Policy Change for Infants Born at the “Cusp of Viability”: A Canadian NICU Experience

abstract

Resuscitation and life-support treatments for infants born at the “cusp of viability” continue to be subject to clinical and ethical debate. Reported positive outcomes for these infants led our Neonatal Program to critically review our historic practice of discouraging resuscitation of infants born at <24 weeks gestational age. This practice change required a multifaceted, collaborative approach including neonatal, perinatal, and obstetric efforts. An exceptional experience was the formation of a dedicated working group that included invaluable input from parents who had lived the NICU experience. The inclusion of family members in the development of clinical policy was a novel experience for NICU staff, which we feel ultimately resulted in a more ethically sound approach to the care of these infants and their families. In this article, we explore our experience of the process of policy change, which although detailed and transparent was also complex and challenging in development and implementation. Pediatrics 2014;134:e1405–e1410
Advances in neonatal intensive care have led to increased survival of infants born extremely premature. These infants are at high risk of long-term health problems and developmental challenges. The contemporary “cusp of viability” in some countries with technologically advanced health care systems is considered to be 22 to 24 weeks’ gestational age. From a review of the literature, it is evident that resuscitation and treatment of this gestational age group continue to receive clinical scrutiny and ethical dispute.1-4 Finding the balance between an individual infant’s best interest, as a standard for ethical decision-making in the care of the newborn, and other ethically valid interests might be difficult in actual clinical practice.5,6 Moreover, resolving what actually constitutes an infant’s best interest is a subject of ethical debate.5 An emergent theme is that decision-making must incorporate informed consent based on professional standards as well as parental values and beliefs.7,8 A “negotiated model,” as an alternative to an “expertise model,” has been proposed as an ethically appropriate approach to decision-making.9 An expertise model privileges health professionals’ medical judgment such that best interest is actualized on the basis of an infant’s medical prognosis and response to medical treatment. In comparison, a negotiated model incorporates parental values and input throughout decision-making, in addition to acknowledging the objective medical facts and health professionals’ values.9,10 Negotiation thus means more than respecting parents’ rights in decision-making. It means involving parents in the process of decision-making even if a unified and valid medical plan has yet to be formulated.

Health professionals tend to rely on guidelines to give clarity and direction, to summarize complex literature, to promote rationale consensus, and to culminate consistency in practice.11 For ethical decision-making, however, there is no universal agreement on the clinical approach to resuscitation and treatment decisions at birth. Varying guidelines exist. The most recent Canadian Pediatric Society position statement supports active treatment at 23 weeks’ gestation provided decisions are individualized for each infant and his/her family, while recommending a non-interventional approach for infants born at 22 weeks’ gestation.12 Considerable debate and controversy surround this position statement. Some clinicians have requested the statement to be withdrawn or revised, arguing that the recommendations are unsupported by the literature and lack explicit ethical underpinnings.13 In contrast, the American Academy of Pediatrics does not give specific criteria for the initiation of resuscitation for extremely premature infants but rather proposes general guidelines for consideration.14 The Nuffield Council on Bioethics proposes that a complete ban on intensive care is unjustifiable at 22 to 23 weeks’ gestation, and that resuscitation can be offered for these infants upon parental requests if the clinician agrees that it is in the infant’s best interest.15 Comparison of guidelines and statements is somewhat problematic because each reflect different time periods that do not necessarily correlate with institution-specific factors nor general advances in medical treatments. In addition, there is no evidence on how formal guidelines are followed in practice across disparate legal jurisdictions.

OUR LOCAL HISTORY: THE GROUND FOR PRACTICE CHANGE

A local population–based study at our institution during the 1980s to 1990s revealed poor outcomes when resuscitation was routinely offered to all infants weighing <500 g.16 In response, the practice in our unit from the 1990s to mid-2000s was to strongly counsel families toward compassionate care if their infant was born before 24 weeks’ gestation and/or with a birth weight of <500 g.

