Why the ethics of medical education research differs from that of medical research

Olle ten Cate

This journal has recently adjusted its requirements for research papers, referring to the World Medical Association's Helsinki Declaration on Ethical Principles for Medical Research Involving Human Subjects.[1,2] Many advances in medicine have been attained by research involving patients. Individual patients' best interests have sometimes been sacrificed for the benefit of future patients' health. Most countries have established legal regulations and procedures, based upon this declaration, along with institutional review boards (IRBs).

Such universal requirements do not exist for education research or social science research in general. For this reason, many countries, but not all, have included medical education research in their ethical review procedures, which are designed for medical research. Human subjects here are usually students or residents, but teachers and patients can also be involved. This journal will now require proof of ethical research conduct before publication. This step can be considered to represent an advance in research standards and may be taken up by other journals in the field. Like patients, learners are potentially vulnerable subjects of research, specifically if the investigators simultaneously exercise power as teachers or examiners.

The Netherlands is among those countries that do not require ethical approval for medical education research. Dutch IRBs typically respond to submitted requests for review of education projects with statements like 'exempt from ethical review' because, firstly, patients are not involved and, secondly, no medical interventions are applied. So far, journals have accepted and published such statements without further question. Researchers often find this a comfortable stance as it avoids the bureaucratic burden of approval that has seriously hampered research elsewhere.[3–5] For instance, I saw the recent 3-month stay in the UK of one of my research staff end without the planned interview and questionnaire project carried out, only because of a late and negative response from the IRB. Not that the project was unethical; the application simply lacked the requisite paperwork, despite the fact that extensive written and oral information was supplied. The question here is not whether ethical review in medical education research is justified – of course it is – but whether existing IRB procedures are most suitable for medical education research.[6]

Dutch researchers find 'exempt from ethical approval' a comfortable stance as it avoids bureaucratic burden

Given the requirements journals will put upon submissions, in terms of providing other proof of ethical conduct of medical education research if institutional review is not possible,[1,7] independent ethical review will also become important in those countries without relevant procedures, such as the Netherlands. In a recent survey about experiences with IRBs among clinical course directors in the USA, it was suggested that national guidelines for ethics review would enhance transparency and stimulate inter-institutional research collaboration.[8] When suggesting that the Netherlands Association for Medical Education take the lead in devising such guidelines, I began to wonder what ethical review of education research should look like, *vis à vis* the Helsinki Declaration. I concluded that education differs from health care in a number of aspects that might affect how ethics review should take place.

Patients usually need care because of ill health. They are often very dependent on doctors and hospitals for their essential wellbeing. Students are also dependent as they must abide by the regulations of an institution and its teachers to pass necessary examinations, but they themselves are responsible for whether or not they enrol in particular courses and for whether they attain their self-chosen goals in life. They are, by far, not as dependent as patients. Next, students determine to a large extent the outcome of educational interventions, much more so than patients can

Utrecht, The Netherlands

Correspondence: Professor Olle ten Cate, University Medical Centre Utrecht, School of Medical Sciences, PO Box 85500, 3508 GA Utrecht, The Netherlands.
Tel: 00 31 30 250 7010;
Fax: 00 31 30 253 8200;
E-mail: t.j.tencate@umcutrecht.nl, t.j.ten.cate@freeler.nl

doi: 10.1111/j.1365-2923.2009.03385.x

determine the outcome of medical interventions. Personal study effort is a major determinant of academic success; medical treatment successes are determined to a far greater extent by health care providers.

Students determine the outcome of educational interventions far more than patients can determine the outcome of medical interventions

Medical research may involve risks of harm to a patient's health, which, in some cases, may be serious and irreversible. This type of research requires the utmost caution. Harm in education research may be defined as the risk that less than optimal education is provided, resulting in less acquiral of knowledge and skills, and harm to academic progress. Harm to progress can be serious. I have witnessed a financial claim by a medical student who argued that an examiner had caused loss of income as a result of failing this student on tests and thus extending the required course length. The claim was not sustained and in this case no research was involved, but an educational experiment could be envisioned to carry a risk for such potential harm. In other cases, harm may imply psychological stress and discomfort. Still, this type of harm does not compare with potential physical harm resulting from medical experiments.

Potential harm resulting from educational experiments does not compare with potential harm from medical experiments

Furthermore, there is no clear distinction between administration and research purposes in data collection on student progress and programme quality. Schools collect data on student progress and the quality of educational processes as part of their core business. This type of data collecting is usually not subject to ethical approval, as registering test results and, to a lesser extent, registering students' opinions of education are unavoidable. Enrolment in education must represent the subject's tacit approval that his or her personal data are registered. These data serve both students and educational quality. Reports based on aggregated data of student progress and educational quality can be considered to serve a necessary research aim; indeed, not using these data to improve education could be considered unethical. The necessity of gaining ethical approval or informed consent to use these data as part of research results for publication in a journal is questionable if harm to students is clearly not at stake. Researchers now sometimes label investigations as 'evaluation' in order to avoid the burden and delay incurred by a review procedure, but this does not seem a proper way to go. Rather, clear specifications of the types of data collection and uses that require ethical approval should guide researchers in their ethical conduct.

