Editorial

The real ethical problem

In this issue, we publish a study of medication errors [1] and an accompanying editorial [2] that raises several ethical concerns about the study and also about the decision to publish the article. As the editor, I wish to explain my position.

When do we need ethical oversight?

I have argued previously that we need more ethical oversight of quality improvement projects, whether they are called research or not [3]. However, many research ethics committees will refuse to assess a project that serves primarily quality assurance purposes. Thus, the same data collection exercise will bypass ethical review if it is aimed at local decision-makers, but would have to be reviewed if the intent is to write up the results for a scientific journal. Worse: if you collect data on quality without having obtained research ethics clearance beforehand, you will be charged with unethical behaviour if you try and publish the findings, but all will be fine if you file the report in a drawer. This makes no sense—either the project put the patient at risk, in which case ethical overview was needed, or it did not. Current practice, by focussing on whether or not a project can be called research, rather than focussing on the patients' welfare, misses the point entirely.

Is individual informed consent always necessary?

'Informed consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research' [4]. This principle works well when the object of inquiry is the individual, as in much biomedical research. However, in quality-related research, as in health services research in general, the object of inquiry is often a complex system. Observation of the system requires observation of all involved. If enough individuals opt out, either this will change the way the system operates, or the system will not be described properly. For system-oriented research, procedures for informed consent must be developed that both protect the individuals involved and allow the study of complex systems to proceed. Individual informed consent is mandatory when study procedures impose substantial added risk on the participants, but this was not the case of the study by Prot [1].

Can observation be ethical?

If anyone, researcher or bystander or colleague, notes something that endangers a fellow human being, they have an obligation to intervene—that is a basic rule of rescue. This I believe was done during the study [1]. On the other hand, I am not convinced that when the object of inquiry is medical error, the researcher must act in real time to correct any error that is noted. The researcher may not realize immediately that an error has occurred—for this a comparison with reference documents such as the medical prescription or the patient's chart is needed. Furthermore, if the researcher intervenes repeatedly, he will alter the behaviour of the health care workers and invalidate the purpose of the observational study. In general, it is prudent to separate the roles of health care provider and of researcher.

The main ethical problem

The thoughtful ethical concerns raised by the editorialist should stimulate a much needed discussion of ethical oversight in quality improvement. But let us not forget the ethics of *not* dealing with quality improvement. In my view, the main ethical problem related to this discussion is not that a limited number of errors was studied at one hospital over a few months without optimal ethical oversight, but that countless errors continue to occur in thousands of hospitals worldwide over years and decades. No ethics committee is appointed to worry about that. The article by Prot *et al.* increases awareness of this problem, identifies risk factors, and hopefully contributes to progress in this area. In that, it is fundamentally ethical.

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