THERAPEUTIC MISCONCEPTION:
What is it, Why it matters, and How to minimize it

Mark Repenshek, PhD
Columbia-St Mary’s

Ryan Spellecy, PhD
Medical College of WI

Objectives

▪ Define therapeutic misconception and its importance;
▪ Distinguish between therapeutic misconception and other factors that may inhibit the informed consent process;
▪ Develop useful criteria to identify and minimize instances of therapeutic misconception and apply these criteria to cases

Definitions

▪ When clinical research subjects fail to recognize the ways in which research participation may involve the sacrifice of some degree of personal care, they are said to manifest a "therapeutic misconception."
Definitions

*Therapeutic Misconception is not equivalent to mere failure to understand the nature and purpose of the research study or the procedures involved.*

*Conversely, understanding the goals and methods of a research project does not mean that subjects will not necessarily avoid endowing them with therapeutic intent.*

Definition

*Therapeutic Misconception seems to involve interactions among several phenomena:*
- Presumptions acquired by individuals in clinical treatment and brought with them to the research setting;
- Subjects’ hopes for benefiting from research participation; or
- Shortcomings of the informed consent process

The power of the [research subject’s] mind to hear only that which fits its preconception cannot be over-estimated. In addition, it is questionable whether investigators would be willing to be...brutal about shattering subjects’ therapeutic misconceptions. The perception of potential benefit, after all, is one of the most powerful incentives for subjects to agree to take part in research projects.

**Why Therapeutic Misconception Matters...**

- Since the initial description of TM in a study of consent of psychiatric research two decades ago, TM is still not uncommon in research:
  - Subjects appear frequently to overestimate the likely benefits of entry into research studies;
  - Underestimate risks;
  - Confused about randomized assignment;
  - Generally conflates research with ordinary treatment.


Featherstone and Donovan. “Why don’t they just tell me straight, why do I care??” The struggle to make sense of participating in a randomized controlled trial.” *Social Science and Medicine* 55 (2002): 99-111.


**Why Therapeutic Misconception Matters...**

- Subjects appear frequently to overestimate the likely benefits of entry into research studies:
  - Of 225 participants in 44 different studies, 51.1% manifested an unreasonable belief in the nature or likelihood of benefit;
  - Examples (participant interview)

  *Participant*: “I don’t think they’d be in this if they didn’t. You know it’s just like being a doctor with a sign on the door. You know, they’re healers.

  *Interviewer*: “So do you think that they are giving everyone the best treatment?”

  *Participant*: “I think it’s a win-win for anybody. I don’t think they would ask you to do this or present this to you if they didn’t think it was going to help you.”

  *Interviewer*: “That’s the only reason. They’re concerned with helping the people. You know, they are helping the people.”

  *Participant*: “Um, disagree. I think so, yes. I think they do take into account what each person needs?”

  *Interviewer*: “So you think in the study they are allowed to pick which group you’re going to be in?”

  *Participant*: “I think so.”

  *Interviewer*: “So you’re definitely going to get [the active medication]?”

  *Participant*: “Well, I told them this is what I want. I don’t have that long to go through researches. Do that on younger people, you know.”

  *Interviewer*: “(the choice of treatment) does depend on what each individual needs?”

  *Participant*: “I think so yes. I think they do take into account what each person needs.”

**Why Therapeutic Misconception Matters...**

- Confused about randomized assignment:
  - Of 225 participants in 44 different studies, 31.1% of participants expressed inaccurate beliefs regarding the degree of individualization of their treatment

  Examples (participant interview)

  *Interviewer*: Ager or disagree: Doctors are not allowed to choose the treatment I receive based on my needs.

  *Participant*: Um, disagree

  *Interviewer*: So you think in the study they are allowed to pick which group you’re going to be in?

  *Participant*: I think so.

  *Interviewer*: So you’re definitely going to get [the active medication]?

  *Participant*: Well, I told them this is what I want. I don’t have that long to go through researches. Do that on younger people, you know.

  *Interviewer*: “(the choice of treatment) does depend on what each individual needs?”

