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GOOD ETHICAL PRACTICE IN VACCINE RESEARCH

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The main idea of this article to present and to build up an open discussion about the principles of the Good Ethical Practice in vaccine research – was born out of a clearly perceived need: to facilitate critical decision making in nowadays' vaccinology. The article aims to provide the readers with a comprehensive overview of this increasingly complex field. The generally accepted ethical standards for vaccines clinical trials, and various social, economic, ethical and political issues connected with the development and successful implementation and sustaining of the current vaccination programmes are dealt with. The article is based upon fundamental ethical standards and includes the presentation of universal principles of ethics in vaccine research and review of the main and essential international guidelines on ethics in this field. The paper has been prepared and introduced in collaboration of the Educational and Ethics Working Parties of the European Forum for Good Clinical Practice (EFGCP).

***Key words**: ethical problems in vaccination, universal ethical principles, international guidelines on ethics in vaccine research.*

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Основная цель данной статьи представить материалы и открыть дискуссию о принципах качественной этической практики в исследовании вакцин. Настоящая цель была порождена черезвычайной необходимостью найти и совершенствовать путь принятия ответственных решений при осуществлении вакцинопрофилактики в современном мире. Статья познакомит читателей со сложными этическими вызовами, имеющими место в данной области и представит общепризнанные этические стандарты исследования вакцин, а также социальные, экономические и политические аспекты, влияющие на развитие и успешное внедрение современных программ вакцинации. Данная статья основана на универсальных этических принципах, включает фундаментальные основы этики исследования вакцин и обзор международных руководств по данной проблеме. Материал подготовлен по инициативе рабочей группы по образованию и рабочей группы по этике Европейского Форума по качественной клинической практике (EFGCP).

***Ключевые слова:** этические проблемы вакцинации, универсальные этические принципы исследований, международные руководства исследования вакцин.*

Vaccination is considered being one of the most beneficial and successful preventive health care measures. Nevertheless, both in its early history and also nowadays, it is frequently faced with some poorly defined criticism, popular concerns and even fears, fuelled by various conspiracy theories and pseudoscientific claims of vocal activists of its opposition. Those criticisms are sometimes posed as alleged serious ethical problems, and together with uncritical stepping in of the seriously biased media, they may indeed influence the efficacy and even safety of well established, necessary vaccination programs, both as seen from the public health, and from an individual perspective [18, 22, 23]. There are several important reasons to be concerned about nowadays vaccinations, including the respective epidemiological, scientific, social, economical and political aspects [1, 4, 19, 20]. Each of these reasons and each stage of the research and development of vaccines, as well as, of their practical implementation, bear also upon itself a strong "ethical part" of the problem. Therefore, it could only be solved in full by a simultaneous analysis and appropriate dealing with the said inherent ethical and legal aspects of the vaccination policies.

Currently, as already mentioned, one of the most critical and obviously dangerous players in the field is the so-called anti-vaccination movement. Paradoxically enough, the population scale, publicly funded, regular vaccination programs are subjected nowadays to elaborated attacks led by the activists of the quite influential anti-vaccination lobby. Albeit relaying upon so many times rebuffed „arguments" based on the 'bad science' and 'conspiration theories', the real impact of the anti-vaccination movement, unfortunately, is posing a serious public health problem in many countries, especially in those with a well developed vaccination systems and basically good enough situation within their health care provision [16]. Part of the confrontation, interestingly, takes place in the ethical realm, as the anti-vaccination activists allege that the vaccines themselves, as well as the

programs of regular (in many countries compulsory) vaccination are un-ethical. An excellent illustration of the urgency of the situation mentioned above, and of the necessity to deal seriously with the ethical issues in contemporary vaccinology, including the need of better information and systemic education of the general public, could be the data about ethical problems in vaccination in different countries (including Russia and Slovak Republic). The comprehensive analysis of the situation with regard to the applicable national legislation; the practice of scientific and ethical evaluation of the vaccine research; and the system of epidemiological surveillance and monitoring of the vaccination programs in Russia and in the Slovak Republic demonstrated serious risks involved in the situation, when a well-established, state funded, compulsory vaccination system becomes the target of a concerted attack from an unexpectedly effective anti-vaccination movement [1, 2, 17]. As it presented in Slovakia, this had grown up and risen to its present self-made public prominence during about the last decade, and, would probably stay present, no matter what, for still some time to go. The case story of managing this 'all-out attack' on the regular vaccination system in Slovakia might resemble similar developments in other countries of the Central and Eastern Europe that might had been seen after falling down of the former 'Iron Curtain' [17]. The historical event that was followed by considerable economic, social and cultural changes and the advent of a widely available internet and other social media is characterised the using of any possibility to influence on the public mind and opinion, including the religion aspects what could provide the vaccination refusals [5, 6].

