Addressing diversion effects

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ABSTRACT

Alan Wertheimer argues that those who promulgate principles of research ethics have a responsibility to take into account the diversion effects of those principles. In this commentary, I argue that Wertheimer’s proposal that diversion effects should be considered when promulgating principles of research ethics makes sense, but it often may be best to deal with these effects once a principle has been accepted and implemented, rather than focusing on them at the outset.

KEYWORDS: research ethics, principles, diversion effects

In a thought-provoking article published in a recent issue of the Journal of Law and the Biosciences, Alan Wertheimer argues that those who promulgate principles of research ethics have a responsibility to take into account the diversion effects of those principles.1 Diversion effects may occur when acceptance of a principle of research ethics encourages sponsors or investigators to refrain from conducting some types of research or to conduct research in another locale where the principle has less influence. Though he is careful to avoid claiming that adverse diversion effects are a reason for rejecting or modifying any of the principles he discusses, his view implies that one could cite potential adverse diversion effects as a reason for critiquing a principle.

Wertheimer considers four examples of principles of research ethics that he claims have possible diversion effects. The first is the idea that research conducted in low- and middle-income countries (LMICs) should be responsive to the needs of the host country. The second is the requirement that subjects in the control arm of a clinical trial receive the local standard of care unless there is no proven effective therapy for the disease or condition. The third is the obligation to provide research subjects with access to treatments shown to be effective in a clinical trial after the trials ends. The fourth is the duty to provide medical treatment to human subjects beyond what they would receive as part of a research protocol, ie ancillary care. He argues that adopting these


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principles could encourage sponsors to avoid conducting research or to conduct research in locales where the principles do not have a significant impact.

Wertheimer also discusses some instances in which well-intended public policies have had adverse diversion effects. The most germane for our purposes is India’s experimentation with a policy to compensate human subjects for research-related injuries. The policy required sponsors to provide subjects with free treatment for any health problem arising in research, regardless of whether it was caused by the research procedures or due to the subject’s underlying medical condition. Because the policy imposed substantial financial burdens on research sponsors, many of them, including the National Institutes of Health, started to pull clinical trials out of India. The policy was later revised to minimize adverse diversion effects.

I am sympathetic to Wertheimer’s position since I think it is incumbent upon those who defend principles with practical implications to attend to the consequences of accepting (and implementing) those principles. Those consequences might include implications for those who are directly impacted by the principle, such as research participants, sponsors, institutions, and investigators, as well as those who are indirectly impacted, such as other members of society. One of the truisms of public policy is that statutes and regulations often have unintended consequences that should be addressed. Though ethical principles are not laws, Wertheimer makes the salient point that they can have the force of laws if they are accepted as a guide to conduct.

My quarrel is, therefore, not with Wertheimer’s general idea but with its application. It can be difficult to determine the diversion effects of a principle, since many variables may come into play, such as the motivations, interests, and resources of the different parties affected by a principle; economic, political, and social conditions in the areas affected by the principle; the likelihood that the principle will be widely accepted and followed; and how the principle will be implemented in different locales if it is accepted. Alleged diversion effects may be speculative concerns that are unlikely to come to fruition. For example, the evidence does not show that sponsors have diverted clinical trials from LMICs to avoid paying for ancillary care in clinical research.

Paying too much attention to potential diversion effects when promulgating ethical principles for research can also lead to gamesmanship if parties impacted by the principle learn that diversion effects are a significant concern and they make idle threats in order to defeat the principle. For example, suppose that sponsors threatened to stop supporting some types of research in response to the possible acceptance of an ethical principle, such as the requirement that research be responsive to the needs of the host LMIC. If these threats were taken as a reason not to adopt the principle, they could interfere with the development of ethical policies, even if the sponsors have no intention of carrying out those threats.

If it is difficult to determine the diversion effects of an ethical principle, the best way of addressing these effects may be to deal with them after the principle has been accepted for a period of time. Waiting to address diversion effects at some later time

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3 Wertheimer, supra note 1, at 1–5.
4 Robert Merton, The Unanticipated Consequences of Purposive Social Action, 1 Am. Soc. Rev. 894 (1936).
5 Bridgett Pratt et al., Ancillary Care: From Theory to Practice in International Clinical Research, 6 Pub. Health Ethics 154 (2013).
Addressing diversion effects instead of dealing with them upfront would provide researchers, ethicists, and policymakers with the opportunity to obtain evidence concerning diversion effects. If the principle has adverse diversion effects that should be avoided, then the principle can be modified or even rejected once these effects are better understood. This way of responding to diversion effects would be similar to a Sunset Clause that is often included in legislation. A Sunset Clause is a provision in legislation which states that the law will cease to have effect beyond a specific date unless it is reapproved. The main purpose of a Sunset Clause is to allow policymakers to study the effects of the law, so that it can be adjusted or allowed to expire if necessary.6

Although ethical principles, guidelines, and codes do not come with Sunset Clauses, they can be revised if adjustments are necessary to account for changes in the research environment or technology, or new and emerging ethical and social concerns. For example, the World Medical Association has revised its Helsinki Declaration nine times since first adopting these ethical principles for medical research in 1964.7 The American Medical Association also periodically revises its Code of Ethics, including sections that deal with research ethics.8 Additionally, scientists, ethicists, and policy analysts can develop and revise ethical principles in light of new arguments and evidence pertaining to research involving human subjects. For example, numerous writers have proposed revisions to the principle of clinical equipoise since it was first articulated in the 1970s.9

Thus, Wertheimer’s proposal that diversion effects should be considered when promulgating principles of research ethics makes sense, but it often may be best to deal with these effects once a principle has been accepted and implemented, rather than focusing on them at the outset.

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9 Rieke van der Graaf & Johannes van Delden, Equipoise Should be Amended, not Abandoned, 8 CLIN. TRIALS 408 (2011).