OBSTETRICS

Resuscitation of likely nonviable infants: a cost-utility analysis after the Born-Alive Infant Protection Act

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OBJECTIVE: The purpose of this study was to compare the effects of universal vs selective resuscitation on maternal utilities, perinatal costs, and outcomes of preterm delivery and termination of pregnancy at 20-23 weeks 6 days’ gestation.

STUDY DESIGN: We used studies on medical practices, prematurity outcomes, costs, and maternal utilities to construct decision-analytic models for a cohort of annual US deliveries after preterm delivery or induced termination. Outcome measures were (1) the numbers of infants who survived intact or with mild, moderate, or severe sequelae; (2) maternal quality-adjusted life years (QALYs); and (3) incremental cost-effectiveness ratios.

RESULTS: Universal resuscitation of spontaneously delivered infants between 20-23 weeks 6 days’ gestation increases costs by $313.1 million and decreases QALYs by 329.3 QALYs; after a termination, universal resuscitation increases costs by $15.6 million and decreases QALYs by 19.2 QALYs. With universal resuscitation, 153 more infants survive: 44 infants are intact or mildly affected; 36 infants are moderately impaired, and 73 infants are severely disabled.

CONCLUSION: Selective intervention constitutes the highest utility and least costly treatment for infants at the margin of viability.

Key words: decision-making, extreme prematurity, nonintervention, resuscitation, withholding medical care

FIGURE 1
Schematic of decision trees

A, Preterm delivery (PTD). B, Induced termination of pregnancy.

D&E, dilation and evacuation; Del, delivery; GA, gestational age; NICU, neonatal intensive care unit; TAB, therapeutic abortion; wks, weeks.

Labor Act or Child Abuse Prevention or Treatment Act violation. BAIPA clarified the legal status of liveborn infants. It did not further specify what should be considered appropriate medical care for infants who are born at the margin of viability. To date, resuscitation practices currently vary across centers and may diverge from professional board guidelines. Providers therefore may believe that they could be subject to medicolegal suits or to federal enforcement of BAIPA legislative mandates.

We wished to characterize the theoretic effects of universal resuscitation of potentially viable infants on clinical outcomes (death, morbidity, and intact survival) of extreme prematurity. As a first analytic step, we designed decision-analytic models to test how universal resuscitation of all liveborn extremely premature infants would impact costs and maternal quality of life in comparison with current selective nonintervention practice.

**METHODS**

Decision-analytic models were developed with TreeAge Pro 2009 software (TreeAge Software, Inc, Cambridge, MA). We used the entire cohort of US deliveries to model a cost-utility analysis that compared selective with universal resuscitation of infants who were born at 20-23 weeks 6 days' gestational age. We restricted our analysis to this narrow, but controversial, range because infants who are born at <20 weeks' gestational age have not been recorded to survive and because infants who are born at ≥24 weeks' gestation routinely are resuscitated by most neonatologists. Two decision-analytic models were constructed to compare the outcomes of spontaneous preterm delivery and induced preterm deliveries/therapeutic abortions. We classified neonatal outcomes among survivors into 4 groups: (1) intact (no significant neurodevelopmental, visual, or auditory impairment), (2) mild sequelae (mild neurodevelopmental sequelae or correctable visual or auditory impairment), (3) moderate impairment (functionally independent with ambulant cerebral palsy [nonprogressive abnormality of movement and posture, with increased tone and stretch reflexes in ≥1 extremities], moderate cognitive deficit [Bayley Mental Developmental Index, <2 SDs below the mean], hearing loss that required amplification, or visual losses other than blindness, or (4) severe disability (dependent life with nonambulant cerebral palsy, profound cognitive deficit [Bayley Mental Developmental Index, >2 SDs below the mean], profound hearing loss, or blindness).

The fifth neonatal outcome was death. Utilities were applied to each outcome status to generate quality-adjusted life years (QALYs). We examined costs from the societal perspective and utilities from the perspective of the mother. Sensitivity analyses were performed to test how robust both models are in response to changing outcome probabilities.

