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What Counts as Empirical Research in Bioethics and Where Do We Find the Stuff?

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Alexander Kon's (2009) target article on empirical research in bioethics is among the most sensible published on the subject matter. However, a deep irony goes unnoticed in his article: the more useful and profound an original empirical study is for bioethics, the less identifiable it is as an empirical research study in bioethics. Consider the following two publications.

First, Khan and colleagues (2000) reviewed data from 45 studies in the United States Food and Drug Administration database that tested the safety and efficacy of antidepressants. These studies involved a total of 19,639 participants. They found no statistically significant differences in rates of suicide and attempted suicide among groups of individuals assigned to receive an investigational antidepressant, an active control, and placebo. However, rates of suicide and attempted suicide were noticeably lower in the placebo groups. They concluded that the "assumption that depressed patients who are assigned to placebo in antidepressant clinical trials are exposed to substantial morbidity and mortality is not based on research data" (Khan et al. 2000, 311). The lead author of this study was a psychiatrist and the article appeared in the *American Journal of Psychiatry*. The article was subsequently used by ethicists in considering the ethics of placebo-controls in clinical trials of antidepressants (DuBois, 2008).

Second, Finucane, Christmas, and Travis (1999) reviewed data in Medline from 1966 to 1999 to evaluate the outcomes of tube feeding with patients with advanced dementia. They found no data suggesting that tube feeding can prevent aspiration pneumonia, prolong survival, improve function, or provide palliation; in short, tube feeding provided none of the ordinarily intended benefits within the population of patients with advanced dementia. They concluded that the "widespread practice of tube feeding should be carefully reconsidered, and ... for severely demented patients the practice should be discouraged on clinical grounds" (Finucane 1999, 1365). The article was published by geriatric physicians in *JAMA*. It has been subsequently cited by ethicists as they try to determine how best to apply often complex ethical norms surrounding tube feeding to specific populations (Gummere 2008; Post 2001).

Both of these articles contribute fundamentally to our understanding of how best to treat certain groups of human participants in research or patients. In other words, both articles contributed to the highest aims of empirical research in bioethics that Kon (2009) identified: *improving*

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care and *changing ethical norms* (not general principles, but specific norms of practice). However—and this is what concerns us at present—neither article:

1. was published by a “professional ethicist”;
2. was published in an ethics journal;
3. contained an explicit discussion of the relevant ethical debates; or
4. contained the term *ethics* as a keyword

DuBois and colleagues (2008) demonstrated that this phenomenon is common. We reviewed all articles published in three health journals—*AIDS*, *American Journal of Psychiatry*, and *Pediatrics*—across a 2-year period to determine how many articles provided data directly relevant to one of the seven requirements for ethical research identified by Emanuel and colleagues (2000). We found 26 such articles, which constituted 2.2% of the research articles published in those journals during the 2-year period. Of the 26 articles, less than 50% contained a discussion of the ethical implications of their findings and only seven contained keywords clearly related to research ethics. If our mean number of articles per journal per year (4.33) were extrapolated to the top 100 of the approximately 5,000 journals indexed in Medline, then at least 433 such “hidden ethics” articles would be published each year in the top health journals alone.

All of this raises at least 3 key questions. First, what exactly is empirical research in bioethics? Second, how should we address the fact that much of the best empirical research remains hidden from the view of bioethicists? Third, what role should ethicists play in the development or use of empirical research data?

WHAT COUNTS AS EMPIRICAL RESEARCH IN BIOETHICS?

It is impossible to state what should count as empirical research in bioethics without first answering the question, *What is ethics?* One controversial answer is: Human ethics—ethics as an endeavor concerned with how humans should treat each other—has to do with how we best respect each other. Each of the traditional principles of biomedical ethics has something to do with a core dimension of human beings. Autonomy concerns respect for humans insofar as they are rational and self-determining; beneficence concerns respect for humans insofar as they are finite and in need of basic goods; nonmaleficence concerns respect for humans insofar as they are vulnerable to many harms; justice concerns respect for humans insofar as they are all of equal worth; and relationality or the principle of the common good concerns respect for human beings insofar as they are essentially part of a community of human beings (DuBois 2008).

If that is the case, then empirical research in bioethics is research that is *relevant to determining* what constitutes respectful treatment of humans through the lens of various principles.¹ While others may want to embrace a different definition, one aspect of the definition ought to remain constant: empirical research in bioethics is research that is *relevant to determining* what is right or wrong, good or bad, respectful or disrespectful, caring or non-caring, or virtuous or vicious, within a bioethical debate. Thus, it might be best to speak of *ethically relevant* empirical data. In any case, empirical data in bioethics are not data that determine what is right or wrong, but rather are relevant to such determinations.

¹One could also develop an ontology and principles to address ethics as a cross-species enterprise, one that addresses our relationship to all living creatures—though presumably the ethical principles would differ (e.g., autonomy might make less sense when applied to vegetative life).

Kon (2009) successfully avoids the implication that empirical research determines what is ethical by referring to “empirical research *in* bioethics” (59). However, in using his term we must bear in mind the need to go out and find the relevant data—for many of the best studies exist outside the boundaries of bioethics.

HOW SHOULD BIOETHICISTS ACCESS ETHICALLY RELEVANT DATA?

As noted previously, ethically relevant data are ubiquitous, yet ironically they are sometimes difficult for ethicists to find because they are often published in non-ethics journals, by professionals who do not identify as ethicists, without the use of ethics keywords. This problem should be addressed in several ways. First, we should encourage researchers in other fields, editors, and database indexers to add ethics-related keywords whenever data are highly relevant to an ethical debate. Second, ethicists and institutional review board members should be trained to search for relevant data using non-ethics terms. Third, the prevalence of ethically-relevant data in health journals reinforces the need for ethics committees and institutional review boards to be composed of a diverse cross-section of health professionals who are familiar with literature in their disciplines and specialties.

EMPIRICAL RESEARCH IN BIOETHICS: WHAT IS THE ROLE OF THE BIOETHICIST?

Empirical research is arguably relevant to the work of all bioethicists. Nevertheless, while some bioethicists today have excellent empirical research skills, most lack the knowledge of research methods and statistics needed to gather original empirical data relevant to bioethical questions. However, what Kon (2009) describes as the highest use of empirical research in bioethics may well be within the scope of competency of most bioethicists who are at least trained to *read* empirical literature. He writes that so-called *Changing Ethical Norms* publications “use the data obtained in previous projects to form the basis of a bioethical argument to change an ethical norm” as illustrated by the evolving norms surrounding medical decision-making (59). Working in concert with researchers and health care practitioners, bioethicists may use empirical data to generate “evidence-based” recommendations about how ethical principles should be realized in specific settings.

Just who—if anyone —should count as a bioethicist is a question best left for another day.

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