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Evidence-Based Research Ethics

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It is not remarkable to call for an evidence-based approach to ethics. What is remarkable is that there should be a debate in academia about whether or not to take a scholarly, evidence-based approach to ethics. While there is much reason to be skeptical of relying solely on well-controlled research studies, that does not mean that we should abandon such studies. A case in point is our attempts to provide education in research ethics.

Kon (2009) has proposed dividing empirical bioethics research into four categories, subsequently re-named by Wynia (2009): 1) *Descriptive* (assessing the *is*); 2) *Comparative* (comparing the *is* to the *ought*); 3) *Intervention* (testing approaches to reconcile *is* and *ought*); and then when appropriate reconsidering our principles and finding a new 4) *Consensus* (analysis of multiple lines of evidence). Sugarman and colleagues (2009) note that “this attempt is not the first to categorize this [the bioethics] growing literature” (66). While true, it is also fair to note that the arguments raised by Sugarman and colleagues as well as those raised in this essay, are also not new. The arguments in all cases, however, highlight a continuing tension between theory and data, and in how we choose to define our words.

The discussion of evidence-based or empirical ethics is a recent extension of an earlier move toward evidence-based medicine (Evidence-Based Medicine Workgroup 1992). In the first description of evidence-based medicine, a summary of the assumptions underlying this “new paradigm” concluded with the seemingly non-controversial statement that: “… physicians whose practice is based on an understanding of the underlying evidence will provide superior patient care” (2421). In the intervening years, we have heard arguments that this is what physicians were already doing as well as arguments that this is a dramatic and unwelcome change to the appropriate practice of medicine. Parallel arguments have been made against evidence-based ethics.

At the core of these arguments is a tension between “philosophical scholarship and empirical research” (Sugarman et al. 2009, 66). This parallels a longstanding rivalry in physics (theory versus experiment) and is currently debated in both medicine and ethics. A case is often made that these two qualities of inquiry should be kept separate: “… empirical inquiry and philosophical inquiry have very different primary goals, which affects both the types of questions they ask and the types of answers they are likely to find useful” (Wynia 2009, 68).

Despite the continuing debate, it is reasonable to ask, independent of the definitions, should decision-making be limited to ‘scientific evidence’ or is there reason to count knowledge gained in other ways. The argument against a broader view is straightforward. Once the door is opened to personal experience, biases, values, and principles, then we may choose to act based on false assumptions or beliefs. Because we wish something to be true, does not necessarily make it true. Because we have seen a desirable outcome once or even a dozen

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times does not mean that the outcome was necessarily caused by some coincident event. Therefore if our goal is to know how something works, or to know what is truly effective, then we need rigorous, scientific experimentation to objectively test our hypotheses.

Unfortunately, although we would like to view experiments as a definitive source of answers, they are, as noted by Carter (2009), sources of information contingent on numerous factors (e.g., theories, values, assumptions). Experiments provide a particular answer that is imperfect in its construction and, because the answer is for a population, uncertain in applicability to the individual. Given these limitations, it would be worrisome to make binding decisions based solely on experimental findings. However, in the case of evidence-based medicine, this was not intended to be the case. As clarified by some of its original proponents (Sackett et al. 1996):

> Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice.

The worry for many is that while this may work for medicine, relying on empirical research in ethics risks replacing *ought* with *is*. Clearly this is unacceptable. The majority has often chosen practices, such as slavery, that would violate highly defensible ethical principles. However, the question is not whether we should change our principles because of evidence that the majority believes differently. The question instead is whether we might need to change our approach to achieving particular goals in light of information about prevailing standards, limitations, challenges, for example. The practice of evidence-based ethics should be something more than just relying on well-controlled experimental studies. There is room for qualitative data from descriptive studies as well as information that may be based on individual experience or the specific circumstances of a particular case.

The point of *evidence-based* is not that the *evidence* is sufficient guidance for all of our actions. The point is that we should seek to accumulate that evidence to help better inform our decisions. This approach is neither radical nor unworkable. As noted by both Carter (2009) and Sugarman et al. (2009), empiricism is intertwined with the theoretical.

In the face of the increasing attention to evidence-based or empirical ethics, it is appropriate to ask whether anything is to be gained by defining *evidence-based research ethics*. The attempt may seem premature given that the definition of evidence-based medicine remains controversial, much less the definition of evidence-based ethics. Nonetheless, exploring possible definitions may help to differentiate those areas that require more attention from those that are on firmer ground.

Research ethics has been variously defined, but for the purpose of this discussion:

> Research Ethics is defined here to be the ethics of the planning, conduct, and reporting of research … The domain of research ethics is intended to include nothing less than the fostering of research that protects the interests of the public, the subjects of research, and the researchers themselves (Kalichman 2009).

This definition is not limited to human subjects or biomedical research, and need not be limited to the experimental or natural sciences. The domain is all kinds of inquiry resulting in new knowledge.

Therefore, paraphrasing Sackett and colleagues (1996), a reasonable definition of evidence-based research ethics would be:

> Evidence based research ethics is the conscientious, explicit, and judicious use of current best evidence in making decisions about the conduct of research. The practice of evidence based research ethics means integrating individual expertise with the best available external evidence from systematic research (71).

