

ETHICS EDUCATION IN NEONATOLOGY:
THE PAST, THE PRESENT, AND HOPE FOR A FUTURE

BY

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A Thesis Submitted to the Graduate Faculty of
WAKE FOREST UNIVERSITY GRADUATE SCHOOL OF ARTS AND SCIENCES

in Partial Fulfillment of the Requirements

for the Degree of

MASTER OF ARTS

Bioethics

May 2012

Winston-Salem, North Carolina

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ABSTRACT

The discipline of bioethics came into being in the early 1970s in the wake of the major societal revolutions of the 1960s and the rapid rise of medical technology. Neonatology was first recognized as a subspecialty within the field of pediatrics in 1975. The extent to which advances in medical technology have transformed the field of neonatology is unmatched by those in any other field. This transformation has, in turn, given rise to ethical dilemmas in neonatal intensive care units with a regularity and intensity equally unmatched. In spite of this, very few fellowships in neonatal-perinatal medicine offer formal education and training in ethics.

This thesis will begin with a historical overview of prior efforts at ethics education in American medical schools, pediatric residency programs, and neonatology fellowships. The second and third chapters will describe and critically analyze a pilot educational module in ethics designed for and presented to the Division of Neonatology at Wake Forest School of Medicine. In closing, recommendations for future endeavors in ethics education for neonatology training programs will be outlined.

INTRODUCTION

The idea for this thesis was born out of my experience as a former pediatric resident and current neonatology fellow with a special interest in bioethics. The American Board of Pediatrics requires that all fellows pursue some form of scholarly activity as an integral part of their fellowship and I elected to pursue a Masters of Arts in Bioethics through Wake Forest University to fulfill this requirement. As I progressed in my Masters coursework and in fellowship, I was struck by the absolute and unapologetic lack of attention paid to the ethical issues that inevitably arise in the day-to-day practice of neonatology. This inattention to ethics was underscored by a failure to incorporate any form of ethics education into the formal fellowship curriculum. In recognition of this deficiency and in an effort to address it proactively, I set out to design a pilot educational module for the faculty and fellows in the Division of Neonatology at Wake Forest School of Medicine.

By way of educating myself on ethics education in neonatology, I began with a literature search seeking to learn more about the process of ethics education in American medical schools, pediatric residency programs, and neonatal-perinatal fellowship programs. The results of this literature review are presented in Chapter 1. Most of the available literature is focused on ethics education at the medical school level. The focus of related discussion in this thesis is on the debate as to the proper goal of such educational efforts, with a brief discussion of how and by whom such curricula should be taught. Ethics education in American pediatric residency programs is governed by the American Academy of Pediatrics (AAP), the American Board of Pediatrics (ABP), and the Accreditation Council for Graduate Medical Education (ACGME). A brief historical overview of the respective roles of these governing bodies is provided. This is followed by an extensive review of two empirical

studies – “Pediatricians’ Reports of Their Education in Ethics,” a 2008 *Archives of Pediatric and Adolescent Medicine* by Kesselheim et al. and “Ethics and Professionalism in the Pediatric Curriculum: A Survey of Pediatric Program Directors,” a 2009 *Pediatrics* article by Lang et al. – that examined ethics education in pediatric residencies as perceived by recent graduates and by residency program directors respectively. With regard to ethics education in neonatal-perinatal fellowships, the results of a literature review and a description of an ethics curriculum as outlined in a 2009 *Seminars in Perinatology* article by Salih and Boyle are presented.

Chapter 2 details the development and implementation of a four-session pilot educational module that I presented to the Division of Neonatology at Wake Forest School of Medicine in January and February of 2012. This module consisted of four ninety-minute sessions – Ethics in the NICU, Decision-Making in the NICU, Futility in the NICU, and Research Ethics – that included a didactic lecture presented by myself followed by a case-based discussion led by Professor Moskop. The objectives and content matter of each session are outlined in detail in this chapter.

In Chapter 3, I critically examine the pilot educational module. Much of this chapter is devoted to the pre- and post-intervention testing that was administered in an effort to evaluate the efficacy of this educational module. The pre- and post-tests consisted of 21 fact-based questions and 5-6 attitudinal questions. The results of the pre-test confirmed a deficiency in ethics knowledge on the part of all participants that was complemented by an apparent interest in correcting this deficiency. The results of the post-test revealed a 15% increase in the number of questions answered correctly, indicating that the ethics knowledge base of participants was directly increased by the implementation of this

educational module. The remainder of this chapter is devoted to my personal reflections on the process of developing the module, its relative successes and failures, and specific recommendations for further development of this particular curriculum.

The fourth and final chapter of this thesis discusses the future of ethics education in neonatology. Given the empirical evidence presented in Chapter 1, coupled with my personal experiences in fellowship and especially those gained in the course of the pilot educational module, I emphasize the urgency of the need for direct attention to improving ethics-related learning opportunities for neonatology fellows and practicing neonatologists alike. In recognition of the fact that endeavors to this end will require efforts on multiple levels, I outline recommendations to be implemented on the level of the respective governing bodies (AAP, ABP, ACGME), training institutions (medical schools, residency and fellowship programs), and individual neonatologists and neonatology fellows.

The purpose of this thesis is to bring explicit attention to the lack of formalized efforts in ethics education for neonatologists in training, to describe a pilot educational module that was designed to fulfill the need for formalized ethics education in one American neonatology fellowship program, and to provide specific recommendations for a brighter future for ethics education in neonatology.

CHAPTER ONE

ETHICS EDUCATION IN NEONATOLOGY – A BRIEF REVIEW

For centuries, the medical profession has recognized and accepted the fundamental role of ethics in the science, art, and practice of medicine. This history, dating back to the days of Hippocrates, can perhaps be most directly traced to the late eighteenth century when Thomas Percival, an English physician, drafted the first known code of professional ethics for physicians and surgeons. Percival, who penned this code in response to the abandonment of patients by feuding surgeons in the midst of an infectious epidemic, is credited as a “dominant influence” in modern-day American bioethics. In the words of Pellegrino, “we are obliged to take Percival’s moral philosophy seriously today when we are in the midst of an unprecedented reappraisal of the whole of medical morality” (Stirrat, 2003).

Just over half a century later, in 1847, the inaugural meeting of the American Medical Association (AMA) was held. In dedicating itself to the establishment of uniform standards for professional education, training, and conduct, the newly formed AMA’s top priorities at that meeting were to establish a code of ethics and to create minimum requirements for medical education and training (Stirrat, 2003). Although these were separate and equal priorities in 1847, the time would come when these two priorities would converge as, in the late twentieth century, bioethics rose to a position of newfound importance in medical schools and training institutions across the country. In retrospect, as Eckles et al. have noted: “Many factors accounted for this emergence in society generally and in United States medical schools in particular, including: major developments in science and technology,

especially in advances in medical, surgical, and intensive care; significant societal changes in the 1960s, including the rise of the women's and civil rights movements; a better-educated public; and an increasing distrust of authority" (Eckles, 2005).

The purpose of this chapter is to provide an overview of the history and current state of ethics education in medical training programs in the United States. The vast majority of the literature on this topic has addressed educational efforts in medical schools and I will offer several perspectives on ethics education at this level first. This will be followed by a brief review of the ethics-related competencies established by governing bodies of graduate medical programs at the national level. Lastly, I will describe several empirical studies examining ethics education in the specialty of pediatrics and, in particular, the subspecialty of neonatology.

ETHICS EDUCATION IN AMERICAN MEDICAL SCHOOLS

A brief history of medical ethics education in the United States, as presented by Fox et al., reveals that, in just over two decades, the percentage of medical schools that included a formal and separate course in medical ethics as part of the required general curriculum rose from just 4% in 1972 to 34 % in 1989 and, ultimately, to 100% by 1994 (Fox, 1995). This recognition of the importance of incorporating ethics into the formal education of physicians in training posed a new challenge – identifying the primary goal of these educational efforts. Generally speaking, two distinct goals emerged – the creation of virtuous physicians and the provision of a skill set to be used in the analysis of ethical dilemmas – and the virtue-skill dichotomy was born.

Edmund Pellegrino and David Thomasma, among others, lay claim to the former, declaring that “virtue can be taught by practice, by example, and even by the study of ethics” (Fox, 1995). Likewise, some have suggested that the focus of formalized ethics education should be to produce “doctors who not only behave ethically” but are, indeed, ethical doctors who embody virtuous traits such as honesty, respect, compassion, and integrity (Goldie, 2004). Those who embrace this noble goal of creating virtuous physicians are driven, at least in part, by a small body of empirical evidence that suggests that the moral reasoning of *prospective* medical students is, in fact, superior to that of *graduating* medical students. This apparent decline in moral reasoning and ethical sensitivity, referred to by some as “ethical erosion,” is thought to arise from an overarching sense of cynicism that seems to be imparted and propagated in the greater process of socialization and enculturation within the medical education system. Acknowledgment of such ethical erosion and the desire to contend with it in a more formal manner has led many authorities in the fields of ethics and medical education to insist that the proper focus of formalized ethics education in medical schools should be the creation of truly virtuous physicians.

In contrast to the position described above, the vast majority of those in the fields of ethics and medical education who have commented on this matter are in support of the provision of a knowledge base and associated set of skills for analyzing ethical dilemmas as the primary goal. Citing debate as to whether or not virtue is at all teachable, this group views the goal of creating virtuous physicians as one that is entirely unrealistic. Eckles et al. (2005) suggest that skill-based curricula may have gained favor over virtue-based curricula if for no other reason than the fact that there are “difficulties in measuring virtue among physicians and medical students.” While there is incomplete agreement as to precisely

what skills should be taught, those that have been proposed include self-examination of one's personal and professional moral commitments; foundations in law, ethics, and philosophy; and interpersonal and communication skills, among others. Gordon Stirrat suggests that formalized ethics education should occur throughout training and even into one's medical career, with courses in medical school serving as a basic introduction to bioethics. He goes on to mention three primary objectives of such courses – increasing knowledge (emphasizing basic ethical theories and principles), developing skills (in analysis, judgment, and rational argument), and improving attitudes. The process of obtaining informed consent serves as an excellent illustration of the practical application of the three objectives outlined by Stirrat. Obtaining informed consent requires that one understand the essential elements of informed consent (knowledge), possess the capacity to communicate effectively and to elicit the patient's informed and voluntary choice (skills), and appreciate the value of the basic ethical principle of autonomy (attitude). He places particular emphasis on the third objective – improving attitudes – in recalling that during his time as dean of a medical faculty, “the problem of the failing student is more often a problem in attitude rather than ability” (Stirrat, 2003). The same could be said of the handling of ethical issues in clinical medicine. Arguably, one of the greatest contributions of formalized ethics education would be a heightened awareness of the pervasive nature of ethics in medicine. In emphasizing this attitudinal objective, Stirrat seems to suggest that, perhaps, the inclusion of attitude improvement within a structured skill set is the best way to create the virtuous physicians sought by Pellegrino and the like. Of course, the distinction between knowledge, skills, and attitudes as they relate to clinical ethics often becomes blurred, making this tripartite division somewhat academic in nature.

The literature on ethics education does not clarify whether or not the aforementioned virtue-skill dichotomy as termed by Eckles et al. (2005) is, in fact, as dichotomous as it may seem at first glance. Even those who view the creation of virtuous physicians as the ultimate goal of these endeavors concede that there is some skill involved. Likewise, those who favor the transmission of knowledge and skills as the primary goal acknowledge that virtuous physicians may come to be as a result. It seems that neither a strict emphasis on the inculcation of virtue nor a comprehensive set of “ethical” skills in isolation can ensure that a physician will become “ethical” or “virtuous” in the process. Perhaps a parallel between the virtue-skill dichotomy and the longstanding “medicine as art-medicine as science” dichotomy can be drawn. Insofar as the matter is one of theory, these dichotomies may well continue to exist; yet, in practice, it would appear that the distinction may, in fact, simply be one of irrelevance or, at a minimum, one that has been greatly overstated.

There are also those who have challenged efforts to formalize ethics education in medical schools. In a 1994 *Academic Medicine* article in which they claim that “the medical school functions as a moral community,” Frederic Hafferty and Ronald Franks argue that “formal instruction in ethics makes only a small contribution in that community, since most of the critical determinants of physicians' identities lie not within the formal curriculum but in a more subtle hidden curriculum” (Hafferty, 1994). This so-called hidden curriculum is subsequently described as “being more concerned with replicating the culture of medicine than with the teaching of knowledge and techniques ... what is ‘taught’ in this hidden curriculum often can be antithetical to the goals and content of those courses that are formally offered” (Hafferty, 1994). Put otherwise, the hidden curriculum has been defined as “all those things that physicians are taught during their socialization as physicians that

reflect the values and mores of the profession” (Egan, 2002). The hidden curriculum claim made by Hafferty and Franks is based on three primary assumptions – 1) formal ethics education can neither correct past ethical ills nor prevent future ones; 2) the morality of medical students is predetermined prior to entering medical school, and formal ethics education does not substantially affect a student’s beliefs or actions with regard to morality; and 3) if there is anything to be learned regarding ethical behavior in medical training, it is best taught informally through clinical experience, peer interactions, and role modeling (Hafferty, 1994). Having completed medical school, pediatric residency, and most of a neonatology fellowship, I can attest to the indisputable presence of this hidden curriculum. This will be further discussed in Chapter 4.

Despite such significant differences of opinion regarding the need for formalized ethics education courses in medical schools, there is relative consensus as to how and by whom these courses should be taught. The traditional model, by which ethics is taught as a separate required course in the formal curriculum of the first and second years of medical school, generally consists of a didactic lecture followed by small group case-based discussions. There is some variation within this model, in that some curricula are strictly theory-based which others are more problem-based. This traditional model, albeit a popular one, is not without its critics. Despite empirical evidence that the case-based approach is perceived by students to be more enjoyable and ultimately more effective, some have questioned the wisdom of relying on case studies as the “salvation of ethics teaching and discourse” (Pattison, 1999). Conceding that “case studies introduce context, persons, emotions, and realism into what can otherwise be abstract and sterile theoretical debate,” Pattison et al. (1999) warn that they are also edited works that carry the risks of suggesting

that “problems and controversy form the whole of morality and ethical discourse” and of “reinforcing and giving publicity to dramatically bad practice rather than emphasizing and using examples of good everyday practice.” In response to these concerns, proponents of the use of case studies in ethics courses have emphasized the importance of the use of “real-world” cases rather than age-old paradigmatic cases that are prone to editorialization.

It is generally agreed that an interdisciplinary team of ethicists and physicians should share the responsibility of teaching ethics to medical students (Eckles, 2005; Fox 1995). Some have suggested that ethics teaching during the preclinical years should be done by philosophers with the teaching during the clinical years to be done by physicians, while others would endorse a team-teaching approach throughout the years of medical school. Either way, this interdisciplinary approach is commonly justified on grounds that “rarely are clinicians sufficiently trained in ethics and do ethicists have sufficient clinical knowledge and experience to teach alone competently” (Fox, 1995). Regardless of who the ideal teacher would be, most would agree that “ethics needs a product champion in every medical school – it is easy for it to become everyone’s and therefore no one’s responsibility” (Mattick, 2005).

ETHICS EDUCATION IN AMERICAN PEDIATRIC RESIDENCY PROGRAMS

In a 1974 publication entitled *Foundations for Evaluating the Competency of Pediatricians*, the American Board of Pediatrics (ABP) outlined the attitudes, knowledge, and skills that pediatricians in training should possess. It should be noted that there was no explicit requirement related to ethics in this document. In 1982, the ABP issued a notice requiring

pediatric residency program directors “to evaluate and attest to the applicant’s ethical and moral behavior as it affects his or her professional performance” (ABP, 1987). In that same year, the ABP charged a subcommittee with the task of determining the feasibility of including a subset of medical ethics questions on future certification examinations. Five years later, in 1987, ethical decision making became an official subject area on general pediatrics certification examinations. In an attempt to support efforts in ethics education, the Ethics Committee of the ABP has published and regularly updated an annotated bibliography of bioethics since 1983 and the American Academy of Pediatrics’ (AAP) Section on Bioethics and Committee on Bioethics have developed a case-based modular curriculum that is designed to “function as a how-to resource for residency and fellowship programs” (Adam, 2011).

Subsequently, in 1997, the Residency Review Committee required all accredited residency programs, pediatrics notwithstanding, to offer a structured curriculum in medical ethics. In 1999, the Accreditation Council for Graduate Medical Education (ACGME) outlined six general competencies to be taught and evaluated in all residency programs – 1) patient care, 2) medical knowledge, 3) practice-based learning and improvement, 4) interpersonal and communication skills, 5) professionalism, and 6) systems-based practice. Within the realm of professionalism, trainees are expected to demonstrate:

a commitment to carrying out professional responsibilities
and an adherence to ethical principles

compassion, integrity, and respect for others

responsiveness to patient needs that supersedes self-interest

respect for patient privacy and autonomy

accountability to patients, society, and the profession

sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation

The ACGME specifically states that “proficiency in this competency domain is primarily behavioral and attitudinal and is demonstrated as part of all other competency domains. Therefore, teaching and evaluation is most effective when done in the context of patient care and related activities” (ACGME Core Competencies, 1999). The ACGME Program Requirements for Fellowship in Neonatal-Perinatal Medicine, made effective July 1, 2007, explicitly outline the manner in which this competency is to be taught:

Medical ethics and professionalism should be emphasized in the didactic curriculum and modeled by the faculty in all aspects of their practice. A structured curriculum with meaningful venues for teaching that extends beyond the traditional lecture to include interactive learning (e.g. small group discussions of vignettes or case studies, computer-based modules, role play, etc.) will meet this requirement (ACGME Program Requirements, 2007, p. 32).

While such an emphasis on formalized ethics education in residency and fellowship is to be commended, the structure and function of such educational efforts has proven to be poorly defined. This is likely due to the fact that regulation and oversight are essentially nonexistent. As Bolin notes, “Graduate medical education becomes bifurcated when medical students leave medical schools for residency programs, and no single organization controls or directs the process of ethics training. In contrast to other professions' ethics training requirements (e.g., law, accounting, insurance, real estate, business administration), there are no uniform or national standards governing ethics training in graduate medical education programs” (Bolin, 2006).

