RESEARCH ETHICS

Distinguishing treatment from research: a functional approach

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The best way to distinguish treatment from research is by their functions. This mode of distinction fits well with the basic ethical work that needs to be carried out. The distinction needs to serve as an ethical flag, highlighting areas in which the goals of doctors and patients are more likely than usual to diverge. The distinction also allows us to illuminate and understand some otherwise puzzling elements of debates on research ethics: it shows the peculiarity of exclusive conceptions of the distinction between research and treatment; it allows us to frame questions about therapeutic obligations in the research context, and it allows us to consider whether there may be research obligations in the therapeutic context.

A good deal of attention has been lavished on discussing the norms that should govern research compared with those that should govern treatment. This discussion presupposes that there is some decent way of saying what research is and what treatment is. Discussions on what distinguishes these activities are thin on the ground. In this paper, I argue that research and treatment should be distinguished on the basis of their functions. I use this mode of distinction to cast light on a recent dispute between F Miller and H Brody[1] on the one hand, and C Weijer and P Miller[2] on the other, regarding the therapeutic duties owed to research subjects.

The question of how to distinguish treatment from research is pressing because of a worry that is perhaps most apparent in medicine, but which will arise in any context in which a group of people act, or are perceived to act, both as investigators of people and as carers to the same people. Medicine will be the focus of this paper.

Here is how the problem arises. For the sake of brevity, let us call those who engage with medical professionals ''patients'', and those who are medical professionals themselves ''doctors''. These terms are unfortunate here: the implications for the character of the engagement in question are quite different, depending on whether we use the term ''patient'' or a different one such as ''research subject''. The motivation for drawing a distinction between research and treatment is to find a taxonomic division that allows us to demarcate situations in which the interests of patients are likely to be promoted by doctors acting in accordance with their own goals, and situations in which this is, or may be, less likely. If a doctor's goal is to improve a patient's health, then the actions of the doctor may promote the interests of the patient. This is not guaranteed in all cases—the doctor may be incompetent or the maintenance of health may not be the patient's most pressing interest—but it is none the less a reasonable supposition. If a doctor's goal is to make some medical or scientific breakthrough, then there is more room for the doctor's actions to be detrimental to the interests of the patient, even when the doctor's competence is not in question. Here again, there is no guarantee that the doctor's actions will depart from the patient's interests—the doctor may subscribe to an ethical code that restricts what a patient is put through in the name of science; the patient's own long-term health interests may be best served by the very piece of knowledge the doctor generates, the mode of gathering and storing information to facilitate knowledge generation may be so innocuous as to have no noticeable negative effect on the patient to whom that information relates—yet, there is a good argument that, in the broad run of cases, there is more room for a mismatch between the patient's interests and the outcome of the doctor's actions in these circumstances than in the circumstances mentioned earlier.

The fact that these two types of situations can arise may not present a problem, or it will at least be less of a problem, if it is always transparent to both doctors and patients that their interactions can take many forms, that doctors may have various goals they wish to pursue through their interactions with patients, and that the question of what kind of interaction each of them is engaged in is something that needs to be cleared up by discussion between the two parties. Yet, such things are not always transparent. Patients often wrongly assume that doctors have only the improvement of a person's health in mind; they assume that doctors view them only as patients in the strict sense of that term.[3] It may also be that doctors, too, are not always entirely clear on the nature of their relationship with patients in the research context. The distinction between research and treatment is introduced, then, in the hope that some way of defining these terms will allow us to pick out situations in which mutual assumptions about doctors' goals are most likely to be right and those in which mutual assumptions about doctors' goals are more likely to be wrong. As is so often said, research is a domain in which particular caution is needed in making explicit what the goals of patients and doctors are, and what the likely effects of patient–doctor interactions are. The distinction

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between research and treatment has the role of an ethical warning flag: it is useful to separate research and treatment, not because we are looking to demarcate medical encounters that are inevitably morally dubious from those that are not, but because we want a pair of labels that alert us to situations whose potentials for misunderstanding (and for consequent resentment) are of a different order.

