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Editorial

Why we need ethical oversight of quality improvement projects

The jury is still out on whether ethical oversight is needed for quality improvement projects. Many quality practitioners argue that as long as the quality improvement project is not primarily research, ethical review is unnecessary. In this editorial, I would like to defend the opposite view, that ethical oversight is indeed desirable for most initiatives to improve the quality of health care.

Let us redefine the nature of health care. Much of health care would amount to reckless endangerment or even to bodily harm if it were not covered by the tacit covenant between patient and doctor (think of surgery or chemotherapy). Under this covenant, the doctor is allowed to perform potentially dangerous treatments as long as she or he acts solely in the interest of the patient. If the doctor served any master other than the patient's welfare, his or her actions would be unlawful. This is why strict oversight by an external body is needed when doctors perform research, an activity that aims to produce knowledge for the benefit of society, and not necessarily to help the patient.

Clearly, the rule should be: for anything the patient requested you do not need external ethical oversight, for anything else that affects patient care you do. Unfortunately, the rule that is prevalent today has perversely shifted to this: for medical research you need ethical oversight, for anything else you don't. Several authors have endeavoured to define 'research' to delimit the jurisdiction of ethics committees [1–3]. Others have argued that the emphasis on research is misguided: what matters is whether an activity entails risk to patients [4]. Since health care is intrinsically risky, all decisions that bear on health care should be subjected to ethical oversight—except, that is, when they are specifically authorized by the patient in the course of clinical care. Many management and policy decisions that may have a significant impact on care are made in the background, unbeknownst to the patient. Here are a few examples: 'gag rules' that limit the doctor's ability to discuss treatment options not covered by a health insurance contract, reductions in health care personnel to improve productivity, structural overwork of doctors in training, limitation of resources to investigate medical mishaps, reliance on paper-based patient records, pharmacy formulary decisions, closure (or opening) of hospital beds. Such decisions may threaten or enhance patients' welfare yet are not made in response to patients' demands. That they are not overseen by an ethics committee suggests that health care management in 2004 is like medical research before Nuremberg: unsupervised and possibly harmful.

Quality improvement projects face the same predicament. While such projects aim to improve or maintain the quality of patient care, those in charge cannot be sure that the intervention will be effective. A risk exists that the proposed innovation will be ineffective or even harmful. Furthermore, evaluations of quality improvement projects are much like research in terms of the risks they pose for patients. The key difference is that their goal is to produce locally relevant knowledge, not generally applicable scientific knowledge. As with medical research, the proponents of the project have too much at stake to be trusted with an even-keeled assessment of potential harms and benefits.

Such an assessment should be done by a body whose sole mandate would be to look after patients' interests—let us call it a 'management ethics committee'. This committee would assess the merits of all proposed quality improvement projects (and by extension, any management decision that may impact on the quality of care), and decide whether the project may or may not go forth. The analysis would be guided by ethics frameworks proposed for public health activities, and focus on the expected effectiveness of the intervention, the associated risks and burdens, and fairness in the distribution of benefits and risks [5]. The committee should include representatives of management, of the health professions and possibly of patients.

Several objections can be raised to this proposal. Some would say that quality improvement does not require ethical oversight because it is a moral obligation of health care systems—not to do it would be unethical. This is correct, and the same argument is true for medical research. However, that the general area of activity is commendable does not imply that any given project is acceptable. 'Quality improvement' is the aim of the project, not a guaranteed result.

Another objection to ethical oversight of quality improvement projects is that it would be impractical or impossible to obtain individual informed consent [2]. This is also correct. However, ethical oversight does not necessarily imply individual informed consent [6,7]. The requirement for individual consent is routine in medical research, where the proposed intervention is to be applied to the individual, and the risks and benefits are borne by the same. In contrast, most quality improvement projects are systemic. If doctors' working hours are reduced in order to decrease fatigue and the likelihood of errors, an individual patient cannot elect to be treated by an intern at the end of a 36-hour shift. Individual consent is simply not relevant in such a case [7]. I would suggest that obtaining an independent assessment of risks and benefits for the project is sufficient in most cases, and formal consent to participate is unnecessary.

In some circumstances, the patient population directly affected by the project may need to be formally consulted. How such a community informed consent can be obtained is an open question—perhaps from a panel of former patients, or from other representatives of society at large, much like the

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Citizens Council established by the National Institute for Clinical Excellence in the UK (www.nice.org.uk). The body that grants consent should be independent from the ethics committee that has authorized the launch of the quality improvement initiative. Community informed consent may be particularly useful when the proposed systemic intervention poses a substantial risk to patient health, and not merely, say, to the confidentiality of medical records. For individual interventions, individual consent remains an option.

Another possible objection is that ethical oversight would add an unseemly layer of bureaucracy to hospital operations, stifling, rather than encouraging, quality improvement initiatives. Similar arguments are sometimes heard from medical researchers who consider the review of their projects by research ethics committees as an obstacle to research. No doubt this is in part true. But surely principle should take precedence over practicality. Furthermore, even though ethical oversight requirements may reduce the number of quality improvement projects, those that will get done will be better formalized and more thoroughly evaluated than is currently the case. Quality improvement projects are sometimes felt to require less rigour in conception and less care in implementation than scientific research projects. There is little justification for such uneven standards.

Finally, ethical oversight of quality improvement projects appears to place an unfair burden on innovations, as opposed to the status quo. This is true, but one has to start somewhere. Hopefully, hospital processes that pose the most problems are the most likely to be subjected to a quality improvement initiative. Hence, ethical oversight will be directed at the most problematic areas first. Furthermore, with time, most hospital procedures that affect patient care will change, and hence will be screened by the management ethics committee. In this way, the work of management ethics committees will ensure that the functioning of hospitals is primarily concerned with the needs of patients.

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