Informed consent to participation in interventional studies: second-order in a different sense

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A peer commentary on Alan Wertheimer’s (Why) should we require consent to participation in research?—Journal of Law and the Biosciences

Alan Wertheimer’s important article shows that while ‘the balance of [first-order] moral reasons might well tell against the use of coercion in most cases’ of interventional biomedical research, it does not tell against its use in all those cases.1 Wertheimer is right, for example, that coercive research does not always treat subjects as mere means or disrespect their autonomy rights. His article then adds that a broad consent requirement (CR) remains justifiable as a matter of ‘second-order’ morality. By that Wertheimer means, ‘moral decisions that take into account the fact that first-order moral reasoners are not omniscient or are perceived to be so by others’.2

Wertheimer does not lay out in detail the determinate non-omniscience-related reasons for CR in intervention studies (except for suggestive analogies from other areas where non-omniscience supports strict rules).3 Whichever the exact reasons, his suggestion is that our non-omniscience is—somehow—why CR obtains so broadly in intervention studies, far more broadly than first-order reasoning can explain. I shall try to show that there must be more to the justification of CR than nonomniscience, and to characterize the remaining justification.

Let me start by indicating that Wertheimer’s is not a full account of the CR in interventional biomedical research. I shall then suggest a key additional part of the account.

THERE IS MORE TO THE FULL ACCOUNT

Here are five indications that Wertheimer does not provide a full account of the CR in interventional studies. One indication can be titled CR’s unresponsiveness to variance in

1 Alan Wertheimer, (Why) Should We Require Consent to Participation in Research?, JLBIOS, 176 (2014).
2 Id. at 168. See also 179.
3 Id. at 177–8.
our knowledge. We possess greater advance knowledge about some intervention studies than about others. We often know more about the likely effects on the 100th patient studied than about those on the first one. We know more about interventions in late phases of research than about ones in early phases. And yet, the strength of CR does not usually vary dramatically between such different studies. In none does CR disappear completely. Since CR can last, fairly immutable, across intervention studies concerning which we have very different levels of advance knowledge, CR seems to be justified not (only) by our lack of full advance knowledge but (also) by other factors.

A second indication that CR addresses more than non-omniscience-related complications can be called unresponsiveness to variance in risk from lack of knowledge. Wertheimer worries about non-omniscience only because of the risks and burdens that it creates. For example, without full knowledge, we may make calculation errors, which worry Wertheimer because they are dangerous for health and society. Indeed, Wertheimer focuses on intervention studies not on observation ones, presumably not because we are omniscient about the latter, but because their risks are usually lower. However, pace Wertheimer, the necessary level of consent does not track purely the level of risk generated by a study. While minimal risk or de minimis risk studies do tend to require less than fully comprehending and voluntary consent, participation in them should not be imposed on candidates who explicitly refuse to participate, certainly not on a regular basis. There seems, therefore, to be at least additional grounds for the CR.

A third indication against Wertheimer’s account or its fullness can be called unresponsiveness to alternate ways to enhance safety. If risks from non-omniscience were the only ultimate concern, then risk-reduction mechanisms other than CR would have often rendered CR redundant, but CR is not redundant. CR rarely enhances safety beyond the level already reached thanks to oversight bodies’ safety reviews. A study candidate usually knows less about the procedures and their dangers and social implications than does the review committee. And yet, CR surely retains some point. Suppose that we boosted safety review: even low risk triggered bans on studies; several review bodies would have to deem a study safe before it could take place; patient advocates and community representatives could veto studies. Could such exceeding protections render CR completely redundant? Intuitively, something valuable would remain in seeking people’s permission before intervening in their bodies. Imagine a research institute where, to save time for all, only every fifth participant’s consent is sought. Four out of five intervention study participants are never approached for consent. The institute penalizes researchers who had garnered many refusals, thereby maintaining incentives to create appealing, safe, and beneficial packages for participants. Suppose that studies in that institute turned out to be as safe as any others. Intuitively, something would remain amiss in that institute’s policy of skipping some participants for any consent. The value of seeking the consent of all participants before intervening in their bodies may spring in part from sources different than Wertheimer’s bulwarks against risk and social cost.

A fourth reason to doubt the fullness of Wertheimer’s suggestion surrounds the consent requirement outside research. Clinicians seek explicit, signed consent before major surgeries, and minor clinical interventions usually remain forbidden when patients

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4 Id. at 179.
5 Nir Eyal, Informed Consent, in STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed., fall 2011), http://plato.stanford.edu/archives/fall2011/entries/informed-consent/.
absolutely refuse them. But any risks from non-omniscience are somewhat lesser in the clinic. These clinical interventions are rarely experimental, and clinicians’ interests are typically better aligned with patient safety than investigators’, so Wertheimer’s protections in the face of nonomniscience are less necessary. Now, Wertheimer may respond that part of the justification of consent requirements in clinical care is that there remains a lot we do not know, even about approved interventions and their physical and psychological effects on patients and society, partly because some conflicts remain. To be fair, Wertheimer cites John Stuart Mill’s argument against coercive paternalism as an illustration of his own position, and Mill’s argument more readily supports banning coercive paternalistic care than coercive non-paternalistic trial participation. However, in many areas outside medicine with high uncertainty and risk to welfare, consent requirements remain weaker than in either medical trials or medical practice. Medicine attracts CRs in ways that do not track quite neatly the risks from non-omniscience.