The literature in the 2000s reported improving survival rates to discharge for infants born at 23 weeks’ gestation, ranging from ~40% to 75%.17-21 Centers with the highest reported survival rates were those with a “proactive” approach that provided practices such as transfer of high-risk mothers to a tertiary care center, early antenatal corticosteroids, comprehensive antenatal counseling, and attendance of the NICU team at deliveries. During this time, our center did not report any survivors born at 23 weeks’ gestational age, reflecting our consensus practice to discourage resuscitation of infants born at <24 weeks’ gestational age.

In the late 2000s, a gradual change in clinical approach to the immediate management of neonates born at 23 weeks’ gestation developed, although in an ad hoc manner. This change resulted from the growing literature reports of increased survival rates at 23 weeks’ gestation and appointments of new NICU staff physicians with experience of successful management of such infants. Consequently, progressively more infants born at 23 weeks’ gestation were resuscitated and admitted to the NICU.

This informal change in practice was challenged by a lack of formal policy change in addition to other complexities, such as the NICU’s multidisciplinary team environment with varying experiences and expectations for such immature infants. Overall, the result was inconsistency in the approach to antenatal counseling and clinical management, contributing to confusion, frustration, and distress for families and staff.

THE 23 WEEKS WORKING GROUP

The challenges encountered with the management of infants born at 23 weeks’ gestation led our Neonatal Program to critically review our clinical practices
for care related to this gestational age group. From review of the literature and preliminary discussions among the clinical team, the following was proposed: resuscitation at 23 weeks’ gestation is a reasonable option and the former accepted policy and practice to counsel toward compassionate care should be changed. Our multidisciplinary health professional team felt strongly that parental input should be obtained before embarking on such a change of practice. The NICU Family Advisory Care Team (FACT) was approached as a parent source to get involved in the process of policy change.

FACT was established in 2009 and includes 11 parents who have lived the NICU experience in addition to 11 NICU staff and hospital administrators. The team has monthly meetings with the mandate of supporting activities that assist in moving toward a family-integrated approach to care in the NICU. The parent members of FACT are a group of committed parents who are strong, thoughtful advocates for infants and their families in the NICU. They voluntarily give their time to review aspects of NICU care to enhance the quality of care for infants and their families. Although the parent members of FACT do not represent the total spectrum of NICU families, they do comprise various ethnic, religious, socioeconomic, and educational backgrounds. Obtaining a representative sample of NICU parents is an ongoing challenge for FACT, given that parents who face economic hardships, social challenges, or other issues are generally harder to engage in volunteer activities. Still, we consider FACT parents to have had meaningful experiences in the NICU and thus offer a valuable, and often unique, perspective to matters pertaining to NICU care.

From discussions with FACT, we formed the 23 Weeks Working Group (23 WWG) to develop policy for the care of infants born at 23 weeks’ gestation. This 18-member working group had an official family member representative from FACT in addition to an inclusive multidisciplinary staff attendance composed of staff physicians (neonatology, perinatology, and obstetrics), neonatal nurse practitioners, bedside nurses, social workers, a clinical ethicist, and learners. Although we realized that the name “23 Weeks Working Group” focuses exclusively on gestational age, by consensus it was felt that this title best described the clinical issue that was causing staff and family distress. Gestational age group thresholds certainly should not be the only clinical factor to guide treatment decisions, given measurement errors in assessing pregnancy gestation and the existence of other important prognostication factors. Nevertheless, in clinical practice, gestational age is often the first and sometimes only piece of information made available to the NICU team and serves as a pivot point for initiating a discussion with a family that leads to a treatment plan for their infant. FACT was involved with the 23 WWG through the family member representative as well as through combined 23 WWG and FACT meetings.

DISCUSSIONS BETWEEN PATIENT FAMILIES AND HEALTH PROFESSIONALS

For the medical staff, sharing experiences and presenting dilemmas faced by the NICU team formally to a parent group was a novel experience. Neonatologists, as experts, more usually review the literature, critically appraise it in relation to their unique work environment, develop new policies, and implement the changes. Family involvement has traditionally been minimal, usually including a parent who is nominally on a committee reviewing practice change or simply informing a parent group of a practice change already made. As such, the involvement of family members in the actual process of policy development, in a more negotiated fashion, was uniquely felt.