Several empirical studies of the structure and quality of ethics education for pediatricians have been published. A 2008 *Archives of Pediatric and Adolescent Medicine* article by

Kesselheim et al., "Pediatricians' Reports of Their Education in Ethics," described a cross-sectional survey administered to 150 recent graduates of American pediatric and internal medicine/pediatric residency training programs. The purpose of the study was to assess the quality of the respondents' ethics education, the impact of various learning methods employed to teach ethics, and ultimately their confidence in handling ethical dilemmas in clinical practice. Respondents were first asked to rate the impact (ranging from major impact to no impact at all) of various learning methods, including discussions with fellow residents, attending physicians or hospital ethicists; formal teaching conferences; participation in ethics consultations; and literature review. Greater than 80% of respondents reported that discussions with fellow residents and attending physicians had a moderate to major impact, while only half of the respondents reported that formal teaching conferences had a similar impact. It should be noted, as the authors concede in their closing comments, that this study could not determine whether a particular learning method was considered to have had little or no impact on the quality of ethics education because it was ineffective or simply because it was unavailable. With regard to the quality of ethics education, respondents were asked to rate the overall quality, the degree of administrative support for ethics education, and the level of attention paid by attending physicians to the ethical dimensions of patient care. Approximately 45% of respondents described their ethics education as fair or poor, while 35% described it as good and only 20% described it as very good or excellent. Approximately half of the respondents described administrative support as fair or poor, while 23% described it as good and 29% described it as very good or excellent. Interestingly, almost half of the respondents reported that the attention paid by attending physicians to ethical dimensions of patient care was very good or excellent. Bivariate analysis revealed that respondents who rated the quality of their ethics education more favorably than others were more likely to have reported that formal teaching

conferences, discussions with other residents, attending physicians, and ethicists, and involvement in ethics consultations had a large effect on their ethics education. To assess confidence in confronting ethical challenges in clinical practice, respondents were presented with 23 such challenges (ranging from discussing newborn screening results with parents to administering opioids for symptom relief to patients near the end of life to obtaining assent to enroll a ten year old child in a clinical trial) and asked to rate themselves as not confident, a little confident, moderately confident, confident, or extremely confident. More than 60% of respondents rated themselves as confident or extremely confident in just 4 of the 23 cases, while 40-60% rated themselves similarly in 8 cases and < 40% rated themselves as confident or extremely confident in the final 11 cases. The 24th and final question – “Overall, how confident are you in your ability to assess the ethical challenges that arise in your practice as a pediatrician?” – was posed. 55% of respondents described themselves as confident or extremely confident, 39% described themselves as moderately confident, and 6% described themselves as a little confident or not confident at all. Further analysis of these results revealed a mean confidence score of 3.4 (range 1.2-5.0, standard deviation 0.8). Higher mean confidence scores were significantly associated with gender and current practice setting, with males and respondents in academic settings reporting themselves to be more confident than their respective counterparts. Moreover, mean confidence scores were significantly higher for respondents who reported a higher overall quality of ethics education, greater administrative support for ethics education, and greater attention paid by attending physicians to ethical dimensions of patient care. Acknowledging that this study was limited by its reliance on self-report (making it subject to recall and social desirability biases) and the use of confidence assessments (a subjective domain that is difficult to externally validate) as a primary outcome, the authors noted three major findings – the quality of ethics education was rated as fair or poor by almost half of the

respondents, informal discussions with colleagues and supervisors had a greater impact than formal teaching conferences, and respondents reported limited confidence in almost half of the ethical dilemmas that they were asked about, especially in those related to research ethics and end-of-life care. In closing, the authors make three primary recommendations. First, they suggest that educators need to clarify the core content of ethics curricula in pediatric residencies. Second, acknowledging that formal ethics teaching (didactic lectures, interactive case studies, small group learning) is “one proper avenue to meeting pediatricians’ needs,” they recommend that a core curriculum in ethics and professionalism should be developed for residency programs nationwide (Kesselheim, 2008). Finally, they suggest that the informal learning methods that were so highly ranked by respondents should be further studied and enhanced given the obvious substantial impact they have on the ethics education of residents.

A second study of note, “Ethics and Professionalism in the Pediatric Curriculum: A Survey of Pediatric Program Directors,” was published by Lang et al. in *Pediatrics* in 2009. This study was designed to gather data regarding the implementation of the 2007 ACGME requirements for the documentation of teaching and evaluation of professionalism. A survey, developed on behalf of the AAP's Section on Bioethics, was distributed to 394 directors and co-directors of pediatric and internal medicine/pediatric residency programs, of which 233 were returned. The survey included questions about the number of hours dedicated to ethics, topics covered, formats and venues used to teach ethics, use of resources available through the ABP, reading assignments, evaluation methods, and barriers to establishing curricula in ethics. (The same questions were asked regarding

curricula in professionalism however, those will not be further discussed as they are beyond the scope of this chapter.)

Programs were relatively evenly divided on whether ethics was taught as a separate curriculum (47%) or integrated into the greater pediatric curriculum (53%). 99% of program directors who reported not having an ethics curriculum thought one would be useful. Regardless of how ethics education was offered, two-thirds of respondents reported that < 10 hours per year were dedicated to such efforts. There was great variability with regard to the venues in which ethics was taught, with > 40% reporting that ethics was taught in structured conferences (resident lectures, morning report, grand rounds, intern orientation). Significantly fewer respondents reported the use of online modules, participation on ethics committees, and incorporation of ethics teaching into clinical care rounds. The vast majority of respondents reported that lectures (80%) and case-based seminars (72%) were the primary formats by which ethics was taught, and of those, most were coordinated by a specific individual or individuals. Most programs did not assign required reading as preparation for the lectures or case-based seminars. Only half of the programs had implemented a specific method to evaluate the ethics education that was offered. Nine general ethics topics were identified by $\geq 75\%$ of respondents – consent with/for minors, privacy/confidentiality, truth-telling and disclosure, neonatal ethics, ethics of adolescence, child abuse/neglect, advocacy, multiculturalism, and hospice/palliative care. Several barriers to developing an ethics curriculum were identified. Nearly 80% of respondents cited a crowded curriculum, making it, by far, the most commonly cited barrier. Nearly 40% of respondents cited lack of ethics expertise among faculty members as a barrier, while approximately 20% cited lack of interest on either the part of the learners

or the faculty and approximately 10% cited lack of administrative support as identifiable barriers. The data obtained in this study suggest significant shortcomings in the ethics education offered in pediatric and internal medicine/pediatrics residency programs. Nevertheless, the authors reported that, over a two year period from July 2007 to April 2009, only three programs were cited for failing to ensure adequate core competency training in professionalism and only four programs were cited for failing to evaluate this training. The primary limitation of this study was missing or incomplete data, which reflected the unfamiliarity of program directors with the specifics of the content and structure of their ethics curricula. In closing, the authors suggested that ethics and professionalism training should be integrated into a core competency given the "broad overlap in foundational principles" (Lang, 2009). In addition, they identified the following needs for improvement in ethics education: appropriate guidance regarding curriculum content and adequate training of faculty to facilitate ethics education. Finally, they commented that "teaching and evaluation tools need to be widely disseminated and their effectiveness evaluated if the ACGME requirements for competencies in these areas are to be meaningfully realized" (Lang, 2009).

ETHICS EDUCATION IN NEONATAL-PERINATAL MEDICINE FELLOWSHIP

While some view neonatal intensive care as one of modern medicine's greatest successes, it has also been described as "one of the best examples of modern medicine's moral ambiguity or hubris" (Lantos, 2006, p. 4). Few would deny the everyday presence of moral ambiguity in neonatal intensive care units across the country, and yet a review of the literature suggests that the formalized ethics training of fellows in neonatal-perinatal medicine leaves much to be desired. In "Ethics Education in Neonatal-Perinatal Medicine in the United

States,” a 2009 *Seminars in Perinatology* article, Salih and Boyle describe a literature review on formalized ethics curricula for neonatal-perinatal fellowships and report on a curriculum developed at Indiana University School of Medicine. Their comprehensive literature search revealed only one published syllabus and one article, both from Canada.

The syllabus was developed by Dr. Jonathan Hellman, a neonatologist at the Hospital for Sick Children in Toronto. In the course of the two year neonatology fellowship program there, a maximum of six hours is devoted to formal ethics teaching. Dr. Hellman conducted two internet searches – one through the National Reference Center for Bioethics Literature based at the Kennedy Institute of Ethics at Georgetown University and a second through Google – but was unable to find any neonatology-specific ethics curricula for review. In addition, he surveyed eight colleagues from the United States, Canada, Israel, India, and Australia, none of whom were aware of any existing neonatal ethics curricula, but all of whom expressed interest in such. A total of fifteen topics were identified and the first iteration of this web-based curriculum focused on the first four of those topics – professionalism and the technological imperative; communication and physician-parent relationships in the NICU; best interests of the infant; and end of life decision-making. For each topic, Hellman outlined learning objectives (e.g. “The student will understand the issues that arise in the implementation of withdrawing/withholding life-sustaining medical treatment.”); ethics messages (e.g. “A physician is a moral agent and is judged as such.”); and teaching tools, modalities, and formats to include interactive discussions based on responses to provocative questions, case analysis, fellow-led presentations, self-reflective exercises, and readers theater presentations (Hellmann, 2006). In addition, a lesson plan outline and extensive list of readings were provided for each session. The syllabus was

carefully designed so as to balance the “fascination with details of the medical case and its problem solving potential” with the “need to convey principles and procedures underlying case discussion and to denote the depth of reasoning and moral theory that can be applied” (Hellmann, 2006). Interestingly, Dr. Hellman states that the major ethical dilemmas for trainees at the Hospital for Sick Children are 1) communication and joint decision making with parents and 2) transitioning to a multidisciplinary team approach to communication. These challenges are compounded by the fact that the fellows hail from multiple developed and developing countries with very diverse social and medical cultures. Although not mentioned elsewhere, it should be noted that this syllabus cannot strictly be classified as an ethics curriculum, given that the first two topics fall largely within the realm of professionalism. Dr. Hellman addresses this matter in the introduction to the syllabus: “While communication is often not regarded as ethics per se it is included in this curriculum because of the overall respect for persons and its importance in setting up the foundations for ethical decision making” (Hellmann, 2006). There is no information available regarding the efficacy and outcomes of this web-based curriculum to date.

The only article identified by the literature search described above was entitled “A Curriculum for Teaching Clinical Ethics in Neonatal-Perinatal Medicine.” It was written by Dr. Deborah Davis, a physician in the Departments of Obstetrics and Pediatrics at the University of Ottawa and Professor Hubert Doucet of the Department of Theology at St. Paul's University in Ottawa, and published in the *Annals of the Royal College of Physicians and Surgeons of Canada* in February of 1996. With respect to formal neonatal ethics curricula, it remains the most widely cited article to date.

The authors, who were involved in the development of the neonatal-perinatal medicine and maternal-fetal medicine programs at the University of Ottawa, endorse the value of proper bioethical teaching for trainees in these fields. Perhaps more importantly, they recognize that the informal training offered to fellows via the observation of role models and participation in multidisciplinary team meetings would be “deficient if it was based solely on this approach,” due to the inconsistencies with which ethical dimensions of care were approached and the unpredictability of ethical cases to which fellows would be exposed during their years of training (Davis, 1996). The curriculum, designed to fulfill the needs of fellows and attending physicians in neonatal-perinatal medicine and maternal-fetal medicine, was based on the responses of attending physicians in these fields to a written questionnaire and other forms of personal communication.

Based on responses to these inquiries, a two-year ethics curriculum, consisting of twelve seminars that were coordinated by an ethicist, was implemented at the University of Ottawa. The first part of the curriculum was designed to provide a basic foundation in ethics that focused on “the meaning, the contribution, and the limits of ethics” in the respective fields of interest (Davis, 1996). This was accomplished in three sessions entitled Ethics in Biomedicine: History, Schools of Thought, Goals; Ethical, Moral, Legal: What are our Responsibilities?; and Decision-Making in Biomedical Ethics that consisted of didactic lectures and a question-and-answer period. Particular emphasis was placed on the discussion of “both promoted and neglected ethical values” because one of the principal goals of these introductory sessions was to “promote personal thinking” (Davis, 1996). Following the three introductory sessions, participants attended nine case-based seminars during which fictitious case scenarios were presented and analyzed under the guidance of

an ethicist. The topics for the case-based seminars, which were chosen based on responses to the aforementioned questionnaire, were: The Right to Live, The Right to Die; Ethics and Prenatal Diagnosis: Maternal versus Fetal Rights; Ethics and HIV/AIDS; Palliative Care; Experimental Therapies and Fetal Research; Organ Transplantation and Donors; Informed Consent; and Ethics in Research. At the time of publication in 1996, this curriculum had been in place for three years. Based on participant evaluations, the original curriculum had been modified so as to better differentiate the topics of the case-based seminars and to allow for discussion on an appropriate variety of ethical matters. In addition, and thought more important by the authors, the case-based seminars were restructured so that each session began with a brief didactic lecture on a specific ethical concept in order to focus the subsequent discussion more precisely. Given the small number of participants, a formal evaluation of the program's efficacy was not felt to be feasible. In spite of this, the authors cite multiple indirect indicators of efficacy, including fewer ethics consults, more open communication regarding ethical issues among physicians, and reports from the nursing staff that the handling of ethical issues was perceived to be more consistent and methodical. In closing, the authors note that they have "placed the emphasis, not on ethical principles, but rather on the nature of ethics in clinical medicine and have given participants a framework to facilitate their clinical decision-making ... Because of our emphasis on allowing participants to examine and talk about their ethical values and why decisions are made in clinical medicine, the concepts learned or solidified can be used throughout their careers" (Davis, 1996).

Not to be deterred by the lack of precedent set forth in the existing literature, the authors of "Ethics Education in Neonatal-Perinatal Medicine in the United States" set out to create a

formalized ethics curriculum for the neonatology fellowship at Indiana University School of Medicine. At the outset of developing this curriculum, they addressed several fundamental questions – Is there a need and does it make a difference? What should the goal be? Who should teach? How should this be taught and evaluated? (Salih, 2009). The authors proffered four arguments in support of the need for such curricula. These arguments included the current lack of uniformity in ethics education in fellowship training leading to uncertainty as to how well-equipped graduating fellows are in managing ethical dilemmas; the fact that many ethical topics that would be taught in a formal curriculum simply cannot be taught in any other way; the symbolic meaning of such courses; and the reality that it is, in fact, an ACGME requirement. Claiming that medical ethics “cannot improve the character of the doctor as some may hope,” the authors’ proposed goals of formalized ethics education were to improve the behavior of future neonatologists, to enhance their appreciation of the various ethical factors involved in medical decision-making, and to aid them in the process of evaluating those factors in promoting the best interests of patients (Salih, 2009). In considering whether or not formalized ethics education makes a difference, the authors cite previous studies that have shown improvement in ethical attitudes and sensitization toward and clarification of ethical issues; but in the end, the authors’ own estimation of the value of formalized ethics education remains unstated. In keeping with the general consensus of those who have commented on this subject matter, the authors of this article believe that formalized ethics courses should be taught by an ethicist and physician. They contend that the presence of the physician demonstrates that “ethics is not exclusively the domain of a specialist, but within the realm of a doctor” (Salih, 2009). Acknowledging that ethics can be taught in a variety of ways, the authors actually place great value on the methods by which experienced physicians can share their stories and struggles with physicians in training, namely reflective exercises, narratives, storytelling, role modeling,

role play, and simulation. Likewise, the authors suggest multiple means, such as written evaluation, peer evaluation, and reflective writing, by which ethics curricula can be evaluated. They note the importance of assessment as a means of reinforcing the “centrality of ethical analysis and reasoning as essential skills in clinical decision-making” (Salih, 2009).

A group of four ethicists and eight neonatologists led by the neonatology fellowship director incorporated this literature review, the ACGME requirements, and discussions with the neonatology faculty and fellows in the development of a formal ethics curriculum at Indiana University of School of Medicine. Five specific learning objectives were outlined: 1) To recognize ethical issues in medical practice and health policy, 2) To identify ethical alternatives in difficult health choices, 3) To recognize the nature of the value systems of patients and/or parents and others, 4) To analyze systematically the conflicting considerations supporting ethical alternatives, and 5) To formulate, defend, and effectively carry out a course of action that takes account of this ethical complexity and maintains one’s ethical integrity (Salih, 2009). Six one-hour learning sessions were offered each academic year for a total of 18 required sessions over the course of the three year fellowship. An interdisciplinary team of neonatologists, surgeons, obstetricians, bioethicists, geneticists, palliative care experts, social workers, and clergy shared the responsibility of facilitating these sessions, most of which consisted of a PowerPoint presentation followed by a small group discussion. The first session of each year consisted of an orientation, analysis of a paradigm case, and a lecture by a guest speaker. The final session of each year was designated for the presentation of essays and case analyses by fellows. The remaining sessions focused on a variety of topics, ranging from limits of viability to maternal-fetal conflict to social justice and resource allocation and so on. Additional educational

opportunities, including monthly meetings with the pediatric ethics consultation service, a nurse ethicist-led service called Facilitated NICU Ethics Conversations, and reflective writing exercises, were encouraged. In the future, communication skill simulations will be incorporated into the curriculum. Multi-faceted evaluations were conducted on a regular basis. At the time of publication, the curriculum had been in place for two years and short of positive feedback from participating fellows, data assessing its overall effect had not been collected. In closing, the authors bemoan the lack of both a conceptual model of ethics education and outcome assessments of prior attempts at such models. They cite an “urgent need to evaluate the current status of formal ethics teaching in neonatal-perinatal medicine fellowship programs in the United States and also to assess the needs of fellows” (Salih, 2009). Moreover, they suggest that such research should be shared on a national level so as to guide future recommendations put forth by the ABP and ACGME.

Cameron Swinton, a neonatologist, and John Lantos, a well-known pediatric ethicist, in a 2010 *Acta Paediatrica* article reviewing ongoing empirical research in neonatal bioethics, devoted a section to the topic “Can We Teach Ethics?” They plainly state that “for a field rife with ethical dilemmas, formalized ethics curricula should be the norm,” although they insist that an isolated course in ethics cannot be relied upon to teach relevant subject matter or to ensure that those taught will behave “ethically” (Swinton, 2010). Acknowledging the ongoing debate as to how best to develop and implement ethics curricula in neonatal-perinatal fellowship training, they warn that careful attention must be paid to the presence and undeniable effect of the hidden curriculum. Ultimately, they claim that “effective ethics education will impart the knowledge needed to understand and discuss the pertinent issues

while encouraging the embedding of ethical principles into the physicians' identity" (Swinton, 2010).

