EXTREMELY PRETERM INFANT

Epidemiology, Perceptions, and Practices

1

INTRODUCTION

Three-year-old D is a vivacious small child who smiles and giggles freely. Her abdomen is criss-crossed with scars, the result of neonatal surgery for necrotizing enterocolitis for which she had surgical resection of some of her bowel. This was followed by the fashioning of an ileostomy that was closed at two years of age. There is also a scar over her left axilla, which followed a thoracotomy and the closing of a patent ductus arteriosus that had caused heart failure during the early neonatal period. She is the elder of twins, born at an uncertain gestation of 25 weeks weighing 810gs. Both babies were resuscitated at birth, but one twin died on day of life 4. Baby D received prolonged ventilation, required tracheostomy, and was discharged home on a ventilator after many months in the hospital. The daily nursing assistance the family received in their apartment was discontinued following the weaning of ventilation when the baby was aged 15 months. Her early years are remarkable for frequent visits to different specialists in the hospital who have monitored and managed her neurological development, pulmonary status, eyes, and gastrointestinal function. Her family, who have limited economic resources, have undergone the most challenging of economic and emotional strains, and although they have faced the challenges most often with determined stoicism and love, there has often been anguish. However, D has conducted her only known life with the full gamut of emotional sparkle and oppositional irritation that would be expected from any able-bodied child. She has done this without the use of speech – a consequence of her tracheostomy and her profound deafness, the latter perhaps related to either her prematurity or aminoglycosides she received during the neonatal period. She is now a candidate for a cochlear implant, an option that would not have been available only a short time ago. She has started to use consistent sign to communicate, and her nonverbal developmental quotient is within the normal range.

Five-year-old B was born at 24 weeks' gestation, weighing 580gs. At birth she did not breathe spontaneously, had a gelatinous feel to her skin, and could be held in the hand like a pound of butter. She was resuscitated and ventilated without much difficulty, and required about two weeks of intermittent positive pressure ventilation followed by a period of continuous positive airway pressure ventilation. She developed a grade II intraventricular hemorrhage, and following weaning from the ventilator there were many episodes of apnea and bradycardia, which responded to tactile stimulation. After 10 weeks in the hospital, she was bottle-feeding well and was discharged home one week later on an apnea monitor. During her early months, she was often an irritable baby who required frequent feeding, which was followed by episodes of regurgitation. The consequence of this gastroesophageal reflux was failure to thrive and choking episodes. The reflux failed to respond to medical treatment and after an admission to the hospital, because of severe aspiration pneumonia, she underwent a gastric fundoplication. Her irritability improved and she began to thrive. However, her development was relatively slow. She walked independently at 19 months and started to use two-word phrases at about three years of age. Her single-parent mother, who was aged 17 years at the birth of the baby, is now concerned and challenged because B demonstrates a reduced attention span, poor frustration tolerance, impulsivity, and emotional lability. These neurobehavioral difficulties have had an impact on her schooling, where she has difficulty staying in her seat, and with social interaction. Despite this, she is often a loving, affectionate child, with considerable charm. Psychometric evaluation was hampered by variable attention, but a minimum IQ level was measured at 86. There were some findings that suggested she may be at risk of demonstrating a specific learning disability, such as dyslexia, in elementary school. Despite her present difficulties, for which there are successful management strategies, and her extreme prematurity, she is expected to become an independent adult whose life will be governed by similar influences and fates that mould the outcome of any individual who was born normal at term.

J is a four-year-old boy who has recently started to walk using a walker. He is small, with relative undergrowth of the lower half of his body. He has a scaphocephalic head on which are perched thick glasses, and below these is an infectious open-mouthed grin, which is occasionally disfigured by a small amount of drooling. This, when he is reminded, is wiped away by an incoordinated splayed hand. He loves to demonstrate his walking ability and can hurtle down a corridor, albeit in an ungainly fashion, with hips and knees bent and knees knocking and on his toes. This is accompanied by much mirth shared by J and his onlookers. He is adored by his parents and two older sisters, and he adores them. J was born at 24 weeks, weighing 610gs. He required several weeks of artificial ventilation and developed a grade III intraventricular hemorrhage and pronounced periventricular leukomalacia. He required gastrostomy feeding for the first two years of his life, and he has had surgery for retinopathy of prematurity and for a strabismus. His cerebral palsy and poor development was apparent during the first year of life, and repeated cognitive assessments place him in the mild mental retardation range with non–gross motor developmental quotients ranging from 60 to 70. He is expected to achieve adulthood and live a life that, although requiring some assistance and protection by others, will be one in which he is competent in the activities of daily living and able to benefit from some basic education and training.

T is aged five years. He was born at 25 weeks' gestation, weighing 700gs. Resuscitation was achieved easily after birth, and he was ventilated with relative ease for about three weeks. On day of life 5, he had developed a grade IV intraventricular hemorrhage, which was accompanied by severe periventricular leukomalacia. By one month of life, he was breathing independently but was unable to feed and would later require a gastrostomy. It was soon clear that he would develop substantial neurological handicap. Severe spastic quadriparesis, anarthria, pseudobulbar palsy, microcephaly, and what appears to be severe mental retardation now confine him to a wheelchair. He is unable to feed himself and continues to be fed by gastrostomy. He is incontinent and cannot indicate his needs. However, he appears to respond to familiar voices and smile socially and laughs with his siblings. Successful voluntary movements are not possible, and any stimulus or attempt at movement invokes mass, uncoordinated, stereotypic postures. There are contractures in his arms and legs that hamper dressing, toileting, and hygiene.

These cameos are very familiar to anyone involved in neonatal care and follow-up. They represent some of the complications of prematurity, which vary in their severity and cause considerable individual, social, and economic burden. Although it is the severely disabled child that may be most readily remembered, this outcome is not the rule. However, all adverse outcomes become more likely as birth weight and gestation decrease. Survival rates for low birth weight and preterm infants are giving rise, it appears, to an increasing prevalence of childhood neurodevelopmental disability, including severe forms of cerebral palsy. This has raised bioethical and legal questions concerning this population of children. These include topical and debatable concepts such as the limits of viability, end of life decisions for those without capacity, futility, parental and physician autonomy, distributive justice, the role of statutory and case law, and so on.

For the purposes of this book, I define the extremely preterm infant (EPTI) as one who is born at less than 28 weeks' gestation. I also include the extremely low birth weight (ELBW) infant born weighing less than 1,000g. The two are not synonymous as the latter may include infants who are small for gestational age and more mature than the former. However, the literature includes both groups, and for the purposes of argument I do the same.

Extreme prematurity is uncommon, occurring in about 1% of live births(1). However, the moral dilemmas that arise from intensive care for EPTIs is a continuing cause for concern. Although, for some attitudes are fixed, for many the situation is fluid. But the question remains the same. How far should those go, who care for children, to preserve life at the inevitable expense to some babies, families, and society of disability, emotional trauma, and financial cost? Furthermore, attempts to answer this question are clouded by uncertainty arising from the limitations of early prognosis, variable and changing results of management, and differing subjective judgments from health professionals, parents, guardians, and the creators and arbiters of the law. Attempts to resolve the conflict are sought from religion, bioethics and moral philosophy, sociocultural acceptance of certain behaviors, and the law, both civil and criminal. But before these can be considered, it is necessary to briefly provide some history and then document the epidemiology of EPTIs, the perceptions of those involved in their care, and the resources expended.

2

HISTORICAL ASPECTS

Depending on cultural, religious, and socioeconomic circumstance, infanticide occurred throughout history.(2,3) During the classical period, infants deemed abnormal were left to die in the open,(4) and infanticide was not unusual up until the 20th century.(5,6) But as medical expertise and technology have become increasingly sophisticated, active measures are now taken to keep alive such infants, and the degree of this endeavor has mirrored changes in societal attitude. This is particularly evident for the EPTI. However, the requirement that physicians should not provide treatment that they believe will be of no benefit can also be dated back to the classical era, and there may well be a positive obligation not to do so. Hippocrates wrote that: "[W]henever therefore a man suffers from an ill which is too strong for the means at the disposal of medicine he surely must not expect that it be overcome by medicine," and, he continued, for the physician to provide treatment in such a situation was "allied to madness."(7)

And Plato, in *The Republic*, advised that the physician should:

> For those whose bodies were always in a state of inner sickness he did not attempt to prescribe a regime . . . to make their life a prolonged misery . . . medicine was not intended for them and they should not be treated even if they were richer than Midas.(8)

Out of this history has arisen a requirement to care for the EPTI, but not to oblige a physician to provide treatment that is perceived as not beneficial. However, because of differing beliefs, perceptions, and interpretations, there may be a conflict between the requirement and the obligation.

3

SURVIVAL

From 1980 to 2000, the infant mortality rate in the United States has been reduced from 12.6 to 6.9 per 1,000 live births.(9,10) This has occurred with an approximately 17% increase in preterm birth rates,(9,11) and reductions in mortality have been highest for those with the lowest birth weights.(9) This has been mainly attributable to gains in technology as well as improvements in medical practice.(12–15) ELBW infants account for nearly half of total perinatal mortality, despite being only a very small percentage of total live births.(16) Much of the improvement in mortality has occurred in the very and extremely preterm groups.(17,18) There can be considerable variation in the results of studies reporting mortality for the EPTI. To some extent this is governed by the conduct of the studies,(19,20) for example, whether the figures reported include total births, live births, or neonatal intensive care unit (NICU) admissions; whether the numbers were small or based on geographic populations; and whether there were consistent approaches to management. Clearly this variability may introduce uncertainty and incomprehensibility into the counseling of parents. Furthermore, one can speculate whether it might encourage a paternalistic use of figures by physicians, when counseling, allowing for a reflection of their biases. One physician might aggressively resuscitate, whereas another might not.(21,22) But most well-conducted studies quote similar figures, or if there is variability, explanations can be found. More recent improvements in survival are particularly notable for those born at less than 26 weeks' gestation. Reasons for this include the use of surfactant and steroids and an increase in the provision of artificial ventilation, as well as a change in attitudes.

In the United States, during the 1990s, survival for infants born at 24 weeks' gestation was reported as 33–57% and at 25 weeks was 60–75%.(21–29) In the NICHD Neonatal Network Study, the findings were that babies born during 1994 to 1995 weighing 501–800g have a mortality rate of 43%, and 15% of these were not artificially ventilated.(30) The reported survival for those born at 23 weeks is 20–25%, with reports in some centers of 41–48%.(31) El-Metwally, Vohr, and Tucker determined the survival rates of infants born at 22 to 25 weeks' gestation during the 1990s in Rhode Island.(21) The rate of fetal death (stillborn) was 24%. Of those born alive, 46% survived to discharge. Survival rates, including fetal death, at 22, 23, 24, and 25 weeks were 1.8%, 34%, 49%, and 76% respectively; and excluding fetal death, they were 4.6%, 46%, 59%, and 82% respectively. In addition to gestational age, variables associated with increased chances of survival were birth weight, female gender, and the use of surfactant. These authors concluded that it was important, when considering survival rates at the limits of viability, that interpretation took account of whether all births or just live births were analyzed. This was a retrospective study and there were circumstances where treatment decisions could affect outcome. For example, if the infant had no heart rate at birth, resuscitation often was not started, although, as the authors wrote: "[O]ccasionally chest compressions were started and resuscitative medicines given if the neonatologist thought the infant appeared more mature than the estimated gestational age, or if requested by parents." Thus it appears that survival at 22 weeks' gestation is extremely unusual, although it does occur,(21,32) but it dramatically increases for each week of gestation.

In a Canadian report of infants born weighing less than 500g, between 1983 and 1994, 25% were not given intensive care and all died.(33) In 2001, Chan et al. reported survival rates for EPTIs from 17 Canadian NICUs(34) born at less than 26 weeks' gestation from 1996 through 1997. These EPTIs were 4% of NICU admissions, but accounted for 22% of deaths. Of the 949 EPTIs delivered, 42% died in the delivery room. The percentage of those admitted to the NICU increased from 20% at 22 weeks to 91% at 25 weeks. Survival rate after admission was 14% at 22 weeks (range 0–33%), 40% at 23 weeks (range 0–100%), 57% at 24 weeks (range 0–87%), and 76% at 25 weeks (range 57–100%). The overall survival rate for all infants was 1% at 22 weeks, 17% at 23 weeks, 44% at 24 weeks, and 68% at 25 weeks. Of interest was the finding that surviving lower gestational age infants had fewer low Apgar scores, which, to the authors, suggested that resuscitation bias may have existed. In another Canadian study, Effer and colleagues published the survival rates of 860 live births born at 24 and 25 weeks' gestation from 13 tertiary centers.(35) At 24 weeks, survival was 56%, and it was 68% at 25 weeks.

Figures from Japan show impressive improvement over time. Japanese neonatal mortality rates have fallen from 27.4 to 2.3 per 1,000 live births between 1950 and 1993, and in 1991 the survival of infants born less than 1,000g reached about 72%.(36,37) For 1,655 infants born with birth weights less than 600g between 1984 and 1993, studied by Oishi, Nishida, and Sasaki,(38), about 28% survived to hospital discharge. Of those born less than 24 weeks, 17% survived, and of those over 24 weeks about 36% survived. The survival rate for those less than 600g increased, when surfactant therapy became widely available, from 22% in 1988 to 33% in 1989. The majority of deaths (68%) were within the first week of life, and only 10% died after the neonatal period. Improved survival for the smallest and most immature EPTI was likely also affected by the Japanese Eugenic Protection Act, which defines the fetal viability limit as "minimal duration of gestation which renders fetuses capable of extrauterine life."(39) This was amended to 22 completed weeks in 1991.

In Australia, survival rates for the EPTI are similar to those found in recent reports from other developed countries.(31) In a study from Melbourne,(40) Gultom and colleagues reported changes over time in attitudes to treatment and survival for infants born at 23 to 27 weeks' gestation. The authors noted increases in survival rates over time and more frequent active management of labor for gestations, they stated, that were previously considered as nonviable. Overall, 85% were treated intensively, but the proportion rose from 74% in 1983–1985 to 91% in 1992–1994. In 1983–1990, 51% of live born infants born 23 to 27 weeks' gestation died, and this decreased to 28% for those born from 1992 to 1996.(41) The authors' conclusions were that improving survival rates were not only because of treatment factors such as antenatal steroids and exogenous surfactant, but also because of a willingness to treat the EPTI intensively.

In the large United Kingdom (UK) and Ireland population-based study, reported in 2000 by Wood and colleagues,(42) data was derived from 4,004 births born between 20 and 25 weeks' gestation. There were only 1,185 live births, of which about one-third died in the delivery room, and a further 43% died in the hospital. That is, the survival rate overall was only 27% for live births and 39% for those admitted to intensive care. For this latter group, intensive care was withdrawn from 55% who died in the unit. Consistent criteria for this were not documented. In a 2002 report from Paris, France,(43) on infants born between 24 and 28 weeks' gestation, about one-third died before discharge. All received resuscitation at birth. Survival was most affected by birth weight, with 42% surviving below 700g and 83% above 900g.

4

INFLUENCE OF OBSTETRIC MANAGEMENT

How physicians, in particular obstetricians, view and assess viability can affect perinatal survival figures. In an American study(44) that examined the relationship between obstetric care during labor and delivery and the survival of EPTIs, the authors compared the outcomes of those who were considered viable antenatally and those who were not. The factors evaluated in the judgment of viability were estimated age (> 26 weeks) and estimated weight (> 650g), lethal anomalies, and parental requests. In the total population studied, some were misclassified (usually weight estimation), or parents had requested aggressive management or the opposite. This "allowed" the authors to study the survival of infants who, by their standards, would have been considered nonviable but who received antenatal and perinatal care as if they were viable. Although in some groups the numbers were small, the chances of survival were strongly associated with the antenatal assessment of viability. The odds of survival for all fetuses treated as viable were 17 times the odds for those considered nonviable. Birth weight alone did not explain wholly the relationship between antepartum viability assessment and outcome. Thus, in this study, survival of the EPTI was related to judgments of viability that determined their care. Silver et al. also published similar findings.(45) These studies, which had relatively small numbers, do not suggest that there is no limit to fetal viability, but they do caution the reader to take into account obstetric management strategies when examining figures concerning the outcome of the EPTI. Obstetricians evaluate antenatal data to make decisions concerning the management of an anticipated extremely preterm delivery. Bottoms et al.(46,47) evaluated whether antenatal information could accurately predict the survival of ELBW infants with and without major morbidity, using data collected in 1992–1993. The reported findings were that the willingness of an obstetrician to perform a cesarean section at 24 weeks' gestation was associated with an improvement in survival from 33% to 57%, but the risk of serious morbidity doubled from 20% to 40%. Survivals, and survival without disability, were significantly better when birth resulted from active medical management, compared to a passive approach, with or without cesarean section. The use of prepartum ultrasonographic data could not reliably distinguish who would survive without serious morbidity, although there was a threshold below which no survivors were found.

5

EFFECT OF RESUSCITATION IN THE DELIVERY ROOM

In 1996, Rennie wrote that outcome after full cardiopulmonary resuscitation (CPR) following delivery of a very preterm infant was “appalling.”(48) Her justifications for this conclusion were reports published in the early 1990s. In one, from Manchester, England, three of five babies born less than 28 weeks’ gestation, who received full CPR, including adrenaline, died and the survivors were handicapped.(49) In a report from Oklahoma, there were no survivors of very low birth weight (VLBW) infants who required more than one resuscitative attempt.(50) In similar circumstances there were only two normal survivors, during the years 1989–1993, reported in a study from Cambridge, England, and all six infants given full CPR in Ottawa, Canada, with birth weights less than 750g, during 1989–1992, died.(51) In sharp contrast to these reports are later ones that suggest that condition at birth of an EPTI may not be a good indicator of viability or later outcome.(52) Jankov, Asztalos, and Skidmore evaluated whether vigorous resuscitation of ELBW infants at birth improved survival or increased the chances of major neurodevelopmental disability. They reported the outcome of a group of infants born weighing

750g or less who received CPR (positive pressure ventilation, cardiac compression, +/− adrenaline) in the delivery room. About 57% survived, and 88% were free of major neurodevelopmental disability at follow-up.(53) Similar findings have been published by several other authors(54–56) and it does appear that CPR in the delivery room for the EPTI does not necessarily lead to a large decrease in survival or an increase in major neurologic sequelae compared to those who survived following only intubation and positive pressure ventilation.

6

NATIONAL COMPARISONS

Outcomes for the EPTI may differ from country to country; the reasons include economic resources and access to sophisticated technological care in developing countries and varying attitudes and perceptions in the more developed countries. The latter will be discussed later in this chapter, but here I briefly document findings concerning the Netherlands and survival in some developing countries. Lorenz et al.(22) reported on the outcome of EPTIs born less than 26 weeks in two population-based cohorts, New Jersey (NJ), United States and the Netherlands, who received systematically different approaches to their care during the mid-1980s. In the NJ cohort, almost all babies received intensive care, whereas the policy was more selective in the Netherlands. Assisted ventilation was more commonly used in NJ, 95% versus 64%, and almost all the difference resulted from the use of assisted ventilation in infants who subsequently died. Mortality at 28 days was about 46% in NJ and 73% in the Netherlands. No infant less than 25 weeks' gestation survived to 28 days in the Netherlands. Survival to 2 years in NJ was twice that in the

Netherlands. The prevalence of disabling cerebral palsy was 17.2% among survivors in NJ and 3.4% in the Netherlands. In the NJ cohort, 1,820 ventilator days were expended per 100 live births compared to 448 days in the Netherlands, but the difference in nonventilator days was not statistically different. In summary, the management approach in NJ resulted in 24 additional survivors per 100 live births, 7 additional cases of disabling cerebral palsy per 100 live births, and at a cost of 1,372 additional ventilator days per 100 live births.(22) That there is a significant difference in approach to the management of the EPTI in the Netherlands compared to NJ that is of great consequence is clear. How this is accomplished can be found in an article by Van der Heide and associates published in 1997.(57) They reported on end of life decisions for neonates in the Netherlands, and although only some of the babies were EPTIs, it does reflect attitude and practice. In the report, they stated that 57% of all infant and neonatal deaths had been preceded by a decision to forego life-sustaining treatment, and was accompanied by the administration of potentially life-shortening drugs to relieve pain or other symptoms in 23% and by the administration of drugs with the explicit aim of hastening death in 8%. Parents were involved in 79% of decisions.The most common reason for not involving parents was stated as “it was so obviously the only correct decision.”(57)

The rates for neonatal mortality differ between developing and developed countries, as does the practice of neonatal care. Most worldwide neonatal deaths occur in the developing world, and at least one-third of these are in preterm infants.(58,59) In a study published in 2003,(58) the mortality rate for infants born at 28–29 weeks was 478 per 1,000 live births in a geographically diverse group of developing countries (Brazil, Colombia, Thailand, India, and the Philippines) compared to 83 in two developed countries

(United States, Ireland). In the developing countries, interventions such as surfactant, ventilators, blood gases, and oximetry were variable, and several physicians considered pregnancies less than 28 weeks nonviable. How physicians judge viability affects perinatal interventions and mortality not only in developed countries but also in developing ones.

7

PREDICTION OF OUTCOME

There can be substantial error rate when physicians estimate outcome for the EPTI.(60–63) Tyson and associates(30) reported error rates of 52% and 21% in the prediction of death and survival for infants weighing 501–800g at birth. Despite the requirement that physicians practice according to the best available evidence, this may not always be the case, and in such circumstances they may incorrectly estimate the chances of death and disability,(64) which affects their decisions as well as the counseling of parents.(44,60)

In 2001, it was reported that at the University Medical Center in Leiden, a leading center for the the treatment of preterm infants in the Netherlands, a decision, in principle, was taken to stop active intensive treatment of babies born less than 25 weeks' gestation.(65) However, the head of neonatology at the center stated that, "infants born before 25 weeks would still be given 'vigorous support' if the parents wished and the medical team considered the infant viable at birth."(65) The decision was made because, in their study of premature births from 1996 through 1997, 66% of those born at 23 and 24 weeks died, and half the survivors had severe physical or mental handicaps.(65)

8

LIMIT OF VIABILITY

Although there is no sharp demarcation point, over time the limit of viability has become progressively lower, from a birth weight of 1,500g before 1940, to 1,000g and 28 weeks' gestation by the 1970s.(20) Survival is now common for infants of less than 750g and for those of 25 weeks' gestation. The lower limit of viability appears, at present, to be approximately 22–23 completed weeks of gestation, with survival and morbidity improving markedly with each later week of gestation. It is now governed by technological capacity, medical intervention, and the attitudes of the medical profession.(63,66)

9

MORBIDITY

Extremely preterm birth is associated with several morbidities ranging from the very severe to the relatively mild, and the risk increases as gestational age decreases.(67) The morbidities include cerebral palsy, mental retardation, learning and language disability, disorders of attention and behavior, visual and hearing impairment, chronic lung disease, gastrointestinal dysfunction, and poor growth.(68–74) Furthermore, survivors may require prolonged hospital stays, in-home nursing and technological services, and societal and state support, all of which add to emotional and financial family burdens.(75,76) Although there is some relationship between disorders of higher brain function and psychosocial, socioeconomic, and environmental factors,(77,78) there is now substantial evidence that neurodevelopmental disability arises from poor brain development apart from frank parenchymal brain injury. Former EPTIs have been reported to show decreased regional brain volumes, compared to term controls, including reduced volumes of cortical gray matter, the hippocampi, and corpus callosum, in addition to an increase in the size of the lateral ventricles,(79–87) all of which have adverse neurodevelopmental correlates.

