Obese patients with T2DM. Cost-effectiveness (INR/unit of effectiveness) varied from 3.7 to 45.2. Seventeen percent of the patients with T2DM included in this study received less cost-effective antidiabetic drugs. 

Conclusions: Prescriptions of cost-effective antidiabetic drugs (83%) were more common than less cost-effective antidiabetic drugs (17%) in patients with T2DM from Mumbai, India. 

Key words: antidiabetic, cost-effectiveness, diabetes mellitus, India. 

Disclosure of Interest: None declared.

References 


A STUDY TO ASSESS THE VACCINATION COVERAGE OF UNIVERSITY STUDENTS IN MUMBAI, INDIA

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Background: Immunization is the most cost-effective intervention for infectious diseases, which are the major cause of morbidity and mortality worldwide. Vaccines not only protect the individual who is vaccinated but also reduce the burden of infectious vaccine-preventable diseases for the entire community. Adult vaccination is very important given that >25% of mortality is due to infectious diseases. There is a scarcity of information on the vaccination status of young adults and the role of socioeconomic conditions in India.

Objectives: The present study explored the adult vaccination status and influence of income and education of parents on adult vaccination status in university students from Mumbai, India.

Methods: This descriptive study was performed from January to April 2015 among undergraduate pharmacy students from Mumbai University, India, by using a validated study questionnaire. Students were contacted by a study team member in their classrooms and were given a brief introduction about the research project. Those who desired to participate in the study were explained the purpose and objectives of the study. On the basis of the eligibility criteria (those who gave written informed consent and were between the age group of 18-25 years), 149 students were selected for the present study. A total of 8 vaccines (namely, Tdap/DTP, varicella, measles-mumps-rubella [MMR], influenza, pneumococcal, hepatitis A, hepatitis B, and meningococcal) were included in this study for all the respondents. In addition to these vaccines, human papillomavirus (HPV) vaccine was also included for female respondents.

Results: There were total of 149 (75 males and 74 females) respondents with a mean age of 21.5 years. The top 3 immunizations were Td/Tdap (97.3%), MMR (66.4%), and hepatitis B (55%) among the respondents. Only 4 (5.5%) female respondents had been immunized against HPV. The lowest income group (<50,000 INR/month) had the least vaccination coverage for all the vaccines except for MMR and HPV. Vaccination coverage was lesser for respondents with parent’s education below a high school than those with parent’s education of graduation and above, except for pneumococcal vaccine.

Conclusions: India’s National Centre for Disease Control has recommended Td/Tdap, MMR, and varicella for all adults and influenza, pneumococci, hepatitis A, hepatitis B, meningococcal, and HPV for adults with certain risk factors. Td/Tdap (97.3%) and MMR (66.4%) coverage was in line with the recommendations. For all the other vaccines, the coverage was low, varying from 3.5% to 35.4%. The vaccination coverage was better in respondents with higher educated and higher income parents. We suggest that patient education, planning by government for the implementation of a policy for adult vaccination, and involvement of physicians are needed for better adult vaccination coverage.

Key words: adult vaccines; education; income; Mumbai, India; university students.

Disclosure of Interest: None declared.

IN DEFENSE OF MEDICALLY ENHANCING HUMAN MORALITY

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Our species may plausibly boast that, in the relatively short period since it first emerged, it has enormously advanced in knowledge, science, and technical progress. When it comes to our moral development, however, the distance we have covered is comparatively negligible. As a result, man today resembles a mighty giant who has no clue how to use his powers; and just like a child playing with grenades, man has become utterly dangerous to himself, to other species, and to the globe in general. The situation is bound to steadily deteriorate as long as the gap between our powers and our morality continues to increase. What if, however, we could medically accelerate our moral development? Even better, what if we could one and for all render our species totally immune to certain vices? The advances in biomedicine nowadays seem to hold such a promise. In this essay, I will discuss the prospect of medically intervening with the moral disposition of humans in such a way as to even eliminate morally unjustifiable choices. I will claim that such an intervention would not necessarily compromise either the free will or the autonomy of moral agents. To support my view, I will provide a set of arguments based on the Kantian tradition in ethics, since the opponents of moral enhancement mostly evoke arguments that focus on autonomy and free will. I will conclude with the view that moral enhancement by means of pharmaceutical intervention might even be a perfect duty for moral agents in the light of Kantian ethics.

Key words: autonomy, biomedicine, free will, Kantian ethics, moral enhancement, utilitarianism.

Disclosure of Interest: None declared.

UNETHICAL ACADEMIC CLINICAL TRIALS

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Background: Many clinical trials, including those performed in the developing world, are designed and conducted by academics without pharmaceutical sponsorship, input, or supervision. Although many academics are adept at asking and answering basic scientific questions, unfortunately few academic institutions or investigators are equipped to provide the same quality of clinical trial design, conduct, and oversight as those done by the pharmaceutical industry.
Methods: A review of academic clinical trials and documents dealing with the proper conduct of clinical trials was combined with both personal and published regulatory experience concerning the quality of data produced by academic clinical trials.

