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The Biomedical Ethics Ontology Proposal: Excellent Aims, Questionable Methods

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Abstract

Koepsell et al. (2009) Describe an ideal biomedical ethics committee environment with efficiencies such as electronic and universal application forms and consent templates, automated decision-trees, and broad sharing of data. However, it is unclear that a biomedical ethics ontology (BMEO) is necessary or even helpful in establishing such environment. Two features of any applied ontology are particularly problematic in establishing a useful BMEO: (1) an ontology is a description of a domain of reality; and (2) the description is subject to ongoing revision as it is developed through open processes, e.g., the use of a wiki. A BMEO would need to address two main kinds of entities, regulatory definitions and ethical concepts, and is ill-suited to both. Regulatory definitions are fiats and ought to be adopted verbatim to ensure compliance, but in such cases we do not need the assistance of ontologists, and their modes of working (constant revision within open wiki-based communities) might even be counterproductive. Ethical concepts within pluralistic societies are social constructs, not *a priori* concepts or biological natural kinds, and the prospects of generating intuitive definitions that enjoy broad acceptance across cultures and institutional settings are slim. In making these arguments, I draw from the writings of leading applied ontologists and Koepsell et al.'s own proof of concept.

Keywords

ontology; biomedical ethics ontology

Koepsell et al. (2009) Describe a world much better than ours, a world with electronic and universal IRB application forms and consent templates, automated decision-trees, and broad sharing of IRB data. We should work to make that world a reality. However, it is unclear that a biomedical ethics ontology (BMEO) is the best path toward this goal for reasons that applied ontologists have identified elsewhere.

I will focus on only two features of any applied ontology that are problematic for the development of a useful BMEO: (1) an ontology is a description of a domain of reality; and (2) the description is subject to ongoing revision as it is developed through open- source processes within a wiki community. To summarize, I argue that a BMEO needs to address two kinds of entities—ethical concepts and regulatory definitions—and it is ill suited to both. *Ethical concepts* within pluralistic societies are social constructs—not *a priori* concepts or biological natural kinds—and accordingly the prospects of generating intuitive (and thus easy-to-use) definitions that enjoy broad acceptance across cultures and institutional settings are slim. *Regulatory definitions* are fiats and ought to be adopted verbatim to enable compliance, but in such cases we do not need the assistance of ontologists, and their modes of working

(constant revision within open wiki-based communities) might even be counterproductive. In making these arguments, I draw from writings of leading applied ontologists and Koepsell et al.'s own proof of concept.

Can Ontologies Be Developed for Ethical Concepts that Are Not Universal?

The Austrian philosophers and early phenomenologists who developed ontology as a field assumed—as did Aristotle and many others before them—that there are different kinds of entities and that the differences between them matter greatly (Burkhardt & Smith, 1991; Smith, 1994). Consider just three kinds of entities: a square, a gene, and a research protocol. Early ontologists tended to focus on entities like squares, numbers, logical propositions, and other objects that they considered to be *a priori* in the following sense: their structure appears to be necessary, timeless, and intelligible (DuBois, 1995). Even when they engaged contingent, mundane objects such as works of art, they focused upon the necessary and universal elements—e.g., the relationship between minds, works of art, and the constitution of an aesthetic object (Ingarden, 1974). The recent work of applied ontologists (Smith et al., 2007) is highly creative because it extends ontological categorization to a whole new category of entities—entities Aristotle called “natural kinds”: these are universals that occur in nature, which may be intelligible and governed by laws, but can be known only through the methods of the natural sciences. Developing ontologies is possible because their universal nature is *discovered*—even if only slowly and imperfectly. Although our descriptions may be imperfect, we have methods of resolving disputes about competing descriptions, e.g., by examining their predictive value, parsimony, and consistency with well-accepted data. This is why an open-source approach works well: concepts become more adequate through an ongoing revision process using broadly accepted scientific standards.

