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# Beyond informed consent: the therapeutic misconception and trust

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## ABSTRACT

The therapeutic misconception has been seen as presenting an ethical problem because failure to distinguish the aims of research participation from those receiving ordinary treatment may seriously undermine the informed consent of research subjects. Hence, most theoretical and empirical work on the problems of the therapeutic misconception has been directed to evaluate whether, and to what degree, this confusion invalidates the consent of subjects. We argue here that this focus on the understanding component of informed consent, while important, might be too narrow to capture the ethical complexity of the therapeutic misconception. We show that concerns about misplaced trust and exploitation of such trust are also relevant, and ought to be taken into account, when considering why the therapeutic misconception matters ethically.

Recent reassessments of research ethics standards have challenged familiar concepts such as coercion,<sup>1</sup> equipoise,<sup>2</sup> and the protection of vulnerable subjects.<sup>3</sup> Such discussions can assist in public policy proposals for the protection of human subjects, clarify concepts, and elucidate ethical concerns.

In this essay, we want to call attention to aspects usually neglected in ethical discussions. In particular, we will reassess the way in which the therapeutic misconception is usually framed. In what follows, we will argue that the problem with the therapeutic misconception goes beyond the validity of participants' consent. Equally important is that it undermines the trustworthiness of the research enterprise. We will first discuss the traditional way of presenting the therapeutic misconception as an ethical problem. We will then show that misplaced trust and exploitation of such trust play an important role in the formation and maintenance of the therapeutic misconception.

## INFORMED CONSENT AND THE THERAPEUTIC MISCONCEPTION

Although some disagreement exists about what exactly the therapeutic misconception is,<sup>4,5</sup> it has been often understood as the conflation by research subjects between the goals of research and those of medical care.<sup>6-9</sup> Clinical medicine's aim is to provide the best medical care for individual patients. Exposing patients to risk is here justified by the prospect of compensating medical benefits for that *particular* patient and his/her voluntary and informed consent. Clinical research, on the other hand, aims at answering a scientific question in order to provide generalisable knowledge that can help *future* patients.<sup>10</sup>

The differences between the goals of clinical care and research are so significant that some have argued that they ought to be governed by distinct ethical norms.<sup>2,11</sup> While treating physicians have a duty of therapeutic beneficence to their patients, clinical researchers cannot promise to do what is best medically for the participant. Instead, researchers' obligations are to protect subjects from exploitation and unnecessary harm, and to ensure the scientific validity of the trials.

The therapeutic misconception has been seen as presenting an ethical problem because failure to distinguish the aims of research participation from those of receiving ordinary treatment may seriously undermine the informed consent of research subjects.<sup>8,9</sup> If subjects incorrectly attribute a primarily therapeutic intent to research procedures, they are likely to underestimate risks or overestimate benefits.<sup>12</sup> Although participation in some trials might not be contrary to subjects' best medical interests, enrollment in placebo-controlled or double-blind trials might disadvantage them.

Most theoretical and empirical work on the problems of the therapeutic misconception has been directed to evaluate whether and to what degree this confusion invalidates the consent of subjects. This focus on the understanding component of informed consent, while important, may be too narrow to capture the ethical complexity of the therapeutic misconception. In what follows, we argue that concerns about misplaced trust are equally important when considering why the therapeutic misconception matters ethically.

## THE THERAPEUTIC MISCONCEPTION AND TRUST

Trust is a dynamic aspect of interpersonal relationships that involves the complex and interwoven perspectives of the truster, the one trusted, and the object of one's trust.<sup>13</sup> For example, a patient may trust that his physician will apply her skills to treat his cancer. Trust is a function of human interaction and social exchanges, or the innate basis for all forms of human sociability. Although disagreements exist about what exactly trust is, few dispute its importance for human well-being and professional-patient relationship. Without trust, we would not be able to interact with others even at a superficial level or carry out any co-operative activities, and the things that matter to human beings could not flourish.<sup>14</sup>

In general, trust in identifiable relationships arises when the truster is optimistic about the competence and good will of the trusted.<sup>15,16</sup> Trust, whether expressed among investigators, or placed by subjects in individual scientists, research institutions, and oversight agencies, is crucial for the

proper functioning and continued success of clinical research practices.<sup>17</sup> Although empirical evidence about how much and why participants trust researchers is scarce, there seems to be “a large reservoir of trust concerning medical research on the part of most patients.”<sup>18</sup> Recent concerns of eroding trust in the research community also indicate that trust is an important consideration for the flourishing of the research enterprise.<sup>17 19 20</sup>