The decision model structures for preterm delivery and induced termination of pregnancy are shown in Figure 1. The preterm delivery decision tree (Figure 1, A) begins with a decision node the branches of which represent 2 neonatal intensive care unit (NICU) management schemes: selective delivery room resuscitation vs universal delivery room resuscitation followed by intensive care, chance nodes whose branches represent live birth vs stillbirth, death in the delivery room vs survival to NICU admission, treatment of the infant, and finally infant outcomes. Figure 1, B, shows the decision tree for induced termination of pregnancy, with the insertion of an earlier decision node for delivery by dilation and extraction (fetal) vs induction termination, with subsequent nodes similar to the preterm delivery model.

Probabilities were derived from a PubMed literature search of studies that had been published within 5 years of the 2005 guidelines for enforcement of BAIPA whenever possible (Table 1). When no recent study was available, we extrapolated data from the most recent and robust of available relevant studies. We used population-based birth rates for prevalence estimates at each week of gestation, when available. We used geographically-based cohort studies of extreme prematurity, therapeutic abortion, and induced termination of pregnancy when population-based data were not available. Whenever available, we used data on outcomes of extreme prematurity from studies in the United States in preference to European population-based studies. When no other data were available, we extrapolated from clinical practice data from 2 university hospitals in San Francisco.

**Sample**

We used a theoretic cohort of all pregnancies in the United States over 1 year as a basis for modeling this 2010 analysis. We estimated that a total of approximately 6.39 million pregnancies result in 4.11 million live births, 1.22 million induced abortions, and 1.06 million embryonic or fetal losses. For the preterm delivery tree, we used data on live births and stillbirths from the 2006 Office of Statewide Health Planning and Development California birth cohort to estimate that 13,563 pregnancies deliver between 20 and 23 weeks 6 days' gestation (0.33%). Using proportions for live births by week of gestation (5.19%, 49.0%, 57.3%, and 61.0% at 20, 21, 22, and 23 weeks), we calculated that 7518 infants (5.54%) are liveborn.

Previous reports document that 1.4-2% of legal abortions occur at ≥21 weeks' gestation. For the termination of the pregnancy tree, we used a 1.5% estimate for the proportion of induced late abortions between 20 and 23 weeks 6 days' gestation and calculated that approximately 18,300 pregnancies are terminated in that gestational age range. We estimated that 12.8% of terminations at 20-23 weeks 6 days' gestation currently are done as medical abortions, likely by induction of labor and that the remaining 87.2% are done by dilation and extraction. We derived an estimate of overall live birth rate after nonsurgical termination as 3.4% from prospective data on inductions at <24 weeks' gestation for conditions other than preterm prolonged rupture of membranes at our university hospitals in San Francisco. By this calculation, 0.4352% of terminations between 20 and 23 weeks 6 days' gestation in the United States would result in 80 live born infants after attempted termination. Using the proportions from the premature delivery tree, we estimated that only 6 infants would survive to nursery discharge if all
<table>
<thead>
<tr>
<th>Variable</th>
<th>Preterm delivery at 20-23 wk 6 d gestation</th>
<th>Therapeutic abortion at 20-23 wk 6 d gestation</th>
</tr>
</thead>
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<tr>
<td>Deliveries per y, n 31,32</td>
<td>13,563</td>
<td>18,300</td>
</tr>
<tr>
<td>Proportion of liveborn infants 33,34,37,38</td>
<td>0.5544</td>
<td>0.0044</td>
</tr>
<tr>
<td>Proportion of liveborn infants</td>
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<td>0.4304</td>
</tr>
<tr>
<td>resuscitated in delivery room 20,35,36</td>
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<td>0–1.00</td>
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<tr>
<td>Proportion surviving resuscitation 8,36</td>
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<tr>
<td>Outcome probabilities of infants</td>
<td></td>
<td>0–1.00</td>
</tr>
<tr>
<td>admitted to the neonatal intensive care unit 6,9,36,37</td>
<td>0.5544</td>
<td>0.0044</td>
</tr>
<tr>
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<td>0.013</td>
</tr>
<tr>
<td>Mild sequence 6</td>
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<td>0.013</td>
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<tr>
<td>Moderate morbidity</td>
<td>0.021</td>
<td>0.021</td>
</tr>
<tr>
<td>Severe morbidity</td>
<td>0.032</td>
<td>0.032</td>
</tr>
<tr>
<td>Death</td>
<td>0.921</td>
<td>0.921</td>
</tr>
<tr>
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<tr>
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<td>Preterm delivery 45</td>
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<tr>
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<tr>
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<td>6096</td>
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<td>3048–12,192</td>
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<td>Nonsurvivors-all</td>
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<td>45,517–182,066</td>
</tr>
<tr>
<td>Survivors</td>
<td></td>
<td>45,517–182,066</td>
</tr>
<tr>
<td>20–20 6/7 wk</td>
<td>509,032</td>
<td>509,032</td>
</tr>
<tr>
<td>21–21 6/7 wk</td>
<td>477,127</td>
<td>477,127</td>
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<tr>
<td>22–22 6/7 wk</td>
<td>445,221</td>
<td>445,221</td>
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<tr>
<td>23–23 6/7 wk</td>
<td>413,315</td>
<td>413,315</td>
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<tr>
<td>Incremental cost of long-term care, $42c</td>
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<td>26,028–104,112</td>
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<tr>
<td>Survivor with mild sequelae 52,056</td>
<td>52,056</td>
<td>52,056</td>
</tr>
<tr>
<td>Survivor with moderate sequelae 578,958</td>
<td>289,479–1,157,916</td>
<td>289,479–1,157,916</td>
</tr>
<tr>
<td>Survivor with severe sequelae 1,139,657</td>
<td>569,829–2,279,314</td>
<td>569,829–2,279,314</td>
</tr>
</tbody>
</table>

