Outcomes of Extremely Preterm Infants

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I have no relevant conflicts of interest to disclose
Premature Babies May Survive at 22 Weeks if Treated, Study Finds

By PAM BELLUCK  MAY 6, 2015

A small number of very premature babies are surviving earlier outside the womb than doctors once thought possible, a new study has documented, raising questions about how aggressively they should be treated and posing implications for the debate about abortion.

http://www.nytimes.com/2015/05/07/health/premature-babies-22-weeks-viability-study.html?_r=0
Learning objectives

At the end of this talk, you should know:

1. Recent data on survival for extremely preterm infants

2. The spectrum of neurodevelopmental outcomes among surviving extremely preterm infants
Survival improving for Extremely preterm infants
Causes and Timing of Death in Extremely Premature Infants from 2000 through 2011


Table 2. Overall Causes of Death among Extremely Premature Infants, 2000–2011.*

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total live births</td>
<td>7440</td>
<td>7684</td>
<td>7124</td>
</tr>
<tr>
<td>Total deaths</td>
<td>2043</td>
<td>2193</td>
<td>1839</td>
</tr>
<tr>
<td>Overall mortality rate per 1000 live births (95% CI)†</td>
<td>275 (264–285)‡</td>
<td>285 (275–295)‡</td>
<td>258 (248–268)*</td>
</tr>
</tbody>
</table>

Patel RM, et al. N Engl J Med. 2015 *P=0.003
Survival for extremely preterm infants

Changes in survival over time in US

Data from NICHD Neonatal Research Network
Survival of extremely preterm infants in high-income countries

- EPIPAGE 2 (France, 2011)
- SNN (Switzerland, 1997-2013)
- EPICure (UK, 2006)
- Victoria (Australia, 2010-2011)
- Pediatrix (US, 1997-2013)
- CNN (Canada, 2010-2011)
- NICHD NRN (US, 2013-2015)
- EXPRESS (Sweden, 2004-2007)
- Japan NRN (Japan, 2003-2005)
Importance of denominators in understanding birth outcomes

- Patient admitted at 22wk gestation
  - Stillbirth
  - Live-birth
    - Comfort care
    - Resuscitation (active treatment)
      - Delivery room death
      - Survival to NICU admission
  - Survival to hospital discharge
  - Death in hospital
Importance of denominators in understanding birth outcomes

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  - Stillbirth
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Importance of denominators in understanding birth outcomes

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          - Survival to hospital discharge
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Importance of denominators in understanding birth outcomes

- Patient admitted at 22wk gestation
- Stillbirth
- Live-birth
- Comfort care
- Delivery room death
- Resuscitation (active treatment)
- Survival to NICU admission
- Survival to hospital discharge
- Death in hospital
Birth outcomes in population-based cohorts

- Survived
- Died in delivery room
- Stillbirth
- Died after NICU admission

**EPICure 2 (UK)**

- 22wk (n=272)
- 23wk (n=416)
- 24wk (n=494)
- 25wk (n=550)

Adapted from Costeloe KL, et al. BMJ 2012
Birth outcomes in population-based cohorts

- **EPIPAGE-2 (France)**
  - 22wk: (n=377)
  - 23wk: (n=371)
  - 24wk: (n=364)
  - 25wk: (n=407)

- **EPICure 2 (UK)**
  - 22wk: (n=272)
  - 23wk: (n=416)
  - 24wk: (n=494)
  - 25wk: (n=550)

- **Express (Sweden)**
  - 22wk: (n=142)
  - 23wk: (n=183)
  - 24wk: (n=191)
  - 25wk: (n=250)

