F I S C A L I M P A C T R E P O R T

SPONSOR Sharer **ORIGINAL DATE** 2/3/16 **LAST UPDATED** _____ **HB** _____

SHORT TITLE Late-Term Abortion Ban **SB** 242

ANALYST Chilton

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY16	FY17	FY18	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total		Minimal	Minimal	Minimal	Recurring	General Fund

(Parenthesis ( ) Indicate Expenditure Decreases)

Relates to SB 243, HB 275

SOURCES OF INFORMATION
LFC Files

Responses Received From
Administrative Office of the Courts (AOC)
Attorney General's Office (AGO)

Responses Not Received From
Department of Health (DOH)

SUMMARY

Synopsis of Bill

Senate Bill 242 changes the Partial Birth Abortion Ban in several ways:

- Changes the title to "Late-term and Partial-Birth Ban Act"
- Expands prohibition to include a ban on late-term abortions.
- Defines "reasonable medical judgment" as a "medical judgment made by a reasonably prudent physician knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved."
- Defines viable as "the state of fetal development when, in reasonable medical judgment, there is a likelihood that the life of the fetus can be sustained outside the woman's uterus with or without artificial support."
- Defines late-term abortion as an abortion performed on a viable fetus after twenty or more weeks of gestation. Viability is defined as the 20th week of pregnancy. The physician must determine under accepted obstetrical and neonatal standards if the fetus is "viable" before performing the procedure, using such specified measures as gestational age, weight and lung maturity.

- States that late-term abortions may be justified by the need save the life of a pregnant woman endangered by a *physical problem* (mental concerns are not mentioned) or the pregnancy is the result of sexual abuse, rape, or incest and states that in this case the physician must "take all reasonable steps to preserve the life and health of the unborn child (if the pregnancy is interrupted because of a physical problem)."
- Removes the exception allowing abortion in the case that "the child will probably have a grave physical or mental defect."
- Allows the following to sue for damages when a person has performed a late-term or partial-birth abortion: the mother, the biological father, the parents of a minor on whom the abortion was performed, unless the pregnancy was caused by an illegal act (e.g., rape) of the person bringing the action, or the person bringing the action had consented to the procedure.
- Defines a physician's violation of the act as a fourth degree felony and prescribes appropriate penalties for a fourth-degree felony.
- Prescribes civil penalties for a physician who performs a late-term abortion of not less than $5,000 fine and not less than one year revocation or suspension of the physician medical license. The NM Medical Board and NM Osteopathic Board are mandated to enforce the provisions of this section regarding discipline of the physician.
- Allows hospitals and individuals to refuse to perform abortions with no recrimination against such an institution or individual. Previously, 2015 HB 390 also specified pharmacists as among those who could refuse to participate in late-term abortion procedures, but pharmacists are not specifically mentioned in this bill, although AOC indicates that the language of SB 242 would include pharmacists among the class of persons who could refuse to participate in pregnancy termination. AOC indicates that this provision would be likely to face legal challenges.
- Notes that if any parts of the act are held invalid, the rest will stand.
- Enacts an emergency clause, requiring that the act take effect immediately.

FISCAL IMPLICATIONS

AOC notes that "There will be a minimal administrative cost for statewide update, distribution and documentation of statutory changes. Any additional fiscal impact on the judiciary would be proportional to the enforcement of this law and commenced prosecutions and the imposition of civil fines, appeals from the same, and legal challenges to the constitutionality of the provisions of SB 242. New laws, amendments to existing laws and new hearings have the potential to increase caseloads in the courts, thus requiring additional resources to handle the increase."

SIGNIFICANT ISSUES

AOC notes the similarity of this bill to 2015's HB 390 with its two committee amendments. Like the amended form of that bill, SB 242 indicates that the only exception to the prohibition on late-term abortion is to preserve the life or *physical* health of the mother. AOC notes that the U.S. Supreme Court has stated that both physical and mental health be considered; AOC indicates that more narrow definitions of "health" have been struck down.

AOC summarizes provisions from the Guttmacher Institute's Brief on "State Policies on Later Abortions" as follows:

In its landmark 1973 abortion cases, the U.S. Supreme Court held that a woman's right to an abortion is not absolute and that states may restrict or ban abortions after fetal viability, provided that their policies meet certain requirements. In these and subsequent decisions, the Court has held that

- even after fetal viability, states may not prohibit abortions "necessary to preserve the life or health" of the woman;
- "health" in this context includes physical and mental health;
- only the physician, in the course of evaluating the specific circumstances of an individual case, can define what constitutes "health" and when a fetus is viable; and
- states may not require additional physicians to confirm the attending physician's judgment that the woman's life or health is at risk in cases of medical emergency.

Although the vast majority of states restrict later-term abortions, many of these restrictions have been struck down. Most often, courts have voided the limitations because they do not contain a health exception; contain an unacceptably narrow health exception; or do not permit a physician to determine viability in each individual case, but rather rely on a rigid construct based on specific weeks of gestation or trimester.

