Challenging Your Practice and Heart – The Limits of Viability

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Disclosures

- I have no financial disclosures
- I will not be discussing use of off-label therapies



Polling instructions

- Go to pollev.com/benjaminmack277
- Click on answers as slides come up
- Your answers are anonymous



Objectives

- 1. Understand and define limits of perinatal viability
- 2. Understand change in outcomes over last 40 years
- 3. Identify ethical arguments for- and againstintervention at the limits of viability



Outline

- Review most recent outcomes for infants born at the limits of viability
- Summarize most recent statements by AAP, ACOG, and SMFM
- Discuss ethics surrounding resuscitation of the periviable infant



Keep in Mind

- Arguments against treatment of extremely premature infants
 - Futility
 - Cost
 - Adverse outcomes



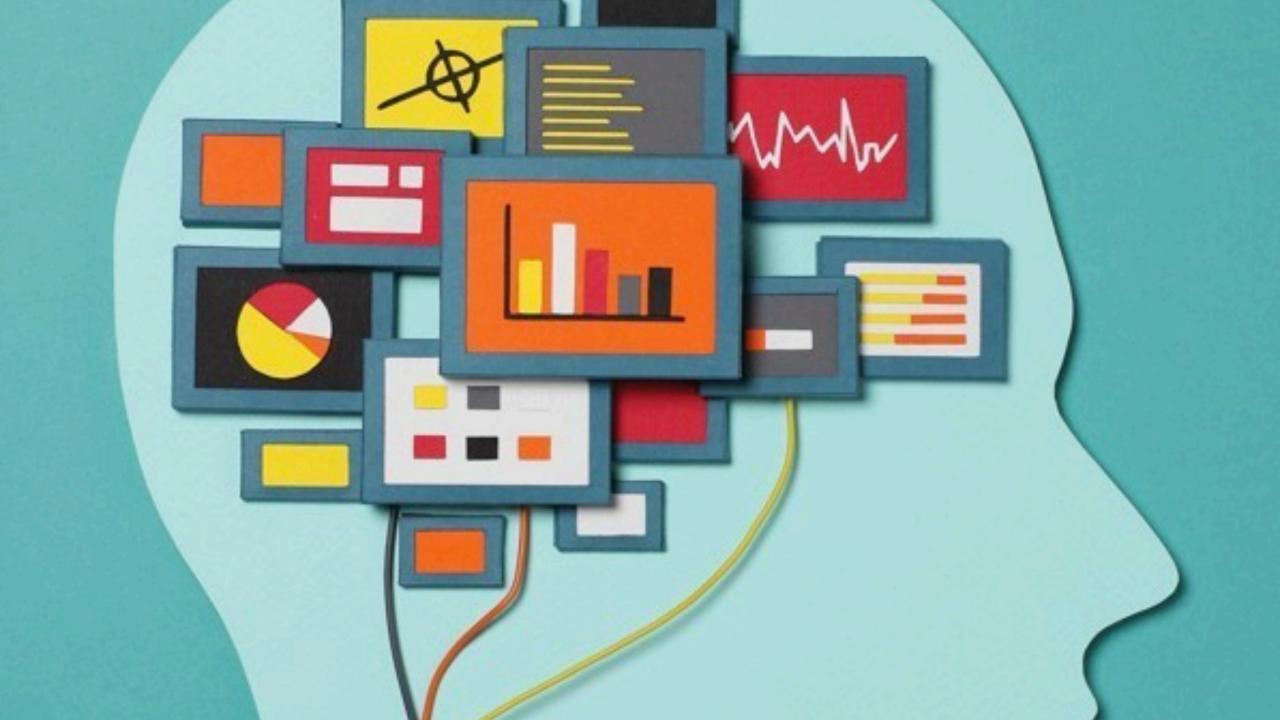
Review of Outcomes



Periviability

• Infants born at 20 0/7 wks EGA to 24 6/7 wks EGA





Factors that affect Data - Source

- Variations in regional and local practices
 - International
 - National
 - Regional
 - Single institution



