

International Regulations and Medical Research in Developing Countries: double standards or differing standards?¹

GODFREY B. TANGWA*

Introduction

International regulations governing medical research, healthcare and/or medical practice, such as the *Nuremberg Code* (1947), *Declaration of Helsinki* (WMA, 1964, amended 1975, 1983, 1989 and 2000), *International Guidelines for Ethical Review of Epidemiological Studies* (CIOMS, 1991), *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS, 1993, revised 2002), *Universal Declaration on the Human Genome and Human Rights* (UNESCO, 1997), *Operational Guidelines for Ethics Committees That Review Biomedical Research* (WHO, 2000), *Ethical Considerations in HIV Preventive Vaccine Research* (UNAIDS, 2000), and other similar documents are, obviously, meant to be *guidelines* and not detailed procedural rules of thumb that can be applied unreflectively with the certainty of avoiding moral wrong. Their most important value is arguably for practical people such as scientists, politicians, business managers, bureaucrats and government functionaries who daily have to take medically relevant decisions of great import without the luxury of prior exhaustive moral deliberation or reflection. In this respect they can also be said to be 'peeling roasted potatoes with finger nails', according to the metaphor in the parables below.

Some of these guidance documents have undergone several revisions² in the course of their life and it is almost certain that they will continue to be revised and updated in the future. These revisions have been necessitated, *inter alia*, by rapid advances in biotechnology and biomedical research, criticism of the shortcomings, inadequacies and lacunae of the existing texts in the light of practical experience in applying them in concrete situations, and a general improvement in the level of moral awareness and sensitivity in the relevant domains.

These guidance documents will continue to evolve with developments in science and technology and with the moral progress of humankind. For these reasons, they need to remain plastically flexible rather than castiron rigid in their stipulations and recommendations. Their purpose and aim is certainly not to put researchers and practitioners in a straight jacket but to ensure that they do not engage in unethical conduct in the course of doing their work. Moreover, such regulations are meant to apply *internationally*, and no set of straight jacketed rules of thumb can conceivably apply, equally and uniformly, to all human societies and

* University of Yaounde, Cameroon; Board of Directors of the IAB.

communities of the world, extremely diverse and variegated as they are. The mark of a good international guidelines or regulations, in my view, is that it should provide clear principles of action that are sensitive to both moral agency and moral patients and that plastically apply equally to all global communities and societies without necessarily attempting to uniformize particular rules of action or foist the particular moral dilemmas, quandaries, obsessions and preoccupations of some on all. Moral principles may hold good universally and timelessly but their application in particular concrete situations is marked by interpretation and adaptation and cannot dispense with perspective and context. Moreover, freedom and voluntariness rather than constraint and coercion are the marks of genuine morally praiseworthy action.

In this paper, I argue that, because moral obligations are obligations only from the point of view of a particular moral agent, we need always to keep in mind the context and perspective in discussing the morality or otherwise of particular actions or procedures, without, however, falling into moral relativism. The moral worthiness or otherwise of an action is to be determined from the point of view/perspective of the agent of the action and not from that of the patient, although it is quite possible for one and the same person to be moral patient in one respect and moral agent in another (See Tangwa, 2000). For this reason, I believe that we need, in particular, as far as biomedical research goes, to make appropriate distinctions between the ethics of developed world research in the developing world, collaborative or cooperative research between the developed and developing worlds, developed world research in the developed world and developing world research in the developing world. A consequence of looking at things this way is that, while there certainly are ethical concerns, imperatives and obligations at all levels, and while the general moral principles that should guide correct moral action would be the same, different standards may and, in fact, cannot but be applied in different contexts at different levels, without resorting to double standards, which can never be morally justified. What this means, in effect, is that, while the use of double standards can never be morally justified, different standards are not only permissible but also inevitable.

Two putative scenarios

The point I am trying to make may come out more clearly if told in a metaphor or parable. The general moral of the following two “thought experiments” is a truism which amongst my people, the Nso’ of the mountainous North West region of Cameroon, is expressed in many different ways and told in many a folktale, to the effect that ‘for want of a knife you may peel roasted potatoes with your finger nails’ whereas no one provisioned with a knife would be peeling potatoes with finger nails. In the folktale versions of this ordinary truism, some traveling stranger, with an abundance of what you lack, would usually come along and express great surprise at your doing such an odd thing as peeling potatoes with your fingernails, when the world is so full of knives. Your answer is simple and straightforward: “If I had a knife, I would not be peeling potatoes with my fingernails.” In the folktale, the surprised stranger would then immediately offer

you one of his many knives but, outside the folktale and in the light of the palpable lessons of human history, we may not be sure of the reaction you may get to your frank confession of need.