As one author laments, "clinicians often believe that if they are moral, ethical people they are fully prepared to handle moral and ethical conflicts in their medical practice" (Egan, 2002). The literature would suggest otherwise, both in pediatrics as described above and in essentially every other medical specialty. While it may be true that "physicians generally tolerate ethics education grudgingly," it is equally true that "medical ethics is medicine" (Egan, 2002). This latter fact is one that has been slow to be realized by those within the field of medicine and by those governing the field of medical education. It may be true that the relationships among knowledge, skills, and attitudes outlined by the ABP and later by Gordon Stirrat often become blurred within the realm of ethics. Nonetheless, the time to formalize ethics education has arrived and the challenge of garnering the necessary attention to the matter has given way to the challenge of how best to go about doing it. It is important to accept that ethics education is not likely to be best achieved through the development of didactic courses to be taught in isolation. In fact, it has been argued that such self-contained courses, while valuable, may have the "paradoxical effect of marginalizing ethics" (Hafferty, 1994). Going forward, efforts in ethics education simply must be integrated into the larger curriculum of medical training regardless of specialty. These efforts must be implemented both horizontally and vertically; that is, across the curriculum within academic years and over the years. This will be best accomplished by the employment of a variety of learning venues – guest lectures, dedicated health law and ethics courses, capstone courses designed to integrate ethics and patient care, case studies, grand rounds, and web-based courses, to name a few (Bolin, 2006). Fox et al. suggest that, if

formalized ethics education is to be effective, five basic principles of adult learning should be applied: 1) Curricula must be goal-driven, 2) Education must be stage-specific, 3) Learning must be tailored to the educational environment, 4) Active learning must be promoted, and 5) Varied and innovative approaches must be utilized (Fox, 1995). Much has been made of the need for evaluative methods for ethics curricula that are in place and in development, endorsing the sentiment of Gordon Stirrat that “it is not sufficient to assert that education in ethics is a good thing” (Stirrat, 2003). Conversely, one author claimed that “it is not necessary to demonstrate an effect of ethics education for medical students or residents in order to justify teaching ethics, any more than it is necessary to demonstrate an effect of biochemistry education in order to justify teaching biochemistry” (Sulmasy, 1993). Either way, it is essential to recognize that the focus on the evaluation of ongoing and future endeavors in ethics education can be overstated and done so to a fault.

The continued progress of modern medicine in the face of evolving resource concerns within the larger context of an ever-changing society gives rise to a need for "ethical medicine" like never before. The success of this ethical medicine hinges on the successful implementation of a formalized ethics curriculum for physicians in training. The profession dictates it, the governing bodies of medical training demand it, and the patients deserve it. The need is great and the time is now.

CHAPTER TWO

A PILOT EDUCATIONAL MODULE

The central feature of my bioethics practicum was the design and presentation of a pilot educational module for the neonatology faculty and fellows at Wake Forest School of Medicine. Few of the physicians in this group have previously been exposed to a dedicated formal ethics curriculum of any sort in residency or fellowship. This educational module was developed for the purpose of directly addressing this curricular deficiency in the face of Accreditation Council of Graduate Medical Education (ACGME) requirements for ethics education in neonatal-perinatal fellowships that now date back more than a decade. As recently as 2008, informal “ethics rounds” were proposed in the NICU at Brenner Children’s Hospital. The stated purposes of this program were to:

- discuss ethical issues relating to particular patients
- have input into communication plans for the families of particular patients
- discuss, in general, ethics issues within the neonatal population
- discuss various points of view or perceptions
- build the NICU team through better understanding

These rounds, offered on a quarterly basis, were open to a multi-disciplinary group, including physicians, neonatal nurse practitioners, nurses, social workers, and chaplains. Unfortunately, they were poorly attended and canceled within the academic year. Since then, there have been no concerted efforts to offer any education or training in ethics to this group.

PARTICIPANTS

There are a total of 11 faculty members and 6 fellows in the division of Neonatology at Wake Forest School of Medicine, with clinical experience ranging from as little as six months to as much as thirty years. Four of the faculty members and two of the fellows completed medical school outside of the United States; however, all have completed pediatric residency and either have already completed or will complete a fellowship in neonatology in the United States. One of the faculty members serves on the Ethics Consultation Subcommittee at Wake Forest Baptist Health and has a stated interest in bioethics and palliative care; otherwise, there is no direct involvement of anyone within the division in ethics-related activities, with the exception of the author of this thesis who is currently enrolled in the Masters of Arts in Bioethics program at Wake Forest University.

The faculty and fellows provide intensive care for critically ill neonates at Brenner Children's Hospital and Forsyth Medical Center in Winston-Salem, North Carolina. The NICU at Brenner Children's Hospital, affiliated with Wake Forest Baptist Medical Center, is a 44-bed level IIIC referral center. This relatively acute patient population is comprised of premature infants delivered at outlying hospitals and infants of all gestational ages with a variety of conditions requiring surgery or other subspecialty care. Forsyth Medical Center is a 54-bed level IIIB delivery center with a large maternal-fetal medicine program, jointly managed with the Department of Obstetrics and Gynecology at Wake Forest. With greater than 6500 deliveries and 1100 NICU admissions on an annual basis, the patient population consists of premature infants (very low birth weight and extremely low birth weight) and term infants with a variety of acute medical problems, including sepsis, hypoxic-ischemic encephalopathy, respiratory failure, and neonatal abstinence syndrome, among others.

Caring for these two very diverse patient populations poses an array of ethical dilemmas for faculty and fellows alike. The intent of this pilot educational module was to foster appreciation for these dilemmas and to provide a core knowledge of the principles and skills available to address and resolve them.

STRUCTURE

This module consisted of four ninety-minute presentations during regularly scheduled educational sessions on Wednesday afternoons. These sessions are “required” for all faculty and fellows, although the average attendance was only approximately 50% due to numerous scheduling conflicts. The first session consisted of the administration of a pre-test and a didactic lecture entitled “Ethics in the NICU.” The pre-test was designed to assess participants’ factual knowledge of the ethics topics to be presented throughout the series, to survey the extent of participants’ prior ethics learning opportunities, and to examine the attitudes of participants to ethical matters. The second and third sessions, entitled “Decision Making in the NICU” and “Futility in the NICU,” consisted of didactic lectures followed by interactive case discussions. The final session, entitled “Research Ethics,” consisted of a didactic lecture followed by a brief case discussion. A post-test was administered during the week after the final session of the series. The didactic portion of each session consisted of a Powerpoint lecture lasting 45-60 minutes, allowing for 30-45 minute interactive case discussions. The results of the pre- and post-tests will be discussed later in Chapter 3.

Professor John Moskop's "Method for Moral Reasoning in Clinical Cases" was used as a framework to guide participants through each case analysis. This five-step method requires participants to: 1) State the moral problem as clearly as possible, 2) State the most relevant information, 3) Identify the most important options and their likely consequences, 4) Identify and evaluate arguments for and against the alternative courses of action, and 5) Choose a course of action and defend it (Moskop, unpublished). This process was introduced during the course of the second lecture and likened to the process of medical decision making described by Anderson and Hall in an article entitled "Parents' Perceptions of Decision Making for Children" in the *Journal of Law, Medicine, and Ethics* (Anderson, 1995). Although presented in a stepwise fashion, participants were reminded that, due to the complexity and ever-changing nature of the ethical issues in neonatal intensive care, one can rarely work through this process of moral reasoning without moving back and forth among the steps listed above. In fact, approaching this process in a more cyclical fashion often enhances understanding and more appropriate evaluation of the situation at hand. Professor Moskop attended each session for the purpose of facilitating the case discussions among faculty and fellows.

As noted above, the four sessions of this pilot educational module were entitled "Ethics in the NICU," "Decision Making in the NICU," "Futility in the NICU," and "Research Ethics." The first session was designed to provide participants with a very brief review of bioethics in general and then to refocus the discussion more specifically on ethics in neonatology. The primary objective was to provide participants with a core knowledge of fundamental ethical precepts and to assist them in practically applying this knowledge. The topics for the second and third sessions were chosen based on the extent to which they are relevant, and

particularly troublesome, in the NICU. The subject matter for the fourth and final session was selected to address specific learning objectives outlined by the American Board of Pediatrics' (ABP) Content Outline for Neonatal-Perinatal Medicine (ABP Content Outline, 2010). It should be noted that the only explicit ethics-related ABP requirements for trainees in neonatal-perinatal medicine address issues of ethics in clinical research.

ETHICS IN THE NICU

“Rarely have the processes and products of scientific medicine been as heralded and harangued, as lauded and condemned, as publicized and misunderstood as they have in the context of neonatal intensive care units...” (Lantos and Meadow, 2006, p. 1)

Opening with these words from the first page of John Lantos and William Meadow's book *Neonatal Ethics – The Moral Challenges of Medical Innovation*, this first session was intended to serve as a general introduction to the neonatal ethics educational module and to ethics on a larger scale. The objectives of this introductory session were to:

- define ethics
- review the major approaches to and theories of ethics
- reflect on the history of ethics and ethics education in medicine
- examine the history of neonatology from medical, legal, and ethical perspectives

Ethics was defined as “a generic term to describe several different ways of examining and understanding the moral life” with the moral life, or morality, being defined as “norms about right and wrong human conduct that are so widely shared that they form a stable social agreement” (Beauchamp and Childress, 2009, pp. 1-2). Recognizing that many definitions of ethics have been proposed, this particular one was selected because it acknowledges the fact that there are many ways to examine or understand the moral life and because it has been put forth by Tom Beauchamp and Jim Childress, two of the most

well-known authors in bioethics. Likewise, with regard to the approaches to bioethics, particular emphasis was placed on the principles of bioethics – autonomy, beneficence, nonmaleficence, and justice – championed by Beauchamp and Childress. This approach is commonly taught in American medical schools, and therefore, was presumed to be relatively familiar to participants. These principles were presented in the context of neonatal intensive care to the extent possible. For example, the concept of parental authority was presented as a theoretical alternative to patient autonomy in the sense that infants, as patients, are incapable of possessing autonomy.

An abbreviated version of the history of medical ethics presented in Chapter 1 followed, including the publication of Thomas Percival's first code of professional ethics in 1794 and the American Medical Association's (AMA) establishment of a code of ethics at its inaugural meeting in 1847 (Stirrat, 2003). As a means of focusing on the place of medical ethics in the field of pediatrics, and more specifically in the field of neonatology, the official stances of the ABP and ACGME were discussed. Particular emphasis was placed on the fact that, despite the presence of ethics curricula in American medical schools for the past three or four decades, residency and fellowship programs have been very slow to follow suit. This fact was presented as especially regrettable given that the ethics taught in medical schools is so general so as to be nearly impracticable in the real world of the practice of various medical subspecialties. Evidence of the shortcomings of ethics education as described in the aforementioned articles by Kesselheim and Lang were presented followed by an extensive discussion of the literature review and recently developed ethics curriculum by Salih and Boyle in *Seminars in Perinatology*.

The remainder of the first session drew almost exclusively on the work of John Lantos and William Meadow as presented in *Neonatal Bioethics – The Moral Challenges of Medical Innovation*. John Lantos, Professor of Pediatrics and Director of Pediatric Bioethics at the University of Missouri – Kansas City School of Medicine and William Meadow, a senior neonatologist with over twenty-five years experience who has experienced the moral challenges of neonatal intensive care firsthand, are two of the preeminent authorities in the field of neonatal ethics. In this book, they locate the beginning of neonatology in 1965 (although it was not officially recognized as a subspecialty until 1975) and divide the history of neonatology into three “eras”: The Era of Innovation and Individualism (1965-1982), The Era of Exposed Ignorance (1982-1992), and The End of Medical Progress (1992-2006). For each era, Lantos and Meadow provide medical, legal, and ethical perspectives which were, in turn, presented during the lecture so as to pique the interest of participants and to lay the groundwork for subsequent sessions.

The presentation concluded with a brief review of the multiple ethical issues that arise with some regularity in the NICU ranging from futility to personhood to distributive justice and beyond. Participants were left to ponder whether neonatology should ultimately be considered “the pinnacle of modern medical success” or the “best example of modern medicine’s hubris and moral ambiguity” (Lantos and Meadow, 2006, p. 4).

DECISION MAKING IN THE NICU

The second presentation in this lectures series focused on medical decision making in the NICU. The objectives of this presentation were to:

- discuss the concept and basic elements of decision making capacity
- explore standards for surrogate decision making, with particular emphasis on the best interests standard
- consider three approaches to decision making in the NICU
- examine moral and policy controversies surrounding the “Baby Doe” case
- investigate the withdrawal and withholding of life-sustaining treatment, a special case of medical decision making in the NICU

Issues related to the assessment of decision making capacity seldom arise in neonatology since infant patients clearly lack capacity and their natural guardians, the parents, generally have such capacity; however, because parents are authorized to make treatment choices on behalf of their children, the scope and limits of their authority as surrogates is a key issue for neonatologists. Since the assessment of decision making capacity and the identification of an appropriate decision maker so commonly comes into question in other fields of medicine, the basic elements of decision making capacity and the hierarchy for naming surrogate decision makers outlined in the North Carolina informed consent statute were briefly presented. Similarly, the three most widely-accepted standards of surrogate decision making – expressed preferences, substituted judgment, and best interests – were discussed and it was emphasized that the best interests standard is the only one of these that can be invoked in the decision making processes that arise in the NICU. Because so much has been written on this best interests standard in pediatric medicine, several perspectives on it were offered, ranging from Buchanan and Brock’s “traditional model” to Loretta Kopelman’s “good enough” principle (Hester, 2007). Three approaches to decision making in the NICU described by Lantos and Meadow – the “broad shoulders,” “objective information,” and “shared deniability” approaches – were also discussed (Lantos and Meadow, 2006, pp. 114-115).

The case of Baby Doe, one of the landmark cases in bioethics relevant to surrogate decision making for infants, was presented in detail. This 1982 case out of Bloomington, Indiana centered on parental refusal of surgical intervention for an infant with Down Syndrome and tracheo-esophageal fistula and resulted in a trial court ruling that “parents have the right to choose a medically recommended course of treatment for their child in the present circumstances” (Lantos and Meadow, 2006, p. 68). Following a thorough account of the “Baby Doe Rules,” federal regulations authorized under the Child Abuse Amendments of 1984, the Baby Doe case was discussed in relation to the concept of best interests.

Given that the decision to withhold or withdraw life-sustaining treatment is an extremely common, and certainly the most agonizing, decision that parents and physicians are forced to contemplate in the NICU, the latter part of this session was devoted to this matter. Among the information presented was the history of the debate over withholding and withdrawing life-sustaining treatment in the larger context of medicine, the official stance of the Neonatal Resuscitation Program on the matter, and data from several articles regarding the primary factors most often considered in this life-and-death decision. In closing, the withholding and withdrawal of fluids and nutrition was discussed, given its particular pertinence in the NICU where conditions that are associated with overwhelming morbidity in the absence of inevitable mortality, such as neurologic devastation and total intestinal failure, are encountered with some frequency. Acknowledging that this is often considered a “special” case of withholding and withdrawal, those aspects that make it “different” and so difficult were discussed in detail.

The case presented for analysis to close this session was a “real-life” case that had unfolded in the NICU at Brenner Children’s Hospital a few weeks prior. This case involved a term infant who was noted to have multiple subtle congenital anomalies that had not been detected prior to birth. In the process of evaluating these anomalies, a cranial ultrasound was found to be grossly abnormal and an echocardiogram revealed a cardiac defect thought to be amenable to surgical repair. In light of the intracranial anomalies and the parental assessment that these anomalies could portend a suboptimal quality of life for this infant, they elected not to pursue surgical repair of the cardiac defect in favor of taking the infant home with hospice care. The case analysis focused on the factors that went in to the making of this decision, the propriety of the decision, and the medical team’s view of the decision.

FUTILITY IN THE NICU

The third presentation in this lecture series focused on the concept of futility in the NICU.

The objectives of this presentation were to:

- define and describe the various types of futility that have been described in the literature
- relate the concept of futility to Beauchamp and Childress’ principles of bioethics
- review relevant landmark legal cases
- provide an international perspective
- examine, in detail, the “gray zone” at the margin of neonatal viability – a special case of futility in the NICU

Although the theme of futility dates back to the writings of Hippocrates, it was not until the late 1980’s that appeals to futility emerged as a topic of heated debate within the medical and bioethics communities. The presentation opened with a discussion of several definitions and criteria of medical futility, with particular emphasis on the distinction between qualitative and quantitative futility. Following this, futility was considered in the context of Beauchamp and Childress’ principles of bioethics. First, the autonomy of patients

versus that of physicians was discussed, focusing on whether the right of patients to request and receive possibly futile treatment should impose an expectation on physicians to comply with such requests. Then, the question of whether a treatment that prolongs irreversibly unconscious human life should be construed as futile or beneficial was considered in relation to the principle of beneficence. Finally, despite the rarity with which matters of distributive justice are acknowledged in the NICU, this principle was mentioned in the context of futility on the grounds that provision of futile treatment is a misuse of limited medical resources.

Since much has been made of the matter of futility in the judicial and legal realms, three landmark cases were presented. The case of Baby Doe was revisited so as to further examine the role of futility judgments in the final version of the Baby Doe Regulations issued in 1985 that came about in the wake of this case. *In re: Baby K*, the legal decision that authorized a mother to demand treatment for her child with anencephaly, is perhaps the most prominent lawsuit related to medical futility. This case was considered especially important to discuss because anencephaly, a uniformly fatal neural tube defect, is one condition that is viewed as unequivocally futile by this group of faculty and fellows, such that parents are only offered the option of palliative care for affected infants born at Forsyth Medical Center. Finally, *Hudson v. Texas Children's Hospital*, the case of an infant with a fatal skeletal dysplasia, was presented as an introduction to the 1999 Texas "futile care law," contained within the Texas Advance Directives Act. This piece of legislation represents a unique attempt at empowering physicians to limit futile life-sustaining treatment, while providing legislative safe harbor for those who chose to do so.

Because futility in the NICU is a matter of worldwide interest, an international perspective was presented. To the extent they were available, national laws and policies, and standards adopted by national medical professional organizations regarding treatment of extremely premature neonates were reviewed. Among the nations included in this review were Canada, Great Britain, France, Germany, and Italy. Particular attention was paid to the issue of medical futility in the Netherlands, home of the Groningen Protocol, a pediatrician-developed protocol that describes circumstances in which neonates may be considered for active euthanasia and establishes a transparent means by which such acts of euthanasia are to be performed and reported.

Although there are many medical conditions in the NICU that could be construed as futile, the “gray zone” of peri-viability is encountered most frequently, and therefore, the latter half of this session was devoted to the discussion of this special case of futility. This discussion focused largely on the varied attempts at defining this gray zone and on what considerations influence treatment decisions made by parents and physicians who find themselves in this gray zone.

The case of Baby Isaac as detailed in a 2005 *Pediatrics* article by Fine et al. was presented for analysis. Baby Isaac was an 825 gram infant born via an extraordinarily complicated vaginal delivery at 25 weeks gestation to a 14 year old mother. His NICU course was complicated by evolving chronic lung disease, bilateral grade III intraventricular hemorrhages with severe posthemorrhagic hydrocephalus, and multiple episodes of bacterial sepsis. Baby Isaac developed necrotizing enterocolitis on day of life 21, requiring exploratory laparotomy three days later. He developed multiple postoperative

complications and had to be taken back to the operating room two weeks later, at which time it was determined that his bowel was nonviable and the abdomen was closed. As the article reads, “The family was apprised of the infant’s condition and lack of any chance of long-term survival, but they refused to remove life support postoperatively as recommended by the care team” (Fine et al., 2005). Given that total intestinal necrosis is a diagnosis made not infrequently in the NICU at Brenner Children’s Hospital and that the case of Baby Isaac was one painfully familiar to participants, they were asked how to respond to the request of the family in this case and how claims about futility could or should influence treatment decisions in this situation.