Factors that affect Data – Cohort Selection

- Exclusion
 - Newborns that did not survive to NICU admission (results in overestimated survival)
 - 10/50 = 20% OR 10/100 = 10%



Factors that affect Data – Cohort Selection

- Inclusion
 - Non-resuscitated infants (results in underestimated survival)
 - 20/100 = 20% OR 20/50 = 40%
 - Anomalous infants (results in underestimated survival)

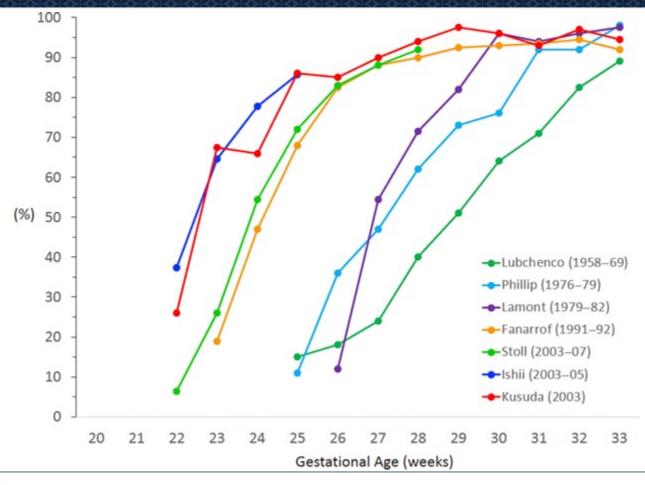


Births and Deaths in the US

- ~3 million people die each year in the US
- ~4 million babies born each year
 - 1% of births are < 1000g (~ 40,000)
 - 0.6 % of all births will die (~ 24,000)
 - Half of neonatal deaths are due to prematurity (~ 12,000)

