

# Pursuing “Reasonableness” in the Communication of Research Evidence to Parents

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# Health Ethics

- Still an emerging profession.
- Not “oversight.” - Collaborative facilitation.
- A collaborative endeavor with 2 primary aims:
  - well-made, informed decisions
  - preventing and managing moral distress

# Collective ethics learning

-Many of you likely have ways of approaching this issue that are effective.... Please share.

My role here is to introduce the issue – for us to chew on collectively.

# Objectives

- Review and discuss the challenges around deciding how to advise parents optimally.
- Encourage a sharing of wisdom about how experienced researchers convey information to parents.

# Key general question

How should we decide what information to share, and which recommendations to offer, without *undue* influence?

# More specifically - how to respond to...

“...What do you think ... is it a good idea for me to enroll my child in this clinical trial?”

# Background

# From *Pediatrics* 2021; 147(5)

## Supporting Families Considering Participation in a Clinical Trial: Parent-Provider Perspectives

Terence R. Flotte, MD,<sup>a</sup> Blyth Taylor Lord, EdM,<sup>b</sup> Jennifer Siedman<sup>b</sup>

The emergence of efficacious human gene therapy for life-limiting genetic diseases such as spinal muscular atrophy type 1<sup>1</sup> has raised hopes

basics, such as efficacy; trial design, including the phases; participation criteria; and the emotional impact of decision-making. Its elements include

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Our middle child, Benjamin, was diagnosed with ...Sanfilippo syndrome in 1997 at the age of 15 months. At the time, this was a young age of diagnosis and, although devastated, we considered ourselves lucky. It seemed to us that with a fairly long runway, a breakout treatment would come in Ben's lifetime. Our coping strategy was to take action. We single-mindedly devoted ourselves to advocating and raising money for research. We became knowledgeable and invested in the science, connecting with each of the researchers working on Sanfilippo syndrome. When Ben was 4, the first actionable treatment, a stem cell replacement trial, began.

...The instinct to do anything to save our son, combined with pressure from the research team, was intense. Our own knowledge of the science convinced us of the greater potential of emerging gene and enzyme replacement therapies. And although no medical profession confirmed this, we believed that enrolling Ben in the stem cell trial would likely exclude him from later trials. We decided not to enroll him, ...

# Quote

When your child is a potential candidate for a clinical trial, you must consider the following: Is this the best option? How do you know? What do you “owe” to medical research, if anything? Some specialists are helpful, others are not. Industry is eager to have you. . . . Decisional regret can be the source of angst for many families, particularly when their child dies.

# Shared Decision-making.

Balance between “old-fashioned paternalism” and “radical autonomy.”

Clinician / researcher and patient/parent in partnership.

# Anatomy of an ideal decision

- Well informed.
  - Aware of options – risks, benefits, alternatives.
- Well considered.
- Shared between patient, physician, others.
- Inherent difficulties and uncertainties are accepted.
- Physician and team absorb as much of the ***burden*** of the decision as the patient/parents need.

# “Reasonableness”

“Reasonable person standard”

-see Norman Daniels’ writing for more on this.

# Clinical Equipoise

-idea that a researcher must recognize that knowledgeable experts have an honest uncertainty about which arm of any trial is preferable.

# Ethicist Benjamin Freedman on Clinical Equipoise...

- I suggest an alternative concept of equipoise, which would be based on present or imminent controversy in the clinical community over the preferred treatment. According to this concept of “clinical equipoise,”~ the requirement is satisfied if there is genuine uncertainty within the expert medical community — not necessarily on the part of the individual investigator — about the preferred treatment.

# Equipoise in Clinical Practice

- The idea that one needs to convey to patients not only one's own opinions about treatment, but also the predicted opinions of one's colleagues.
  - In order to give the full range of options to patients facing difficult, “grey zone” decisions.
  - In order to expand your own sense of “reasonableness.”

# Uncertainty

-To what degree should this be shared?

- within self
- among team
- with parents

# Conflicts of Interest

- primarily exist within the minds of individuals.
- Should be recognized, if they are to be managed.
- Are subtle ... who might you be trying to please, unconsciously?
  - colleagues?, Funders?, supervisor?

# Research vs. Therapy

Dividing line between these is not always clear.

How do you explain this reality to parents?

# “Undue” influence?

In shared decision making, some *influence* is required.

Self awareness and honest discussion among teams should help determine how best to share decisions. - to avoid a sense that you have “oversold” the benefits of a trial.

# Sufficiently Informed?

Close communication among core decision-makers enables each to be aware of how the other has approached any decision.

-achieving this sensibility is key to preventing future regret.

# Breastfeeding, Physical Growth, and Cognitive Development

Jordyn T. Wallenborn, MPH, PhD,<sup>a,b</sup> Gillian A. Levine, MPH, PhD,<sup>a,b</sup> Angélica Carreira dos Santos, MPH, PhD,<sup>c</sup> Sandra Grisi, PhD,<sup>c</sup> Alexandra Brentani, PhD,<sup>c,\*</sup> Günther Fink, PhD<sup>a,b,\*</sup>

**BACKGROUND AND OBJECTIVES:** Breastfeeding is an evidence-based recommendation for all countries, but breastfeeding rates have been declining in many middle-income settings. One reason behind this decline is the perception that breastfeeding may not be necessary in modern urban settings, where clean water is available and alternative foods are abundant. We investigate the importance of breastfeeding for early childhood development in the modern

abstract

# Randomized $n$ -of-1 Trials: Quality Improvement, Research, or Both?

Joyce P. Samuel, MD, MS,<sup>a</sup> Alyssa Burgart, MD,<sup>b</sup> Susan H. Wootton, MD,<sup>a</sup>  
David Magnus, PhD,<sup>b</sup> John D. Lantos, MD,<sup>c</sup> Jon E. Tyson, MD<sup>a</sup>

The regulatory demarcations between clinical research and quality improvement (QI) are ambiguous and controversial. Some projects that were undertaken as a form of QI were deemed by regulatory agencies to be research and thus to require institutional review board approval. In the era of personalized medicine, some physicians may ask some patients to participate in  $n$ -of-1 trials in an effort to personalize and optimize each patient's medical treatment. Should such activities be considered research,

abstract



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# Questions

- In your practice, what steps do you take to help parents appreciate the risks and benefits of a trial?
- What advice do you have for colleagues about how to enable good decisions?

# Discussion

Please raise hand to speak, or use chat function to comment or ask a question.

# Thank you!



# Sources of moral burden in health care?

- Difficult decisions with insufficient information.
- Bearing witness to unnecessary suffering.
- Imprecise language
- Solitary practice
- Bureaucracy
- Caregiver indifference and distress
- Others?

# The reasonable person?

- .....seeks to be aware of...
- the foreseeable risk of harm his actions create versus the utility of his actions;
- the extent of the risk so created;
- the likelihood such risk will actually cause harm to others;
- any alternatives of lesser risk, and the costs of those alternatives.

# Where do your limits come from?

- Courts?
- Conscience?
- Peers?
- Evidence?

# Communication within Shared decision making

- Empathy – how does this decision look through eyes of parents?
- Emphasizing risks, and benefits
- Informed Fear, and Informed Hope

# Quality of Life Assessments

- Estimating levels of possible future suffering
- Estimating whether expected physical challenges will be out of proportion – relative to the benefits of a possibly short life.
- -both estimations are very difficult.