It is for this reason that some of the problems in distinguishing research from treatment have been rejected as pseudoproblems. Robert Levine, for example, quotes Thomas Chalmers, a doctor, who worried that,

> It is extremely hard to distinguish between clinical research and the practice of good medicine. Because episodes of illness and individual people are so variable, every physician is carrying out a small research project when he diagnoses and treats a patient.[4]

Medical practitioners are used to the idea that particularly interesting encounters with particular patients may come to be regarded as research when written as case notes. Chalmers's worry seems to be that at the limit we may regard even routine diagnoses as research on the grounds that they deliver new knowledge of the patient in question. Levine regards such statements to be true but obfuscating. It is true that the doctor is asking a question, discovering something new and performing a small experiment to learn some truth about the patient. Why, then, is this not research? The answer is that we should tune our definition of research to mark out situations in which the actions of doctors have a greater chance of departing from the interests of patients. We need to find a definition of research that does not equate it with the discovery of unknown facts, because patients will expect doctors to try to discover unknown facts that may promote their own health. They will expect the doctor to attempt an accurate diagnosis. But they may not expect the doctor to ask questions in ways that are at odds with the promotion of their health. The context in which the treatment/research distinction is used makes it plausible to dismiss comments about the distinction that presupposes a different context of debate as true but obfuscating.

TURNING TO THE PHILOSOPHY OF SCIENCE

Some readers may think that philosophers of science are the best people to tell us what research is. I am sceptical of this approach. Philosophers of science are not primarily interested in saying what makes research on humans different from treatment. Their goals are quite different—sometimes to give a generic characterisation of an experiment; sometimes to say what marks the difference between experimental and theoretical research; sometimes to assess whether all sciences aim at the formulation of general laws. Their work is useful none the less, partly because it highlights the very diversity of things that typically go by the name of research: this makes it particularly hard to use a content-based or methodological criterion to say which activities generating new knowledge should count as research. So consider the following:

- Not all research is empirical in character; some consists in the articulation of abstract models. Research in theoretical physics or in pure mathematics will typically be undertaken ''in the armchair'', but it is still research. This kind of research may be applicable to humans despite its abstract features. Some branches of complexity theory, for example, are regularly applied to such things as crowd behaviour.
- Some research strives to articulate general natural laws, but this is not always the case. It is often said of the evolutionary sciences that they strive to document actual historical patterns, not general biological laws.[5] This may be the case for some research on humans. Analyses of DNA data may offer reliable conclusions about the biological relatedness of different ethnic groups, for example. Yet, what is exposed here is a single historical fact rather than a general law of human physiology.
- Within the domain of research related to humans, research sometimes involves interaction with, and manipulation of, human participants. But this is not always the case, even when the research is empirical in nature. Epidemiological research can provide reasonably reliable conclusions about the causes of disease by using the data already gathered for other purposes.
- Within the domain of research related to humans, and indeed research in general, some results have fairly direct practical relevance, whereas others do not. Here, we may contrast research in social anthropology, for example, which rarely, if ever, makes claims to immediately improving either human life in general or the lives of those studied, with clinical trials, which do generally seek this.

The philosophy of science can remind us to be cautious in making generic statements about the character of research, but we should be sceptical of how much additional insight we can expect from this discipline when it comes to distinguishing research from treatment in the context of medicine. One way of dividing labour in this task draws on a certain kind of distinction between fact and value that I am suspicious of. The picture is of some neat, descriptive distinction between treatment and research, which a philosopher of science may be asked to clarify. Once this is achieved in a tolerably clear way, the ethicist steps in and examines treatment and research and the nature of their mode of distinction, to see what the ethical relevance of the distinction may be. I am sceptical of this way of looking at things because the function of a good distinction between treatment and research should be to enable us to make certain normative claims about each practice. If this is right, we cannot assess the adequacy of a distinction between treatment and research independently of the ethical work that we may use it for.