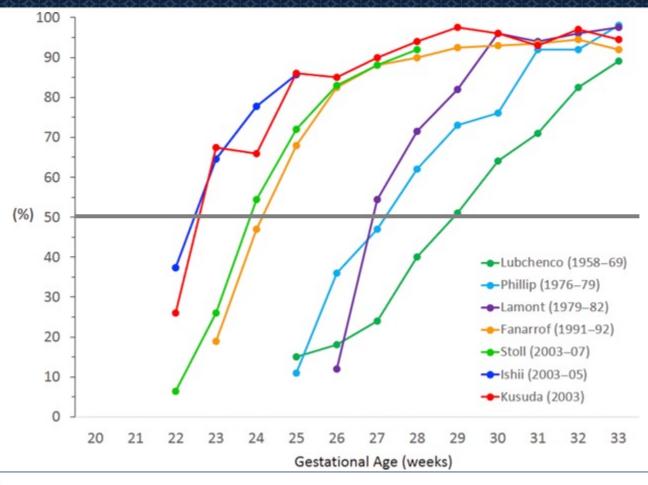


Survival Over The Decades



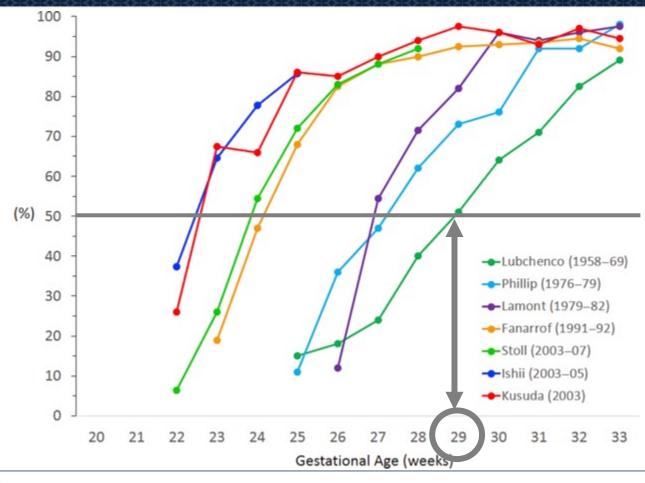






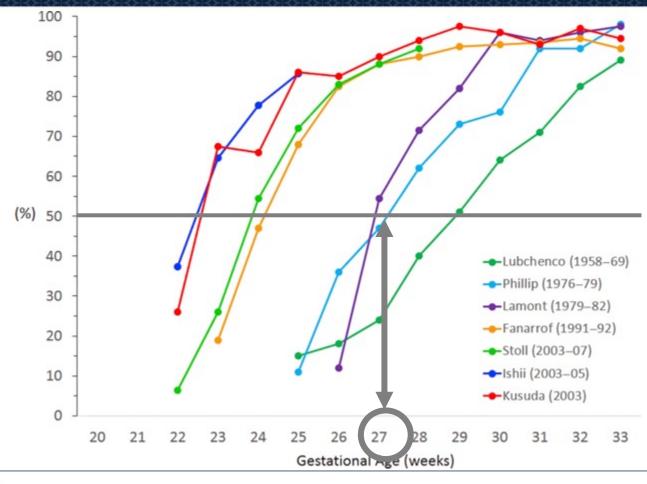






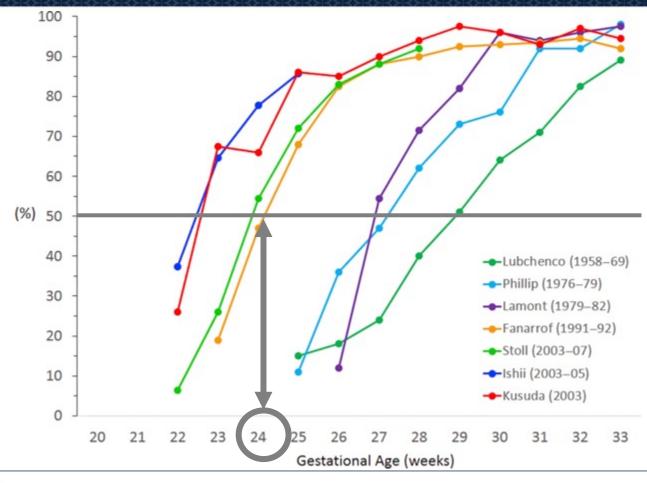






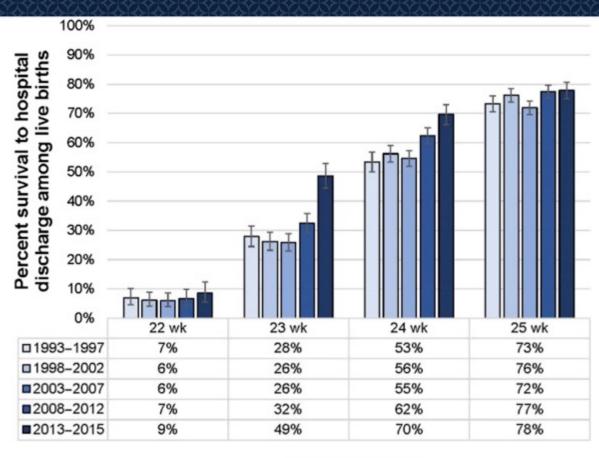










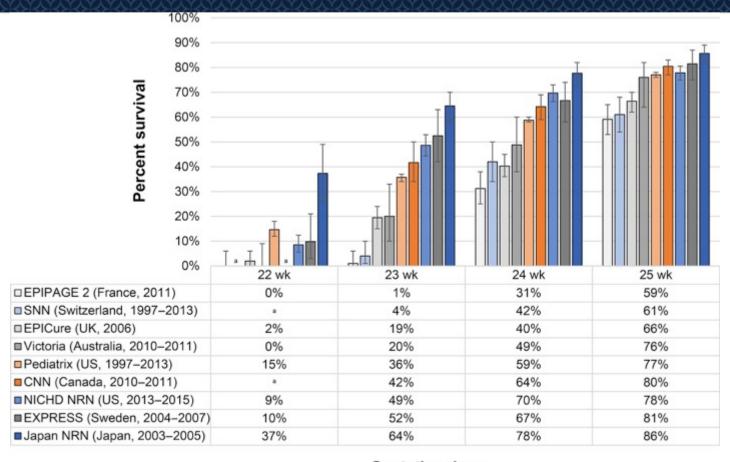


Gestational age





Survival by country

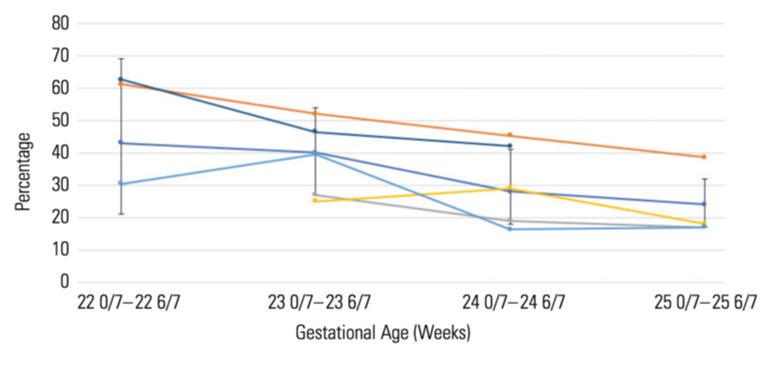


Gestational age





Survival and Neurodevelopmental Outcomes

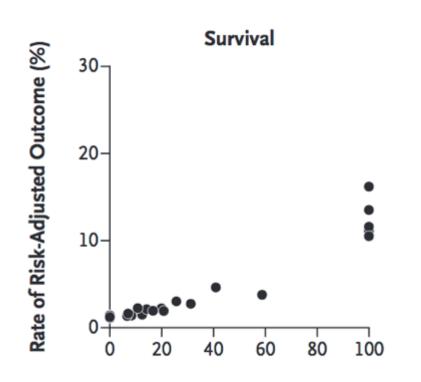


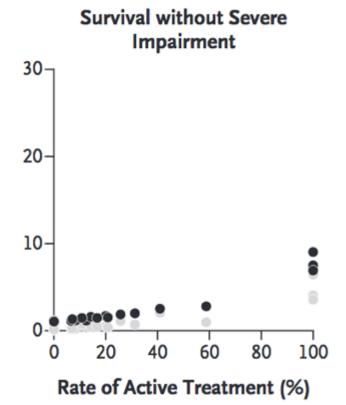
- Rysavy 2015 Percentage survival with moderate or severe impairment among surviving newborns*
- Wood 2000 Reflects 1995 data; percentage survival with severe disability at 30 months[†]
- Moore 2013 Percentage survival with moderate to severe impairment at 4–8 years[‡]
- Marlow 2005 Reflects 1995 data; percentage survival with overall severe disability at 6 years§
- Ishii 2013 Percentage survival with profound neurodevelopmental impairment
- Younge 2017 Percentage of surviving neonates with neuro-developmental impairment at 18–22 months corrected age Epoch 3 (2008–2011)[¶]

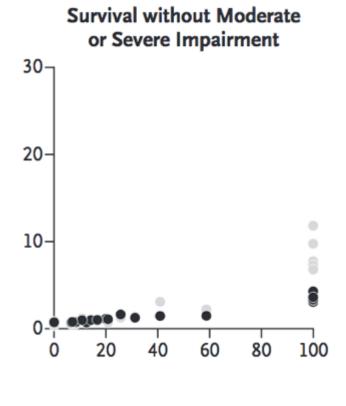


Hospital Variation

A 22 Wk of Gestation









What about babies <400g?

