Editorial

Using Medical Students as Research Subjects: Is It Ethical?

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Should medical students be allowed to participate in clinical research? One guiding principle, as stated in the rules governing the use of medical students in medical experiments in Harvard University (the first to issue such guidelines), is "the belief that as far as their health and well-being are concerned, no student should be exposed to risk different from that considered generally acceptable for normal adult subjects by the Committee on Human Studies."[1] The tradition of self-experimentation and self-sacrifice in medicine should not justify the exposure of medical students to unacceptable levels or types of risks to health and well-being, even if some investigators are willing to undertake such risks to achieve their professional goals. The principle does not, however, rule out the permissibility of recruiting students to participate in research which poses higher than minimal risks, including Phase 1 drug trials. Universities that bar students from doing so, or that create special protections such as echelons of review that do not extend to other participant pools, have been criticised as overly paternalistic,[2-4] and for fostering an elitist double-standard for "considering the participation of medical students versus the public at large."[3,5] (As Angoff asks: "One may wonder why it is acceptable to ask the masses to accept risk in the name of science but not the very people whose futures are linked to the successful perpetuation of biomedical research."[2]) While these critics contend that students should be as free as the rest of the population to participate in clinical research as an expression of their autonomy, the tragic case of the death of a freshman participating in an experiment involving invasive procedures at the University of Rochester points to the need for close ethical scrutiny whenever students are involved as research participants.[6]

The case for liberalising the use of medical students as clinical research participants can be argued on the ground that their capacity to be informed participants is higher than most other participant pools.[2] This applies especially to students in their clinical years who are well-trained in scientific discourse and methods and who have been exposed to some form of research ethics training. Given their training, they should be able to understand and judge for themselves the risks and benefits of participation, including the extent in which their primary interests as students would be affected by possible side effects or time commitment. They should also be aware of their rights as participants, including the right to withdraw. In an era of healthcare which stresses the development of the ethical clinician scientist, the experience of being a research participant is undoubtedly valuable for appreciating that research entails a different set of ethical rules and conduct than practice, what it means for example to treat and respect a person as a research participant, as opposed to being simply a patient or a subject.

Nevertheless, the potential for exploiting student participants is an ever present issue. Medical students have been likened to a "captive population", with their ability to exercise free choice vulnerable to the pressures, whether applied or intended or not, of their institutional situatedness.[7,8] The Commentary on Guideline 13 "Research involving vulnerable persons" of the CIOMS International Ethical Guidelines for Biomedical research states that the "quality of the consent of prospective subjects who are junior or subordinate members of a hierarchical group requires careful consideration, as their agreement to volunteer may be unduly influenced, whether justified or not, by the expectation of preferential treatment if they agree or by fear of disapproval or retaliation if they refuse."[9] Because of perceived or actual dependency on faculty members in general for their academic or professional development, medical students may feel obliged to enrol in studies and to comply with protocol requirements if approached or invited by faculty investigators.[10] The moral problem of inequitable distribution of research benefits and burdens is raised if students are routinely enrolled into clinical research as research participants because of their ready availability and cooperation. To reduce coercion and to ensure a fair representation of the study population at the same time, it is now a common practice in many medical schools to issue group or general invitations to participate in a research project via public forums, rather than carrying out direct recruitment of individual students.

The use of incentives to increase recruitment remains, however, a subject of debate. Should research participation be offered as a course component with credit awarded to the final grade?[10] It is argued that if such a component is included, it should be optional with students being able to select an alternative way of earning credit without penalty.[11,12] Nevertheless, if students are provided with the alternatives of regular classroom work and assessment, then research participation may be viewed as the only reasonable choice that would not make a student, already encumbered with the heavy demands of coursework, worse off.[11] The spectre of coercion, albeit a subtle form, or rather manipulation, is raised by giving students such options. To counter such a charge, the use of payments has been proposed to divorce research participation from any links with academic and professional benefits, thus ensuring that the type of risks and benefits that a student would consider is similar or comparable in range to what any other potential participant would consider.[11]

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Such a proposal, however, brings the problem of setting the right amount of payment that would not constitute an undue inducement for medical students.

To be sure, if there is potential for direct benefits accruing to student participants, then the issues of exploitation, inequity and coercion will diminish in significance. But how should the requirement of fair benefits for students who assume the risks and burdens of clinical research be determined in content and scope? The Declaration of Helsinki states that "medical research involving a… vulnerable population or community is only justified it the research is responsive to the health needs and priorities of this population or community and if there is reasonable likelihood that this population or community stands to benefit from the results of the research."[13] Should such criteria be used to assess the ethical acceptability of clinical research whenever medical students are used as the sole or predominant study population, if we assess and accept that they are vulnerable participants? Would this provoke the "double-standard" criticism?

Regardless of which criteria are used, ethical concerns would not be wholly excluded. As Bonham and Moreno argue, "justifying a research intervention on the ground that it benefits the subject… can obfuscate risks to individual autonomy."[7] Privacy and confidentially are also perennial issues of concern, especially since medical students would and should be concerned about the collection of any potentially negative information about themselves.[3,14] No research protocol should be approved without the assurance of appropriate confidentiality procedures, such as the removal of specific identifiers, whenever sensitive data about students is gathered. Levine and colleagues[14] underscore the importance of anonymity in survey studies that seek to assess the mental health of medical students to protect their interests as well as the validity of the data. All kinds of psychological or behavioural research with medical students should aim at an appropriate balance between confidentiality and harm to the public good.

In the drive towards "evidence-based education", more and more medical education research activities are conducted. Yet, as Roberts and colleagues highlighted, little attention has been paid to issues and standards of safeguards in such research in the medical education literature.[15] Dubois[16] proposes that for instructional or curriculum assessment research, the burden of proof is on the IRB to show why the explicit voluntary consent of students should be sought, since such research is of clear benefit to students, consent may be implied and that the validity of the study could be damaged by allowing students to opt out of participation. Indeed, through an empirical study with medical students on their perceptions of medical education research and their roles as participants, Forester and McWhorter[17] argue that IRB oversight of student consent to medical education research may be unnecessary and even inappropriate, since students understand the value of medical education research and would not mind their survey responses being used for this purpose so long as their anonymity is preserved. In this current climate of increased ethical scrutiny over research, such a finding may be welcome news to medical education researchers as it points to less burdensome protocol procedures for consent. Nevertheless, if the involvement of students in research participation is always an opportunity – some would argue that it is an obligation – to inculcate the right values and habits of mind and behaviour in research investigation, then it is important to maintain some form of consent procedure, which understandably need not be as rigorous as informed consent for clinical research, for both student data collection in medical education research and the dissemination of the findings (such as through journal publication). In this way, a culture of cynicism may be prevented with regard to promulgating the ideals of research ethics.

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