Medical Staff Guidelines for Periviability Pregnancy Counseling and Medical Treatment of Extremely Premature Infants

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ABSTRACT

OBJECTIVES. The goal of this report is to describe the collaborative formation of rational, practical, medical staff guidelines for the counseling and subsequent care of extremely early-gestation pregnancies and premature infants between 22 and 26 weeks. The purposes of the guidelines were to improve knowledge regarding neonatal outcomes, to provide consistency in periviability counseling, and to promote informed, supportive, responsible choices.

METHODS. To formulate the guidelines, a 5-step process was conducted; it began with a series of multidisciplinary meetings among maternal-fetal medicine specialists (MFM)s, obstetricians, neonatologists, neonatal nurse practitioners, and nurses from both the labor and delivery unit and the NICU at Providence St Vincent Medical Center (Portland, OR). First, our discussions reviewed mortality rates, morbidity rates, and long-term neurodevelopmental outcomes for extremely premature infants. Second, we explored the variations in counseling that pregnant women received, based on providers’ individual beliefs and disparate knowledge of neonatal outcomes. Third, we asked participants to complete a survey that focused on the theoretical impending delivery of a premature infant, presenting at each week between 22 and 26 weeks of gestation. Participants indicated their recommendations for NICU care at each gestational age by using a numeric scale. Fourth, the survey results were tabulated and used as a basis for the formation of guidelines related to the recommended obstetric and neonatal care at each week of gestation. MFM and neonatologists were urged to use these specific guidelines as a framework for counseling pregnant women between 22 and 26 weeks of gestation. Fifth, we surveyed women ~3 days after they were counseled by their MFM and neonatologist, to assess comprehension, utility, consistency, and comfort with the periviability counseling.

RESULTS. Twenty pregnant women with the possibility of delivery between 22½ and 26½ weeks of gestation (mean: 24½ weeks) received periviability counseling with our consensus medical staff guidelines. The respondents rated the counseling...
process as highly understandable (80%), useful (95%), consistent (89%), and performed in a comfortable manner (100%). All (100%) of the pregnant women thought they were given enough information to make critical decisions related to the potential level of care of their infant.

CONCLUSIONS. Informative, supportive, clear, medical staff guidelines developed to assist in the counseling of women delivering extremely premature infants have been designed and implemented successfully at our hospital. These guidelines form the basis of periviability counseling, which is appreciated by our at-risk pregnant patients. We recommend that all hospitals that provide high-risk obstetric and neonatal intensive care develop similar consensus guidelines based on published outcomes and local provider experience.

THE APPLICATION of neonatal intensive care to extremely premature infants (<27 weeks of gestation) is a fundamental controversy in neonatology. Rates of death and various morbidities, such as chronic lung disease, intracranial hemorrhage, and retinopathy of prematurity, are distressingly high.1 Frequently, long-term neurodevelopmental outcomes for infants born before 27 weeks of gestation or at <1000 g are poor.2–14

Recently, 2 commentaries in this journal highlighted the controversies that surround the resuscitation decision-making process related to extremely premature infants. Silverman15 charged that neonatologists have become self-appointed guardians of the rights of borderline, barely viable neonates and that this decision-making power is trumping the competing rights of families and society. He called for nothing less than a formal national inquiry to address whether opportunism has overwhelmed compassion in the US neonatal intensive care industry. Lorenz16 emphasized that parents are the rightful decision-makers for premature infants and thus the important question becomes how physicians can best counsel parents in a manner that is clear, consistent, accurate, and not overly directive. He recommended more research into the decision-making process, specifically evaluating whether eventually parents are at peace with their decision to initiate or to withhold life support.

It was our experience at Providence St Vincent Medical Center (PSVMC) that the counseling pregnant women received near the threshold of viability (gestational age of 22–26 weeks) varied significantly depending on which physician was caring for each woman and her infant at the time of admission. Health care providers' knowledge and experience related to neonatal outcomes and life support recommendations were uneven; therefore, the consultation process fluctuated with the physician call schedule. This variance created confusion and dissatisfaction among patients, physicians, and nurses. We suspect our experience is shared by other obstetrics and neonatology services. The purpose of this article is to describe the development and implementation of medical staff guidelines for periviability counseling and medical treatment of extremely premature infants.