- 2008-2016 NICHD NRN
- 22-26 wks EGA
- 101/205 actively treated
- 26/101 survived
 - 6/36 22-23 wks EGA survived (17%)
- 19/90 were evaluated at 18-26 mths
 - 14/19 with mod-severe NDI (74%)



Summary of Statements



AAP/ACOG/SMFM Statements

- AAP Committee on Fetus and Newborn
 - 2002 MacDonald
 - 2009 Batton
 - 2015 Cummings



AAP/ACOG/SMFM Statements

- Joint AAP/ACOG/SMFM Workshop 2014
- ACOG/SMFM
 - Obstetric Consensus #3 2015
 - Obstetric Consensus #4 2016
 - Obstetric Consensus #6 2017



Decision-Making Zones

- Beneficial intervention is indicated because of good outcomes
- Futile intervention is not recommended because of improbable survival
- "Gray zone" outcomes could justify either life support or withholding life support



1980

20 21 22 23 24 25 26 27 28 29 30



1990

20 21 22 23 24 25 26 27 28 29 30



2000

20 21 22

23 24 25 26 27 28 29 30



2019

20 21 22 23 24 25 26 27 28 29 30



Gestational Age is a Poor Predictor of Outcome

- Rapid rate of fetal growth and development between 22 wks and 25 wks
- First trimester ultrasound gold standard for dating:
 - Can be wrong by 4-7 days (some data show up to 14 days) at 24 wks EGA
- Most precise measure of GA is with assisted reproductive technology



Gestational Age is a Poor Predictor of Outcome

- Is a 23 6/7 wks fetus very different from a 24 0/7 wk infant?
- Conclusion: GA should NOT be the only factor used in discussing outcomes with parents



Antenatal Factors

- Beyond gestational age at birth and active treatment, factors that increase probability of survival:
 - Higher fetal weight
 - Female sex
 - Singleton gestation
 - Receipt of antenatal steroids
- NICHD outcomes calculator (uses data from 1998-2003)



Physical Exam

- Physical exam at birth to determine level of development and likelihood of survival?
 - We're not very good at it



2014 Joint Workshop – Obstetric Interventions

	Weeks of gestation ^b		
Variable	<22 0/7	22 0/7-22 6/7	≥23 0/7
Antenatal corticosteroids	Not recommended	Consider if delivery at $\geq\!\!23$ 0/7 is anticipated	Recommended
Tocolytics to enhance latency for potential steroid benefit	Not recommended	Not recommended unless concurrent with antenatal steroids	Consider
Magnesium sulfate for neuroprotection	Not recommended	Not recommended	Recommended
Antibiotics for preterm premature rupture of membranes to enhance latency	Consider if delivery not imminent	Consider if delivery not imminent	Recommended if delivery not imminent
Intrapartum antibiotics for group B streptococcus prophylaxis ^c	Not recommended	Not recommended	Recommended
Continuous intrapartum electronic fetal monitoring	Not recommended	Not recommended	Recommended
Cesarean delivery for fetal indication ^d	Not recommended	Not recommended	Recommended
Aggressive newborn infant resuscitation	Not recommended, comfort care only	Not recommended unless considered potentially viable based on individual circumstances	Recommended unless considered nonviable based on individual circumstances



2014 Joint Workshop – Obstetric Interventions

Weeks of gestation ^b				
<22 0/7	22 0/7-22 6/7	≥23 0/7		
Not recommended	Consider if delivery at $\geq\!$ 23 0/7 is anticipated	Recommended		
Not recommended	Not recommended unless concurrent with antenatal steroids	Consider		
Not recommended	Not recommended	Recommended		
Consider if delivery not imminent	Consider if delivery not imminent	Recommended if delivery not imminent		
Not recommended	Not recommended	Recommended		
Not recommended	Not recommended	Recommended		
Not recommended	Not recommended	Recommended		
Not recommended, comfort care only	Not recommended unless considered potentially viable based on individual circumstances	Recommended unless considered nonviable based on individual circumstances		
	Not recommended Not recommended Not recommended Consider if delivery not imminent Not recommended Not recommended Not recommended Not recommended	✓22 0/7 22 0/7-22 6/7 Not recommended Consider if delivery at ≥23 0/7 is anticipated Not recommended Not recommended unless concurrent with antenatal steroids Not recommended Not recommended Consider if delivery not imminent Consider if delivery not imminent Not recommended Not recommended Not recommended Not recommended Not recommended Not recommended Not recommended Not recommended unless considered potentially viable based on individual		