The presentations to FACT of the medical literature, our past experiences, and the more recent haphazard change in practice were emotionally charged, highly informative, and educational for both parents and staff. Some of the parents had in fact been caught in the “23 week dilemma” and had waited anxiously to get past that critical gestational age group cutoff before their child would be “eligible” for attempted resuscitation and admission to the NICU. They bravely voiced their recollections and emotional responses to that experience. FACT parents relatively quickly appreciated that the medical team was caught in a complex dilemma in which many clinical factors had to be blended with family beliefs and preferences, and that there was no single right answer available for all cases. The parents understood that if our policy and practice changed, we could not guarantee that our clinical results would be similar to other centers where such a practice existed. FACT parents expressed their gratitude at being asked for their opinion and involvement in examining such a complex situation. In the words of 1 parent, “This is what we signed up for.” It became clear as a result of these discussions that if there was any possibility of survival at <24 weeks’ gestation, parents were entitled to know this. FACT parents were clear that health professionals should not make unilateral decisions to limit or withhold life-support treatments without involving families. The parents stressed that such decisions are indeed ethical and moral parenting decisions.

Parents from FACT expressed strong feelings toward the supportive management of infants born at 23 weeks’ gestation, and that counseling leaning heavily toward compassionate care was not appropriate. They specifically stated...
that hope should not be taken away from families at 23 weeks’ gestation before birth despite the possibilities of death and/or disability. Parents strongly felt that the option of resuscitation at birth with NICU admission and life-supporting treatment should be offered but not mandated and that family decisions ought to be supported whenever possible.

DEVELOPING PRACTICE CHANGE THROUGH RECOMMENDATIONS AND TOOLS

The 23 WWG developed recommendations from dialogue and review of the literature (Table 1). The literature on antenatal counseling of extreme prematurity was presented during formal educational meetings with frontline neonatal, perinatal, and obstetric staff. The information content of antenatal consultations was discussed, and communication techniques for more effective and empathetic consultations were presented (Table 2). Decision aids and other validated tools such as pictorial materials for antenatal consultation were also reviewed and have been tabled as a future quality-improvement project.

A parent information leaflet was developed for the interim with input from NICU staff and FACT.

We recognized the need for quality assurance for treatments provided to infants born at 23 weeks’ gestation. A retrospective review of all deliveries at 23 + 0 to 23 + 6 weeks’ gestation from October 2008 to October 2012 was completed after ethics and administrative approval. This time frame spans 2 benchmarking years (October 2008 to October 2010) as well as the 2 transition years (October 2010 to October 2012) when the discussions and change in clinical practice began.

The benchmarking years included 20 infants: 15 infants were born alive and 5 were stillborn. Of the 15 live-birth infants, 10 died in the delivery room (7 infants died following compassionate care and 3 infants died following attempted resuscitation) and 5 infants were admitted to the NICU. Of these 5 infants admitted, 4 subsequently died in the NICU, all after withdrawal of intensive care, and 1 survived to discharge. Developmental follow-up for the 1 child at an adjusted age of 3.5 years revealed intellectual skills well below age level (verbal comprehension, working memory, and visual-spatial skills in the “extremely low for age” range), with moderate language delay and poor quality of attention, in addition to moderately delayed fine motor skills. These developmental challenges qualify the child for funded early education.

The transitional years included 25 infants: 21 infants were born alive and 4 were stillborn. Eighteen infants had an antenatal plan for active resuscitation, whereas 7 infants’ families opted for compassionate care only. Of those 7 infants’ families who opted for compassionate care, 3 were stillborn and 4 were live births. These latter 4 infants received comfort care, dying in the delivery room with their family. Of the 21 live-birth infants, 5 died in the delivery room (4 infants were for compassionate care only and 1 was attempted resuscitation) and 16 infants were admitted to the NICU. Of these 16 admitted infants, 8 survived to discharge, whereas 8 subsequently died in the NICU (6 died after withdrawal of life-supporting treatment and 2 infants died while on maximum support). Developmental follow-up at an adjusted age of 18 months for 7 infants and at an adjusted age of 6 months for 1 infant revealed that none had severe neuromotor and/or neurosensory impairment (including cerebral palsy, blindness, or deafness). Six of these infants were assessed with the Bayley Scales of Infant Development—III at 18 months adjusted age, and none had a Mental Developmental Index <70.