Many articles have documented the short- and long-term outcome of EPTIs. However, as with reports on survival, there can be variability in the results both within and between countries. The causes include variable perinatal and neonatal practices; case ascertainment and attrition rates; gestational age limits and birth weight restrictions; age at follow-up; diagnoses sought; criteria for disability with differing definitions and inclusions; and the use of different methodologies when assessing outcome, including a failure to use concurrent norms.(20,31,88–93) But despite a plethora of outcome studies, there is a relative dearth of reports on the functional outcome of disabilities and their effect on quality of life.(31,94) The characteristics of different national populations studied, and the conduct of their health delivery systems, may also appear to affect the statistics reported, even when these populations are geographically close. Field and colleagues(95) compared the neonatal intensive care services of two European countries, the UK and Denmark, during the period 1994–1995; these countries have different approaches to neonatal intensive care. The populations compared were live born infants 22–27 weeks' gestation or less than 1,000g. The British services were more centralized and specialist based, but they had higher rates of prematurity and sicker babies with worse outcomes, despite the delivery of more intensive care. The authors rejected the notion that this was the result of systematically worse care and suggested it was "a reflection of innate reproductive health in the two countries" and social circumstances, as the teenage pregnancy rate was about four times higher in the UK,(96) as well as the lower social spending per head of population.(97)

El-Metwally et al.(21) determined neonatal morbidity rates for infants born in Rhode Island, United States, during the 1990s, at 22 to 25 weeks' gestation. The rate of severe intraventricular hemorrhage or periventricular leukomalacia was 27% but was higher at lower gestational ages. Chan and associates(34) reported the neonatal morbidity for babies born less than 26 weeks, in 17 Canadian centers, during 1996 and 1997. Major neonatal morbidity, defined by the authors as grades III or IV intraventricular hemorrhage, stage 3 or worse retinopathy of prematurity (ROP), chronic lung disease, and necrotizing enterocolitis, was found in some form in 77%. The percentage was 89% at 22 weeks and 71% at 25 weeks. As with survival, there was wide intercenter variation with survival without major early morbidity ranging from 0% to 26%. Vohr and associates, in a U.S. multicenter cohort study,(98) reported the outcome of 1,151 ELBW infants at a corrected age of 18 to 22 months. This number represented only 78% of the total survivors, which could represent an underestimate of the disability rate.(91) Abnormal neurologic examinations were found in 25% and an abnormal Bayley Mental and Psychomotor Developmental Index of less than 70 in 37% and 29% respectively. Vision impairment occurred in 9%, hearing impairment in 11%, and cerebral palsy in 17%. The probability of abnormal neurological findings increased as birth weight decreased – 25% for birth weights 901–1,000g and 43% for those weighing 401–500g. The risk of cerebral palsy also increased with decreasing birth weight – 15% for 901–1,000g and 29% for 401–501g. In a prospective population-based study from the UK and Ireland, Wood et al.(42) published the outcome of infants born less than 26 weeks' gestation during a 10-month period, beginning in March 1995, who were admitted to a NICU. The survivors were assessed at a median age of 30 months after the expected date of delivery. The mean Bayley Mental Developmental Index was 84 +/— 12, and the mean Psychomotor Developmental Index was 87 +/— 13. Nineteen percent of the children had scores more than 3 standard deviations below the mean and were classified as severely disabled. There were 11% who scored between 2 and 3 standard deviations below the mean ("other disability"). Interestingly, the scores did not vary substantially with gestational age, but boys had significantly lower psychomotor scores than girls. Cerebral palsy was diagnosed in 18%, and in about one-half of these it was characterized as severe. Again there were no differences related to gestation. About 2% were blind, and 3% had uncorrectable hearing loss. Overall, 23% were reported to have severe disability in the developmental, neuromotor, sensory, or communication domains. In a multicenter study involving NICUs in Canada, the United States, Australia, and Hong Kong,(99) on infants born weighing 500–999g between 1996 and 1998, 18% developed cerebral palsy, 26% had cognitive impairment, 2% had hearing loss requiring amplification, and 2% had bilateral blindness. In San Francisco, Piecuch et al.(100) reported on 24- to 26-week gestation survivors. About 25% had a developmental quotient of less than 70, and 14% had cerebral palsy. When the same group reported on a larger number of infants of ELBW born between 1979 and 1991, and reported on in 1997,(101) about 14% were reported to have cerebral palsy, 1% were blind, 0.2% were deaf, and 14% had cognitive dysfunction. Other reports have placed the risk of cerebral palsy at early follow-up as between 7% and 18%.(102–106)

10

SCHOOL AGE OUTCOME

There have been several reports of follow-up to school age, as well as into adolescence, which show some variability in their results for the reasons previously stated. Although major disability does not occur in the majority of survivors, when they reach school age, a high percentage appear to experience functional impairments, including disorders of higher mental function, that affect education and behavior.(78,90,107–109) Psychosocial and socioeconomic factors may also play a role in these outcomes.(78) The Victorian Infant collaborative study from Australia(90) reported that the IQ of their extremely preterm study group (gestation less than 28 weeks, birth weight less than 1,000g) was within the normal range but averaged about 9 points less than abnormal birth weight control group. In the preterm group, poorer scores were found in verbal comprehension, perceptual organization, freedom from distractibility, and processing speed. The infants were born in 1991 and 1992, and although they have lower mean test scores than normal birth weight controls in reading, spelling, and arithmetic, these scores were much improved when compared to earlier previous reports. Saigal and colleagues, from Canada,(110) reported on the outcomes of ELBW infants at 5.5 years. Their findings were that 9.5% had cerebral palsy, 4.8% were blind, and 20% had mental retardation. Using the Vineland Adaptive Behaviour Scales they found that approximately 8% were significantly functionally disabled (composite score more than 2 standard deviations below the mean). Areas of limitation included motor skills, activities of daily living, communication, and socialization. In a similar population at a similar age, Msall et al., from the United States,(111) found that 5% had cerebral palsy, 10% had mental retardation, 1% were blind, and 5% had multiple impairments. Basic functional limitations were uncommon, and most functional disability was mild to moderate.(112) However, when actual school performance is examined many authors have found that nearly half of EPTIs require resource or special educational support at some time.(68,98,110,113,114) In 2003, Saigal et al.(89) compared the outcomes of infants born weighing 500–1,000g in four international population-based cohorts and reported their cognitive abilities and school achievement. The four cohorts were from central New Jersey, central-west Ontario, Bavaria, and Holland. Adjustments were made for comparison of all measures based on reference norms within each country. The live births in the United States and Canadian populations were more immature and smaller than those in the European groups, although the survival rates were similar between the international groups, ranging from 44 to 45%. There were also differences between the populations when neonatal management was compared, and some of these differences were striking. The proportion of survivors ventilated in Holland was 53%, and in Bavaria, New Jersey, and Ontario, it was 95%, 93%, and 82% respectively. The median number of days of ventilation was 6 days in the Dutch group, compared with 16 days in New Jersey, 32 days for Ontario, and 38 days for Bavaria. There were also differences in the length of hospitalization. As the authors stated: neonatal intensive care was most aggressive in Bavaria, and then Ontario and New Jersey, and more selective in Holland. The prevalences of cerebral palsy, deafness, blindness, and mental retardation more than 3 standard deviations below the mean were recorded as 22%, 27%, and 25% respectively. The prevalence in the Dutch population was 11%. The cerebral palsy rates were 19% for New Jersey, 13% for Ontario, 16% for Bavaria, and 8% for Holland. Although a significant number of children, who were ELBW, have serious neurodevelopmental disabilities, the majority do not, and the rate is least in the Dutch population. However, when cognition and achievement, in those without serious neurodevelopmental disability, is evaluated, high numbers fall below the normal range. Overall, the percentages of children who performed within the normal range on IQ testing ranged from 44% to 66%; for reading the range fell between 46% and 81%, arithmetic 31% and 76%, and spelling 39% and 65%. Those from New Jersey had the highest cognitive and achievement results, and those from Bavaria the lowest, relative to their peers and the other populations. It should be noted that for New Jersey the ascertainment rate for psychometric testing was only 60% compared to 87% and 90% for the Bavarian and Ontario research subjects. It has been reported that similar nonparticipants in other studies are more likely to have intellectual and behavioral difficulties.(115) Furthermore, the Canadian and German researchers used concurrent norms whereas the U.S. researchers used older standardized test norms, which may have produced overestimations. What is clear is that ELBW and EPTIs may perform poorly on tests of school performance in all of the four populations. Whereas these figures might provoke a fear of socioeconomic burden within the populations examined, it should be noted that the total numbers of survivors are relatively small, ranging from 397 in Ontario to 263 in Bavaria.

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ADOLESCENCE

There have been a number of studies documenting adolescent outcomes. Most of these adolescents do not have major motor, sensory, or intellectual handicap, but as a group, they do not fare as well in school as their normal birth weight peers. However, they do not view their quality of life as different.(116) A 14-year follow-up study of ELBW infants born during 1970–1980 was reported from Melbourne (117) and compared to a normal birth weight control group. Survival rate was 25%, and of the survivors 10% have cerebral palsy, 6% are blind, 5% are deaf and required hearing aids, and 46% have an IQ score more than 1 standard deviation below the mean compared to controls. Overall, 14% are severely disabled. In a Canadian population of ELBW infants followed into adolescence,(118) 28% had neurosensory impairments compared to 1% of term controls. Reading scores were significantly low in 38% of those born less than 750gs and 18% of those born weighing 750 to 1,000g compared to 2.5% of terms controls. Special educational services were required at some time in 50% of the study group and 10% of the controls. The ELBW cohort tended to be smaller and use health and educational resources far more than controls.(119) Similar findings have been reported from Britain(120) and the United States.(121,122) However, although adolescents who were born extremely preterm are more likely to have to cope with more health and educational challenges, studies on quality of life seem to demonstrate that most of this group do not feel that their quality of life is very different from others.(123,124)

Despite some variability in the reported rates of impairment and disability, a reasonable figure for the rate of major disability among survivors of extremely preterm birth is 20–25%(125) and for cerebral palsy 10–18%.(126) Even more common are disorders of higher mental function such as attention deficit and specific learning disabilities, which can occur in more than 50%.(127–129) However, local results should be taken into account when counseling parents, and it is thus incumbent on those who run NICUs to collect these data and make them available.

12

PERCEPTIONS AND PRACTICES

It has been stated that the decisions to forego life-sustaining treatment for an EPTI should be a joint one combining the knowledge of the physician with the wishes of the parents.(130) But the purported decision makers are not homogeneous groups, the knowledge of the physicians is not necessarily reliable or certain in all cases, and the wishes of all parents are also not necessarily realistic or reasonable. There are different times at which a decision to forego life-sustaining treatment could be made. The first is at the time of birth, although obstetric decisions prior to this might affect the perinatal outcome. But at birth, there is often a competent team of doctors and nurses who initiate resuscitation, often perhaps without all the information required for prognosis. Birth weight may be only estimated and gestational age uncertain. Even so, care is not rendered only when absolute success is assured. As Lorenz and Paneth wrote,(131) treatment of the EPTI often falls into one of the three categories. The first is where most would treat. The second is where most would not treat, and a third group exists where there is variability and disagreement. They also noted that the personal characteristics and views of the physicians strongly influence their decision making, and that they may impose their own values on the family. But the situation is one in which there is often uncertainty. Because of this, many neonatologists, Rhoden wrote,(132) follow a "least-worst" strategy, that is, intensive care treatment followed by repeated prognostic evaluation and a decision on whether to treat or withdraw care. But there are still problems with this approach as it assumes the ability to very accurately predict prognosis, which is often not the case, and the question of deciding between a quality of life decision and the worth of life still exists.

In a study from the United States in 1997, Wall and Partridge(133) reported the frequency of selective nontreatment of extremely preterm, critically ill, or malformed infants in the NICU at the University of California San Francisco between 1989 and 1992. There were 108 infant deaths, the majority of whom were ELBW, following the withdrawal of life support, and 13 deaths followed the withholding of treatment. These deaths represented 73% of the total deaths, the others occurring while the infants continued to receive maximal life support. For 74% of the deaths attributable to foregoing of life-sustaining treatment, the reasons given were that death was imminent and treatment was futile. Quality of life concerns were also given as reasons in about one-half of these. Quality of life was the only reason given for limiting treatment in 23% of the deaths ascribed to foregoing of life-sustaining treatment.

Despite an aversion toward allowing the courts to interfere in the practice of medicine in the United States, some physicians may still act in accordance with a fear of litigation. In a study reported in 2002,(134) Ballard and colleagues surveyed a large representative population of U.S. neonatologists on whether they would be willing to resuscitate a hypothetical 23-week gestation baby weighing 480g. With no information about the parents, 47%

thought that resuscitation was "the most appropriate treatment." If requested by the parents to "do everything possible," 91% would resuscitate; however, if the parents requested them "to provide comfort care only," only 11% would resuscitate. From these figures, it appears that there is a clear desire to respect parent requests. On further questioning and analysis, the authors showed that a perceived risk of litigation (litigious parents) influenced the possible action of several physicians whose initial judgment was not to resuscitate and who had predicted a very poor prognosis. These physicians were more likely to follow parental wishes if there was a perceived risk of litigation. This did not apply to those whose initial uninfluenced judgment was to resuscitate. They indicated that they would defer to parental requests regardless of how they might perceive prognosis or the risk of litigation. Thus in some circumstances, some physicians in the United States, as stated by the authors, "may resuscitate infants against their better judgment," if they believed the parents were litigious. The converse also applied. If the physicians were informed that the parents were unlikely to be litigious, and were "easy to deal with," they were more likely to favor nontreatment. Although this study has methodological flaws, and in particular it reports responses to a hypothetical situation, it does demonstrate not only the influence of parental wishes, but also how the response to these wishes may be altered in some by a fear of litigation. Perhaps at the limit of viability, because there is uncertainty not only concerning prognosis but also concerning what the right action is, the introduction of some reasonable factor, be it a parental wish or a fear of litigation, can bear weight on a decision and alter it.

In a Canadian study, Saigal et al.(135) collected and compared preferences for selected health states from the perspectives of neonatologists, nurses, parents of ELBW or normal birth weight infants, and adolescents who were either ELBW or normal birth weight infants. The different health states the participants were asked to rate were ones in which there were varying degrees of disability, from mild to severe. Physicians and nurses, for the five health states defined, had similar preferences, and similar proportions viewed some health states as worse than death (59% of neonatologists, 68% of nurses). There was a significant difference between how physicians and nurses rated health states and how parents of ELBW and term infants rated them. One or more of the health states was rated as worse than death by 64% of the health professionals and 45% of the parents. The difference was statistically significant. Differences in scores between health professionals, parents, and adolescents were greatest for the two health states in which there was the most severe disability. Health professionals rated these two health states significantly lower than parents ($p < 0.001$). A significantly fewer number of adolescents rated at least one of the health states worse than death. Health professionals and parents rated mild to moderate disability similarly, but parents were far more likely to accept disability. Adolescents who were ELBW or term infants, as a group, rated the same health states lower than their parents, but there was more consistent agreement between adolescents and parents than there was between these two and health professionals when severe disability was considered.(136) In a similar vein, other studies have suggested that patients appear to perceive their own disability states, or life-threatening situations, in a better light than do health professionals.(137,138)

The same Canadian group examined the attitudes of parents and health professionals toward the treatment of ELBW infants.(139) The health professional group was composed of neonatal physicians and nurses, and the parents' groups were two matched groups, one of which had experienced the birth of a preterm infant less than 1,000g and the other a full-term infant.

About 64% of parents agreed, or strongly agreed, that an attempt should be made to save all infants regardless of birth weight or condition at birth compared with only 6% of health professionals. There was no difference between the two-parent groups, or between the physicians and nurses. Although the majority of both groups, parents and health professionals, believed that there should not be a standard policy on whether to save such infants, a greater proportion of parents than health professionals believed this. Among those who did not believe that all infants should be saved, 65% of physicians and 75% of nurses gave the economic costs of intensive and lifelong care as a reason, compared with 7% of parents of ELBW infants and 26% of parents of full-term infants. In this study, having a child with a disability did not greatly affect the responses of the parents of an ELBW infant. As for who should make the final decision regarding whether to forego life-sustaining treatment, the majority, in all groups, believed parents should "have the final say." However, there was a difference between the groups. Health professionals believed that they should have "the last word" significantly more than parents believed they should. The role of hospital ethics committees was accorded less influence, although nurses were more supportive of their role than parents, who were more supportive than physicians. As for other potential sources of authority, health professionals were more in favor of standards issued by medical bodies than parents, and only a minority in all groups supported a role for the courts. This occurred in 20% of nurses, 13% of parents, and only 2% of physicians. The conclusion from this study that, in general, parents support the aggressive treatment of EPTIs also has been reported in other studies.(54,140,141) Furthermore, the literature seems to support the notion that physicians are more likely than parents to forego treatment based on a perception of a later poor quality of life.(133,142–144)

In Scotland, McHaffie, Laing, Parker, and McMillan(145) examined the practices of 176 neonatologists and nurses, in addition to the perceptions of 108 parents of 62 babies for whom there was discussion about withholding invasive treatment. All the infants had a prognosis of either early death or a serious disabling impairment. All of them died, and the parents were interviewed at 3 and 13 months after the death. The conclusions were that the actual decisions to forego life-sustaining treatment were made by the physicians with or without the parents. Although the majority believed that parents should be involved, only 3% of physicians and 6% of nurses thought parents should "take the ultimate decision," even though 58% of physicians and 73% of nurses were in favor of a joint approach. In contrast, when the parents were interviewed 56% perceived that the ultimate decision had been theirs, of which 46% believed they were alone in accepting the responsibility and 14% felt it had been a joint decision along with the physicians, following advice or a recommendation. The authors noted that even though professional opinion may consider that it is "too great a burden" for parents to decide to withdraw treatment, the majority of parents saw this as "part of parental responsibility." At the second interview, 13 months after the event, 98% felt the decision had been right, although there was some concern over the validity of the prognosis and the distressing dying process. The authors determined that the role of the physicians is strongly influential as they "are not only the purveyors of fact but also of arguments," which in themselves may be self-fulfilling prophecies that bolster future argument.

In a study from Denmark it was reported that most Danish physicians would treat a 24-week infant at birth but would withdraw treatment if severe complications occurred. However, they would continue life-sustaining treatment if the parents wished this.(146) An Australian survey published in 2001,(147) examined when and how a neonatologist would counsel parents expecting the delivery of an EPTI. Counseling included the survival prognosis and almost always morbidity. The most important factor was the gestational age of the infant. At 22 weeks' gestation only 24% always or often counseled, and this rose to 77% at 25 weeks. Otherwise it was the obstetrician who did the counseling. Of the neonatologists who did counsel, 86% would recommend nonresuscitation at 22 weeks, and 14% at 24 weeks. The majority of neonatologists believed that legal action to limit parental decisions "had no useful place . . . regardless of the gestation." Where there was disagreement, 58% believed the parents should decide, and 35% believed it should be the neonatologist. Only 6% believed a court or an ethics committee should decide. When questioned concerning the withdrawal of life support, only 2% supported that "all interventions should be taken to preserve life, however severe the prognosis," and a similar low percentage agreed that "even with severe physical disability, life is better than death." Only 8% supported the notion that "even with severe mental disability, life is better than death."

The experience of foregoing life-sustaining treatment in the Muslim country of Oman was reported by DaCosta, Ghazal, and AlKhusaiby.(148) They believed that for religious and sociocultural reasons "when the question of withdrawal of life support measures is raised . . . we meet with near universal refusal." They stated that parents and extended family do not want to be seen as having acquiesced in their child's demise. However, when the child is not ventilated, but a decision not to resuscitate or to limit vital support is made, none have objections to limiting therapy. The authors wrote that they always say, "in our opinion, and if this was my child, I would not put the child on the ventilator," and the parental response to this is to acquiesce silently, or say, "[Y]ou do what is best for my child." The authors interpreted this as parents not wanting to make a life or death decision themselves, "but are willing to accept transferring the responsibility onto a person in authority."

It is apparent that there are conflicting views between parents and physicians, as well as varying opinions within and between countries.(44,149–153) De Leeuw et al.(154) compared the treatment choices of physicians and nurses in 11 European countries for a hypothetical case of an EPTI born weighing 560g at 24 weeks' gestation and an Apgar score of 1 at 1 minute. The responses, collected in 1996 through 1997, came from 143 NICUs in Italy, Spain, France, Germany, the Netherlands, Luxembourg, Britain, Sweden, Hungary, Estonia, and Lithuania. In summary, most physicians in every country, except the Netherlands, would resuscitate the baby. However, should the baby's condition deteriorate following seizures and a severe, although unilateral, intraventricular hemorrhage with parenchymal involvement, most physicians in France, the Netherlands, and Luxembourg, and most, but fewer, in Sweden, Britain, Spain, and Lithuania would favor limiting or withdrawing intensive care. Physicians in Estonia, Hungary, Germany, and Italy were less likely to support this approach. Of interest was that most in Estonia, France, and Italy, and a significant number in Hungary, Sweden, Spain, and Lithuania, would carry out their decision, whatever it was, without involving the parents. In Estonia, Hungary, Italy, Germany, and Spain, most physicians would only withhold treatment in circumstances such as a cardiac arrest, if the parents requested a withdrawing of intensive care, in the circumstance described. However, in Britain, the Netherlands, and Sweden, they would withdraw mechanical ventilation, and a substantial number of physicians in France and the Netherlands would administer drugs with the purpose of ending the baby's life. There were other factors, apart from parental wishes, that influenced the decisions of physicians. For example, those who claimed that they personally found religion “fairly” or “extremely” important were less willing to make nontreatment choices. Male physicians who held junior professional positions, and those with experience of neonatal follow-up, were more willing to involve parents in decision making. But overall, the main significant predictor of attitude was country. This finding was similar for neonatal nurses. In a similar U.S. 1992 study,(142) about 95% would resuscitate and 60% would start “full intensive care.” If there was marked deterioration, about 45% would encourage withdrawal. These studies demonstrate that the attitudes of physicians vary within, and between, countries. Although the individual characteristics of the physicians affect their attitudes, it is the nation in which they practice that appears to influence their responses the most.

In 2000 Rebagliato and associates(155) reported the neonatal end of life decision-making practices in 10 European countries, as part of a study for EURONIC (European Project on Parents’ Information and Ethical Decision Making in Neonatal Intensive Care Units: Staff Attitudes and Opinions). The group had previously reported(156) that the frequency of withdrawing mechanical ventilation was highest in Northern European countries and lowest in south Mediterranean ones. In the 2000 study they examined physicians’ attitudes toward the value of life and life with a disability; the appropriate use of medical technology; the relevance of family burden, economic costs, and legal constraints; the influence of country of origin; personal and professional characteristics; and the relationship between attitudes of self-reported practices. The countries included were France, Germany, Italy, the Netherlands, Spain, Sweden, Britain, Estonia, Hungary, and Lithuania. About one-fourth to one-third of physicians in Italy, Lithuania, and Hungary agreed with a sanctity of life principle, and “that everything possible should be done to ensure a neonate’s survival, however severe the prognosis." In contrast, most physicians in every country equated severe mental disability as "an outcome equal to or worse than death." There was less agreement when severe physical handicap was considered. In all countries the majority of physicians believed that family burden was an important concept when making end of life decisions. However, more than half of those in Baltic countries thought their ability to limit treatment was legally constrained. This was in stark contrast to those who believed this in Sweden (3%) and France (5%). As for the argument invoking economic justice, most did not believe that this should affect their decisions, although about 25% in France, Britain, and the Baltic countries did believe that there should be a consideration of cost. Considerable variation was found when the mode of foregoing life-sustaining treatment was evaluated. Most physicians in every country but Lithuania appeared to make an ethical distinction between withholding intensive care from the very beginning and withdrawing it afterward. Interestingly, and perhaps disturbingly, about one-third of the physicians form France, the Netherlands, and Estonia "found no ethical difference between treatment withdrawal and the administration of drugs with the purpose of ending a patient's life," and in France and the Baltic countries more than half agreed that "withholding intensive care without simultaneously taking active measures to end life" may increase the chances of future severe disability. Using multiple linear regression analysis the authors attempted to identify variables that might help to explain the variation in findings. The characteristics that were more likely to be associated with a quality of life stance versus a sanctity of life one were being female, having no children, being Protestant or having no religious background, considering religion not important, an intermediate length of professional experience (6–15 years), and working in units with a higher number of ELBW admissions.

Among physicians who found religion important, those from Italy, Hungary, and the Baltic countries were significantly more in favor of sanctity of life approach. For those physicians who did not report religion as important, Italian physicians did not differ from those in Spain, France, and Germany, whereas those in Hungary and Estonia continued to follow a pro-life stance. However, country remained the strongest single factor explaining differences in practice, even though there was variability of beliefs within countries.

13

RESOURCE EXPENDITURE

Some might argue that intensive care for the smallest of EPTIs raises the level of societal economic burden in an unjustified manner. But the cost of such care should be examined in relationship to how much and the manner in which society spends on other aspects of health care and the proportion of this that is generated by the population in question. Neonatal intensive care cost per life year gained is likely to be considerably less than that for many adults given intensive care.(30) When the figures for resource use by NICUs on caring for the EPTI are examined in isolation, they appear daunting. For example, in a study of 17 Canadian NICUs(34) it was found that although EPTIs comprised only 4% of admissions, they accounted for 22% of deaths, 31% of severe intraventricular hemorrhage, 22% of chronic lung disease, 59% of severe retinopathy of prematurity, and 20% of necrotizing enterocolitis. They consumed 11% of NICU days, 20% of mechanical ventilator use, 35% of transfusions, 21% of surgically inserted central venous catheters, and 8% of major surgical procedures. Lorenz et al.(22) reported on the resource expenditure in the perinatal period generated by EPTIs born less than 26 weeks in two population-based cohorts, New Jersey (NJ) and the Netherlands, who received systematically different approaches to their care during the midmed-1980s. In the NJ cohort, almost all the babies received intensive care, whereas the policy was more selective in the Netherlands. Assisted ventilation was more commonly used in NJ, 95% versus 64%, and almost all the difference resulted from the use of assisted ventilation in infants who subsequently died. Mortality at 28 days was about 46% in NJ and 73% in the Netherlands. No infant less than 25 weeks' gestation survived in the Netherlands cohort. Survival to 2 years in NJ was twice that in the Netherlands. In the NJ cohort 1,820 ventilator days were expended per 100 live births compared to 448 days in the Netherlands, but the difference in nonventilator days was not statistically different. In summary, the management approach in NJ resulted in 24 additional survivors per 100 live births, 7 additional cases of disabling cerebral palsy per 100 live births, and at a cost of 1,372 additional ventilator days per 100 live births.

It is important, when considering cost, to realize that most EPTI deaths occur in the first 3 days, and it is the least mature who die the earliest.(157) Those who survive day 4 are very likely to survive to discharge. Meadow and Lantos(157) make the argument that as the smallest babies, for example, those who weigh 600g, are more likely to die, and to die in the first few days after birth, they consume fewer resources than the larger babies, for example, those weighing 900g.(157) About 85% of bed days are allocated to infants who will be discharged home, independent of the initial mortality risk. Furthermore, as Meadow and Lantos wrote, "the vast majority of NICU resources are directed to infants who ultimately survive to go home to their families," that is, the longer the EPTI stays in the NICU the more likely that infant will survive, which is not necessarily the case in the adult ICU. In Japan, Nishida(39,158) calculated the economic cost of providing for ELBW infants, including lifelong costs, and concluded that there was a net financial benefit, which was generated by "normal" survivors. Also, when considering cost, it should be remembered that the number of survivors is relatively very small compared to the numbers in the rest of the population who consume health care and social services. In the Saigal et al. paper(89) comparing outcome in four national regional cohorts (NJ, Ontario, Bavaria, and Holland), the total number of survivors ranged from 397 in Ontario to 263 in Bavaria. Thus, the financial cost of intensive care for EPTIs, at least in countries with advanced health care systems, should be evaluated in relationship to how they compare to other expensive health resource allocation. It might also be argued that a relatively favorable outcome for an EPTI generates potentially more lifelong beneficence than that gained from resource allocation to the elderly.

PART 2

BIOETHICS

14

MORAL THEORY

Beauchamp defines the term *morality* as traditions of belief about right and wrong human conduct.(159) In particular this book is concerned with the morality of special groups, that is, health care professionals, those who care for children, and the state. Right and wrong conduct is conduct that affects the interests of others.(159) The theories that are used to argue what constitutes morality are ethics (although the term is also used as a synonym for morality), and the ethics that apply to a special group, such as health care professionals, are bioethics. The application of bioethics can be used when there are different choices concerning health care that affect the interests of individuals. Fundamental to what might be deemed the right choice is correct knowledge, which is the explanation for the first section that includes the epidemiology and prognosis of extreme prematurity, even though these topics may not always be "cut and dried." However, central to the use of bioethics, or any argument, is that there are clear shared definitions. In addition, for a conclusion to be reached, and a course of action agreed on, boundaries should be delineated and common moral theories, codes, and principles adopted.(160) This does not mean that there always should be a universally adopted answer to any moral question or dilemma, but that any conclusion reached should have consistency and generalizable coherence.