RESEARCH ETHICS

The fourth presentation in this lecture series focused on research ethics, but did not attempt a specific emphasis on such issues that are unique to research done in the NICU. As mentioned above, the learning objectives were taken directly from the ABP’s Content Outline for Neonatal-Perinatal Medicine. This outline defines the specific elements of knowledge from which certification and recertification examination questions are drawn. The elements of knowledge related to ethics in research are described in the section entitled “Core Knowledge in Scholarly Activities.” They are as follows:

- conflicts of interest and commitment
- professionalism and misconduct in research
- principles of research with human subjects
- principles of consent and assent
- vulnerable populations

Specific learning objectives related to each element of knowledge are further outlined by the ABP. These learning objectives were the focus of the Powerpoint slides for this fourth and final session.

Acknowledging that there are many ways to conceptualize conflicts in research, the definitions and descriptions of conflicts of interest, commitment, and obligation as established by the Institute of Medicine in a 2009 document entitled “Conflict of Interest in Medical Research, Education, and Practice” were presented. Beauchamp and Childress’ suggested approaches to such conflicts – elimination, management/mitigation, or disclosure – were also briefly mentioned (Beauchamp and Childress, 2009, p. 316).

All of the learning objectives outlined under “Professionalism and Misconduct in Research” relate most directly to the actual publication of research. Acknowledging that many descriptions of misconduct have been considered, the requirements for a finding of misconduct as described by the United States Department of Health and Human Services’ Office of Research Integrity were presented. Additionally, the various forms of misconduct – plagiarism, fabrication, and falsification – explicitly mentioned both by the Office of Research Integrity and by the ABP were defined. The International Committee of Medical Journal Editors’ criteria for authorship were presented (Welker, 2007).

The remainder of this session focused on ethical issues that arise in human subjects research. It was noted that some of the most well-known cases in bioethics are related to this matter. A majority of the information presented was drawn directly from The Belmont Report, a “statement of ethical principles and guidelines that should assist in resolving ethical problems of human subjects research” created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979 (Belmont, 1979). By way of framing the remainder of the discussion, “human subjects” and “research” were defined, followed by a brief review of the principles of respect for persons,

beneficence, and justice that had been presented in the first lecture in this series. With regard to the ethical considerations of proposed research, risk/benefit analysis, equipoise, the therapeutic misconception, and a number of study designs were discussed in detail. Regarding the institutional regulation of research, the functions of institutional review boards and data safety monitoring boards were discussed as well.

Within the context of human subjects research, and in an effort to focus attention on research involving children, particular emphasis was placed on the concepts of consent and assent and the approach to vulnerable populations, of which children are but one. The elements of informed consent, as outlined in the Belmont Report, were reviewed and clear distinctions among informed consent, parental permission, and a child's assent were drawn. The potential for consent and assent to be subject to coercion and/or undue influence was also mentioned. Vulnerable populations and the special protections afforded them by The Common Rule were discussed, with emphasis on the variable definitions of "child" and the interpretation of "minimal risk" as it applies to research involving children.

The case presented for analysis was based on a proposed study of Surfaxin, a synthetic form of surfactant investigated for the prevention and treatment of respiratory distress syndrome in premature infants, in four Latin American countries. In 2000, Discovery Labs, a private US-based pharmaceutical company, proposed a multi-center, double-blinded, randomized, two-arm, placebo-controlled trial of Surfaxin. This study design could be considered somewhat of a last ditch proposal after the sponsor rejected the FDA's recommendation for a superiority trial and after the FDA rejected attempts to design a noninferiority trial. Internal FDA documents from 2001 deemed this trial "unethical" in the

United States due to its inclusion of placebo as control (Lavery, 2007). In retrospect, this trial has been criticized on multiple grounds – the use of placebo control in the face of a proven effective treatment, the intent to study the drug in impoverished countries where it would not be marketed or made readily available (a matter of distributive justice), and the added protections that would be required due to the use of infants as subjects in this economically disadvantaged population (matters of respect for persons) – and it has even been likened to the AZT studies conducted in sub-Saharan Africa in the 1990's.

Rather than analyzing this case with Moskop's "Method for Moral Reasoning in Clinical Cases" in the usual fashion, participants were asked to consider seven requirements for determining whether a research trial is ethical as presented by Ezekiel Emanuel et al. in *JAMA* in 2000. These requirements are as follows (Emanuel et al, 2000):

- social or scientific value
- scientific validity
- fair subject selection
- favorable risk:benefit ratio
- independent review
- informed consent
- respect for persons and enrolled subjects

Due to time constraints, the post-test was not administered at the close of this session. Instead, the post-test was distributed the week following the session. Results will be presented in the third chapter of this thesis.

The four sessions described above comprise the pilot educational module presented to the neonatology faculty and fellows at Wake Forest School of Medicine as the central feature of my practicum in bioethics. The purpose of the module was to stimulate interest in

bioethical matters and to provide participants with a core knowledge of the bioethical concepts most relevant to neonatology. Albeit far from complete, this module represents the first attempt of its kind at this institution and will hopefully serve as the basis for further development of a formalized ethics curriculum in the near future.

CHAPTER 3

REFLECTIONS

The purpose of this chapter is to critically examine the pilot educational module I presented to the neonatology faculty and fellows at Wake Forest School of Medicine in January and February of 2012. The results of the pre- and post-tests, which were primarily used to gain a rough estimate of the efficacy of the teaching offered, will be presented. Particular emphasis will be placed on the subjective input obtained, both formally, through the pre- and post-tests, and anecdotally, from participants. Finally, as the creator and presenter of this module, I will critically reflect upon the written evaluative methods and the four sessions, both individually and collectively.

PRE-TEST

A twenty-five question pre-test was administered at the beginning of the first session of the pilot educational module. The first twenty-one questions were designed to evaluate the participants' knowledge of the subject matter to be presented. All questions were in multiple-choice format and an average of five questions per session was asked. Questions twenty-two through twenty-four, two of which were multiple-choice and one open-ended, were designed to evaluate the participants' attitudes and current approaches toward bioethics in neonatology. The final question inquired about the extent and quality of formal ethics training participants had received in their previous years of medical education. A total of eight pre-tests (four completed by neonatologists, three completed by neonatology fellows, and one completed by an ethicist) were returned for analysis. On analysis, questions left unanswered were considered to be incorrect.

When analyzed by topic, the number of correct answers was highest for questions related to research ethics and lowest for those related to futility. One question, on research misconduct, was answered correctly by all eight test-takers. One question, on research in children as addressed in The Common Rule, was answered incorrectly by all test-takers; however, on retrospective review, the wording of the answer choices was such that either one of two answers could have been perceived to be correct. The number of questions answered correctly on the pre-test ranged from six to thirteen, for an average score of 9.75, or 46% correct.

The final four questions on the pre-test were primarily attitudinal and behavioral in nature. As such, they were not answered by the participating ethicist. Question twenty-two asked “How important do you feel ethics is in neonatology?” Only six participants answered this question, all of whom felt ethics to be “very important.” Question twenty-three asked “How often do ethical considerations arise for you in practice?” Five participants answered “weekly,” one participant answered “daily,” and one participant left this question unanswered. The responses to these questions suggest that the faculty and fellows at Wake Forest find ethics to be an important aspect of practice in neonatology and one that is encountered with great regularity. It is conceivable that a formalized ethics curriculum would increase the perceived importance of ethics in practice and the frequency with which ethical considerations are explicitly addressed because it would enhance the ability to identify and address such considerations.

The next question “When ethical considerations arise, how do you handle them?” was answered by five participants, all of whom sought input and guidance from other colleagues

within the division. Another theme common to most answers was the practice of engaging the infant's family in discussions, but the nature and content of these discussions was unclear. Presumably, and understandably, the medical problems giving rise to various ethical dilemmas are the primary focus of these discussions, which are considered an essential part of the family-centered approach to care. Such an approach may grant secondary consideration to the core ethical issues, although it is also entirely possible that such ethical issues are never dealt with directly. The reliance of this group on discussions with families begs the question as to whether or not such discussions are, in fact, an acceptable method by which ethical considerations can or should be handled. Furthermore, one must question why this particular approach is so heavily favored by this group of neonatologists. Is this approach truly felt to be the most effective or is it simply leaned upon because it allows the physicians to stay in their "comfort zone" where medical issues take precedence, thereby overshadowing the very ethical issues prompting the need for discussion?

The twenty-fifth and final question "Did you receive any formal ethics training in your residency/fellowship?" was answered by six test-takers. Of those, three answered "yes" or "some," one answered "no, only in medical school," and two answered "no." Two of the test-takers who answered "yes" received training in fellowship, one of whom completed fellowship at Wake Forest. This training in fellowship consisted of didactic lectures (e.g. "Having Difficult Conversations"), "consults" with a faculty "expert," (who, incidentally, had no formal training in ethics) and "on-the-job training." The participant who answered that she had only received training in medical school went on to say that if she received any training in fellowship, it consisted of "one or two lectures that I cannot recall ... obviously

not very effective.” Of note, this participant also completed fellowship at Wake Forest. The third participant who answered “yes” to this final question is a first year fellow whose prior training in ethics exceeded that of anyone else. During her residency, monthly ethics presentations – consisting of case presentations and panel discussions led by ethics committee members, risk management, and legal counsel – were offered. Interestingly, she felt that those sessions related to risk management and the law – subject areas that are conflated with bioethics not infrequently – were most helpful in retrospect.

A particularly troublesome aspect emerged in analyzing the responses to the attitudinal and behavioral questions on the pre-test. This group of physicians, admittedly dependent on each other as primary advisors in dealing with ethical dilemmas, had had very little formal education and training in bioethics. In effect, those whose guidance is sought are really no better equipped, short of experience, to deal with such dilemmas than those who are seeking guidance. But for the “hidden curriculum” alluded to by only one test-taker, the lack of bioethics education amongst this group, whose experience in neonatology ranges from less than one year to nearly three decades, simply cannot be denied. This troublesome realization highlights the pressing need for a permanent formalized bioethics curriculum to be developed and implemented at Wake Forest.

POST-TEST

A twenty-six question post-test was administered during the week after the final session of the educational module was presented, due to time constraints prohibiting its administration at the end of the final session. The first twenty-one questions were

duplicated from the pre-test, after the answer choices for the question on The Common Rule were clarified so as to yield only one correct answer. The final five questions were subjective in nature and designed to grant participants the opportunity to evaluate the course and to make suggestions for improvement. Participants were asked whether or not they would be in favor of the implementation of a formalized ethics curriculum and, if so, how frequently they felt the sessions should be held (weekly, monthly, every other month, quarterly, on an as needed basis). Participants were then presented with a list of potential topics drawn from the curricula presented by Davis and Doucet in *Annals of the Royal College of Physicians and Surgeons of Canada* (1996) and by Salih and Boyle in *Seminars in Perinatology* (2009) and asked to select those topics that they would like to see included in future educational endeavors. Finally, participants were asked to comment on both the format and content of this course and to make any suggestions for improvement. A concerted effort was made to ensure that the eight participants who completed the pre-test also completed the post-test so as to assess whether or not factual knowledge increased as a direct result of this educational module.

A total of eight post-tests were completed and returned for analysis. With the exception of one test-taker, the number of total questions answered correctly increased, from as few as one to as many as eight. Likewise, when analyzed by subject matter, the number of correct answers increased for each topic presented, with the greatest increase noted on questions related to fertility and the least noted on questions related to research ethics. When compared to the results of the pre-test, both of these results were to be expected given that performance on questions related to research ethics was highest with that on questions related to fertility poorest. The number of questions answered correctly on the post-test

ranged from six to sixteen, for an average score of 12.75, or 61% correct. This represented an improvement by three questions, or 15%.

Each and every test-taker answered “yes” to the question “Would you be in favor of the development of a formalized neonatal ethics curriculum at WFU?” There was some variability in the answers to the question asking how frequently sessions on neonatal ethics should be held if such a curriculum was to be implemented. Four test-takers answered “monthly,” two answered “every other month,” and one answered “quarterly.” One test-taker suggested that the number of sessions that should be offered could potentially vary by the target audience, stating that “faculty, fellows, and residents might need different numbers of sessions at different intervals.”

A list of twenty potential topics to be considered for future curricula was presented. It should be noted that the final three topics of this pilot educational module – decision-making, futility, and research ethics – were included on this list, as were the “special cases” of withdrawal/withholding of life-sustaining treatment and limits of viability. Three test-takers indicated that any and all topics should be considered for inclusion. All of the topics that were presented in this pilot educational module were selected by each participant, with the exception of one who did not select research ethics. The only topic that was uniformly selected by the remaining five test-takers was maternal-fetal conflict (including refusal of care during pregnancy). Interestingly, of these five test-takers, no one indicated interest in spiritual sensitivity or technology dependent children.

The final two questions, regarding participants' opinions of the format and content of this pilot educational module, were answered by all but one test-taker. Each test-taker indicated that both the format and content were satisfactory. Multiple respondents commented on the need for additional time to be allotted for case analyses. One respondent suggested that the didactic portion of each session be presented in a more informal manner so as to optimize the learning experience by allowing for more interaction amongst participants. Given the volume of information presented in each session, and with the goal of maximizing retention of this information, one respondent suggested that reading material be made available prior to didactic sessions while another suggested that handouts be made available either prior to or after each session.

In general, this pilot educational module seemed to be well-received by participants, both those who suggested as much on the post-test and anecdotally in discussions with those who were unable to complete the post-test. The results of this post-test would suggest that participants benefitted both objectively, as evidenced by improvement on the post-test, and subjectively, as indicated by responses to the attitudinal questions.

PERSONAL REFLECTIONS

Creating this ethics curriculum for the neonatology faculty and fellows at Wake Forest School of Medicine proved to be quite the challenge. While I firmly believe ethics to be an integral part of the practice of medicine, neonatology notwithstanding, I found the body of literature on neonatal ethics to be both vastly expansive and yet narrow in that much has been written on a select few topics. Attempting to identify proper learning objectives for

the first three sessions proved to be very difficult in the absence of prescribed objectives set forth by the American Board of Pediatrics (ABP) as in the case of research ethics. Given my personal lack of knowledge of the participants' familiarity with this material, it was equally difficult to determine the appropriate scope of information to be presented on each topic. One expected challenge that did not actually materialize was that of engendering interest among participants. Attendance ranged from just over 50% to 75% per session, which exceeds the average attendance at other regularly scheduled educational events offered on Wednesday afternoons. Actual participation varied from session to session, but appeared to increase from one session to the next.

In retrospect, I believe the topic selection was perhaps one of the greatest strengths of this curriculum. The decision to begin the series with a basic introductory lecture was a simple one, as it was reasonably assumed that participants would lack the foundational knowledge of bioethics that would prove to be necessary for the remainder of the curriculum. Likewise, the decision to devote one session to research ethics was a straightforward one given that this is an explicit requirement for neonatologists set forth in the ABP's board content specifications for neonatal-perinatal medicine. The frequency with which issues related to fertility and decision-making arise in the NICU, highlighted by the fact that such issues are actually recognized as being ethically relevant by most, made it only logical to devote the other two sessions to these topics. Interestingly, two of the most ethically troublesome cases of late in the NICU at Brenner Children's Hospital arose prior to and just after the completion of this curriculum, the former being directly related to decision-making and the latter directly related to fertility. The timeliness of these cases, the first of which

served as the basis for the case analysis in the second session, only confirmed the appropriateness of these topics for this brief curriculum.

In general, I believe the format – a didactic lecture followed by case analysis – is the most appropriate format for a curriculum such as this. Unfortunately, due to the depth and breadth of information that I attempted to present in each session, there was little opportunity for the involvement of participants during the didactic portions of each session, which often ran long at the expense of the case analysis. In turn, participants often seemed to be somewhat overwhelmed by the sheer volume of information presented in a short time and it was, therefore, difficult to transition to the case analyses. This, complicated by the inexperience of participants with this type of case analysis (based on Professor Moskop's "Method for Moral Reasoning in Clinical Cases") usually resulted in the case analyses ending abruptly and without resolution. Despite the fact that ethical dilemmas often end without clear resolution, this generated a perceived lack of fulfillment among participants.

As previously mentioned, the first session "Ethics in the NICU" was designed for the purpose of providing participants with a foundational knowledge in ethics. In attempting to provide this, I sought to pare down the material that comprises entire textbooks and is generally taught over the course of a semester into a few slides to be presented in a matter of minutes. While an overview of the definitions, types, and theories of ethics may have served as a reasonable introduction, I believe, in retrospect, that participants would have benefitted much more from a more detailed, yet focused, presentation on the principlism of Beauchamp and Childress. This belief is based on the fact that participants seemed to have some baseline familiarity with this approach to bioethics, thereby making it a bit more

teachable, and because these principles served as common threads throughout the remainder of the curriculum. With regard to the literature review, while the articles were presented as concisely as thought to be possible, the raw statistical data could have been omitted so as to allow greater emphasis to be placed on the actual conclusions of the articles. Finally, although the presentation of Lantos and Meadow's "three eras" of neonatology seemed to be quite interesting to participants, it is somewhat difficult to appreciate the relevance of this information to the remainder of the curriculum in retrospect. While it is undoubtedly important to place things in context medically for this particular audience and ethically for the purposes of this project, in reality, it seemed that the focus of this portion of the first session was largely legal in nature. In the future, should this "era" approach be utilized, it would be advisable to limit the legal perspective to the presentation of landmark cases and legislation only.

In considering the second session, "Decision Making in the NICU," the opening slides on decision making capacity, surrogate decision making, and the standards for decision making could, and probably should, have been omitted given their general irrelevance within the walls of any NICU. Instead, greater emphasis should have been placed on discussion of the best interests standard as this is the only standard of surrogate decision making that is applicable in the NICU. Given the wealth of literature on this best interests standard in neonatal ethics, this shift in emphasis is one that could easily be accomplished and one that would likely prove to be much more valuable to participants both in theory and in practice.

With regard to the third session, "Futility in the NICU," the general information presented in the opening slides was essential. In contrast to surrogate decision making, which is limited

in the NICU by virtue of the lack of autonomy of infants, the principles of futility are much more broad-based and generally applicable. The types of futility, reasons for which it persists as a primary ethical issue, and the bases on which futile treatments are demanded all are directly relevant both in theory and practice for participants. Albeit interesting, the survey of international perspectives on neonatal viability should have been omitted in the interest of time and due to the fact that it was not entirely relevant for this particular group. (Perhaps in the future, and in the context of a more comprehensive curriculum, a session could be devoted to an international perspective on neonatal ethics.) However, due to its unique nature and the intense ethical scrutiny to which it has been subjected, the Groningen Protocol should be considered worthy of mention in any presentation on futility in neonatal ethics. Finally, despite a multitude of cases from which to choose for this session's case analysis, the case of Baby Isaac that was ultimately chosen proved not to be the best choice. Initially selected for the striking similarities to cases that are encountered not infrequently in the NICU at Brenner Children's Hospital, the case of Baby Isaac was one of such extreme circumstances that participants quickly deemed it be somewhat of an "open-and-shut" case. This perception by the participants made the case analysis quite difficult in that they seemingly failed to even appreciate the need for such analysis in this particular case.

