Background: Why is this important?

- Danger in stacking the Born-Alive law, EMTALA, CAPTA could lead to mandated "emergency" medical treatment (Sayeed, Pediatrics 2005)
- Two legal cases to explore this issue of "emergency"
  - Preston v. Meriter Hospital Inc., WI - EMTALA case
  - Re HCA v. Miller, Texas - an emergency exception to informed consent –
- Robertson's recommendations of trial of assessment and treatment for ***all premature infants***

Background: Emergency Medical Treatment and Active Labor Act (1994)

- 23 2/7th weeks, no resuscitation efforts, Infant died at 2 ½ hours of life. (1999)
- Courts dismissed claims for:
  - Medical Negligence
  - Failure to obtain informed consent
  - Neglect of a patient
- Potential violation of EMTALA
  - imposes a duty upon a hospital to provide a ***medical screening examination*** to a newborn who 1) presents to the emergency room of the hospital or 2) ***is born in the birthing center*** of the hospital and otherwise meets the conditions set forth in 42 C.F.R. §489.24 (b) (1999).
- One Risk Manager interpreted this to mean we have to resuscitate ***all*** preterm newborns

Preston v. Meriter Hospital Inc. WI, 2004

Case: HCA v. Miller

- 22 4/7 weeks with re-dating to 23 1/7 weeks on admission (1990)
- Counseled as an "unfortunate late miscarriage" and parents agreed to the ***recommendation*** of ***no*** resuscitation
- Father was sent out to make funeral arrangements
- Hospital "ethics committee" argued hospital policy and state and federal laws required them to resuscitate a live born infant
- Infant delivered, resuscitated, and spent 8 months in the NICU, and everything parents consented for was based on premise of comfort or reduction in further harm
- Parents remained steadfast for DNR
- Parents sued the hospital based on ***breech of informed consent*** and were awarded $29.4 million for medical expenses, $13.5 million in punitive damages, and $17.5 million in accrued interest

HCA v. Miller: Texas Supreme Court

- Circumstances in the case provide an exception to the general rule imposing liability on a physician for treating a child without consent: that a physician providing life-sustaining treatment to a minor child under "***emergent circumstances***" is not liable for failing to obtain consent from the parents first
- The evidence established that an infant could only be properly evaluated when she was born
- Any decision by the parents concerning her treatment at or after her birth would necessarily be based on speculation
- Every birth of an infant at the limits of viability is an ***emergent circumstances***, and a physician is not liable for failing to obtain consent from the parents first

Trial of Assessment & Treatment

- Robertson argues this is good reasoning and ***all*** infants should be given a trial of assessment and treatment. This includes an assessment of gestational age and vigorousness, with the goal to test treatment response for 24 hours to gain more facts to help determine prognosis. This is reasonable because treatment withdrawal is often ethically justified later when there has been more time to discuss.

Robertson JA Extreme prematurity and parental rights after Baby Doe. Hastings Center Report 2004

Trial of Assessment & Treatment: 4 premises

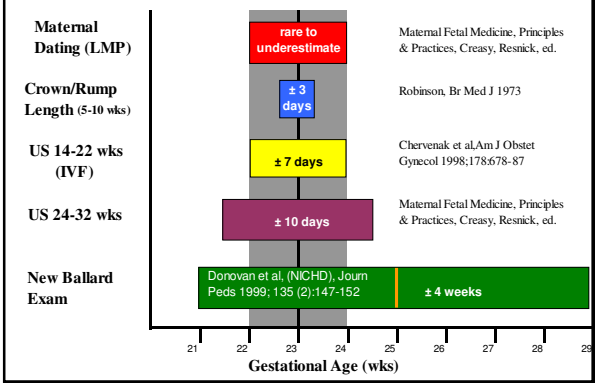
1. Assessment of gestational age after birth is more accurate
2. Assessment of vigorousness adds prognostic information
3. Testing treatment responses in first 24 hours provides more "facts" or certainty to help determine long term prognosis and therefore decrease speculation
4. Treatment withdrawal is ethically equivalent to withholding

- Are these premises true for ***all*** cases at the limits of viability?

Premise 1

- Is assessment of gestational age after birth more accurate than prenatal assessment of gestation age in all pregnancies?

Certainty of Gestational Age Measures



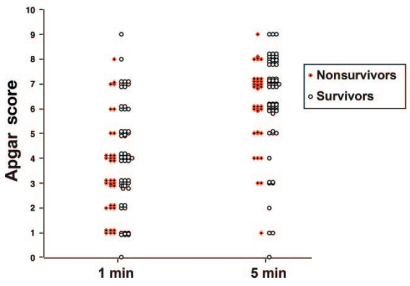
Premise 2

- Is the neonatal assessment of vigorousness predictive of long term outcome – mortality or morbidity?