With respect to prescribing penalties for physicians who performed partial- or late-term abortions, the statute would in effect repeal a portion of the Criminal Abortion Statute by removing previous exceptions ("justified medical termination") allowing for abortion when death to the woman, grave impairment would result to the physical or mental health of woman, where child would "probably have a grave" physical or mental defect or where pregnancy resulted because of rape. SB 243 deletes the need for a special hospital board committee as these exceptions would no longer require their review.

RELATES to HB 275, which requires medical care be given to all "born alive infants," defining that term.

RELATES to and partially **CONFLICTS** with SB 243, which makes some of the same and some different changes to the Partial-Birth Abortion Ban Act.

In contrast to SB 243, this bill

- Defines "reasonable medical judgment," using that definition in turn in its definition of "viable."
- Defines viable as when, in reasonable medical judgment, "there is a likelihood that the life of a fetus can be sustained outside the woman's uterus with or without artificial means", whereas the definition in SB 243 states that "viable" means "when the life of the unborn child may be continued *indefinitely* (italics added) outside the womb by natural or artificial life-supportive systems."
- Allows late-term abortion in the case of sexual abuse, incest or rape (SB 243 makes no such allowance).
- States that institutions and individuals may refuse to participate in pregnancy termination without fear of recrimination, where SB 243 does not include this provision.
- Enacts an emergency clause.

OTHER SUBSTANTIVE ISSUES

The bill defines late-term abortion as one occurring "with the intent to destroy a viable fetus of twenty or more weeks gestational age." "Viable," in turn, is defined in the bill as "the state of fetal development when, in a reasonable medical judgment, there is a likelihood that the life of the fetus can be sustained outside the woman's uterus with or without artificial support." "Likelihood" is not defined, and a duration during which that likelihood would persist is not mentioned; i.e., it would be possible that signs of life might persist for minutes or even hours with or without artificial support, with little or no possibility of longer term survival.

A recent consensus statement from the National Institutes of Child Health and Human Development, the American Academy of Pediatrics and the American College of Obstetrics and Gynecology (see attachment) concludes that there is virtually no chance of life before 22 weeks of completed gestation.

The AGO in this regard states that "the definition of "viable" as having a "likelihood" that the life of the fetus can be sustained outside the woman's uterus, is unconstitutionally vague and does not clearly define when this "likelihood" exists. Furthermore, the Supreme Court has defined viability as a "realistic probability" not a "likelihood" of surviving outside the womb. See Casey, 505 U.S. at 870, 112 S. Ct. at 2817 (explaining "that the concept of viability . . . is the time at which there is a realistic possibility of maintaining and nourishing a life outside the womb, so that the independent existence of the second life can in reason and all fairness be the object of state protection that now overrides the rights of the woman")."

Another concern from the Attorney General's Office is that physicians who violated this act would have their license to practice suspended or revoked without apparent due process procedures.

Attachment: Periviable Birth

LAC/jo

Current Commentary

Periviable Birth

Executive Summary of a Joint Workshop by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, Society for Maternal-Fetal Medicine, American Academy of Pediatrics, and American College of Obstetricians and Gynecologists

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VOL. 123, NO. 5, MAY 2014 OBSTETRICS & GYNECOLOGY 1083

This is an executive summary of a workshop on the management and counseling issues of women anticipated to deliver at a periviable gestation (broadly defined as 20 0/7 through 25 6/7 weeks of gestation), and the treatment options for the newborn. Upon review of the available literature, the workshop panel noted that the rates of neonatal survival and neurodevelopmental disabilities among the survivors vary greatly across the periviable gestations and are significantly influenced by the obstetric and neonatal management practices (eg, antenatal steroid, tocolytic agents, and antibiotic administration; cesarean birth; and local protocols for perinatal care, neonatal resuscitation, and intensive care support). These are, in turn, influenced by the variations in local and regional definitions of limits of viability. Because of the complexities in making difficult management decisions, obstetric and neonatal teams should confer prior to meeting with the family, when feasible. Family counseling should be coordinated with the goal of creating mutual trust, respect, and understanding and should incorporate evidence-based counseling methods. Since clinical circumstances can change rapidly with increasing gestational age, counseling should include discussion of the benefits and risks of various maternal and neonatal interventions at the time of counseling. There should be a plan for follow-up counseling as clinical circumstances evolve. The panel proposed a research agenda and recommended developing educational curricula on the care and counseling of families facing the birth of a periviable infant. (Obstet Gynecol 2014;123:1083