A fifth indication that Wertheimer’s suggestion is incomplete pertains to the commonsense phenomenology of consent requirements. While Wertheimer is right that first-order factors like self-ownership, respect for autonomy, and refrain from using individuals as mere means fail to justify CR, it would remain odd for an investigator not to mention any such factor in explaining her refrain from coercive imposition of study interventions, mentioning instead only the risks emanating from nonomniscience (‘I figured that tying you to the bed despite your refusal, to inject this last hope experimental drug, carries too much risk of upsetting social order and public health—a cumulative risk that weighs more than the medical risk from letting you make mistakes on your own’). We expect investigators and oversight bodies to think of CR as more than cold balancing of benefits and risks in particular cases. Commonsense morality expects somewhat deeper faith in CR, and some appeal to values like patient rights to autonomy and independent judgement, their dignified separateness from their caretakers, or the like.

A SUGGESTION

Incorrect as it may be, the perception that extreme coercion in either clinical or intervention contexts disrespects autonomous, dignified persons is both prevalent and persistent. We typically perceive highly intrusive coercive care and experiments as evincing utter disrespect toward the patient or the study participant, no matter what the doctor explained to convince such a patient or participant otherwise. False as Wertheimer and others may have shown these perceptions to be on many occasions, they can generate what I shall call ‘dignitary’ harms: for the patient or study participant, a painful sense of humiliation and decline in her subjective self-respect, mood, and willingness to pursue plans; for determinate populations chronically coerced in care or in experiments in ways broadly perceived as disrespectful, a decline in the respect, concern, or friendship of third party witnesses and hence neglect, stigma, exclusion and discrimination; and, in a society where doctors impose intervention on all, decline in the beneficial culture of respect for autonomy, affecting everyone. In brief, coercive actions that

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6 Id.
7 Wertheimer, supra note 1, at 178–9.
8 Eyal, supra note 5.
9 JOHN RAWLS, A THEORY OF JUSTICE (Belknap Press of Harvard University Press Rev. ed., 1999).
jeopardize, touch, penetrate or alter our bodies carry high risk of dignitary harm. No matter how much an individual investigator or clinician tries to convince other people that imposing care can be perfectly respectful toward autonomous beings, in the foreseeable future most will continue to perceive imposed intervention in the body as disrespectful, leading to dignitary harms. A broad range of ethical theories would view these harms as suboptimal and recommend their reduction. Instituting a CR across interventional research and care (and not only in cases where first-order moral reasoning or Wertheimer’s non-omniscience consideration justify it) can help mitigate that dignitary harm.

Now Wertheimer has shown that potential harms including such dignitary harm do not suffice in themselves to justify CR across interventional research and care in a first-order way. But there is a second-order way in which dignitary-harm reduction, in conjunction with Wertheimer’s other first-order factors and non-omniscience, may provide a full account of CR to intervention studies.

In order to reduce the potential dignitary harm of coercive intervention in the body, many moral theories will tell investigators and clinicians to preserve and foster their natural tendencies to believe (false) that intensive medical intervention on an autonomous adult, by always violating autonomy, is always disrespectful. Each individual should preserve and cultivate any beliefs that coercive interventions in the body, including ones in interventional research and care, are indeed profoundly disrespectful. Once an individual cultivates these inclinations, she will tend to follow CR, out of respect for the ethos that typically underlies CR, even on occasions that the balance of first-order factors is known to permit coercion. She would do so out of deep belief in CR, and condemn others who transgress CR. Let me argue that such beliefs, and the behavioral tendencies that they tend to spark, would help reduce dignitary harm to research participants, patients, and others.

It may seem as though cultivating such beliefs is unnecessary in order to minimize dignitary harm. Isn’t refrain from actively violating CR enough? A clinician might explain

I actually believe that there is nothing truly disrespectful about coercive intervention, which, after all, would benefit you medically and arguably protect your long-term well-being and autonomy. But patients usually perceive coercive intervention as disrespectful. Therefore, to protect you from incorrectly feeling offended, I will not impose care.

