ETHICS OF PREVENTION THROUGH VACCINATION

Vaccination in accordance with the collective immunization programs accepted by all countries is a public health priority. The success of the Extended Immunization Programs for the control of infectious diseases causing numerous deaths and disability in the past was encouraging. Smallpox eradication, certified by the World Health Organization in 1980, and the optimistic outlook of polio eradication in the near future, keeping under control other diseases such as measles, diphtheria, tetanus, whooping cough, etc., health and life-threatening conditions less than a century ago, have encouraged the development of the science of vaccinology in order to obtain preparations with a high degree of specific protection and reduced risk for the individual (1).

Despite the benefits demonstrated in hundreds of years of vaccine use, initially obtained by empirical techniques and more recently by advanced technologies based on knowledge of molecular medicine, applying the principles of ethics lead to controversies related to the acceptance by the population of forced or mandatory immunizations. Conflicts between individual rights and the interests of society in achieving immunization by ensuring vaccination coverage close to the ideal value, which scientifically certifies protection against aggression of some microorganisms are inevitable. For collective immunization programs implementation 7 ethical principles were formulated. Thus, Verweij and Dawson (2) take into account the ethical aspects of immunization programs implemented in the general population, starting from the questions: how should the inclusion of a new vaccine be decided? or in what circumstances mandatory immunization is acceptable?

Ethical principles relate to: only severe vaccine-preventable infectious should be targeted, each vaccine has to be safe and effective, the risk to individuals should be minimized, the risk / benefit ratio of the program should be favorable compared with that of alternative programs, benefits and risks should be properly distributed, voluntary participation should be a primary goal in applying immunization, public confidence must be cherished and protected. Establishing a balance between individual rights and community benefit, immunization strategies will continue to pursue the achievement of protection against those diseases that are real public health issues or of interest for the individual unable to protect himself by other effective means.

Ethical issues related to vaccines are particular and very different from those specific to other drugs. Ethical considerations related to vaccination refer to how to design and conduct clinical and postmarketing trials on vaccines safety and distribution. The threat of possible future pandemics or bioterrorism are arguments supporting the need for comprehensive review of ethical issues on prevention through vaccination. They can rely on the analysis of the steps taken in obtaining vaccines, from the first research stage to the introduction of a new preparation in the national immunization programs by administering it
to vulnerable population groups.

**Prevention versus treatment.** In contrast to drugs or other medical interventions, vaccines act to prevent disease rather than treating it. Ethics of prevention differs greatly from that of treatment, and the most important factors are associated with the different significance of risk.

As to treatment-related ethical issues, it is believed that when a disease is treated the risks are limited to two broad categories: risk associated with a particular treatment (a certain medication) and risk associated with the lack of treatment (risk that arises from the fact that treatment is not administered according to the given clinical situation). These risks must be weighed against the anticipated potential benefits. A treatment decision should be taken based on the evaluation of all options in terms of risks and benefits, all compared with the consequences of not taking any attitude. Ethics of prevention leads us to believe that when you decide to prevent a disease through vaccination, risk assessment due to lack of action is more complicated because in this case the consequences of disease progression and the likelihood the disease to occur even tough given the progress in the past decades of immuizing preparations the incidence of many vaccine-preventable diseases has decreased significantly both in developed and developing countries have also to beevaluaeted. When discussing issues of **prevention and treatment ethics** the main difference between the 2 categories is: prevention is important at both individual level and that of the society as a whole, while the last broader perspective does not apply to treatment. Also, issues related to justice and scarce resources are of major ethical relevance in therapeutic decision making.

As a preventive measure, vaccination requires individual autonomy to overlap with the interests of society, the ethical consequence of these dual values being "herd immunity", protection of population (against a disease) through increased vaccination rates and resulting in reduced circulation of the pathogen in the community. Unvaccinated individuals bear some benefits by "herd immunity", and thus a potential ethical issue of "free-riders", defined as individuals who benefit from vaccination programs without taking any personal risk to the direct administration of the vaccine.