The counseling and management of women at risk for delivering near the limit of viability, referred to in this document as the “periviable period” (broadly defined as 20 0/7 weeks through 25 6/7 weeks of gestation), remains one of the most challenging issues faced by obstetricians and neonatologists. When delivery is anticipated or occurs during this period, the health care team and the family must quickly make complex, ethically challenging decisions—often in an emotionally charged and evolving setting. Such decision making continues through the infant’s hospital course in the neonatal intensive care unit (NICU).1

Despite guidelines from professional societies regarding maternal and neonatal care at periviable gestations, many issues remain unresolved.2–4 For example: where should women at risk for periviable birth be cared for; when should tocolytic agents and antenatal corticosteroids be given to delay delivery and to advance fetal lung maturation; when should electronic fetal monitoring be instituted to assess the fetal status; when should cesarean delivery be offered for fetal indications; how should the potential benefits to the infant and the risks to the mother from cesarean birth at a periviable gestation be balanced; when and how should the family be counseled regarding these complex issues and what should the contents of such counseling be; and when and how should decisions regarding initial or continued intensive newborn care versus comfort care be made?

To address these issues, the Society for Maternal- Fetal Medicine, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the Section on Perinatal Pediatrics of the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists convened a joint workshop, which was held concurrently with the annual meeting of the Society for Maternal-Fetal Medicine in San Francisco, California, on February 12–13, 2013. This executive summary reviews the benefits and risks of obstetric and neonatal interventions related to periviable birth, provides an outline for counseling these patients, describes newborn outcomes after periviable birth, and outlines research and educational agendas regarding care and treatment of these patients. Suggested treatment outlines are based on review of the available literature and extrapolation from relevant articles by the expert panel.

DEFINITIONS

There are numerous terms used to refer to preterm delivery at a very early gestational age (eg, extremely low gestational age, extreme preterm, very preterm), at a very small size (extremely low birth weight, micro preemie), of a very immature fetus (immature born, marginally viable), or near the limit of potential survival (margin of viability, border of viability, threshold of viability, periviable).5–13 Each encompasses a gestational age spectrum that includes high rates of mortality and severe morbidities among survivors at the lower end, and significantly higher rates of survival and survival without major disabilities at the upper end. We recognize that there is no ideal definition and that no phrase precisely reflects all components of the epidemiology and the dilemmas associated with decision making during this time frame. We have opted for the phrase “periviable birth,” defined as delivery occurring from 20 0/7 weeks through 25 6/7 weeks of gestation, to reflect the gestational age range in which survival rates range Morbidity and Mortality Rates and Ethical Dilemmas

Approximately 0.4–0.5% of all births occur at or before 27 weeks of gestation, and these account for over 40% of infant deaths14 and most neonatal deaths. Infants born at 20 weeks and 21 weeks of gestation do not survive, irrespective of resuscitation efforts. The survival data for births at 22, 23, 24, and 25 weeks of gestation (excluding infants with birth weight lower than 401 g, greater than 1000 g, or higher than the 97th percentile for gestational age; infants with ambiguous genitalia or major anomalies; and survivors not requiring mechanical ventilation) reported from the NICHD Neonatal Research Network were 6%, 26%, 55%, and 72%, respectively, at initial discharge from the hospital.15 Investigators from the same network later reported an additional 2.2% of extremely low gestational age

infants (before 27 weeks and birth weight less than 1000 g) died after discharge and before 22 months of age.16 Many studies have noted that from the mid 1980s through the late 2000s, there has been an increasing rate of survival after periviable birth.15–30 However, survival data for periviable births from the reports published since 2000 show remarkable variability in outcomes among studies15,21,24–29 (Table 1). There are multiple reasons for this variation, some of which include nonmodifiable factors (eg, fetal sex and weight, singleton birth), modifiable factors (eg, intent to intervene, antenatal corticosteroid administration, lifesustaining interventions at birth), and study design and reporting features (eg, single-center, regional, or national data; definition of mortality; inclusion of all live births versus resuscitated newborns versus only those admitted to a NICU) (Table 2). Other factors that might affect the reported survival are local practices and protocols for withholding or withdrawing intensive care after birth.

Data regarding long-term outcomes are likewise complex. Woods et al reported the outcomes at 30 months of age for infants born at or before 23 weeks, at 24 weeks, and at 25 weeks of gestation in 1995 in the United Kingdom and Ireland.31 These authors found a progressive decline in the proportion of children with "severe" disability (Bayley Scales of Infant Development-II score 54 or lower) with increasing gestational age, ranging from 27% at 23 weeks to 19% at 24 weeks and 17% at 25 weeks of gestation. In the same cohort followed to 6 years of age, similar trends in the rates of "overall disability" (a combined measure of cognition, neuromotor function, hearing, and vision) were evident; 25%, 29%, and 18% at 23, 24, and 25 weeks of gestation, respectively.32 A recent systematic review, published since the workshop was held, evaluated long-term neurodevelopmental impairment at 4–8 years among survivors born between 22 weeks and 25 weeks of gestation. The risk of moderate-to-severe neurodevelopmental impairment decreased 6% (95% Sample Size Survival (%) 22 weeks 23 weeks 24 weeks 25 weeks 104 (2001–2003) 31 114 40 4,446 51 208 41 76 82 80 134 33 58 87 4,160 6 26 55 72 3,048 5 28 60 VOL. 123, NO. 5, MAY 2014 Raju et al Periviable Birth: Management and Counseling 1085 confidence interval [CI], 1.7–10.3%) for each week gained in gestational age.33 However, morbidities were common and the confidence intervals for point estimates were wide: 43% (21–69%), 40% (27–54%), 28% (18–41%), and 24% (17–32%) at 22, 23, 24 and 25 weeks of gestational age, respectively. Importantly, survival after birth at 22 weeks and 23 weeks of gestation was uncommon (n512 and n575, respectively). Severe neurodevelopmental impairment did not significantly decrease with increasing gestational age at birth.