No study comparing the vigorous 23 weeker with the non-vigorous one that demonstrates one does better long term

Premise 2

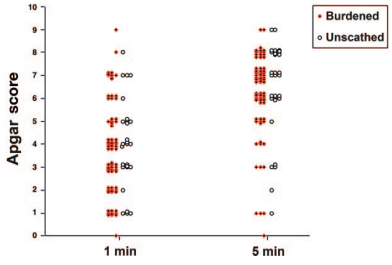
FIGURE 3
Distribution of Apgar scores at 1 and 5 minutes as a function of survival versus nonsurvival for 102 extremely premature infants (BW: 640 +/-86 g; GA: 24.9 +/- 1.5 weeks). There was no Apgar score cutoff above which survival was assured or below which death was assured.



Singh J. *Pediatrics* 2007;120;519

Premise 2

FIGURE 4
Distribution of Apgar scores at 1 and 5 minutes as a function of morbidity for 86 extremely premature infants. There was no Apgar-score cutoff below which a burdensome outcome was assured or above which an unscathed outcome was likely.



Singh J. *Pediatrics* 2007;120;519

Premise 3

- Does treatment response provide more "facts" or certainty to help determine long term prognosis and therefore decrease speculation?

What responses provide factual vs. speculative predictions?

- Grade 3-4 IVH increases risk, but…
- Normal head ultrasound at one week
  - 1/3rd of infants with significant neurologic handicaps
- Response to surfactant and ventilation?
  - Doesn't necessarily predict BPD or any other outcome
- 24 hours provides no more prognostic value
  - No added information on risk of NEC, BPD, PDA, iatrogenic infection, AKI, ROP, long-term neurologic morbidity (CP, MR, autism…), late death

Can we predict who will die?

- SNAP Scores? No good
- Intuition of death? Actually right about 50 % of the time
- Serial assessments of impending death for an individual infant are imperfect to begin with and grow less accurate each day
- If absolute certainty about mortality is the only criterion to justify withholding/ withdrawing, decisions are difficult on the first day and are more problematic thereafter
- Intuition of death + abnormal HUS = 100% predictive of either death or severe disability

Meadow W. Pediatrics 2002
Lagatta

Can we predict who will die?

- "If we acknowledge medicine is an inexact science, and that clinical predictions can never be perfect, we can ask the more interesting question of whether good but less-than-perfect predictions of imprecise but ethically relevant clinical outcomes can still be useful."

Meadow W. Pediatrics 2002

Does assessment and treatment after delivery really improve precision of the less-than-perfect predictions for the ethically relevant clinical outcomes?

Premise 4

- Is treatment withdrawal ethically equivalent to withholding from the parents perspective and ability?

Premise 4

- Mr. Miller said to me that he was offered the option to withdraw support when his baby girl had a bad IVH, but

  "now they are asking me to kill my child that they wanted to save."
- Ethical and legal arguments allow withdrawal
- Commonly practiced in neonatology
- But if parents or physicians do not buy into the argument, the premise falls apart

Conclusions

- The Courts and Robinson's reasoning is based on four false assumptions.
  - Medical evidence supports that maternal and obstetrical dating, if known, are more accurate than a neonatologists exam
  - No data supporting that vigorousness adds to prognosis
  - 24 hours provides no more prognostic certainty to the ethical decision-making
  - Not all parents consider withdrawal ethically equivalent to withholding

Therefore, the facts may be worse, prognosis remains speculative, and ethical decisions are not necessarily easier

Conclusion

Requiring or allowing neonatologists to override parental refusal based on their assessment of the infant at birth and treatment response is to make an ethical decision on less accurate or unproven facts. The trial of assessment and treatment is ***not necessary*** for good ethical decision-making for ***all*** infants at the limits of viability.

Montalvo Facts:

- Pre-term labor symptoms
- Ultrasound: 23 3/7 weeks & 679 gm infant
- Informed consent for Cesarean procedure
- Unable to stop labor
- Cesarean section delivery
- Life-saving measures by neonatologist
- Infant lives
- Parents sue

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Parents' Claim:

- MD's violated Informed Consent statute
- MD's did not advise parents of the risks r/t premature birth
- Extraordinary care decisions should be made by parents, not MD's

Note: ***No allegation of harm or disability***

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Appellate Court Holding

- No obligation to obtain informed consent because no viable alternative existed:
  1. WI case law (Edna MF)
  2. Federal Law (Child Abuse Protection & Treatment Act)
- Emergency exception applicable
- Public policy
- Claim dismissed

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Appellate Court decision:

- "Thus, in Wisconsin, in the absence of persistent vegetative state, the right of a parent to withhold life-sustaining medical treatment from a child **does not exist**."
- Because Montalvo infant was not in pvs the "alternative of withholding life-sustaining treatment did not exist."