The information presented in the fourth and final session, "Research Ethics," was drawn directly from the ABP's board exam content specification and, therefore, is not subject to much interpretation. Unfortunately, the ABP elected to focus largely on the actual process of research, a process in which the majority of neonatologists are not directly involved. As such, a significant portion of the information presented on research misconduct did not seem to be entirely relevant for participants. Similarly, the failure of the ABP to focus its

learning objectives related to vulnerable populations on neonates (or pediatric populations in general) as a specific vulnerable population resulted in the presentation of a great deal of information (e.g. research in prisoners) that seemed irrelevant in the NICU setting. In contrast, information related to the therapeutic misconception, informed consent, and minimal risk research was perceived to be markedly more relevant given the frequency with which this group of physicians attempts to enroll patients in ongoing research projects at both Brenner Children's Hospital and Forsyth Medical Center. Albeit inarguably germane to this topic and for this group of participants, the case presented for analysis – the study of Surfaxin in Latin America – was complicated by the fact that the issues related to basic research ethics in this particular case were largely overshadowed by those related to international research. Despite this, and despite choosing to analyze this with an unfamiliar method (as presented by Emanuel et al. in “Ethical Requirements for Clinical Research”), this case analysis generated considerably more discussion among participants than any of the previous cases.

Perhaps the greatest weakness of this pilot educational module was the evaluative method employed. Upon review of the pre- and post-tests and in discussion with participants, it became clear that the fact-based test questions were so specific as to not really be effective in evaluating either the baseline knowledge of participants or the knowledge gained during the course. In the interest of time, a multiple-choice format was selected, although admittedly, a better format for questions related to ethics would be open-ended short answer questions. With regard to the subjective questions at the end of each test, it is entirely possible that the well-established personal and professional relationships between the participants and myself may have influenced the answers to these questions. In light of

this, the validity of the subjective assessments of this pilot educational module may be brought into question.

All things considered, I felt that this pilot educational module on neonatal ethics presented to the faculty and fellows at Wake Forest School of Medicine was successful. As evidenced by the performance on the pre-test and responses to subjective questions, it certainly fulfilled a need for this group. Based on the extent to which participants became involved during the sessions, especially during the case analyses, and responses to subjective questions on the post-test, the module seemed to have been both enjoyable and useful. I would absolutely encourage further development of this module, incorporating the suggestions offered on the post-test regarding topic selection and format restructure, for future implementation at this institution.

CHAPTER 4

THE FUTURE OF ETHICS EDUCATION IN NEONATOLOGY

The advances of modern medicine have proven to be both a blessing and a curse in the discipline of neonatology. The question, as raised by Lantos and Meadow, remains – Will neonatology prove itself to be the “pinnacle of modern medical success” or simply “the best example of modern medicine’s hubris and moral ambiguity?” (Lantos and Meadow, 2006, p. 4) Either way, it is clear that medical progress is not without its victims. One of those victims has been consideration of the ethical dilemmas that have come in its wake. In the absence of a concerted effort to the contrary, the ethics of neonatology is in danger of being altogether neglected. Such an effort is long overdue and it must begin now. The fundamental changes that should underlie this effort will have to occur on multiple levels, from the governing bodies of graduate medical education down to the individual neonatologist or neonatology fellow. In this fourth and final chapter, I will outline my recommendations for advancing the cause of ethics education in neonatology.

GOVERNING BODIES

Three governing bodies – the American Academy of Pediatrics (AAP), the American Board of Pediatrics (ABP), and the Accreditation Council for Graduate Medical Education (ACGME) – are responsible for the oversight of neonatology fellowships across the country. The mission of the AAP’s Section on Perinatal Pediatrics is “to improve the health of the pregnant mother, the unborn fetus and the newly-born child through the *sponsorship of programs which encourage the professional growth of the neonatal-perinatal providers, continuously improve clinical care delivery, support continuing and postgraduate education,*

foster basic clinical and outcomes research and seek to attain federal and local funding for programs directed towards maternal/child health” (AAP online, italics added for emphasis). To that end, the Section has outlined goals and core values, some of which, although not explicitly stated as such, could be interpreted as directly relevant to the purpose of ethics education. The first stated goal is “to provide for postgraduate trainees, neonatologists and members of the perinatal delivery team high quality educational offerings which foster lifelong learning in its members” (AAP online). Two of the core values are professional growth and dedication. Professional growth is embodied in the acknowledgment that the dynamic specialty of neonatology requires commitment to lifelong learning. With regard to dedication, the Section states that it will “accept the challenge to seek and defend the social and medical needs of pregnant mothers and children they conceive and deliver” (AAP online). Taken together, the purpose, goals, and core values of the AAP’s Section on Perinatal Pediatrics can, and perhaps should, be interpreted as supporting formalized ethics education for neonatology fellows, because the difficult moral questions encountered in this subspecialty cannot be properly recognized or resolved without such education. Given this, the AAP should explicitly address this matter, yet neither the Section Committees, nor the Education Working Groups, nor the Section’s Strategic Plan make mention of any such educational endeavors.

Perhaps the Section on Perinatal Pediatrics defers to the AAP’s Section and Committee on Bioethics with regard to efforts at formalized ethics education. As discussed in Chapter 1, these groups have developed a case-based modular curriculum for pediatric residents. Developed in recognition of the need for bioethics education in pediatric training programs, this curriculum, which consists of fifteen modules, provides an overview of relevant

resources and a question-and-answer format to guide case discussions. Of the fifteen sessions, only two – Maternal-Fetal Conflict and Critically Ill Newborns – are neonatology-specific. It should be noted that this curriculum was designed specifically for *residents* and that it is strictly elective. The spirit in which this curriculum was created is to be admired, yet it simply is not enough. It does not relieve the Section on Perinatal Pediatrics of the obligation to follow suit and design a curriculum specifically for neonatology fellows, thereby working toward the goal of fulfilling its aforementioned purpose and goals while honoring its core values.

The ABP, one of the certifying boards of the American Board of Medical Specialties, “strives to improve training, establishes the requirements for certification, and sets the standards for its examinations” (About the ABP, ABP online). Founded in 1933, nearly fifty years would pass before the ABP established a requirement for the assessment of an applicant’s “ethical and moral behavior as it affects his or her performance” in 1982 (About the ABP, ABP online). Another five years would pass before, in 1987, ethical decision making became an official subject area on the pediatric certification examination.

As described in Chapter 1, the ABP’s Ethics Committee created an annotated bibliography of bioethics in 1983. This document, an extensive list of relevant books, book chapters, and journal articles, is updated on a regular basis and is available online at <https://www.abp.org/abpwebsite/publicat/bioethics.pdf>. The most recent version, issued in 2011, consists of 21 sections, numbering 86 pages. Like the AAP’s case-based modular curriculum, however, only two sections are devoted to neonatology-specific topics, Maternal-Fetal Conflict and Imperiled Newborn Infants; although there is at least one other

section – Critical Care, End of Life, and Limitations on Medical Intervention – that is relevant, albeit not specific, to neonatology. Noting that a structured curriculum in medical ethics is a requirement of pediatric residency programs, the stated purpose of this bibliography is to “promote familiarity with ethical principles and concepts (theories) and to provide published guidelines for problem solving via ethical analysis” (ABP Bibliography, 2011). The ABP website goes on to proclaim: “It is hoped that attention to these publications will serve to increase physician awareness regarding some of the moral ambiguities in our pluralistic society and to emphasize the need to pursue educational opportunities in this area ... The references comprise a reasonable starting point” (ABP Bibliography, 2011).

While the ABP is to be commended for the progress it has made toward recognizing the place of medical ethics in the context of pediatric training, the pace of progress in this area leaves much to be desired. Given that it took over half a century for the assessment of ethical behavior to be required, it remains to be seen how long it will take for progress from the “starting point,” that is, the aforementioned bibliography, to commence. Each subsequent version of this bibliography has been more robust than its predecessor, yet the fact that the self-proclaimed “starting point” seems to have become the apparent stopping point thus far is cause for concern. The time is now for the ABP to take its commitment to ethics education to the next level. This should take the form of well-structured, individualized curricula for general pediatrics and the various pediatric subspecialties, to be designed either by its own Ethics Committee or to be designated for assignment to the respective AAP committees.

Furthermore, by way of intensifying its efforts in formalized ethics education, the ABP should expand the ethics-related board exam content specifications to include more than research ethics alone. It is well-known that graduate medical education is driven by board examination content. Given this, the effort to expand ethics-related content specifications could very well have the greatest single influence on the extent to which the directors of and trainees in pediatric residency and fellowship programs are motivated to pursue ethics education. As Bob Hilliard, a pediatrician and clinician-educator at The Hospital for Sick Children in Toronto, said in his closing remarks at a meeting of the ABP's Residency Review and Redesign Project (R3P, a now defunct part of the Initiative for Innovation in Pediatric Education):

“Examinations and evaluations influence, direct and drive resident learning: what, how and why. Students know what is on the exams. *If there is not a question about ethics, they will not study the ethics. The exams drive the program*” (ABP R3PII, italics added for emphasis).

An increased emphasis on the teaching and learning of research ethics has come about as a direct result of its inclusion on certification examinations. Presumably this would also hold true for other ethics-related topics, should they become a part of the board content specifications identified by the ABP. Currently, the board examination for neonatology utilizes a multiple-choice format; given the complexities of ethics, one may question whether or not such material could or should be tested in such a format. Undoubtedly, open-ended short answer questions would more effectively evaluate the ability of the test-taker to display comprehension of and to properly apply ethical principles. I would argue, however, that many of the critical care topics that are covered on this board examination do not exactly lend themselves to the multiple-choice format and, instead, could best be tested with the asking and answering of short answer questions. Yet, this has not precluded them from inclusion on the examination, nor should it preclude ethics-related topics from being

included. The ABP must heed the words of warning of Dr. Hilliard and modify ethics-related board examination content specifications so as to promote the teaching and learning of those relevant topics in neonatology fellowships around the country.

The ACGME, established in 1981, is a private, nonprofit council that evaluates and accredits residency programs in the United States. Its stated mission is to “improve health care by assessing and advancing the quality of resident physicians' education through exemplary accreditation” (ACGME At A Glance, online). It is comprised of 28 residency review committees, of which Pediatrics is one. As mentioned in Chapter 1, all accredited residency programs have been required to offer structured curricula in ethics since 1997. Two years later, in 1999, the ACGME outlined six core competencies to be taught and evaluated in all residency programs. The requirement for “adherence to ethical principles” falls in the realm of the fifth of these six competencies, professionalism. Acknowledging that proficiency in this particular competency is “primarily behavioral and attitudinal,” it recommends that professionalism be taught primarily in the context of patient care (ACGME Core Competencies, 2007, online). In 1999, upon the release of these competencies, the ACGME remained silent as to what precisely was meant by “ethical principles” and how adherence to these principles could be satisfactorily demonstrated and evaluated. Nearly a decade later, in 2007, the ACGME Program Requirements for Fellowship in Neonatal-Perinatal Medicine were implemented. These requirements were notable for having outlined the methods by which professionalism were to be taught – didactic lectures and modeled behaviors – answering the question of “how” yet completely neglecting the question of “what” should be taught. Perhaps it is not the purview of the ACGME to

determine this with any specificity, but if not, this task must be delegated to the proper governing body.

Much like the influence of board content specifications on the motivations of trainees, the influence of the authority of the ACGME to accredit residency and fellowship training programs across the country could certainly be invoked as a means to strongly encourage – or force, if need be – program directors to take the matter of this professionalism training seriously. Once explicit expectations and requirements have been set forth by a governing body, be it the ACGME, ABP, or otherwise, and program directors have been given ample opportunity to implement plans to fulfill these expectations and requirements, the failure to do so should be punishable by either public reprimand, probation, loss of accreditation, monetary fines, or some combination thereof.

It is my personal opinion that the decision of the ACGME to incorporate ethics into the competency of professionalism was to the serious detriment of the ethics component. It is unclear to me how and why these two concepts are necessarily related. For instance, in the 2009 *Pediatrics* article by Lang et al. referenced in Chapter 1, the following professionalism topics were endorsed by pediatric program directors: reporting mistakes; defining professionalism; unprofessional behaviors in faculty, students, and colleagues; unprofessional attitudes in faculty, students, and colleagues; impaired physicians; admitting mistakes; pharmaceutical gifts/payments; conflicts of interest/perceptions of conflicts of interest; boundaries (patient/family-physician); and obligations to physician's family (Lang, 2009). These topics, which may very well have some ethical underpinnings (i.e. truth

telling) and are certainly worthy of discussion, cannot and should not take the place of dedicated ethics curricula.

As a matter of fact, there are many, many physicians and physicians-in-training who have mastered the art of professionalism, which I believe is best characterized as demonstrating a particular type of decorum and deportment in one's professional interactions. Yet many of these same physicians and trainees have absolutely no inclination toward a respect for or mastery of bioethics. Because "adherence to ethical principles" is but one subpart of the six explicitly outlined expectations related to this competency, it is easily neglected in the greater scheme of professionalism. This tendency to neglect the teaching of ethical principles and modeling of ethical behavior is compounded by the lack of self-confidence and expertise among faculty members as reported in the articles by Kesselheim and Lang that were described in Chapter 1. It is further compounded by the fact that ethics is an immensely broad subject for which no structured curriculum for medical trainees currently exists. If ethics education is to be afforded the respect and standing that it rightly deserves in the training of physicians, neonatologists notwithstanding, I believe that the ACGME must divorce it from the competency of professionalism. Short of this, the next most appropriate action to be taken by the ACGME is to explicitly delineate the ethics-related components of professionalism, with particular emphasis on the essential nature of ethics within the larger scope of the competency of professionalism.

One of the first steps toward the development of formalized ethics curricula is one that could and should be taken by the AAP, ABP, and ACGME either independently or concurrently. Further empirical studies must be conducted to formally assess the existence

and current status of such curricula and to evaluate the perceived ethics education-related needs of training program directors and trainees alike. These studies should be conducted as soon as possible to properly guide the development and implementation of formalized ethics curricula in a timely fashion.

TRAINING INSTITUTIONS

As discussed in Chapter 1, American medical schools have led the way with respect to the implementation of formalized courses in ethics, as evidenced by the fact that every medical school in the country included at least one ethics course in its curriculum as of 1994. For these efforts, the deans and curriculum committees of medical schools are to be commended.

The traditional four-year medical school curriculum consists of two pre-clinical years and two clinical years. Introductory courses in bioethics are taught as a part of the didactic curriculum during the pre-clinical years. In some medical schools, additional courses may be offered as electives during the fourth and final year. This curricular structure effectively marginalizes ethics as a “pre-clinical,” and potentially “non-clinical,” subject matter, a regrettable distinction that is only reinforced in residency and fellowship, where ethics education falls woefully short of the desired mark (as illustrated in Chapter 1). Because these years are some of the most formative in a physician’s professional life and given that some empirical studies have raised concern about the potential for “ethical erosion” during medical school, it is simply unacceptable to continue to allow this marginalization to occur. Basic ethical principles must continue to be taught in American medical schools, with a

newfound emphasis on the integration of these principles into the practice of learning to be a “good” doctor. This foundation is an absolute necessity for the success of subsequent efforts at ethics education in residency and fellowship.

It is during the years of residency and fellowship that medical trainees transition into the independent practice of medicine that will be their life’s work. During these years, trainees must be taught to identify, appreciate, and manage those ethical issues that will be most relevant in their chosen specialty. Granted, there are a number of ethical issues that are common across many fields of medicine and it is precisely those issues that may be introduced, and perhaps thoroughly covered, during the basic bioethics courses taught in medical school. In reality, however, the ethics of the many medical specialties and subspecialties, including neonatology, are so distinctive that they do not lend themselves to being taught on such a general basis. It is for this reason that formalized ethics education must continue through the years of residency and fellowship with increasing focus on those issues that are most pertinent to the particular field of practice.

Because fellowship programs are relatively small and the task of tailoring ethics curricula to specific fellowships may seem so onerous as to be remarkably inefficient or virtually impossible, training institutions could consider the option of developing and implementing curricula for certain types of fellowships. For instance, within the larger context of pediatrics, a “critical care” ethics curriculum could be devised to be offered to fellows in critical care, i.e. neonatal and pediatric intensive care. While this would serve the purpose of streamlining the teaching of some ethical concepts, such as withholding and withdrawal of life support or surrogate decision making, it would not preclude the need for the

individualized teaching of others, such as maternal-fetal conflict or margin of viability in neonatology. Yet to the extent that formalized curricula can be structured in this way, thereby maximizing their efficiency, they should be.

On a larger level, medical training institutions could reinforce efforts at formalizing ethics education in residency and fellowship programs by providing a supportive infrastructure for doing so. This could be accomplished in two primary ways. First, the establishment of centers for bioethics would provide medical institutions with “local authorities” in ethics who could be utilized in the teaching of medical students, residents, and fellows alike. For instance, the Center for Bioethics, Health, and Society at Wake Forest University claims the promotion of “bioethics as integral to research, scholarship, and practice in the health professions, the life sciences, and scientific and health-related research” as one of its primary missions (WFU, online). This mission, and others like it, could certainly be fulfilled through the teaching of bioethics to medical trainees at all levels. Second, an institutional requirement that would mandate the hiring of an ethics “expert” within each division would prove prudent in the development and implementation of ethics curricula. For example, most divisions currently have a quality improvement “expert” or a clinical research “expert” on faculty. These “experts” are highly sought after because of the perceived value of quality improvement and research in the current medical climate. The hiring of an expert in ethics would exhibit a similar level of interest and perceived value in this discipline, meanwhile advancing the cause of a formalized ethics curriculum within that division.

The institutional changes that must take place to allow for the proper development of formalized ethics curricula in American medical training programs need not be dependent

on efforts of national governing bodies. Such institutional changes would optimally take place in the larger context of a genuine multi-level cultural shift, yet in the absence of this, institutions should begin work now on the changes outlined in this section.

INDIVIDUAL

Regardless of whether or not governing bodies and training institutions heed the call for formalized ethics curricula, I maintain that individual neonatologists and neonatology fellows must accept personal responsibility for making ethics a priority in their training and in their careers. This personal responsibility is required of a physician in order to fulfill his or her obligation to his or her patients and to the profession of medicine. Accepting this responsibility will require attitudinal and practical changes on the part of these individuals.