Data are shown for cohort numbers, outcome probabilities, and maternal utilities for premature deliveries and for terminations of pregnancy from 20-23 weeks 6 days gestation. Input ranges are calculated as ±0.10 of baseline value when no published data were available.

* Assuming an equal distribution between intact survivors and those survivors with mild sequelae; ** Assuming costs for termination of pregnancy to be two-thirds that for preterm delivery; *** Costs for sensitivity analyses were calculated as 50% and 200% of baseline value.

infants at 20–23 weeks 6 days’ gestation were resuscitated.

Interventions
We used data on provider resuscitation practices in California before the passage of BAIPA to estimate the proportion of attempted delivery room resuscitations at each week of gestation. Using cumulative percentages to estimate selective resuscitation, 2%, 3%, 47%, and 85% of liveborn infants would be resuscitated at 20, 21, 22, and 23 weeks respectively; by this calculation, 3236 infants (43%) would be resuscitated in the delivery room. For universal resuscitation, we assumed all 7518 liveborn infants would be resuscitated. Because there are no week-specific data on survival after delivery room resuscitation of liveborn infants at <24 weeks’ gestation, we used a summary statistic that 97.8% of resuscitated infants who would be born at 22-23 weeks 6 days’ gestation would survive to NICU admission and assumed that no infants at 20-21 weeks 6 days’ gestation would survive delivery room resuscitation, for an overall survival of 94.6%. Because no data were available, we assumed that the small proportion of liveborn infants who were resuscitated after a termination and the proportion of infants who survived resuscitation would be the same as infants who delivered spontaneously.

Outcomes
We used the following outcome proportions for this cohort: death, 92%; moderate disability, 2.1%; severe impairment, 3.2%; and survival intact or with mild sequelae, 2.6%. We divided the intact survival group into intact and mild impairment, assuming a 50:50 split between intact and mild, given the paucity of data that differentiated the 2 subgroup outcomes. We did not adjust specifically for sex, ethnicity, or birthweight, which can affect mortality and morbidity statistics. We also estimated the number (as additional survivors per 1000 infants treated) and the proportions who would survive intact or with mild sequelae, moderate impairment, or severe disability if all infants 20–23 weeks 6 days’ gestation were resuscitated.