Although we might view bioethics as a subject that encompasses codes and concepts on how physicians should behave, it is much broader than that, for within the discipline are philosophies and principles enshrined within the culture in which the physician practises. As such, although themes may remain constant, or some new ones appear, the moral interpretation of what may be the correct approach to these themes has not always been constant throughout recorded time. Jonsen wrote that Hippocrates in *Epidemics I* declares that the physician "help and not harm."(161) A modern interpretation of this is that a physician should weigh carefully the risks and benefits of treatment. However, according to Jonsen, the context is one of prognostication and that the "good physician" should distinguish between fatal and nonfatal disease so that "the patient can benefit from medical ministrations."(162) The interpretation is "that the experienced physician should never be blamed for refusing to take on desperate cases."(162) Harm, in this context, occurs when medicine is practiced with no hope of effect. In medieval times, Western medicine was primarily governed by the work of the church. This cemented a tie between Christian ethics and a duty to the sick. As Jonsen noted,(163) there was a version of the Hippocratic Oath in which the Greek gods are replaced by "God the Father of our Lord Jesus Christ," and the prohibition against abortion is strengthened and the requirement against "cutting for the stone" is removed.(164) From the 13th century the practice of medicine began to return to the lay sector, although the behavior of physicians continued to be advised strongly by ecclesiastical doctrine, which commanded that there was a duty to the sick and the poor.(165) Medical ethics were also influenced by Islamic and Jewish teachings, particularly in Spain and the near East, with the common themes of sanctity of life, duty toward all patients, and the absolute power of a higher being.(166) As Western medical practice entered into the renaissance, medical ethics were characterized by decorum, duties and obligations, and politic ethics. The latter, which had risen in importance, is defined by Jonsen(167) as "the duties of those whose work is intimately related to the welfare of a political unit, a community." The physician is now viewed as one who not only has an obligation to provide services for any individual who seeks help, rich or poor, but also has to act in a manner that benefits the community as a whole.(168) This notion of politic ethics and a duty to society can also be found in the influential 19th-century text by Thomas Percival,(169) and it is during that century that it is now written that the duties of physicians should be balanced by their rights,(170) which included an expectation that their prescriptions be followed and their duty to sustain life be respected. However, by the end of the 19th century, although deontological forces were still in play in medical ethics, the science of statistical probabilities was available and allowed for utilitarian choices whereby the aim was to provide the greater good.(171) In addition, as expounded by Cabot from the Massachusetts General Hospital, incompetent practice was unethical, to the dismay of some practitioners who believed that the public exposure of medical mistakes was not an act of decorum.(172,173) As the 20th century passed, medical ethics brought into play concepts such as autonomy, patients' rights, justice, and the regulation of research. But it was not until the 1960s and early 1970s, and the ability to care better for very premature and disabled infants, that moral questions began to be asked about the extent and consequences of their care.

There are various ethical theories and schools of thought that can be invoked when considering the care of the extremely preterm infant, and in particular foregoing life-sustaining treatment, the topic with which this book is mainly concerned. Although virtue ethics will not be discussed, an integral part of moral behavior derives from this. This is the consistent performance of that behavior and the desire to do good. These are classical virtues and can, and should, be integrated into other theories.(174) One of these theories is deontology. This involves acting in accordance with duties and obligations. These can be based on religious teachings or on the "categorical imperative" proposed by Kant(174) in which an action should only be taken if it is right for anyone to take the action. That is, there is a universal law concerning what is right and that some actions are intrinsically immoral. He stated that one should: "act so that you treat humanity, both in your own person and in that of another, always as an end and never merely as a means."(174) This is the respect principle.

This obligation may be special to a group. A special obligation is created by a specific relationship, and the obligation is limited to people in this relationship. Parents have special obligations to their children, and physicians to their patients, such as sick preterm infants. Kantian moral theory applies to an act that is under the control of the individual and not the outcome. An act is judged by how it accords to negative or positive duties. A negative duty is "do not kill." A positive duty might be "to let a patient die when death is inevitable." Negative duties are universally binding and have priority over positive ones. As Freeman and McDonnell wrote:(175) the physician has a positive duty to provide medical care that is effective and available and to respect the wishes of an informed individual. If the patient is a baby it is usually the parents who are surrogate decision makers. But their autonomy is restricted, as they have a special negative duty not to harm their child. The strengths of deontology are that it is consistent and takes account of special obligations and individual justice.

Its weaknesses are that there are no real rational justifications for the rules; there may be conflicting duties and obligations; it is not situational; and it is not necessarily benevolent as it is indifferent to the consequences of an action.(176)

Another ethical theory that is used to address various questions of morality is act utilitarianism. This follows from the work of Jeremy Bentham (1748–1832) and John Stuart Mill (1806–1873). Utilitarianism teaches that a course of action is morally right if it leads to overall benefit. How an individual acts is judged on the net utility of that action. Akin to utilitarianism is consequentialism that argues that actions are good or bad based on their consequences(177) and that it is good to take actions that lead to happiness. The actor should treat the parties who are affected as if the consequences to them are equal. Inevitably, in this approach, net happiness is pitted against varying individual states and interests. Furthermore, it requires that the future can be predicted, even though the consequentialist might argue that we need only to act in a way that reasonably predicts the outcome. In act utilitarianism it would be desirable to forego life-sustaining treatment for the disabled infant if the death of the child would relieve the family and society of a burden and inconvenience and would lead to the greatest good for the greatest number. A utilitarian approach might be accepting that actions that either promote the death of the extremely preterm infant or enable the child to survive but with certain disability, the nature of which is not entirely predictable, are two moral evils. Then the lesser of the two evils is the one that promotes the greatest happiness. However, from the perspective of the infant, one has to accept that death is a state that can be measured against an arguably undesirable life. The moral calculation would be an abstraction versus an uncertainty and thus would negate any conclusion on the basis of noncommensurability. A calculation might still be made from the perspective of the parents or society. Examining the case of the former, the happiness of the parents and family should have as least as much moral weight as that of the infant. But the happiness of the infant is incalculable. Furthermore, parents as surrogate decision makers for their child would still have to decide between incommensurable states. That is the net happiness derived from the death of the baby versus life with a disabled child. From the family's perspective alone, life with a disabled baby might be less happy than life without. In this calculation, the interests of the baby are not taken into account. As for society, its well-being will depend on local and general resources. In a local situation where resources are limited, for example, ventilators, the moral calculation might favor other infants who require ventilation and would survive without disability. Similarly, in poor countries where the need for food, sanitation, and security is acute, an attempt to set up sophisticated neonatal intensive care units would have a lower moral priority and result in less well-being in that society where resources may be better spent. But in relatively rich societies it has been argued that neonatal intensive care, for the extremely preterm infant, does not substantially take away resources that would lead to more happiness in society,(38,158) and it could be said that living in a society that provides for the very vulnerable, in itself, raises the overall sense of well-being in that society. Thus, as Ridley wrote,(176) the utilitarian method surveys all possible courses of action and predicts what consequences, in terms of happiness and suffering, each of these courses will have. A calculation is made that produces the best balance of good results over bad results. No one individual's happiness or suffering is intrinsically more important than anyone else's. The goal is to maximize happiness and satisfaction on the basis of a calculation and on a case-by-case basis. The strengths of act utilitarianism are that it is rational, situational, and benevolent.(176) Its weaknesses are that it has too much faith in predictability; it does not account for incommensurable values or special obligations; and it is inconsistent and has no concern for justice.(176) A modification, which addresses some of these weaknesses, is rule utilitarianism.(176) This theory states that one should act in accordance with rules that if you and everyone else always acted on would produce the greatest amount of happiness for the greatest number.(176) There is still the deontological problem of finding a rational procedure to decide which rules to adopt. However, the strengths of rule utilitarianism are that it is consistent, benevolent, takes account of special obligations, and has a concern for justice.(176) Weaknesses are still present as there may still be incommensurable values, conflicting rules, and too much faith in predictability.(176)

Another approach is rights theory. This can be used with any ethical theory that includes mention of obligations and can be used in tandem with wider ethical perspectives.(176) In this theory, rights are balanced by duties, and there are rights that everyone has, regardless. Any duty one might have corresponds to someone's right. Thus a patient has a right to the best medical care that a physician can provide, and a physician has a duty to provide it. But physicians also have rights, and patients have duties, and these can clash. Furthermore, rights, in general, are often loudly expounded, but duties less so. The right to "Life, liberty, and the pursuit of happiness" is appreciated better than any correlative duties.(175) Individual rights may oppose each other, or be said to apply to one group but not another. Also, as with moral imperatives, there is a problem with the origin of rights.(175) For rights theory to stand on its own and carry moral weight it requires a metaphysical or religious origin. A moral right should compete with, and be part of, rules, obligations, and consequences. That is, without invoking an overriding abstract source, rights theory should be subject to, or made part of, other major moral theories.

The ethical theories described have their strengths and weaknesses. To better address bioethical questions and dilemmas, we can apply principilism. This is based on the notion that a common morality contains a set of moral norms that includes principles,(178) and these principles can be applied in moral discourse concerning the extremely preterm infant. These principles guide moral argument and provide a structure on which the direction of an argument can be made. The commonly used principles are respect for autonomy, beneficence, nonmaleficence, and justice. But is there a common morality? This is defined by Veatch as a "pretheoretical awareness of certain moral norms."(179) Whether this is the case across different cultures and during different epochs is not proven empirically.(180) But there could be an element of calming reassurance if there were some moral norms we all hold in common.(181) Even if there was some consensus on common moral norms, it is unlikely that this would easily resolve moral dilemmas but rather provide a common language across cultures with which to address the dilemmas. As Macklin wrote, there may not be ethical absolutes, but there are ethical norms.(182) Support for the concept of the universality of some principles, across cultures, can be found in the teachings of the 13th-century Muslim scholar Mawlana.(183)

15

AUTONOMY

An important principle in bioethics is respect for autonomy. Clearly, extremely preterm infants do not have autonomy, and surrogates, usually parents, are granted the right to make decisions for them, on the basis of a special relationship. This is not without limits, and where consent to treatment is concerned they have a duty to act in the best interests of the child, from the perspective of the child. Determining this may be difficult. Correct respect for autonomy demands that parents are given ample opportunity to express their views and that these are heard and addressed in a considerate manner. Physicians have a duty to recognize and protect the future of the child, who is both vulnerable and without autonomy.(184) Babies, of any gestation, require the protection of parents, health professionals, and society and have a moral and legal right to receive this protection. Other physicians' duties, which relate directly to the health-related interests of the baby, include the correct exercise of knowledge and expertise; the acknowledgment of any lack of knowledge; and a requirement to seek knowledge and guidance, not to provide ineffectual treatment, to respect the law, and to provide alternative care when required. The duty of physicians, and their perceptions of these, when they are centered on the infant, may conflict with parental wishes and lead to severe emotional and economic family burden and threaten its very integrity. Conflict may arise that leads to intervention by ethics committees, and sometimes the courts, which in itself may further division.(185,186) Based on the reasonable expectation of extreme family burden, in the presence of a clear severe outcome for the infant, there are those who argue that there is an obligation to respect parental requests to forego life-sustaining treatment.(185) But how well parents make such choices, and how much they are influenced by others, health professionals or otherwise, is variable and complex. Although parents or guardians are granted a limited surrogate autonomy, as Meyers wrote:

> genuine autonomy entails more than the mere making of decisions. It requires both the capacity to make free and informed decisions and the active development of character by which persons understand and are able to act upon self-defining choices . . . autonomy undercutting power asymmetries prevail and decision making in routine care relies much more on assent than on consent . . . healthcare in general, and critical care in particular, represent profoundly difficult contexts for genuinely autonomous choices.(187)

The decisions of surrogates are not only influenced by their own prejudices, pressures to avoid perceived taboos, incriminating statements, and other emotional, social, and economic pressures, they are also shaped by the fear of an alien environment and the, perhaps unintentional, posture of physicians whose requirements are, in an intensive care situation, that they control the variables. There is an undoubted pressure on physicians to make decisions and move on. This provides an impetus that not only impedes shared knowledgeable decision making but also fashions how physicians may be perceived and how they see themselves.

16

BENEFICENCE AND NONMALEFICENCE

From classical times health care professionals have been obliged to avoid harming their patients and to promote their welfare. But in the medical and surgical management of preterm infants harm is often inflicted that is considered justified because of the presumed benefits. The harm may be relatively minor, such as taking blood samples or placing intravenous lines, or it may have the potential to cause long-term damage, such as with prolonged high pressure artificial ventilation or the surgical removal of bowel damaged by necrotizing enterocolitis. At what point does treatment no longer offer a benefit? Some may argue that a supposed long-term benefit, for example, survival, may not further the welfare of the infant, the family, or society. This argument might arise when it is proposed to place a ventriculo-peritoneal shunt into a severely brain-damaged preterm infant with progressive posthemorrhagic hydrocephalus. In all aspects of health care there is a balance between beneficence and nonmaleficence. The principle of nonmaleficence would support foregoing treatment if it was of no benefit and the treatment would inflict harm and suffering. But the use of the principle correctly requires that lack of benefit, harm, and suffering can be recognized and predicted. The principle of beneficence would support an action, or lack thereof, if it was in the best interests of the infant. Correct use of the principle requires that it is understood what interests the infant has, or perhaps will have, from the perspective of the infant. The principle of beneficence is the primary principle when dealing with medical decisions that concern the welfare of children. It can be a subjective notion that generates different interpretation depending on circumstance, situation, prognostic knowledge, and the moral notions of those involved in the care of an infant. Those who invoke the best interests standard state they are acting to maximize benefits and minimize harms.(188) Its use as a general guideline is clearly important when deciding between different options for the treatment of a child. It allows for standards to be set and boundaries to be drawn. However, it should be recognized that there may be situations in which its use is not applicable, and where its use, as Kopelman wrote, is "unknowable, vague, dangerous, and open to abuse."(188)

She argued that it should be understood "not as absolute duty, but as a *prima facie* duty, or an ideal that should guide choices."(189) As may occur, ideals may not be possible always. It would be ideal for an extremely preterm infant, once resuscitated and supported, not to have to live a life challenged by serious disability. But if this ideal cannot be met, and the infant survives, then as Holmes stated, we must consider what our prima facie duties toward the child are and how we justify these.(190) For this to occur, we have to state that the infant has moral rights, which it is not able, nor obliged, to reciprocate.

Does providing life-sustaining treatment to the extremely preterm infant cause more harm than benefit and violate the nonmaleficence principle?(191) Jonsen and Garland wrote that the principle is not violated if there is "inability to survive infancy, inability to live without severe pain, and inability to participate, at least minimally, in human experience."(192)

This assumes prognostic accuracy, which may be uncertain. However, there are circumstances where application of the principle might apply in the newborn nursery, for example, with anencephaly and an extremely preterm infant may suffer such complications that the conditions laid down by Jonsen and Garland would clearly apply.

How much brain injury should constitute such harm that continuing treatment would be immoral? Later mental retardation is not relevant when determining treatment. What interests the infant has should take priority over those of the family and society when weighing the options. It is true that a patient may have an interest in the welfare of his or her family, but if the incompetent patient has never been competent, it is wrong to impute altruism, or any other motive, to that patient, against his or her interests.(178)

Freeman and O'Donnell noted that physicians do not have the luxury of retrospective analysis of a situation(175) in the way that some philosophers, lawyers, and judges have but must make prospective judgments based on knowledge, which may be uncertain, and experience, which is not stereotypic. But it is important not only to know the facts, but also to recognize the ambiguity and power of words. For example, a ventilator-dependent preterm infant with a grade IV intraventricular hemorrhage (enlarged ventricles and hemorrhage into the ventricle in addition to the substance of the brain) may be described as neurologically devastated by some. Clearly the infant is at high risk for varying degrees of neurologic disability. But it is not always clear how to distinguish which infant will survive with a moderate degree of cerebral palsy and sufficient cognition to be a sentient, but dependent, human being from one who is truly unable to interact in any meaningful way. It is important not to make value judgments and to act in the best interests of the infant, from the perspective of the infant. This is not easy, nor wholly possible, for we do not know the future perspective of the infant. The best interests concept is a fuzzy notion. However, making the infant central to the process narrows the argument. But can existence itself be an injury? When one states that an infant would be "better off dead," is it possible to compare the dead state with the state that would have occurred should the infant have lived? The two states are not commensurable, as one is nonexistence. This is not to say that continued existence will be good for the infant. But it is to say that when deciding whether to forego life-sustaining treatment for an extremely preterm infant, a utilitarian calculation comparing lack of existence to a life with disability should not apply. Feinberg argued that a surrogate

> exercises his judgment that whatever interests the impaired party might have, or come to have, they would already be doomed to defeat by his present incurable condition. Thus, it would be irrational – contrary to what reason decrees – for a representative and protector of those interests to prefer the continuance of that condition to non-existence.(193)

The problem with this is predicting when potential interests will be "doomed to defeat." It is not only uncertainty that clouds the decision-making process, but also the perceptions, and perhaps even the knowledge of those who discuss these situations. Paris, when giving his opinions on a legal case in which a baby was disconnected from a ventilator by a parent, stated that the parents of this 25-week gestation infant were given a 20–40% risk of severe intracranial hemorrhage should the baby survive. Paris viewed this as "more than sufficient evidence of the disproportionate burden that awaited this child to justify a decision to withhold resuscitation."(194)

This conclusion was made even though should the infant have survived, the statistical risk of a major disability was considerably less than not having a major disability. Furthermore, should the major neurological complications of extreme prematurity occur, prediction of the degree of disability may be difficult, particularly during the early stages after birth. Paris also proposed a "popular fallacy" argument by stating that treatment is based on objective criteria such as birth weight throughout Europe. Even if this was totally true, which it is not as there is much variability (see Section I), it is not a moral justification. He also wrote that because the baby was described as "lifeless, hypotonic, hypoxic, purple-blue, with no grasp or grimace, at birth," that this should have precluded resuscitation, even though the baby had a heart rate of 90. Many extremely preterm infants have this appearance at birth. The reasoning that the baby's appearance should have precluded resuscitation begs the question, are infants such as these, who are resuscitated at birth, more likely to have severe neurologic disability if they survive? Or, if they die, are they more likely to have a long lingering dying process? The scientific literature appears to support an answer of no to both these questions.(49–53,157)

Whereas considering the interests of the infant is paramount, this is not to discount the interests of others. Parents who are left to raise a disabled extremely preterm infant suffer significant stress. They may enter a morass of frustration, guilt, denial, anger, and disbelief that may be rekindled during their years of caring. It should be argued that if the state has a strong duty to protect the vulnerable and the susceptible, then it also has an obligation to provide social, educational, psychological, and economic support for those who care for disabled children.

So it can be seen that principles may compete, and the interpretation of their uses vary. Phrases such as *best interests* are difficult to define for an infant, and it is arguable whether the use of such a phrase can apply to nonexistence. Parents may find themselves enveloped in myth and uncertainty. It is in such circumstances that physicians, who may have little time or expertise in moral argument, shape the discussions with parents and in effect determine the decision. This is not to say that physicians should not impart their knowledge and wisdom to inform and guide parents. Rather it is recognition of the prejudices and moral fallibility of all involved and the slippery nature of moral standards and boundaries. Some might argue that physicians should stay within the sphere of their technical and scientific knowledge. But the practice of medicine has never had this as its sole aim. The origin of the word *doctor* is learned teacher, a *sensei* who is expected to act like a priest and think like a scientist. Most physicians recognize this professional burden and may feel compelled, or duty bound, to shape life and death decisions according to their moral judgment.

17

JUSTICE

In general, the principle of justice concerns fairness and rights and dictates that the extremely preterm infant should be treated in the same way as other infants with the same treatable condition, for example, the extremely preterm infant and the full-term infant with progressive hydrocephalus. This ethical principle protects certain moral rights even though, it can be argued, it may conflict with the principle of beneficence.(195) As Foot wrote: "an act which is 'more humane' than its alternative may be morally objectionable because it infringes rights."(196)

Invoking justice as a principle can become arguable if it cannot be agreed that the recipients of an action are equal in some agreed on respect. Another form of justice is distributive justice. This refers to a fair and equitable distribution of resources. It might be argued that the costs of neonatal intensive care for the extremely preterm infant, and the costs and burdens to society of providing for disabled children, are not justified as they threaten the overall welfare of society. If a justification is to be made for limiting such neonatal intensive care on these grounds, then the proponent must provide some measure of the social burden and compare it with other burdens that society agrees to take. The proponent would be required to show that other accepted commitments such as military defense, education, and other aspects of healthcare would be substantially lessened. Costs are relatively small when compared with some treatments in adults(2) and represent only a small proportion of total health costs for children.(197) If resources are limited, it could also be argued that they are more effectively spent on the very young than on the very old.(198)

18

SANCTITY OF LIFE

In the Judeo-Christian tradition, the sanctity of life principle might be stated as follows:

> human life is of infinite value. This in turn means that a piece of infinity is also infinite and a person who has but a few moments of life is no less of value than a person who has sixty years to live . . . a handicapped individual is a perfect specimen when viewed as an ethical concept. The value is an absolute value. It is not relative to life expectancy, to state of health, or to usefulness to society.(199)

The sanctity of life principle is sometimes employed in such a way that would suggest that the use of the words themselves should put an end to moral argument,(200) what could be seen as an exchange of reasoning for dogma rather than seeking an understanding of what life is, when it has moral worth, and what the relative role of other principles is. Even in a strictly religious context, in the Western tradition, the need to sustain human life, purely because it is that, is not overriding.(201–203) Glover defined the sanctity of life principle as one in which taking life is intrinsically wrong.(204) He argued that the doctrine "is not acceptable, but there is embedded in it a moral view we should retain." He does not argue that it is not wrong to take away life, but that "conventional moral views about killing are often intellectually unsatisfactory."

In the sanctity of life doctrine, the act of killing can never have a justification, or there can never be a circumstance where it is morally correct. It cannot be justified to save the life of another or oneself. However, many would support the concept of deadly self-defense, or the prosecution of a "just war," but might not agree with allowing nonterminal, severely handicapped infants to die.

19

ACTIVE AND PASSIVE EUTHANASIA

Kuhse wrote that killing is not always morally worse than letting die and sometimes may be better.(205) She argued that active euthanasia is morally no worse than passive euthanasia and sometimes morally better. This, she stated, is based on the motivation of the agent, as the two acts have the same outcome. The actors, parents and physicians believe they are doing good, which, in itself, is based on the notion that the outcome, death, is good, or much better, than the alternative, a life with severe disability. Although the moral notion, in some circumstances, may be seen by some as acceptable, it is based on an abstraction akin to the legal term *non actus reus nisi mens sit rea* (knowledge of the wrongfulness of an act at the time of its commission) and in the case of foregoing life-sustaining treatment for an extremely preterm infant, is not a verifiable proposition. Whereas the actors may believe they are doing good, this is based on their perceptions and judgments, which have been molded by anecdote, bias, prejudice, custom, and taboo. For example, it was not that long ago that children with Down syndrome were left to die from conditions that were correctable. Recent history is replete with acts performed by professionals that at the time were not believed by them to be bad but would be judged as such now.(206,207) Thus if a coherent argument for foregoing life-sustaining treatment for an extremely preterm infant cannot be made on the basis of the beneficence of the actors, nor on a verifiable outcome, if the life-sustaining treatment is continued, can the action be considered allowable? Apparently the action can only be good based on the motivation of the actors, which is predicated on their belief in the outcome. It would appear that an impasse has been reached. But this is not necessarily the case for, while not disregarding the arguments, it can be said that for ethical rules that determine behavior to work there needs to be a degree of trust, both in the actions of agents and in a reasonably foreseeable future. The former are required morally to be virtuous, and the outcome is not required to be absolutely verifiable. The physicians can agree on what is required to be the actor, and what the outcome will be on a probabilistic basis, and society, through its representatives are required to take into account the fallibility of the actors, and the uncertainty of the outcome. As Kuhse stated, "answers to public-policy questions are rarely derived from first ethical principles, but are, quite properly, based on common intuitions."(205)

20

PERSONHOOD

According to Englehardt,(208) it is morally acceptable to allow a severely disabled infant to die when it is unlikely that the infant can attain a developed personal life, that is, become a person, and when it seems clear that providing continued care would constitute a severe burden for the family. He argued that there is "an injury of continued existence"(208) and that a child has a right not to have his or her life prolonged in those cases where life would be "painful and futile."(208) He does not define futile. He proposed that allowing a severely disabled infant to die is not only morally acceptable but also morally demanded. Although Englehardt used the principles of nonmaleficence – beneficence and justice and preventing a continuing injury – removing a burden from the family and the right not to have a painful futile life, as well as suggested that there might be a universal law that demands that a severely disabled infant be allowed to die, he also stated that the attainment of personhood is important to the argument. Singer defined a person as an individual who has rationality and selfawareness.(209) He asked if the life of a being that is conscious, but not self-conscious, has moral value, and if so, how the value of such a life compares with the life of a person. Singer believed infants are beings that are neither rational nor self-conscious.(209) They have not reached a neuropsychological standard required to attain personhood, but will do so some time after birth. Tooley also argued that to have a moral right to life a human should possess those characteristics that identify that human as a person.(210) He suggested that a person, in the moral sense, must be able to envisage the future for itself and have desires about its own future states. The personhood argument is that only personal life has a unique moral claim to existence.(211) If this characteristic, the possession of higher brain functions such as self-awareness, rationality, and a sense of the future is accepted as the basis for a moral claim to life, it does carry with it the weight of logical consideration. However, in our society, this approach might be considered counterintuitive and viewed as unreasonable by many.(211)

If one is to argue that the potential to become a person is the criterion for claiming a moral right to life, and that this claim is diminished in proportion to degrees of disability, then not only does this presuppose prognostic accuracy, particularly in terms of higher mental functions, it also suggests that there is a potential personhood continuum that can be viewed in a categorical rather than a continuous fashion. That is, there is some specific time in development, normal or abnormal, when a person appears, rather than viewing the continuum as a threaded chain that, if broken at any point, destroys that chain. There is, of course, a point at which the continuum starts. This point starts when an organism will develop into a person given a normal course of events. The potentiality argument is refuted by those who state that if it is followed it leads to accepting that a sperm or an ovum are potential people.(212) But a tree is not a table in the normal course of events. There comes a time when the constituent parts of a human come together to form an organism that unarguably has the developmental potential to become a human person. The constituent parts, and their origins, do not, in themselves, have this potential. I do not argue when this occurs, but it is certainly present after birth.

