Health systems research and the Gadchiroli debate: a plea for universal and equitable ethics

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We were pleased to read, in the January-March 2010 issue of this journal, Abhay Bang's response to criticism of the Gadchiroli trial on ethical grounds (1). While it is not within the ambit of this article to comment on the Gadchiroli trial principal investigator's clarifications, we would like to extend the debate on standards of care that he discusses to standards of ethics, with particular reference to health systems research.

Health systems research (HSR) can be distinguished from conventional analytical research by its comprehensive approach that recognises and considers multiple non-linear interrelations among components of health systems. HSR can include the study of any constituent of a health system, but never in isolation and always in a unique context. HSR is focused on solving practical problems, with the aim of improving the system (2). The Gadchiroli trial shares several characteristics of health systems research: it tried to find a solution for "a hopeless case" (newborn mortality) in a specific context (Gadchiroli district, rural Maharashtra, 1993), and successfully "strived to influence policy at the state and national levels", as explained by Bang in his response (1). Within all the limitations of time and context, the Gadchiroli trial's design - non-randomised, but controlled - was even innovative (3). So far, so good.

Yet in 2007, Marcia Angell - renowned North American medical scholar with an impressive curriculum vitae - severely criticised the Gadchiroli trial as unethical (4), which apparently surprised external observers (3) and the principal investigator (1) alike. The latter challenged the validity of Angell's central reproof: not having offered state-of-the-art standards of care to the trial's "control" population. In the last sentence of his response, the principal investigator questioned the ethics of the critic (1). In this comment, we want to depersonalise and generalise this matter, by questioning the nature and application of medical research ethics today. We argue that current medical research standards are too limited in scope, and are unethical in being inequitably applied.

According to the World Health Organization, ethics provides a framework without prescribing a specific set of rules (5). Indeed, few ethical guidance documents are legally binding (6) and a range of parallel national and international guidelines are in circulation (7), with different interpretations leading to lively discussions (8, 9). It is useful to recall the origin and scope of these guidelines. The Declaration of Helsinki can be considered to be the predominant guidance. Authored by the World Medical Association, its first version in 1964 (10) was an elaboration on the principles of the 1947 Nuremberg Code (11), which itself was a legitimate (yet late) response to inadmissible experiments by doctors on human subjects under the Nazi regime. The Declaration of Helsinki has undergone six revisions and two clarifications between 1964 and 2008. Most controversial has been the inclusion of the ethical universalism principle through the explicit insistence on delivery of state-of-the-art care in control groups - first in the 1996 revision (12), then reformulated in the 2000 revision (13) and sole subject of the 2002 clarification (14). This led to a longstanding debate between advocates of universalism and relativism (15). In developing countries in particular, the Declaration of Helsinki has been accused of being biased by a western worldview. However pertinent this statement might be, we argue that it detracts from the fact that it refers to a specific paradigm: one that presumes the superiority of biomedical logic in health, and consequently glorifies randomised control trials and systematic reviews. It is the narrow adherence to a particular analytical method that makes current ethical guidelines inappropriate for health systems research, in developing and developed countries. A conventional analytical approach to research can be effective in biomedical research - with a focus on few variables, and essentially linear interactions. This is not necessarily so in health systems research that focuses on essentially non-linear interactions and necessarily uses a range of research methods (2). Accordingly, the scope of medical research ethics rooted in one particular scientific method cannot meet the needs of health systems research. The limitations of the conventional analytical approach are wittily (disrespectfully, some have argued) illustrated by Smith and Pell in their mock systematic review of parachute use: those "who insist that all interventions need to be validated by a randomised controlled trial need to come down to earth with a bump". (16)

In developing countries, a key challenge of applying universal ethical standards is to take into consideration contextual issues on moral grounds without resorting to ethical relativism (17). This consideration is too often lacking, as the debate on the Gadchiroli trial illustrates (1, 4). At the same time, the application

of these standards in developed countries is far from perfect. Today - 63 years after the Nuremberg Code was formulated to avert atrocities in the name of science - protection of humans in medical research is still an unfulfilled need, as recent disclosures on medical experiments on detainees in US custody illustrate (18). Both the lack of consideration of context and ongoing human subject experimentation can be termed inequitable, unfair and unethical. To achieve the universal ethical standards that this world needs, we might want to go further back than Nuremberg and look for inspiration from Aristotle's concept of complementary general and particular justice (19). Such balance - as proposed more than 2,000 years ago - is needed if we want ethics to be both universal and equitable.

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