2017 ACOG/SMFM – Obstetric Interventions

	20 0/7 weeks to	22 0/7 weeks to	23 0/7 weeks to	24 0/7 weeks to	25 0/7 weeks to
	21 6/7 weeks	22 6/7 weeks	23 6/7 weeks	24 6/7 weeks	25 6/7 weeks
Neonatal assessment for resuscitation*	Not recommended	Consider	Consider	Recommended	Recommended
	1A	2B	2B	1B	1B
Antenatal corticosteroids	Not recommended	Not recommended	Consider	Recommended	Recommended
	1A	1A	2B	1B	1B
Tocolysis for preterm labor to allow for antenatal corticosteroid administration	Not recommended	Not recommended	Consider	Recommended	Recommended
	1A	1A	2B	1B	1B
Magnesium sulfate for neuroprotection	Not recommended 1A	Not recommended 1A	Consider 2B	Recommended 1B	Recommended 1B
Antibiotics to prolong latency during expectant management of preterm PROM if delivery is not considered imminent	Consider 2C	Consider 2C	Consider 2B	Recommended 1B	Recommended 1B
Intrapartum antibiotics for group B streptococci prophylaxis†	Not recommended	Not recommended	Consider	Recommended	Recommended
	1A	1A	2B	1B	1B
Cesarean delivery for fetal indication [‡]	Not recommended	Not recommended	Consider	Consider	Recommended
	1A	1A	2B	1B	1B



2017 ACOG/SMFM – Obstetric Interventions

20 0/7 weeks to	22 0/7 weeks to	23 0/7 weeks to	24 0/7 weeks to	25 0/7 weeks to
21 6/7 weeks	22 6/7 weeks	23 6/7 weeks	24 6/7 weeks	25 6/7 weeks
Not recommended	Consider	Consider	Recommended	Recommended
1A	2B	2B	1B	1B
Not recommended	Not recommended	Consider	Recommended	Recommended
1A	1A	2B	1B	1B
Not recommended	Not recommended	Consider	Recommended	Recommended
1A	1A	2B	1B	1B
Not recommended	Not recommended	Consider	Recommended	Recommended
1A	1A	2B	1B	1B
Consider	Consider	Consider	Recommended	Recommended
2C	2C	2B	1B	1B
Not recommended	Not recommended	Consider	Recommended	Recommended
1A	1A	2B	1B	1B
Not recommended	Not recommended	Consider	Consider	Recommended
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Recommended Approach

Prenatal discussion as a team with parents is best



Prenatal Counseling

- No "cookie-cutter" approach every family is different
- Avoid framing bias
- Determine if goal is to optimize the chance of survival or minimize the likelihood of suffering
- Comfort care should be offered as an option



Comfort Care

"A decision not to undertake resuscitation of a live born infant should not be seen as a decision to provide no care, but rather a decision to redirect care to comfort measures"



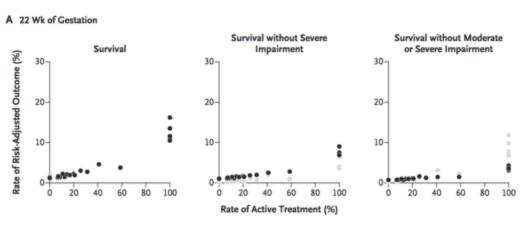
Maternal Health Considerations

- Little/no risk to mother:
 - Fetal monitoring
 - Steroids
 - Magnesium sulfate
- Possible short- and long-term consequences
 - Emergent cerclage
 - Classical c-section



Numbers – Active Treatment

"Policies do not just reflect outcomes, they shape them." – Janvier and Lantos





Ethics



Ethics

Premature infants are a vulnerable population



Principles of Biomedical Ethics

Autonomy

Respect for parental decision-making authority

Beneficence

Do what is best for the patient

Non-Maleficence

"Do no harm"