If the reasoning of those who champion a neuropsychological standard for personhood, which they argue will appear in infants at some ill-defined time during their development, is followed, then unless there is absolute certainty that this will never occur, and there is often uncertainty concerning this, then a certain time period will need to be determined before life-sustaining support is removed from a disabled infant. It might be argued that the concept of personhood, or potential personhood, should not be used as the sole determinant for foregoing life-sustaining treatment from a disabled infant in the absence of more rigorous ways of defining and recognizing its presence. In addition, this notion of self that grants a person rights and duties does not necessarily remove moral consideration from a nonperson. Many cannot justify cruelty to animals but have no qualms about considering exterminating cockroaches with noxious substances. Perhaps we allow moral consideration based on a tier of situational acceptability that is built according to moral consensus. Qualms are moral intuitions. That is, they are doubts and uncertainties concerning what is right or wrong, in a particular situation, without reasoning.(213) These intuitions may vary between people and will depend on knowledge, preconceived notions, and cultural education. In addition, an intuition will depend on the language used to deliver a proposition. So there may be qualms when the statement is we need to kill this baby because it is a burden to itself and others, but it may be more acceptable to state that it is in the best interests of the baby, and secondarily for others, to let this baby die. The response to these statements is still intuitive, as the words *burden* and *best interests* are not defined, reasoned, or argued. An intuition is sought rather than a moral truth based on theory or principle. In such a situation, agreeing with one of the propositions may be counterintuitive. The first requirement for testing moral intuitions, whatever language is used, is acceptable fact, and only then can moral theory and principle be applied. If the conclusion is still counterintuitive, then there should be a reexamination of whether facts are incorrect or whether reasoning or principles are inconsistent. An example could be that moral status is granted by an arbitrary definition of personhood. This definition then determines that an infant does not have moral status and a right to life.

The definition of a person comes from Locke in the 19th century, who wrote that a person is “a thinking intelligent being that has reason and reflection and can consider itself as itself, the same thinking thing, in different times and places.”(214)

This person, human or otherwise, has moral status with rights, duties, and obligations. Those without this rationality and self-consciousness are not entitled to this moral status. This neurological standard, if followed logically, would lead to an unacceptable conclusion, for example, that it is morally acceptable to experiment on human newborn infants – nonpersons – to study disease in adult gorillas – persons. This does not necessarily mean that the converse is morally acceptable – experiments on primates to benefit babies. Clearly, however, we do practice speciesism, even though it may not be morally justifiable. So do those who propose a personhood argument to justify foregoing life-sustaining treatment for an extremely preterm infant propose something that is counterintuitive and morally absurd? Is it because they equate a right to life with moral status and moral status with personhood? It seems that the argument centers on moral status. It could be argued that we should grant moral status to those with both continuing consciousness and developmental potential, and not necessarily just rationality. It may be arguable just how much, or the degree of, consciousness an extremely preterm infant has, but in biological terms the infant is not just a brain stem preparation. If we grant the infant moral status then we grant a right to life, and there are duties that we owe the infant. In fact there are special duties that physicians owe the baby, not only because of the degree of vulnerability and susceptibility of the baby, but also because the baby is a patient. The baby deserves the dignity and respect that comes with moral status. It is intuitively the virtuous thing to do, and it would be morally wrong not to do so. Although the concept of personhood may be a long-standing topic among philosophers, who argue what it is to be a person and gain moral status, the concept has little if any practical application in the practice of managing the extremely preterm infant. It would be highly unlikely that anyone in this practice would consider that a living 24-week gestation infant was any less a person than a 24-year-old, however philosophically incorrect. That is, those decisions, including the foregoing of life-sustaining treatment, ought not be made on the basis of the moral worth of the infant. As Higginson wrote: “it is not obvious that doctors have any special expertise that allows them to presume to judge the ultimate value or significance of another human life.”(215)

Thus the application of any personhood argument would have no clear application given the real nature of clinical decision making and would be out of social context. That is not to say that the concept of personhood is unworthy of examination. That is up to the philosophers. But it is to say that, in all likelihood, the concept would be rejected by others actually involved in the clinical situation. Other reasons and arguments would be used, and the personhood argument would be rejected on cultural grounds, which afford the most vulnerable, human dignity.(216)

It is a powerful general view that the life of an infant is a very highly placed value, and the death of a baby is a sad and undesirable occurrence. Is there something in us, nonmetaphysical, that places this high value on life and particularly on the life of an infant? Neuroscientists have demonstrated that there are strong neurochemical rewards, expressed as pleasure, but seen as activation of neurochemical pathways, that are triggered by interaction with infants, and in particular our own.(217,218) This visualized response is the passion aspect that is pitted against a reasoning personhood argument. This is probably why the latter is counterintuitive. The passion is not necessarily directed in favor of life-sustaining treatment, but might be strongly felt when a parent, or a physician, strongly believes that he or she may be severely harming a disabled infant by allowing life-sustaining treatment.

As Wocial wrote: “ethics involves not only understanding principles and respecting rights, but reasoning through deep emotions.”(219)

With this may come moral distress that occurs when an individual perceives that what he or she believes is the right thing to do is obstructed in some way.(219)

However personhood is defined and described, it is not the only basis for moral standing(220) and use of the term, in arguments concerning foregoing life-sustaining treatment for extremely preterm infants, does not appear to be operational.

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QUALITY OF LIFE AND BEST INTERESTS

Is it true that the life of an individual with a severe disability may be so difficult for that individual that should the opportunity arise, during early infancy, to extinguish the possibility of that life, taking that opportunity is a morally good act and not a morally harmful one? In the best interests argument it is held that treatment for a severely disabled infant should be such that it is based on a reasonable assessment that its benefits outweigh its burdens. In this approach there is an acknowledgment that there is a balance to be struck between the value of an infant's life, and "a life that, on balance, does not warrant aggressive treatment."(211) The proposal is that treatment of certain infants harms their interests. How can we judge this for infants who are unable to express their interests? It is clear that some severely disabled infants endure painful surgical interventions, and medical complications, that are performed and managed to improve, as well as sustain, their lives. In terms of the interests of such infants, is the endeavor worth the outcome? It is not the act that is morally indefensible, as we allow medical and surgical interventions to be performed on others, and attempt to alleviate their pain and maximize their outcome. Is it, then, the outcome that is nonbeneficial? That is life as a severely disabled individual. The argument cannot be sustained for the majority of disabled infants who will live lives of sentience and individual significance. But what of the infant who is destined to be profoundly retarded and multiply handicapped?

Robertson wrote that:

> the essence of the quality of life argument is a proxy's judgment that no reasonable person can prefer pain, suffering, and the loneliness of, for example, life in a crib with an IQ level of 20, to an immediate painless death . . . a standard based on healthy ordinary development may be entirely inappropriate to this situation. One who has never known the pleasure of mental operation, ambulation, and social interaction surely does not suffer from their loss as much as one who has . . . life and life alone, whatever its limitations, might be of sufficient worth . . . one should also be hesitant to accept proxy assessments of quality of life because the margin of error in such predictions may be very great . . . even if the judgment occasionally may be defensible, the potential danger of quality of life assessments may be a compelling reason for rejecting this rationale for withholding treatment.(221)

The argument is that we cannot truly objectively judge what a profoundly handicapped individual might prefer. This was not the way authors of a Hastings Center Report saw it.(222) They supported the use of a quality of life standard that, they stated, should be made in reference to the well-being of the infant. They concluded that it was in the best interests of an infant not to receive treatment when continued life would be worse for the infant than an early death. Foregoing treatment, they believed, would not be unjust discrimination when the infant's handicap was so severe that there could not be a meaningful comparison with an otherwise normal child. They did make it clear that any decision should be made from the child's perspective, but did not state how this was to be determined, other than that there were certain states marked by pain and suffering that could be viewed as worse than death. They did allow themselves another option, but without dismissing the best interests approach. They stated that they were proposing not only a best interests standard, but also an alternative relational potential standard, where it could be said that if an infant lacked any present or future potential for human relationships, because of severe neurological impairment, they could be said to have no interests, except to be free from pain and discomfort. If the child is judged not to have interests, apart from being free from pain and discomfort, foregoing treatment is allowable, but not obligatory, as although continued treatment would not benefit the infant, neither would it cause harm. According to the Hastings Center Report participants, the relational standard differs from the best interests standard in that it allows the interests of others, such as family and society, to decide whether to treat.

There is thus a dilemma that revolves around the indefinable nature of best interests, a lack of interests, and the notion that there is not an absolute requirement to attempt to prolong life in all situations. Singer, in arguing for nonvoluntary euthanasia of severely disabled infants, wrote:

> [His] arguments presuppose that life is better without a disability than with one, and is this not itself a form of prejudice held by people without disabilities . . . the error in this argument is not difficult to detect. It is one thing to argue that people with disabilities who want to live their lives to the full should be given every possible assistance

> in doing so. It is another, and quite different thing, to argue that if we are in a position to choose, for our next child, whether that child shall begin life with or without a disability, it is mere prejudice or bias that leads us to choose to have a child without disability. If disabled people who must use a wheelchair to get around were suddenly offered a miracle drug that would, with no side effects, give them full use of their legs, how many of them would refuse to take it on the grounds that life without a disability is in no way inferior to life with a disability? In seeking medical assistance to overcome and eliminate disability, when it is available, disabled people themselves show that the preference for a life without disability is no mere prejudice.(223)

To use this as an argument to support nonvoluntary euthanasia of disabled infants does not appear to be coherent. First, even if we could predict, a supposed good life for a disabled infant is not necessarily commensurable with a possible good life for a nondisabled infant. If you ask a nondisabled adult, Which would you prefer, to live as you are now or in a wheelchair with poor sphincter control?, a reasonable response would be that, with the choices available, remaining ambulant and continent is not a bad or biased choice. However, if the choice is one between wheelchair existence or death in early infancy, then the response might be different. The argument is not which is a preferable life, if one could choose, but it is whether adult persons can make that decision for a disabled infant, based on the argument that it is so much more preferable to live a life as a nondisabled person. Of course we would prefer to have bright able-bodied children. There are many things we would all prefer, but the vulnerable have a right to protection, morally, socially, and in law, whether it is a preference to live a disabled life. This right to protection is bound by the duty of those with special interests in the child, such as parents or physicians, to protect the child. Preference utilitarianism is not only incorrect and unjust, it could justify a eugenics theory that many would find unacceptable.

Understanding, and agreeing on, what is meant by quality of life for another individual is subjective, a value judgment. Despite this, most of us can agree on disorders that would detract from the quality of living, chronic pain, frequent unpredictable poorly controlled seizures, chronic emotional distress and anguish, and so on. We also acknowledge that it is the duty of a physician to attempt to relieve these disorders, without further adding or substituting another unacceptable disorder. In general, physicians attempt this, and competent patients readily consent. There is no ethical discord here. But there is when the patient is not capable of consent and intervention will sustain life that is deemed by some to be of poor quality. The degree of this poor quality may not be entirely predictable. This is the situation that exists for an extremely preterm infant with brain damage. Prediction of this infant's present and future quality of life may be based on ignorance and prejudice. There may be ignorance of the type of lives lived by severely multiply handicapped individuals and prejudice toward the deformed and intellectually impaired. Quality of life judgments, in this situation, as with best interests, should be from the perspective of the disabled infant. As this is not knowable, in the present, and perhaps in the future, it could be argued that quality of life judgments should not be used to justify foregoing life-sustaining treatment for the extremely preterm infant. But there are those who believe there are situations where, in all likelihood, the future quality of life of a damaged infant "can confidently be judged to be undesirable for, and undesired by, any human being."(224)

They would then argue that it is ethically justifiable, in this situation, to forego life-sustaining treatment. Good people might disagree. Not based on a sanctity of life argument, but rather on the inability of the observer to know the mind of the infant with severe disability, however undesirable that future life might appear.

When making a decision to forego life-sustaining treatment for an extremely preterm infant is there a boundary beyond which most would agree stopping treatment is not unethical? There probably is, in our society, but there are difficulties recognizing this boundary in advance. There might be a high degree of consensus between all involved if there was certainty that the outcome would be a chronic vegetative state. The consensus would lessen if the outcome was a final mental age of 3 years. If we could predict this in the neonatal unit, would this be an acceptable boundary? To some it might, as the capacity for self-determination would be limited; to others it would not, for all the reasons previously stated. Specific prognostic uncertainty clouds the ability to make these decisions. Even when there is clear evidence, from clinical and radiological information, that a cerebral palsy syndrome will develop, the degree of severity may be difficult to predict. When outcome statistics are given for extremely preterm infants, they tell us little about the severity of handicap and the quality of life from the perspective of the disabled individual.

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FUTILITY

Although often stated in medicine, the term *futility* has little agreed-on meaning without definition or qualification. The term should only be used with respect to a stated outcome. Physiologic futility is an ability to produce a desired physiologic response by any intervention.(225) Quantitative futility is the probable failure of any intervention to provide a benefit to a patient derived from previous knowledge and experience.(225) Qualitative futility refers to an intervention whose outcome is deemed not worthwhile.(225) The use of the term, defined and qualified, does not necessarily prescribe procedure and lead to a readily agreed on conclusion. Its use, defined and qualified, does provide an understandable topic for discussion that can be used in conjunction with moral theory and concepts. For example, when considering foregoing life-sustaining treatment for an extremely preterm infant, providing further intervention may be futile in terms of short-term survival or in terms of leading to a worthwhile life. These are qualifications of the term *futility*. The use of the term in this way helps to set the stage for discussion of scientifically derived facts and moral arguments that might apply to the act and consequences of life-sustaining treatment for an extremely preterm infant.

However, the term *futile* can trigger an emotional response that is counterproductive. For example, if parents disagree with physicians concerning the withdrawal of life-sustaining treatment from their infant, and they are told that the treatment is futile (qualified or otherwise), what they may hear is that they are being told that the treatment is not worthwhile, it is a waste of time, which may quickly become it is a bothersome waste of time. When the physician uses the term, what is meant is that the treatment in question cannot achieve a certain goal, and the use of the term strongly reflects his or her feelings concerning the continuation of treatment. Because the term has been used, it might only serve to entrench differences of opinion, however valid either opinion is. The word is best avoided in these situations. It might also best be avoided in discussions between health and allied professionals and reduce the risk of euphemistic misunderstanding. Professionals may still argue that they are not obliged to provide treatments they consider useless or harmful. One of the difficulties generated by the use of the term *futility*, and its pejorative nature, is that it threatens to change the focus of the argument from when it is right to forego life-sustaining treatment to one concerning power and influence, the right of parents to control what is happening to their child against a perceived professional authority of physicians. Tactful language is as much a part of the practice of medicine as it is of political diplomacy. That physicians, in practice, have the determining role in recognizing when it may be appropriate to forego life-sustaining treatment does not constitute the final step in the process. The next step is one of counseling, which is a complex subtle exercise that may turn on the use of a word. Skill in this counseling process is part of the art of medicine and can be the exercise of an ideal virtue. The virtue is that proper conduct leads to a lessening of harm, that is, conflict and misunderstanding, and the promotion of good, that is, the resolution of a question based on sound moral principles.

PART 3

REPORTS, OFFICIAL OPINIONS, AND GUIDELINES

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UNITED STATES

The first important U.S. report that related to the extremely preterm infant came from a president's commission published in 1983.(226) In the section on seriously ill newborns, the commission reported that between 1970 and 1980 the neonatal mortality rate almost halved and that this was the greatest proportional decrease in any decade since national birth statistics were first recorded in 1915. The decrease was "especially dramatic" in the very low birth weight (<1,500g) and the extremely low birth weight (<1,000g) infants, with 50% of the latter surviving (at that time) compared to less than 20% twenty years previously. However, they noted that there was a downside to this, as the survivors could be impaired. This, they stated, tested "the limits of medical certainty in diagnosis" and "raises profound ethical issues." The commission attempted to provide ethical and legal guidelines in order to provide a framework for those in health care and the law. To aid them in this, testimony was provided by various experts. One such testimony came from Carole Kennon, a neonatal intensive care social worker, who stated that anguished parents "watching the suffering of an infant the size of an adult's hand – connected to awesome machinery and offered only distant prospects of a somewhat normal survival – inevitably takes an emotional toll"; and for those families who leave the unit with a handicapped child: "they must often travel a financially and emotionally perilous path." The commission also noted that withdrawing life support from a seriously impaired infant was a relatively frequent occurrence in U.S. neonatal intensive care units and this was usually following parent and physician agreement. But questioning of this system was reflected by the statement of parents Paul and Marlys Bridge that "we regard any decision making by concerned physician and parents behind closed doors of the pediatric unit as a haphazard approach."(227) This sentiment was supported by the commission who wrote that:

> appropriate information may not be communicated to all those involved in the decision;
> professionals as well as parents do not at times understand the bases of a decision to treat or not to treat; and
> actions can be taken without the informed approval of parents or other surrogates.

Further emphasis was made concerning the problems of adequate communication between physicians and parents, with a particular note on the "preconceptions held by physicians and parents about the quality of life of handicapped individuals." Physicians and parents may differ on who, in reality, has the final responsibility for continuing life-sustaining management. As Diane Crane wrote: "[V]ery few doctors seem to have given such matters enough consideration to have worked out a philosophical position toward them,"(228) and one parent told the commission: "I am very uncomfortable with the doctor assuming that if there are two equal choices, he will decide and take the responsibility."

In coming to their conclusions, the commission relied on the following concepts. The first was parental autonomy, and they stated that: "Public policy should resist state intrusion into family decision making unless serious issues are at stake and the intrusion is likely to achieve better outcomes without undue liabilities." Parental autonomy was to be balanced by the best interests of the child. If these interests did not appear to be followed, "the stage is set for public intervention." Quoting a U.S. Supreme Court decision (*Prince v. Massachusetts*, 321 US 158, 166, (1944)) they stated that "parents are not entitled to make martyrs of their children." They emphasized that parents or guardians must be given up-to-date relevant information from caring and empathic health care professionals. The commission acknowledged that best interests might be difficult to assess and recommended that conclusions be based on whether:

1. a treatment is available that would clearly benefit the infant.
2. all treatment is expected to be futile, or
3. the probable benefits to an infant from different choices are quite uncertain.

Beneficial therapies were those where there was "medical consensus that they would provide a net benefit to a child." Parents could choose between reasonable alternatives but should not "reject treatment that is reliably expected to benefit a seriously ill newborn substantially, as is usually true if life can be saved." Where the expectation of handicap entered into the consideration, the commission applied what they termed a very restrictive standard. That was that "permanent handicaps justify a decision not to provide life-sustaining treatment only when they are so severe that continued existence would not be a benefit to the infant." Although they agreed that this was imprecise and subjective, their view was that applying this concept would exclude idiosyncratic views, particularly if benefits and burdens were evaluated from the perspective of the infant.

The commission were clearer in their description of futile therapies, which were those that offer no benefit and "no reasonable probability of saving life for a substantial period." Comfort, pain relief, and respect for the dying patient and grieving family were paramount. Where a course of action or where the interests of an infant are uncertain, the commission wrote that professional associations and health care institutions should "ensure that the best information is available and is used when decisions about life-sustaining treatment are made." Specialist consultation should be available and sought. Although the commission acknowledged that the courts might adjudicate, in situations where there was a dispute, they did not find this was a very satisfactory course. They observed that judicial proceedings take time. This was stated ably by Kennon when she said in her testimony that:

> I think we have . . . a real contrast in time-frame analysis between the medical and the legal profession. . . . When we talk about quick court decisions we are talking about 12 days. When I talk about quick, it means running down the stairs rather than taking an elevator . . . you have to understand when physicians want an answer they want it in 10 minutes. When lawyers produce an answer, they congratulate themselves for producing it in 10 days.

The commission were also critical of the adversarial nature of the courts in these situations. They were particularly scathing when considering the government regulations that followed the

Infant Doe case (*Infant Doe*, 52 US LW 3369 (1983)), of which more will be discussed later in this book. The commission wrote:

> Instead of adding further uncertainty to an already complex situation, the Federal government would do better to encourage hospitals to improve their procedures for overseeing life and death decisions, especially regarding seriously ill newborns. Using financial sanctions against institutions to punish an 'incorrect' decision in particular cases is likely to be ineffective and to lead to excessively detailed regulations that would involve government reimbursement officials in bedside decision making.

The commission concluded that "hospitals that care for seriously ill newborns should have explicit policies on decision making procedures in cases involving life sustaining treatment for these infants." This might require specialist consultation about a condition, or if the benefits of therapy are in dispute, or unclear, an ethics committee might be designated to review the decisions. Finally, they stressed that society should make provisions for handicapped children as there is "an obligation . . . to provide life continuing care that makes a reasonable range of life choices possible."

Thus the commission set the stage on which other opinion makers could perform, and on which bioethicists could pontificate, governments could regulate, and lawyers dissect.

In 1994, the American Academy of Pediatrics issued their guidelines on foregoing life-sustaining treatment.(229) They noted early in their statement that: "sometimes limiting or stopping life support seems most appropriate, especially if treatment only preserved biological existence or if the overall goal of therapy has shifted to the maintenance of comfort." They acknowledged that, philosophically speaking, there was little distinction between not starting treatment and discontinuing it. However, because uncertainty was often present, they recommended initiating an intervention that, if later proved to be unhelpful, could be stopped. Not only could it be stopped, it should be stopped, according to the Academy, as “continuing non-beneficial treatment harms many patients and may constitute a legal, as well as moral, wrong.” This approach, they stated, was supported by the moral notion that the reasons to start or stop treatments are “based primarily on the relative benefits and burdens for the patient.” Thus the introductory remarks in the Academy’s guidelines favor a best interests approach and suggest consideration of quality of life when deciding on life-sustaining treatment for children. As with the recommendations in the earlier president’s commission,(226) it was advised that informed parents should be the decision makers, when advised by the responsible physician. If there are disagreements that cannot be resolved, despite appropriate consultation, the courts can become involved. Physicians are responsible for providing adequate information and alternatives, but, the guidelines state, “they should recommend what they believe is the best option for the patient under the circumstances and give any reasons, based on medical, experiential, or moral factors, for such judgments. However, physicians should remind families that they may accept or reject the physician’s recommendations.” Although there is no clear answer to this, that is, who guards the guardians, the reader may want to consider the presumption that physicians may be the best moral arbiters when considering life and death decisions for children based on a best interests approach.

Over the next 2 years, the American Academy of Pediatrics published three more pertinent reports. Two were in 1995 through the Committee on Fetus and Newborn and one of these was in association with the American College of Obstetricians and Gynecologists.(230,231) The first report published concerned foregoing life-sustaining treatment for high-risk newborns, which included extremely preterm infants.(230) As with previous reports, this one stated that treatment should be based on what is in the best interests of the infant but qualified this by stating that what constituted "best interests" was not always clear. They stated that "intensive treatment . . . sometimes results in prolongation of dying or occasionally iatrogenic illness; nonintensive treatment results in increased mortality and unnecessary morbidity." The report's recommendations were as follows:

1. Ongoing evaluation of the condition and prognosis of the infant is essential, and the physician as the spokesperson for the healthcare team must convey this information accurately and openly to the parents of the infant.
2. Parents should be active participants in the decision-making process concerning the treatment of severely ill infants.
3. Humane care must be provided to all infants, including those from whom specific treatment is being withheld. Parents should be encouraged to participate in the care of their infant as much as they wish.
4. If the viability of the infant is unknown, or if the curative value of the treatment is uncertain, the decision to initiate or continue treatment should be based only on the benefit to the infant that might be derived from such action. It is inappropriate for life-prolonging treatment to be continued when the condition is incompatible with life or when the treatment is judged to be futile.(230)

The first three statements are no more than should be expected from good medical practice. The fourth statement only partially addresses the dilemma. Most would agree that life-prolonging treatment, such as artificial ventilation, is inappropriate for conditions that in the near future are inevitably terminal, whatever the management. However, in the last part of the sentence the committee stated that treatment is inappropriate when it is judged to be futile. Futility is not defined or qualified, but as conditions incompatible with life have been stated as reason for foregoing life-sustaining treatment, one can only presume that it is a life with unacceptable quality that is the criterion. No mention is made of how well the perceived criterion can be predicted nor what types or levels of disability are acceptable and why. The only guideline is the infant's best interest.

The second report is on perinatal care at the threshold of viability.(231) The committees acknowledge the relatively high mortality rates of preterm infants born at 25 weeks or less and the high proportion of disability, of varying severity, in the survivors. They noted that mortality and morbidity changes with each additional week of gestation and caution that practitioners "should allow for some error in the best estimate of gestational age and fetal weight." As they stated, even in ideal circumstances, the 95% confidence limits for a formula-based estimate of fetal weight are ±15% to 20%,(232) and small discrepancies in the estimation of gestational age have major implications for survival and morbidity. They therefore recommended that when counseling, a range of possible outcomes should be given. They also noted that multiple gestation complicates the prognosis, as it relates to weight and gestation. The report then goes on to discuss modes of delivery and the need for frequent evaluations of the infant, including at birth, to determine management, as well as compassionate, dignified, treatment of the infant and family should there be a foregoing of life-sustaining medical treatment. However, no guidelines are given to help in how to determine when this should occur.