When counseling parents, it is appropriate to present the data regarding the rate of survival and long-term disabilities separately, since the parents' perspectives and the importance they give these may be different. Physicians should recognize that the parents' views on what is a "severe" disability may be different from those of the researchers or clinicians, who traditionally report the combination of death and severe disability together. Coping with a child's behavior problem, considered a "minor" disability in the published literature, may be difficult to handle for some families, while other families may be able to adapt more readily to disabilities typically considered to be major (eg, cerebral palsy).

An appreciation of the complex issues discussed earlier will help health care providers to engage in counseling efforts without being biased by one's personal values and experiences. Future studies are

needed to develop accurate prediction models to permit better counseling of families based on their individual risks, rather than based on gestational age alone.

OBSTETRIC CARE

Ideally, all periviable births should occur in tertiary care centers with expertise in maternal-fetal medicine and the availability of the highest level of neonatal intensive care services. Maternity hospitals without such resources should develop partnerships with a tertiary care center, and the latter should maintain requisite resources, including timely availability of needed experts to care for the mother, her fetus, and the newborn infant. Protocols should be developed to clarify the processes for consultation and transfer as well as management prior to and during transfer (eg, antenatal corticosteroid administration for fetal maturation, magnesium sulfate for neuroprophylaxis, antibiotics for infection and group B streptococcus [GBS] prophylaxis).

Obstetric interventions at periviable gestations have included measures to delay delivery and to improve newborn outcomes when delivery is anticipated, for example: emergent cerclage, tocolytic therapy to delay delivery for antenatal steroid benefit, Table 2. Factors That Affect Survival Outcomes and Estimates Among Periviable Births Variable Effect Data source International, national, regional, single institution data reflect variations in regional and local practices. Cohort selection Postnatal transportation and exclusion of inborn newborns not surviving to NICU admission results in inclusion of those with higher potential for survival. Inclusion of nonresuscitated infants reduces overall rates of survival. Inclusion of stillbirths reduces survival potential due to lack of resuscitation. Inclusion of anomalous infants may decrease survival estimate due to inclusion of lethal anomalies. Gestational age assignment In vitro fertilization and ovulation induction provide accurate gestational age assignment. Last menstrual period estimates conception on day 14. Ultrasound initially performed at less than 24 weeks of gestation estimates gestational age within 5–10 days. Nonmodifiable risk factors Race/ethnicity, plurality (singleton versus multiple gestation), sex, birth weight for gestational age all affect newborn survival but are not modifiable. Modifiable obstetric practices Antenatal interventions to improve outcomes (eg, corticosteroids, tocolysis, antibiotics, magnesium for neuroprotection, fetal monitoring, willingness to perform cesarean delivery for fetal benefit). Modifiable neonatal practices Initial resuscitation and care (eg, approaches to ventilation and oxygenation, nutritional support, and treatment of newborn infections). Approaches to comfort care Influenced by institutional and physician philosophies, parental wishes, and religious convictions. Regional/hospital legal and practice guidelines Policies concerning neonatal resuscitation; “self-fulfilling prophecy” of nonintervention/initial comfort care. NICU, neonatal intensive care unit. 1086 Raju et al Periviable Birth: Management and Counseling OBSTETRICS & GYNECOLOGY antibiotics for GBS prophylaxis or to reduce infection and prolong latency after preterm premature rupture of the membranes (PROM), antenatal corticosteroids to enhance fetal maturation, and a willingness to intervene to prevent stillbirth or fetal trauma at delivery. The potential effect of these interventions on newborn outcomes as well as maternal well-being varies according to individual circumstances and with advancing gestational age.

Evidence-based data regarding obstetric interventions for those delivering at 20–25 weeks of gestation are limited, since these gestational ages were considered nonviable in the 1970s and early 1980s when

many studies on these interventions for anticipated preterm births were conducted. Further, because a small number of women actually deliver at or before 25 weeks of gestation, most studies and meta-analyses involving these patients lack power to assess the effect of such interventions.