The above outcomes are now included in a second parent information sheet that we make available to parents who wish to have this detailed information. Cognitive and language outcomes will be added to the information sheets when a complete 3.5-year follow-up is available for this group of children.

ONGOING CHANGE AND CHALLENGES

Despite the broad, multidisciplinary membership of the 23 WWG, the ensuing dissemination of the recommendations was challenging. The summary recommendations were disseminated via e-mail communication to staff in neonatology, obstetrics, and perinatology. Clinical leads contacted referral centers.

On a regional level, our program serves 4 different hospitals within the city, with a broad geographical referral catchment area that covers northern Alberta, the Northwest Territories, the Yukon, Nunavut, Northern British Columbia, and western Saskatchewan. This area represents an approximate population of 2 million people with ~25 000 births per year. Any policy change has the potential to have repercussions on the entire region. We are continuing to learn of consequences of this perinatal

---

TABLE 1 Summary of Antenatal Recommendations for 23 WWG

- Mothers at high risk of preterm delivery at 23 weeks’ gestation should be transferred to a tertiary perinatal care center, given antenatal steroids, and a joint obstetric-neonatal consult initiated.
- Resuscitation and life-support treatments should be available but not obligatory. This option should be discussed and offered as a choice to parents of infants born at 23 weeks’ gestation.
- In the absence of time for a complete antenatal consultation, initial resuscitation should be provided to infants born at 23 weeks’ gestation followed by further discussion with parents.
- A primary multidisciplinary team should be formed early in the care of infants born at 23 weeks’ gestation to promote consistency of care.
practice change, because anecdotally it seems that high-risk maternal transfer numbers and cesarean delivery rates at our perinatal center are increasing. Engaging frontline staff in different institutions across this broad catchment area is clearly an ongoing challenge.

At a local level, the 23 WWG, including FACT parent members, engaged frontline staff in multiple forums such as pediatric grand rounds, neonatology rounds, neonatal follow-up clinic multidisciplinary teaching rounds, perinatology rounds, and lunchtime sessions with bedside staff. These events facilitated dissemination of recommendations and gave staff the opportunity for questions and discussion. Although these discussions were generally positive and engaging, it is apparent that not all staff experienced the policy development as “negotiated.” Simply having a working group involving multiple disciplines does not guarantee universal staff acceptance. In retrospect, other methods of engaging clinical stakeholders during the actual process of policy development might have been useful, such as open staff communication forums or using electronic media for draft policy feedback. There was also no mechanism to ensure that all staff were able to attend dissemination events. Certainly, online media, such as an e-learning course, might have also facilitated information sharing. Fortunately, the cohesive NICU physician and nurse practitioner groups have helped to facilitate the adoption of this clinical practice change.

NICU hospital staff continue to need support in caring for children born at the cusp of viability. Guidelines and policy change clearly do not attenuate all of the moral-ethical issues encountered when infants born at the cusp of viability are offered resuscitation and continued intensive care. Formal support systems, integral to the NICU, must be available for health practitioners who encounter moral distress when a parental decision collides with their moral frameworks. Stepping aside, or handing over, might not be a feasible option in a team environment in which cross-coverage is routinely provided. Debriefings, facilitated by our hospital ethicist, have been 1 method that our program has used in such challenging situations.

It is apparent that some hospital staff still prefer simple rules that can be applied to all infants born before 24 weeks’ gestation. The nuances of the new, negotiated model are complex. For example, we have observed that some staff oversimplify the recommendation that “all infants should be offered the option for life support treatments” to “all infants must be provided with life support treatments.” Also, the understanding that gestational age is not always precisely known has meant that mothers who are a few days less than the best estimate of 23 weeks’ gestation are counseled similarly. Clearly, the resuscitation and treatment of infants who are not yet “exactly” 23 weeks’ gestational age have led to another level of complexity in the management of these mothers and infants and in the discussions that continue.

