Are ethics promulgations self-defeating?

Derrick Gray

Department of Philosophy, Carnegie Mellon University, Baker Hall 161A, Pittsburgh, PA 15219, USA
Corresponding author. E-mail: derrick.f.gray@gmail.com

ABSTRACT

Alan Wertheimer argues that promulgating some ethical standards of international clinical research may be self-defeating: the intended purpose of these standards is to promote the interests of subjects and communities in LMICs, while the outcome of promulgation could be to undermine these very same interests. If enforced, such standards would increase the costs of performing beneficial research in LMICs, potentially diverting opportunities to participate in this research away from those who have no other access to the care participation allows. I argue that these standards are really intended as deontological constraints protecting subjects from being exploited by research sponsors. First, I show that Wertheimer begs the question against this deontological interpretation of ethics promulgations, rejecting it on non-deontological grounds. I go on to show that non-exploitation is an important goal on its own, sometimes independent from—and sometimes even outweighing—the goal of promoting the interests of subjects and communities in LMICs. I conclude by suggesting that those who criticize the promulgation of non-exploitation on the grounds that exploitative practices help those badly off might do best to reconsider the background assumption that sponsors in wealthier countries have no pre-existing obligation to promote the interests of the world’s poor.

KEYWORDS: exploitation, research ethics

The philosophical community has suffered a genuine loss in the passing of Alan Wertheimer. He was admirably careful and creative in his writing, and very subtle. His work is not to be taken lightly by anyone writing in ethics or political philosophy. Wertheimer laid the foundation for modern philosophical discussions of exploitation, and I wish that I had joined the conversation in time to have called him my colleague.

Though Alan Wertheimer does not give an unambiguous answer to this question, he argues that there is good reason to think they are. Promulgations of principles...
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requiring responsiveness, post-trial access, and others might be self-defeating, he argues, for while their ‘whole point’ is ‘to promote the well-being of the community or research subjects’, the promulgations could create disincentives to conduct research where it is most beneficial to subjects and communities. Whether they are self-defeating is an empirical question, claims Wertheimer, and one to which promulgators have failed to pay sufficient attention.

In the following, I first defend an alternative goal for ethics promulgations (EPs): preventing the exploitation of research subjects, where this is independent of the goal of promoting subjects’ well-being. I then argue that the goal of non-exploitation can conflict with others, like promoting the well-being of populations in lower- and middle-income countries (LMICs), and that non-exploitation can be a weightier goal than Wertheimer seems to acknowledge.

THE GOAL OF EPs

According to Wertheimer, EPs are intended ‘to promote the well-being of the community or research subjects’, and ‘many of the principles contained in those promulgations seem designed precisely to advance the interests of people in LMICs’, but they are potentially self-defeating. Sponsors currently have financial incentives to conduct research in LMICs because, for example, they may not have to provide the same standard of care required in wealthier countries. Nevertheless, such research provides some measure of healthcare to many individuals who would otherwise not have such access to it. If EPs are successful, however, they could nullify the incentives sponsors have to conduct research in LMICs by increasing costs. Whereas EPs were supposed to promote the interests of those in LMICs, they instead undermine them.

But there is an alternative purpose to attribute to EPs, one Wertheimer recognizes for IRBs. Specifically, EPs might serve the purpose of protecting research subjects. Note that the protection of subjects is not the same goal as advancing their interests. If the latter were the goal of EPs, we might expect them to straightforwardly demand that research be conducted in LMICs whenever it would be beneficial. This might incline researchers to carry out research in LMICs even absent a financial incentive. But EPs do not include this principle, and its absence could be taken to imply one of the following three claims: (1) promulgators (qua promulgators) are not seeking to advance the interests of (current or prospective) subjects in LMICs; (2) promulgators are trying to advance the interests of these subjects but do not believe (as a matter of empirical fact) their promulgations will actually prevent beneficial research; or least charitably (3) promulgators have not actually considered the consequences of the acceptance of their promulgations. Wertheimer suggests something like (3) is the case. While I believe (2) is a possibility, I will assume that the facts do not unequivocally rule out diversion effects. In what follows, I’ll instead present a case in defense of (1): Promulgators are not trying to advance the interests of subjects in LMICs, but only trying to protect them by preventing their exploitation.