RESEARCH, TREATMENT AND PLANNING

The discussion in the first section suggests that the ethical context of efforts to distinguish treatment from research makes a ''functional'' classification the most appropriate way to characterise them; to describe some activity as research is to say something about its goal, function or purpose. For an activity to be classified as research, it is at least necessary that its function is the generation of knowledge. Note that the term ''function'', when used in this sense, tells us what some object or process is supposed to achieve, not what it does achieve. A definition in terms of the function of an activity is not a definition in terms of the effects of that activity. Bad research is still research—it is an activity that aims at producing knowledge but is not properly designed to do so. Good research, on the other hand, is likely to succeed, or does succeed, in achieving its goal. Both research and treatment should be understood as activities, directed towards particular kinds of goals.

On the face of it, the function or goal of an activity is what it is intended to achieve. Let us flesh out our understanding of research and treatment by linking these activities to philosophical work on agency and intention. To say that I intend to do something is not merely to say that I desire it. I could desire something that I have no intention of doing (it is not convenient for me to set about achieving it, I do not think

I am equipped to attain it), and I could intend to do something I do not desire (I feel duty bound to achieve something that I do not care for). On this view, to intend to do something entails making some plan for how to achieve this end.[6] An activity whose goal is the production of knowledge is one that the author has planned, or structured, to bring about the attainment of knowledge.

It is part of this view that a general plan of action, which equates to an intention to achieve some broad end, will necessitate the formulation of subordinate plans if it is to be effective. These subordinate plans will contain subordinate intentions. So, if an aspiring doctor intends to become the most famous doctor of the age, this broad plan will necessitate the formulation of subordinate plans regarding, let us say, gaining employment at the most prestigious hospitals. These plans in turn will necessitate further subordinate plans regarding how best to go about accumulating the knowledge to attain basic medical qualifications. Such young doctors may be entirely absorbed in the pursuit of gaining knowledge—indeed, it may be best for their ultimate ambition if their desire for fame is suppressed and their subordinate plan to acquire knowledge takes over—while they are engaged in their basic medical training. So we should not expect every action from a person working in fulfilment of some broad intention to be actively directed at the end specified by that intention.

We see such nested structures of plans and intentions when we look at research and treatment. If a doctor's broad intention is to improve the health of a patient, this can lead to the subordinate intention to discover what is wrong with the patient. It is no surprise that many activities designed to generate knowledge—and diagnosis is such an activity—will appear nested within a broader series of activities designed to improve a person's health: activities generating knowledge are a means to improving the person's health.

Again, this underlines and explains Levine's claim that the equation of research with any process that aims at generating new knowledge is true, but obfuscating. Treatment aims at improving health. Research aims at generating knowledge. Sometimes treatment, understood in this way, will contain episodes that can be termed research: a series of diagnostic procedures will yield a piece of new knowledge, for no one would have known what was wrong with the patient before. But the generation of new knowledge, when a doctor's efforts to acquire that knowledge are subordinate to a more general plan to set about improving the patient's health, will not trigger the kind of ethical concern that the distinction between research and treatment seeks to capture.

Conversely, research will sometimes be embedded within a more general plan not just to improve the health of an identifiable person, but instead to improve the health of mankind. Yet this does not mean that research of this kind triggers no ethical concern: even if improving health is a researcher's overall aim, the interests of people may be compromised in its attainment.