Education is a process that cannot easily be stopped. Programmes must be offered to enrolled students and schools should continue to aim to deliver high-quality curricula. Many medical schools evaluate and try to improve their curricula, either gradually or by instigating large innovations all at once. Viewed from a research perspective, an educational method can be considered an intervention, just as a medical treatment is an intervention. At variance with medicine, medical education is only at a very early stage in the development of evidence-based practice.

Education research – still – offers only little evidence to support a claim that one method is superior to another, despite the growing medical education literature.[9,10] One reason for this is that students themselves determine to a large extent the effect of education.[11] The counterside of the coin is that institutions can change their educational methods if they feel the need to do this, with limited risk for damage to the curriculum or harm to students. Let's now compare curriculum development with education research. Consider a complete overhaul of the medical curriculum for a new student cohort, say, from a traditional to a problem-based learning (PBL) format. Does this 'experiment' require ethical approval? Not likely. Not even when national examination results are compared with those of the previous cohort and published in support of the new development. This holds true if the results of students from two medical schools with such different curricula are compared. Next, consider a complete overhaul of the second year of a curriculum for only part of a student cohort. Students could be randomly assigned to either a PBL or a traditional programme, and their scores on national examinations could be compared. Would this 'experiment' require ethical approval? Most likely it would in most countries. But what is the difference in terms of potential harm to students? Probably none. In general, schools and curricula differ in their educational methods and it is often hard to claim that students are better off with one school or method than

another. Twenty years of external review of the eight medical schools in the Netherlands have not raised any serious conclusions that one school is clearly superior to another. Of course, checklists were used and the scores calculated showed differences on points, but no sound basis has ever emerged in support of real qualitative differences in outcome.

This example shows how close educational development is to education research. The difference may only be that one instance is considered research, as it has a systematic project description, labels a new method as an intervention, formulates outcome measures and analyses data. What actually happens with students – the basis for ethical review – may be the same in the other instance.

This PBL example may not sound very experimental because the format of PBL has been researched extensively, but such research has usually happened only after PBL has been introduced into a curriculum, not before. In other words, is it logical to require ethical approval when methods are compared within cohorts, but not to do so with scientifically less sound approaches, such as historical or inter-institutional comparisons? Providing a completely new educational method to a new cohort without any comparison does not require ethical approval, but it is day-to-day practice in many schools.

Why require ethical approval when methods are compared within cohorts, but not historically or inter-institutionally?

One important element of ethical research conduct concerns the obligation to provide subjects with the option not to be involved in the investigation, so that potential candidates are asked to give their informed consent to participation and provided with options for withdrawal. In education research in a field setting, participation in research often equals participation in education. For example, introducing a new knowledge test – in fact, most knowledge tests in educational settings can be considered as 'new' instruments if test items have not been used before – cannot include an option for non-participation when a pass/fail decision must be based on such a test. Informed consent can be sought, but often there is no alternative available.

In conclusion, education research should be carried out ethically and the journals that publish such studies have a responsibility to stimulate ethical research conduct. This includes the proper protection of the interests of any human subjects. However, the criteria with which we may evaluate the ethical conduct of education research are not necessarily equivalent to those required in medical research involving patients. Ethical research requires the maintenance of a reasonable balance, between yin and yang, so to speak, or between the risks of harm to subjects and the expected scientific yield of the investigation. This balance may well differ between medical and education research.[12]

I believe it would help to formulate specific criteria with which we can evaluate the ethics of medical education research. Pugsley and Dornan cite a helpful list of 10 ethical questions for research involving students, formulated by Cardiff University.[7] This might represent a starting point for the development of such criteria and could result in a review procedure that both upholds ethical research standards and stimulates, rather than discourages, teachers and students to engage in medical education research.

REFERENCES

1 Eva K. Research ethics requirements for medical education. *Med Educ* 2009;**43** (3):194–5.
2 World Medical Association. *The Helsinki Declaration.* http://www.wma.net/e/policy/b3.htm. [Accessed 7 April 2009.]
3 Robinson L, Drewery S, Ellershaw J, Smith J, Whittle S, Murdoch-Eaton D. Research governance: impeding both research and teaching? A survey of impact on undergraduate research opportunities *Med Educ* 2007;**41**:729–36.
4 Stewart PM, Stears A, Tomlinson JW, Brown MJ. Regulation – the real threat to clinical research. *BMJ* 2008;**337**:a732.
5 Godlee F. It's time to change how Europe regulates research. *BMJ* 2008;**337**:a2986.
6 Kanter S. Ethical approval for studies involving human participants: *Academic Medicine*'s new policy. *Acad Med* 2009;**84** (2): 149–50.
7 Pugsley L, Dornan T. Using a sledge hammer to crack a nut: clinical ethics review and medical education research projects. *Med Educ* 2007;**41** (8):726–8.
8 Dyrbye LN, Thomas MR, Papp KK, Durning SJ. Clinician educators' experiences with institutional review boards: results of a national survey. *Acad Med* 2008;**83** (6):590–5.
9 Colliver JA. Effectiveness of problem-based learning curricula: research and theory. *Acad Med* 2000;**75**:259–66.
10 Albanese M. Problem-based learning: why curricula are likely to show little effect on knowledge and clinical skills. *Med Educ* 2000;**34**:729–38.
11 ten Cate TJ. What happens to the student? The neglected variable in educational outcome research. *Adv Health Sci Educ* 2001;**6** (1):81–8.
12 Eva KW. The yin and yang of education research. *Med Educ* 2008;**41**:724–5.