1 Alan Wertheimer, The Ethics of Promulgating Principles of Research Ethics: the Problem of Diversion Effects, 2 J. L & BIOSCI. 1, 27 (2015).
2 Id.
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I do not assume all promulgators would say they are trying to prevent exploitation as opposed to some other wrong. However, I’ll stipulate for now that to exploit someone is to take unfair advantage of him, and I’ll assume that a promulgator would agree that a violation of her chosen EP is an instance of a sponsor taking unfair advantage of a subject or subject community.

I will argue non-exploitation is what Wertheimer calls a ‘deontological constraint’ on international research. Such constraints typically ‘serve to protect the targets of actions against harms or rights violations that could otherwise be justified on consequentialist grounds’.³ Wertheimer himself seems to allow for some such principles, including informed consent. In the cases of research to which EPs are intended to apply, however, not only are the subjects assumed to provide informed consent, they are also assumed to benefit from participation relative to their non-transaction baseline, so ‘appeals to deontology seem out of place’.⁴

Yet, Wertheimer also allows that violations of EPs may constitute exploitation, and considers whether principles of non-exploitation in consensual, mutually beneficial transactions can be legitimate deontological constraints on research.⁵ I take his argument to be as follows. We insist on non-exploitation because it promotes the interests of those who are, or would be, exploited. However, the EPs under examination would fail to promote (and would actually undermine) the interests of the exploited. Therefore, such principles should not be promulgated as deontological constraints on research.

But Wertheimer fails to engage with deontology on its own terms. Most generally, to say a principle is deontological is to say it’s duty-based, that it rules out some action that violates a duty, where this trumps whatever good consequences the action might bring about. For instance, the duty to not lie persists even when lying might generate better consequences for both the liar and the person lied to. If a principle of non-exploitation is deontological in this way, the exploitative nature of a transaction is a reason to not engage in that transaction, and also a reason to prevent others from carrying it out, even if the action would have better consequences. Wertheimer is therefore saying that deontological requirements of non-exploitation in research should not be promulgated as deontological constraints given their negative consequences.⁶ But the consequences are exactly what shouldn’t matter to the deontologist. In his quick dismissal of ‘observing the constraint of fairness’ to ‘honor some abstract principle’,⁷ Wertheimer is begging the question against exactly the kind of reasons he’s supposed to be arguing against. Only, if the reader has already rejected this deontology could she be willing to reject EPs on the grounds that their consequences are unacceptable.

So, Wertheimer has not provided a good argument for why EPs, if deontological, can be outweighed by appeal to their consequences. I now want to argue that at least some of these principles are just such constraints.

³ Id.
⁴ Id.
⁵ Id. at 27–28.
⁶ Or, such principles should perhaps not be promulgated, if they are likely to result in diversion effects.
⁷ Wertheimer supra note 1, at 28.
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A THOUGHT EXPERIMENT
To make my case, I’ll build on Wertheimer’s analogy between EPs for research and promulgations for safer factories in LMICs:

Suppose that insisting on minimal safety standards in industrial production in LMICs would divert investment to better off countries, thus making (prospective) workers in LMICs worse off. Given their background conditions, and unfortunate as it is, it may well be that unsafe jobs are better than no jobs. … If people in a given society would in fact be better off if we relaxed safety standards, I think that does tell in favor of relaxing those standards. I am prepared to bite that bullet.8

I’m not so prepared, and I think a little reflection might show the reader to be equally unprepared.

Imagine we live in a world in which safe working conditions backed by an effective global regulatory framework have existed for some time. Factories in LMICs must pass stringent construction requirements, factory fire exits must remain unlocked at all times, and workers are provided with proper gear for handling hazardous chemicals. Meeting these safety requirements is relatively expensive; therefore, considerably less labor is outsourced to LMICs, meaning fewer people desperately in need receive jobs better than those otherwise available in local economies.

It comes to our attention, however, that by relaxing these standards, we could provide employment to more people desperately in need. Even if rolling back the standards would provide less (ex ante) benefit to each worker due to increased risks, he or she would still benefit considerably compared to local alternatives, and more total workers would benefit.