A variety of factors regarding participants' perceptions of their researchers' competence and motives may help to explain their trust.<sup>21–26</sup> In particular, some participants seem to be confident that these scientists are highly competent professionals in their fields of research.<sup>24</sup> Many researchers have extensive knowledge in various areas of medicine, and they are experienced in performing clinical trials by using appropriate instruments and making careful data analysis. Moreover, many research participants have a favourable attitude toward medical research.<sup>18</sup> Many believe that the motivation of biomedical research, that is, the pursuit of knowledge that can help restore and promote people's functioning and/or quality of life, is a noble and important goal.

In addition to general competence and motive, participants also seem to rely on the researchers' good will towards them, that is, they are confident that researchers are suitably motivated by the thought that the participants are counting on them.<sup>15</sup> Research participants generally trust that investigators will protect them from unnecessary harm in exchange for their contribution to the public good of science.<sup>23</sup> This reason for trust is understandable, especially since the mushrooming of research ethics boards and other oversight agencies has given the impression that research projects are carefully monitored and regulated.

However, because many participants cite the hope of benefit as a prominent reason for enrolling in clinical trials,<sup>24</sup> we hypothesise that participants also base their trust on the assumption that investigators will promote their individual health interests. The fact that subjects are often ready to sign consent forms before reading them underscores this hypothesis.<sup>24 27</sup> Given the different goals of research and medical care, this particular form of trust is misplaced. This is not because researchers are untrustworthy, given that most researchers do act with integrity, but because subjects trust researchers as if the investigator's role was that of the physician.

Generally, patients trust physicians to diagnose and perform various procedures on them based on the belief that these professionals are motivated to promote their patients' individual health interests by virtue of their voluntarily-chosen profession. Physicians have taken upon themselves the task of caring for the sick, and this imperative is built into the nature of clinical medicine.<sup>28</sup> Patients allow physicians access to private body parts, discuss the most intimate details of personal and bodily life,<sup>29</sup> and agree to medical procedures that might have significant side effects and risks not only because they believe in the physicians' competence, but also and mainly because they trust that their physicians share a common goal with them, that is, to promote their health interests. Patients trust that their physicians would not intentionally act against their patients' interests or subject them to any harm that would not be outweighed by potential benefits to the individual *patient*.

Because clinical researchers' main goal is to perform valuable investigations that generate valid data,<sup>30</sup> their projects cannot be designed to maximise direct health benefits to particular subjects. This is especially the case in early-phase trials, in which researchers are still testing the toxicity and side-effects of the experimental drugs or procedures. Certainly, the favourable

belief in researchers' goodwill implies that investigators are trusted to present all information truthfully and not put subjects at unnecessary risk or exploit them.<sup>2 23 30</sup> But these researchers do not hold as their primary goal to restore a particular subject's health or to pursue what is best for his or her health. This appears clear when we consider the case of clinical trials that enrol healthy participants. Indeed, trusting a clinical researcher *qua* researcher is to rely on his/her competence and goodwill to design and undergo experimental trials that are worthwhile and produce scientifically valid information. Such competence and goodwill certainly include a commitment to the principle of non-maleficence and careful attention to the subjects' welfare. But, a researcher who, for instance, ignores legitimate scientific procedures on a randomised, double-blind, placebo controlled trial in order to benefit his or her research subjects is not trustworthy *as a researcher*.

Relations of trust are not relevant only to individual physicians and researchers; trust also extends to institutions. Patients put their trust on healthcare oversight agencies based on their confidence that these agencies will ensure the competency of physicians, monitor high standards of care, develop regulations directed to protect their safety, and promote efficiency. Protection of patients' best interests is then one of the main goals of these agencies.