The workshop panel reviewed available literature and considered interventions and the levels of supporting evidence across the spectrum of periviable gestations.34–50 Some of these interventions pose little risk to the mother while others impose a significant burden.

Tocolytic therapy is proposed to reduce uterine activity for the purpose of delaying delivery to increase the time for antenatal corticosteroid effects. However, data regarding currently available therapeutic tocolytic agents fail to consistently demonstrate either pregnancy prolongation beyond 24–48 hours or newborn benefits, and no studies specifically address women with preterm labor or PROM at 20– 25 weeks of gestation.

Physical examination–indicated cervical cerclage is performed when the fetal membranes are seen to bulge to or past the external cervical os in the absence of contractions. Observational studies describe that physical examination–indicated cerclage, performed at an average gestational age of 22 weeks, can be associated with a mean pregnancy prolongation of 7–9 weeks, compared with 2–3 weeks for those treated without cerclage placement, as well as increased live birth and neonatal survival.35–38

Antenatal corticosteroid administration is one of the most effective antenatal interventions to improve infant outcomes.39–43 Lung tissue in explant culture from 12–24-week human fetuses has been shown to respond to corticosteroids with an increase in epithelial maturation and the appearance of lamellar bodies. 39 Data from the Eunice Kennedy Shriver Neonatal Research Network observational cohort revealed death or neurodevelopmental impairment at 18–22 months to be lower for infants exposed to antenatal corticosteroids and born at 23 weeks of gestation (83.4% vs 90.5%; adjusted odds ratio [AOR] 0.58 [95% CI, 0.42–0.80]), at 24 weeks (68.4% vs 80.3%; AOR 0.62 [95% CI, 0.49–0.78]), and at 25 weeks (52.7% vs 67.9%; AOR 0.61 [95% CI, 0.50–0.74]), but not at 22 weeks of gestation (90.2% vs 93.1%; AOR 0.80 [95% CI, 0.29–2.21]).40 Death, intraventricular hemorrhage (IVH), or periventricular leukomalacia and death or necrotizing enterocolitis were also significantly less frequent among infants born at 23, 24, and 25 weeks of gestation after antenatal corticosteroid exposure. The benefits regarding reduced death persisted through 18–22 months (OR 0.59 [95% CI, 0.53–0.65]) for infants born at 22–25 weeks of gestation. Similarly, Mori et al reported that infants exposed to antenatal corticosteroids before birth at 24–25 weeks of gestation had less frequent respiratory distress syndrome (OR 0.77 [95% CI, 0.60–0.98]), less frequent severe IVH (OR 0.49 [95% CI, 0.36–0.67]) and lower mortality (OR 0.65 [95% CI, 0.5–0.86]) compared with unexposed infants at the same gestations.41 In fact, even among the infants born at 22–23 weeks of gestation, antenatal corticosteroid exposure decreased mortality rates (OR 0.72 [95% CI, 0.53–0.97]). In 2008, Tyson et al estimated that antenatal corticosteroid administration increased the "functional" (in terms of maturity) gestational age of those born at 22–25 weeks by 1.1, 1.2, and 1.3 weeks for survival, death or profound impairment, and death or any impairment, respectively.25

Magnesium sulfate for neuroprotection has been studied among women at risk for imminent early preterm birth in five randomized controlled trials, including women recruited at 24–25 weeks of

gestation.44 Overall, magnesium sulfate treatment reduced cerebral palsy (relative risk [RR] 0.68 [95% CI, 0.54–0.87]) and substantial gross motor dysfunction (RR 0.61 [95% CI, 0.44–0.85]) among survivors without increasing mortality (RR 1.04 [95% CI, 0.92–1.17]). Similar effects were seen with administration before 30 weeks of gestation for any cerebral palsy (RR 0.69 [95% CI, 0.52–0.92]), moderate-to-severe cerebral palsy (RR 0.54 [95% CI, 0.36–0.80]), and death (RR 1.00 [95% CI, 0.87–1.15]). However, data specific to those treated at 20–25 weeks are not available.

Intrapartum antibiotic prophylaxis against GBS reduces newborn infection, and antibiotic treatment during conservative management of preterm PROM both prolongs pregnancy and reduces newborn infections. Studies of these interventions have included only limited numbers of women near the limit of viability and specific data for those at 20–25 weeks of gestation are lacking. Management and Counseling 1087 Cesarean Delivery If a decision is made to provide intensive interventions for an infant in the periviable period, a second decision is required regarding the mode of delivery. This second decision can be divided in two: Is routine cesarean delivery appropriate for all such pregnancies? And, if not, will emergency cesarean delivery be considered to prevent trauma, stillbirth, or fetal asphyxia for specific indications? The published literature regarding cesarean delivery for periviable birth is limited by a lack of adequate data reflecting the causes, interventions, and contribution of current practices on outcomes related to cesarean delivery for periviable births.45–49 Further, randomized controlled trials of adequate size regarding planned cesarean delivery compared with planned vaginal delivery for periviable births have not been performed. Currently available data do not consistently support routine cesarean delivery to improve perinatal mortality or neurologic outcomes for early preterm infants.45 There is no clear evidence that routinely performed cesarean delivery improves survival or long-term outcomes with growth restriction, and data suggesting improved outcomes with cesarean delivery for fetal malpresentation are limited.49 Alternatively, cesarean delivery in the periviable period incurs greater maternal morbidity, both immediately postoperatively and for future pregnancies, which must be considered in the risk–benefit balance when counseling women.