Unpublished data
Birth outcomes in population-based cohorts

- **EPIPAGE-2 (France):**
  - 22wk: stillbirths 85%
  - 23wk: stillbirths 75%

- **EPICure 2 (UK):**
  - 22wk: stillbirths 45%
  - 23wk: stillbirths 19%

- **Express (Sweden):**
  - 22wk: stillbirths 65%
  - 23wk: stillbirths 45%

Unpublished data
Birth outcomes in population-based cohorts

- **EPIPAGE-2 (France)**
  - 22wk (n=377)
  - 23wk (n=371)
  - 24wk (n=364)
  - 25wk (n=407)

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  - 22wk (n=142)
  - 23wk (n=183)
  - 24wk (n=191)
  - 25wk (n=250)

Unpublished data
Survival after admission to the NICU

Original Investigation

Survival Among Infants Born at 22 or 23 Weeks’ Gestation Following Active Prenatal and Postnatal Care

Katrin Mehler, MD; André Oberthuer, MD; Titus Keller, MD; Ingrid Becker, Markus Valter, MD; Bernhard Roth, MD; Angela Krubs, MD

Single center in Germany (n=106)
81% received active care

<table>
<thead>
<tr>
<th>Outcome</th>
<th>22 wk</th>
<th>23 wk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcome</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survival without severe complications</td>
<td>6/27 (22)</td>
<td>16/58 (28)</td>
</tr>
<tr>
<td><strong>Secondary outcome</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survival</td>
<td>17/26 (65)</td>
<td>41/57 (72)</td>
</tr>
</tbody>
</table>

Box. Key Features of Active Prenatal and Postnatal Care at University of Cologne Medical Centre.

- Use of prenatal steroids after parental counseling from 22 weeks of gestation
- Cesarean delivery with local anesthesia as preferred mode of delivery
- Delayed cord clamping
- Comfort positioning (lateral) of the infant
- Establishment of spontaneous breathing via a stepwise increase in positive end-expiratory pressure
- Less invasive surfactant application

Mehler K et al. JAMA Pediatrics 2016
Effect of resuscitation (active treatment) on survival
Between-Hospital Variation in Treatment and Outcomes in Extremely Preterm Infants

Modes of active treatment

<table>
<thead>
<tr>
<th>Active Intervention</th>
<th>22 Weeks n (%)</th>
<th>23 Weeks n (%)</th>
<th>24 Weeks n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intubation</td>
<td>62 (78.5)</td>
<td>503 (92.8)</td>
<td>1006 (89.9)</td>
</tr>
<tr>
<td>Surfactant</td>
<td>56 (70.9)</td>
<td>474 (87.5)</td>
<td>1037 (92.7)</td>
</tr>
<tr>
<td>Chest compressions</td>
<td>11 (13.9)</td>
<td>80 (14.8)</td>
<td>148 (13.2)</td>
</tr>
<tr>
<td>Epinephrine</td>
<td>7 (8.9)</td>
<td>51 (9.4)</td>
<td>84 (7.5)</td>
</tr>
<tr>
<td>Parenteral nutrition</td>
<td>47 (59.5)</td>
<td>422 (77.9)</td>
<td>1023 (91.4)</td>
</tr>
<tr>
<td>Bag-valve-mask</td>
<td>72 (91.1)</td>
<td>501 (92.4)</td>
<td>1013 (90.5)</td>
</tr>
<tr>
<td>HFV</td>
<td>28 (35.4)</td>
<td>295 (54.4)</td>
<td>638 (57.0)</td>
</tr>
<tr>
<td>CV</td>
<td>42 (53.2)</td>
<td>365 (67.3)</td>
<td>948 (84.7)</td>
</tr>
<tr>
<td>SMV</td>
<td>11 (13.9)</td>
<td>99 (18.3)</td>
<td>287 (25.6)</td>
</tr>
<tr>
<td>CPAP</td>
<td>20 (25.3)</td>
<td>227 (41.9)</td>
<td>720 (64.3)</td>
</tr>
</tbody>
</table>
Rates of active treatment by hospital