The third policy statement from the American Academy of Pediatrics came from the committee on Bioethics(233) and concerned the ethics and care of critically ill infants. The committee again followed a best interests approach, which they believed should be individualized for all children, regardless of age. They did make it clear that decisions regarding resource allocation, and distributive justice, should be addressed at the public policy level and not at the bedside. They allowed that "good medical practice may favor initiation of life sustaining medical treatment until clarification of the clinical situation and relevant ethical values can occur." However, they stated that "many think that laws, regulations, and government policies have unduly constrained parents and physicians from exercising reasonable judgments about whether to forgo life sustaining medical treatment." There was no clear guidance on what constituted a reasonable judgment for an extremely preterm infant, except that it should be made, by parents on the advice of physicians, on a case-by-case basis, and the judgments that are made should be equivalent to those made for critically ill older children. The inference here is that the recognition of benefits and burdens of life-sustaining treatment for the extremely preterm infant may be similar to, for example, that for an older child with end stage cancer. But the uncertainty of outcome may be very different. That the justice principle should apply to children, no matter what their age, is clear. But the principle is applied properly only if they have similar conditions. The committee summarized their recommendations as follows:

1. Decisions about critical care for newborns, and children should be made similarly and with informed parental permission.

2. Physicians should recommend the provision or forgoing of critical care services based on the projected benefits and burdens of treatment, recognizing that parents may perceive and value these benefits and burdens differently from medical professionals.
3. Decisions to forgo critical care services on the grounds of resource allocation, generally speaking, are not clinical decisions, and physicians should avoid such "bedside rationing."(233)

This third policy statement provides little clarification on what constitutes moral legitimacy for forgoing life-sustaining treatment for the extremely preterm infant, except the use of the ill-defined terms *benefits* and *burdens*, which appear to have become a mantra. The statement, however, is useful, in part, because it invokes the principle of individual justice, which can be argued for the individual and for allocation of resources, but in different ways, in different venues.

In 2002, the American College of Gynecology and Obstetrics (ACOG) issued a practice bulletin on perinatal care at the threshold of viability,(234) which they defined as 25 or fewer completed weeks of gestation. They noted the very low prevalence of these births but their high contribution to perinatal mortality. They also recognized a past difficulty with interpretating the results of outcome studies because of variable methodologies, incomplete data, and small populations but believed the results from large multicenter studies provide sufficient detailed data to assist in the management of the extremely preterm infant (see Part 11). They emphasized the need to counsel parents on the basis of specific gestational age, estimated weight, and gender, as each affects outcome, and they quoted the National Institute of Child Health and Human Development (NICHD) Neonatal Research Network trial, which was a large prospective study of 4,633 infants weighing between 400g and 1,500g at birth, conducted at 14 tertiary centers across the United States between 1995 and 1996.(236) Based on this, and similar studies, three types of counseling recommendations were given. The first recommendations were based on good and consistent scientific evidence as follow:

> In general, parents of anticipated extremely preterm fetuses can be counseled that the neonatal survival rate for newborns increases from 0% at 21 weeks of gestation to 75% at 25 weeks of gestation, and from 11% at 401–500g birth weight to 75% at 701–800g birth weight. In addition, females generally have a better prognosis than males.
>
> In general, parents of anticipated extremely preterm fetuses can be counseled that infants delivered before 24 weeks gestation are less likely to survive, and those who do are not likely to survive intact. Disabilities in mental and psychomotor development, neuromotor function, or sensory and communication function are present in approximately one half of extremely preterm fetuses.(236)

These appear to be reasonable recommendations. But if the morbidity outcomes were stated as written to parents, they could be misleading. Using the study quoted by the college,(42) about 25% of the survivors would have severe disability. The remainder of the impaired survivors would have varying lesser degrees of disability, which include relatively mild learning and attentional difficulties. If the morbidity outcomes, for survivors, derived from birth weight reported by the NICHD study(98) are used, as they are in the text of the ACOG report, at age 18 months 57% of the tiniest babies with birth weights of 401–500g and 71% of those weighing 501–600g had normal examinations. Although some of these survivors may have had intrauterine growth retardation, and therefore a potentially better prognosis, the point is that language can be manipulated, purposefully or otherwise, which affects communication with parents and thus their perceptions. The next type of counseling recommendations were stated to be based on limited or inconsistent scientific evidence and were as follows:

> Based on data from retrospective studies, maternal transport to a tertiary care center before delivery should be considered when possible.
>
> The effects of aggressive resuscitation at birth on the outcome of the extremely preterm fetus also are unclear. Therefore, management decisions regarding the extremely preterm fetus must be individualized.
>
> Prospectively collected outcome data for extremely preterm fetuses are available. Whenever possible data specific to the age, weight, and sex of the individual extremely preterm fetus should be used to aid management decisions made by obstetricians and parents of fetuses at risk for preterm delivery before 26 completed weeks of gestation. This information may be developed by each institution and should indicate the population used in determining estimates of survivability.(236)

The second recommendation in this set reflects the difficult conjectural nature of decision making when considering foregoing life-sustaining treatment for the extremely preterm infant. Stating that management decisions should be individualized begs the question and does little to clarify the dilemma. That is, in matters concerning life and death decisions, can a best interests approach be used, or a more substantive, but not certain, approach, such as survivability? The text of the report does not mention two papers published in 2000 by Jankov, Asztalos, and Skidmore(53) and Costeloe et al.,(56) that suggested that aggressive resuscitation at birth on an extremely preterm infant improved survival and did not appear to increase morbidity. The committee does state in the text that the ethics of this situation are complex and "the decision to withhold or withdraw support should not be made entirely on the basis of gestational age or birth weight, but should be individualized based on the newborn's condition at birth, survival and morbidity data, and the parents' preferences." But if the efficacy of aggressive resuscitation at birth is unclear, that just leaves parents' preferences. As the boundaries of parental preference remain arguable, the ethical dilemma remains but does allow for the resolution of a situation in a functional manner. How U.S. law responds to this will be seen later.

The final set of recommendations are based primarily on consensus and expert opinion and are:

> When extremely preterm birth is anticipated, the estimated gestational age and weight should be carefully assessed, the prognosis for the fetus should be determined, and each member of the health care team should make every effort to maintain a consistent theme in their discussion with family members regarding the assessment, prognosis, and recommendations for care.
>
> Because it is difficult to predict how an extremely preterm newborn will develop, proactive programs to assess and support the infant through early school years are desirable. When the extremely preterm newborn does not survive, support should be provided to the family by physicians, nurses, and other staff after the infant's death.(236)

In the same year as the ACOG report, the Committee on Fetus and Newborn of the American Academy of Pediatrics issued a further report on perinatal care at the threshold of viability.(236) This is similar to the ACOG report and covers the recorded mortality and morbidity rates of extremely preterm infants, the potential flaws in estimated birth weight and gestational age, the uncertainty of early prognosis, and the need for repeated reevaluations and repeated knowledge-based counseling of parents providing a range of possible outcomes. There were some important specific recommendations that, in full, were as follows:

> . . . non initiation of resuscitation for newborns of less than 23 weeks gestational age and/or 400g in birth weight is appropriate. Parents should be counseled that decisions about viability and neonatal management made before delivery may need to be altered in the delivery room and beyond depending on the condition of the neonate at birth, the postnatal gestational age assessment, and the infant's response to resuscitative and stabilization measures. Decisions regarding the extent of continuing support require frequent re-evaluations of the infant's condition and prognosis and reconsideration with the parents.
>
> When a decision is made to withhold resuscitation, discontinue resuscitation, or forgo other life-supporting treatments, the family should be treated with compassion, focusing on their needs. Humane and compassionate care must be provided to the nonviable or dying infant and the family. This includes careful handling, maintaining warmth, avoidance of invasive procedures, and unobtrusive monitoring – sometimes called comfort care.
>
> When medical support is discontinued or death is inevitable, time and opportunity should be provided for

> the parents and other family members to hold, touch, and interact with the infant before and after the infant dies. Simple personalizing acts, such as naming the infant, obtaining a photograph, footprint sheet, crib card, name band, or even a lock of hair; and recording birth weight and other measurements may be important to the parents and should be provided. Clergy and supportive family and friends should be encouraged to have access to the infant in a setting that maintains dignity.
>
> Support should be provided to the family by physicians, nurses, and other staff beyond the time of the infant's death. This may include referral to perinatal loss support groups, repeated telephone contact, other simple acts of condolence, and a conference with the family to review the medical events surrounding the infant's death and to evaluate the grieving response of the parents.

These are clearly virtuous statements and reemphasize the importance of decorum and empathy in the practice of pediatrics.

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CANADA

In 1994 the Fetus and Newborn Committee of the Canadian Paediatric Society and the Maternal-Fetal Medicine Committee of the Society of Obstetricians and Gynaecologists of Canada published guidelines for the management of the woman with a threatened birth of an infant of extremely low gestational age.(237) Their recommendations were:

> According to current Canadian outcome data, fetuses with a gestational age of less than 22 completed weeks are not viable, and those with an age of 22 weeks rarely viable. Their mothers are not, therefore, candidates for cesarian section, and the newborns should be provided with compassionate care, rather than active treatment. The outcomes for infants with a gestational age of 23 to 24 completed weeks vary greatly. Careful consideration should be given to the limited benefits for the infant and potential harms of cesarian section, as well as to the expected results of resuscitation at birth. Cesarian section,

> when indicated, and any required neonatal treatment are recommended for infants with gestational ages of 25 and 26 completed weeks; most infants of this age will survive and most survivors will not be severely disabled. Treatment of all infants with a gestational age of 22 to 26 weeks should be tailored to the infant and family and should have fully informed parents.

In the text of the report, the committees acknowledged the ethical complexities surrounding the extremely preterm infant and noted that the birth of a child with a gestational age of 22 to 26 weeks "is fraught with uncertainty concerning the chance of survival and the risk of impairment and disability." They noted the extreme difficulty of making a prognosis before birth and during the first few days after birth. The guidelines did not deal with later management in the neonatal intensive care unit. This was addressed in a position statement by the Bioethics Committee of the Canadian Paediatric Society.(238) They also invoked the best interests concept, but their interpretation allowed only a limited consideration of quality of life. They stated that the primary concern of physicians caring for children must be the best interests of the individual child, and all infants have intrinsic value and deserve respect and protection. Their view on mental or physical handicap as a determining factor was that "all children, regardless of handicap either actual or potential, have a justified claim to life and therefore to such medical treatment as is necessary to either improve or prolong life." They emphasized that the interests of the child were paramount over other interests and that "usually, the best interests of the child will favour the provision of life-sustaining treatment. This is self-evident where the result of the treatment will be survival of a child with no or little handicap, but should be equally true even when a chronic physical or mental handicap will continue to be present." Their exceptions to the general duty of providing life-sustaining treatment were:

1. irreversible progression to imminent death;
2. treatment that is clearly ineffective or harmful;
3. instances where life will be severely shortened regardless of treatment and where non-treatment will allow a greater degree of caring and comfort than treatment;
4. lives filled with intolerable and intractable pain and suffering.

Further guidelines were given concerning the responsibility for decision making and its implementation. Parents were morally and legally responsible for their children and for providing consent to their treatment. Exceptions to this were:

1. they are incompetent to make decisions for themselves,
2. there are unresolvable differences between the parents, or
3. they have clearly relinquished responsibility for the child. In that case, the identification of a legal guardian should precede any decisions regarding withholding treatment.

Other points included the intervention of the court should there be irreconcilable disagreement between physicians and parents. Where there was agreement, and life-sustaining treatment was foregone, it was recommended that there be a post hoc ethical review. The Canadian Paediatric Society issued a further position statement (B2004–01) in 2004, concerning treatment decisions for children.(239) It contained new information concerning consent and assent for treatment of children and adolescents but contained no new information or recommendation pertaining to the extremely preterm infant.

25

UNITED KINGDOM (UK)

In the UK, in 1997, the Royal College of Paediatrics and Child Health issued guidelines on foregoing life-sustaining treatment for children.(240) These were based on a best interests approach. Five situations were given where the foregoing of life-sustaining treatment might be considered:

1. Brain death
2. Permanent vegetative state
3. The "no chance" situation. The child has such severe disease that life-sustaining treatment simply delays death without significant alleviation of suffering. Medical treatment in this situation may thus be deemed inappropriate.
4. The "no purpose" situation. Although the patient may be able to survive with treatment, the degree of physical or mental impairment will be so great that it is unreasonable to expect them to bear it. The child in this situation will never be capable of taking part in decisions regarding treatment or its withdrawal.

5. The "unbearable" situation. The child and/or family feel that in the face of progressive and irreversible illness further treatment is more than can be borne. They wish to have a particular treatment withdrawn or to refuse further treatment irrespective of the medical opinion on its potential benefit.

Some might find the language used in these guidelines unsuitable (no purpose, no chance). Be that as it may, situation 4 demands specific accurate prognosis, is vague, and requires value judgments.

In 2000, the British Association of Perinatal Medicine (BAPM) issued a memorandum concerning fetuses and newborns at the threshold of viability.(241) They defined threshold viability as a gestation of 22 to less than 28 weeks (about 500–1,000g) but acknowledged that in developed countries the term was more often used in reference to infants of less than 26 weeks. The authors stated that because of the risk of disability or early death, serious ethical dilemmas were raised. The specifics of how these dilemmas should be addressed are not discussed. They do advise the use of a best interests approach but leave this to be interpreted by the reader. Some of their recommendations for management are as follows:

> Decisions on management should be based on what is perceived by parents and their medical advisors to be in the child's best interest, uninfluenced by the child's gender or by religious, eugenic, demographic or financial factors.
>
> Medical staff have a responsibility to keep parents informed as to the likely clinical outcome resulting from the decisions in which the parents need to participate.

Counseling must be honest and accurate. Parents may have unrealistic expectations not only as to what is medically possible but also as to future prospects for their infant . . . .

Perinatal mortality, morbidity and future outcome relate closely to gestational age at birth. There needs to be an agreed policy for the antenatal estimation of the expected date of delivery. This is usually based on early ultrasound measurements and the menstrual history. Physical examination of the infant after birth may lead to a revision of the original estimate. This needs to be explained in advance to parents who otherwise may be confused or feel that an error has been made . . . .

The perinatal team needs to be aware of up-to-date national statistics on infant mortality and morbidity outcome according to gestational age, as well as results of local audit. This should include the incidence and severity of disability amongst survivors at the age of 2 years or more. Following delivery, more accurate on-going advice concerning the individual child's prognosis will become available with the passage of time as the result of clinical observation and investigation.

Following counseling on the likely prognosis, some parents may wish to give advance authorisation for the non-resuscitation and non-provision of intensive car for infants at the extreme margin of viability. While appreciating their wishes, such authorization cannot be considered binding on the health care team . . . .

> . . . It may be appropriate to institute intensive care to threshold-viability infants at birth until the clinical progress of the infant and further consultation with the parents has clarified whether it is better to continue or withdraw this form of medical care . . . .
>
> . . . The doctor counseling parents on the withholding or withdrawal of life support should be senior and experienced. When appropriate the doctor may wish to consult colleagues or, in exceptional circumstances, an ethics committee or the courts . . . .
>
> . . . The doctor counseling parents should be careful not to impose his or her own cultural and religious convictions on those whose beliefs may be different, bearing in mind the requirements of the law. When a doctor's beliefs prevent the disclosure of all possible management options open to the parents, the doctor has a duty to refer them to a colleague who is able to do so.
>
> . . . When the parents do not agree with each other, or when they do not accept their doctor's advice on whether or not to withhold or withdraw care, treatment should be pursued until a change in the baby's status or further counseling and discussion clarifies the situation. Only as a last resort and in exceptional circumstances after all other options have been exhausted, should the problem be referred to the Courts.(241)

These examples of the guidelines issued by the British association are sensitive to a difficult situation. It is clear that they come from experienced clinicians who acknowledge uncertainty and the principle role of parents in the decision making but recognize limits to their autonomy. However, there is still no clear resolution of how much a perceived quality of life for a disabled child should play in the decision to forego life-sustaining treatment. There is not a clear answer to this, when the guidelines ask that a best interests standard be applied in a compassionate paternalistic manner. In the final analysis, this may be the best functional approach, but it places on the physicians an assumption that they have a uniformity of excellence in ethical and prognostic analysis that may not be the case.

In 2001, the British Medical Association published guidelines for foregoing life-sustaining treatment.(242) Although they continued to support the use of the term *best interests*, they were more specific in their interpretation and provided more detail than other definitions. The report stated that:

> Legally and ethically decisions to treat or not to treat are justifiable only where this is in the child's best interests. But reasons for differences in perception may be significant and require further analysis. Willingness to continue with treatment may reflect the fact that a decision to stop striving to maintain life is emotionally more difficult to make for children than adults or that outcomes may be less predictable for children due to a small evidence base from which to judge the likely outcome. The developmental potential of children is also important and paediatricians will consider the quality of this potential for progression from incompetence as a factor in decision making . . . the ethical underpinnings of paediatric, adult, and geriatric medicine are the same . . . where there is reasonable uncertainty about the benefit of life-prolonging

> treatment, there should be a presumption in favour of initiating it, although there are circumstances in which active intervention (other than basic care) would not be appropriate since best interests is not synonymous with prolongation of life. Criteria for deciding best interests are the same as those for adults, including whether the child has the potential to develop awareness, the ability to interact and the capacity for self-directed action and whether the child will suffer severe unavoidable pain and distress. If the child's condition is incompatible with survival or where there is broad consensus that the condition is so severe that treatment would not provide a benefit in terms of being able to restore or maintain the patient's health, intervention may be unjustified. Similarly, where treatments would involve suffering or distress to the child, these and other burdens must be weighed against the anticipated benefit, even if life cannot be prolonged without treatment.(242)

The guidelines, as they relate to the extremely preterm infant, are now narrower. What constitutes a life not in the best interests of the child is one in which there is no awareness, no ability to interact, no capacity for self-directed action, as well as unavoidable severe pain and distress. This may be difficult to predict and only applies to a relatively small proportion of survivors. It would not apply to those destined to be moderately disabled.

26

FRANCE

In 2000, the French National Consultative Ethics Committee reported on ethical considerations regarding neonatal resuscitation.(243) They noted that in France extreme prematurity causes 50% of neonatal mortality and is associated with a high risk of serious sequelae. They reported that the survival rate for live births less than 24 weeks was 0%, and for those at 24 and 25 weeks, survival rates were 31% and 50% respectively. This is substantially less than U.S. figures. The committee noted the history and ethical dilemmas associated with extreme prematurity and stated that they did not aim to "set up rules or recommendations" but to help those involved find solutions by "highlighting the issues which need to be taken into account." The first issue they emphasized was prevention, which they strongly believed was a priority for health policy. They had previously noted a recent increase in prematurity that they had, in part, related to late pregnancies, multiple pregnancies and faulty or poorly monitored medical prescription of ovulation induction drugs, and the transfer of several embryos during in vitro fertilization. They urged control and research in this area, as well as accountable improvements in prenatal services and further research into the causes and consequences of prematurity.

The next issue they wished to highlight was the practice of nonmaleficence. This was expressed as respect for four "categorical prescriptions": do no harm, prevent a harmful effect, eliminate a harmful effect, and provide a beneficial effect. They realized that for this to work it was necessary to consider what was desirable and what we wish to avoid. They noted that what was desirable was only defined "in the light of a person's rights, but what we wish to avoid was the onset of major disability which would not be beneficent." However, they stated that "independently of age, state of health, and particularly handicaps human dignity and value must be recognized as worthy of respect" and "a child is obviously to be considered in the same way as any other human being. Ethical principles applying to a person can and must apply to a child." The committee recognized that because of an infant's dependence, he or she deserved special consideration, but

> . . . to question or worry about the quality of life of a particular newly born infant or the child's future capacity for autonomy, and the kind of relationship which he or she may or may not establish with loved ones and the surrounding world is perfectly legitimate. However, that is no justification for a process of dehumanization which denies an endangered human child the right to dignity.(243)

The difficulty was putting into practice this respect for dignity. They believed there was a further major difficulty, and that was that severe disabilities are "sometimes . . . the adverse result of deliberate human action, the fruits of increasingly sophisticated medical practice." Because of this, they pronounced that the nonmaleficence principle was "eminently applicable" and defined aggressive and futile therapy as "irrational obstinacy," a failure of recognition that a newborn may be dying and cannot be cured. Following these strong words, they acknowledged prognostic uncertainty but tempered this with the statement that "there is also the issue of responsibility for irreversible damage which may be attributed to the treatment delivered . . . the actual process of neonatal resuscitation." The committee, having swayed the reader one way and then the other, stirred the stormy sea further by discussing the decision-making process. They stated that "the appraisement" of parents, even if they did not originate the medical decision, was the "sole criterion for evaluating the ethical demands of consent." Decisions concerning foregoing life-sustaining treatment must involve both health professionals and parents, but health professionals must avoid placing a burden of guilt on the parents, and they have an obligation to take full responsibility for professional decisions. I believe this infers incorrectly that one can differentiate between the ethical and the professional, in this situation. But the committee appreciates that there are intertwining ethical dilemmas. There is "conflict between several moral standards, all of which have a restricted degree of legitimacy." But having appreciated this, the committee returned to their previous strong reproachful tone:

> . . . [T]he lure of performance for performance's sake and ensuring survival of even younger infants, at the risk of severe future consequences for the child, is obviously (sic) non-ethical because it denies the notion of another's identity to satisfy either a narcissistic pursuit of personal satisfaction or a view of medical progress which has become completely disconnected from its true object, that is the well being of patients . . . these possibilities, including

> extreme action, must be considered when discussing initiation of resuscitation, in spite of (or perhaps because of) uncertainty regarding consequences . . . it therefore does seem that all ethical considerations and responsibilities originate from the moment when the initial decision to resuscitate is taken.(243)

The committee opened their report by stating that they were not providing rules or guidelines and that decisions should not be based totally on the possible later chance of disability. However, their tone appears to contradict this: "when at the time of delivery, the possibility of disability-free survival is nil or negligible, initiating systematic or standby resuscitation raises the issue of futile therapy." This suggests that therapy that prevents death but ends in disability may be futile. The committee might argue that they are only referring to the severest of disabilities, perhaps bordering on a minimally conscious state. But this is not made clear, nor is it recognized that this latter outcome is a small proportion and not easily predicted early in the course of management. The committee goes further when they discuss the purposeful ending of life, not just foregoing life-sustaining treatment:

> . . . [T]he issue of a medical ending of life sometimes arises. It is clear that this would be an obvious transgression of the law. . . . However when faced with tragedies for which no satisfactory solution can be found, there could perhaps be a measure of understanding for such transgression. Whatever outcome is chosen, whether or not it constitutes a transgression of texts of law as they are now applicable, there must be a guarantee that the decision is taken as a result of conscience-bound, humane, open and progressive

> processes, with due regard for the wishes of parents who alone are able to measure the burden of the life ahead of them.(243)

Some might find these frightening words that attempt to justify nonvoluntary euthanasia of an infant. However, the committee end their report by stressing the need to avoid difficult decisions relating to foregoing life-sustaining treatment for the disabled infant by early definitive measures, but then state that "these necessary efforts should not blind us to the lack of social investment in the management of disabled children." Whether there is general consensus among French neonatologists concerning the general approach given by the committee is arguable. In 2001, neonatologists from Marseille recommended that in the majority of situations intensive care should be given at birth *a priori*, (244) and decisions to withdraw treatment, on an individual basis, should be made later. They believed that gestational age– or birth weight–based restriction of access to intensive care may not be acceptable in most countries.

27

ITALY

The Italian Code of Profession Medical Ethics warns against treatment that will not bring a benefit or an improvement in quality of life (Codice di Deontologia Medica 1998 art 14). However, as will be described later, Italian law is very restrictive concerning quality of life decisions for neonates.

28

GERMANY

The German Society for Medical Law has strict recommendations concerning foregoing life-sustaining treatment for neonates. They are specific about stating that an infant's life should be protected, whether severely damaged or not. Any deliberate shortening of life is an act of killing.(247)

29

INTERNATIONAL

In 1988, 33 delegates from 10 countries met to produce a set of guidelines for discussion concerning decisions to forego medical treatment. A study edition of the guideline was distributed to 152 discussion groups that met in 15 countries for study and comment. Their responses were summarized for 24 delegates who met in Appleton, Wisconsin, and produced the document *The Appleton International Conference: Developing Guidelines for Decisions to Forego Life-Prolonging Medical Treatment.*(245) Part III dealt with decisions involving neonates. The guidelines were as follows:

1. Regard for the value of life does not imply a duty always to employ life-prolonging treatment for patients in this category. In setting reasonable limits for such treatment 'third person' judgments about quality of life are inevitable. Responsible third-person quality-of-life judgments consider, in so far as possible, how the options must appear from the perspective

of one in the patient's condition and determine what would most reasonably be thought to count as quality for most such patients.

The delegates warned that the quality of life judgment should not be based on concepts of minimal social worth, which was not morally justifiable. Some argued that to consider how options appear to an infant, who has never been competent, is misguided. They considered that this was an "inappropriate projection of others' interests onto the infant." Even so, it was felt that if a quality of life judgment was to be made it was the responsibility of those making the judgment to ascertain ". . . as far as possible, what most such patients would count as quality."

2. Assessing quality of life of these patients for purposes of medical decisions involves weighing the ratio of benefits and burdens.(245)

Although it was agreed that there were differences between people when weighting benefits and burdens, sometimes irreconcilable, the delegates, nonetheless, believed the terms useful "to help focus on clinically significant variables and to avoid employing judgments of social worth." Perhaps, but it still begs the question what constitutes a benefit or a burden and to what degree do they need to be present to justify foregoing life support?

3. In most decisions involving patients in this category, at least four sets of interest may be discerned:
    (a) the patient's
    (b) the surrogate's or family's
    (c) the doctor's and those of other caregivers
    (d) society's

> Normally, the patient's interests should be regarded as paramount. However, difficult moral dilemmas arise when the patient's interests are unclear or clearly conflict with a number of other interests . . . it is important to remember . . . in the cases most commonly encountered, the various interests are not necessarily in conflict. Often the patient's own interest is integrally interwoven with the interest of the family and the community. Part of the doctor's clinical wisdom consists of responsibly weighing interests and creatively resolving apparently irreconcilable conflicts.(245)

This approach has been discussed in the previous section. But in summary, it is felt to be a mistake to impute altruism from an extremely preterm infant. Furthermore, there is no universal generic ethical wisdom that comes with a degree in medicine, though it may be easier to argue that there may be paternalistic hubris. The next two recommendations concern honest, effective communication and adequate documentation and are not dealt with here, in any more detail. The last two recommendations concern weighing benefits and burdens.