Research oversight agencies, however, do not have this as one of their principal goals. Their aims are to ensure research integrity, promote responsible conduct of research, monitor clinical trials, develop regulations to protect research subjects, and assure an adequate balance of risks and benefits. Given the different duties of healthcare and research oversight agencies, it would be inappropriate to trust research oversight agencies to go beyond their duty to protect to also ensure that research responds to the health needs of individual research participants. Indeed, if an institutional review board (IRB) were to evaluate protocols using such criterion, it would be confusing and overstepping its obligations and roles. IRBs review research protocols to ensure that the benefits to individual subjects *and to society* outweigh the risks to those subjects. When subjects count on research oversight bodies to promote their own medical needs, they are misplacing their trust.

Certainly, these institutional aims are sometimes difficult to separate. Hospitals are common sites for clinical research, and individual physicians often also administer clinical trials. Research subjects are often also patients, who may be recruited or encouraged by their own physicians to participate in various trials. When such roles become intertwined, and patient participation is essential to the pursuit of generalisable knowledge, there is a danger of direct or indirect blurring of such goals by researchers and other interested parties. Indeed, as some have argued, from investigators to government officials and patient advocates, different groups and social institutions have fostered this misplaced trust by perpetuating the therapeutic misconception.<sup>31</sup> For example, studies have shown that recruitment tools and consent forms for certain types of clinical trials often describe research in therapeutic terms or suggest likelihood of direct benefits.<sup>9 32–34</sup> Similarly, US government agencies emphasise the benefits of participating in clinical research by indicating that such participation allows subjects to “gain access to new research *treatments* before they are widely available” (emphasis added).<sup>35</sup> By calling compounds and procedures that are yet to be proven safe and effective “*treatments*” and using such confusion as an incentive for participation, these agencies are perpetuating the therapeutic misconception. Significantly, in spite of increasing evidence showing the extent of the

therapeutic misconception,<sup>36</sup> and notwithstanding numerous calls to implement strategies to eliminate or reduce it,<sup>37–39</sup> the therapeutic misconception continues to be tolerated and even fostered.<sup>27 31 40 41</sup>

In a social context where research and therapy are presented as tightly connected, where there is an unwillingness to separate these activities, it is not unreasonable that subjects would misplace some of their trust on researchers. Nonetheless, such misplaced trust presents serious ethical problems. It may have devastating effects on the research enterprise; but more importantly, it questions the trustworthiness of researchers and institutions.

### SOME CONSEQUENCES OF MISPLACED TRUST

As we explained earlier, trust is essential to human cooperation—intimate and professional relationships are impossible without trust, and trust encourages us to see and respect each other as moral agents.<sup>15 16 42</sup> Without trust in the research enterprise, voluntary participation would be unlikely, and clinical research could not proceed, thus depriving the public of potential benefits.

If subjects under the therapeutic misconception trust researchers and research oversight agencies to not only protect them but also promote their particular health interests, then their trust is misplaced. Given the importance of trust in human well-being and the flourishing of the research enterprise, it seems clear that the presence of misplaced trust in the relationship between investigators and research subjects is ethically problematic.

Four potential negative consequences are particularly salient. First, misplaced trust may have a damaging effect on self-trust. The informed consent process presumably gives participants the power to make research decisions as they see fit. However, when subjects, especially those disappointed by trial results, realise that they have misplaced part of their trust towards researchers because of the therapeutic misconception, they may lose self-trust in their competence to make other medical decisions that will be consistent with their priorities.<sup>43</sup> While critical evaluation of one's reasoning is generally healthy, ironically, a loss in self-trust may once again prompt participants who may already be physically and psychologically vulnerable because of their health conditions to accept medical paternalism.

Second, misplaced trust may lead to unfair burdens on researchers, especially those with other healthcare professional responsibilities. Patients who conflate the goals of treatment and research are likely to hold favourable expectations, albeit misdirected, that the scientists are competent in using the clinical trial method to heal them. If the trials do not deliver the desired outcomes, however, participants may misjudge the researchers' competence and unfairly blame them for the failure.<sup>26</sup>

Third, misplaced trust may also disrupt other trust relationships with medical professionals. Since participants undertake risks and trust researchers partly on the assumption that they share similar goals, that is, to promote the health and well being of the participants, and given that they often enrol in clinical trials based on their physicians' recommendation, realisation of this misplaced trust on researchers may also lead patients to question the competence of their own physicians and to lose trust in them. This may have important impact on patients' compliance with their own treatments and their willingness to engage in further research.