METHODS

Setting and Design
PSVMC is a tertiary referral center for both high-risk obstetric care and level 3 NICU care. There are ~6000 deliveries and 800 admissions to the NICU per year. Approximately 150 of these infants are born at <1500 g and ~30 infants are admitted to the NICU at 23½ to 26½ weeks of gestation each year.

The departments of obstetrics and neonatology conduct a joint monthly conference that is attended by maternal-fetal medicine specialists (MFM), neonatologists, obstetricians, neonatal nurse practitioners, and nurses from the labor and delivery unit and the NICU. Between June 2002 and July 2003, this monthly meeting served as the forum for a 5-step process designed to produce the periviability guidelines. Attendance at the meetings was voluntary and not monitored strictly; however, the importance of active participation by all PSVMC MFM and neonatologists was emphasized, because these physicians were the primary providers of periviability counseling. Other obstetric and NICU caregivers were invited to participate in an effort to solicit a wider spectrum of experience and opinions. We asked that all physicians and nurses attend enough of the meetings (steps 1 and 2) to feel comfortable contributing to steps 3 and 4.

Step 1: Education
The first goal was to review as a group what we regarded as a representative accurate sample of the published literature regarding mortality and morbidity (particularly neurologic) rates for premature infants born before 27 weeks of gestation or at <1000 g. Our intent was to give providers a basic understanding of this complex literature. In the interest of efficiency, we focused on peer-reviewed articles that were published relatively recently in major obstetric or pediatric journals and were cited frequently in review articles pertaining to neonatal outcomes.2–14

Step 2: Review of Local Practices
At these conferences, we reviewed the current practices at PSVMC, with special emphasis on the variability in provider knowledge of neonatal outcomes. We also discussed the interactions of personal experiences, religious and cultural differences, medical training biases, societal expectations, and medical-legal pressures and how these
affected our practices. For the purpose of clarity and for use in steps 3 and 4, we formed a summary table of survival and neurologic disability rates (Table 1). The survival rates that we estimated from the literature survey took into account the fact that various publications used different denominators in their calculations (eg, all pregnancies, all live births, or all NICU admissions). The Vermont Oxford Network and PSVMC data used in Table 1 included all live births at >500 g when calculating the survival rate and included the combined obstetric and neonatal best estimates of gestational age.

Step 3: Survey
We formulated a survey centered on a theoretical impending delivery at each week of gestation between 22 and 26 weeks, with the purpose of identifying general medical recommendations with which all providers would be comfortable if they were involved directly in the care of the pregnant woman and her infant. The surveys were completed in a voluntary and anonymous manner and only after participation in the education and discussion described in steps 1 and 2. Statistical comparison of the survey results from MFM and neonatologists versus other participants (obstetricians, nurse practitioners, nurse midwives, and nurses) was performed by using \( \chi^2 \) analysis and Student’s \( t \) test.

Step 4: Guideline Formation
We tabulated the results of the all-provider survey described in step 3 and combined them with a concise summary of the neonatal outcome literature reviewed in steps 1 and 2. The PSVMC NICU mortality data were also included. The number of infants at PSVMC assessed for long-term neurodevelopmental outcomes is not yet sufficient to provide reliable estimates; therefore, our own data were not included in the summary. Using the survey results and our understanding of the follow-up literature, we developed medical staff guidelines intended for periviable counseling during pregnancy and medical treatment of extremely premature infants. We encouraged every health care provider to use these guidelines when counseling pregnant women and their families regarding neonatal outcomes, and we recommended that a copy of the guidelines be given to each woman. We also encouraged the nursing staff members to become familiar with the guidelines, because of the recognized informal but important interactions they had with patients. Only pregnant women at 22% to 26% weeks of gestation who were admitted to the labor and delivery unit and were considered to have significant chances of delivering their infants before 27 weeks of gestation were considered potential study subjects. The guidelines focused on survival rates and neurodevelopmental issues, but the neonatologists also discussed thoroughly other common NICU morbidities, such as chronic lung disease and necrotizing enterocolitis.