Effect of active treatment at 22wk

### Table 2. Crude Outcomes by Gestational Age at Birth.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>All Infants</th>
<th>Infants Who Received Active Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall Rate†</td>
<td>Hospital Rate‡</td>
</tr>
<tr>
<td></td>
<td>mean (95% CI)</td>
<td>median (interquartile range)</td>
</tr>
<tr>
<td>22 Wk of gestation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survival</td>
<td>5.1 (3.2–7.9)</td>
<td>3.4 (0.0–10.6)</td>
</tr>
<tr>
<td>Survival without severe impairment</td>
<td>3.4 (1.9–5.9)</td>
<td>0.0 (0.0–6.9)</td>
</tr>
<tr>
<td>Survival without moderate or severe impairment</td>
<td>2.0 (0.9–4.1)</td>
<td>0.0 (0.0–0.7)</td>
</tr>
</tbody>
</table>

*Children’s Healthcare of Atlanta*
Change in survival with active treatment

Change in survival estimates after birth by postnatal age

Daily mortality of infants born at less than 30 weeks' gestation

Christoph P. Hornik a,b, Ashley L. Sherwood a,b, C. Michael Cotten a, Matthew M. Laughon c, Reese H. Clark d, P. Brian Smith a,b,*

a Department of Pediatrics, Duke University School of Medicine, Durham, NC, United States
b Duke Clinical Research Institute, Duke University School of Medicine, Durham, NC, United States
c Department of Pediatrics, The University of North Carolina at Chapel Hill, Chapel Hill, NC, United States
d Pediatrix–Obstetrix Center for Research and Education, Sunrise, FL, United States

Study in 362 NICUs in the US from 1997 to 2013 among 64,896 infants born at 22 to 29 weeks’ gestational age.

Overall survival increased from 80% in 1997 to 88% in 2013

Hornick CP et al. Early Hum Dev 2016
Point prevalence of survival by age

Hornick CP et al. Early Hum Dev 2016
Long-term outcomes: How do we define disability?
Definitions of neurodevelopmental disability (or impairment or delay)

• Cognitive impairment (mental retardation)
  – Evaluated using Bayley Scales of Infant and Toddler Development (BSID)

• Motor impairment (cerebral palsy)
  – Evaluated using BSID and Gross Motor Function Classification Scale (GMFCS)

• Deafness

• Blindness
BSID used to define cognitive impairment

https://youtu.be/lGEkpadxo1E
BSID used to define impairment based on population norms

(Bayley Scales of Infant and Toddler Development)
BSID used to define impairment based on population norms

(Bayley Scales of Infant and Toddler Development)
GMFCS used to determine severity of motor impairment
**Long-term outcomes in extremely preterm infants**

<table>
<thead>
<tr>
<th>Study</th>
<th>Follow-up</th>
<th>Details</th>
<th>Definition of moderate disability</th>
<th>Definition of severe disability</th>
</tr>
</thead>
<tbody>
<tr>
<td>NICHID NNRN¹⁷</td>
<td>18–22 mo corrected age</td>
<td>Multicenter cohort evaluating 2,630 (65%) of 4,329 inborn live births receiving active treatment with survival to 18–22 mo corrected age</td>
<td>Bayley-III cognitive or motor score 1 to 2 SD below mean, moderate CP, or a GMFCS level of 2 or 3.</td>
<td>Bayley-III cognitive or motor score &gt; 2 SD below mean, severe CP, GMFCS level of 4 or 5, bilateral blindness, or severe hearing impairment not corrected with bilateral amplification</td>
</tr>
<tr>
<td>EXPRESS²</td>
<td>2.5 y</td>
<td>Population-based cohort evaluating 491 (69%) of 707 live births surviving to 30 mo corrected age</td>
<td>Bayley-III score 2 to 3 SD below mean (any scales), moderate CP, moderate visual or hearing impairment</td>
<td>Bayley-III composite cognitive, language, or motor score&lt;3 SD below mean, severe CP, or bilateral blindness or deafness</td>
</tr>
<tr>
<td>EPICure⁷⁷</td>
<td>3 y (range of 27–48 mo)</td>
<td>Population-based cohort evaluating 584 (57%) of 1,031 live births surviving to 3 y. Age at assessment was variable, with use of multiple scales</td>
<td>Ambulant CP (GMFCS 2), functionally impaired vision, hearing loss improved by aids, or a developmental score within 2 to 3 SD below mean</td>
<td>Nonambulant CP (GMFCS 3–5), blindness, profound sensorineural hearing loss not improved by aids, or a developmental quotient&lt;3 SD below mean</td>
</tr>
</tbody>
</table>