Fourth, because the research enterprise cannot succeed without appropriate trust, taking advantage of subjects' misplaced trust can result in the loss of the social legitimacy that allows investigators to do their work. Even if manipulation of trust can allegedly be justified by other norms such as social utility, such justification may not be adequate, since the public may not condone questionable practices in pursuit of medical advances.<sup>44</sup> We bestow investigators autonomy and discretionary power over their work because it is an earned feature of the standing of the profession in its social context.<sup>45</sup> We assume that they are a special group with unique knowledge, and that they will police themselves. When trust is betrayed, the social endowment of professional autonomy will destabilise, and the research enterprise will suffer.

### TAKING ADVANTAGE OF MISPLACED TRUST

We recognise that empirical research is needed to confirm the extent of such potential consequences. Nonetheless, our concern with misplaced trust does not rest only on potential outcomes. In addition to these consequences of misplaced trust by participants, the existence of the therapeutic misconception highlights an inherent ethical problem: investigators' and institutions' complacency towards research subjects' confusion. The prevalence of the therapeutic misconception, documented by numerous studies, underscores researchers' willingness to allow such misconception to occur and their readiness to take advantage of the resulting misplaced trust to enrol participants in a clinical trial. Because investigators, who are experts on scientific methodology, have the knowledge, the authority, and the means to dispel such misconceptions, it is reasonable to hold them responsible for doing so. Their professional position engenders a duty to actively work against it and prevent the enrollment of participants who suffer from the therapeutic misconception.

As in the case of other interpersonal relationships, taking advantage of the misplaced trust of participants is corrosive of institutions and professions whose practices depend on misusing or abusing such trust. Indeed, a test for the moral decency of a trust relationship between participants and researchers is whether those in authority have fostered or ignored the existence of such misplaced trust, and whether continuation of the research relies on the therapeutic misconception. If the success of the research enterprise depends on a misplaced trust and professionals continue to allow the therapeutic misconception to occur, the professional relationship is inherently problematic or even morally rotten.<sup>15</sup>

Attempting to justify the acceptance of the therapeutic misconception on grounds of social utility are often not the end of the story for participants who feel used or manipulated.<sup>46</sup> This manipulation of research participants' misplaced trust, whether intentional or not, reflects and can further affect researchers' trustworthiness and integrity. Those who continue to carelessly use recruitment language that may contribute to such problems, or decline to employ strategies that are likely to dispel the therapeutic misconception are open to the charge of being exploitative and uncaring.<sup>19</sup> If participants cannot trust researchers and oversight agencies to be attentive and vigilant in upholding the highest level of integrity, such relationships cannot thrive. This cannot be of benefit to anyone.

### CONCLUSION

We have argued that the therapeutic misconception matters ethically not only because it is incompatible with adequate

informed consent but also because it undermines the trustworthiness of the research enterprise. Disregarding, fostering, or taking advantage of misplaced trust may affect subjects' self-trust and their perception of researchers' personal character, disturb other trust relationships, and erode public confidence in biomedical research. More importantly, the continuing existence and prevalence of the therapeutic misconception emphasises researchers' and institutions' readiness to take advantage of participants' misplaced trust and their unresponsiveness to the problem.

If we are correct, and trust is an important element of the problem, then this has practical implications that need to be considered. First, when the therapeutic misconception is framed as a problem of misplaced trust and exploitation of such misplaced trust, then such misconception becomes ethically problematic whether or not a clinical trial promotes the participants' medical interests, and whether or not a participant would have made the same decision in the absence of the therapeutic misconception.<sup>47 48</sup>

Second, framing the problem as one that involves trust and its abuses calls attention to the importance of assessing the context in which research takes place. Rather than limiting our analysis to issues of personal autonomy, focusing on trust requires that we reflect both on personal and institutional problems.

While some of our predicted negative consequences of misplaced trust may require confirmation by further empirical research, the inherent ethical problems of manipulating such mistrust cannot be ignored. After all, "trust is a notoriously vulnerable good, easily wounded and not at all easily healed."<sup>49</sup> If we believe that biomedical research is a good worth pursuing, then we must all take necessary steps to ensure that appropriate trust is sustained. Given the prevalence of the therapeutic misconception, the responsibility to reduce or eliminate its presence lies not only with individual investigators, but also with the scientific community and oversight agencies.

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