Step 5: Postconsultation Interview
Three to 4 days after the initial MFM and neonatologist consultations, each woman was asked to participate in a survey designed to assess their perception and comprehension of the counseling process and the medical staff guidelines. Informed consent was obtained before participation, and the PSVMC institutional review board approved the study. The patient survey was administered by a labor and delivery unit ward clerk not involved in patient care. Each interviewer was trained in standard interviewing techniques, including open-ended question delivery and probing without leading. Analysis was blinded with respect to patient identifiers, and clinical data were merged with the interview data on the basis of numeric codes.

RESULTS
Steps 1 and 2: Education and Review of Local Practices
Multidisciplinary meetings were held on a monthly basis from June 2002 through July 2003. All 8 MFM and 16 neonatologists on staff at PSVMC participated. Obstetricians, neonatal nurse practitioners, nurses from the labor and delivery unit and the NICU, and the chairman of the PSVMC bioethics committee were also invited to participate at least enough so that they would be comfortable contributing to steps 3 and 4. Open discussion

| TABLE 1 | Survival and Neurologic Disability Rates Among Extremely Premature Infants, as Used for PSVMC Obstetric and Neonatology Medical Staff Guidelines |
|----------|----------------|----------------|----------------|----------------|----------------|
| <23      | 5              | 8              | 0              | ?              | ?              |
| 23% to 23% | 15             | 32             | 10             | 30–35          | 20–30          |
| 24% to 24% | 40             | 58             | 68             | 25–30          | 20–30          |
| 25% to 25% | 60             | 76             | 74             | 20–25          | 20–30          |
| 26% to 26% | 75             | 83             | 83             | 15–20          | 20             |

Severe disability indicates IQ of <70 (or >2 SD below the mean); cerebral palsy, blindness, and/or deafness. Moderate disability indicates IQ of 70 to 84 (or 1–2 SD below the mean); moderate disorders of motor skills, vision, hearing, academic achievement, social performance, and/or behavior were included in some follow-up references. VON indicates Vermont Oxford Network.
promoted a better understanding of neonatal outcomes, and every effort was made to encourage all providers to participate actively by voicing questions, concerns, and personal experiences.

**Step 3: Survey**

All 8 MFMs and all 16 neonatologists who cared for patients at PSVMC completed the survey. In addition, 20 obstetricians, 4 midwives, 7 neonatal nurse practitioners, 19 obstetric nurses, 32 NICU nurses, and the chairman of the bioethics committee completed the survey. The total number of surveys completed was 107.

Figure 1 summarizes the results of the NICU resuscitation survey, including all participating physicians and nonphysicians. The survey recommendation menu at each week of gestation ranged from strongly discourage resuscitation (choice 1) through strongly encourage resuscitation (choice 5). Purposely, the available choices did not include resuscitation against the parents’ request or no resuscitation despite the parents’ request to resuscitate. This is because the goal of the collaborative project was the formation of consensus guidelines (Table 2) to be used when counseling the family, with consideration of individual circumstances. We were not trying to design practice parameters to mediate disputes. In our experience at PSVMC, the initiation or withholding of NICU care against the parents’ wishes has been quite rare.

Figure 1 shows that the great majority of providers did not recommend resuscitation of premature infants born at <24% weeks of gestation. A substantial majority did recommend resuscitation of premature infants born at ≥25% weeks. At 24% to 24% weeks, 3 providers (3%) strongly discouraged resuscitation, 36 (34%) recommended no resuscitation, 37 (35%) were neutral, 26 (24%) recommended resuscitation, and 5 (5%) strongly encouraged resuscitation.

At PSVMC, women with the possibility of premature birth between 22 and 27 weeks of gestation are treated almost exclusively by MFMs and neonatologists. Typically, these physicians, in conjunction with the pregnant woman, are responsible for final decision-making (eg, whether an operative delivery is performed and whether an infant is placed on mechanical ventilation). Figure 2 summarizes the NICU resuscitation survey for the 8 MFMs and 16 neonatologists who participated in the formation of the guidelines. There were no statistically significant differences between the survey results for the