Antenatal consultation is challenging. The recommendation for honest, empathetic, and nonbiased antenatal counseling with confirmation of understanding by parents might be hard to meet in actual clinical practice given the rapidity with which these mothers often present and deliver. The recommendation for ongoing, detailed discussions after the infant’s birth is widely accepted, but in a busy tertiary care NICU with frequent changes in medical and nursing staff this expectation might be simply impossible to satisfy. The commitment to primary care for such infants and families, in addition to all of the care requirements of other infants and families in crisis, can be physically and emotionally exhausting for staff. In a different way, hospital transfers might also complicate the relationships established between these families and health professionals. Despite all of these challenges, our professional approach to care is to approximate the ideal as closely as possible, and the efforts involved in changing our resuscitation policy involved a similar commitment to excellence.

**CONCLUSIONS**

Neonatology is a relatively young field in which progress interconnects with new procedures, novel therapies, and emerging technologies. Matters pertaining to our actual clinical practice, individual cultural beliefs, and uncertainty in outcomes complicate practice change. Our experience with the change in clinical practice in the management of extreme premature infants born at 23 weeks’ gestation was detailed and transparent but also complex and challenging in implementation. Our experience suggests that, although an individualized, negotiated model to decision-making is more ethically appropriate than a simple clear-cut
policy based on medical criteria (eg, gestational age), in practice it is more complex and involved and requires a great deal of time, energy, and emotional commitment.

ACKNOWLEDGMENTS
We thank all our patients and their families; all the NICU staff at the Royal Alexandra Hospital; and the 23 WWG, FACT, and the Neonatal and Infant Follow-Up Clinic at the Glenrose Rehabilitation Hospital, Edmonton, Alberta, Canada. We also thank Ms Marni Panas, a family member from FACT, for her perspective letter (Supplemental Information).

REFERENCES

18. Hoekstra RE, Ferrara TB, Couser RJ, Payne NR, Connett JE. Survival and long-term neurodevelopmental outcome of extremely premature infants born at 23-26 weeks’ gestational age at a tertiary center. Pediatrics. 2004;113(1 pt 1). Available at: www.pediatrics.org/cgi/content/full/113/1/e1
Policy Change for Infants Born at the "Cusp of Viability": A Canadian NICU Experience
Linda Mahgoub, Michael van Manen, Paul Byrne and Juzer M. Tyebkhan
Pediatrics 2014;134;e1405; originally published online October 13, 2014;
DOI: 10.1542/peds.2014-0904

Updated Information & Services
including high resolution figures, can be found at:
/content/134/5/e1405.full.html

Supplementary Material
Supplementary material can be found at:
/content/suppl/2014/10/08/peds.2014-0904.DCSupplemental.html

References
This article cites 25 articles, 5 of which can be accessed free at:
/content/134/5/e1405.full.html#ref-list-1

Subspecialty Collections
This article, along with others on similar topics, appears in the following collection(s):
Administration/Practice Management
/cgi/collection/administration:practice_management_sub
Fetus/Newborn Infant
/cgi/collection/fetus:newborn_infant_sub

Permissions & Licensing
Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at:
/site/misc/Permissions.xhtml

Reprints
Information about ordering reprints can be found online:
/site/misc/reprints.xhtml

PEDIATRICS is the official journal of the American Academy of Pediatrics. A monthly publication, it has been published continuously since 1948. PEDIATRICS is owned, published, and trademarked by the American Academy of Pediatrics, 141 Northwest Point Boulevard, Elk Grove Village, Illinois, 60007. Copyright © 2014 by the American Academy of Pediatrics. All rights reserved. Print ISSN: 0031-4005. Online ISSN: 1098-4275.
Policy Change for Infants Born at the "Cusp of Viability": A Canadian NICU Experience
Linda Mahgoub, Michael van Manen, Paul Byrne and Juzer M. Tyebkhan
Pediatrics 2014;134;e1405; originally published online October 13, 2014;
DOI: 10.1542/peds.2014-0904

The online version of this article, along with updated information and services, is located on the World Wide Web at:
/content/134/5/e1405.full.html