Editorial

Publication of ethically suspect research: should it occur?

In this issue of *International Journal for Quality in Health Care*, a prospective, observational study has been published that confirms frequent error in drug administration, a now well-recognized risk to patient safety [1–3]. As a peer-reviewer, I suggested rejection of this manuscript for publication on ethical grounds as it raises a series of ethical concerns including (i) lack of oversight by a Research Ethics Board (REB) or equivalent; (ii) lack of a written informed consent procedure; and (iii) the lack of intervention by the observers when potential harms to patients were identified. These concerns raise further issues. Which jurisdictional standards should apply in the assessment of research for publication? What are the consequences of rejecting a manuscript? What are the potential benefits to publishing ethically suspect work?

Research ethics oversight

Many national and international standards guide the ethical conduct of human research [4–6]. All of these statements promulgate respect for the person, with a prohibition to using participants as a means to an end, and an obligation to recognize participants’ autonomy through free and informed consent. These guidelines all require an independent assessment by a REB or equivalent (e.g. Article 13 Declaration of Helsinki) [4]. It would appear that failure to comply with ethical regulations frequently occurs because of ‘innocent’ oversight in study design by otherwise well-intentioned researchers. It is precisely for this reason that REB reviews must focus their evaluative efforts on both the science and the ethics procedures of the proposed project. It is recognized that countries may operationalize the application of the tenets of the Declaration of Helsinki to account for geopolitical and cultural context, in respecting the local needs of research participants.

This study was approved by the French National Committee on Informatics Technology and Freedom (commission nationale de l’informatique et des libertés). This committee does not appear to satisfy the requirements for a properly constituted constituted REB committee as detailed in the French Huriet-Serusclat Law (Article 1123–6) governing biomedical research. This is a serious oversight.

The Declaration of Helsinki recommends to editors that ‘Reports of experimentation not in accordance with the principles laid down in this declaration should not be accepted for publication’. However, the stringency with which these guidelines are adhered to have been shown to vary [7,8]. The International Committee of Medical Journal Editors (ICMJE) recommends research be conducted in accordance with the Helsinki Declaration, but do not then go on to explicitly ban publication if the standards have not been met. *International Journal for Quality in Health Care* requires that authors adhere to these ICMJE recommendations.

A possible explanation for the lack of research ethics oversight for this study is that it was considered by the authors to be a project of quality assurance. I believe the submission of this article for publication and its methodology places it out of the context of quality assurance [9]. A second explanation may be that this study was not strictly biomedical research. I would argue that even if not testing an intervention, the principle of respect for humans mandates oversight, especially when there is risk involved, as in this study.

Lack of written informed consent

The authors state that the nurses observed in this study were informed of the objectives of the research. However, no written informed consent procedure was described despite potential serious risks to these nurses. Individuals could have been identified to have a high personal frequency of error or a nursing practice that was suboptimal. These observations may have resulted in legal liability, institutional sanctions or both.

Ethical guideline of the Council of Europe and Council for International Organizations of Medical Sciences (CIOMS) [6,10] allow for a waiver of consent in some circumstances. However, there were no obvious impediments to informed consent, the study involved more than minimal risk, and there were potential adverse effects on the subject’s rights and welfare in this study. I believe, therefore, that a waiver of consent cannot be invoked for this research study.

Lack of intervention by observers

The study design explicitly stated to be a real-time, ‘undisguised direct observation…to detect drug administration errors.’ Observers were fifth-year pharmacy students who were trained and assessed by a pharmacy student and a senior pharmacist. Observers were instructed to intervene *only* if they detected a potentially life-threatening error. This methodology fails to acknowledge a responsibility on behalf of the observers to prevent recognized errors that might cause harm of any degree to patients. The lack of intervention for these errors (some requiring major treatment modification, additional investigations or monitoring) would seem the most reprehensible component of the study.

Although the observers were students, they had advanced training and are in a profession that carries an obligation to avoid harm. The pharmacist who trained them should have,
by extension of his or her professional responsibilities, provided a study design that would protect patients. The value of an uninterrupted observation should not have superceded the individual right of patients to protection from harms. From the point of view of a patient who was the unwitting recipient of the errors, one would anticipate a perspective of a major violation of trust.

What are the consequences of rejecting a manuscript? What are the potential benefits to publishing ethically suspect work?

The withholding of publication of unethical research provides a significant deterrent by potentially impacting directly upon the researcher’s opportunity for academic advancement. A uniform ban on publication of research that does not meet ethical standards sends a strong message [11]. However, many research policy breaches are likely unintentional. It becomes, therefore, a question of what ought the researchers to have done and what ought they to have known about their individual responsibilities.

Others have argued that ethically suspect research, with potentially valuable and unique contributions (a criterion that I do not believe this research has achieved), should be published with an accompanying editorial [12,13]. This allows for the use of data, which in itself is not intrinsically immoral [14]. There are clearly potential harms to rejecting publication. Withholding publication hides the fact that unethical research is being conducted and potentially stifles the debate around emerging ethical issues. The study may need to be repeated, thereby exposing participants to the risks of (re)acquiring the data and the funding public to additional costs.

Which jurisdictional standards should apply in the assessment of research for publication?

This review brings up the interesting observation that the research was conducted in France, provided to an editor based in Switzerland, and a publisher based in the United Kingdom, with a reviewer recruited from Canada. Each country could reasonably be expected to have different national guidelines and contextual circumstances with respect to research ethics procedures. As context is critical to respecting the person, it would seem appropriate that guidelines in the country in which the research was conducted be the main arbiter for decisions. However, given the increasingly international nature of research collaboration, it will be very important to widely recognize and respect international standards of human research conduct.

In the end, the journal editor has decided to accept publication of this manuscript despite its ethical flaws. There is no evidence that these flaws were mal-intentioned. I would urge future authors to avoid the pitfalls described above, many of which would have been preempted by a thorough review by an REB committee constituted to uphold the tenets of the Declaration of Helsinki.

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References