The ethical work that the distinction between research and treatment is designed to achieve makes it inappropriate in this context to make aiming at the generation of new knowledge a sufficient condition for an activity to count as research. We have already observed one reason: those activities that aim at new knowledge, yet which are subordinate to an overarching intention to augment the health of the person who is the subject of these investigations, need not count as research. We can add a second more general reason to resist thinking of aiming at the generation of knowledge as a sufficient condition for research. We normally think that research should produce knowledge that is significant. Not any new piece of information will do. How are we to define what is significant? At this point, we touch on important questions that lie outside the scope of this paper. Should the significance of a question be measured in terms of its importance for general welfare, in terms of its salience within some project to capture and systematise knowledge or in some other way? And what should we say when different scientists disagree about which questions count as important? In so far as our aim is to capture how research is conceived by the scientific community, we can remain content with using the medical research community to define what counts as significant knowledge. Research is an activity designed to answer questions that members of the medical research community would generally regard as scientifically important. This rough-and-ready definition is not intended to foreclose important discussion on the role of non-scientists in setting priorities for research agendas or on disagreement over research priorities among scientists themselves.

Finally, let me say a little to link this approach to the wider literature on distinguishing research from treatment. Freedman *et al*[7] give a threefold taxonomy of efforts to draw that distinction: ''Some organizations believe research to be distinctly characterized by its design, others by its intention, others by its use of novel agents or techniques.'' The approach in this paper undermines this taxonomy. On the face of it, the functional approach is most strongly allied to those who define research in terms of design. I, however, earlier defined design in terms of intention. When research is successful it generates considerable new knowledge. Although this will often entail the acquisition of some new technique, or the development of some novel agent, this is not a necessary condition. We will sometimes generate important knowledge regarding the efficacy of techniques (eg, in surgery) that have long been in use, but never been subjected to scrutiny. I see no reason not to count this as research.

DISTINGUISHING AND DEMARCATING

Should we distinguish research and treatment? Yes and no. Research and treatment name different functions—in this sense they are distinct. A series of events has treatment as its function if it is structured with the aim of improving the health of the patient receiving treatment. To describe our project as one of demarcation, however, is to get ahead of ourselves. It implies that events, or series of events, should be sorted exclusively into those that are research and those that are treatment. But events and tools can often have multiple, distinct functions. Getting from A to B and showing your sex appeal are certainly distinct functions, yet sports cars have both among their functions. If treatment and research are functional categories, then can some series of events not count as both? Can some series of events not be structured with the twin aims of improving the health of the patients concerned and yielding knowledge that members of the medical community would regard as important? If so, why is the category of therapeutic research so often denounced as a contradiction?

A Swiss-army knife has a tool that is used as a screw driver and for removing caps from bottles. But often, when things are designed to perform multiple functions, they are plagued by optimisation problems—making something a better screwdriver makes it a worse bottle opener. We often value objects that perform several different jobs tolerably well. Such multifunctional items, however, are typically compromise solutions.

This rather banal observation helps us understand why research and treatment are often defined in ways that make it impossible for a series of events to fall into both categories at the same time. We are not forced to do this by the general logic of the functional approach to distinguishing treatment from research; a plan of action can be structured in a way

designed to achieve more than one goal. There is no general contradiction, then, in saying that a set of activities that issues from such a plan has multiple intentions behind it. Moreover, a general concern to mark out those circumstances where the goal of generating knowledge may result in the actions of the doctor conflicting with the health interests of the patient does not require that we make the distinction between research and treatment exclusive. It requires only that those activities that count as research be recognised as such, even if they sometimes also count as treatment.

The contrast in functional definitions of research and treatment can be seen quite clearly in the following definitions from Levine, which summarise those used in the *Belmont report* (the report that summarised the stance of the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research). This report drew heavily on a background paper by Levine himself (the emphasis is mine):

> The term ''research'' refers to a class of activities *designed* to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles, or relationships (or the accumulation of data on which they may be based) that can be corroborated by accepted scientific observation and inference.
> The ''practice'' of medicine or behavioral therapy refers to a class of activities *designed solely* to enhance the well-being of an individual patient or client. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment, or therapy.[4]