And, paraphrasing Sugarman and colleagues (2001), in practice research on research ethics includes, but is not limited to: “the application of research methods in the social sciences (such as anthropology, epidemiology, psychology, and sociology) to the *direct* examination of issues in *research* ethics”.

Assuming that the object of promoting ethics in research is to foster ethical action by researchers, then one dimension of research ethics is the teaching of the next generation of scientists. Admittedly, there is a risk here of confusing the research designed to support or inform ethics with ethics per se (Sugarman et al. 2009). However, although not directly ethics itself, research ethics education is an example of the tension between theory and evidence.

This year marks the 20th anniversary of the first implementation of an National Institutes of Health (NIH) requirement that trainees funded by training grants should receive instruction in the responsible conduct of research (RCR) (NIH 1989). Whether the purpose of that requirement was to decrease research misconduct or to more generally improve the socialization of the next generation of scientists, it probably seemed a simple enough expectation. Unfortunately, it is hard to judge how well that expectation has been met because the goals of this training remain neither clear nor consistent (Kalichman and Plemmons 2007), there is little evidence for what is being taught or how, the few attempts to assess effectiveness have shown little or no positive benefit (e.g., Heitman et al. 2001; Powell et al. 2007), and there are worrisome signs that commitments written into grant applications to provide such training are often not carried out (Kalichman and Plemmons 2007).

Using Kon’s (2009) framework, it is readily apparent that many key questions about research ethics education remain unanswered and to some extent unaddressed (Table 1). Finding answers to these questions should be a high priority for anyone wishing to promote education in research ethics. In the face of new National Science Foundation requirements (America COMPETES Act 2007) to teach responsible conduct of research, studies to answer these questions are needed now.

Although preferable to have clearly defined words to describe what we do and why we are doing it, this discussion is a reminder that we still have work to do. In the meantime, the lack of consensus about definitions should not be allowed to detract from the underlying conclusion that we need both theory and evidence.

References

America COMPETES Act. [accessed April 10, 2009] Section 7009. Responsible Conduct of Research. The America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act (COMPETES) HR 2272. 2007. Available at: http://democrats.science.house.gov/Media/File/Commdocs/hr2272_conference_report.pdf

Carter SM. Beware dichotomies and grand abstractions: Attending to particularity and practice in empirical bioethics. American Journal of Bioethics. 2009; 9(6–7):76–77. [PubMed: 19998127]

Evidence-Based Medicine Working Group. Evidence-based medicine: A new approach to teaching the practice of medicine. Journal of the American Medical Association. 1992; 268:2420–2425. [PubMed: 1404801]

Heitman, E.; Salis, P.; Bulger, R. Teaching ethics in biomedical science: Effects on moral reasoning skills. In: Steneck, NA.; Sheetz, MH., editors. Proceedings of a Research Conference on Research Integrity. Washington, DC: Office of Research Integrity; 2001. p. 195-202.Available at: http://ori.hhs.gov/documents/proceedings_rri.pdf

Kalichman, M. [accessed April 10, 2009] Introduction: Resources on Research Ethics Education. 2009. Available at: http://research-ethics.net/introduction

Kalichman MW, Plemmons DK. Reported goals for responsible conduct of research courses. Academic Medicine. 2007; 82(9):846–852. [PubMed: 17726389]

Kon AA. The role of empirical research in bioethics. American Journal of Bioethics. 2009; 9(6–7):59–65. [PubMed: 19998120]

Powell S, Allison MA, Kalichman MW. Effectiveness of a short-term course in the responsible conduct of research for medical students. Science and Engineering Ethics. 2007; 13(2):249–264. [PubMed: 17717736]

National Institutes of Health (NIH). Training grant requirement. NIH Guide for Grants and Contracts. 1989; 18(45):1.

Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: What it is and what it isn't. British Medical Journal. 1996; 312:71–72. [PubMed: 8555924]

Sugarman, J.; Faden, R.; Weinstein, J. A decade of empirical research in bioethics. In: Sugarman, J.; Sulmasy, DR., editors. Methods in Medical Ethics. Washington, DC: Georgetown University Press; 2001. p. 19-28.

Sugarman J, Kass N, Faden R. Categorizing empirical research in bioethics: Why count the ways? American Journal of Bioethics. 2009; 9(6–7):66–67. [PubMed: 19998121]

Wynia M. Answering the "so what?" question for empirical research in bioethics. American Journal of Bioethics. 2009; 9(6–7):68–69. [PubMed: 19998122]

Table 1

Examples of Questions Amenable to Observational or Experimental Study to Inform the Practice of Teaching Research Ethics[1]

Descriptive	What are the goals of teaching research ethics?
	Who is the audience? And who are the teachers?
	How is it taught?
Comparative	Are the goals being met?
Intervention	Which approaches work best?
Consensus	Are the goals of research ethics education consistent with the evidence?

[1] Based on the framework of Kon (2009) as modified by Wynia (2009).