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The Question

"An untimely birth is better off than a living person, for the miscarriage goes into darkness, where its name disappears: it has not seen the light nor known anything, yet it finds a rest denied to the living"

Book of Ecclesiastes 6. 3-5

Thinking about Best Interest

- "What would I do if this were my child?"
- The underlying assumption in that question, if it were your child you would have a choice.
- If you ask, and if you would like to answer it, you must be willing to let others answer it for their children.
- If you want to maintain that right, you must be willing to allow others to make decisions that you would not.

"I disagree with everything you say, but I will defend to death your right to say it." Voltaire

Harm & Uncertainty

- Premise: Death can be preferable to severe, intolerable deficits
- Vector of technical progress:

Neonatal Death ⇒ Serious Handicap ⇒ Moderate Handicap or Normal

- Value-ordering of outcomes

Serious/ intolerable Handicap ⇒ Neonatal Death ⇒ Moderate Handicap or Normal

Harm & Uncertainty

- Uncertainty #1
  - What is the definition of intolerable deficits?
- Uncertainty #2
  - At the time of intervention we do not know whether the baby has been benefited or harmed
- Uncertainty #3
  - It is not clear how one can judge the rational acceptability of a ratio between the likelihood of the best outcome and the worst outcome
  - Who decides what risk to take for an individual infant?

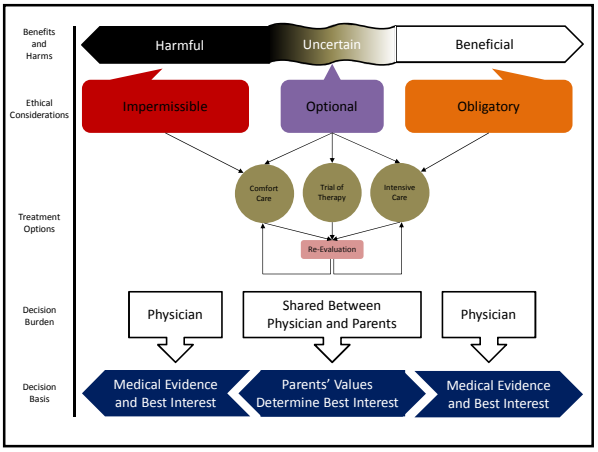

Figure 3. Ethical Framework for Considering Prenatal Decisions. The harms and benefits of resuscitation and intensive care should be considered based on the anticipated prognosis of the individual infant. If the harms clearly outweigh benefits, then only comfort care should be offered; the decision burden falls on the clinician and is based on medical evidence and the best interests of the infant. Conversely, if the benefits clearly outweigh harms, active treatment is obligatory, and only intensive care should be offered. Again, the decision burden falls on the physician, and the decision is based on medical evidence and the best interest of the infant. In between, when benefits and harms are uncertain, therapies are optional, and intensive care, comfort care, or the "middle ground" approach of a trial of therapy (with re-evaluation after delivery) should be offered. The decision burden in these situations is shared between physicians and parents, and the decision should be based on the parents' values determining the infants' best interest.

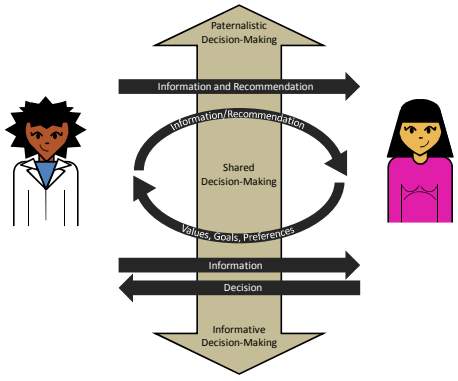

Figure 2. The Decision-Making Spectrum. In Paternalistic decision-making, the physician provides information and a recommendation to the patient. In Informative decision-making, the Physician provides information, and the patient makes a decision. Between these two models is the spectrum of shared decision-making, in which the physician provides information, the patient describes their values, goals, and preferences, and the physician may make recommendations or share in decision deliberations with the patient so that the decision made is based on both the medical information and the patient's values, goals and preferences.

Conceptual Quagmire

- "The most fundamental problem with technological medicine is two-fold; that it can give us a longer life and a slower dying and that it can keep us alive when we might be better off dead"

Callahan D. Living and dying with medical technology.
Critical Care Medicine 2003

The Gift of Life

"The right to personhood granted by law to a newborn infant is an empty gift. Only parents or equally committed surrogates can make this gift meaningful."

Silverman, Pediatrics 1992;70:66-70

Conclusion

"Decisions regarding appropriate resuscitation and treatment of the ELBW infants should neither be the triumph of hope over reason nor the victory of ego over uncertainty"

It is ethical acceptable for parents to choose a trial of assessment and treatment or to choose comfort care as not to overburden their infant

Finer & Barrington. Pediatrics 1998