> 6. When a patient lacks a surrogate, little difficulty arises when the benefit-burden ratio clearly favours administration and continuation of life-prolonging treatment. When the benefit-burden ratio is less certain or reversed, a wide variety of mechanisms have been proposed to aid or to review the doctor's decision-making.(245)

The reader is referred to a 1987 Hastings Center report,(222) which, as discussed in the previous section, uses a fairly restrictive, but subjective, quality of life standard to justify foregoing treatment. That is a condition that lacks potential for future relations or the probability of a life full of pain and suffering, which is worse than death. The problem with this is accurate prognosis. If uncertainty is acknowledged in the majority of situations, then those cases where the above criteria are undoubtedly fulfilled will be relatively few.

> 7. The doctor may appropriately withdraw or withhold life-prolonging treatment when, in the view of the informed surrogate and doctor, continued treatment would lead to unacceptable burdens without sufficient compensating benefits to the patient. What counts as a benefit or a burden and the relative ratio between them depends on specific situational factors and, therefore, good decisions in this category of patients demand individual discretion. While these patients possess vulnerability which makes them frequently subject to social discrimination and stigmatism, their interests are not protected by the elimination of decisional discretion. On the contrary, a trustworthy doctor and the processes of appropriate review are better means of protecting the interests of vulnerable patients.(245)

There seems to be little basis for this reasoning. The questions are not so much whether the infants' interests are not protected by the elimination of decisional discretion but whether the infant is particularly at risk if decisional discretion is too broad. Of course there needs to be trust between physicians and parents, and it is hoped that vulnerability and susceptibility to bias and ignorance will be appreciated by a physician. However, in matters concerning life and death the question must be asked, how much can we allow when the statement is “trust me, I’m a physician”?

In 1997 the International Federation of Gynecology and Obstetrics published a report on ethical aspects in the management of newborn infants at the threshold of viability.(246) The recommendations in this report are similar to those stated in the more recent guidelines in the United States and the UK concerning a threshold of viability (vide supra). A best interests approach is advocated, and this is determined by patients on the advice of experienced knowledgeable physicians.

In 2000, international guidelines for neonatal resuscitation were published by an international consensus group.(248) In these it was recommended that noninitiation of resuscitation in the delivery room was appropriate for infants with a confirmed gestation of less than 23 weeks or a birth weight of less than 400g. When there is an uncertain gestational age, options included a trial of therapy and noninitiation or discontinuation of resuscitation after assessment of the infant. Initiation of resuscitation at delivery did not mandate continued support. Withholding and withdrawing of life support were viewed as ethically equivalent, but the advantages of resuscitation and later withdrawal were that it allowed ongoing evaluation and counseling. Delayed, graded, or partial support were not encouraged.

In 2001, the Confederation of European Specialists in Paediatrics published recommendations concerning ethical dilemmas in neonatology.(249) They listed a number of ethical principles that could be applied to each newborn infant. These “principles” appeared to be tightly prescriptive. However, the confederation then placed their interpretations on these principles, which left the reader with more latitude on which to act, should he or she choose to follow these interpretations. Some of these principles and the confederation's interpretations are as follows:

> Every human individual is unique and has the right to live its own life.
>
> Every human individual has its own integrity which must be acknowledged and protected.
>
> Every human individual has the right to optimal treatment and care.
>
> Every human individual has the right to take part in society and what society has to offer.
>
> The optimal purpose of all measures and decisions should focus on the "best interests" of the patients. It is acknowledged that the definition of "best interests" can be more difficult to establish in the newborn infant.
>
> Decisions should not be influenced by personal or social views on the value of life or absence thereof by the caregivers.
>
> Retardation or disability alone is not a sufficient reason to stop treatment.
>
> Withholding or discontinuation of life support measures are ethically equivalent.
>
> The opinion of parents or the responsible representatives should be included in all medical decisions. Doctors treating the sick infant first should come to the conclusion on the basis of comprehensive facts. This should then be discussed with parents in thoughtful dialogue.
>
> Every form of intentional killing should be rejected in paediatrics. However, giving medication to relieve suffering in hopeless situations which may, as a side effect, accelerate death, can be justified.

> All decisions have to be based on evidence as solid as possible.(249)

Some of these statements are not strictly principles but contain interpretations and qualifications. Be that as it may, further interpretations followed. In their discussion on whether every human has a right to be treated, the confederation made it clear that treatment need not necessarily be life sustaining: "When there is a right to be treated, then there is also the right to withhold treatment based on the best interests of the patient. Treatment can also consist merely of symptom relief."(249) The committee had already stated that the best interests of a newborn infant has difficulties. They noted the autonomy of an adult in situations of intractable suffering or imminent death and that parents act as surrogates for infants in decision making. The extent of this obligation was uncertain. Similarly, the duty of physicians to sustain life in all situations was uncertain. To address this, some ill-defined, but useful, recommendations were given to the reader when considering the prediction of the expected life of an infant:

> Projected suffering and burden. If it can be foreseen that the life of the infant will be full of suffering and pain that cannot easily be relieved, one has to ask whether this is a life to be lived.
>
> Communication with the environment. A unique feature of a human being is its possibility to interact with its environment. If this will never be possible, an important quality of life is lost.(249)

These conditions are difficult to predict in the extremely preterm infant, and if they could be predicted, a future life of intractable pain and suffering, or a life in which there is no possibility of any meaningful interaction, would apply to only a relatively few potential survivors.

> Dependence on medical care. The option for the child to live his or her own life can be severely impaired when they are almost completely dependent on medical care for survival. This can limit the development of the infant to an inaccessible degree.(249)

In itself, this is a reasonable statement. The question is whether this degree of dependency, on its own, is sufficient to justify foregoing life-sustaining treatment. The important part of the statement is, "almost completely dependent on medical care for survival."(249) Presumably this means survival, which is dependent on lifelong artificial ventilation, or dialysis and renal transplant followed by the burdens of immunosuppression. This is a difficult dilemma. But it is certainly an action that is taken for older children and adults, who have the ability to share in the decision. Even so, the situation would apply to very few extremely preterm infants.

> What is the life expectancy of the infant? One has to balance the life expectancy against the burden of treatment. If the burden of treatment is intense and the life expectancy rather short, initiation or continuation can be questionable.(249)

The term *rather short* is rather subjective and needs defining. Even so, foregoing life-sustaining treatment when death is imminent and irreversible is justifiable. Some judgment would have to be made concerning imminence. Further in their discussion, the confederation discuss the role of physicians and parents when death of the infant is imminent. They state that:

> (a) the paediatrician should stop further medical treatment and use all possible resources to prevent suffering and pain of the infant and of the parents.
>
> (b) the decision to stop treatment is a medical decision. The decision has to be communicated to the parents. The parents, however, cannot force the paediatrician to institute or continue a treatment when this treatment will only increase the suffering of the patient without any chance of survival.

In the reverse situation, where the parents want to forego life-sustaining treatment but the physicians do not, it is recommended that, after consultation with colleagues, treatment is continued and legal measures be taken.

PART 4

THE LAW

30

INTRODUCTION

Decisions regarding life-sustaining treatment for extremely preterm infants are frequent in neonatal intensive care units. These decisions are determined by prognostic judgment, the perceptions and ethical beliefs of health professionals and parents, and the prevailing law of the land. However, specific prognoses may be difficult and perceptions of later outcome and ethical beliefs are variable. There is disagreement concerning the circumstances in which life-sustaining treatment should be withdrawn or withheld and who should decide this. In different ways, legal practices have developed around the world that attempt to address this problem. Laws have arisen – cases, statutes, and legal code that, to a varying degree, indicate the authority and actions of physicians, parents, and the courts. Legal systems differ between countries and they may be single systems or federations where provinces or states can regulate medicine. Countries such as Britain, Canada, and Australia have common law systems where the law is based on judicial precedent and legislation. Holland, Poland, Germany, France, and Japan have civil and criminal codes, although courts of appeal can make authoritative rulings.(250)

The relationship between ethics and law has been discussed and argued since classical times and will continue to be argued. However, those that frame and adjudicate the law, at a minimum, are required to set clear acceptable operational boundaries. Laws are not determined, necessarily, by ethical rules. For example, in law the clinical conduct of a physician and the standard of care delivered may be considered acceptable if it follows the professional behavior of similar physicians in the community. But this is a legal standard not a moral one. Customary behavior is not perforce a moral justification. The arguments for moral and legal rules may share similar origins, but they are not, by definition, the same. An act that an agent commits in a special relationship may be justifiable morally, but the reasoning that makes it so may be insufficient, or incorrect, for that act to be permissible as a matter of public policy or law. How much the law should proscribe behavior will continue to be debated. To a large extent, in Western civilization there is a belief that the law will not intervene in moral matters except where society, through its representatives and the courts, finds it necessary to create or apply law to protect the public interest.(251) The boundaries of public interest are defined by the political process and are created to proscribe the conduct of people in a community whose moral values and behavior may vary. For it to be acceptable, the law must arise out of reason and thus be reasonable and prudent.

When considering types of treatment for, or the foregoing of life-sustaining treatment from, the extremely preterm infant, questions arise that concern both the law and morality. These involve concepts such as parental autonomy, state or physician paternalism to avoid harm, and the right of a physician not to have to give treatment that is of no benefit. Many approach these bioethical questions in a "legal frame of mind."(252) As Capron wrote, the focus is more often on the right of an individual to do something and who is the proper decision maker than it is on what is the right thing to do,(253) and as Hart stated,(254) there is “. . . the danger that law and its authority may be dissolved in man’s conceptions of what law ought to be and the danger that the existing law may supplant morality as a final test of conduct and so escape criticism.”

31

U.S. LAW

During the 1970s, it was a matter of public record that large numbers of infants died each year in U.S. hospitals as a result of the withdrawal or withholding of treatment,(255) and surveys demonstrated that a large percentage of physicians were willing to forego life-sustaining treatment for disabled infants.(256) In one study it was revealed that 85% of pediatric surgeons and 65% of pediatricians surveyed were willing to honor parental wishes not to perform necessary surgery on an infant with Down syndrome, but less than 6% would deny similar treatment for a child without the disability.(256) Furthermore, some physicians made decisions not to treat without parental consultation,(257) although on the basis of the law at the time it was generally considered unlawful.(258) In 1975, John Robertson, professor of law, wrote:

> In the case of a defective infant the withholding of essential care would appear to present a possible cause of homicide by omission on the part of parents, physicians, and nurses, with the degree of homicide depending on the extent of premeditation. Following a live birth the law

> generally presumes that personhood exists and that there is entitlement to the usual protections, whatever the specific physical or mental characteristics of the infant may be. Every state imposes on parents a legal duty to provide necessary medical assistance to a helpless minor child. If they withhold such care, and the child dies, they may be prosecuted for manslaughter or murder . . . likewise physicians and nurses may face criminal liability . . . even when all parties, including the parents, are in agreement.(259)

In the United States, the treatment of a patient without valid consent constitutes a battery,(260) and it is parents who ordinarily decide what medical treatment is appropriate for their children:

> It is cardinal with us that the custody, care, and nurture of the child resides first in the parents. . . . (261)

If there is disagreement between parents and physicians a court can consider prognosis without treatment. In *Newmark v. Williams*, the court refused to order painful and invasive chemotherapy for a child with leukemia where it was judged that the treatment had only a 40% chance of success.(262) However, the state has a compelling interest to preserve human life, which justifies interference with individual rights.[263] These include the right of parents to make medical decisions for their children(264–266) and a constitutional right of privacy in child rearing.(267–268) But this parental authority is limited if it is held that parental actions might threaten the health or safety of a child,(261,269) for example, parents' decisions to withhold consent for necessary blood transfusions for religious reasons.(270–271) The common law doctrine of *parens patriae* permits the state to exercise protection and guardianship over persons disabled by means of minority, insanity, or incompetency,(272) and this doctrine has a long legal history. However, 30 years ago parents and physicians were left to make life and death treatment decisions concerning disabled infants. In 1971, three babies with Down syndrome and intestinal atresia were born at Johns Hopkins hospital. Two were "allowed" to die, at the parents' request, and the parents of the third requested treatment for their infant, who survived.(273–274) This type of approach was made more evident by two Yale pediatricians who published that they had accepted parents' decisions to forego treatment on 43 impaired infants who, they stated, subsequently died early.(275) This article was, to some extent, a response to one published in 1971 by the English physician John Lorber, who suggested that some babies with myelomeningoceles were so severely impaired that it was better for them not to receive treatment.(276) Similar criteria to those selected by Lorber for deciding on nontreatment of an infant with a myelomeningocele were used in some U.S. centers.(273) But there was a reaction to this type of approach at the federal level of government. In Bloomington, Indiana, in 1982, Baby Doe was born with Down syndrome and a tracheo-esophageal fistula.(277) The child's parents and obstetrician wanted no surgical intervention, as the obstetrician believed there was a dismal prognosis. The hospital administrators and members of the pediatric staff disagreed.(273) An unrecorded nighttime hearing was conducted in the hospital by county judge John Baker, without the appointment of a guardian ad litem for the infant, and he ruled that the parents had the right to make the decision about treatment versus nontreatment.(278) The case was appealed up to the U.S. Supreme Court,(279) but was not heard as the baby had died. The U.S. Commission on Civil Rights, when reviewing this case, stated that the prognosis given by the obstetrician was: ". . . strikingly out of touch with the contemporary evidence on the capabilities of people with Down syndrome."[278]

Prior to the commission, there was a reaction from the White House administration. The publicity surrounding the Infant Doe case was the impetus that prompted President Reagan to direct the Departments of Justice and Health and Human Services (HHS) to mandate treatment services in future similar cases.(277) To avoid a conflict between federal and state law, the latter defining crimes such as homicide and gross negligence,(273) new rules were announced pursuant to section 504 of the Rehabilitation Act of 1973, which bars discrimination against the handicapped in programs receiving federal assistance, such as hospitals that accept Medicare and Medicaid patients. The new rules barred hospitals from denying medical care to infants on the basis of handicap, and violation of this would lead to loss of federal funds. Opposition to any such denial was encouraged by the creation of "Baby Doe squads" comprised of lawyers, administrators, and physicians who could be available at short notice to investigate alleged violations of the Act.(277) Accusations that these had occurred could be made anonymously through a toll-free number that was openly advertised and easily seen by anyone visiting or working in neonatal units. But the courts did not support this interpretation of the Rehabilitation Act, and the U.S. District Court for the District of Columbia, in *AAP v. Heckler 280*, ruled that it "could never be applied blindly and without consideration of the burdens and intrusions which might result." The regulations were revised but were again invalidated by the court.[281] Around the same time, two lawsuits were in the courts concerning Baby Jane Doe.(282) This baby was born with a myelomeningocele and hydrocephalus and transferred to the State University of New York campus at Stonybrook. The attending surgeon, Arjen Kenscamp, recommended immediate surgery, but the child neurologist who was involved, George Newman, advised against this, stating later that "the child was not likely ever to achieve any meaningful interaction with her environment, nor ever achieve any interpersonal relationships, the very qualities which we consider human."(282) The parents did not consent to surgery but requested palliative care, which included food, water, and antibiotics. The parental refusal to consent to surgery was challenged in court by an independent attorney, who sought to be appointed guardian ad litem for the child, although he had no legal relationship to the child or the circumstances of the birth. A New York State lower court ruled that surgery should be performed, but the ruling was reversed on appeal, and this was affirmed by the state's highest court, but on the grounds that the attorney had no genuine connection with the circumstances and thus had no standing or right to bring such litigation, which, they stated was the responsibility of the state's child protection services.(283) Furthermore, as there were, in the opinion of the court, two medically reasonable options, the law allowed the parents the choice. The second, and more important, Baby Jane Doe lawsuit was brought by the U.S. Department of Health and Human Services and was based on the Rehabilitation Act revised rules concerning disabled infants. The department wanted to inspect the hospital records to evaluate whether there had been a violation of Baby Jane Doe's civil rights. The hospital refused to make available the records, in part because of parental refusal to consent to the release. Two lower Federal courts held that Congress did not intend to authorize review of individual medical decisions for disabled infants under section 504 of the Act, and the case went to the U.S. Supreme Court,(284) which affirmed this decision, stating:

> In broad outline, state law vests decisional responsibility in the parents, in the first instance, subject to review in exceptional cases by the state acting as *parens patriae* . . . the

> Federal government was not a participant in the process of making treatment decisions for newborn infants. We presume that this general framework was familiar to Congress when it enacted section 504 . . . the Secretary has acknowledged that a hospital has no statutory treatment obligation in the absence of parental consent and it has become clear that the "Final Rules" are not needed to prevent hospitals from denying treatment to handicapped infants. . . . By itself, section 504 imposes no duty to report instances of medical neglect . . . that undertaking derives from state law reporting obligations or a hospital's own voluntary practice.

The Supreme Court made it clear that parental consent was a matter of state law, and exercise of this consent, as well as other rights, accorded to the traditional family were protected under the Constitution.(285,286) The Court was particularly critical of HHS when they ruled that:(284)

1. HHS has no authority to compel medical treatment absent parental consent.
2. Parental refusal to consent does "not equate with" refusal by a hospital or physician to treat.
3. HHS's "perception that the withholding of treatment in accordance with parental instructions necessitates federal regulation is manifestly incorrect."
4. "[S]tate child protective service agencies are not field offices of HHS bureaucracy and they may not be conscripted against their will as foot soldiers in a federal crusade."
5. HHS's view "that the basic provision of nourishment, fluids, and routine nursing care" was "not an option for medical judgment" was untenable.

The rulings of the Supreme Court should not be viewed as negating the role of the federal government in the protection of life, which is ranked first in the Declaration of Independence. However, it is the states that carry the legislative responsibility for child protection and welfare. In addition, the Supreme Court ruling is an example of the balance of powers that, in this case, curtailed the heavy-handed approach of the White House administration.

The response to *Bowen* came from Congress, rather than directly from the White House administration, and was in the form of amendments to The Child Abuse Prevention and Treatment and Adoption Reform Act (PL 93–247, 88 stat 4 (1974)). These were the Child Abuse Amendments of 1984 (PL 98–457), also known as the Baby Doe rules, and they made conditional the receipt of certain federal funds by a state on that state satisfying certain criteria. These criteria were that a state would respond, under state child abuse laws, to cases of medical neglect (42 USC 5106 (b) (2) (B)). Medical neglect was defined as "withholding of medically indicated treatment" from disabled infants with "life threatening conditions." Medically indicated treatment was then effectively defined as treatment:(287)

> which, in the treating physician's reasonable medical judgment, will be most likely effective in ameliorating or correcting all [of the infant's life threatening] conditions, except that the term does not include the failure to provide treatment . . . to an infant when, in the treating physician's reasonable medical judgment,
>
> (A) the infant is chronically and irreversibly comatose;
> (B) the provision of such treatment would (i) merely prolong dying, (ii) not be effective in ameliorating or correcting all of the infant's life threatening condition,

> or (iii) otherwise be futile in terms of the survival of the infant; or
>
> (C) the provision of such treatment would be virtually futile in terms of the survival of the infant and treatment itself under such circumstances would be inhumane.

It is important to note that these amendments were interpretative guidelines and came with commentary.(288) "Virtually futile" was interpreted as:

> "highly unlikely to prevent death in the near future" on the basis of reasonable medical judgment (45 CFR pt 1340 app at 306).

A treatment is inhumane if:

> the treatment itself involves significant medical contraindications or significant pain and suffering for the infant that clearly outweigh the very slight potential benefit of the treatment for an infant highly unlikely to survive . . . the balance is clearly to be between the very slight chance that treatment will allow the infant to survive and the negative factors relating to the process of the treatment.(288)

A conference committee report added that:

> the use of the term inhumane is not intended to suggest that the consideration of the humaneness of a particular treatment is not legitimate in any other context; rather, it is recognized that it is appropriate for a physician, in the exercise of reasonable medical judgment, to consider that factor in selecting among effective treatments (US CCAN 2969, 2970 (1984)).

In the commentary to the amendments, the primary role of parents is made clear, except in specific circumstances, which are defined: ". . . except in highly unusual circumstances, decisions to provide or withhold medically indicated treatment should be made by the parents or legal guardian" (50 Fed. Reg. 14, 878 14, 880 (1985)). Although the commentary also stated that: "the parents role as decision maker must be respected and supported unless they choose a course of action inconsistent with applicable standards established by law" (50 Fed. Reg. 14, 880).

It is state law that applies under such circumstances. The Child Abuse Amendments do not prescribe medical treatment, nor do they determine specific state law, in this respect. Rather they require state child protective services:

> to pursue any legal remedies including the authority to initiate legal proceedings in a court of competent jurisdiction, as may be necessary to prevent the withholding of medically indicated treatment from disabled infants with life threatening conditions (45 CFR s 1340.15 (c) (2) (iii)).

But, as Frader wrote, by the time the Baby Doe rules came into force, practices relating to disabled infants had begun to change in the United States, and the "heavy-handed" federal approach likely had more political significance than production of meaningful changes in the care of most disabled infants.(289)

A further effort by the federal government to regulate physicians' actions can be found in the Born Alive Protection Act of 2001, which became Public Law 107–207 in 2002. The law established that:

> infants who are born alive, at any stage in development, are persons entitled to the protections of the law . . . regardless of whether or not the infant's development is believed to be, or is in fact, sufficient to permit long term survival, and regardless of whether the infant survived an abortion.(290)

However, a report from the Committee on the Judiciary stated that the Act: "would not mandate medical treatment where none is currently indicated . . . and would not affect the applicable standard of care, but would only insure that all born alive infants – regardless of their age . . . are treated as persons for purposes of Federal law."(290) It was the opinion of the American Academy of Pediatrics that the debate regarding the efficacy of providing treatment to extremely preterm infants was not relevant in the context of this law.(290)

The situation is that U.S. courts do not judge what they believe is a correct medical option, which might differ from that chosen by parents; rather, it is for state courts to proscribe parental or medical neglect. There is no neglect, in terms of medical care, when parents select from among professionally recommended options for treatment and "have provided an acceptable course of treatment for their child in light of all the surrounding circumstances."(291) The Baby Doe rules do not compel state courts to follow federal regulations. The federal statute stipulates that child protective services, a state body, have the authority, in certain circumstances, to pursue any legal remedies that may be necessary to prevent the foregoing of life-sustaining treatment.(292) This does not guarantee that the federal standard will be applied in state courts as the statute sets criteria for federal funding of state programs and does not set legal standards independent of state law. On this basis, federal law supremacy doctrines probably would not apply.(258)

It is up to the states, through their own law, to judge the matter. As has been shown, there are two doctrines that may clash: respect for parental autonomy when making health care decisions for their children and the state's right to protect children against harm. In general the U.S. courts are unlikely to override a reasonable parental decision not to treat if the condition is not extremely severe or life threatening, particularly if the condition can wait until the child is old enough to participate in the decision(293,294) or if there are risks that outweigh benefits.(266) An infant's lack of capacity allows parents, as natural guardians, to act in the best interests of the child.(288,295–302) The exercise of this legal right is rebuttable if the decisions or actions of the parents are not in the best interests of the child or amount to neglect or abuse.(262,288,295,303–309) But it has not always been certain how state courts will rule in matters concerning disagreements between parents and physicians concerning the foregoing of life-sustaining treatment from an infant. *In re Steinhaus*,(310) shortly after the Baby Doe rules had been issued, it was held that it would not constitute neglect to issue a do not attempt resuscitation order for a baby who was diagnosed as being in a chronic and irreversible comatose state. But *in re KI*, this order was also authorized, despite parental objection, for an infant whose condition, allegedly, did not satisfy the federal criteria for withholding treatment from a disabled infant.(311)

As the states were writing and modifying their statutes dealing with end of life issues, a number of landmark cases were heard that influenced these statutes and the action of health professionals. They have in common the drama of the law courts; intensive care units caring for the most fragile and moribund infants; and the actions and anguish of distraught parents. In Illinois in 1991, the Health Care Surrogate Act was signed into law. It followed a well-publicized case that occurred at the Presbyterian-St. Luke's

Center in Chicago.(312) In August 1988, Sammy Linares, an infant aged 6 months, had become asphyxiated by inhaling a rubber balloon and suffered a cardiac arrest. He was maintained on life support in a persistent vegetative state. In April 1989, following a refusal by the hospital and attending physicians to discontinue life support in the absence of a court order, the father, Rudy Linares, performed this act while keeping hospital workers at bay with a hand gun. This followed an incident the previous December when the father had disconnected the baby from the ventilator, but was physically restrained by security guards while the ventilator was reconnected.(312) Despite the manner in which the father acted, there clearly was much sympathy for him. A coroner found that asphyxiation from a balloon was the primary cause of death,(312) and a grand jury declined to issue an indictment for homicide. Mr. Linares did receive a suspended sentence for a misdemeanor arising from a weapons charge. The statutory law that followed made it clear that life-sustaining treatment could be withdrawn, without judicial involvement, from a patient without decisional capacity. The conditions that would allow this were that a surrogate could request withdrawal if two physicians certified one of the following:

(a) imminent death; that is, when death is inevitable within a short time, "even if life sustaining treatment would be initiated or continued";
(b) permanent unconsciousness, for which initiating or continuing life support, in light of the patient's medical condition, provides only minimal medical benefit;
(c) incurable or irreversible condition that imposes severe pain or an inhumane burden that will ultimately cause the patient's death and for which initiating or continuing life-sustaining treatment provides only minimal medical benefit.

The Act protects the parties involved provided they follow the legislation "with due care."

