

Medical Research and the 'Sugar Pill' Debate

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Sugar pill is the popular term for Placebo, an entity which has been the subject of much debate over the last several decades. Well known is the 'Placebo Effect' where a treatment with no demonstrated therapeutic effect ends up alleviating the symptoms of the illness and at times even resulting in cure. Placebo treatments are most commonly employed by clinicians when they perceive the cause of the symptoms to be more psychosomatic than actual pathology. When the placebos work, everyone's happy, when they don't, usually no harm is done and the clinicians switch to standard regimes.

In the context of medical research, placebos carry an entirely different significance. Whereas in the treatment of individual patients, use of placebos are not guided by scientific principles; when it comes to medical research, there are some very rigid scientific and ethical guidelines under which placebos should and should not be used.

Whenever a new preventive, diagnostic or therapeutic measure is to be tested, scientifically the best method is to compare it to a scenario of no intervention, which is usually done using a placebo in the control group. This method provides the most accurate information regarding the effectiveness, efficiency and adverse effects of the new measure. But if an existing measure is widely available, it is considered to be unethical to expose one section of the participants to potential harm by depriving them the benefits of the existing measure. Article 33 of the latest iteration of the Helsinki Declaration¹ – a set of governing principles on everything pertaining to ethics in medical research – has the following to say about the use of placebo:

"The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

and the patients who receive any intervention less effective than

the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option."

Though article 33 appears to be quiet clear about the use of placebo, in actual practice it presents too many grey areas. These pertain to the interpretation of certain clauses in the article by researchers as well as critics of research. For instance, a proven intervention available in one country may not be available in another country, either because it is not licensed for use or because of cost barriers. Also the need to assess the cost effectiveness and cost benefits of implementing health programmes in particular countries could be a compelling scientific reason to use placebo. And again, the clause of serious or irreversible harm can be worked around by providing information about the availability of standard intervention outside of the trial.

In this context, worth mentioning is a recent article in Indian Journal of Medical Ethics about 254 women dying of cervical cancer in the no-intervention arms of 3 trials done to test cervical cancer screening methods in India. The article provides some insight in to how guidelines related to use of placebo can be interpreted in diverse ways to suit clinical trials, done especially in developing countries.²

The debate over the use of placebo in medical research is nothing new. Several authors have pointed out the harms of neglecting the healthcare needs of patients in the control arm of clinical trials. Chiodo et al have tried to put the entire issue in to perspective and also have recommended additional measures to ensure that the use of placebo does not violate rights of participants.³

The issue lies with the difficulty in interpreting the guidelines brought out by the governing bodies of different countries. ICMR in India though has brought out elaborate ethical guidelines for medical research,⁴ it more or less falls back on the Helsinki Declaration when it comes to the use of placebo. One welcome departure from this general lack of clarity is the CIOMOS/WHO Guidelines, which has gone great distance to elaborate the ethical implications of placebo use in various scenarios.

It is high time the medical research community decides to let

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go of the ghosts of the Nuremberg trials and started working on the highly pertinent ethical issues of the 21 century. The CIOMOS/WHO Guidelines is a good place to start.

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References

1. WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects [Internet]. 64th WMA General Assembly, Fortaleza, Brazil, October 2013. Available from: <http://www.wma.net/en/30publications/10policies/b3/>
2. Suba, E. US-funded measurements of cervical cancer death rates in India: scientific and ethical concerns. Indian Journal Of Medical Ethics, (2014) Available from <http://ijme.in/index.php/ijme/article/view/2072/4511>
3. Chiodo GT, Tolle SW, Bevan L. Placebo-controlled trials - good science or medical neglect? West J Med. 2000 Apr;172(4):271–3.
4. Ethical Guidelines for Biomedical Research on Human Participants, Indian Council of Medical Research New Delhi, 2006
5. International Ethical Guidelines for Biomedical Research Involving Human Subjects, Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Geneva, 2002