  *Participant*: “I think so yes. I think they do take into account what each person needs.”
Why Therapeutic Misconception Matters…

- Generally conflate research with ordinary treatment:
  - Clinical trial “branding” which may contribute to a subject’s therapeutic misconception by biasing his or her assessment of the experimental drug
  - A.L.I.V.E. (Adenosine Lidoceaine Infarct zone Viability Enhancement trial)
  - B.E.S.T. (Beta-blocker Evaluation of Survival Trial)
  - M.A.G.I.C. (Magnesium In Coronaries)
  - M.R.A.C.E. (Myocardial Ischemia Reduction with Aggressive Cholesterol Lowering)
  - PROVED (Prospective Randomized study of Ventricular failure and the Efficacy of Digoxin).

Why Therapeutic Misconception Matters…

- Participant and Study Characteristics Associated with the Therapeutic Misconception
  - Increased age;
  - Lower levels of education;
  - Less optimism about one’s current health;
  - Greater optimism about one’s health in 6 months.

- In general, the worse one’s self-described health and functional status, the higher one’s level of therapeutic misconception


Why Therapeutic Misconception Matters…

If Therapeutic Misconception is not avoided, it smuggles the virtues accorded exclusively to the sacredness of the patient physician relationship into the researcher subject relationship...

...in order that physician-researchers may continue to see [themselves] as compassionate physicians in the midst of service of dispassionate science.”


How to Minimize Therapeutic Misconception

- Edward Fried Model
  1. Forbidding any physician from referring a patient into a protocol in which he or she has a financial interest and forbidding any physician from conducting research on any patient of his or hers, whether or not for gain.
  2. Requiring immediate dismissal from the protocol of all subjects who show unexpected or expected and disabling side effects. This would probably require regular independent assessment of subjects
How to Minimize Therapeutic Misconception

3. Consent procedures must require all physician researchers to explain to their subjects in comprehensible language,

1. That they are relieving said researchers from any fiduciary duty they might have them to have as a physician and that the researchers they meet will not be acting in that capacity to them;
2. That the financial and other interests of the researchers' clients may be more important to them than the interest of the subject in his or her health;
3. That the most important risks of participation are unforeseeable, and the belief many subjects have that their personal situation "can not get any worse" is false; and
4. That most subjects who consent to research do not believe these things when they are told them; they are under the impression that its purpose is to help them personally.
How to Minimize Therapeutic Misconception

- Integrate a “neutral discloser” into the informed consent process
- Trained to teach patients about how research participation would differ from clinical care;
- Has no involvement with the research projects that were seeking participants; and
- Has no involvement with the patients’ medical care.

- Physician researcher who recruit own patient would open IC forms with statement stressing the distinction between research and care:
  - Ex: “... research is an intervention with little evidence suggesting whether effects will be beneficial or harmful.”
  - Ex: “This medical research project is not expected to benefit you.”


How to Minimize Therapeutic Misconception

- Use of community member as center of authority assessing therapeutic misconception:
  - Similar to Section 46.107(a) of the Common Rule related to Community consultation to prevent group harm:
    - Specific accountability;
    - Education and awareness re: therapeutic misconception in research;
    - Barometer of misconception as it relates to a potential subject;
    - Recognize patient enrolling as research subject as a vulnerable population where community members would understand not just IC form, but recruitment process;
    - Community members as secondary reviewer in a primary/secondary reviewer model.


Resources

- Stephen Joffe, E. Frances Cook, Paul D. Cleary, Jeffrey W. Clark, Jane C. Weeks. “Quality of Informed Consent: A new measure of understanding among research subjects.” Journal of the National Cancer Institute 93 (2001): 139-47; Similar to Section 46.107(a) of the Common Rule
- W. Glannon. “Phase I Oncology Trials: why the therapeutic misconception will not go away.” Journal of Medical Ethics 32 (2006): 252-55; Ex.: “This medical research project is not expected to benefit you.”
- Franklin G. Miller and Steven Joffe. “Evaluating the Therapeutic Misconception.”