Within this framework, a team approach to counseling is recommended for those presenting at 20 or more weeks of gestation. The use of different obstetric interventions should be based on an individual analysis of the risks and benefits. When death is anticipated, the parents should be informed about the option of termination of pregnancy if this is consistent with regional statutes. A plan for reevaluation and follow-up counseling should also be in place. Importantly, providers and families should understand that initiation of intervention to enhance outcomes (eg, antibiotics for preterm PROM, antenatal corticosteroid administration) does not mandate that all other aggressive interventions (eg, cesarean delivery) be undertaken regardless of clinical circumstances in the periviable period.

Optimally, guidance regarding perinatal management of anticipated or imminent periviable birth would be offered based on a firm knowledge of the likelihood of infant survival and a known likelihood of long-term morbidities. Gestational age alone and currently available predictive algorithms do not provide information that is sufficiently accurate or generalizable. Regardless of local or regional differences, there are substantial current data supporting that infants born at or before 21 weeks of gestation do not survive after birth, regardless of aggressive intervention, and that the majority of infants born at or beyond 24 weeks of gestation do survive if live-born and resuscitated. Alternatively, at 22–23 weeks of

gestation, the majority of live-born resuscitated infants will not survive, and it is likely that local and other individual factors will have the greatest effect on outcomes for these infants born at the cusp of viability. In certain circumstances (eg, unknown or irregular menstrual history with late prenatal care), gestational age cannot be determined accurately. In this circumstance, gestational age is estimated based on data available when periviable birth is imminent, and the accuracy of this estimate should be considered during counseling and decision making. Table 3 offers guidance based on current evidence and expert opinion. In many cases, data specific to the periviable period are lacking, so guidance is offered based on extrapolation from available data regarding interventions at more advanced gestational ages. Interventions to delay delivery prior to 22 weeks of gestation may not succeed in prolongation of pregnancy. In such circumstances, it is appropriate to withhold continued intrapartum interventions for fetal benefit, neonatal resuscitation, or both, despite initiation of aggressive therapy. With delivery before 22 weeks of gestation, interventions that significantly increase maternal morbidities (eg, cesarean delivery) should be avoided, where possible, and the live-born infants should be offered comfort care. Because most newborns at 24– 25 weeks of gestation will survive if resuscitated, efforts to prolong pregnancy, intrapartum interventions for fetal benefit, and neonatal resuscitation should generally be offered, if appropriate. At 22–23 weeks of gestation, management decisions will need to be made based on whether the fetus is considered potentially viable based on individual clinical circumstances and whether the family desires aggressive measures to improve the potential for newborn survival after birth. In general, those born at 23 weeks of gestation should be considered potentially viable, as survival with resuscitation is 26–28% or more. Those considered nonviable at 22–23 weeks of gestation can be treated similarly to pregnancies at 20–21 weeks of gestation, while those considered potentially viable should be treated in a manner consistent with similar pregnancies at 24–25 weeks of gestation. If feasible, delivery of potentially viable infants should be undertaken in settings in which resources are available to care for extremely small and immature infants. This approach has the potential to increase the opportunity for survival and reduce morbidities among survivors.

NEWBORN CARE

Optimally, decisions regarding newborn resuscitation will be made after family counseling. Such counseling cannot be provided before delivery in all cases, as periviable birth often occurs emergently. Where detailed family counseling and input cannot be accomplished before delivery, follow-up counseling should be performed after initial newborn evaluation and care and should incorporate information available, such as the newborn's initial response to intervention. It is emphasized that preterm infants born in the periviable period do not survive without life-sustaining interventions after birth, regardless of obstetric interventions.

Life-Sustaining Interventions

It is expected that the team responsible for stabilizing the periviable infant will have successfully completed training provided by the Neonatal Resuscitation Program and be competent to implement all of the components of the International Liaison Committee on Resuscitation neonatal guidelines.51 It is helpful to carry out simulated scenarios to make sure the processes are implemented smoothly.