Justice

Equals ought to be treated equitably



- Futile/painful
- Too expensive
- Majority of survivors are disabled

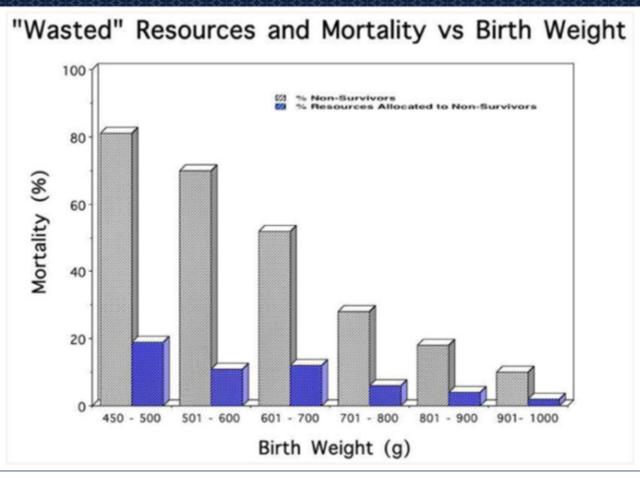


- Futile
 - With treatment 20-70% of patients at 22-23 wks
 EGA survive
 - Pancreatic cancer survival: 1-yr 20%, 5-yr 7% (Hirschberg Foundation)

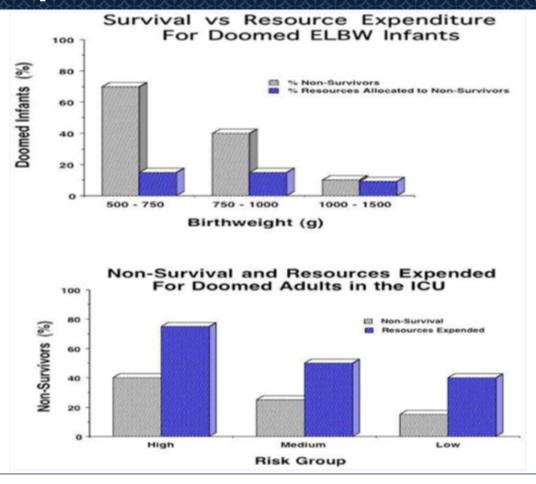


- Too expensive
 - NICU care is expensive but cost-effective
 - <\$10,000 per quality-adjusted life-year (for ELBW)</p>
 - More cost-effective than routine Pap smears, treatment of severe hypertension, coronary artery bypass surgery (5X), and renal dialysis (5X)









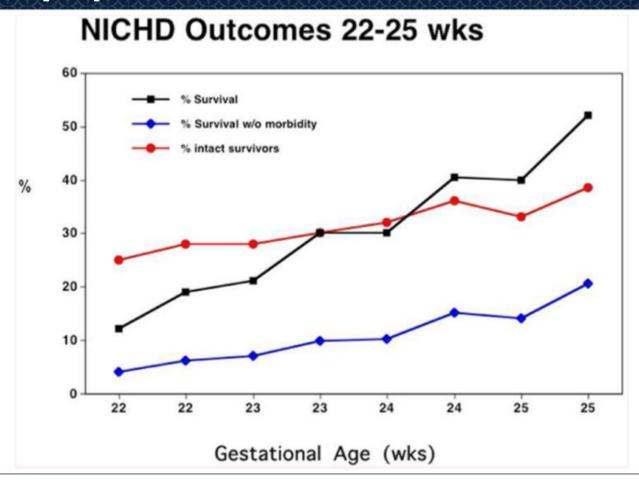


Majority of survivors are disabled - are they?



- 4 possible outcomes after birth
 - 1. Comfort care death
 - 2. Resuscitation at birth death before discharge
 - 3. Resuscitation at birth survival with neurodevelopmental impairment (NDI)
 - 4. Resuscitation intact survival (no NDI)







- Majority of survivors are disabled
 - Maybe not



How do we measure quality of life?



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Questions?



References

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