Consent in the NICU: what do parents understand?

John D. Lantos MD
Children’s Mercy Bioethics Center
Kansas City, MO
The problem

• Big split between theory and reality with regard to informed consent
• True for standard therapy and research
Theory versus reality

• We aspire to give parents information to make informed decisions about treatment and research.

• Studies show that we usually fail.
An ideal model (from a study of consent for cancer clinical trials)

Journal of Pediatric Psychology vol. 30 no. 3 © Society of Pediatric Psychology 2005; all rights reserved.
The reality

• **MD:** Ms. C, I know you got a lot of information before Noelle was born. How did you feel about that information? Did it prepare you for when she actually arrived?

• **MRS C:** Most of the information that I received was at 3 AM when I was in premature labor—you only hear bits and pieces. Of the information they gave me that night, the only phrase that stuck in my head was cerebral palsy.

• Richardson, JAMA 2001
Qualitative study of understanding

• Semi-structured interviews
• Parents, MDs, RNs
• After the death of an infant
• Interviews by a hospital chaplain
• Focus on
  – understanding of the baby’s condition
  – the decision making process,
Themes in parental interviews

• Powerlessness
• Denial
• Concerns about decision making process
Powerlessness

"The doctor came in and told me...(the baby) was in critical condition. That's all I remember...I kept drifting off."

* * * * * * * *

"The nurses in Labor and Delivery were very good, very kind, but I was sort of in shock."

* * * * * * * *
Denial

Mother: A pediatrician came by and told me that they had about a 50/50 chance to survive. Then she told me all the awful problems they could have in.”

I: “Do you remember your reaction?”

M: “I don’t think I really reacted. I think I heard her, but not really. I just let her talk, but I kept believing my babies would be OK. I was in disbelief really. This just couldn’t be happening.
How did we get here?

• Two kinds of NICU narratives
  – “Miracle baby”
  – “They ruined my life”

• The second became the basis for current approach.
Doctors continue to treat preemie over parental objections.

Set in 1979.

Published in 1983.
Parents felt ignored

• “Our wishes, judgments, and thoughts were rarely of interest to the medical staff, who arrogated decisions to themselves as though we did not exist.”

• “Pessimistic assessments of Andrew’s condition and prognosis had been made by the Neurology Department, though they were never mentioned to us by anyone.”

• Long Dying of Baby Andrew
Bitter parents

• “If doctors and nurses knew what our life was going to be like, why shouldn’t we have known? They need to be more honest with parents.”
  – Debby Barrett, mother of Michael, born at 1 lb, 15 oz and 24 5/7 weeks.

Principles of family-centered care

- Parents must have available to them the same facts and interpretation of those facts as the professionals.

The problem

• The existential situation of a new mother of a critically ill baby is a totally unique situation
  – Stress
  – Uncertainty
  – Hormones
  – Role confusion
The data

• Studies of other populations
  – Parents who had a preemie long ago
  – The general population
  – Memoirs written in retrospect

• It is like studying a drug in one population then using it in a very different one
This Lovely Life

• “My milk had come in. I needed to decide if I would pump my milk or not, if there was a purpose to that act of motherhood. Everything was happening in the now and there was no standing back. I wished I could find word to describe how this whole mess felt oddly fated, that I was somehow meant to be Evan and Ellie’s mother.”
Research vs therapy

• Throughout the early years...
  – No bright line between research, innovative therapy, and standard care.
  – Information-giving and consent were individualized and unregulated

• Today – artificial bright line between “research” and “therapy.”
Paradoxical consent requirements

• Research in NICU generally safer than standard therapy
  • Only studies where there is genuine uncertainty
  • Consensus of experts about need for study
  • Careful monitoring for adverse events
  • Data safety monitoring boards

• But it is treated as much riskier
“Illogically, a mischievous view has been promoted that the interest of the vast number of patients involved in the poorly controlled experiments of informal medical ‘tinkering’ are less in need of protection than are those of the relatively small number of patients who are involved in planned, properly controlled clinical experiments.”

- Chalmers I, Silverman WA, Cont Clin Trials, 1987
• “The clinician who is convinced that a certain treatment works will almost never find an ethicist in his path, whereas his colleague who wonders and doubts and wants to learn will stumble over piles of them.”
  – Medical ethics: should medicine turn the other cheek? Lancet, 336 (1990), pp. 846–847
Consent: an impossible dream?

• “Most codes dealing with human experimentation start out with the bland assumption that consent is ours for the asking. This is a myth. The reality is that informed consent is often exceedingly difficult or impossible to obtain in any complete sense.”

What we need

• Studies of the right study population: mothers in labor or post-partum
  – What do they really want to know?
  – When and how do they want to be informed?
  – How can we know if they understand enough?
  – How to deal with communication:
    • Uncertainty
    • Probability
    • Range of outcomes
Goal

• Patient-centered informed consent
Thanks