The most important and possible approaches to combat existing problems stand on correct information about the real nature of ethical aspect and special attention should be paid to the role of education in the renewed acceptance of the ethical conception of vaccination, as well as in building of the adequate communication and trust in the primary health care to enable the transfer of the relevant, necessary knowledge from the scientists and experts to the general public. The model of perfect functioned system for vaccination should be based on a wide scale education of the general public and marked with a strong respect of the principle of autonomy seems to be successful enough to maintain acceptable vaccination rates. The way to combat the problem brought in also an interesting experience of using a well developed strategy to counter the anti-vaccination activities effectively. It included mobilisation of decisive stakeholders for taking up the appropriate, necessary actions that helped to finally prevail in the confrontation [17].

All statements and arguments mentioned above have the real chance for its practical realisation only in the case if they will be based upon the well established, shared and implemented ethical standards. This requires from the medical professionals and researchers to possess an adequate knowledge and understanding of the universal principles of ethics in vaccine research and following of the pertinent international professional and ethical guidelines in the field.

According to the general principal of ethics in vaccine research, first of all, it is absolutely important to accept that the research on and with new vaccines encompass a huge area of the pre-clinical and clinical research activities, prompted by the still unmet and growing health needs of contemporary human populations – and those to come. Challenges for the vaccines preventive uses aimed to ameliorate devastating epidemics, or even eradicate completely at least some of the most dangerous pathogens, are being broadened by novel therapeutic strategies in some areas of modern medicine, not least by the need to deal with the ever increasing microbial resistance rendering gradually the present-days antibiotics ineffective against scores of boldened nosocomial pathogens [21].

Down the long way each new vaccine makes – from the perceived particular clinical/health need, through an innovative researchers' idea, via in vitro and in vivo (cell, tissue, and animal) pre-clinical experiments and testing, till the first safety studies in healthy human volunteers, then to clinical and field safety and efficacy studies and, after obtaining marketing authorization, to the meticulous monitoring of the vaccine's performance in the 'real life' clinical practice – numerous ethical issues are being encountered by researchers, research subjects (and their parents or relatives), and also by the society enlarge, which is understood to be represented within some parts of these complex processes by independent (research) ethics committees and competent state authorities. These tasks are further extended towards respected intergovernmental bodies and/or their specialised agencies. [16]

Albeit several of the said ethical issues might pose interesting objects for an ethical enquiry, there are some of them deemed to be of a particular practical importance, especially in connection with contemporary public debate in many countries with opponents of regular vaccination, especially those made compulsory by the applicable national legislation.

In the area of yet an experimental phase of the vaccine research, the question about the origin of human cell lines used is frequently risen (connection to the procured abortion), needless to say anything about the restrictions placed on the use of animals in the experiments or in vaccines (or prospective medicinal drugs) testing. [16]

In the realm of clinical testing, all well-known ethical requirements and limits apply to the vaccines clinical research and field testing in humans, as in the case of any other biomedical research preparation, conduct, evaluation and reporting. Those are well embodied in the WMA Declaration of Helsinki (1964, 2013), CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (1982, 2002, 2016) and CIOMS International Ethical Guidelines for Epidemiological Studies (1991, 2008) and other widely accepted 'soft law' international texts, as well as in the Council's of Europe Convention on Human Rights and Biomedicine (Oviedo, 1997) and in its Additional Protocol on Biomedical Research (Strasbourg, 2004) [11, 13-15, 25].