If my car is not designed solely for getting from A to B, but also has as one of its functions a compensation for my inadequate masculinity, is it no longer a means of transport? Of course not. Stipulating that an activity is treatment only if it has the enhancement of health as its sole function is unusual, so why is this unusual route taken here? One possible rationale derives from our basic goal of flagging those situations in which the health interests of the patient may not be best served by the actions of the doctor. If we define treatment not merely as a series of events designed to promote the health of the patient, but as a series of events optimised solely for the promotion of the health of the patient, then anything that is not optimised solely for the promotion of the health of the patient does not count as treatment. Some research does aim partially at the promotion of the health of those who participate in the study. In refusing to label it treatment, we ensure that patients will be made aware of the ways in which health promotion may have been partially sacrificed for other ends, and we encourage a careful scrutiny of whether the promotion of health has not been unduly sacrificed in experimental design. This gives a practical reason to support the otherwise puzzling decision to stipulate that only work that is optimised solely for therapeutic ends deserves the name of treatment.

THERAPEUTIC OBLIGATIONS IN CLINICAL RESEARCH

I want to move on to a brief discussion of an influential paper by Miller and Brody.[1] They argue that much of research ethics is mistaken in thinking that doctors have therapeutic obligations to patients enrolled in clinical trials. Some people worry that doctors conducting randomised controlled trials face a dilemma; on the grounds that offering patients access to a trial in which they have a high chance of receiving placebo seems to involve the doctor in recommending suboptimal treatment to that person. The alternative seems to be a sacrifice of the scientific standards of the trial. Miller and Brody, however, say there is no such dilemma. They claim that this dilemma disappears once we clearly distinguish research from treatment and recognise that they are different kinds of activities, governed by distinctive norms: ''The 'therapeutic obligation' of investigators, forming one horn of the RCT dilemma, constitutes a therapeutic misconception about the ethics of clinical trials.''[1]

I think we can question Miller and Brody's arguement, but in the end I find myself sympathetic with the major conclusion of that argument. We cannot use the fact that research and treatment have different functions to argue that doctors have no therapeutic obligation to people enrolled in clinical trials. Yes, well-designed research is optimised for yielding knowledge. But this does not somehow rule out, on logical grounds, the claim that doctors also owe high standards of treatment to the people enrolled in clinical research, nor does it deny that the design of research should ensure that participants are not exposed to unjustifiably high health risks, both of which may demand that research be suboptimal with respect to generation of knowledge to ensure that treatment standards are maintained. More banal examples of conflicting functions make this clear. Travelling and looking after the environment are different functions, but distinguishing these goals does not imply that aircraft manufacturers have no duties towards the environment or that aircraft speed should never be sacrificed in the interests of fuel efficiency, or that there is an ''environmentalist misconception'' in confusing the obligations of travel providers and environmental managers.[8]

Hence, distinguishing treatment from research does not by itself show that researchers have no therapeutic obligations. Indeed, the role of distinction between research and treatment, if the arguments in the first section of this paper are correct, is not to show that researchers owe *no* treatment standards to their subjects; rather, the role of the distinction is to act as a flag, indicating to potential participants receiving treatment that they should not expect their interaction with medical professionals to be aimed solely at maximising their individual health prospects. On the other hand, nothing in the foregoing argument has established anything about what therapeutic obligations researchers may have, and doctors face a strong dilemma in clinical trials only if their therapeutic obligations in research are to give the research subject the best treatment they can at every stage of the research process. This view may seem to follow from the refusal to characterise a process as treatment at all unless it is optimised solely for therapeutic ends. This may lead us to say that levels of treatment should never be compromised for the sake of research design. In fact, no such inference follows. The argument for defining treatment as that which is optimised solely for therapeutic ends did not show that doctors show have an obligation to optimise individual health. It was defended merely on the grounds that by defining treatment in this way we generate an effective flag—''if something is research, then it is not therapeutically optimised''—to mark out circumstances where we may want to make patients aware that their health interests may be compromised. This is not the same as saying that the health interests of patients should never be compromised in their dealings with doctors. Much more controversially, we are reminded by this argument that calling a series of events as treatment only when they are optimised solely for the improvement of individual health is compatible with the view that doctors *never* owe patients treatment in this sense. It is certainly worth raising the question of whether there may be reasons to be always on the lookout for how we can modify the doctor–patient encounter so as to yield valuable new knowledge. The fact that this may result in doctors never giving treatment in the sense derived from Levine is not to

