Abstract

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 (post trial provisions), most recently in 2013. Both are inextricably 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.
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None declared.

References


TYPE 2 DIABETES MELLITUS: RISK EVALUATION AND ADVICE IN UNDERGRADUATE STUDENTS IN ASHRAFEH, LEBANON

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Background: Type 2 diabetes mellitus (T2DM) is a chronic lifestyle disease. It has become evident that T2DM occurs even among the younger age groups.1 In Lebanon, T2DM has a major public health impact through high disease prevalence, significant downstream pathophysiologic effects, and enormous financial liabilities.2

Objectives: The aim of this study was to determine the risk of T2DM among undergraduate students from Ashrafieh city by using the validated Diabetes Risk Score Questionnaire. This study also offered T2DM education and awareness to respondents.

Methods: A cross-sectional study was conducted by using a validated questionnaire. Of the total 100 students approached, 79 accepted to participate in the study. Respondents were interviewed and scored by using the Diabetes Risk Score Questionnaire on the basis of 4 parameters: age, abdominal obesity, physical activity, and family history of diabetes.

Results: Of 79 students screened by using the Diabetes Risk Score Questionnaire, 39 (49%) were male, and 40 (51%) were female. In description, 23 (29%) respondents were not doing any exercise, and only 40 (51%) respondents were without abdominal obesity. Overall, 10%, 44%, and 46% of the respondents were found to be in the high, moderate, and low diabetes risk groups, respectively.

Conclusions: According to the International Diabetes Federation, the projected prevalence of T2DM among adults in Lebanon for 2020 is 20.4%. Our study found that only 46% of respondents were in the low-risk category. Thus, it is essential to enhance awareness among the youth regarding T2DM and also of obesity and physical activity, as most of the respondents were found to lead a sedentary lifestyle. Therefore, as per the study plan at the end of the questionnaire, a booklet on “Diabetes Prevention Advice” was provided to all the respondents.

Key words: Lebanon, type 2 diabetes mellitus.

Disclosure of Interest: None declared.

LIFESTYLE AND CHRONIC DISEASES

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Background: The lives of far too many in the world are being blighted and cut short by age- and lifestyle-related chronic diseases such as heart disease, stroke, cancer, chronic respiratory diseases, and diabetes resulting from urbanization, sedentary lifestyles, changing diets, and rising obesity levels. Even problems of child overweight and obesity are increasing worldwide, leading to a growing incidence of type 2 diabetes. India is the second most populated country with a population of >1.2 billion. Along with this, India’s working population is also increasing, which will help the Indian economy to grow at a much faster rate than the other emerging economies. The working population in India is expected to be close to 64% in 2026. However, with the increase in the young working population and change in lifestyle of this young population, there has been an increase in lifestyle-related diseases. The current generation, which is used to deskbound work, alcohol consumption, and smoking, is more prone to such lifestyle-related diseases.2 It is of great concern to observe elevations in the key risk factors that contribute to chronic diseases: use of alcohol/tobacco, obesity, and environmental first have tried unsuccessfully to obtain the property right of a license from the owner. Furthermore, this property right has to be in effect and in place. The licensee must have the ability and the willingness to use the intellectual property right for his own account. Thus, a compulsory license cannot be assigned to third parties. If these aforementioned conditions are met, there are 2 conditions for granting a compulsory license: (1) the licensee has a licensing related to the dependent property rights, which is an essential advancement of the patented technology; or (2) there is a public interest in granting a compulsory license, which is much more common in the case of pharmaceutical patents. Normally, public interest is defined that a medical treatment method or a drug (in the legal sense) should be accessible for each person in principle. This accessibility is not been given if a treatment method or a drug is only offered subjectively too expensive. Rather, a particularly high benefit must be claimed; e.g., initial treatment option of common diseases with good prospects of efficacy, e.g., the domestic market is insufficient supplied or if the drug or the investigational medicinal product has much less side effects so far. Public interest is, in this case not stated, if the treatment results can be achieved with other, more or less equivalent, alternatives. For example, the European Union (EU) published on May 17, 2006, a Regulation (EC Regulation No. 816/2006) on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. This regulation establishes a procedure for companies in the EU wishing to manufacture generic medicines for use in the developing world to apply for a compulsory license from a patent holder, which allows their manufacture. The legislation is part of wider EU action to tackle public health concerns that the world’s least developed and developing countries face, in particular access to safe, effective, and affordable medicines. This article compares arguments of both opponents and proponents of compulsory licensing, which is a legitimate safeguard provided under the EU and in the same line as the TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights by the World Trade Organization) to check misuse of monopoly and to deal with situations of public health crisis, especially in the Third World.

Key words: access to drugs, compulsory licensing, pharmaceutical patents, public health, TRIPS flexibility.

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References


COMPULSORY LICENSE IN THE EU—TWO SIDES OF THE SAME COIN

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A compulsory license state-order is limiting the effects of an industrial property right. To obtain a compulsory license, a licensee must

Abstract

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