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**FIGURE 1**

NICU resuscitation survey results for all physicians and nonphysicians. The survey question was as follows: “A pregnant woman with the impending birth of an infant at the listed gestational age is about to deliver. The pregnancy to this point has been uncomplicated and the fetus has been healthy and is of an average size for gestational age. What would be your recommendation at each gestational age? (5 = strongly encourage resuscitation; 4 = recommend resuscitation but would be comfortable with parent’s request to provide comfort care only; 3 = neutral; 2 = recommend against resuscitation but would be comfortable with parent’s request to resuscitate; 1 = strongly discourage resuscitation).” Each solid mark represents 1 vote. The number in the right corner of each box is the percentage of the total vote at each week of gestation.
MFMs and neonatologists versus the other participating caregivers. No MFM or neonatologist recommended resuscitation of infants born at ≤24 6/7 weeks of gestation. A substantial majority did recommend resuscitation of infants born at ≥25 5/7 weeks, and none recommended against resuscitation. At 24 6/7 to 24 6/7 weeks, 8 (33%) recommended no resuscitation, 12 (50%) were neutral, and 4 (17%) recommended resuscitation.
Step 4: Medical Staff Guidelines
Table 2 shows the consensus medical staff guidelines we developed to provide a framework for periviability counseling. During the consultation process, physicians emphasized that many of the percentage figures used for neonatal outcomes were approximate values and needed to be considered in the context of each pregnant woman’s individual clinical circumstances. Close attention was given to relevant issues such as gender, reliability of gestational age estimates, intrauterine growth restriction, and a history of infertility. We made it clear that neonatal outcome reports were influenced strongly by factors such as inherent population differences and length of follow-up monitoring.

The decision to recommend resuscitation of the infant (or not), as determined from step 3, clearly influenced the obstetric care guidelines, particularly the statements regarding whether operative delivery was recommended. The MFM and neonatologist discussed management options with the pregnant woman and her family and provided a recommendation based on their best professional judgment. In an effort to maintain clarity and fairness, this recommendation was provided along with the majority opinion summarized in the periviability guidelines (Table 2). Each physician documented his or her consultation in the chart, with a summary of the clinical situation and the medical care plan for the woman and infant based on the woman’s choice and the physicians’ input. If the woman did not deliver the infant soon, then the clinical situation and consultation process were reassessed and updated regularly as indicated.

Step 5: Postconsultation Interview
One hundred seventy-four pregnant women at 22½ to 26½ weeks of gestation were admitted to the PSVMC labor and delivery unit during the study period of August 21, 2003, to September 30, 2004. Ninety-four women did not exhibit an immediate threat to deliver before 27 weeks of gestation and thus did not receive periviability counseling. Of the 80 women deemed to be at significant risk of delivering their infants before 27 weeks, ~15 did not receive the formal guideline-based counseling because the admitting obstetrician was not aware of the postconsultation interview process. Four women delivered so quickly after admission that the formal counseling was not feasible. Approximately 40 women received the guideline-based counseling but the patient consent and interview process was not activated properly. Only 1 woman declined to be interviewed after engaging in our periviability counseling process.

Twenty women participated in the guideline-based counseling with the MFM and neonatologist and consented to the interview process. The average maternal age was 31 years (range: 20–38 years). It was the first pregnancy for 11 women. The average gestational age at the time of admission was 24½ weeks (range: 21½ to 26½ weeks). Two women delivered their infants before the time of the interview. Table 3 summarizes the survey questions and responses. After periviability counseling, all of the women indicated some understanding of premature infants, and a large majority rated the consultations as useful and consistent from both physicians and nurses. The women felt comfortable asking doctors and nurses questions about obstetric and neonatal issues, and all indicated that they were given enough information to make difficult life support decisions.

DISCUSSION
Physicians and nurses who participate in the medical care of pregnant women presenting at risk for delivery at the edge of viability should possess knowledge and sympathetic understanding of the enormous medical, social, emotional, and financial problems associated with premature infants. Some would argue that we sometimes fall short of this ideal. The American Academy of Pediatrics and the American College of Obstetricians and Gynecologists addressed this matter by stating that pregnant women and their families should be provided with an overview of the potential complications of extreme prematurity and should be informed of the range of survival and long-term morbidity rates. The American Academy of Pediatrics and the American College of Obstetricians and Gynecologists recognized the high rate of neurodevelopmental disabilities among survivors born at 23 to 25 weeks of gestation and, while noting that nondirective counseling is desirable, acknowledged that sometimes more directive counseling is appropriate. A recent survey of New England neonatologists assessed attitudes associated with delivery room decision-making regarding extremely premature infants. There was variation in neonatologists’ beliefs about the gestational bounds of clearly beneficial treatment and attitudes toward parental wishes in the context of uncertainty. Those authors suggested that neonatologists need to make their management recommendations explicit (transparent) and to make the basis for their beliefs clear.