Evaluation of any foreseeable risks for a study participant must be at the core of any ethical evaluation prior to the study commencement, and during its conduct. Especially, when medical issues involved are complex, or if there is any contextual duress or a dramatic shortage of time (e.g. developing a new vaccine vis a vis a devastating epidemic). As vaccines are usually developed to be used with distinctly preventive aim on a large, truly population scale in infants, young children and minors, besides their use in adults, the requirements concerning their safety profile are especially important and demanding. Those and any other applicable ethical requirements must be fully embodied in the vaccine testing clinical protocol, which must be, in parallel to the meticulous scientific scrutiny, the subject of an appropriate ethical review by an independent (research) ethics committee. Any procedural or professional shortcomings in the protocol review process are unacceptable. On the other hand, their adequate observance supports credibility of the said research data, as well as of the developed vaccine itself. [16]

The next relevant aspect dealt with a thorough information and analysis from a practical clinical research perspective of the International Guidelines on ethics in vaccine research. It should be stressed the importance of a meticulous implementation of the accepted international standards and pointed out some of the still unmet needs in this area, especially the need to improve the professional education in this area, as well as to inform adequately the general public.

Nowadays there are around 400 international guidelines, recommendations, and statements on the subject of research ethics. The first attempt to systemise them on the principal of the organisations, where they were produced, was done by Dr. Sev S. Fluss, Secretary General of CIOMS in 2000. The critical point in the huge list of these documents is the understanding of its different roles and value. There should be done the identification of the main purpose (aim) for the creation of different guidelines. Concerning to this point, it could be dedicated three types of guidelines. The priority purpose of one of them is to express and to adopt the common agreement on the universal ethical principles. The best example of such guidelines could be Council's of Europe Convention on Human Rights and Biomedicine (Oviedo, 1997) and its Additional Protocol on Biomedical Research (Strasbourg, 2004). The purpose of the others guidelines is to ensure: protection human rights (UNESCO Declaration "On Bioethics and Human Rights", 2005); the moral background for cooperation and collaboration (WMA Declaration of Helsinki, 1964, last update 2013) or the common recognition the ethical and efficacy's standards in research (ICH GCP and E6 Addendum, Brussels, 1991) [11, 12, 24, 25]. The special aim of the other documents is to give the practical recommendations for ethical actions in relevant field. The example of such document is "International Ethical Guidelines for Epidemiological Studies", prepared by the CIOMS in collaboration with the WHO, Geneva, 1991, updated 2008 and lately included into the updated CIOMS Biomedical Research Guidelines of November 2016, cited above) [13-15].

The next important difference of the number of international guidelines is the status of the document. From this point of view, there could be indicated the documents with legal force/power, provided legal obligations for the

partners joined/ratified these guidelines (for ex., CE Convention and its Additional Protocol, 1997, 2004). The other type of guidelines includes the documents with high moral force, such as Nurnberg Code (1948) and Declaration of Helsinki (1964, 2013). And at last, but not least, among the number of different international documents, there are the guidelines with unique practical force, what usually depends on the authority/prestige the organisation, where such guidelines were prepared. In the case of ethical aspect of the vaccines research, such role could be played by mentioned above "International Ethical Guidelines for Epidemiological Studies", CIOMS/WHO, Geneva, 1991, 2008. This document consists of 24 special guidelines which target to all most important ethical aspect of research and all together cover the whole spectre of the urgent problems for protection authority, dignity of the potential participants and data integrity, clinical quality and compliance, as well as, the justice of research in general. The detailed analysis concerning the subject how to use and follow the international guidelines with the aim to reach the ethical justification and scientific validity of vaccine research involving human subjects was presented by us recently in special publication [3]. New technology in research raises new challenges about ethical aspects of using the internet or stored biological samples and related data. Many global world communications and deep differences in vaccine R&D between developing and developed countries face many questions concerning the ethical obligations of external sponsors in host countries; vaccine research in populations/communities/countries with limited resources with local input to health-care services. Many ethical questions are still opened for involving vulnerable populations in vaccine research. Thus, some needy improvements in so far not very positive attitudes of the public toward the vaccine trials might be achieved.

Following upon the same line, the paper on the National Guidelines on Ethics in Vaccine Research in Russia, stressed the need to strictly observe applicable national legislation and relevant ethical standards to ensure the high quality and credibility of the vaccine research, together with a strong protection of research subjects [7-10].

In conclusion, it should be clearly indicated that the best way to have the ethical comfort in vaccination all over the world is the education of specialists and of the public and that the reasonable bridge to reach this ethical comfort connected both sides acceptation of universal ethical standard and future development ethical and legal regulation in local, regional and global levels.

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