Patel RM. Am J Perinatol 2016
Prevalence of mild or no disability

Weeks of completed gestation

- 22wk
- 23wk
- 24wk
- 25wk

Prevalence among survivors

NICHD NRN (US)  EXPRESS (Sweden)  EPICure (UK)

Patel RM. Am J Perinatol 2016
Prevalence of moderate disability among survivors

Weeks of completed gestation:
- 22wk
- 23wk
- 24wk
- 25wk

Prevalence among survivors:
- NICHD NRN (US)
- EXPRESS (Sweden)
- EPICure (UK)

Patel RM. Am J Perinatol 2016
Prevalence of severe disability

Weeks of completed gestation

- 22wk
- 23wk
- 24wk
- 25wk

Prevalence among survivors

- NICHD NRN (US)
- EXPRESS (Sweden)
- EPICure (UK)

Patel RM. Am J Perinatol 2016
Factors beyond gestational age

Tyson JE, et al. NEJM 2008
Wide spectrum of neurodevelopmental outcomes, with dynamic changes in early childhood
Disability for extremely premature infants at 6 years of age (EPICure)

• Severe Disability **22%**
  – Versus 0% in classmate controls

• Moderate Disability **24%**
  – Versus 1% in classmate controls

• Mild Disability **34%**
  – Versus 18% in classmate controls

• No Disability **20%**

Cognitive scores for extremely preterm infants at 6 years of age (EPICure)

Cognitive scores for extremely preterm infants at 6 years of age (EPICure)

Cognitive gain over time

Gain of 20 points in cognitive score
A child scoring 68 at 18 mo could score 88 at 5yr

Schmidt B et al. JAMA 2012
Social variables influence cognitive gains between 18 mo and 5 years

Social advantages:
- Maternal college education
- Paternal college education
- Employed caregiver

Spectrum of long-term outcomes among survivors

Disability at 18-22 mo corrected age:  
- No or mild
- Moderate
- Severe

Weeks of completed gestation

Data from Rysavy et al. NEJM 2015
What about more mature preterm infants


N=153,730
How do extremely preterm infants do in adulthood?
Researchers evaluated 100 of 165 very-low birth weight survivors in Ontario, CA who were aged 29 to 36 years.

Outcomes compared to normal birth weight infants. 