The question we have to ask is whether the biomedical ethics “things” that ontologists now want to categorize are sufficiently like squares or even genes to make the project feasible. Do we discover a law-governed and intelligible nature of a Research Ethics Committee (REC) protocol? Is there some object in the world—like a gene—that we can appeal to when research ethicists disagree whether a descriptive inequity (e.g., a disproportionate percentage of minority members in a study) is an *injustice*? If not, we should not attempt to develop a standard ontology, especially given the risk that regulators could impose such definitions upon the entire research community.

In this regard, it is worth observing that the assumption that a BMEO will require little training to use and will improve the consistency of ethical reviews rests upon the assumption that BMEO's definitions will be intuitive to users or even familiar. When these assumptions are violated, the empirical results of ontology development may be poor (Smith, 2006).

The fact that some terms do not refer to invariant, universal features of the world and that this poses a serious problem for applied ontology is already recognized from previous collaborative endeavors. Bodenreider, Smith, and Burgun (2004) observe that:

Some names represent invariant features (classes, universals) of biomedical reality (i.e., they are a matter for ontology). Other names, however, convey also how this reality is perceived, measured, and understood by health professionals (i.e., they belong to the domain of epistemology)... We show that epistemology-loaded terms are pervasive in biomedical vocabularies, that the “classes” they name often do not comply with sound classification principles, and that they are therefore likely to cause problems in the evolution and alignment of terminologies and associated ontologies. (p. 185)

Whether we view certain terms (e.g., “justice in recruitment”) as referring to how a reality is perceived and understood by biomedical ethicists or as referring to socially constituted and highly variable constructs is not terribly important; what matters is that certain key ethical terms do not correspond to universal and invariant features of reality.

Regulatory Definitions and the Open-Source Development Method

What has been said so far pertains to ethical concepts that may be interpreted in widely variant manners, taking the example of “justice in recruitment” as a paradigm. This concept has been interpreted differently since the time of the Belmont report (Beauchamp & Childress, 1983; Engelhardt, 1996) and even its practical demands have evolved over the past two decades such that it is difficult to judge when an inequity in recruitment constitutes an injustice (King, 2005). One solution to this problem might be to focus upon regulatory definitions rather than ethical concepts. This seems compatible with advice that Smith (2006) offered in the course of troubleshooting a problematic applied ontology. He recommended re-using available sources when possible or staying “as close as possible to the terms already used by your intended audience and to their already established meanings” (p. 18).

To the extent that regulations provide definitions, it clearly makes sense to re-use them. In fact, given that research ethics committee review requires one to comply with regulations, it hardly seems optional.

However, we see here too that the open-source, wiki-based approach to ontology development is problematic. First, it is unnecessary—the relevant definitions are already on the shelf. Second, and more importantly, regulatory definitions cannot be changed by an open group of wiki-users. Yet this violates one of the fundamental tenets and quality-control mechanisms of ontology development (Smith, 2006). The fact that we can address this problem by simply denying users the ability to edit regulatory definitions just reinforces the point that assistance from applied ontologists is not needed in defining concepts that appear in regulations.

The Proof of Concept

For better or for worse, like many research ethics committee members, I sometimes imagine risks to a project that have little foundation in reality. I would like to think my worries about the BMEO are a case in point. However, the appendix to Koepsell et al.’s paper is meant to serve as a proof of concept and rather it illustrates some of the problems mentioned above.

First, it stays largely in safe territory offering definitions of entities and relationships that are uncontroversial because they are uninformative: “protocol document *is_a* document” or “clinical trial review *is_a* review.” Of course, computer programming requires some such definitions, but these definitions also fail to demonstrate the unique value that a BMEO would bring to an electronic uniform document system.

Second, the BMEO proof of concept does in fact simply adopt some regulatory definitions. The concept of “minimal risk,” which is riddled with trouble and proves the challenges of establishing “inter-rater reliability” (Shah et al., 2004) is adopted from the regulations without modification: “a minimal risk is a risk whereby the probability and magnitude of harm or discomfort anticipated in the research *are not* greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” While this is probably the right thing to do, it also fails to show why a BMEO is needed; such definitions must be set outside the boundaries of an open-source process because an open wiki-community lacks the authority to change regulatory definitions.