Elements of successful stabilization include a preresuscitation checklist to evaluate equipment functionality, clearly assigned roles and responsibilities for each person involved in newborn resuscitation, and adherence to the Neonatal Resuscitation Program algorithm. 52 After stabilization, a debriefing session can provide time for self-reflection and help improve the function of the group for future resuscitations. The goal of the initial stabilization of the periviable infant is no different from that for an infant at a more advanced gestational age. However, because of extreme fetal immaturity and small size, there are special considerations (Table 4). Between 22 weeks and 25 weeks of gestation, there may be mitigating factors (eg, intrauterine growth restriction, small fetal size, the presence of fetal malformations or aneuploidy, and pulmonary hypoplasia due to prolonged membrane rupture) that will affect the potential for survival and the determination of viability (Table 2). The majority of survivors born at 25 6/7 weeks of gestation or less will incur major morbidities, regardless of gestational age at birth. † Infants born before 22 0/7 weeks of gestation are generally considered nonviable. Data from recent large studies suggest survival with delivery at 22 0/7 weeks through 22 6/7 weeks to be 5–6%.25,27 With survival rates of approximately 26–28% and higher, infants born at 23 0/7 weeks through 25 6/7 weeks of gestation are generally considered potentially viable (Tables 1 and 2). ‡ Group B streptococcus carrier or carrier status unknown. § For example, persistently abnormal fetal heart rate patterns or biophysical testing (Category II–III). The feasibility of enhancing placental transfusion by delaying cord clamping for up to 30 seconds should be explored. Neonatologists, neonatal fellows, or senior respiratory therapists, if available, should intubate these newborns to keep the number of intubation attempts to a minimum. If effective pulmonary ventilation is established, cardiopulmonary resuscitation (CPR) is rarely needed. In one study, the chance of disability-free survival was only 14% in extremely low birth weight infants who attained a 5-minute Apgar score less than 2 after CPR in the delivery room, indicating that prolonged CPR is a marker for higher mortality rates.52

Hypothermia is a major threat to the survival of a periviable newborn. In a cohort of over 500 infants born at or before 24 weeks of gestation, 72% had an admission temperature below 36°C and 34% were below 34°C.53 For every 1°C decrease in admission temperature, the odds of late-onset sepsis increased by 11% (OR 1.11; 95% CI, 1.02–1.20), and risk of death increased by 28% (OR 1.28; 95% CI, 1.16–1.41). The World Health Organization and the International Liaison Committee on Resuscitation recommend that the delivery room should be at least 25°C (77°F) to prevent neonatal hypothermia.54 Other steps include using wool or plastic hats, wrapping with polyethylene occlusive, and using a thermal gel mattress.

The Golden Hours

Some experts consider the first 48–72 hours after resuscitation of extremely premature infants as “golden hours” during which infants appear to transition from intrauterine to extrauterine life. Apparent stability is often followed by deterioration, most likely due to failure of multiple organ systems and in some cases aggravated by hypothermia. Even if hypothermia is prevented in the delivery room, many periviable infants become hypothermic during transfer to the NICU, potentially compounding metabolic acidosis. The lungs of such infants may be so immature that it may be difficult or impossible to ventilate them. Over half of preterm infants at periviable gestations manifest low mean blood pressure values during the first 3 days. Since there are no evidence-based guidelines for either defining “hypotension” or

its treatment, the health care team should assess the overall status of the infant prior to deciding on fluid, medication, and other interventions. However, since physiological functions are interconnected, management of one “clinical problem” may affect others. For instance, an attempt to correct serum electrolyte imbalance might lead to fluid overload and adversely affect the respiratory and cardiovascular functions. Thus, one should plan for vigilant monitoring to assess rapidly changing physiological functions and to fine-tune management options.

The First Week

Critical to the continued survival of the periviable infant are respiratory and cardiovascular support; fluid, electrolyte, and nutritional management; treatment of acidbase imbalances; and utilization of cerebral protection measures.27 Periviable infants require all components of intensive care, but their needs are often more acute with a narrow margin for error. For instance, because of extreme thinness of the skin and subcutaneous tissue, there is a risk of profound water loss unless a neutral thermal temperature environment with high humidity is maintained. Slight imbalance in administered fluid volume could compromise cardiac, respiratory, and renal functions. The role of noninvasive respiratory management in improving outcomes has not been well-studied in periviable infants.

Intracranial hemorrhage is a major neurological complication in the first week of life for periviable infants. Antenatal corticosteroids are known to reduce the occurrence of patent ductus arteriosus and IVH.41–43,55–59 Systematic reviews and meta-analyses of the studies of prophylactic postnatal indomethacin have confirmed the significant reduction in severe IVH. In 14 trials including over 2,500 newborns, a 35% reduction in severe IVH was evident (RR 0.66 [95% CI, 0.53–0.82], P,.001).58 However, a well-conducted study of prophylactic indomethacin did not show a benefit on neurodevelopmental outcomes, despite a reduction in severe IVH (Grades 3 and 4) from 13% to 9%.59 The demonstrated reduction in severe IVH, serious pulmonary hemorrhage, and the need for surgical ligation of patent ductus arteriosus59 may well be considered significant benefits by families.