argue against the position. After all, we would undermine the status of an activity as treatment if the only modification we made to it were to make (non-invasive) observations for use in anonymised epidemiological studies: such a modification would make false the claim that the activity was ''designed solely to enhance the well-being of a patient or client'', but it hardly threatens individual health.

Setting these more controversial speculations aside, is there any positive argument for thinking that doctors have very strong therapeutic duties—duties to provide optimal effects on individual health—in the research context? Doctors regularly enrol healthy people in clinical research, which is not optimised to benefit the health of these people, even though doctors will incorporate safeguards so as not to endanger their health. Why should patients who are ill also not participate in trials that are safe enough, but that are not optimised to benefit their health?

We may look for an answer in the supposed nature of the doctor–patient relationship. Charles Weijer and others argue that this relationship is a fiduciary one: the role of the doctor with relation to the patient is that of a trustee. In their response to Miller and Brody[1], Weijer and Miller[2] write, ''If the research subject who is ill has any interests at all, first among these must be to receive competent medical care, as required by clinical equipoise.'' Weijer and Miller themselves explicitly require only that patients receive competent care, not optimal care. So even for Weijer and Miller, there is no obligation in the research context to ensure that doctors do not sacrifice standards of care in the interests of research design. Those standards need only remain competent. Weijer and Miller's position does not yield the dilemma that Miller and Brody fear, in which doctors must ensure that patients in trials receive optimal care, while also redesigning care regimens to yield valuable information for research.

CLINICAL EQUIPOISE

At this point we may wonder what, if anything, is at stake between Miller and Brody[1] and Weijer and Miller.[2] After all, Miller and Brody do not think that a person's enrolment in research gives doctors carte blanche to take any course of action, no matter how dangerous it is to the subject, so long as it promises to generate knowledge. Risks to research subjects, they think, must be carefully monitored and managed. So all parties agree that there are duties to maintain the health of research subjects, and no party thinks that these duties include providing optimal care. Perhaps Weijer and Miller's claim that care should be competent is consistent with Miller and Brody's position and the disagreement merely arises from a mutual misunderstanding of the term ''therapeutic'' duties. When Miller and Brody deny that there are therapeutic duties in the research context, they mean that the doctor is not obliged to act in ways designed solely to improve the health of the patient (here, a contrast is drawn with the duties we may believe to apply in the context of treatment). Weijer and Miller take this to be a denial of any duty to ensure that health is maintained, and consequently assert that there are therapeutic duties in the research context after all.

I think there may be more to the debate than this. The key question is whether Weijer and Miller are correct to equate competent care with care that meets the demands of clinical equipoise. The interpretation of clinical equipoise is tricky, making it hard to assess this equation.[9] I can only scratch the surface of the epistemic and normative issues raised here, issues that lie at the heart of important debates on the proper standards for clinical trials. As a first pass, we may say that clinical equipoise obtains when the generally accepted opinion in the medical community is divided, or uncertain, regarding the efficacy of standard treatment compared with the intervention under investigation. This is an ambiguous statement. One ambiguity (and there are more) concerns the notion of evidential neutrality that seems to be at work in the notion of uncertainty. To consider just two readings, we may hold that clinical equipoise obtains when we are lacking conclusive evidence for the proposition that the experimental treatment is less efficacious than standard treatment. Alternatively, we may think that to attain equipoise our evidence must indicate that the efficacy of the experimental treatment is the same as that of standard treatment. The first condition will almost always be satisfied, whereas the second will hardly ever be satisfied. To see this, consider a newly synthesised member of a well-known family of drugs. Imagine that no other member of the family has been found even nearly as efficacious as the standard treatment for some condition. We therefore have plenty of inductive evidence to suggest that the new drug will probably be less efficacious than standard treatment, but our evidence for this suggestion is only partial, based as it is on the profiles of drugs that are different, albeit related. Whether such a drug is in equipoise with standard treatment depends on how strongly we read the demand for uncertainty regarding the relative efficacy of the two interventions.