Third, some of the definitions or relationships that are informative are also controversial and can be used to illustrate the real problems that research ethics committees face: “a risk is a disposition that *inheres in* a subject whereby the subject is susceptible to physical or mental harm.” This seems like a better definition of “vulnerability” in the ordinary English sense. In a research setting “risks” involve not merely the subject but most especially something *posed by the study*—a probability of specific harms caused by the study intervention, not inherent in the subject. Moreover, even after this definition is fixed through open wiki-based processes, it will remain difficult to use. This is because current problems with risk assessment are not due to the definition alone. They are due to the facts that (1) we have imperfect knowledge of probabilities and magnitudes of harm (which is precisely why we conduct clinical trials) and (2) we lack a uniform set of values to guide judgments regarding when, e.g., a one-in-a-million chance of causing a serious harm is significant enough to mention in a consent form. Similarly, the authors define “justice” as “an ethical duty that entails treating persons with fairness relative to their situation in life including meting out goods, services, and the like, according to need, or contribution, or merit.” Even after this definition is refined to apply specifically to the research setting, we will find that our real problems pertain to the application of the definition. *Does justice require excluding vulnerable people from a study or rather ensuring access to research that could benefit them or their respective communities? When does a mere inequity amount to an injustice?* It is not clear that an applied ontology can solve these problems because they are not problems of definitions or ontologies, they are problems of ethics or practical reasoning.

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References

- Beauchamp, TL.; Childress, JF. Principles of biomedical ethics. 2. New York: Oxford University Press; 1983.
- Bodenreider, O.; Smith, B.; Burgun, A. The ontology-epistemology divide: A case study in medical terminology. In: Varzi, A.; Vieu, L., editors. Proceedings of FOIS 2004; International Conference on Formal Ontology and Information Systems; Turin: Amsterdam: IOS Press; 2004. p. 185-198.
- Burkhardt, H.; Smith, B., editors. Handbook of metaphysics and ontology. Munich: Philosophia Verlag; 1991.
- DuBois, JM. Judgment and Sachverhalt: An introduction to Adolf Reinach’s phenomenological realism. Dordrecht: Kluwer; 1995.
- Engelhardt, HT. The foundations of bioethics. 2. New York: Oxford University Press; 1996.
- Ingarden, R. The literary work of art. In: Grabowicz, G., translator. An investigation on the borderlines of ontology, logic, and literary theory. Evanston: Northwestern University Press; 1974.
- King, PA. Justice beyond Belmont. In: Childress, JF.; Meslin, EM.; Shapiro, HT., editors. Belmont revisited. Ethical principles for research with human subjects. Washington, D.C.: Georgetown University Press; 2005. p. 136-147.
- Koepsell D, Arp R, Fostel J, Smith B. Creating a controlled vocabulary for the ethics of human research: Towards a biomedical ethics ontology. Journal of Empirical Research on Human Research Ethics 2009;4(1):43–58. [PubMed: 19374479]
- Shah S, Whittle A, Wilfond B, Gensler G, Wendler D. How do institutional review boards apply the federal risk and benefit standards for pediatric research? Journal of the American Medical Association 2004;291(4):476–482. [PubMed: 14747505]
- Smith, B. The legacy of Franz Brentano. Chicago: Open Court; 1994. Austrian philosophy.

- Smith, B. Against idiosyncrasy in ontology development. In: Bennett, B.; Fellbaum, C., editors. Formal ontology and information systems (FOIS 2006). Amsterdam: IOC Press; 2006. p. 15-26.
- Smith B, Ashburner M, Rosse C, Bard J, Bug W, Ceusters W, Goldberg LJ, Eibeck K, Ireland A, Mungall CJ, Leontis N, Rocca-Serra P, Ruttenberg A, Sansone S-A, Scheuermann RH, Shah N, Whetzel PL, Lewis S. the OBI Consortium. The OBO Foundry: Coordinated evolution of ontologies to support biomedical data integration. *Nature Biotechnology* 2007;25(11):1251–1255.

Biography

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