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Beliefs, Hopes, and Deal Breakers in Research Consent: Dissecting Mathews, Fins, and Racine on the Therapeutic Misconception

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In an earlier *Dissecting Bioethics* contribution, Debra J. H. Mathews, Joseph J. Fins, and Eric Racine[1] challenge the standard ways of thinking about the therapeutic misconception in the context of consent for research participation. They propose that instead of demanding "rational congruence" between how researchers and participants conceive of a given protocol, we should accept a less stringent standard of "reasonable coherence." Although Mathews, Fins, and Racine (MFR) provide some important insights, their proposal needs refinement. There is room for a wide but not unlimited range of participant hopes and motivations. However, their model of reasonable coherence is too weak a standard for whether participants have adequate understanding of the scientific goals of a protocol. By the time participants are recruited for medical research, the goals of the protocol, having been set and agreed to through accepted scientific processes, are no longer open for alternate interpretations. This paper discusses this and other objections to MFR's proposal. It then suggests that a concept of "deal breakers" might be useful in this context.

The Therapeutic Misconception and Related Concepts: The Received View

Research participants do not always understand what they have been recruited for.[2] When this happens, they may experience one or more aspects of

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the therapeutic misconception. MFR elucidate three related concepts, distinguished earlier by Sam Horng and Christine Grady,[3] that all fall under a general concept of therapeutic misconception. MFR explain these as follows: therapeutic misconception (TM), which is "misconstruing research as clinical care"; therapeutic mis-estimation (TME), which is "incorrectly estimating the probability of risk or benefit"; and therapeutic optimism (TO), "belief that one is more likely to benefit than statistically predicted."[4] Glossed in this way, these three concepts all involve false beliefs.

The received view is that the TM in any form is a very serious problem and incompatible with ethically valid informed consent. This makes sense, as consent based on misinformation or mistaken beliefs is not fully informed. The received view goes back at least to the 1980s,[5] and continues to be influential.[6] MFR sum up the force of the received view thus: "The implication is that in all cases, when TM, TME, or TO is detected, corrective measures should be taken."[7]

Standard approaches to consent for research participation involve more than just the received view of the TM. Lack of false beliefs about the research is obviously not enough for informed consent. Among other things, participants should also have positive knowledge about research procedures, risks, and benefits. Hans Jonas argued that truly robust consent requires that participants understand and identify with the scientific goals of research such that they "will" the goals of the researchers as their own goals.[8] Jonas's ideal of participants identifying with researchers, embracing researchers' ends as their own, describes the kind of "rational congruence" between investigators' and participants' understanding of the research that MFR discuss.

Mathews, Fins and Racine's Concerns about the Received View and Their Alternative Standard

MFR point out aspects of the TM cluster that are not as bad as the received view suggests, or that at least should be treated with greater subtlety. They are concerned that overemphasis on eliminating the TM and related phenomena, particularly TO, can be disruptive and even cruel: "…to disabuse patients of hope seems both wrongheaded and in itself a misunderstanding of normal human functioning and adaptation."[9]

One aspect of MFR's explanation of why it is appropriate to revise the TM is that times have changed:

> …the research environment has improved, oversight structures are now well established, and norms with regard to human subject protection are in place (although certainly neither of these are perfect or perfectly functioning).[10]

Furthermore, they argue, studies in oncology and other areas are "… increasingly designed to include the possibility of individual benefit."[11] These shifts in the research environment suggest to MFR that "the locus of concern may be wrong." Instead of focusing on "…the (potential) participant's conceptions of a research project," we should look at "the interaction between the participant and investigator, and the results of that interaction."[12]

MFR suggest that researchers do not come to the consent encounter with the one correct understanding of any research protocol. Instead, the meaning of the protocol is a matter of negotiation in which both parties should be prepared to adjust their thinking:

> ...it is critical that investigators... allow for reasons, justifications, and hopefulness that do not necessarily map

> cleanly onto their own decision-making and ways of thinking about and experiencing the world.[13]

Thus instead of judging a participant's understanding in terms of whether it is rationally congruent with the investigator's understanding, we should apply a less stringent standard that takes into account both sides:

> …a standard of reasonable coherence… would acknowledge differences in assessment between researcher and patient, and creates an opportunity for a negotiated understanding. The standard of reasonable coherence implies that some disagreement is admissible—perhaps even expected—given differences in knowledge, experience, and perspective…[14]

On this picture, investigators and individual participants would work out an overlapping set of understandings about the research. These understandings may contradict each other on some topics. Such contradictions would preclude consent under the standard view's demand for rational congruence, but on MFR's view consent could be accepted if it is at least reasonably coherent with the investigator's understanding.