Results: Academic clinical trials often produce data that are not accepted by regulatory authorities for the approval or labeling of the treatments studied in the trials. Participants in such trials are therefore exposed to risks without producing any personal or societal benefits; by definition, such trials are unethical.

Conclusions: It is proposed that only clinical studies, including those done by academics, that are designed, conducted and monitored in such a way as to produce data suitable for regulatory approval should be funded, approved by institutional review boards/ethics committees, or conducted in the developed or developing world. Increased training of academic investigators, institutional review boards/ethics committees, as well as the public and private groups that fund clinical trials, are needed to decrease the number of unethical academic clinical trials performed.

Key words: academic clinical trials, developing world, ethics, regulatory approval.

Disclosure of Interest: None declared.

RESEARCH PROPOSAL WRITING
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Background: Proposal writing is a skill of fundamental importance to the researchers, and the proposal is an important step in developing a research project that gives an overview of it. It enables other people to understand the scope of the research and the significance of the research, as well as the proposed methodology and chosen research method. The purpose of this paper is to define the research proposal and review its importance and its different types. It also provides a generic outline that focuses on the components and sections of the research proposal and the basic format of each section.

Objectives: The main objectives are to highlight the importance of writing a research proposal. It also aims to define the research and its different types as well as to identify the components and sections of a research proposal and to explain the content of each section.

Methods: A comprehensive literature review on research proposal writing has been conducted by using academic databases and some search engines. The focus was on the general format, guidelines, and presentation that suit students and scholars in different disciplines of life sciences. Various sections of a research proposal are discussed in detail. The focus is to motivate young researchers to take up challenging problems.

Results: The basic definitions of research and proposal in general and in health in particular were given and explained. Useful guidelines for the identification and selection of a research topic were also discussed in detail. The questions relating to whether a research problem is adequately analyzed and whether it is clearly stated were also addressed. Development of research objectives and literature reviews were also discussed. A special emphasis was given to elements of the “Methods” section of a research proposal, as well as the development of a work plan, and the preparation of a budget was highlighted.

Key words: proposal, research, research health system, research methodology.

Disclosure of Interest: None declared.

CLINICAL RESEARCH AND STANDARD OF CARE—AN UNRESOLVED QUESTION?
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Background: Ever since the 1996 revision of the Declaration of Helsinki, the World Medical Association has attempted to address ethical and scientific concerns of its diverse stakeholders for Articles 33 (use of placebo) and 34 (posttrial provisions), most recently in 2013. Both are intricately linked to standard of care, an essential element of any comparative, interventional clinical trial. But has this now 20-year-long ethical debate truly been put to rest? The choice of standard of care in clinical trials remains a complex issue, particularly for comparative trials conducted in emerging countries. Interpretations of the Declaration of Helsinki as the cornerstone document for medical ethics range from best intervention available worldwide to any locally available standard of care for the comparator group, which in the worst case could mean no interventional care at all.12

Objectives: Our aim was to examine the current status of clinical research practice and ethical guidance on standard of care, with a focus on international health research, and to review corresponding guidance issued by pharmaceutical sponsors in their publicly accessible policies on clinical research.

Methods: We reviewed ethical recommendations before and after 2013 and scientific literature, as well as major clinical trial registries (European Union, United States, and World Health Organization), to assess current clinical research practice related to standard of care. Furthermore, the websites of the top-ranked 25 pharmaceutical companies on sales figures in 20144 were reviewed for publicly accessible policies with reference to standard of care in clinical trials in emerging regions.

Results: After a period of active scientific-ethical debate before the 2013 revision of the Declaration of Helsinki, few ethical discussions or recommendations have since been published that could provide additional guidance to clinical researchers. The recent scientific literature reflects the continued challenge for researchers to design an ethically and scientifically sound study, especially in vulnerable populations. However, ~20% of registered open clinical trials across major trial registries are designed with a placebo control, suggesting that the question of standard of care remains highly pertinent. The review of pharmaceutical sponsor websites revealed a highly variable picture with regard to publicly available policies or statements on this issue, particularly for research conducted in low- to middle-income countries. The review outcome spans results from any policy published to very clearly worded statements on clinical research in developing countries, the standard of care aspect during the trial conduct, and regulatory strategies after completion of product development.

Conclusions: Investigators, ethics committees, and sponsors continue to be confronted with the challenge of ensuring ethically and scientifically sound clinical studies with appropriate standard of care. We have attempted to examine available ethical guidance and summarize recommendations for clinical trial designs that could assist in addressing these challenges. Care should be taken to maintain a high level of awareness for the importance of a sound ethical framework for a scientifically valid clinical trial design. Pharmaceutical companies, as major sponsors of clinical research, should demonstrate awareness and an appropriate management of these aspects, particularly in regions with limited resources. As part of the ongoing debate on transparency, one option could be to formulate positions and make them available to the public, regardless of whether such a statement is legally required. A few examples already exist where such clarifying statements have been provided. This approach would prepare the ground for an open and transparent communication to agencies, ethics committee, and, last but not least, patients.

Key words: bioethics, clinical research, Declaration of Helsinki, international health research, placebo, standard of care.

Disclosure of Interest: None declared.