Attitudinal changes must occur in two contexts. Experienced neonatologists must accept that the ethics of yesteryear are not the ethics of today any more so than the medicine of yesteryear is the medicine of today. Accepting this reality necessarily entails the rejection of the so-called “hidden curriculum” as an accepted means by which to teach ethics. As discussed in Chapter 1, this “hidden curriculum,” as characterized by Hafferty and Franks is “more concerned with replicating the culture of medicine than with the teaching of knowledge and techniques” (Hafferty, 1994). In this enculturation process, senior physicians teach ethics by example such that physicians-in-training learn to be ethical physicians by doing as is done rather than as they are told (or taught). Because this means of education by enculturation has been long accepted by senior physicians, their willingness and motivation to explicitly address ethical issues is seemingly nonexistent. In turn,

residents and fellows emerge from training with a general sense of apathy toward those ethical issues that are inextricably linked to the everyday practice of medicine. For those who do have some innate sense of responsibility for the recognition of ethical issues, they find themselves ill-prepared to manage them once they have been appropriately recognized. The rapidity with which the practice of modern medicine is changing precludes any responsible physician from relying on this “curriculum” as an appropriate means by which to teach or learn clinical ethics. Compounding this is the fact, illustrated in the article by Kesselheim et al., that the majority of physicians are not confident in their own ability to manage ethical dilemmas. Although the group surveyed by Kesselheim et al. was relatively recently graduated, it is likely that their responses reflect the lack of confidence of pediatricians on the whole. If this is the case, then pediatric faculty members simply should not allow physicians in training to replicate the very behaviors in which they, themselves, have little confidence.

On a practical level, neonatologists and neonatology fellows should incorporate ethics into the daily practice of medicine. Some physicians utilize an organ systems-based approach in which patients and their medical problems are analyzed by organ system (i.e. respiratory, neurology, etc.) while others use a problems-based approach (i.e. respiratory distress syndrome, intraventricular hemorrhage, etc.). Regardless of the approach employed by a physician, ethics could be included as a “system” or “problem” (or “domain” in the event that there are no ongoing ethical “problems” or concerns) so as to ensure that any pertinent ethical issues are thoughtfully considered on a daily basis. Ultimately, this practical change would serve to put ethics on equal footing with the other issues that must be regularly dealt with in the course of patient care.

As previously described, there are several ethics resources available through the AAP and ABP for general pediatricians and pediatric subspecialists. These resources, albeit works in progress, are undoubtedly underutilized. In the absence of formalized curricula or specific board requirements, these resources could certainly serve as an excellent starting point for the ethics education of physicians in practice and those in training. Their existence leaves pediatricians no excuse for being so inadequately prepared to face the ethical dilemmas that arise in the daily practice of medicine.

FINAL THOUGHTS

Efforts at ethics education in pediatrics, and more specifically neonatology, are falling woefully short of the mark as suggested by the literature reviewed in Chapter 1. My experience with the development and implementation of a formalized ethics pilot educational module at Wake Forest School of Medicine as described in Chapters 2 and 3 has proven to me that such endeavors, while extremely challenging, are feasible, valuable, and generally well-received. The responsibility for remedying the current educational shortcomings and for advancing the cause of formalized ethics education for neonatologists in practice and in training falls on the shoulders of the governing bodies, training institutions, and individual physicians alike. The changes recommended in this final chapter are fundamental to advancing the cause of formalized ethics education in neonatology and they should begin now.

For many years, decades even, the battle for the recognition of the central role of ethics has been waged. It has been won, giving way now to the battle for granting ethics equal footing

in the training of physicians. The ever-changing nature of neonatology puts it at the forefront of this new battlefield. The powers-that-be on the levels of the governing bodies and training institutions must lead the way. They owe it to the neonatologists of today and tomorrow. In turn, the neonatologists owe it to the babies and families for whom those ethical dilemmas that have heretofore been contained in the walls of medical schools and the pages of ethics texts suddenly, and often tragically, become a reality.

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APPENDIX I – PILOT EDUCATIONAL MODULE POWERPOINT SLIDES

See pages 75-99

Ethics in the NICU

Kristen Coggin, MD
January 4, 2012

"Rarely have the processes and products of scientific medicine been as heralded and harangued, as lauded and condemned, as publicized and misunderstood as they have in the context of neonatal intensive care units ..."

- Lantos and Meadow

Objectives

- Overview of Ethics
 - Definition
 - Theories
 - History
- History of Neonatology
 - 3 Eras
 - Medical
 - Legal
 - Ethical

Defining Ethics

- Generic term to describe several different ways of examining and understanding the moral life
 - Morality – norms about right and wrong human conduct that are so widely shared that they form a stable social agreement
- Medical Ethics – systematic, reasoned evaluation of justification of the 'right' action in pursuit of human good or well-being in the context of medical practice

Defining Ethics

- Normative – "Which general moral norms should we accept and why?"
- Non-Normative
 - Descriptive: factual investigation of moral beliefs and conduct
 - Meta-Ethics: analysis of language, concepts, and methods of reasoning in normative ethics
- Non-Normative (Is) vs. Normative (Ought)

Experiencing Ethics



Theories of Ethics

- Utilitarianism – John Stuart Mill
 - Rightness or wrongness of an action is based on its consequence
 - “Greatest good for the greatest number”
- Deontology – Kant
 - Acts are intrinsically right or wrong based on universally applicable rules
 - Prohibits using people or things as “means to ends”

Theories of Ethics

- Principlism – Beauchamp and Childress
 - Autonomy
 - vs. Authority in pediatrics?
 - 3 components
 - Beneficence
 - Non-Maleficence (*Primum Non Nocere*)
 - Justice
- Casuistry
 - Case based reasoning

A History of Medical Ethics

- 1792-1794 – Percival drafts 1st code of professional ethics
 - Dominant influence in Anglo-American medical ethics and subsequent AMA code of ethics
- 1847 – AMA Code of Medical Ethics
 - Multiple Revisions
 - Most recently in 2001
- 1982 – ABP required pediatric residency programs to evaluate trainees for ethical behavior
- 1999 – ACGME Core Competencies
 - Professionalism

ACGME

Neonatal-Perinatal Medicine

“Medical ethics and professionalism should be emphasized in the didactic curriculum and modeled by the faculty in all aspects of their practice. A structured curriculum with meaningful venues for teaching that extend beyond the traditional lecture to include interactive learning (e.g., small group discussions of vignettes or case studies, computer-based module, role plays, etc) will meet this requirement.”

ETHICS IN PEDIATRICS: HOW ARE WE DOING?

25 Years and Counting ...

- 1982 – Pediatric residency programs required to evaluate trainees for ethical behavior
- 1987 – ABP made “ethical decision making” a subject area on certification examination
- 1997 – RRC required structured curriculum in medical ethics for all accredited pediatric programs
- 2007 – ACGME required documentation of teaching/evaluation of professionalism

Ethics Education in Neonatal-Perinatal Medicine in the United States

Seminars in Perinatology – Selih and Boyle, 2009

- There should be a formal course in medical ethics in NICU training programs
 - Lack of uniformity
 - Only way to address some ethical issues
 - Symbolic
 - ACGME requirement!!
- Goal – to improve behavior and awareness, not character
- How? Small group teaching, simulation
- By Whom? Clinician and Ethicist

Ethics Education in Neonatal-Perinatal Medicine in the United States

Seminars in Perinatology – Selih and Boyle, 2009

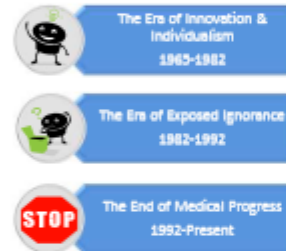
Table 1. Ethics Curriculum for Neonatal-Perinatal Medicine Fellowship Program of Indiana University School of Medicine Riley Hospital for Children

	Year 1	Year 2	Year 3
September	Orientation Annual Guest Lecturer Analysis of a perinatal case Lack of viability decision-making in the delivery room	Orientation Annual Guest Lecturer Analysis of a perinatal case Maternal-fetal conflict School of care during pregnancy Communication	Orientation Annual Guest Lecturer Analysis of a perinatal case Long-term outcomes Tackling dependent child Ethics of research in neonates
December	Fetal case discussions in neonatology Withholding/withdrawing therapy Do not resuscitate (DNR) orders Consentation Essentials of perinatal physician Interventions Perinatal consultation	Disclosure of medical mistakes and medical malpractice Cultural competency and religious sensitivity	
February			Social justice Resource allocation Advocacy
April	Palpable case for newborns and palpable case of Riley Team introductions	Conscience Moral distress in the NICU Team introductions	Ethical dimensions of genetic testing/monitoring and stem cell research
June	Neonatology fellow accepts/case presentations	Neonatology fellow accepts/case presentations	Neonatology fellow accepts/case presentations

NEONATOLOGY: A LOOK BACK IN TIME

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The Moral Challenges of Medical Innovation
By Lantos and Melezer

3 “Eras”

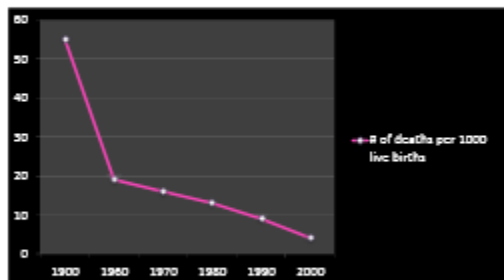


THE ERA OF INNOVATION AND INDIVIDUALISM 1965-1982

The Era of Innovation and Individualism - Medical

- Innovation
 - Respiratory
 - 1965: Intubation/Positive Pressure Ventilation
 - 1971: CPAP
 - Nutrition
 - TPN – “a Gordian Knot, the Holy Grail”
 - Impossible? Impractical? Unaffordable?
- NICU recognized as subspecialty (1975)
- Regionalization

Infant Mortality in US



The Era of Innovation and Individualism - Legal

- No real legal framework re: withholding and withdrawal
 - “Absence of judicial precedent” misinterpreted
- Change—Struggle
 - Which legal paradigms should be applied? How?
- Legislation
 - Rehabilitation Act of 1973
 - Child Abuse Prevention and Treatment Act of 1974
- No landmark court cases

The Era of Innovation and Individualism - Ethical

- 1968 Lucey Conference
- 1972 Stahlman Conference “*Ethical Dilemmas in Current Obstetric and Neonatal Care*”
 - Debate over defective newborns
 - * Fletcher – Utilitarian approach; is life worth preserving or not?
 - * Veatch – Procedural claims suggesting that parents, not doctors, should have the right to make decisions
- 1975 Sonoma Conference
 - Harm >> Benefit = Unethical
 - Neonatal intensive care is harmful if unable to survive infancy, unable to live without pain, or unable to participate in human experience
- NEJM Articles (1973)

THE ERA OF EXPOSED IGNORANCE 1982-1992

The Era of Exposed Ignorance - Medical

- Advances in Treatment of Respiratory Failure
 - Surfactant (FDA approval in 5 months in 1990)
 - High Frequency Ventilation
 - ECMO
- Preventive Treatments
 - GBS Screening
 - Antenatal Steroids
- Practical Refinements
 - Cranial Ultrasound
 - Pulse Oximetry
 - Improved IV Access

The Era of Exposed Ignorance - Legal

- Baby Doe (1982, IN)
 - Infant with Trisomy 21 and TE Fistula
 - Parents, on advice of OB, requested no intervention
 - Pediatricians and hospital administrators disagreed
 - Trial court ruling – “Parents have the right to choose a medically recommended course of treatment for their child in the present circumstances.”
 - Reagan Administration and Baby Doe Regulations
 - Unprecedented endorsement of medical intervention?
 - Unprecedented intrusion of federal government?
- Amendment to Child Abuse Prevention and Treatment Act of 1974

The Era of Exposed Ignorance - Legal

- "Wrongful Life"
 - *McDonald v. Milleville* (1989,WI)
 - DR resuscitation of 600 gram 23 week infant discontinued after poor response—Infant survived with severe neurologic deficits
 - Physician cleared of negligence
- "Wrongful Death"
 - *Velez v. Bethune* (1991,GA)
 - Care withdrawn from 500 gram 24 week infant delivered on side of road because considered to be "in the process of dying"
 - Court ruled that "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."

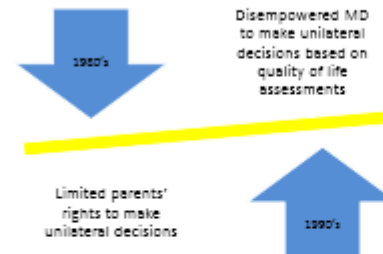
The Era of Exposed Ignorance - Legal

- *Miller v. HCA* (1990, TX)
 - 615 gram 23 week infant resuscitated against mother's wishes → Survived with severe neurological deficits
 - Sued on grounds that baby was treated without their consent and that hospital policy of requiring resuscitation without consent was illegal
 - Awarded \$60 million, but judgment overturned
 - Refusal of treatment only if "terminal" (Court of Appeals)
 - "Time for evaluating Sidney was when she was born" (Texas Supreme Court)

The Era of Exposed Ignorance - Ethical

- 3 Physician Claims (prior to the 1980s)
 - Accurate prediction of outcomes
 - Correctly understand parental wishes re: treatment
 - Authority to understand and evaluate a baby's quality of life
- Recognition of need to include parents in decisions
 - Ignorance is not the difference of opinion between MD and parent but of the fact that pediatricians' attitudes are not typical attitudes.
- Creation of multicenter databases (VON, NICHD)
- The President's Commission for the Study of Ethical Problems in Medicine (1983)
 - Section on Seriously Ill Newborns

Legally Speaking ...



THE END OF MEDICAL PROGRESS 1992 - PRESENT

The End of Medical Progress - Medical

- Most deaths "unpreventable" by mid-1990s
 - To improve upon this, must ↓ VLBW births
- Improved prognostic accuracy
 - Short-Term vs. Long-Term
 - But which outcomes are 'acceptable'?

The End of Medical Progress - Legal

- Born Alive Infant Protection Act of 2001
 - “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.”
 - Does not mandate medical treatment where none is currently indicated and does not affect applicable standard of care

The End of Medical Progress - Legal

- Messenger case (1994, MI)
 - “Well, we’ll see ...”
 - Infant resuscitated and father disconnected ventilator ~1 hour after birth → Acquitted of manslaughter
- *Montalvo v. Borkovek-Montalvo* (2002, WI)
 - 23 week infant delivered via C-section, resuscitated and admitted to NICU
 - Mother sued OB and neonatologist for failure to obtain her informed consent for son’s treatment

The End of Medical Progress - Ethical

- Improved prognostic accuracy = Basis for ethical decision making in the NICU
- Move toward consistency
- Discarding of prior moral views
 1. Preventive care is morally preferable to NICU care because it is both cheaper and more effective.
 2. Neonatology should be curtailed because the harms caused by the increased number of survivors with CP and other neurological deficits outweigh the benefits of increased survival rates.
 3. Parents alone should have the final say as to whether their babies are treated.
 4. Respect for the sanctity of life demands that we never consider ‘quality of life’ in deciding whether to discontinue life-sustaining treatment.

IN CLOSING



The Question Remains ...



"The NICU is often portrayed as a frontier filled with cataclysmic struggles fought by heroic crusaders against implacable biological constraints, with tiny human infants as the battleground. Mostly, it is not. Instead, today's NICU is a surprisingly mundane place that runs like a happy factory, churning out healthy baby after healthy baby, with mostly routine efforts by trained professionals."

- Lantos and Meadow

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DECISION MAKING IN THE NICU

Kristen B. Coggin, MD
January 11, 2012

Objectives

- Decisions, Decisions, Decisions ...
 - Who?
 - How?
 - On What Basis?
- Baby Doe
- Withholding & Withdrawing Life-Sustaining Therapy

DECISION MAKING

Decision-Making Capacity (DMC)

- Vs. Competence
- Situational
- Essential Elements (Grisso & Appelbaum)
 - Ability to understand relevant information
 - Ability to appreciate the significance of the information for one's own situation
 - Ability to reason, using the information to weigh treatment options in relation to one's goals and values
 - Ability to express a choice

Surrogate Decision-Making

- 1 • Guardian
- 2 • Health Care Agent
- 3 • Attorney-in-fact
- 4 • Spouse
- 5 • Parents and Children
- 6 • Siblings
- 7 • Individual – established relationship, good faith

Standards for Surrogate Decision-Making

- Expressed Interests
 - What did the patient say he/she would do in this circumstance?
- Substituted Judgment
 - What would the patient want in this circumstance?
- Best Interests
 - What is best (i.e. provides greatest net benefit) for the patient in this circumstance?
 - Quality of Life

Decision-Making & Moral Reasoning

MEDICAL DECISION-MAKING

- Identifying Goals and Values
- Defining Issues
- Developing Options
- Gathering and Evaluating Information
- Deliberating
- Decision Making
- Re-Evaluating

MORAL REASONING

- Stating the Problem
- Stating the Most Relevant Information
- Identifying Options & Consequences
- Identifying & Evaluating For/Against Courses of Action
- Choosing a Course of Action
- Defending a Course of Action

DECISIONS, DECISIONS, DECISIONS ...

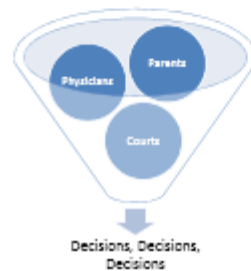
What is best for your baby?

Is your baby worth it?

Is life always preferable to death?

Why put your baby through this?

Who Makes Decisions in the NICU?



3 Approaches to Decision-Making

- The Objective Information Approach
 - Information given in non-directive way
 - Goal – education, empowerment
- The Broad Shoulders Approach
 - MD attempts to understand and appreciate patient's perspective → Recommendation consistent with what patient wants but may not be able to say
- The Shared Deniability Approach
 - Acknowledges tension between 2 wrongs
 - A decision was made? Who made it?
 - Limits on autonomy

Types of Treatment Decisions

- Mandatory
 - Benefit >>> Risk
- Optional
 - Risk >>> Benefit
 - Benefit??
- Investigational
 - New or unproven
- Unreasonable

Best Interests in the NICU

- The Traditional Model - Buchanan and Brock
 - Well-being
 - Self-determination/Self-regard
 - Reasonable persons
- "Constrained Parental Autonomy" - Ross
 - Basic needs
 - Focus on child's lifetime autonomy
 - Intra-familial trade-offs
- The "Harm Principle" - Dickson
- The "Good Enough" Principle - Koppelman
 - Avoiding abuse/neglect (Threshold)
 - Duty to promote the good of children (Ideal)
 - "Best interests" would require parents to do what is best
 - Reasonable given the conditions (Reasonableness)
 - "Do least not unacceptable"
- Others
 - "Better off dead?"
 - "Circumstance of the Unknown"

Making Decisions – Factors for Consideration

- Chances for Survival
 - What is the minimum “acceptable” probability?
 - Is survival, even with severe and enduring morbidity, actually preferable to death?
- Anticipated Quality of Life
 - How good is good enough?
 - 4 Components (Lantos and Meadow)
 - Anticipated cognitive/cerebral function
 - Anticipated physical disabilities
 - Pain/suffering that is associated with the disease
 - Burdens of treatments that may be necessary in the future

Final Thoughts ...