**Vaccination and target populations.** Healthy children are the largest target group for vaccination. Children are ethically vulnerable because they cannot use their autonomy to estimate the risks and benefits of vaccination. Worldwide most vaccines are recommended for children in the first months or years of life, so that the beneficiaries belong to the most vulnerable population groups. Parents or legal caregivers must be able to handle large amounts of information, often contradictory, related not only to vaccines, but covering all aspects of child health care, being forced to make decisions in child’s interest. Children receiving vaccines are healthy, at least in terms of the disease for which vaccination is administered. Public health law requires routine vaccination as a condition for attending preschool and school. This attitude explains the widespread binding of panic, often generated by reports of actual or suspected concerns related to vaccine safety.

A key issue is **communication** between health care providers and vaccine recipients (or their parents/legal guardians) on the **need, benefits and risks** of vaccination, and obtaining the informed consent.

**Research on new vaccines.** According
to modern history of vaccines, the successful development of a new product is based on the collaboration between academic medicine and pharmaceutical industry. The expertise and infrastructure of each research group contributes to the transition from fundamental research to the development and clinical testing of a new vaccine preparation. Financial support for such activities comes through: investment funds, government-sponsored research, philanthropic groups interested in developing vaccines. These groups aim to develop a safe and effective vaccine, but, if uncontrolled, any possible conflict of interest may prevent the obtaining of a final vaccine product, may cause loss of financial resources and lack of protection for human volunteers, which ethically is unacceptable. Each partner involved in vaccine research must meet its obligations and be aware of the usefulness of his work the sole purpose of which is to save lives and prevent suffering. Research partnership becomes even more complex when it includes clinical testing in developing countries and the contribution of local researchers in this field. These collaborations bring the expertise and opportunities needed by the countries without a strong infrastructure for medical research. The ethical benefits of such collaborations are multiple, including the advantage of health care professionals trained to work in this field even after the completion of research, and involvement of local (national, regional) professionals, which provides additional protection to volunteers, especially if these studies are carried out in developing countries.

Ethical controversies are also related to the design of clinical trials, especially in developing countries. An example frequently mentioned in medical literature (3,4) are HIV vaccine trials conducted in developing countries. The level and duration of health care for the study subjects who were HIV infected during the trial may be different, from lifetime treatment with latest generation anti-retroviral medication (usual treatment in developed countries, but practically less available in most economically underdeveloped regions of the world) to current treatment in the country in which the trial is conducted (often under the level of care in the country sponsoring the research). Another example of the use of ethical principles in establishing the population in which a trial for candidate vaccine is conducted is that it should match as close as possible the groups to receive the vaccine once licensed. Violation of this principle has been reported in children with mental retardation included in a vaccine trial in the 50’ and 60’ (5).

Recommendation for vaccination.
Worldwide, countries rely on various vaccination models for general population, the experts in the field developing a National Immunization Program schedule. Mandatory vaccination reflects a sometimes antagonistic relationship between individual autonomy (or parent/legal guardian in children) and health preservation for the general population. Vaccination is not compulsory to primarily protect the health of a single individual but to limit the spread of the pathogen in the population as much as possible. Some contemporary ethical models place autonomy above all consideration. In vaccination, there is a strong argument in favor of immunization, namely its benefits reflected in the number of saved lives and avoided suffering in the community.

The recent introduction of the vaccine to prevent infection with Papilloma virus (HPV) brought up for discussion the con-
sequences of vaccinating children against sexually transmitted infections. Concern expressed by some groups is that adolescent HPV vaccination may impact a decision on subsequent sexual behavior, increasing the likelihood of promiscuity and providing a false security that they are protected against sexually transmitted infections. Scientific evidence suggests that HPV is a trivial factor in decisions regarding sexual behavior among adolescent girls and questions the validity of these concerns about behavioral disinhibition (6). Unlike hepatitis B vaccine (HBV), another vaccine preventing an infection that can be also sexually transmitted, HPV vaccine is given to pre-adolescent children. However, the decision to vaccinate or not the child lies solely with the parents/legal guardians, and therefore finding the best way to communicate accurate information about the type and level of protection provided by that vaccines is essential. Such public health strategies require that professionals in preventive healthcare to provide explicit information on the efficacy of vaccination in reducing the risk of sexually transmitted infections through education programs (7).

Trends in ethics of prevention through vaccination. Progress in vaccination is primarily attributed to gains in scientific knowledge, research discoveries, and coherent public health policy. Vaccination success depends on maintaining public confidence, without which vaccination programs can not succeed. Also, maintaining public confidence requires constant awareness of the fact that the greatest benefit the society enjoys because of vaccination, essentially involves the individual.

References