Utilities and QALYs
We assumed the average life expectancy of parturients as 50 years, adjusted for inflation at 3% annually. We approximated this as the difference between mean maternal age at first birth in 2005 (25.2 years) and mean life expectancy for women who were born in 1980 (77.4 years). We adjusted life expectancy for quality of life using health state utilities. We calculated QALYs by multiplying discounted life expectancy after delivery by the maternal utility for infant health outcome, assuming that utilities remain constant over time after pregnancy. We could find no data on maternal utilities for outcomes of prematurity. Given the focus on maternal quality of life in this analysis, we chose not to use self-assessed utilities among survivors of extreme prematurity or parental utilities for pediatric quality of life. Instead, we conservatively opted to use median utilities for maternal quality of life for trisomy 21, recognizing that utilities are not distributed normally, that median utilities are higher than mean utilities, and that utilities among survivors at <24 weeks’ gestation likely are lower than those for many infants with trisomy 21. For the termination of pregnancy tree, we were forced to input utilities, because no utility values were available from the literature. We chose to set the highest utility as 0.9 for fetal loss, when the woman has prioritized pregnancy loss over a viable fetus. To input utilities for outcomes after termination, we reduced premature delivery utilities for each survival status by an arbitrary 10%. Future studies may allow more evidence-based analysis based on maternal utilities after termination of pregnancy.

Costs
Costs were estimated from studies with a public sector perspective, which encompasses health, social services, and education expressed in US dollars converted to 2010 prices according to the medical component of the US Consumer Price Index. To calculate overall care costs, we used population-based estimates of maternal and infant hospital costs from the study of infants born at <500 grams in California by Schmitt et al. We used these data because week-specific data on costs were not available. For preterm delivery at 20–23 weeks 6 days’ gestation, we estimated prenatal care costs at $10,562 and the maternal hospital costs of preterm delivery at $12,926. We used $1443 as the estimated cost of a termination of pregnancy, after inflating the 2001 cost to 2010 dollars. We assumed that an induction termination entails the same costs as preterm delivery. Delivery room costs were derived from the study by Gilbert et al, although that study included infants at 24–35 weeks’ gestation. Delivery room costs (in 2010 dollars) for preterm delivery were $18,752 for preterm delivery and $6096 for the rare liveborn infant resuscitated after a termination. The costs of neonatal intensive care in 2000 dollars were inflated to 2010 costs and stratified by neonatal survivorship and gestational age. Because an increasing proportion of infants likely would die quickly with each lower week of gestation and we could find no data on intensive care costs for the lowest gestational ages, we elected to decrease costs by the reported difference between 24 and 25 weeks’ gestation progressively for each week of gestation <24 weeks (Table 1).

We estimated the average lifetime costs of mild, moderate, and severe sequelae as incremental costs over the costs of care for an infant who is born at term. We used 2003 cost estimates to be the net present value of total costs inflated to 2010 dollars for mild, moderate, and severe disability: $52,056 for mild, $578,958 for moderate (the mean between costs for cerebral palsy [$1,084,883] and mental retardation [$666,714]), and $1,139,657 for severe (the mean between costs for cerebral palsy [$1,084,883] and mental retardation [$1,194,431]). Future costs were adjusted at a 3% annual rate.

Analytic methods
We performed both the decision analysis and cost-utility analysis of the 2 models. For the decision analyses, outcomes included total survivors in each outcome group and total mQALYs. For the cost-utility analysis, we calculated incremental cost-effectiveness ratios that compared universal vs selective resuscitation policies. A threshold of $100,000 per
QALY was used to delineate cost-effectiveness. We then conducted univariate and bivariate sensitivity analyses, varying each input over feasible ranges. Next, we conducted selective threshold analyses to determine the point estimate of inputs that would make universal resuscitation cost-effective. Finally, we conducted a Monte Carlo simulation using 100,000 trials. By incorporating uncertainty into the probability distribution at each chance node for each trial, this analysis can be used to generate a 95% confidence ellipse in the cost-utility space to examine the robustness of the findings.

**RESULTS**

When compared with BAIPA, the current selective nonintervention regimen yielded greater mQALYs and lower costs (the “dominant” strategy). Compared with current selective resuscitation, universal resuscitation of all infants who are delivered spontaneously between 20-23 weeks 6 days’ gestation would increase costs by $313.1 million, an increase of 28% (Table 2). Similarly, the costs of care for termination of pregnancy, which would include the resuscitation of the small number of liveborn aborted infants, would double, which would be an increase of $15.6 million over selective resuscitation.