But to say so would usually offend patients and study participants in its own right. It appears either condescending or neglectful, and could exacerbate dignitary harm. Can’t the investigator or the clinician hide her real motivation, then? A clinician might lie to patients about why she avoids coercive care, falsely citing their autonomy and dignity. But to say so while believing otherwise runs a big dignitary risk. Involuntary facial gestures, for instance, might betray the clinician’s deceitful scheme, and most patients would feel doubly offended. Over the course of the many years in which such a deceitful scheme were enacted, clinicians would usually cause a lot of serious offense.

The simplest way to reduce dignitary harm over one’s career is to cultivate or preserve a belief in commonsense narratives about autonomy, dignity, and the mere means

10 Wertheimer, supra note 1, at 172.
Informed consent to participation in interventional studies

formula. Inaccurate as they may be, they come naturally to most of us, and are trusted by most others. They would help reduce the dignity harm we cause. To insist to run against the current, reject such beliefs and instead deliberate, either openly or secretly, as a cold calculator about the pros and cons of coercing interventions in particular cases would exacerbate overall dignity harm. It could offend, humiliate, exclude, and stigmatize on many everyday occasions. A type of second-order moral consideration therefore tells doctors to maintain and cultivate belief in CR and in its alleged foundation in autonomy and dignity.

If coercion did not typically cause more harm than good in medical and other first-order terms (pragmatic, autonomy-related, dignitary, and other), then perhaps this concern about dignitary harm would rarely suffice to justify cultivating that deep belief in CR. After all, dignitary harm is merely one type of evil and, as Wertheimer notices, CR comes at a substantial moral cost. However, Wertheimer points out first-order considerations that already make coercive medical interventions typically wrong. What dignitary harm does is to explain, better than Wertheimer has thus far, why commonsense tells us to oppose coercion in many more cases, and rather homogenously. Once we cultivate the deep beliefs about autonomy, dignity, etc. that are necessary for curbing dignitary harm, these deep beliefs prompt us to follow a fairly homogenous CR somewhat regardless of changes in non-omniscience-related risk on particular occasions, out of these deep beliefs and not only out of cold concern for minimizing medical error and the like.

This account is ‘second-order’ in factoring in beliefs about first-order factors and about their relative importance. It also involves norms about which first-order norms to cultivate belief in, follow, and respect. What makes it second-order is these ‘meta’-beliefs. Wertheimer defines ‘second-order’ differently, tying it specifically to degrees of knowledge. But his account is second-order in my sense as well.11

HOW MY SUGGESTION HELPS EXPLAIN THE FULL PICTURE

Because my suggestion is not at all about knowledge or the risks from non-omniscience, it is unresponsive to variance in knowledge and in related risks, and to alternate ways to enhance that knowledge and to mitigate those risks. The suggestion is about something else—about the prevention of dignitary harm, regardless of the level of knowledge and related risk.

The suggestion already contains the moral phenomenology missing from Wertheimer’s account. The beliefs that it tells us to cultivate about the grounds for CR are precisely the ones that are phenomenologically appropriate.

The suggested missing component of the full account remains fairly constant between clinical and investigational interventions. While typically, more is needed by way of informed consent in investigational interventions, that may stem from the components charted by Wertheimer—which remain important parts of the full picture. My suggestion helps explain why either domain requires more by way of consent than many non-medical domains do.

11 Wertheimer’s own ‘political dimension to second-order morality’ (Id. at 180) seems to use ‘second-order morality’ without focus on the deciding agent’s omniscience, and potentially in my sense: surely democratic legitimacy can matter even when executives know that they are right.
Doesn’t the addition of a uniform layer of concern about dignitary harm across medical areas generate the unsavory implication that a strong CR is needed in the bulk of observational studies as well—an implication that Wertheimer’s account elegantly resists? I believe it does not. What tends to be broadly associated with gross violation of the person’s autonomy and dignity is actual non-consensual invasion of her body and modification of her health state, far more than non-consensual use of anonymized information about her. Dogmatic libertarians aside, most people just don’t perceive anonymized data as ‘ourselves’ in the way that we often conceive of our bodies. Observation studies that transgress some consent requirements but otherwise remain safe and unproblematic are rarely perceived as gross violations of the person. Their dignitary harm tends to remain small. Ethically, researchers can afford to forego the self-engineering delineated above for most kinds of observational studies.

CONCLUSION
Alan Wertheimer has given us a fruitful new way to think about CR to intervention research. I believe that a further layer of justification, which is ‘second-order’ in a different sense than his, remains necessary. Fortunately that further necessary justification dovetails nicely with Wertheimer’s. Both are logically compatible and my suggestion allows (and I believe) that Wertheimer’s suggestion captures most of the truth. While my suggestion is not ‘second-order’ in the sense stipulated by Wertheimer because it does not rest on non-omniscience, both my suggestion and Wertheimer’s are ‘second-order’ in containing an ‘about’ or a ‘meta-’ element.