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Commentary on The Ethics of Clinical Trials in Africa

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COMMENTARY ON *THE ETHICS OF CLINICAL TRIALS IN AFRICA*

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Commentary on *The Ethics of Clinical Trials in Africa*

The article ‘Human Rights and Maternal - Fetal HIV transmission Prevention Trials in Africa’ by George & Michael (1998) discusses the morality inherent in conducting HIV prevention trials in developing nations. Their central tenet holds that, in order to minimize the exploitation of developing nations as research subjects, there is a moral duty to ensure equitable accessibility to the beneficial treatment, if a clinically meaningful difference is established in the trial. Selecting a research population in a developing country confers special ethical analysis and consideration by ethicists in order to ensure that trials are undertaken with the highest level of ethics consistent with trials in developed nations. Although subjects within developing nations may provide informed consent, ethical concerns continue to be raised by ethicists whether true informed consent without undue inducement may take place in countries with unequal power and socio-economic relations. Host country agreement or researcher consensus is not a sufficient ethical justification for selecting a research population. If these clinical trials that are sponsored by developed nations are to continue within developing nations, it is a moral imperative to ensure that they carried out as ethically as possible. The authors George & Michael ascertain that, “Actual delivery of health care ... requires a real commitment to human rights and a willingness on the part of developed countries to take economic, social, and cultural rights as seriously as political and civil rights” (1998, p. 562).

In order to objectively analyze the morality inherent in trials undertaken in developing countries, there is a need to examine these trials from multiple ethical dimensions. Thus, the following sections will ethically grapple the morality inherent in HIV prevention trials within developing countries from the utilitarian, Kantian, care ethics, and multicultural ethical lenses.

By applying different ethical positions and perspectives to the debate, a more balanced understanding of the ethics of these trials will be established.

If one adopts a utilitarian lens, then one would need to examine whether the interventions maximized the beneficence to the society in which the study took place in tandem with whether the benefits outweighed the associated costs. Benatar (2004) posits that in order to determine whether a given clinical trial is of utility to a society, there is a need to assess whether the study question seeks to address a relevant health issue facing the community and whether the results from the study may be incorporated into the medical system of the host country (Benatar, 2004). Whilst the clinical trials sought to determine treatment efficacy for maternal-fetal HIV prevention, which is highly pertinent to these countries in which the infection is endemic, the second requirement of integrating the study results into the healthcare system by making them accessible to the local communities was not met. Thus, one may argue that the utility of the trial only pertained to developed nations, resulting in an inequity in the ability to translate the acquisition of knowledge into practice between the developed and developing world.

If one examines these clinical trials from a care ethics standpoint, one must consider the principles of beneficence and non-maleficence in the contextual experience of the study subjects. Benatar (2004) proposes basic standards of care and one basic standard involves treating the subjects with the same level of respect and consideration as one would treat subjects in the developed world. According to Lurie and Wolfe (1997) the same standard of care that is applied to study participants in the developed world was often neglected in trials in the developing world such as the HIV maternal-fetal preventive trials. They argue that ethics boards in developed countries would not find it morally permissible to allow the control group to receive a placebo when there is available treatment that may be used as a comparator as new cases of prenatal HIV

will develop during the study. The undermining of ethical standards as a growing human rights issue in the midst of increasing clinical trials in developing nations has been brought up at the 2011 7th international World Conference of Science Journalists in Qatar according to the UK Guardian (2011).

Bayer (1998) critiques the underlying premise of this double moral standard which is founded on applying the most realistic treatment in the comparator group given the local context as he argues that, “the shift in wording between “best” and local may be slight, but the implications are profound. Acceptance of this ethical relativism would result in widespread exploitation of vulnerable Third World populations for research programs that could not be carried out in the sponsor country” (Bayer, p.568, 1998 as cited in Angell). Thus, given the fact that there had been the possibility to provide care for all subjects during the study comparative to developed nations, a care ethicist would argue that the patients did not receive ethical care in their best interest.

If one adopts a Kantian lens, then one must examine universal humanitarian c1 prima facie duties which are above secondary duties in the moral hierarchy (Fisher, 2009). Thus, if one accepts that researchers undertaking clinical trials have a prima facie duty to receive participant informed consent and the duty to expand scientific knowledge is a secondary or equal duty, then one cannot override the later for the former. Annas & Grodin (1998) argue that the above clinical trials subdued the trial’s primary duty of informed consent due to the fact that study participants came from an impoverished background whereby any access to possible treatment may have acted as an undue inducement. They further point out that had subjects been cognizant of the fact that their participation would not benefit their local community and that treatment would not be provided if proven that it was beneficial at the end of the study, they likely would not have

participated (Annas & Grodin, 2009). Thus, if indeed consent was not truly informed and information pertaining to the benefits of treatment was purposefully withheld from participants, then all arguments of ethical soundness are obliterated. Thus, from the Kantian stance, universal humanitarian duties which form the foundation of ethics failed to be met. Moreover, Kantianism would not support treating subjects as utilities for an end purpose of serving others (Mesac education, 2012).

If one adopts a multicultural ethical lens, then one must be cognizant of not imposing Western imperialism upon developing nations (Fisher, 2009). For the local social and cultural context and developing nations may require a different clinical trial delivery mode than one which is founded on the dominant biomedical model in western society as argued in Bayer (2004). Indeed, Bayer presents 4 dimensions of ethical dilemmas that pertain to the moral divide between moral absolutism which westerners construe as being the hallmark of all studies and moral relativism which realistically meets the moral needs of societies given their current climate. He argues that deciding whether to adopt a placebo control trial is not something which can be easily scrutinized by applying any of the above dualistic divides. He argues that moral absolutism requires a moral idealism which may be unattainable in certain environments. Thus, multicultural ethics requires a consideration of the local morals and social norms that would warrant a given intervention.

Someone may adopt Varmus & Satcher's (1997) stance arguing that the subjects were treated morally by receiving a placebo since they would never have access to the expensive therapeutic protocol in reality. A counter argument response would be that since wealthy pharmaceutical companies and the CDC funded the study, they had the capacity to fund the treatment of all subjects. Had the developed world not initiated the trials but rather the

developing world, then one could argue that providing subjects with the placebo was all that was within the economic capacity of the sponsors. Another objection presented in Varmus & Stacher (1997) is that subjects did not receive treatment after the study ended does not reflect moral flaws in the study design but rather reflects broader social structures of inequity in wealth. A counter argument would be that since the study demonstrated benefits to the mothers, an ethical study would fully fund all participants including controls and expand on providing the community with treatment since the ethical obligation of studies is improving population health in tandem with knowledge acquisition.

In summary, while research involving human subject trials can be strongly beneficial to society there can also be abuses that may have negative consequences for the individual participants. This commentary grappled the ethical dimensions surrounding these trials by applying Kantianism, utilitarianism, multicultural, and care ethics to the debate. It has been argued throughout that, due to the lack of beneficence and informed consent, this case was unethical, violating human subject rights. Therefore, if human subject trials are to exist, they should uphold the highest standards of ethical care to make sure such violations are prevented.

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