With this in mind, our goals were to educate PSVMC medical and nursing staff members regarding neonatal outcomes, to foster open discussion regarding our responsibilities as providers of high-risk obstetric and NICU care, and to promote rational consensus as a means of communicating clearly with pregnant women during a time of considerable stress and confusion. We acknowledge that morbidity and mortality summary tables possess the risk of oversimplifying or distorting complex outcomes and practice guidelines may not provide enough direction for each clinical circumstance and nuance. We based our outcome tables on survival data from our own institution and the Vermont Oxford Network and on neurologic outcomes reported in fre-
consequently cited, peer-reviewed publications from major obstetric and pediatric journals.\textsuperscript{2–14} Neonatal outcome tables have been used by some NICUs\textsuperscript{23}; to the best of our knowledge, however, a format similar to ours, containing specific consensus recommendations related to the medical care of the mother and infant, has not been published.

The PSVMC MFM and neonatologists recognize the importance of discussing multiple variables other than estimated gestational age when considering NICU outcomes and treatment options (e.g., gender, estimated fetal weight, prenatal steroid therapy, chorioamnionitis, and infertility). Unfortunately, frequently periviability counseling must be performed on an urgent basis under circumstances that are less than ideal (e.g., late-night times, labor pain, fatigue, magnesium sulfate sedation, and an absence of family support). Therefore, we attempted to strike a balance between recognition of pertinent clinical variables and the need for reasonably clear, concise, consensus-based guidelines that summarize complex literature findings and reflect the majority position of the medical staff members. We emphasize that physicians may provide counsel that does not agree completely with the majority position outlined in the guidelines. Physicians must be willing to discuss the inability of current NICU care to prevent all poor outcomes, as well as to offer and to support treatment or comfort-care options that might not match those they would choose personally. This approach implies that our response to uncertainty need not be automatically either promotion of invasive, elaborate, and clinically unproven therapies or withholding of potentially beneficial and life-sustaining therapies.

The initial feedback from affected women indicated that our approach was viewed as highly understandable, useful, consistent, and performed in a comfortable manner (Table 3). Our experience is that pregnant women and families need a clear framework for discussion and want responsible guidance from physicians, an observation supported in another investigation.\textsuperscript{24} The medical staff guidelines are now used by all of our physicians and nurses who participate in the care of pregnant women threatening premature birth before 27 weeks of gestation.

**CONCLUSIONS**

Our medical staff guidelines for periviability pregnancy counseling and medical decision-making regarding the treatment of extremely premature infants have given some clarity and direction to the consultation process and have been well received by pregnant women. We plan to continue enrolling women in this investigation, compiling data from both the 3-day interview and a similar 6-month telephone assessment to understand more fully the effects and utility of the guidelines. The latter inquiry will include the choices the women made.

![Table 3](image-url)
(eg, yes or no to NICU care) and a summary of the outcomes of their infants, which could influence their sentiments.

The medical staff guidelines have been adopted unanimously by our obstetricians and neonatologists because (1) the process respects each woman’s individual circumstances and choice, as well as the physician’s personal counsel, (2) the format summarizes succinctly complex literature data, to provide a rational basis for discussion, and (3) the document provides a consensus statement of what their colleagues recommend. We plan to reevaluate the guidelines on a recurring basis to incorporate new neonatal outcome information and our own site-specific neurodevelopmental data and, if indicated, to resurvey providers on the basis of relevant new information and evidence-based therapies. We urge all hospitals that provide high-risk obstetric and neonatal intensive care to develop and to use similar guidelines based on published reports and local provider experience and consensus.

ACKNOWLEDGMENTS

We acknowledge all of the obstetric and neonatal intensive care providers at PSVMC (Portland, OR) who participated in this project with the constant vision of promoting health, fairness, and rationality while attempting to reduce suffering.

REFERENCES