We conducted sensitivity analyses and found these results to be robust to uncertainty in our model assumptions. In univariate sensitivity analyses that varied the model inputs across the ranges that are shown in Table 1, the findings of greater costs and lower QALYs from universal resuscitation under BAIPA enforcement persisted across all analyses. When the probabilities for both moderate and severe morbidity are less than one-half of the baseline estimates that we used, universal resuscitation generates greater estimated QALYs than selective resuscitation, but only in the preterm birth model. However, even with the probabilities reduced to 0, the universal resuscitation policy was still not cost-effective, costing >$100,000 per QALY throughout the ranges. In a multivariable Monte Carlo simulation, we found that, in 100% of the simulation trials, the outcome was dominant; greater costs and lower QALYs would result from a policy of universal resuscitation all liveborn fetuses at 20-23 weeks 6 days’ gestation (Figure 2).

**TABLE 2**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total cost, $</th>
<th>Total quality-adjusted life years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm delivery at 20-23 weeks 6 days’ gestation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Universal resuscitation</td>
<td>1,432,749,607</td>
<td>312,704</td>
</tr>
<tr>
<td>Current selective policy</td>
<td>1,119,646,638</td>
<td>313,033</td>
</tr>
<tr>
<td>Difference</td>
<td>313,102,969</td>
<td>−329</td>
</tr>
<tr>
<td>Termination of pregnancy at 20-23 weeks 6 days’ gestation</td>
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<td></td>
</tr>
<tr>
<td>Universal resuscitation</td>
<td>76,692,757</td>
<td>60,246</td>
</tr>
<tr>
<td>Current selective policy</td>
<td>61,137,288</td>
<td>60,267</td>
</tr>
<tr>
<td>Difference</td>
<td>15,555,469</td>
<td>−19</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Universal resuscitation</td>
<td>1,509,442,364</td>
<td>372,951</td>
</tr>
<tr>
<td>Current selective policy</td>
<td>1,180,783,926</td>
<td>373,299</td>
</tr>
<tr>
<td>Difference</td>
<td>328,658,438</td>
<td>−348</td>
</tr>
</tbody>
</table>

The data represent the cost and quality-adjusted life year totals and cost and utility differences for selective vs universal resuscitation if the Born-Alive Infants Protection Act of 2002, Public Law 107–207, were perceived as a mandate to resuscitate all liveborn premature neonates. (Figure 2). Cost-utility analysis of resuscitation of extreme prematurity. Am J Obstet Gynecol 2012.

**COMMENT**

BAIPA regulations mandate the provision of appropriate medical care for all born-alive infants; however, to date, BAIPA has not been perceived widely as a mandate to resuscitate all liveborn infants. Our analysis shows that universal resuscitation of liveborn infants at 20-23 weeks 6 days’ gestation would increase the costs and worsen maternal quality of life. Although a larger number of infants would be saved, a larger proportion of survivors would have significant handicap than would survive with no or minimal sequelae. However, universal resuscitation of these infants does not appear to be cost-effective. The cost-utility ratios that we found of >$100,000/QALY are 2-fold higher than thresholds for generally accepted interventions, such as screening for congenital adrenal hyperplasia, salvage cardiac extracorporeal membrane oxygenation, or primary cardiac transplantation. This cost-utility analysis admittedly is speculative. Nonetheless, selective resuscitation is a dominant strategy compared with uni-
universal resuscitation and is robust under a wide variety of assumptions in sensitivity analysis.

Selective nonintervention continues to be a challenging medical, legal, and ethical issue in the United States. Previous studies have documented significant variations in perinatal providers’ resuscitation and intensive care practices. Our analysis over-intervention, which potentiates fears of medical-legal liability. Recent court cases have resulted in rulings against both nonintervention and over-intervention, which potentiates fears of medical-legal liability. Our analysis investigates what may occur if providers perceive BAIPA as a strong enough medico-legal incentive for aggressive intervention that they change their practice. Strict enforcement of BAIPA could prompt California obstetricians and neonatologists to use lower thresholds for resuscitation and for providing comfort care alone; conversely, Malloy recently reported that BAIPA affected only fetal and live birth rates at 17 weeks’ gestation.