Objections

MFR's conceptualization resonates with our understanding that research is morally, scientifically, and in practical ways, better when investigators engage community voices. It also reflects our sense that respecting autonomy involves more than allowing someone to say "no" to what is proposed by a professional researcher or clinician. Despite these good intentions, their reconsideration is open to some significant objections.

MFR cite improvement in the research environment since implementation of the Belmont Report as a reason to reconceive the TM. However, the changes they describe, such as increased oversight, greater respect for the mentally ill, and a greater variety of research models, do not weaken the force of the received view. These factors only make it less likely that research participants will have false beliefs about the purposes of research. It could still be just as problematic when participants experience the TM, TME, or TO. Indeed, investigators might even be more culpable for allowing these now that they are explicitly expected to avoid them.

It has become regular practice in some research areas to consult studied populations about research priorities, about how to recruit participants effectively and respectfully, and for review of consent and data collection documents.[15] Some of this community consultation can affect the goals of research. However, in any model of community engagement the scientific (and any clinical) goals of a research protocol are set well before the consent process, the time when the TM, TME, or TO are of concern. The goals of a protocol have been designed, reviewed by funding agencies, and reviewed in conjunction with recruitment and consent procedures by at least one ethics board and often also by a scientific review board. All along, the investigators have promised to run a specific protocol with specific goals. Thus, by the time research staff are asking for consent, there are facts about the goals of the study. The investigators should know them. (They do not always,[16] but they should.) Anyone who believes that the goals of the study are something other than what was approved has a false belief. Renegotiating the study goals at the consent stage would be a violation the process MFR praise as an improvement.

Also notice that the proposed negotiated agreements would be made with individual participants. This requires research staff to have different understandings of the research for each participant. Many studies have more than one researcher conducting recruitment. Furthermore, the person who obtains consent is often not the principal investigator. MFR's suggestion thus leads to an untenable splintering of views about important facets of the research within each researcher and among researchers.

This splintering of views would not be a problem if it were about how bad a risk is, or how good a benefit is. For instance, it might be much worse for Mr. Violinist to lose some feeling in his fingers than it would be for Ms. Weighlifter. However, the TM, TME, and TO are not about assessments like that. They are only about factual, nonnormative beliefs: whether research activities are intended to provide clinical care, the probability of risk or benefit, or how likely one is to benefit. Negotiating individualized agreements on these issues does not work.

Hope, Motivations, and Meaning

When MFR write about allowing research participants to have "… reasons, justifications, and hopefulness that do not… map cleanly onto… [investigators'] decision-making and ways of thinking…,"[17] that is absolutely compatible with the received view. MFR connect TO to hopefulness, but recall their explanation of TO as "belief that one is more likely to benefit than statistically predicted."[18] This does not match Horng and Grady's explanation of TO: "The research subject hopes for the best personal outcome."[19] Belief and hope are importantly different. A belief fails if it does not fit the way the world is. Hope does not have this direction of fit. Hopes can be unrealistic and can rely on false beliefs, but there is nothing wrong with a hope about a future or unknown event if the world does not conform to it. There can be no "false hope" in a literal sense. This explains why Horng and Grady are correct to claim that therapeutic optimism is "*Always* tolerable because hope does not compromise the autonomy of a decision to participate in research."[20]

Participants may also have "reasons and justifications" that are very different from those of investigators without raising any concerns from the received view. People may volunteer for nontherapeutic research to learn more about themselves through testing, to connect with other participants who are like them, to gain access to researchers who could potentially advise them for actual clinical decisions, or to pay back a perceived debt to an individual or institution. If a participant's reason for participating in a nontherapeutic study is to receive treatment, that is a problem. However, there are many acceptable reasons and justifications for participating that are entirely unrelated to the motivations of investigators. Most of these are entirely irrelevant to the received view.

Incomplete Understanding and Dealbreakers

I have argued that MFR's proposal fails because they misplace the point at which potential participants may properly engage in negotiation about research goals, fail to distinguish between beliefs and hopes, and fail to distinguish between beliefs about the scientific goals of research protocols and motivations for participating. For these reasons, they have not shown that the core of the received view of the TM—concern that participants not have certain false beliefs about the research they are asked to contribute to—requires

revision. Neither have they described a workable way to describe which beliefs, hopes, and motivations would indicate that consent to participate could not be ethically valid.