Perhaps a less clear-cut case for the exercise of the quality of mercy is that involving baby Messenger who was born in Michigan. In this instance, the mother went into premature labor at 25 weeks' gestation. The parents were informed that there was a 50–75% chance of mortality and a 20–40% chance of severe cerebral hemorrhage and neurological damage.(313) I would certainly argue that these estimates are too high, but nevertheless these are the figures that were given to the parents. They instructed the neonatologist not to take "extraordinary" measures. However, it was a physician assistant who attended the baby at birth and she resuscitated the baby despite a previous instruction that this should only occur if the baby was vigorous and active at birth. This was not how the baby appeared at birth,(194) which is not particularly unusual for a 25 week, 750g extremely preterm infant. It was after the neonatologist told the parents that she wanted to continue intensive care, at least in the short term, that the father, in the presence of his wife but no others, disconnected the baby from the ventilator, and the baby died shortly thereafter. Not surprisingly, the father was arrested and charged, but the jury found him not guilty. This was despite the fact that at the time the artificial ventilation was removed the baby was in no imminent danger of dying and there was no evidence of severe neurological damage. The Messengers, in their testimony, denied that their actions were because of fear that their child may survive handicapped, but that he might suffer when the likely outcome, they believed, was death.(314)

Parents have the right to be informed to give consent, in the same manner as a competent adult patient, which includes being given alternatives, provided the alternative is legally acceptable.(315) If there is a genuine emergency situation consent may be waived, but it is doubtful that information can be withheld from parents on the basis of therapeutic privilege.(288) In November 1991, in Georgia, Mary Elizabeth Bethune was delivered by her father at the side of the road. She was 24 weeks gestation and weighed 500g. She was taken to the hospital profoundly hypothermic, where she was resuscitated and placed on a ventilator. However, she was considered to be in the process of dying and that her condition was terminal. Thus life support measures were removed, without consent according to the parents, and they sued for wrongful death (*Velez v. Bethune*(316)). The court stated that: "The doctor had no right to decide, unilaterally, to discontinue medical treatment even if the child was terminally ill and in the process of dying. That decision must be made with the consent of the parents (see *In re Jane Doe*(317))."

In contrast, in Milwaukee, Wisconsin, the parents of a baby born at 24 weeks' gestation sued physicians, alleging that they were not sufficiently informed of the risk of disability to their son and that they should have been allowed to decide on whether to treat.(318) However, the appeals court found that the conditions that allowed the foregoing of life-sustaining treatment had not been met and that there was not an absolute right for parents to decide whether to resuscitate a newborn or withhold life-sustaining treatment following informed consent. The court stated that:

> if the parents' claim is allowed to proceed, courts will be required to decide which potential imperfections or disabilities are . . . "worse than death." They will have to determine which disability entitles a child to live and which disability allows a third party surrogate to withhold or withdraw life sustaining treatment with the intent to allow a disabled person to die . . . such a process, not unreasonably, has kaleidoscopic, unending implications.(319)

Parents were also overruled in *MacDonald v. Milleville* with a judgment that went against the later one given in *Velez v. Bethune*.(316,320) Baby MacDonald was born in Milwaukee at 23–24 weeks' gestation, after a difficult breech extraction. The baby was pale, apneic, and bradycardic. After 10 minutes' resuscitation using an Ambu bag, but not intubation, chest compressions, or medications, the baby remained bradycardic with a heart rate of less than 60/minute. The baby was wrapped in a blanket and handed to the parents, who were told the baby was dying despite the best efforts of the staff. About an hour later, a faint cry was heard, and the baby was found to have a heart rate of 130/minute. At this stage the baby was intubated and placed on a ventilator and went on to show severe brain injury, characterized by incapacitating cerebral palsy and profound mental retardation. The parents sued the doctor and hospital, claiming that failing to fully resuscitate constituted negligence and that stopping the partial resuscitation violated the doctrine of informed consent. The ethical and legal question in this case is whether, at the time of the delivery, a firm judgment could be confidently made that aggressive resuscitation would "offer no immediate or long term benefit."(321) Certainly, in 1989 when the baby was born, this was a widely held belief among neonatologists,(320) and physicians do not have a legal duty to provide ineffectual treatment.(322) The court found that the doctor was not obliged to seek authorization to cease resuscitation in the situation in which he found himself, and his actions were not negligent.

How the law has developed in Texas and been applied in the higher courts may reflect what would happen in the future in other parts of the United States. Between 1977 and 1995, the Texas legislature enacted three advance directive laws for end of life treatment decisions. In 1977, Texas recognized "living wills," which were called "directives to physicians." This statutory law was part of the Natural Death Act,(323) which was followed by the Durable Power of Attorney for Health Care in 1989.(324) In these statutes were included situations in which parents, or legal guardians, in conjunction with physicians, could forego life-sustaining treatment for infants. In 1997, in an attempt to address various inconsistencies in the law, a single comprehensive advance directive law was passed by both houses(325) but was vetoed by then Governor George W. Bush because of, as alleged by some,(326–327) pressure from a Right to Life group. Eventually the Act was passed and resulted in a new chapter 166 of the Health and Safety Code, entitled the Advanced Directives Act.(328) The new act does not specifically provide requirements for infants, disabled or otherwise, but refers inter alia to patients less than 18 years of age. A licensed physician may be directed by parents or a legal guardian (166.035) to forego life-sustaining treatment from these patients if they have a terminal or irreversible condition that has been diagnosed and certified in writing by the attending physician. A terminal condition means "an incurable condition caused by injury, disease, or illness that according to reasonable medical judgment will produce death within six months, even with available life sustaining treatment provided in accordance with the prevailing standard of medical care" (166.002). An irreversible condition means a condition, injury, or illness:

(A) that may be treated but is never cured or eliminated;
(B) that leaves a person unable to care for or make decisions for the person's own self; and
(C) that, without life sustaining treatment provided in accordance with the prevailing standard of medical care is fatal (166.002).

Life-sustaining treatment means treatment that:

> Based on reasonable medical judgment, sustains the life of a patient and without which the patient will die. The term includes both life sustaining medications and artificial life support, such as mechanical breathing machines, kidney dialysis treatment, and artificial nutrition and hydration. The term does not include the administration of pain management medication or the performance of a medical procedure considered to be necessary to provide comfort care, or any other medical care provided to alleviate pain. (166.002)

The Act also specifically states that: "this subchapter does not condone, authorize, or approve mercy killing or permit an affirmative or deliberate act or omission to end life except to permit the natural process of dying as provided by this subchapter" (166.050).

An important aspect of the Act was the inclusion of a process for resolving disagreements between treating physicians and legal guardians (166.046). This process created an unprecedented legal role for ethics committees.(327) The Act also provided legal protection for health care personnel and institutions provided the statutory process was followed (166.045): "a physician, a health professional acting under the direction of a physician, or a health care facility is not civilly or criminally liable or subject to review or disciplinary action by the appropriate licensing board if the person has complied with the procedures outlined. . . ." The new Act now mandated that should there be a dispute between parties concerning the foregoing of life-sustaining treatment, there should be an ethics committee consultation, a reasonable attempt to transfer the patient to another provider, and the continuation of life-sustaining procedures for a minimum of 10 days after the ethics committee has provided a written explanation of its review process to the treating physicians and legal guardians. If the dispute continues after this 10-day period, and a new treating physician or health care establishment has not been found, there is no longer an obligation under the statute to continue the life-sustaining treatment (166.046). The aim of this 10-day rule is to provide time during which transfer of the patient might be arranged, and it also enables discussions to continue between the relevant participants. Furthermore, it provides a more orderly approach for families if they should seek judicial review after all reasonable attempts at agreement have failed (166.046).

Two important cases occurred in the Texas courts, the outcomes of which probably reflect the direction other state courts may take. In *Stolle v. Baylor College of Medicine*,(329) the legal arguments mainly concerned whether section 672.016(b) of the Natural Death Act allowed immunity to physicians who did not comply with a written instruction from parents to withhold life-sustaining treatment from their infant. The parents sought damages for negligent disregard of their instructions not to use "heroic efforts"(329) or artificial means to prolong the life of their child. The circumstances were that in 1991 the mother gave premature birth to twins. One of the twins died soon after mechanical ventilation was withdrawn; the other twin survived and suffered a grade IV intraventricular hemorrhage. She was transferred to a large children's hospital where a neurological consultation concluded that she had irreversible brain damage and would have a neurological deficit.(329) The following day the parents executed a written Directive to Physicians on behalf of their infant in which they stated that her life should not be artificially prolonged under the circumstances provided in the directive. The wording was that life-sustaining treatment could be withheld if the infant was certified by two physicians (the new Advanced Directives Act requires only one physician) as having a terminal condition. About 1 month later, the baby had an apneic episode with bradycardia following aspiration of some of her feed. A nurse administered chest compressions for about 1 minute and the episode ended.

When the case went to court, a summary judgment was given against the parents and this was affirmed on appeal. Smith J, giving the majority opinion, stated that "... the parents do not cite us any authority that would have allowed the the withdrawal or withholding of life sustaining procedures in a lawful manner." The limits of parental influence were also demonstrated in *Hospital Corporation of America v. Miller*.(330) In 1990, the mother of Sidney Ainsley Miller went into premature labor and was admitted to a Houston hospital. The baby was estimated to be 23 weeks gestation with an approximate weight of 629g.(330) Both the obstetrician and the neonatologist told the parents that should the baby survive she would be impaired, and the parents requested "no heroic measures," which was recorded in the hospital chart. The parents were also informed that if the baby was born alive and weighed over 500g, the medical staff would be obliged by law and hospital policy to perform life-sustaining procedures.(330) The parents expressed again that they did not want the baby resuscitated. Later that night the mother gave birth, and the baby was resuscitated. She survived and subsequently developed severe neurological impairment. The parents sued the Hospital Corporation of America asserting: 1) vicarious liability for the actions of the hospital in: a) treating Sidney without consent; and b) having a policy that mandated the resuscitation of newborn infants weighing over 500g even in the absence of parental consent; and 2) direct liability for failing to have policies to prevent such treatment without consent. Based on the jury's finding of liability, the trial court entered judgment in favor of the parents in the amount of $29,400,000 in past and future medical expenses, $13,500,000 in punitive damages, and $17,503,066 in prejudgment interest. This verdict was appealed to the Court of Appeals and was reversed. The defendant's arguments were that they did not owe the parents the tort duties they claimed had been breached. They could not be liable for battery or negligence in treating Sidney without parental consent and against their instructions as there was a legal obligation to do so and because the parents had no right to withhold life-sustaining treatment from Sidney. Justice Edelman rendered the majority opinion and stated that there were three fundamental but competing legal and policy interests:

> On the one hand Texas law expressly gives parents a right to consent to their children's medical care.(331) Thus, unless a child's need for life sustaining medical treatment is too urgent for consent to be obtained from a parent or other person with legal authority . . . a doctor's treatment of the child without such consent is actionable even if the condition requiring treatment would eventually be life threatening and the treatment is otherwise provided without negligence(332) . . . the logical corollary of a right of consent is a right not to consent . . . in Texas the Advance Directives Act, formerly the Natural Death Act (collectively, the "Act") allows parents to withhold or withdraw life sustaining medical treatment from their child where the child's condition has been certified in writing by a physician to be terminal *i.e.* incurable or

> irreversible, and such that even providing life sustaining treatment will only temporarily postpone death.(333)

Edelman J continued by stating that "... parents have a legal duty to provide needed medical care to their children(331) . . . the failure of a parent to provide such care is a criminal offense when it causes injury or impairment to the child."(334–337)

The third competing legal and policy interest was that of the state:

> acting as *parens patriae* . . . even where doing so requires limiting freedom and authority of parents over their children(261) . . . in Texas, the rights and duties of a parent are subject to a court order affecting those rights and duties(331) including an order granting a governmental entity temporary conservatorship of a child with authority to consent to medical treatment refused by the child's parents(297,307,338–341)

Edelman J emphasized that:

> . . . in Texas, the legislature has expressly given parents a right to withhold medical treatment, urgently needed or not, for a child whose medical condition is certifiably terminal, but it has not extended that right to the parents of children with non terminal impairments, deformities, or disabilities, regardless of their severity. In addition, although the Act expressly states that it does not impair or supercede any legal right a person may have to withhold or withdraw life sustaining treatment in a lawful manner, the parties have not cited and we have found no other statutory or common law authority allowing urgently needed

> life sustaining medical treatment to be withheld from a non terminally ill child by a parent . . . the state's interest in preserving life is greatest when life *can* be preserved and then weakens as the prognosis dims . . . to withhold urgently needed life sustaining treatment from non terminally ill children would impose imponderable legal and policy issues . . . if parents *had* such a right, would it apply to otherwise healthy, normal children or only those with some degree of abnormality? If the latter, which circumstances would qualify . . . how could any such distinctions be justified legally? . . . we perceive no legal basis or other rationale for concluding that Texas law gives parents a common law right to withhold urgently needed life sustaining medical treatment from children in circumstances in which the Act does not apply.

The appellate court thus made it clear that in these circumstances a best interest approach was not valid. The case went to the Supreme Court, which did not issue an opinion until 2003.(342) They affirmed the appellate court decision and agreed with their reasoning, adding that any decisions concerning treatment for the baby would not be fully informed decisions until birth and that once the infant was born the physician was faced with an emergency situation. The baby might survive with treatment but was likely to die if treatment was not provided before either parental consent or a court order overriding the withholding of such consent could be obtained. The court held that circumstances like these provide an exception to the general rule imposing liability on a physician for treating a child without consent.

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THE UNITED KINGDOM

Although not dealing with prematurity, it is instructive to examine the *R v. Arthur* case,(207) as it reflects the attitudes and behaviors of many physicians and judges toward disabled children in the early 1980s and thus how they might respond to the disabled preterm infant who could be potentially mentally retarded. In the *Arthur* case, a Down syndrome baby was born without any clinically apparent life-threatening complication. Neither the parents nor the doctor wanted the child kept alive, and the baby was prescribed dihydrocodeine and nursing care only and in addition restricted to oral water. The baby died within about 2 days, which suggests that, in the absence of any other clinical factors, there was inordinate sedation and inadequate hydration. Although the original charge was murder, this was changed to attempted murder, as an eminent pathologist had found (not surprisingly) other congenital defects and could not discount that the baby had died of "natural causes." Dr. Arthur was found not guilty, and one cannot discount the influence of the judge's statements, which included "any child who is a Mongol is faced with the most appalling handicap." Although he made it clear that no doctor has the right to kill a disabled child, the situation in this case was different, he believed, as there was a "setting of conditions within which death may occur more expediently than would otherwise have been the case." Not much more needs to be said about this case except that it reflects the misperceptions and ignorance of those involved, both medical and legal. The decision is not binding on civil cases, and as Mason and McCall Smith wrote, it is unlikely that Dr. Arthur's regime would be acceptable today and the case has lost any credibility as precedent.(343) However, examination of the case reminds us that under UK law physicians have a duty to care for patients they have accepted responsibility for, and if a breach of that duty leads to death then that physician, depending on mens rea, is liable for prosecution for manslaughter or murder.(344–347) But that duty of care does not extend to mandatory treatment to prolong life regardless of the circumstances,(348) and furthermore it has been ruled that the provision of appropriate palliative care in a situation where a patient is known to be dying, and the aim is to relieve suffering, may not be judged criminal.(349)

The UK common law pertinent to the extremely preterm infant is best considered by examining those cases that involve disabled infants and the rights and duties of parents and physicians. As will be seen, it is the best interests test, despite its ambiguity, which drives British common law as it relates to treatment, life sustaining or otherwise, for the disabled infant. As Montgomery wrote, three areas should be examined when considering the law relating to foregoing life-sustaining treatment for these infants.(350) The first is, what limits does the law place on the actions of physicians and parents? The second is, which of these two has the greater legal right to make end of life decisions for the infant? Finally, what is the role of the courts in resolving conflicts that might surround end of life decisions for disabled infants?

Parents have a legal duty to seek medical attention for their children and failure to do so risks prosecution for child neglect under the Children and Young Persons Act 1933 S1(2), but it has to be clear that it is needed,(351) or that a "reasonable parent" would have been aware of this.(352) When there is a conflict between doctors and parents concerning life-sustaining treatment, it may be necessary for the courts to make a judgment. In general, treatment cannot be given to an infant without parental consent, unless it is immediately life saving and comes under the doctrine of necessity.(350) In the situation where life-sustaining treatment is demanded by parents, but believed to be inappropriate by physicians, the courts have ruled that physicians cannot be forced to act, provided their decision is not unreasonable.(353,354) Reasonableness is determined by the best interests of the child, as judged by the courts. Thus parents cannot guarantee treatment for their child without the compliance of physicians, nor can they guarantee nontreatment if the physicians view a situation as an imminent life-threatening one.

The authority of parents was tested *in re B*,(355) which was initially heard around the same time as *Arthur*. Both cases involved a baby born with Down syndrome, but the judgments *in re B* were very different. The baby had Down syndrome and duodenal atresia, which required surgery so that the child might survive. The parents refused to consent to the operation and the local authority made the baby a ward of the court. When the surgeon decided the wishes of the parents should be respected, an order was sought authorizing the operation to be performed by another named surgeon. Eventually the case went to the court of appeal where it was judged that where the welfare of a child was at stake the courts were the final arbiter of how a child should be treated based on the best interests of the child. Templeman LJ stated that:

> . . . It is a decision which of course must be taken in the light of the evidence and views expressed by the parents and the doctors, but at the end of the day it devolves on this court in this particular instance to decide whether the life of this child is demonstrably going to be so awful that in effect the child must be condemned to die, or whether the life of this child is still so imponderable that it would be wrong for her to be condemned to die. There may be cases, I know not, of severe proved damage where the life of the child is bound to be full of pain and suffering that the court might be driven to a different conclusion, but in the present case . . . I have no doubt that it is the duty of this court to decide that the child will live. . . .(355)

There are two conclusions that can be drawn from *re B*. One is that parental rights are subordinate to the welfare of the child, and the other suggests that a quality of life determination might justify legally allowing a disabled infant to die.

The court also went against the wishes of the parents in *re J*.(353) But in contrast to the previous case, it was the parent who demanded treatment for her multiply handicapped child and the physicians who wanted to forego this. Initially the High Court agreed with the mother, but the Court of Appeal overruled this, and it was Lord Donaldson who judged that: "the effect of setting aside the order leaves the health authority and it's medical staff free . . . to treat *J* in accordance with their best clinical judgment. This does not mean that we thought, and still less required, that in no circumstances should *J* be subjected to mechanical ventilation."(353) The court made it clear that the determining factors were the best interests of the child. This ruling by Lord Donaldson was consistent with one he made *in re J (a minor)*,(348) in which he judged that:

> there is without doubt a very strong presumption in favour of a course of action which will prolong life, but . . . it is not irrebuttable . . . account has to be taken of the pain and suffering and quality of life which the child will experience if life is prolonged. Account also has to be taken of the pain and suffering involved in the proposed treatment itself . . . in the end there will be cases in which the answer must be that it is not in the interests of the child to subject it to treatment which will cause increased suffering and produce no commensurate benefit, giving the fullest possible weight to the child's and mankind's desire to survive.

Where the line is drawn is not very apparent, although Lord Justice Taylor *in re J (a minor)* (348) made it clear that best interests should be viewed from the infant's perspective, and the presence of severe handicap, per se, is not enough to justify the foregoing of life-sustaining treatment:

> I consider that the correct approach is for the court to judge the quality of life the child would have to endure if given the treatment and decide whether in all circumstances such a life would be so afflicted as to be intolerable to the child. I say to that child because the test should not be whether the life would be tolerable to the decider. The test must be whether the child in question, if capable of exercising sound judgment, would consider the life tolerable . . . where the child is terminally ill the court will not require treatment to prolong life; but where . . . the child is severely handicapped, although not intolerably so, and treatment for a discrete condition can enable life

> to continue for an appreciable period, albeit subject to the severe handicap, the treatment should be given.

Despite these rulings, the use of the best interests test for deciding on whether to forego life-sustaining treatment for a potentially disabled infant is interpreted differently depending on the perceptions of the decision maker. That is, the best interests approach risks an inexact clinical judgment being converted into a judicial value judgment. A best interests argument was also followed in *NHS v. D*.(356) In this case, health professionals recommended palliative care for a disabled child rather than any resuscitation through artificial ventilation, and the parents opposed this. The child was said to have irreversible and worsening lung disease, heart failure, hepatic and renal dysfunction, and developmental delay, and life expectancy was considered to be 1 year at the most.(357) My reading of the clinical situation is that if the child's condition was truly terminal and irreversible, and the remaining time he had left alive was clearly intolerable from the perspective of the child, then foregoing life-sustaining treatment could be justified morally and legally without using a best interests test, and counseling parents on this basis might be more acceptable. Having written this, however, I readily acknowledge the possible inappropriateness of judging from a distance after the event. But the more important legal aspect of this case was whether withholding life-sustaining treatment, in the situation described, contravened the Human Rights Act 1998, which incorporated into UK law the European Convention on Human Rights (ECHR).(358) It was held that there was no conflict with Article 2 of the ECHR, which upholds the right to life, as the best interests of the child was followed,(357) and there was no infringement of Article 3 because in *D v. UK* (359) it was held that the right to dignity is encompassed in the requirement that a person should not be subjected to inhuman or degrading treatment. The principle of best interests of the child also overrules the rights of parents under ECHR Article 8, which grants the right to respect for private and family life (see *re A*).(360) A similar case to *NHS v. D* occurred in Portsmouth and was well publicized. Doctors in a Portsmouth hospital issued a "do not attempt resuscitation" order for baby Charlotte Wyatt on the basis that further "aggressive treatment" was not in the best interests of the child. The parents opposed this. The 11-month-old baby was born at 26 weeks and was said to only experience pain. She had extensive lung and brain damage, was tube fed, and was dependent on supplemental oxygen. The High Court supported the doctors and, in essence, ruled that her quality of life was so poor that she was "better off dead."(361) Some might argue that a correct decision had been reached, but for the wrong reasons.

The last instance involves a British case that was tried in the European Court of Human Rights. This case involved life-sustaining treatment for a severely disabled child and the administration of diamorphine without consent. The events involved physical assault between the medical staff, the family, and the police, in addition to inflexible demands from all involved. The full details of this are not described, but for those interested the situation, as it arose, was an object lesson on how not to proceed when there is a dispute concerning the foregoing of life-sustaining treatment for a severely disabled child.(362) The applicants to the court, the mother and the child, stated that there had been a failure to ensure effective respect for the child's right to physical and moral integrity within the meaning of "private life" as guaranteed by Article 8 of the ECHR. The court considered that the decision to impose treatment (the administration of diamorphine) on the child in defiance of the mother's objection interfered with the child's right to respect for his private life and in particular his right to physical integrity. Surprisingly, the court did not consider it necessary to examine separately the complaint that a "do not attempt resuscitation" notice had been placed in the chart without the consent or knowledge of the mother. The basis for this was that guilt had already been ascertained for a breech of Article 8. The court did observe that: "the notice was only directed against the application of vigorous cardiac massage and intensive respiratory support, and did not exclude the use of other techniques, such as the provision to keep the child alive." This statement fails to address whether there should be legal requirements, including consent, for a "do not resuscitate" order for a patient without capacity. Judge Casadevall entered a separate opinion expressing his judgment that there should have been a ruling on this:

> In the circumstances of this case that notice amounts . . . to an important and aggravating factor regarding the issue in question which helps to understand better the qualms and distress experienced by the mother . . . and her manner of dealing with the situation during the disturbing and unbelievable fight that broke out between certain members of the family and the hospital doctors . . . I can fully understand that the patient's condition was such that it was medically necessary to administer him diamorphine urgently in order to alleviate his suffering . . . however I find it difficult to accept that the doctors unilaterally took the serious decision of putting a Do Not Resuscitate order in the case notes without the mother's consent and knowledge. I find the comment ". . . was only directed against the application of vigorous cardiac massage and intensive respiratory support . . ." inappropriate . . . in my view the complaint deserved an additional examination.(362)

33

CANADA

Although exactly how Canadian courts would rule in cases concerning the foregoing of life-sustaining treatment for extremely preterm infants is uncertain, there are some recent cases that indicate the extent of parental autonomy when they consent or otherwise to medical treatment for their children. As in other jurisdictions, the courts have a *parens patriae* obligation that will be exercised in the best interests of the child. The interpretation of best interests lies finally with the courts, but the law allows, as it should, broad leeway for parents to raise children as they think fit, provided it does not threaten the health and safety of those children. The law also imposes a duty of care on physicians but recognizes that there are circumstances where physicians are not obliged to treat where they believe there would be no overall benefit. In the *Case of Child and Family Services of Central Manitoba v. RL*, (363) a young infant suffered severe nonaccidental brain injury that eventually led to a diagnosis of a permanent vegetative state. The question before the court was whether the infant's physician could issue a "do not attempt resuscitation" order without the consent of the parents, who objected to the order. In ruling against the parents, Twaddle JA stated that:

> there is no legal obligation on a medical doctor to take heroic measures to maintain the life of a patient in an irreversible vegetative state . . . neither consent nor a court order in lieu is required for a medical doctor to issue a non-resuscitation direction where in his or her judgment the patient is in an irreversible vegetative state. Whether or not such a decision should be issued is a judgment call for the doctor to make having regard to the patient's history and condition and the doctor's evaluation of the hopelessness of the case. The wishes of the patient's family or guardian should be taken into account, but neither their consent nor the approval of a court is required.

I assume that the judge is referring to a permanent vegetative state when he refers to the hopelessness of the case. As Sneiderman wrote,(364) the ruling should not necessarily refer to a patient with a different condition. That is, it should not necessarily apply to an infant who is severely neurologically damaged, but not in a permanent vegetative state. However, Twaddle JA appeared not to treat the foregoing of life-sustaining treatment from an infant any differently from any other form of treatment, or rather lack thereof, when he ruled that consent is required in nonemergency situations:(363)

> only when the provision of treatment without it would constitute assault . . . there is no need for consent from anyone for a doctor to refrain from intervening . . . the only fear a doctor need have in denying heroic measures is the

> fear of of liability for negligence in circumstances where qualified practitioners would have thought intervention warranted.

Thus if the court does not see a need to intervene in what it views as a medical decision, it could leave the disabled infant vulnerable and without access to the *parens patriae* protection of the court. Furthermore, if active intervention has taken place such as artificial ventilation and hydration, the decision not to intervene further, let us say, with possible life-sustaining treatment such as antibiotics or a vasopressor, is a treatment decision. Legally defining it as nontreatment and nontouching is specious and denies its consequences, despite the risk of a charge of negligence, after the event. I am not arguing here for treatment at all costs but rather that the withholding of life-sustaining treatment should not be viewed legally as nontreatment and not require consent from legitimate surrogates. There are other ways of determining when it is legally permissible to withhold life-sustaining treatment from an infant, as can be found in the statutory and common law of other international jurisdictions, although there is not unanimous agreement on these ways.