Some ethicists argue that the federal Child Abuse Amendments of 1984 require treatment, regardless of severe physical and mental disabilities. Ethicists and neonatologists argue that early delivery room and NICU interventions allow time to assess response to treatment and diagnostic studies to distinguish those infants who will benefit from intensive care from those who will die despite aggressive life-support. Critics of selective intervention practices contend that birthweight, gestational age, or medical acuity criteria offer no useful discriminatory power in the prediction of vital status or neurodevelopmental prognosis among survivors. Although combining risks improves prognostic certainty, decisions about the application of invasive therapies to premature infants with very low chances of surviving remain controversial.

Physicians’ willingness to resuscitate a hypothetical 480-g 23-week infant is highly influenced by parents’ wishes. Parents usually opt for more aggressive NICU than providers; however, perinatal providers usually defer to parents’ expressed treatment decisions if taken in the best interests of the infant.

We would expect less difference between the 2 policies if most parents wanted aggressive intervention under the selective resuscitation policy. However, if BAIPA were enforced rigidly, perceived threats of liability for nonintervention might motivate some physicians to employ all means to save potentially viable infants, as is seen in other conditions with high morbidity and mortality rates, such as hypoplastic left heart syndrome and congenital diaphragmatic hernia.

Although we believe our model represents the policy at hand, there are, of course, limitations. First, the use of California medical costs and resuscitation and obstetrics practice patterns, in particular for induced terminations of pregnancy, may not be generalizable to the remainder of the United States. Second, decision-analytic models are designed to condense the most important factors into a fungible analytic structure; however, in this first-step analysis of the effects of selective vs universal resuscitation, we did not analyze pediatric quality of life. We recognize that QALYs that accrue to pediatric survivors might counter the results in this maternal cost-utility analysis. Further similarly detailed pediatric cost-utility analyses will likely add important insights into the tradeoffs that are inherent in perinatal decision-making. Nor did we examine paternal...
QALYs, for which few specific data are available. We did not examine costs or utilities that may differ between delivery room nonintervention and nursery comfort care. Parents value sensitive end-of-life care, and supportive palliative care could change maternal utilities for fatal outcomes. However, the inclusion of such differences would further support only the current individualized practice as opposed to a broad mandate on care. Further, there is no widely accepted gold standard for the assessment of maternal quality of life for newborn infant outcomes. However, to be conservative, we believe that our estimated effect on maternal quality of life underrepresents the distress that women experience when perinatal providers resuscitate a liveborn infant after a termination of pregnancy. Finally, this analysis did not consider future changes in costs and maternal quality of life that might result from health care reform or improved intensive care technology.

In our cost-utility models, a selective nonintervention of liveborn infants 20-23 6/7 weeks’ gestation is a dominant strategy that leads to the highest QALYs and lowest cost of care for infants at the margin of viability. Although differences are small, they represent clinically significant effects on women and their fetuses and infants. Although we tested a wide range of costs and utilities and found our model to be remarkably robust, the point at which attempts to save infants’ lives shifts to doing harm will likely remain subjective and poorly delineated. However, it is clear that universal resuscitation would increase societal costs and lower maternal quality of life.

Resuscitation and intensive care for infants at <24 weeks’ gestation has been critiqued as either inappropriate or experimental, rather than standard of care. Our results demonstrate deleterious financial and quality-of-life consequences of routine resuscitation. The results of this analysis may help obstetricians and neonatologists detail some of the consequences of parents’ antenatal choices about resuscitation options for extremely premature infants. As an additional component in shared perinatal decision-making among parents, obstetricians, and neonatologists, the results of our analyses should temper preferences for aggressive measures at the lowest gestational ages and could offer more support for parents who prefer nonintervention. To the extent that BAIPA becomes perceived as a mandate for aggressive intervention, regardless of the intent of the pregnancy, mode of delivery, or degree of immaturity, parental and physician discretion in decision-making could be constrained, which potentially could harm women and their children, rather than protect infants.

Although the clarified legal status of liveborn infants by the BAIPA represented a step forward, the guidelines for enforcement suggest the possibility of an Emergency Medical Treatment and Labor Act or Child Abuse Prevention and Treatment Act investigation. We believe that resuscitation and life-support decisions for pre- and periviable infants are best determined by parents and clinicians rather than legislators. Resuscitation policies should take into account quality of life for infants and their parents and healthcare expenditures. Given the dearth of controlled trials in this area, decision analyses such as this may provide a basis for guidelines for the management of extreme prematurity.

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