- “The best of times, the worst of times ...”
 - Prognostic Uncertainty → Simultaneously increase the likelihood of the best outcome AND the worst outcome.
- Parents’ decisions are NOT:
 - The rational calculus of balancing burdens and benefits
 - The logical conclusion of legal precedents
 - Readily subjected to rational analysis
 - An opportunity to exercise personal values and individual choice
- The matter of personhood – Does it matter?
- Sanctity of Life

A CLOSER LOOK AT BABY DOE

Baby Doe Revisited

- April 1982 – Parents declined TE fistula repair for infant with Trisomy 21, on advice of OB
 - Quality of Life
 - Best Interests
- Emergency Petition → Midnight Trial
 - *“The parents, having been fully informed of the available alternative courses of treatment, have the right to choose a medically recommended course of treatment for their child in the present circumstances.”*
 - Guardian ad litem appointed, no appeal
 - DA petitioned Juvenile Court, denied
 - Dismissed in Indiana Supreme Court

Baby Doe Rules

- First Set – May 1982
 - Based on Rehabilitation Act of 1973
 - Nontreatment justified for any of 3 exceptions
 - Chronically and irreversibly comatose; prolongation of dying; virtually futile or inhumane
 - Otherwise, discriminatory and in violation of infant’s civil rights
 - Interim Final Rule – March 1983
 - Infant Care Review Committees – January 1984
 - Struck Down – June 1984
- Baby Jane Doe
 - *Bowen v. American Hospital Association* (1986)
 - “Federal government was not a participant in the process of making treatment decisions for newborn infants.”

The Supreme Court on Baby Doe

- HHS – no authority to compel medical treatment absent parental consent
- Parental refusal to consent does “not equate with” refusal by a hospital/physician to treat.
- HHS’s “perception that the withholding of treatment in accordance with parental instructions necessitates federal regulation is manifestly incorrect.”
- “State CPS agencies are not field offices of HHS bureaucracy and they may not be conscripted against their will as foot soldiers in a federal crusade.”
- HHS’s view that “the basic provision of nourishment, fluids, and routine nursing care was not an option for medical judgment was untenable.”

Child Abuse Amendments of 1984

- Baby Doe Rules – Second Set
- Medical Neglect – withholding of medically indicated treatment from disabled infants with life threatening conditions
- Medically Indicated – effective in ameliorating or correcting all conditions
 - 3 exceptions
 - “Virtually Futile” – highly unlikely to prevent death in the near future
 - “Inhumane” – significant medical contraindications or significant pain/suffering outweigh very slight potential benefit for infant highly likely to survive
- Except in “highly unusual circumstances,” decisions to provide or withhold medically indicated treatment should be made by the parents or legal guardian

Baby Doe and Best Interests

- “Neonatologists Judge the Baby Doe Regulations”
 - *NEJM*, Kopelman et al., 1988
 - Unnecessary
 - Interfered with parents’ rights to decide
 - Inadequate consideration of suffering
 - Ignored resource allocation
 - In conflict with best interests
- Express prohibition of Quality-of-Life considerations
 - Noncomatose, nonterminal life is always preferable to nonexistence?
- “Reasonable Medical Judgment”
- The Balance of Harm

WITHHOLDING & WITHDRAWAL OF LIFE-SUSTAINING TREATMENT

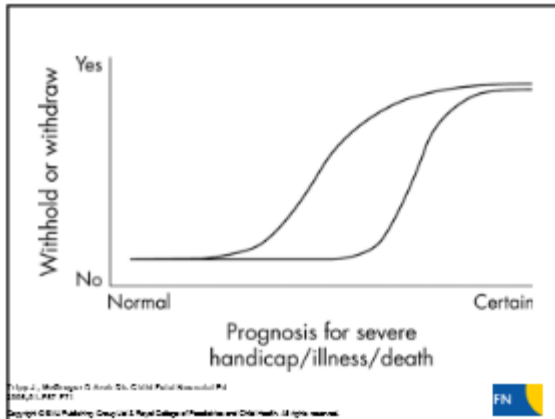
Historically Speaking ...

- Prior to the 1970s, the question of whether to withhold treatment was rarely contested.
- During the 1970s, emergence of bioethics raised questions about ethics and legality of withholding.
- Baby Doe (1981) → Child Abuse Amendments (1984)
 - Focus on genetic and chromosomal anomalies
 - Role in extreme prematurity?
- Technology & Quality of Life Studies
 - Gray Zone → Black and White



From NRP -

- There is **no ethical distinction** between withholding and withdrawing.
- The ethical principles regarding resuscitation of newborns should be **no different** from those followed in resuscitating an older child or adult.
- Ethical and current national legal principles do not mandate attempted resuscitation in all circumstances.
- Health care professionals have a legal and ethical obligation to provide appropriate care for the baby based on current medical information and their clinical assessment.
- Endorsement of AMA Code of Medical Ethics



- ### Factors in Withholding/Withdrawal
- | PARENTS | PHYSICIANS |
|---|--|
| <ul style="list-style-type: none"> • Child's quality of life • Degree of pain and suffering <ul style="list-style-type: none"> – Direct visualization • Likelihood of improvement • Physician recommendations • Past experiences with end-of-life decision making • Will of child to survive • Faith, Family, Finances | <ul style="list-style-type: none"> • Acute prognosis <ul style="list-style-type: none"> – Emphasis on neurologic status • Parent wishes • Baby Doe? • Local Experience • Professional Image |

- ### Death in the Intensive Care Nursery: Physician Practice of Withdrawing and Withholding Life Support – Wall & Partridge, *Pediatrics*, 1997
- Objectives
 - Determine frequency of selective nontreatment
 - Determine reasons for nontreatment as documented by neonatologists
 - Results
 - 165 deaths – 73% withdrawal/withholding
 - * 108 withdrawal, 13 withholding, 44 despite maximal therapy
 - Reasons
 - * Futility – 74%
 - * Quality of life – 23% (sole) to 51%
 - * Prognosis for Severe Disability – 46%
 - * Suffering – 15%
 - Parents initiated discussions in only 13% of cases

A SPECIAL CASE OF WITHHOLDING AND WITHDRAWAL

- ### When to Consider
- Neurologic Devastation
 - Permanent Vegetative State
 - Anencephaly
 - HIE
 - Irreversible Total Intestinal Failure
 - Short Gut
 - Neuronal Dysplasia
 - Proximate Death from any pathologic condition

- ### Official Statements
- American College of Physicians
 - Medical administration of fluids and nutrition is a medical intervention that is subject to the same principles of decision-making as all other medical interventions
 - American Academy of Pediatrics (1994)
 - Life-sustaining medical treatment encompasses all interventions that may prolong the life of patients
 - * Organ transplantation, respirators, dialysis, vasoactive drugs, antibiotics, insulin, chemotherapy, nutrition/hydration provided intravenously or by tube
 - Limiting or stopping life support seems most appropriate, especially if treatment only preserves biological existence or if the overall goal of therapy has shifted to the maintenance of comfort

Why is it different ... and so hard?

- Almost all NICU babies require artificial nutrition/hydration – Most will survive without serious long-term problems
 - Interventions themselves do not determine moral value
- Feeding is “the essence of caring” for all babies
 - Evokes strong emotional responses
- Death takes longer ... but it will come
 - 1 concern re: suffering
 - Wasting
- Starvation vs. Suffocation
- Lack of medical urgency

Questions to be Answered

- Is life always preferable to death?
- If some deficits are considered to be intolerable, how should this be defined?
- At the end of the day, will the baby have benefitted from or been harmed by neonatal intensive care?
- Does the fact that we “can” mean that we “should” or that we “must”?
- Should we respond to uncertainty with regard to outcomes by giving a “chance” to every infant who is even potentially viable?

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FUTILITY IN THE NICU

Kristen B. Coggin, MD
February 1, 2012

According to Hippocrates ...

- 3 Roles of Physicians
 - To alleviate suffering in the sick
 - To reduce the violence of their diseases
 - To refuse to treat those who were overmastered by their diseases
- “Whenever therefore a man suffers from an ill which is too strong for the means at the disposal of medicine, he surely must not even expect that it can be overcome by medicine.”
- A physician who attempts futile treatment displays ignorance that is “allied to madness.”

FUTILITY



OBJECTIVES

- Types of Futility
- Futility's Relation to Principlism
- Legal Cases of Note
 - Baby K
 - Sun Hudson
- Futility – A Global Perspective
- The “Gray Zone” – A Special Case of Futility

Types of Futility

- **Physiologic/Strict** – medical intervention will not produce the usually intended physiologic outcome
- **Imminent Demise** – medical intervention will not allow the patient to survive to discharge or to recover interactive capacity
- **Lethal Condition** – intervention has no effect on underlying condition, which will result in death in the not-too-distant future
- **Qualitative** – medical intervention fails to lead to acceptable quality of life
 - Merely preserves unconsciousness
 - Fails to end a patient's total dependence on intensive medical care
 - Requires all parties to agree on what gives life value to begin with
- **Quantitative** – medical intervention that is likely to fail to provide a benefit based on previous knowledge and experience
 - “Useless” in the last 100 cases of a physician's personal experience or in published reports

Why is Futility Such an Issue?

- Subjective
 - Best Interest?
 - Benefits?
 - Benefit vs. Effect
 - Burdens?
- Diagnostic and Prognostic Uncertainty → “Realistically Indispensable”
- Value-Laden
- Lack of Social Consensus – Plurality of Values
- Patient Autonomy vs. Professional Autonomy/Integrity
- Resource Considerations

Why is Futile Care Demanded?

- Denial, Unrealistic Expectations
 - Belief that diagnosis or prognosis may be incorrect
 - Belief that medicine can work miracles
 - Helplessness
- Faulty Reasoning
- Refusal to Give Up
- Belief in God or other higher power
- Sense of Entitlement

Futility and Principialism

- Autonomy
 - Right to Choose and Refuse
 - Physician vs. Patient/Surrogate
 - Potential for Deception
- Beneficence
 - Prolonging Life vs. Prolonging Death
- Justice (Distributive)
 - Important, but rarely mentioned
 - Value-neutral
 - Rationing?

Futility and The Law

- Child Abuse Amendments to Baby Doe Rules (1985)
 - Did not require treatment that:
 - Would merely prolong the act of dying
 - Would not be effective in ameliorating or correcting all of the infant's life-threatening condition
 - Would otherwise be futile in terms of the survival of the infant
 - Would be 'virtually futile' in terms of the survival of the infant and treatment itself under such circumstances would be inhumane
- *In re: Baby K*
 - Anencephaly
 - EMTALA - ? Emergency Condition ?
- *Hudson v. Texas Children's Hospital*
 - Thanatophoric Dysplasia
 - Texas Advance Directives Act

Texas Advance Directives Act



A Global Perspective

- Canada
 - Candidacy for C-section based on gestational age
 - Broad leeway for parents as decision makers
 - Imposes a duty of care on physicians but recognizes circumstances where there is no obligation to treat
- United Kingdom
 - Life-sustaining treatment can be foregone if "no chance," "no purpose," or "unbearable"
 - Threshold Viability = GA of 22 to < 28 weeks
 - Presumption in favor of treatment, but best interests ≠ prolongation of life in every situation

A Global Perspective

- France
 - Emphasis on prevention of prematurity
 - Severe disabilities are "sometimes ... the adverse result of deliberate human action, the fruits of increasingly sophisticated medical practice"
 - Defined aggressive and futile therapy as "irrational obstinacy"
 - Potential acceptance of neonatal euthanasia
 - "Ability to sustain life at birth" = at least 22 weeks and 500 grams

A Global Perspective

- Italy
 - Code of Profession Medical Ethics warns against treatment that will not bring a benefit or improvement in the quality of life
- Germany
 - Infant's lives should be protected, whether severely damaged or not – Any deliberate shortening of life is an act of killing
 - Withdrawal of treatment from neonates is acceptable when death is inevitable
- Japan
 - Eugenic Protection Act defines fetal viability limit as "the minimal duration of gestation which renders fetuses capable of extruterine life" = 22 completed weeks

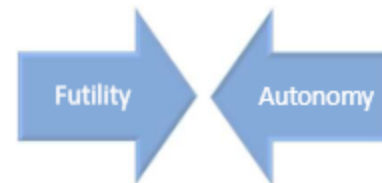
A Global Perspective

- The Netherlands
 - Physicians are not required to give treatment they view as "medically futile"
 - Physicians decide what constitutes futile
 - Physician has no obligation of provide treatment that is judged to be ineffective and inappropriate
 - Life-prolonging treatment is "impossible" if the baby has "no chance of survival" and "futile if the expectations for the baby's future are so poor that treatment would be pointless"

The Groningen Protocol

- 2 Purposes
 - Define circumstances in which active euthanasia of infants can be considered
 - Death is inevitable despite the use of continued invasive medical technology
 - Potentially can survive but expected quality of life is grim
 - Hopeless prognosis – Can survive without technology but only to live life full of suffering that cannot be alleviated
 - Establish a transparent means by which acts of euthanasia are to be reported
- 5 Criteria
 - The diagnosis and prognosis must be certain.
 - Hopeless and unbearable suffering must be present.
 - The diagnosis, prognosis, and unbearable suffering must be confirmed by at least one independent doctor.
 - Both parents must give informed consent.
 - The procedure must be performed in accordance with the accepted medical standard.

A Special Case of Futility: The "Gray Zone"

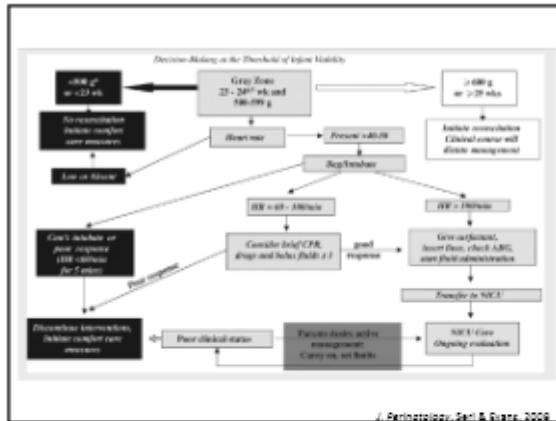


From NRP (2011)

- Noninitiation of resuscitation in the delivery room is appropriate for infants with:
 - Confirmed gestation < 23 weeks
 - Confirmed birthweight < 400 grams
 - Anencephaly
 - Confirmed lethal genetic disorder/malformation
 - When available data support an unacceptably high likelihood of death/severe disability

Defining the Gray Zone

- Gestational Age
 - Inaccurate estimates
 - 23-24 weeks (range 21-25 weeks)
- Evaluation at Birth
 - Physical Exam
 - Weight?
 - Response to Resuscitation
 - Apgar Scores?
 - Heart Rate?
- Consideration of Other Variables (NICHD)
- Statistical Inconsistencies
- A Self-Fulfilling Prophecy?
 - "We never try because it never works. And it might be that it never works because we never try."



- ### What Drives Treatment in the Gray Zone?
- Uncertainty of Outcomes
 - Mortality and Morbidity
 - Short-Term and Long-Term
 - Parental Wishes
 - Legal Mandates
 - Concepts of Justice
 - Physician Perceptions - 2005 *Pediatrics* survey, Singh et al.
 - Major Contributors – Viability, Futility, Quality of Life
 - Minor Contributors – Physician's Religious Beliefs, Fear of Litigation, Resource Allocation

APPROACHES IN THE GRAY ZONE

- ### "Prenatal Consultation Practices at the Border of Viability"
- 77% believed in joint decision making – Decision is jointly made in only 40% of cases
 - Primary Role of Counseling
 - Providing factual information (56%)
 - Assistance in weighing options (27%)
 - Topics of Discussion
 - Maternal status (65%)
 - Desired parental role (77%)
 - Prior experience with premature/handicapped child (54%)
 - Interpretations of good quality of life (42%)
 - Prior experience with death (30%)
 - Religious or spiritual beliefs (25%)
 - Short-Term vs Long-Term Outcomes
 - Length of Hospitalization vs Burden of Hospitalization
 - Predictors of Joint Decision Making
 - Belief that main role is to assist in weighing options
 - Clinical Experience > 10 years
- Pediatrics – Bostick et al., 2005*

The threshold of human viability

Study about surviving newborns: Today's tiny premature babies are born with a compromised respiratory system. Their lungs are still developing, and they are at high risk of respiratory distress syndrome (RDS) and other complications. The threshold of human viability is the point at which a newborn is expected to survive and thrive.

What's new in the gray zone? The threshold of human viability is shifting. Advances in neonatal medicine, particularly in the use of surfactant and mechanical ventilation, have improved the survival of tiny infants. However, the care of these infants is complex and expensive, and the long-term outcomes are uncertain.

What's the challenge? The threshold of human viability is a complex issue that involves medical, social, and economic aspects. Physicians, parents, and society must all be involved in the decision-making process. The goal is to provide the best possible care for these tiny infants while also considering the overall well-being of the family and the community.

PEDIATRICS

Korotkiy et al., Pediatrics, 2011, 128:e1811-1819
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"The threshold of human viability seems to be limited to the physiologic development of the lungs that takes place around weeks 22 to 24. Consequently, survival rate at this age is not expected to improve, at least with the current technologic resources. Moreover, the care of such tiny infants implies a variety of complex medical, social, and economic aspects calling for ethical decisions, because the boundary between utility and futility is not clear."