- 1) I am starving and in danger of dying from starvation. I eat stale food, knowing fully well that it could make me ill. Have I done anything foolish or morally wrong? No. Morality does not come in here and it is certainly more rational to choose survival with the chance of a bout of illness than to risk the certainty of dying of starvation. Now suppose that you come across me dying from starvation. You have food in abundance. From your abundance, you choose food that you yourself would not eat, because it is bad and likely to cause illness, and you give me this bad and potentially dangerous food. Extremely grateful to you, I thank you profusely from the bottom of my heart and eat the food, knowing or not knowing that it may make me ill. Have I done anything morally wrong? No. Has your action benefited me? Yes. Have you done, by your action, any *moral* good or is your action *morally* praiseworthy or commendable? Certainly not, I would think.
- 2) I have a wardrobe overflowing with dresses. Some of my dresses are old-fashioned and can no longer fit me, anyway. I select them out of my wardrobe and put them in an old bag I no longer need or want. I am wondering how to dispose of the bag and its contents without polluting my immediate environment. Miraculously, you come along, almost naked in your rags, begging for anything to cover yourself with. I rush in for my bag of rejected dresses and hand the whole lot to you. You are not only pleasantly surprised but also a little shocked and you hesitate taking my gift, but I repeatedly reassure you to take the whole lot, together with the bag. You can hardly believe your fortune and you continue thanking me as you walk away under the weight of the gift parcel, but I tell you "Don't mention!" and reenter my house with an air of sanctity. Has my 'gift' benefited you? Yes, certainly. Have I done any *moral* good or is my action *morally* praiseworthy? No! not any more than if I had thrown my old unwanted stuff in the nearest garbage dump. I am even probably also a hypocrite.

Moral agency and moral worth

The moral value of an action or procedure can be determined only from the point of view of the moral agent concerned and not from that of the patient or from its actual consequences, although it is important that good consequences be, at least, intended by the agent. The influence of utilitarianism and consequentialism in particular, which admittedly, are quite appropriate in certain circumstances, especially where the moral worthiness of the action or procedure in question is no longer in question, has misled many Western thinkers into the apparent belief or attitude that ethics is basically a matter of considering and balancing competing interests and calculating consequences and benefits. No amount of benefits to the patient of a putative moral action is in itself an adequate moral justification of the said action. While beneficial consequences are certainly important in determining what risks individuals or communities might voluntarily

undertake, it could never be justifiable for another moral agent to directly do harm to others on the grounds that good consequences for them will result. The benefits of what John H. Evans (2000, p. 32) has termed *commensuration* in ethics – ‘a method for discarding information in order to make decision-making easier by ignoring aspects of the problem that cannot be translated to the common metric’, thereby making possible calculability and predictability – cannot be denied. Nevertheless, it is my belief that this method and point of view or attitude runs the grave risk of facilitating the possibility of nicely dressing up self-interest or exploitation in the robes of moral acceptability or even those of altruism and philanthropy. And self-interest and/or exploitation so masked are morally worse than honestly naked and unashamed egoism and exploitation; for against the latter, the victim has the possibility, even the duty, of struggle and resistance whereas, in the former s/he is taken in the manner of an innocent lamb to the slaughter.

Conclusion

The idea of ‘*informed consent*’ whereby the potential subject of a biomedical research project freely and voluntarily accepts to participate in the process after having been fully informed of the purpose and objective of the research, of any possible risks and the benefits to be derived, can be considered as the ‘centre piece’ of guidelines and pragmatic rules regulating biomedical research involving human beings. Taking only this important idea in the light of what I have attempted to say above, I would suggest that the idea of ‘informed consent’, from the point of view of the moral patient, needs to be complemented and balanced with the idea of ‘*moral integrity and noble intent*’, from the point of view and perspective of the moral agent. Concretely, I would suggest that the reverse side of the ‘informed consent form’ which the patient of research is nowadays usually required to sign should be a ‘moral integrity and noble intent form’ which the researcher, sponsor and funder of the research should be equally required to sign. (Of course, the signature, on both sides, is only a symbol which can in no way replace what it stands for and symbolizes). Such a signed statement might read:

We, the investigators, sponsors and funders of this research, hereby solemnly declare, on our honour, that our intentions in carrying out this research are noble and primarily motivated by the desire to acquire knowledge that could help in improving the lot of human beings, without any distinction or discrimination; that we have no overt or covert intentions or hidden agenda to harm, deceive or exploit, now or in the future, any human being or group of human beings. We solemnly pledge that, in carrying out this research, we will maintain the utmost respect for all participants and experimental subjects and objects, including any plants and animals. We will do everything within our powers to prevent knowledge gained through this research being abused or used in ways contrary to the above declared aims and intentions.

Such a statement and the putative underlying approach and attitude it signifies could go a long way in changing the current atmosphere of suspicion and skepticism, especially in certain parts of the so-called developing world, borne out of current abuses and malpractices reminiscent of the Tuskegee experiments.

Notes

¹ This paper was first presented at the International Conference "Science vs Man" in Massa Carrara, Italy, 28-30 September, 2001. A version of the paper is also published in *Developing World Bioethics* (Vol. 1, No. 2, 2001) under the title: "Moral Agency, Moral Worth and the Question of Double Standards in Medical Research in Developing Countries".

² Two notable revisions which are currently the subject of world wide discussion and debate are those of the *Declaration of Helsinki* (2000) and the *CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002).

References

Evans, John H. (2000), "A Sociological Account of the Growth of Principlism", *Hastings Center Report*, Volume 30, No. 5, September-October, pp. 31-38.

Tangwa, Godfrey B. (2000), "The Traditional African Perception of a Person: Some Implications for Bioethics", *Hastings Center Report*, Volume 30, No. 5, September-October, pp. 39-43.