The Canadian courts also ruled against parental autonomy in *B (R) v. Children's Aid Society of Metropolitan Toronto*.(365) But the legal approach was different to the *Case of Child and Family Services* cited earlier and more in keeping with the common law reasoning found in other Commonwealth countries as the best interests test was invoked. The case involved the provision of treatment, against parental wishes, rather than the withholding of treatment, and in addition there was an appeal to statutory law. A young infant was given a blood transfusion, despite a specific instruction by the parents, who were Jehovah's Witnesses, not to give this. This was made possible by the granting of wardship by the Provincial Court (Family Division). The case was eventually appealed to the Supreme Court of Ontario, who were required to determine whether section 19 (1) (b) (ix) of the Ontario *Child Welfare Act*, which defines a "child in need of protection," together with the powers in sections 30 and 41 and the procedures in other sections, deny parents a right to choose medical treatment for their infants, contrary to section 7 of the *Canadian Charter of Rights and Freedoms*.(366) The court ruled that:

> an exercise of parental liberty which seriously endangers the survival of the child should be viewed as falling outside section 7 of the *Charter*. While the right to liberty embedded in section 7 may encompass the right of parents . . . to choose among equally effective types of medical treatment for their children, it does not include a parents' right to deny a child medical treatment that has been adjudged necessary by a medical professional and for which there is no legitimate alternative. The child's right to life must not be so completely subsumed to the parental liberty to make decisions regarding that child. Although an individual may refuse any medical procedures upon their own person, it is quite another matter to speak for another especially when that individual cannot speak for herself. Parental duties are to be discharged according to the best interests of the child. The exercise of parental beliefs that grossly invades those best interests is not activity protected by the right to liberty in section 7. There is simply no room within section 7 for parents to override the child's right to life and security of the person. To hold otherwise would be to risk undermining the ability of the state to exercise

> its legitimate *parens patriae* jurisdiction and jeopardize the *Charter's* goal of protecting the most vulnerable members of society.

The final Canadian case I mention is *R v. Latimer.*(367) Although this involved a severely disabled 12-year-old girl, her condition was one that might be the outcome of extreme prematurity, although not often. It is also interesting to speculate why the treatment of the father in this case was different than the treatment meted out to the father in a U.S. court, not far from the Canadian border, in the *Baby Messenger* case.(314) In the Canadian case, the father of a severely disabled 12-year-old girl asphyxiated her with carbon monoxide. His reasoning for doing this was that he could not let her suffer further pain from proposed and strongly recommended palliative surgery. The father was convicted of second-degree murder and the case was eventually appealed to the Supreme Court of Canada. Essentially the appeal concerned sentencing, as the verdict was not in doubt. The Supreme Court upheld the sentence, which was a mandatory minimum of life with no chance of parole for at least 10 years. Would, or should, the court have shown more clemency if the sentence had not been mandatory? Many Canadians thought so.(368) Dr. Gregory Messenger was not convicted after he disconnected the life support from his extremely preterm infant.(314) The judgment from the Supreme Court of Canada was: "killing a person, in order to relieve the suffering produced by a medically manageable physical or mental condition, is not a proportionate response to the harm represented by the non life threatening suffering resulting from that condition."

34

AUSTRALIA

As in Canada, there is very limited common law specifically relating to extremely preterm infants. How the courts might act if presented with questions concerning life-sustaining treatment for such infants may be derived by considering the legal history of the extent of parental and physician autonomy over treatment decisions for children, and how the courts might exercise the best interests test for disabled children. Australian law recognizes that once a baby is born alive, that baby becomes a legal person,(369–370) with the full protection of the law. However, in 1988 the National Health and Medical Research Council(371) reported that:

> "contrary to popular belief and common practice, parents do not have the legal right to determine that their infant be refused medical treatment without which the infant would die" and that "in cases of extremely low birth weight babies . . . it is likely both doctors and parents make decisions which are not acceptable under present Australian laws."

In 1986, in *F v. F* (unreported, 2 July) Vincent J, in the Supreme Court of Victoria, judged that physicians have a legal obligation to sustain the life of a child without concern for quality of life: "The law does not permit decisions to be made concerning the quality of life nor any assessment of the value of any human life."(372) But this statement was made in an urgent hearing, and the judge made it clear that he was only dealing with the urgent specific question at hand, which was feeding for the infant, who had spina bifida.(373) However, it is consistent with a later judgment from the High Court of Australia in a wrongful birth suit (which was rejected) when it was stated that:

> . . . in the eyes of the law, the life of a troublesome child is as valuable as that of any other; and a sick child is of no less worth than one who is healthy and strong. The value of human life, which is universal and beyond measurement, is not to be confused with the joys of parenthood, which are distributed unevenly.(374)

The *parens patriae* jurisdiction of the court also applies in Australia and its aim is to protect those who cannot protect themselves. This is a value that Brennan J said in *Marion's Case*(375):

> underlies and informs the law: each person has a unique dignity which the law respects and which it will protect. Human dignity is a value common to our municipal law and to international instruments related to human rights. The law will protect equally the dignity of the hail and hearty and the dignity of the weak and lame; of the frail baby and of the frail aged: of the intellectually able and

> the intellectually disabled . . . our law admits of no discrimination against the weak and disadvantaged in their human dignity.

This *parens patriae* jurisdiction *has* to be exercised in the best interests and welfare of the child,[376] and it extends to authorizing medical treatment for an infant, even against the wishes of parents.(377) Thus it would appear that Australian common law is similar to that in the UK. Parents do not have an absolute right to decide treatment for an infant, if there is no reasonable option and without treatment the child is at risk of death or further injury. It also appears that quality of life decisions are discouraged, although to what extent this would be applied if a physician wanted to forego life-sustaining treatment for an extremely preterm infant, and the parents did not, has not been tested in the Australian Courts (at this time of writing). As in the United States there is statutory law that would support the physician if the infant was terminal or in a persistent vegetative state. For example, in South Australia the Consent to Medical Treatment and Palliative Care Act states that a physician who is responsible for the management of a terminally ill patient is:

> under no duty to use, or to continue to use, life sustaining measures in treating the patient if the effect of doing so would be merely to prolong life in a moribund state without any real prospect of recovery or in a persistent vegetative state.(378)

35

JAPAN

In Japan, the extremely preterm infant is protected by the Japanese Eugenic Protection Act, which defines the fetal viability limit as "the minimal duration of gestation which renders fetuses capable of extra uterine life(39) and was amended to 22 completed weeks in 1991. Therefore the expectation would be that such an extremely preterm infant would be given resuscitation after birth. How Japanese courts would respond to a request to allow withdrawal of life-sustaining treatment from an extremely preterm infant is uncertain, although this would be unlikely to occur for quality of life reasons alone. In general, Japanese physicians expect their directions to be followed,(379,380) although the courts do recognize the right of competent adults to have their medical decisions respected.(381) If physicians decide that further treatment is not indicated, Article 35 of the Criminal Code offers a defense of justification for acts done "in the course of legitimate business."(379,382)

36

ITALY, GERMANY, AND POLAND

In Italy, a doctor has a duty to treat conditional on consent (Italian Constitution art 32), and a competent adult can refuse consent (Penal Code art 50). Nontreatment of children with disabling conditions is viewed as a violation of Article 3 of the Constitution, which relates to equality of all human beings.(383,384)

German law takes a strong "pro-life" position, although for the competent adult patient autonomous decision making, as it relates to medical treatment, includes refusing life-sustaining treatment.(379) Withdrawal of treatment from neonates, where death is inevitable, has become acceptable, but the Einbecker Recommendations of the German Society of Medical Law state that the life of a severely damaged neonate should be safeguarded, and any deliberate shortening of that life constitutes killing.(383,385)

In Poland, the Medical Profession Act of 2002 appears to impose "a duty to rescue"(379) as Article 30 states that a physician has a (legal) duty to always save human life when a delay would result in death and or physical or mental injury, and Article 162.1 of the Penal Code provides a punishment of imprisonment for failure to do this.(379) But Article 32 of the Polish Code of Medical Ethics, which does not carry statutory power, states that: (1) in terminal states the physician does not have the duty to undertake and continue resuscitation or persistent treatment, nor to resort to extraordinary measures, and (2) the decision to discontinue resuscitation rests with the physician and should be based on the assessment of the likely therapeutic success.(379) The Medical Profession Act of 2002 does state that a physician may decide to discontinue or not institute a treatment . . . unless prompt medical intervention is necessary. The latter presumably refers to a duty to rescue and save a life.(379) It is unclear whether an intervention would be deemed necessary if it was believed that it would be ineffective in preventing imminent death, but it is clear that Article 150 of the Polish Penal Code 1997 prohibits "mercy killing."(379)

37

FRANCE

In France, if a child is born alive and able to sustain life it has a legal existence. Ability to sustain life at birth is defined as at least 22 weeks' gestation and a minimum weight of 500g.(243) Reported legal cases involving foregoing of life-sustaining treatment for an extremely preterm infant have not occurred, as far as I could ascertain. The Code of Medical Deontology, which is legally binding, warns physicians to "avoid any unreasonable obstinacy in pursuing investigations and treatments." This presumably refers to treatments that might be viewed as medically ineffective,(386) but Article 37 specifically states that "a dying person must be attended until the last, and given appropriate care and suitable support to preserve the quality of life which is ending. A patient's dignity should be protected, and his or her entourage comforted."(379)

Article 223–6(2) of the criminal code imposes a duty to rescue and proscribes deliberately exposing a person to the danger of death or injury (223–1). In 1996, a physician who extubated and withheld resuscitation from a patient with no chance of survival was convicted of involuntary homicide by the Court of Appeal of Rouen. The doctor was described as acting "against all logic, medical ethics, and accepted rules of good practice."(379,387) This decision is in accord with Article 38 of the Code of Medical Deontology, which states that a physician "has no right to bring about death."(379) This judgment is presumably a statement against euthanasia by the court. However, where extremely preterm infants are concerned the literature outlined in previous chapters suggests that neonatal euthanasia is practiced and accepted in French neonatal intensive care units.

38

THE NETHERLANDS

In the Netherlands, physicians are not required to give treatment they view as "medically futile," and they decide what constitutes this.(383) Euthanasia has been made legal in certain circumstances and there is a provision for children older than age 12 years.(388) Active euthanasia of neonates remains illegal although it has been reported.(389) Although there have not been any reported legal cases involving the foregoing of life-sustaining treatment for an extremely preterm infant, there were two cases in the 1990s that appeared in the Courts of Appeal, which addressed the deliberate termination of life of two severely disabled newborns.(390–392) In one, the *Prins* case, the baby had severe spina bifida, and in the other, the *Kadijk* case, the disorder was trisomy 18. In both these cases, the physicians, after discussion with the parents and colleagues, administered lethal doses of medication. The cases were brought by the Minister of Justice and the physicians were acquitted of the charge of murder on the basis that they had acted in accordance with the legal requirement for careful practice(392) (criteria relating to this are used to justify adult euthanasia). The reasoning was that several major surgical interventions would be necessary that would not offer a later reasonable quality of life and would be accompanied by pain and suffering. The courts accepted, on the testimony of expert medical opinion, that such intervention would be an example of medical futility.(392) The reasoning for the next step was more tenuous. It was believed by the treating physicians that both babies were in great pain that could not be adequately relieved, an opinion that was supported after "expert" consultation with colleagues in anesthesiology. Thus, they reasoned, that as the babies would inevitably die, it was their moral duty to provide a short pain-free death. It should be emphasized that there was no claim that this was an example of the doctrine of double effect. The primary intention was to terminate life.

In 1991 the case of *Baby Jeremy* was heard in Utrecht.(393) The baby was born in August 1989 with brain abnormalities that caused severe handicap. In 1990, he was readmitted into hospital with hydrocephalus. His pediatrician recommended that should the possible situation arise, he should not be resuscitated. The parents disagreed and went to court alleging that the conduct of the doctor was unlawful. In addition, they accused the physician of contravening the European Convention for the Protection of Human Rights and Fundamental Freedoms. They cited Article 2, which protects the right to life, and Article 8, which protects the right to family life.(394) The court ruled that a physician has no obligation to provide treatment that is judged to be ineffective and inappropriate. What constitutes this type of treatment is made on the basis of medical judgment, which is required to follow prevailing professional standards. The court may then, if necessary, judge whether the decision was reasonable, based on these standards. As the physician had consulted a number of experts, who agreed that intubation and ventilation would not alter the course of the disorder, the court found that the pediatrician had acted appropriately with care and beneficence. In addition, it was ruled that Articles 2 and 8 do not allow a right to medical treatment that is deemed of no useful purpose.(394) In 1997, the Dutch government produced a report on physicians' behavior and the shortening of a disabled neonate's life (Toetsing als spiegel van de medische praktijk(395)). This report recommended that all cases of deliberate termination of newborn life should be reported, and that these reports be reviewed by an appointed expert multidisciplinary clinic. The committee would report on whether careful practice had occurred to the Board of Attorneys General, who would decide whether to instigate criminal proceedings. Careful practice includes the adequate recognition of an incurable illness, intractable suffering, and appropriate consultation. In legal terms the deliberate termination of a disabled infant's life still qualifies as homicide in the Netherlands. However, the *Prins* and the *Kadijk* cases would suggest that, provided an acceptable case can be made, a successful prosecution would be unlikely. It remains debatable whether this practice of active euthanasia for the severely disabled infant is a practical ethical recognition of reality or whether it is a cautionary tale.

PART 5

EPILOGUE

Truth, Trust, and Boundaries

EPILOGUE: TRUTH, TRUST, AND BOUNDARIES

The 1989 United Nations Convention on the Rights of the Child, Article 3(1), states: "In all actions concerning children whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration."

This principle of best interests also appears in many other parts of the convention (Articles 9, 18, 20, 37, and 40). Clearly, children have interests from the onset of live birth. The question is who should interpret these interests and how can they be protected? Most jurisdictions allow parents to determine the best interests of their child, up to a point. The courts then recognize their duty to intercede, in certain situations. Physicians also have a duty to act in the best interests of their pediatric patients. Although they are required to respond to the wishes of parents or their surrogates, this response is not necessarily the same as it would be for a competent adult.(396) To fulfill their duty toward the child, physicians may attempt to override the instructions of the principal decision makers, should this lead to the good possibility of significant benefit for the child and the avoidance of a serious risk of harm.

For the extremely preterm infant there remains considerable disagreement concerning where this harm threshold is. That is, does a parental decision increase the likelihood of serious harm as compared to other options?(397) Answering this question, if consent for life-sustaining treatment for an extremely preterm infant is refused, requires a comparison between the harms of death versus that of disability, the degree of which may be uncertain. Can such a utilitarian calculation be made, or are the two harms incommensurable? Even though there is evidence that active intervention for the extremely preterm infant improves mortality and morbidity, these remain relatively high,(399) and the incidence of severe disability is not uncommon, although specific degrees of severe disability remain difficult to predict. Improved survival may lead to an increased prevalence of disability but would also lead to an increase in the number of normal survivors or in those only mildly affected.(400) We have seen in the previous chapters that the approach to this situation varies both legally and operationally from country to country, as well as within countries.

In the United States. the *Miller v. HCA* verdict might suggest that there is a clear boundary that defines when parents and physicians may forego life-sustaining treatment and that treatment must take place despite any likelihood of severe disability.(401) Actual practice may be different and occurs when parents and physicians agree to forego life-sustaining treatment for an unqualified infant, and any legal challenge from the state child protection services is unlikely. This is reflected in an article by Wall and Partridge(133), who reported that in a San Francisco neonatal unit treatment was withdrawn or withheld in 23% of those who died based on quality of life decisions alone. Furthermore, the attitudes of physicians may still be governed by parental preferences, as shown by Ballard et al.(134) In this article, neonatologists were asked whether they would resuscitate a 23-week, 480g infant. If the parents requested "do everything possible," 91% would resuscitate, and if parents requested "comfort care only," only 11% would resuscitate. Thus, it is suggested that although the law may require that an infant was in an irreversible coma, was in a permanent vegetative state, or had a condition that was irreversibly terminal, in the near future, before life-sustaining treatment could be foregone, in actual practice this may not occur consistently. This inconsistent practice does not necessarily bolster any argument concerning what the right thing to do is. There remains an ethical dilemma, a lack of moral consensus, and legal differences between and within countries where sophisticated neonatal intensive care exists. Some might argue against a too-strict approach as it imposes an unjustifiable burden on caregivers, particularly if the child does not develop any relational capacity.(401) But reliable, accurate prediction of this may not be possible, especially shortly after birth. There are clinical and investigative methods that can predict later that disability will occur, even severe disability. But predicting the degree of severity eludes us. The difficult question for many is should life-sustaining treatment continue for an extremely preterm infant whose neurological condition is such that should survival eventually occur there is a strong possibility that a life of extremely poor quality would result, with all the attending burdens to the child, family, and the state? Is there even a justification for neonatal euthanasia? In the Netherlands there is a protocol, the Groningen protocol, the following of which determines whether to actively end the life of a newborn infant.(402) How rigorously this is followed in the rest of the Netherlands is unclear, and all cases are not reported to the legal authorities. Infants for whom such an end of life decision might be made are divided into three categories. The first group includes those infants who are said to have no chance of survival. Such infants are, among others, those with renal agenesis, severe pulmonary hypoplasia, or anencephaly. The approach toward the first two conditions might be different if transplantation for these were readily available and effective. Furthermore, can dying from renal failure be described as unbearable suffering? Similarly, the discomfort of respiratory failure can be managed. Are there discomforts suffered by the infant that would justify actively and intentionally ending that infant's life? The next two categories could apply to some extremely preterm infants. Their description is couched in wooly terms without specificity. Infants in the second category are described as having a very poor prognosis and are dependent on intensive care. Although they may survive, it is said that "expectations regarding their future conditions are very grim. They are infants with severe brain abnormalities or extensive organ damage."(402) They are viewed as having an extremely poor prognosis and a poor quality of life. The third category infants are those believed to have "a hopeless prognosis who experience what parents and medical experts deem to be unbearable suffering."(402) The example given is the child with the most serious form (undefined) of spina bifida or the infant who has survived intensive care but whose quality of life will be "very poor" with no hope of improvement. These are the categories that might allow "deliberate life ending procedures." When considering an approach such as the Groningen protocol, it is easy to become embroiled in definition and recognition of what constitutes severe disability. However, it is important to emphasize what is preferable and what is permissible. We do not prefer to have severely handicapped children, or welcome the distress it evokes, but we also have to decide which actions we do not permit parents and physicians to make.

Society has to trust parents and physicians to provide care for children, up to a point. Where to draw the boundary is open to discussion, but not that there should be a boundary. Unfortunately drawing boundaries can also be problematic, for example, using gestational ages or weights as sole determinants for care. In the busy confines of hospital practice, and in particular intensive care, there is a pressure to reduce the complexity of decisions and act on rules that offer resolution of a problem at hand. Thus an a priori limit for intervention might be attractive in that setting. No resuscitation, say, for less than 25 weeks, or 24 weeks' gestation, or less than a certain birth weight. Ethically this is hard to justify if the status of a preterm infant is viewed as the same as an adult with respect to the receipt of medical treatment. This becomes more so when early specific individual prognosis may be uncertain. As Simeoni and colleagues wrote(403):

> There is . . . a difference between saying (1) that a limit in terms of gestational age should be set for intensive intervention in extremely preterm infants, and (2) that every infant deserves a unique approach concerning the application of intensive care, backed by the information available on collective outcomes at the various gestational ages and perinatal conditions. The difference lies in intention. Its denial would challenge by extension the ethical bases of decision making in other medical situations.

Thus treatment decisions for extremely preterm infants should be made based on a combination of factors, which are recognized and interpretated by physicians and decided on by parents. How much actual power parents may have will vary depending on the clinical situation, the legal jurisdiction, and the attitudes of the physicians. Orfali and Gordon posed the questions: "does a system that emphasizes parents' autonomy enable them to cope better as some studies and the bioethical theoretical literature strongly suggest? How do parents without decision making power deal with such situations?"(404) They examined decision making in

American and French neonatal intensive care units. The study was based on the assumption that in the United States parents are viewed as the appropriate surrogate decision makers for their infants and may or may not give informed consent following the receipt of appropriate information and options from physicians. In France, as Orfali and Gordon wrote, "physicians tend to use only the child's best interest as the guiding criterion for decision making. Parental consent is taken as implicit . . . since it is presumed that doctors and parents want the same 'good' for the baby." Although it is arguable whether this contrast is completely true, it is reasonable to allow the premise that French physicians act in a more paternalistic manner than their American counterparts and then examine the consequences of this, recognizing that there is not a sharp divide between autonomy and paternalism between the two countries. The authors' conclusions were that a sensitive empathic, but paternalistic, model was viewed by mothers as providing more satisfaction and reassurance when compared to an autonomy model, despite their support for the ethical principle of autonomy. However, other factors may play a role in providing less satisfaction in the American system and include a lack of continuity in physician availability and perhaps a more detached formal contractual relationship between the parents, physicians, and the health care system. Orfali and Gordon's findings do not refute the doctrine of informed consent or the respect for autonomy principle. The French parents in their study strongly believed they were making a "shared decision" with physicians, when end of life issues were decided for their infants, but the burden of considering and arriving at the decision was carried by the physician. In effect, French physicians decide what is "best" for a neurologically damaged neonate, and by acting to "shape" the decision of parents their intention is to avoid further harm. I would suggest that this approach is followed by many pediatric physicians in modern health care systems. The theoretical discord is that giving the beneficence principle primacy requires faith and trust, risks a loss of respect for autonomy, increases the inherent dangers of quality of life decisions, and perhaps encourages a lack of scrutiny. But in practice it may well lead to more comfort and satisfaction. The creation of faith and trust always has been, and remains, an important component of the art of medicine.

There is a special relationship between patients and parents and physicians that demands special obligations. Society allows physicians powers and privileges that potentially could threaten the welfare of their patients. Although the principle of autonomy ostensibly permits parents to agree to treatments for their children, it is the physician who necessarily frames and defines the circumstances. Thus parents seek care for their children from someone they can trust. But they do not always have the time or the opportunity to choose. Systems in which this occurs can erode the trust between health care professionals and parents and requires considerable skill and virtue from the professionals to gain and maintain trust. This is particularly so in an intensive care unit, where interventions may be poorly understood by parents and the situation may be overwhelming. Apparently good physicians gauge how much autonomy parents want to express and by doing so demonstrate the good aspects of paternalism that should not be lost. Present bioethical theoreticians might question this approach and perhaps risk undermining a delicate trust.(405) As Sherlock stated: “the language of rights and the language of trust move in opposite directions from one another.”(406)

But there is not only the delicate trust that needs to exist between parents and physicians. Society, through its laws and actions, is also required to trust. That is, there is a public trust.(407) But the question is to what extent and in what circumstances? In situations that are beyond our direct control we expect society, through its laws and the actions of our representatives, to define the limits and boundaries that protect both the integrity of the society and the vulnerable individual. It is not enough to rely completely on the assumed benevolent motives of the health care professional.(405) In fact, the knowledge that there are proscriptions against the behavior of physicians, through both the law and professional codes, should bolster trust. A counterargument is that intrusive overregulation might impair trust and confidence by disturbing the behavior of physicians and their interaction with parents. Despite this, there is still a requirement for methods of monitoring clinicians and their practices, and in particular defining boundaries in end and beginning of life issues.

There remains considerable variability around the world in the approach to extreme prematurity with differing professional and personal perceptions and disparate codes, case laws, and statutes. Perhaps the main conclusions we draw are that the extremely premature state is not a preferable choice, and in addition to addressing its clinical, ethical, and legal impact, we should be spending more resources to reduce the incidence of preterm birth. The growth of neonatal intensive care and its successful lowering of the limits of viability have come at a price. This price is not only financial, which compares favorably with intensive care for adults, but also medical and emotional. The dramatic psychosocial strains that stress families following the birth of an extremely preterm infant can never be welcome, even though those who work in neonatal intensive care do so with laudable care and professionalism and have at their disposal increasing technological expertise. In January 2005, a group from Britain and Ireland reported that the outcome for those studied following birth before 26 weeks, during 1995, was disabling cerebral palsy in 12% and moderate or severe disability in 46%.(408) Furthermore, premature birth rates are increasing and adding to the dilemma.(409,410) Survival rates for the extremely preterm infant increased over the last decade of the 20th century,(411) and most deaths occurred in the first few days after birth.(198) If the determining factor is survival, early intensive care appears to be justified as most will survive after the first week or so of life.(411) The question remains whether there can be an acceptable level of disability and whether this be predicted. Such decisions are further complicated by the fact that outcomes change sharply with each week of added gestational age, which can be over- or underestimated.(412) Furthermore, not all preterm infants are at the same developmental level after delivery because of differing genetic and environmental influences.(413)

It would appear clear that the most effective approach to the difficult questions raised by extreme prematurity is prevention. Considerable clinical resources, research money, and effort are expended on neonatal intensive care, and although the causes of preterm birth are multiple and complex, changes in education, health, and social policy might have a greater impact.(414,415) This includes well-funded, accessible, comprehensive prenatal care, and social and financial support during pregnancy.(416,417) Prematurity affects 12% of births in the United State and 17% of births among African Americans. Hospital care of preterm infants costs over $13 billion each year, apart from the medical and social costs incurred following initial discharge from hospital.(418) The causes of preterm birth are multiple and complex. Infection and the inflammatory response appear to contribute to these causes,(419) but this may be complicated by a gene-environment interaction.(420,421) Further research on infection, host response, and genetic susceptibility offers an avenue into treatment and prevention. However, there may be a greater improvement if more research, action, and resources were directed at poor social circumstances,(422) the effects of demanding work,(423) the reduction of multiple pregnancies, and the role of assisted reproduction technology.(424) In the United States, during the decade prior to 2002, there was a 13% increase in the number of preterm births, and in some states the increase was more than 30%.(425–427) Two major contributions to this were advanced maternal age and multiple pregnancy(428) to some extent as a result of the increasing use of assisted reproductive technologies.(429) In this group of women those with lower socioeconomic status were at higher risk for a poor perinatal outcome.(430) There is a strong association between preterm birth and social disadvantage, linked with maternal stress, infection, and lack of prenatal care,(431–433) and the preterm delivery rate in the United States is nearly twice that in Canada and Western Europe.(434)

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