Optimal nutrition is of critical importance to the periviable infant, as is the provision of human milk, which has been shown to decrease necrotizing enterocolitis and mortality rates. Initial intravenous therapy should contain amino acids, and optimal total parenteral nutrition should be started in the first 24 hours after birth. Mothers should be encouraged and taught to express their breast milk. Breast milk expression within 6 hours of delivery is associated with increased production and a longer duration of breast milk feeding. Delay of enteral feeding for a prolonged period is no longer indicated, as early institution of trophic feeds has been demonstrated to be beneficial.

While there is intrainstitutional and interinstitutional variation regarding how the components of intensive care management for the periviable infant are administered, the effect of such practice variations on survival and morbidity rates needs to be assessed.

COUNSELING

The goal of family counseling regarding anticipated or imminent periviable birth is to provide objective information in a compassionate manner, to permit shared decision making, and to support the family.

While developing a standardized approach to counseling is important, there cannot be a single approach for all families. The health care team should be prepared to tailor their approach and language to family needs and preferences (Table 5). Counseling should be a bi-directional, collaborative, and ongoing process. Often, families in crisis do not recall many key components of the counseling. Some parents only want to know "the big picture," while others wish to receive detailed information and statistics.60 Counseling of the pregnant woman can be directive when appropriate (Table 5).50 Some families want to be directed in their decision making, whereas others want to play an active role in making their own decisions. Some parents wish other family members or key supporters to participate in the process. Counseling should continue after the birth of the infant, preferably using designated personnel to update the family during the first hours and days after delivery.

Components of Counseling

Critical components in counseling will vary depending upon whether it is done before birth, after birth, or both; the likelihood of survival; and the likelihood of long-term disability. Depending upon the underlying cause of imminent periviable delivery, the discussion may include the benefits and risks of various obstetric interventions and the utility and timing of transfer to a tertiary care obstetric and neonatal facility. Discussion of the alternatives to and rationale for or against active maternal and neonatal intervention are appropriate. Institutional, regional, or national data regarding outcomes should be provided as available. Although there are visual and Internet tools that augment counseling, their effect on patient satisfaction, understanding, and decision-making have not been well-studied.

Depending on circumstances, discussion of options for redirecting or withdrawing life-sustaining interventions can be brought up either at the initial meeting or at a subsequent meeting. Whenever comfort care is offered, it should be clarified that appearance at birth and Apgar scores are of limited prognostic value, and that comfort care is an approach to caring for the newborn rather than being considered "no care." Health care providers should avoid statements such as "doing everything," "the parents want nothing done," or "there is nothing we can do." Provision of comprehensive palliative and family-centered support is a very important aspect of medical care.

It should be emphasized that management decisions are not necessarily irrevocable. Interventions aimed at improving survival may be initiated prenatally, but a final decision to not institute lifesustaining interventions at the time of delivery can still be appropriate, particularly if the shared decision is that the predicted likelihood of newborn complications that may affect survival and adverse long-term outcomes is considered to be too high. The shared decision regarding management may change with time, and the team should not be "locked" into previous decisions, particularly when clinical circumstances change.

EDUCATIONAL NEEDS AND KNOWLEDGE GAPS

Table 6 outlines the recommendations for research and education developed during the workshop. While this listing is not complete, we anticipate that it can provide guidance in setting priorities for research and education regarding care and counseling regarding periviable birth.

Perhaps the most controversial aspect of the workshop, and difficult aspect of caring for a woman at risk for periviable birth and her periviable newborn, is the lack of highly predictive models for infant morbidities and mortality rates. Estimated gestational age is available before birth based on menstrual dating, ultrasound, or both, but the actual conception date is rarely known. The division between one week and the next is an arbitrary cut-off that does not reflect continuous growth and maturation (eg, a 23 6/7-week and a 24 0/7-week infant [1 day discrepant] are likely more similar in size and maturity than a 23 0/7-week infant and a 24 6/7-week infant [13 days discrepant]). While fetal sex, plurality, and antenatal treatments (eg, antenatal corticosteroids, magnesium sulfate for neuroprotection, antibiotic treatment) can be known with near certainty, other factors such as birth weight can only be estimated before delivery. Similarly, the response of an individual newborn to resuscitative efforts cannot be reliably predicted before birth. Published long-term follow-up outcome data reflect the response of the newborn to interventions that may no longer be in place, or may not reflect newer practices (eg, oscillator and nitric oxide ventilation therapy). While the group consensus was that counseling and treatment should optimally be based on a more refined understanding of an individual infant's likelihood of adverse outcomes, currently available predictive models using individual parameters are not known to be highly accurate. The development of accurate and precise predictive models based on ascertainable and accurate measures, which utilize updated and current outcome data, is an area of particular need.

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