Would we be moved by such considerations to relax our standards, allowing employers to lock the exits in shoddy buildings during work hours, while thinking to ourselves, ‘It’s terrible, but it’s the best way of accomplishing our goal of advancing the interests of the global poor?’ I think the answer is no, for there are ways in which we’re not allowed to use people, even when all things considered it would improve their desperate lot. This includes not subjecting workers to extreme risks, or at least compensating them appropriately when we do. Moreover, we would answer the same way even if we could be assured that those currently working in safe factories would remain employed under safe conditions, and that only future workers would be subject to more dangerous conditions. We would be hard-pressed to describe our refusal to revise our standards as ‘harming’ those prospective workers who would benefit from revision by receiving newly available, unsafe jobs, rather than as protecting them from unacceptable use. In other words, we could recognize the ‘diversion effects’ of our safety standards, but we wouldn’t describe them as such, since these standards were never intended to promote the interests of LMIC populations.

Of course, an intuition by itself isn’t proof of anything. We must explain why relaxing these standards would be exploitative, and why the goal of non-exploitation could outweigh that of improving the lot of the global poor. Wertheimer’s favored account of

8 Id. at 26.
exploitation—that A exploits B when A leverages a bargaining inequality to charge B a price higher than that found in the corresponding hypothetical competitive market\(^9\)—won’t do here. If we thought employers were treating workers fairly in highly competitive markets, then we would actually do away with the kinds of safety standards that prevent a fully liberalized market.

We might instead look to accounts offered by Ruth Sample and Jeremy Snyder, each of whom suggests (roughly) that A exploits the needy B when (i) A gains from the use of B; (ii) B is significantly dependent on A; and (iii) A could provide B with what she needs for a minimally decent human life, yet (iv) A provides her with less.\(^{10}\) Underlying such an account is the recognition that B is a human being with needs and goals, and that there is some threshold amount A must provide B in order to treat her as a human being. This threshold plausibly includes a minimally safe working environment (or sufficient compensation for the lack of one). As the basis of a deontological principle, the account could therefore dictate that only after workers were ensured the threshold level of benefit and protection could we consider whether additional benefits should be used to promote the interests of other needy individuals, including other potential workers in LMICs.

If such an account is plausible, the most significant upshot is that non-exploitation is an important deontological goal. It can conflict with, and even outweigh other goals, including that of advancing the interests of the poor, even when they benefit from and consent to being exploited. That’s not to say that these goals must always conflict, or that when they do, we must always choose non-exploitation. But it is to say that the promulgation of global labor safety standards is not self-defeating simply because it leads to fewer persons in LMICs receiving beneficial, consensual employment.

The question is then whether a similar result would obtain when we instead imagine worlds in which EPs were enshrined in practice. Space limitations prevent a review of each principle, but I’ll consider two in hopes of making some interesting observations.

First, consider ‘standard of care’: new interventions tested in any population must be tested against the best proven effective interventions. This was a central objection to the Surfaxin trial, since Discovery Labs intended to test Surfaxin against placebo rather than another proven surfactant generally unavailable in the intended host communities. The thought experiment above well captures the moral outrage over this proposal, especially since many critics probably believed we did live in a world in which standard of care obtained. These critics would have seen the attempt to skirt standard of care the same way we might have seen the attempt to weaken international labor safety standards in the imagined world above. There, we wouldn’t be willing to weaken such standards just because doing so would increase the number of employed persons in LMICs. In the present case, many would be unwilling to let sponsors use fake surfactant just because doing so would increase the numbers of infants receiving otherwise unavailable care.

But now consider the demand that research in LMICs be responsive to local health needs or priorities. We can imagine a world in which such responsiveness is required in

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\(^9\) Alan Wertheimer, *Exploitation* 230–236 (1996).

\(^{10}\) Ruth Sample, *Exploitation: What It Is And Why It’s Wrong* 69–72 (2003). Jeremy Snyder, *Needs Exploitation*, 11 Ethical Theory & Moral Prac. 389, 395–99 (2008).
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international research. Would we be willing to relax the requirement, if doing so meant many poor persons would receive otherwise unavailable healthcare, albeit within the context of unresponsive research? I think the answer would be yes, but only on condition that in place of responsiveness, some other significant benefit was provided. Moreover, I believe something like the account of exploitation gestured to above might validate this result and the less ambiguous result for standard of care.