—Maria Pignotti and Giampaola Danzelli

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RESEARCH ETHICS

Kristen Coggin, MD
February 29, 2012

Objectives

- Conflicts of Interest and Commitment
- Professionalism and Misconduct in Research
- Principles of Research with Human Subjects
- Principles of Consent and Assent
- Vulnerable Populations

CONFLICTS

Conflicts of Interest

- Interests
 - Primary vs. Secondary
 - Individual vs. Institutional
- Conflicts
 - Circumstances or relationships that create or increase the risk that a primary interest will be neglected as a result of the pursuit of secondary interests
- Management
 - Eliminate
 - Manage/Mitigate
 - Disclose

Other Conflicts

- Of Commitment
 - Between primary responsibility to institution and outside commitment
 - Concern re: time and effort, not undue influence
- Of Obligations
 - Duties that require different actions but only one of which can be taken

PROFESSIONALISM AND MISCONDUCT

Defining Misconduct

- Significant departure from accepted practices of relevant research community
- Committed intentionally, knowingly, or recklessly
- Proven by preponderance of evidence

Forms of Misconduct

- Plagiarism – appropriation of another person's ideas, processes, results, or words *without giving appropriate credit*
- Fabrication – *making up* data or results
- Falsification – *misrepresentation* of research record
 - Manipulating research materials, equipment, or processes
 - Changing data
 - Omitting data

Authorship

- Substantial Contributions to:
 - Conception and Design of research
 - Acquisition, Analysis, or Interpretation of data
- Drafting or Critically Revising
- Final Approval

HUMAN SUBJECTS RESEARCH

Defining Human Subjects Research

- Human Subject - living individual about whom an investigator obtains:
 - Data through intervention or interaction with the individual
 - Identifiable private information
- Research - activity designed to:
 - Test a hypothesis
 - Permit conclusions to be drawn
 - Develop/Contribute to generalizable knowledge*

NOT Human Subjects Research

- Education
- Existing Data or Specimens
 - If publicly available or de-identified
- Public Benefits or Service Programs
- Taste and Food Quality Evaluation
- Consumer Acceptance

The Belmont Report

- Respect for Persons (Autonomy)
 - Requirement to acknowledge or protect
 - Relative/Proportional
 - Voluntary, informed
- Beneficence
 - Maximize potential benefits
 - Minimize potential harms
- Justice
 - Subject selection
 - Application of research

Risk/Benefit Analysis

- Risk – possibility that harm may occur
 - Probability
 - Magnitude
- Benefit – something of positive value relative to health/welfare
 - Subjects
 - Society
- Risks must be outweighed by sum of anticipated benefits in the form of knowledge to be gained
- Central tenet of informed consent

Institutional Review Boards

- 5+ members
 - 1 scientific
 - 1 non-scientific
 - 1 unaffiliated
- Tasks
 - Risk Minimization and Assessment
 - Reasonable with respect to anticipated benefits and importance of knowledge
 - Equitable Subject Selection
 - Informed Consent
 - Data Collection Monitoring and Confidentiality
 - Privacy of Subjects

Data Safety Monitoring Boards

- Review protocols and plans for data and safety monitoring
- Evaluate progress of interventional trials
 - Data quality and timeliness
 - Recruitment, accrual, retention
 - Risk:benefit assessments
 - Performance at trial sites
 - External factors
- Recommendations re: trial continuation or conclusion
- Protect data confidentiality

Equipose

- Clinical – difference of professional opinion as to preferred treatment
 - Often due to lack of evidence
- Behavioral – equivocal beliefs and behaviors of clinicians
 - In spite of evidence
- Theoretical – evidence for 2 alternative treatments is exactly balanced

The Therapeutic Misconception

- Failure of subjects to understand that ...
Research ≠ Clinical Care
- Multifactorial
- Ethical Considerations
 - Respect for Persons/Informed Consent
 - Subjects as means to ends?
- Acceptable or Correctable?

CONSENT AND ASSENT

Informed Consent

- Information
 - “Reasonable Person” standard
 - Purpose and Procedures
 - Risks, Benefits, and Alternatives
- Comprehension
- Voluntariness – Free of Coercion and Undue Influence

Coercion and Undue Influence

- Diametric Opposites ... Equally Concerning
- Coercion
 - Threat of Harm/Worse Consequence
 - Intentional and Overt
- Undue Influence – too good to refuse?
 - 4 Key Characteristics (Emanuel)
 1. Offer of a welcomed good or positive incentive
 2. Excessive or irresistible
 3. Produce bad judgments
 4. Result in ethically, legally, or prudentially undesirable activities

Special Considerations for Children

- Scientifically Sound *and* Significant
- Animals → Adult Humans → Older Children
- “Minimal” Risk
- Parental Permission
 - “Collective Judgment”
 - Physical Presence
 - “Sufficiently Involved ... to Understand Effects”
- Child’s Assent

Assent

- Authorization given by a person whose capacity to understand and judge is somewhat impaired ... but who remains functional
 - Knowledge of procedure
 - Freedom of choice to participate and withdraw
 - Ability to communicate decisions
- Age 7
- ≠ **Absence of Objection**
 - So can objection be overridden?

VULNERABLE POPULATIONS

Vulnerability

- How?
 - Lack capacity
 - Unusually susceptible to coercion
- Who?
 - Infants and Children
 - Pregnant Women and Fetuses
 - Prisoners
 - Mentally Impaired
 - Wards of the State
 - Economically/Educationally Disadvantaged

Special Protections

- Pregnant Women
 - Prior studies on animals and nonpregnant women
- Prisoners
 - Research solely on prisoners as a class or on criminal behavior/incarceration
 - IRB must include prisoner
 - Risks commensurate with those accepted by nonprisoners
 - Irrelevant to parole
 - Appropriate follow-up

Minimal Risk

- Probability and magnitude of harm or discomfort anticipated in research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
- Multiple Interpretations
 - Procedural
 - Relative
 - Objective
 - Standard – “average, healthy, normal” children

More than Minimal Risk

- With Prospect of Direct Benefit
 - Risk justified by anticipated benefit
 - Benefit:Risk at least as favorable as with alternatives
 - Assent + Permission of 1 Parent
- No Prospect of Direct Benefit
 - Likely to yield generalizable knowledge of “vital importance”
 - Experience “reasonably commensurate” with those in actual situations
 - Assent + Permission of 2 Parents

CASE

Surfaxin

- 2001 – FDA considered endorsement of drug-company placebo-controlled study of Surfaxin in 4 Latin American countries
 - 325 infants in placebo group = 17 preventable deaths
- “Internal FDA documents state that ‘conduct of a placebo controlled surfactant trial for premature infants with RDS is considered unethical in the USA.’”
- Study in Latin America —Market in United States of America??

Is This Trial Ethical?

- Social or Scientific Value
- Scientific Validity
- Fair Subject Selection
- Favorable Risk:Benefit Ratio
- Independent Review
- Informed Consent
- Respect for Potential and Enrolled Subjects

"Ethical Requirements for Clinical Research" - JAMA
Emanuel et al. May 21-25, 2000, Vol 283, No 20, pp 2701-2711

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- Welker, James and McCue, Jack (2007). "Authorship Versus "Credit" for Participation in Research: A Case Study of Potential Ethical Dilemmas Created by Technical Tools Used by Researchers and Claims for Authorship by Their Creators." *Journal of the American Medical Informatics Association*; 14: 16-18.

APPENDIX II – PRE- AND POST-TEST OBJECTIVE QUESTIONS

1. Which of the following is not a moral principle identified by Beauchamp and Childress in their theory of bioethics?
 - a. Autonomy
 - b. Beneficence
 - c. Justice
 - d. Utilitarianism
 - e. Nonmaleficence

2. A central tenet of Immanuel Kant's theory of bioethics, deontology, is:
 - a. Ethical decisions can best be made when the facts, history, and context of a patient's situation are known.
 - b. People should not be used as a 'means to an end'.
 - c. The rightness or wrongness of an action is based on its consequence.
 - d. Ethical decisions are best made by comparing new cases to paradigmatically right and wrong actions or to similar and acceptable cases.
 - e. First, do no harm.

3. Regarding requirements for ethics education in residency training, which of the following is not true?
 - a. Pediatric residency programs have been required to evaluate trainees for ethical behavior since 1982.
 - b. Ethical decision making has been a subject area on the pediatric certification exam since 1987.
 - c. The RRC mandates a structured curriculum in medical ethics for all pediatric residency programs.
 - d. Requirements for training in ethics are outlined under the ACGME's core competency of practice-based learning and improvement.
 - e. Didactic teaching sessions are considered an acceptable means of teaching medical ethics to residents.

4. In the 2009 *Pediatrics* article by Lang et al, "Ethics and Professionalism in the Pediatric Curriculum: A Survey of Pediatric Program Directors," which of the following was the most commonly cited barrier to incorporating ethics and professionalism into the residency curriculum?
 - a. Crowded curriculum
 - b. Lack of faculty expertise

- c. Lack of faculty interest
 - d. Lack of housestaff interest
 - e. Lack of administrative support
5. The case of Baby Doe was brought on grounds that it violated which of the following?
- a. The 1st Amendment of the US Constitution
 - b. The Rehabilitation Act of 1973
 - c. The Child Abuse Prevention and Treatment Act
 - d. The Born Alive Infant Protection Act
 - e. The 14th Amendment of the US Constitution
6. The requirement for informed consent in medical research is most closely related to which ethical principle?
- a. Equipoise
 - b. Justice
 - c. Autonomy
 - d. Beneficence
 - e. Competence
7. The Common Rule states that:
- a. Healthy children may participate only in research that involves no more than minimal risk.
 - b. The phrase “no more than minimal risk” is best stated as the probability and magnitude of harm or discomfort anticipated in the research may be greater than those encountered in daily life but are not greater, in and of themselves, than those ordinarily encountered in routine medical encounters.
 - c. Research entailing more than minimal risk cannot be approved even if it potentially offers the child a direct benefit.
 - d. The definition of minimal risk may be altered for sick children or children whose daily experiences include poverty and violence.
 - e. The practical applications of “minimal risk” and “a minor increase over minimum risk” are the purview of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
8. Regarding parental consent for neonates to be enrolled in research, which of the following is true?

- a. The stress of having an imperiled infant, the large volume of clinical information, and the uncertainty of the outcome do not compromise a parent's ability to understand the research for which consent is sought.
- b. In at least one study, a statistically significant relationship existed between the parent's perception of adequate time to make research participation decisions and a parent's affirmative decision to participate.
- c. Regardless of whether research involves "minimal" or "greater than minimal" risk, the permission of only one parent is required.
- d. Longer, more complex informed consent documents lead to better understanding of the research for which consent is being sought.
- e. Verbal explanation does not enhance understanding of the research process for participants regardless of the style of written documentation.

9. Which of the following is not a form of ethical misconduct in research?

- a. Poor research without intent to deceive
- b. Fabrication
- c. Falsification
- d. Plagiarism
- e. Failure to declare a conflict of interest or commitment

10. For research involving vulnerable populations, which of the following is not true?

- a. A vulnerable person is one who is susceptible to social, psychological, physical, economic, or legal harms and is unable to protect his or her own interests.
- b. One disadvantage of identifying vulnerable populations is that individual variations within the group may be overlooked.
- c. The Belmont Report provides for increased protection of vulnerable groups.
- d. Research involving vulnerable populations must be regularly reviewed by an IRB.
- e. Neonates are considered a vulnerable population, but fetuses are not.

11. The standard by which parents are to make decisions on behalf of their neonates is the:

- a. Substituted judgment standard
- b. Pure autonomy standard
- c. Best interests standard
- d. Rational persons standard
- e. Utilitarian standard

12. Per the Neonatal Resuscitation Program, which of the following regarding withdrawal or withholding of life-sustaining treatment is true?
- a. There is no ethical distinction between withdrawal and withholding.
 - b. The ethical principles regarding the resuscitation of a newborn are different from those followed in resuscitating an older child or adult.
 - c. The anticipated quality of life for a newborn with and without treatment is not a factor that should be considered in decisions regarding life-sustaining treatment for seriously ill newborns.
 - d. Preliminary decisions regarding the level of care to be provided after delivery should not be altered in the delivery room.
 - e. Since parents are generally considered the best surrogate decision makers for their own children, health care professionals are exempt from all legal and ethical obligations to provide appropriate care for a baby if such care is not requested by the parents.
13. The common law doctrine of *parens patriae* permits which of the following?
- a. Parents to request futile treatment for a critically ill infant
 - b. The State to exercise protection and guardianship over persons disabled by means of minority, insanity, or incompetence
 - c. The Department of Health and Human Services to compel medical treatment absent parental consent
 - d. One parent to make a decision without the agreement of the other parent
 - e. Parents to deny medically indicated treatment that is not virtually futile or inhumane
14. Which of the following statements regarding withholding and withdrawal of treatment from infants is not true?
- a. During the 1970s, it was a matter of public record that large numbers of infants died each year in US hospitals as a result of the withdrawal or withholding of treatment.
 - b. The decision to withhold surgical correction of Baby Doe's tracheoesophageal fistula was one made on the basis of medical futility.
 - c. Prior to the 1980s, US courts were generally supportive of decisions to remove life-sustaining and curative treatment.
 - d. Per the Child Abuse Amendments of 1984, medical neglect was defined as withholding of medically indicated treatment from disabled infants with life threatening conditions.

- e. In general, medical professionals and family members find it easier from an emotional standpoint to withhold treatment from an infant than to withdraw.
15. When making a quality of life assessment in the scope of decisions regarding withholding or withdrawal of care, which of the following is not an ethically relevant subcomponent?
- a. Anticipated cognitive or cerebral function
 - b. Anticipated physical disabilities
 - c. Pain and suffering associated with the disease
 - d. Burdens of treatments that will be necessary in the future
 - e. Likelihood that the infant will not survive to adulthood
16. Which of the following is not a requirement in order for an infant to be considered eligible for the Groningen Protocol?
- a. The diagnosis and prognosis must be certain.
 - b. Hopeless and unbearable suffering must be present.
 - c. The diagnosis, prognosis, and unbearable suffering must be confirmed by the attending physician and three independent physicians.
 - d. Both parents must give informed consent.
 - e. The procedure must be carried out in accordance with the accepted medical standard.
17. The Texas Advance Directives Act, which outlines a procedural approach to futility disputes, states that if no alternative provider can be found after appropriate measures have been taken, the hospital and physician may unilaterally withhold or withdraw therapy that has been determined to be futile after how many days?
- a. 1
 - b. 7
 - c. 10
 - d. 14
 - e. 30
18. Which of the following statements regarding futility is true?
- a. It is only qualitative in nature.
 - b. It is only quantitative in nature.
 - c. It should be used to refer to goals of an action that can be achieved if repeated often enough.
 - d. It should not be used to refer to an action that is, in fact, impossible to do.

- e. There are multiple legal and ethical principles that require physicians to provide treatment that they consider to be futile.
19. The 2005 *Pediatrics* article by Bastek et al., "Prenatal Consultation Practices at the Border of Viability: A Regional Survey," revealed that
- a. A minority of neonatologists polled felt that the decision to withhold resuscitation should be a decision made jointly by the parents and physicians.
 - b. 90% of decisions made at the border of viability are actually made jointly between parents and physicians.
 - c. Most neonatologists polled felt that their primary role during prenatal consultation was to assist parents in weighing the risks and benefits of various management options.
 - d. Long-term outcomes are discussed more extensively than short-term outcomes.
 - e. Neonatologists with > 10 years of clinical experience were more likely to demonstrate shared decision-making than those with < 10 years of clinical experience.
20. A recent study published in *Pediatrics* suggests that which of the following may be useful in improving counseling at the threshold of viability?
- a. Joint counseling by an obstetrician and a neonatologist
 - b. Visual aids
 - c. Taped testimonials from parents of former premature infants
 - d. Guided NICU tours
 - e. Weekly prenatal consultations done by a neonatologist beginning in second trimester
21. The Eugenic Protection Act of which country has defined 22 completed weeks of gestation as the fetal viability limit which is, in turn, characterized as the "minimal duration of gestation which renders fetuses capable of extrauterine life"?
- a. Japan
 - b. United Kingdom
 - c. France
 - d. Australia
 - e. Canada

APPENDIX III – PRE- AND POST-TEST ATTITUDINAL/BEHAVIORAL QUESTIONS

PRE-TEST

22. How important do you feel ethics is in neonatology?

- a. Very Important
- b. Somewhat Important
- c. Neutral
- d. Somewhat Unimportant
- e. Very Unimportant

23. How often do ethical considerations arise for you in practice?

- a. Daily
- b. Weekly
- c. Monthly
- d. Annually
- e. Never

24. When ethical considerations arise, how do you handle them?

25. Did you receive any formal ethical training in your residency/fellowship? If so, what format was used and how effective do you think it was?

POST-TEST

22. Would you be in favor of the development of a formalized neonatal ethics curriculum at WFU?

- a. Yes
- b. No

23. If a formalized ethics course is implemented at WFU, how often should the sessions be held?

- a. Weekly

- b. Monthly
- c. Every Other Month
- d. Quarterly
- e. On An As Needed Basis

24. If a formalized ethics course is implemented at WFU, which of the following topics should be included? Circle all that apply.

- a. Limits of Viability/Decision-Making in the Delivery Room
- b. Futility
- c. Withholding/Withdrawing Life-Sustaining Treatment
- d. DNR Orders
- e. Communication
- f. Essentials of Parent/Physician Interactions
- g. Prenatal Consultations
- h. Palliative Care
- i. Maternal-Fetal Conflict, including Refusal of Care during Pregnancy
- j. Disclosure of Medical Mistakes
- k. Medical Malpractice/Legal
- l. Cultural Competence
- m. Spiritual Sensitivity
- n. Moral Distress
- o. Research Ethics
- p. Social Justice/Resource Allocation
- q. The Right to Live and the Right to Die
- r. Genetic Testing/Prenatal Diagnosis
- s. Experimental Therapies
- t. Technology Dependent Children

25. Did you find the **format** of this course (didactic lecture followed by case analysis) helpful? How could it be improved?

26. Did you find the **content** of this pilot educational module to be appropriate? How could it be improved?

CURRICULUM VITAE

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EDUCATION

Graduate: Masters of Arts in Bioethics
Wake Forest University
Winston-Salem, North Carolina
January 2010 – present
Anticipated Date of Graduation – May 21, 2012

Fellowship: Wake Forest Baptist Medical Center
Neonatal-Perinatal Medicine
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July 2009 – present
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Residency: University of North Carolina Hospitals
Department of Pediatrics
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July 2005 – June 2008

Medical School: Doctorate of Medicine
Brody School of Medicine at East Carolina University
Greenville, North Carolina
August 2001 – May 2005

Undergraduate: Bachelor of Arts – Psychology, *summa cum laude*
East Carolina University
Greenville, North Carolina
August 1998 – May 2001

WORK EXPERIENCE

Clinical Instructor Duke University Medical Center
Department of Pediatrics – Division of Neonatology
2008-2009

MEDICAL LICENSURE

North Carolina Medical License No. 2008-00495	2008-present
Resident Training Medical License, North Carolina, No. 127332	2005-2008
American Board of Pediatrics Certification Examination	October 2008
USMLE Step III – Passed	July 2007
USMLE Step II CS – Passed	January 2005
USMLE Step II CK – Passed	July 2004
USMLE Step I – Passed	June 2003

SKILLS AND CERTIFICATION

NRP Certification	2005, 2008, 2011
NRP Instructor	November 2009-Present

COMMITTEE MEMBERSHIPS

Clinical Ethics Committee – Wake Forest Baptist Medical Center
Clinical Ethics Consultation Subcommittee, Interim Chairperson – Wake Forest Baptist
Medical Center
Resident Educational Curriculum Committee – Wake Forest Baptist Medical Center

PROFESSIONAL MEMBERSHIPS

American Academy of Pediatrics	2005-present
Alpha Omega Alpha	2005-present
American Medical Association	2001-2005

PRESENTATIONS

Rehder K., Boswell K. Two Year Old Female with Rotavirus Encephalitis.
Presented at Thomas F. Boat Evening of Scholarship, May 2006.

HONORS/AWARDS

Chancellor's Scholar – East Carolina University, 1998-2001