Saigal S et al. JAMA Pediatrics 2016
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ELBW Cohort (n = 100)</th>
<th>NBW Cohort (n = 89)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Educational level</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>5/98 (5.1)</td>
<td>5/88 (5.7)</td>
</tr>
<tr>
<td>High school graduate</td>
<td>37/98 (37.8)</td>
<td>27/88 (30.7)</td>
</tr>
<tr>
<td>College or university graduate</td>
<td>48/98 (49.0)</td>
<td>44/88 (50.0)</td>
</tr>
<tr>
<td>Graduate or professional degree</td>
<td>8/98 (8.2)</td>
<td>12/88 (13.6)</td>
</tr>
<tr>
<td>Years of education, mean (SD)</td>
<td>16.0 (2.8)</td>
<td>16.7 (3.2)</td>
</tr>
<tr>
<td><strong>Employment, income, and housing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed in last year</td>
<td>78/97 (80.4)</td>
<td>78/85 (91.8)</td>
</tr>
<tr>
<td>Full-time work the entire last year</td>
<td>48/78 (61.5)</td>
<td>59/77 (76.6)</td>
</tr>
<tr>
<td>Total personal income, mean (SD), CAD</td>
<td>26 484.65 (23 721.36)</td>
<td>46 551.62 (31 263.84)</td>
</tr>
<tr>
<td>Total household income, mean (SD), CAD</td>
<td>54 450.55 (41 004.41)</td>
<td>78 148.15 (41 985.45)</td>
</tr>
<tr>
<td>Social assistance</td>
<td>12/87 (13.8)</td>
<td>3/81 (3.7)</td>
</tr>
<tr>
<td>Owns home</td>
<td>33/96 (34.4)</td>
<td>36/85 (42.4)</td>
</tr>
<tr>
<td>Subsidized housing</td>
<td>8/96 (8.3)</td>
<td>2/84 (2.4)</td>
</tr>
<tr>
<td>Special living arrangements</td>
<td>7/98 (7.1)</td>
<td>1/89 (1.1)</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Value(^a)</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>----------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ELBW Cohort (n = 100)</td>
<td>NBW Cohort (n = 89)</td>
</tr>
<tr>
<td>Relationships</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not or rarely dating</td>
<td>30/96 (31.3)</td>
<td>11/84 (13.1)</td>
</tr>
<tr>
<td>Never married or single</td>
<td>51 (51.0)</td>
<td>31 (34.8)</td>
</tr>
<tr>
<td>Sexuality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identify as nonheterosexual</td>
<td>9/96 (9.4)</td>
<td>2/86 (2.3)</td>
</tr>
<tr>
<td>Never experienced sexual intercourse</td>
<td>20/97 (20.6)</td>
<td>2 (2.2)</td>
</tr>
<tr>
<td>Age of first intercourse, mean (SD), y</td>
<td>19.7 (4.0)</td>
<td>18.4 (3.3)</td>
</tr>
<tr>
<td>Reproduction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have children</td>
<td>20 (20.0)</td>
<td>29 (32.6)</td>
</tr>
<tr>
<td>No. of children, mean (SD)</td>
<td>1.7 (0.8)</td>
<td>1.5 (0.6)</td>
</tr>
</tbody>
</table>
Table 4. Social Integration and Risk-Taking Behaviors

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ELBW Cohort (n = 100)</th>
<th>NBW Cohort (n = 89)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social relationships, mean (SD)(^a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relationship with partner</td>
<td>13.10 (5.04)</td>
<td>12.59 (4.73)</td>
</tr>
<tr>
<td>Family functioning</td>
<td>40.44 (6.76)</td>
<td>41.13 (6.11)</td>
</tr>
<tr>
<td>Loneliness</td>
<td>34.59 (11.61)</td>
<td>31.11 (10.43)</td>
</tr>
<tr>
<td>Self-esteem</td>
<td>29.16 (24.44)</td>
<td>20.45 (20.31)</td>
</tr>
<tr>
<td>Social support index</td>
<td>102.03 (24.90)</td>
<td>108.64 (24.43)</td>
</tr>
<tr>
<td>Risk-taking behaviors, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current alcohol abuse or dependence</td>
<td>10/81 (12.3)</td>
<td>16/83 (19.3)</td>
</tr>
<tr>
<td>Lifetime alcohol abuse or dependence</td>
<td>17/81 (21.0)</td>
<td>40/85 (47.1)</td>
</tr>
<tr>
<td>Current drug abuse or dependence</td>
<td>4/81 (4.9)</td>
<td>13/85 (15.3)</td>
</tr>
<tr>
<td>Lifetime drug abuse or dependence</td>
<td>13/81 (16.0)</td>
<td>21/84 (25.0)</td>
</tr>
<tr>
<td>Contact with police</td>
<td>7 (7.0)</td>
<td>9/88 (10.2)</td>
</tr>
<tr>
<td>Convicted or incarcerated</td>
<td>4 (4.0)</td>
<td>7/88 (8.0)</td>
</tr>
<tr>
<td>Used protection during sex</td>
<td>65/79 (82.3)</td>
<td>69/87 (79.3)</td>
</tr>
</tbody>
</table>