Given the paucity of local health care infrastructure, the populations in the proposed Surfaxin trial would have been significantly dependent on Discovery Labs for medical care. This sponsor could have planned quite easily to respond to this dependence by testing their product against a proven surfactant, but refused to do so because it was cheaper or because proving effectiveness against placebo was easier. The sponsor chose profit over safer trials, answering dependence with minimal benefit, and this arguably failed to sufficiently recognize prospective subjects as human beings.

Similarly, conducting research responsive to health needs of the host community may be one way sponsors can take seriously subjects’ requirements to live decent human lives, simply because having such a life includes being relatively healthy. However, this is consistent with there being other ways for sponsors to take these requirements seriously (e.g. if the research helps educate local health care workers or helps create better health care infrastructure). Whether responsiveness is best seen as a necessary condition or as a member of a set of jointly sufficient conditions for non-exploitative research, the call for responsiveness embodies an idea at home in the account of exploitation above, namely that fair treatment of those we use can require giving them more than the minimum needed to ensure their voluntary participation.

In each case, our unwillingness to relax ethical standards simply in order to increase the number of subjects or communities benefiting from research suggests that we care about something other than maximizing benefits to the global poor. We recognize that our standards might prevent more desperately needy people from participating in beneficial research, but given the goal of non-exploitation, the standards would not be self-defeating.

I’m not suggesting that in these alternative worlds where the standards are already in place, we find acceptable the fact that many suffer from the lack of basic health care. Wertheimer can plausibly be read as arguing that given the non-ideal conditions of the world, and given our concern for promoting the interests of the poor, the best thing to do is to not promulgate these EPs. But again, the assumed complete and unquestioned priority of this concern over that of non-exploitation begs the question against the deontologist.

Moreover, this line of reasoning commits the same fallacy here as when it appears in attempts to show that a theory of exploitation is too restrictive because it prevents too many mutually beneficial, consensual interactions. What’s disingenuous about such

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11 Snyder, supra note 8, at 394–395.
reasoning is that it often begins with the following assumption:

No prior obligation to interact (NPO): research sponsors and employers in wealthier countries aren’t obligated to transact with potential subjects and workers in LMICs; their refusal to transact does not harm these potential subjects or workers.¹²

It’s at least in part because current regulations build in NPO that EPs would generate diversion effects. Without regulations affirming an obligation to interact, sponsors will conduct research in LMICs only if there is financial incentive to do so, and this incentive is what is lost with successful promulgation. But after positing NPO, this line of reasoning then complains that moral critiques of purportedly exploitative employment or research practices are in some sense faulty because their prescriptions result in fewer beneficial interactions for those in need.

However, it is no flaw in a theory of fairness in international employment or research that it does not successfully achieve every one of our moral goals. Similarly, if a state succeeded in protecting all of its citizens’ negative liberties, these citizens might nonetheless be extremely poor, but this need not be a flaw of the operative theory of negative liberty. Rather, the state might have failed to fulfill its positive obligations to its citizens. And if after succeeding in preventing the exploitation of research subjects, we’re saddened at the number of persons for whom basic medical care is out of reach (where this number would have been smaller if not for so-called diversion effects), this does not impugn our principles of non-exploitation any more than it impugns NPO.

**CONCLUSION**

Wertheimer has not succeeded in showing that EPs are potentially self-defeating, since he has not shown them to fail as candidates for legitimate deontological constraints imposed on research to protect subjects from exploitation. I have argued that at least some EPs might be such constraints, though the argument is incomplete and requires a much fuller and better defended account of exploitation. Finally, I have argued that to the extent that we worry about ‘diversion effects’, this might show only that we have not promulgated *enough* ethical principles of research, since there may be no diversion if we reject NPO.

¹² Wertheimer 1996, supra note 8, at 216–217. ALAN WERTHEIMER, RETHINKING THE ETHICS OF CLINICAL RESEARCH: WIDENING THE LENS 256 (2011).