Difficulties like these must be resolved for clinical equipoise to be a defensible standard, otherwise we risk making that standard impossibly hard or trivially easy to attain. Suppose we can achieve a resolution. Perhaps we will decide that clinical equipoise demands that there is no good evidence to suggest that the experimental treatment is considerably less efficacious than standard treatment. Now is this, as Weijer and Miller claim, merely a demand for competent care in research, or does it demand something stronger? Once again, consider the new member of our well-known family of drugs. We have found that the other drugs in this family are less effective than the standard treatment. On the other hand, let us stipulate that they have not produced dangerous side effects. A betting man, and any sensible betting doctor, would wager against the new drug being as efficacious as standard treatment. We can, however, suppose that it has some interesting and potentially relevant properties not shown by other drugs in the family. It would not seem a fool's errand to establish, by using a trial, whether the new member (contrary to the expectation that family pedigree gives us) is in fact more efficacious than the standard treatment. It seems to me that the use of this drug in a trial could be consistent with the standards of competent care. Yet the new drug and the standard treatment are not in clinical equipoise, at least not on the non-trivial reading I gave at the beginning of this paragraph. Weijer and Miller's more formal reading has it that clinical equipoise ''requires that at the outset of a trial there exists a state of honest, professional disagreement in the community of expert practitioners as to the preferred treatment.''[10] In the case in question, the weight of existing evidence suggests that while enrolment in the trial is unlikely to harm the patient severely, chances are that the drug will turn out to be as inefficacious as other drugs in the same family.

This shows that the most obvious non-trivial readings of clinical equipoise make quite strong demands of treatment standards in research, in ways that are not clearly necessitated by Weijer and Miller's fiduciary conception of the doctor–patient relationship. The requirement of clinical equipoise seems to demand that a doctor should ensure that the therapeutic value of a research intervention seems unlikely (given current evidence) to dip below the level offered by standard treatment. We must remember, however, that a patient has interests other than his own health. Once again, healthy research subjects sometimes enrol in research because they hope that the knowledge the research yields will

be in other people's interests, or because they want to make some money. Can the unwell not choose to sacrifice their health interests for other interests too? Should the doctor say ''I understand that you would rather forgo, for a short period, treatment that meets the level of standard treatment in the interests of future people with your condition. I cannot allow this, because my evidence suggests that your health, while not being seriously endangered, is likely to suffer in this trial compared with how it would perform under standard treatment''?

We may say that there is no inconsistency between the options offered to the healthy and the unwell, perhaps on the grounds that the doctor is generally obliged to maintain health at the level that standard treatments permit. Even if healthy people may properly undergo interventions that are likely to reduce their health prospects for the short term, this does not entail jeopardising their level of health so that it falls below that normally ensured by standard treatments. Indeed, healthy people enjoy a level of health that is already well above that ensured by standard treatments.

I grant there is no inconsistency. Even so, we require a justification for why standard treatment marks the correct level for care in the research context. On the face of it there could be cases where the standard treatment offered is better than the level required for adequate care in the relatively short period of a trial: in some research contexts treatment that is adequate may be good enough. This is not a general license to subordinate treatment aims to research aims. When both health and knowledge are at stake we may have to settle for research that is good enough, too. We should sometimes redesign our research—and that may mean tolerating suboptimal research—to ensure that higher levels of treatment are given to everyone in a trial in a way that allows the acquisition of data that are good enough, given the gravity of the question being asked and the necessity of the treatment that is interrupted.

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