\(^a\) SD: Standard Deviation
Tools for counseling
Intensive Care for Extreme Prematurity — Moving Beyond Gestational Age

Jon E. Tyson, M.D., M.P.H., Nehal A. Parikh, D.O., John Langer, M.S., Charles Green, Ph.D., and Rosemary D. Higgins, M.D., for the National Institute of Child Health and Human Development Neonatal Research Network*
Gestational Age (Best Obstetric Estimate in Completed Weeks): 24 weeks

Birth Weight: 500 grams
Sex: Male
Singleton Birth: Yes
Antenatal Corticosteroids: Yes

Estimated outcomes* for infants in the NRN sample are as follows:

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Outcomes for All Infants</th>
<th>Outcomes for Mechanically Ventilated Infants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival</td>
<td>35%</td>
<td>39%</td>
</tr>
<tr>
<td>Survival Without Profound Neurodevelopmental Impairment</td>
<td>22%</td>
<td>24%</td>
</tr>
<tr>
<td>Survival Without Moderate to Severe Neurodevelopmental Impairment</td>
<td>12%</td>
<td>13%</td>
</tr>
<tr>
<td>Death</td>
<td>65%</td>
<td>61%</td>
</tr>
<tr>
<td>Death or Profound Neurodevelopmental Impairment</td>
<td>78%</td>
<td>76%</td>
</tr>
<tr>
<td>Death or Moderate to Severe Neurodevelopmental Impairment</td>
<td>88%</td>
<td>87%</td>
</tr>
</tbody>
</table>

*Estimated outcomes are based on retrospective analysis and may not fully reflect current clinical scenarios.

http://www.nichd.nih.gov/about/org/cdbpm/pp/prog_epbo/epbo_case.cfm
<table>
<thead>
<tr>
<th>Outcomes for Mechanically Ventilated Infants</th>
<th>Survival</th>
<th>24wk, 500gm, Male, No steroids</th>
<th>24wk, 500gm, Male, with steroids</th>
<th>24wk, 500gm, Female with steroids</th>
<th>24wk, 600gm, Male with steroids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival</td>
<td></td>
<td>26%</td>
<td>39%</td>
<td>50%</td>
<td>52%</td>
</tr>
</tbody>
</table>

http://www.nichd.nih.gov/about/org/cdbpm/pp/prog_epbo/epbo_case.cfm
NRN outcome estimator limitations

- Data do not reflect changes in outcomes over last 15 years
- Misclassification rate of ~25%
- Center is not included as a factor
- Imprecision in outcome estimate not quantified
Other decision aid tools

**At Birth**

**Survival**

- 22 - 22.6 weeks: Range: 2-9%
- 23 - 23.6 weeks: Range: 7-31%
- 24 - 24.6 weeks: Range: 21-65%
- 25 - 25.6 weeks: Range: 40-81%

Things that alter survival:
- Gender
- Race
- Weight
- Multiples
- Steroids

**Long Term**

- Mental Disability: Range: 18-54%
- Cerebral Palsy: Range: 6-36%
- Blindness: Range: 1-15%
- Deafness: Range: 1-9%

Things that affect a poor outcome:
- BPD (lungs)
- IVH (brain)
- ROP (eyes)

Summary

• Survival among periviable infants at 22-25 weeks’ gestation has improved in recent years
  – Death more common outcome at 22 to 23 weeks
  – Substantial center variation in outcomes, largely because of variation in active treatment (resuscitation)

• Neurodevelopmental outcomes are difficult to predict and can change over time

• Limitations in tools for prediction of outcomes should be considered if using to counsel patients
Thank you.

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