I suggest that the concept of "deal breakers" elaborated by Tom Dougherty might point to a better way to do the job MFR want to do with their concept of reasonable coherence. Dougherty discusses deal breakers in the context of consent for sexual relations. Sexual encounters are similar in some ways to biomedical encounters in that both can involve doing things to someone's body that would constitute assault if done without consent. The two are different in that some embellishment or mystery is sometimes expected and acceptable in new sexual partnerships. Dougherty is therefore interested in distinguishing between deception that makes an encounter nonconsensual and seriously wrong (e.g., willful falsehoods or omissions about whether the deceiver is using contraceptives) and deception that would, for most people, be benign (e.g., willful falsehoods or omissions about how much the deceiver likes ABBA).

In his 2013 paper "Sex, Lies, and Consent," Dougherty writes that for a feature of an encounter to be a deal breaker, "It must be the case that the other person is all things considered unwilling to engage in the… encounter, given that it has this feature."[21] In contrast, "If someone would still choose to have sex with another person, were the veil of ignorance lifted, then her sexual consent is unaffected by the deception."[22]

Independent of whether this model of consent is appropriate for sexual relations, it captures MFR's insight that consent for research participation does not require each participant to have all of the right true beliefs and no false beliefs about the research. It also addresses their concern that consent may look very different for different participants. After all, deceptions that would be benign for some will be deal breakers for others. For instance, the requirement to take a medication derived from animals might be irrelevant to most participants but a deal breaker for some vegans. Researchers will also have deal breakers. For instance, they will not want participants who misrepresent themselves regarding inclusion criteria or those who purposefully seek to undermine study goals.

Based on this discussion, it looks like valid consent requires at least that participants have a basic understanding of the research, that there be no TM, and that there be no deal breakers. Additional or more stringent requirements may be appropriate depending on factors such as the risk or complexity involved in participating. I agree with MFR that our theoretical explorations of research consent point toward empirical work that could help us understand how the concepts should be implemented. In particular, it could be helpful to learn what various populations consider to be deal breakers in the research context.

Conclusion

MFR encourage us to re-examine our attitudes to the therapeutic misconception in light of developments in the research community since the 1980s. On their analysis, the received view of the therapeutic misconception imposes an overly strict standard and should be replaced by a model that assigns less privilege to the view of researchers. I have given several reasons for rejecting their proposal, and suggested that the spirit of their reexamination might be better captured by a *no deal breakers*

requirement for consent. This is not a full proposal for a standard of informed consent for research participation, but I hope it moves our understanding of consent forward in some small way.

Notes

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4. See note 1, Mathews et al. 2018, at 155.
5. Cf. Appelbaum PS, Roth LH, Lidz C. The therapeutic misconception: Informed consent in psychiatric research. *International Journal of Law and Psychiatry* 1982;5(3–4):319–29.
6. Cf. Perry J, Wohlke S. Dealing with misconception in biomedical research. *Journal of Empirical Research in Human Research Ethics* 2019;14(5):428–32.
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8. Jonas H. Philosophical reflections on experimenting with human subjects. *Daedalus* 1969; 98(2):236.
9. See note 1, Mathews et al. 2018, at 157.
10. See note 1, Mathews et al. 2018, at 156.
11. See note 1, Mathews et al. 2018, at 156.
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13. See note 1, Mathews et al. 2018, at 160.
14. See note 1, Mathews et al. 2018, at 160.
15. Cf. Fisher CB, Wallace SA. Through the community looking glass: Reevaluating the ethical and policy implications of research on adolescent risk and sociopathology. *Ethics and Behavior* 2000;10(2):99–118.
16. Cf. Joffe S, Weeks JC. Views of American oncologists about the purposes of clinical trials. *Journal of the National Cancer Institute* 2002;94(24):1847–53.
17. See note 1, Mathews et al. 2018, at 160.
18. See note 1, Mathews et al. 2018, at 155.
19. See note 3, Horng, Grady 2003, at 12.
20. See note 3, Horng, Grady 2003, at 12 (emphasis theirs).
21. Dougherty T. Sex, lies, and consent. *Ethics* 2013;123(4):719.
22. See note 21, Dougherty 2013, at 740.