

Bioethics and mass childhood vaccination

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Resumo

As vacinas são consideradas como uma das maiores conquistas da humanidade no controle e erradicação de doenças infectocontagiosas e também uma das técnicas biomédicas mais polêmicas e de maior controvérsia considerando os riscos de efeitos adversos e a sua forma compulsória de utilização em milhões de crianças saudáveis. O atual paradigma preventivo de vacinação em massa tem sido desafiado nas últimas décadas por mudanças nas relações com a imunização, melhoria das condições sanitárias das populações e pelos surgimento de declarações universais de proteção do ser humano. Com isso, o presente artigo pretende analisar a vacinação infantil em massa sob a ótica da bioética no contexto individual e coletivo e criar um ambiente de discussão para reflexão ética sobre os programas de vacinação. Concluímos que a bioética em sua nova concepção conceitual propõe novos referenciais teóricos e metodológicos que podem ser utilizados para o debate ético das atuais políticas sanitárias.

Palavras-chave: Bioética. Vacinação em massa. Efeitos adversos. Política de saúde. Brasil

Resumen

Bioética y la vacunación infantil masiva

Las vacunas son uno de los mayores logros de la humanidad en el control y erradicación de las enfermedades infecciosas y también una de las técnicas biomédicas más discutidas y de mayor controversia teniendo en cuenta los riesgos de efectos adversos y su obligatoriedad de uso en millones de niños sanos. El paradigma actual de la vacunación masiva preventiva ha sido cuestionada en las últimas décadas por los cambios en las relaciones con la inmunización, la mejora de la salud de la población y la aparición de las declaraciones universales de protección humana. Por lo tanto, este artículo tiene como objetivo analizar la vacunación infantil masiva desde la perspectiva de la bioética en el contexto individual y colectivo y crear un ambiente propicio para la discusión de la reflexión ética sobre los programas de vacunación. Llegamos a la conclusión de que la bioética en su nuevo concepto propone nuevos marcos teóricos y metodológicos que se pueden utilizar para el debate ético de las políticas de salud actuales.

Palabras-clave: Bioética. Vacunación masiva. Efectos adversos. Políticas de salud. Brasil.

Abstract

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Vaccines are considered one of the greatest achievements of mankind in the control and eradication of infectious diseases and also one of the most controversial biomedical techniques and greater controversy considering the risks of side effects and their compulsory use in millions of healthy children. The current paradigm of preventive mass vaccination has been challenged in recent decades by changes in relationships with immunization, improvement of sanitary condition of populations and the emergence of universal declarations for human protection. Thus, the present work aims to analyze the mass childhood vaccination from the perspective of bioethics in the individual and collective context and create an environment for discussion of ethical reflection on vaccination programs. We conclude that the new bioethics' approach proposes a new theoretical and methodological framework that can be used for the ethical debate of current health policies.

Key words: Bioethics. Mass vaccination. Adverse effects. Health policy. Brazil.

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Vaccines are considered one of the most effective and lower cost-effective medical technologies. It is used worldwide in the control and prevention of infectious diseases, revealing itself to be particularly important in developing countries that have poor sanitary conditions and lack of resources for public health actions. Because it is clearly one of the most universal and globalized medical safety policy and technique, it seems difficult to eliminate the ethical attraction exerted by the ideology of vaccination for all ages, sexes, all races and all peoples.

It is undisputed that the policies of compulsory childhood vaccination contributed substantially to the success of vaccines, resulting in increased immunizations and the consequent reduction in the incidence of vaccine-preventable diseases. As these diseases become extremely rare, and even unknown by most of the world population, a paradox was established in health achievement: the public's attention is no longer focused on vaccine-preventable diseases, but in the safety and efficacy of vaccines¹. Thus, the ethical question of vaccines has changed², considering they are sometimes forcibly administered to healthy children without proper perception of epidemic risk or moral issues related, for example, autonomy and vulnerability.

The success of a vaccination program is directly related not only to increased immunization coverage rates, but also to the need for vaccines that have high safety standards and full acceptance by the population. In developed countries, the fears of adverse effects of vaccines have become more evident with decreasing risk perception caused by preventable diseases³. This fact led to falling immunization coverage rates and the resurgence of diseases that had been controlled in the past^{4,5}. However, the poorest countries, whose populations still live in direct contact with the problems related to infectious diseases, are less reluctant to take risks to protect themselves through vaccines.

The vaccine, and especially its form of universal use, seems to be the panacea for solving contemporary health problems of former and current public health whether to face persistent epidemics or emerging diseases that are only heard about in encyclopedias of human health. The war against germs, associated alarmism pandemic has caused disturbing situations.

When checking the vaccine cards randomly for children 1-5 years old, when comparing the number of doses recommended by the manufacturer regarding the number of doses recorded on the card, Nogueira⁶ found the tendency to extrapolate doses

considered sufficient to immunization. Although the increased number of doses recorded refers only to oral polio vaccine, which does not bring danger to children who receive it, the fact illustrates the tendency to extrapolate the prescribed dose.

However, this dominant health paradigm has been challenged in recent decades by changes in relationships with immunization⁷, improvement of health conditions of populations, the adverse effects of vaccines and the emergence of universal declarations of human protection, such as the Universal Declaration on Bioethics and Human Rights⁸ - events that create an environment for ethical discussion on current health policies adopted by countries.

Thus, this article aims to analyze the current model of mass childhood vaccination from the perspective of bioethics. To do so, considering the close relationship physician/health professional versus patient, the principlist current⁹ will be used, which although not unanimous even in their country of origin for the resolution of conflicts in these relationships¹⁰, it was created as a theoretical framework to defend the weakest individuals in the relations between health professionals and their patients. It will also be used another theoretical approach of bioethics more related to the social dimension of health and considers their moral reflections the fragility and vulnerability of groups or social segments such as anti-hegemonic epistemological proposal, enlarged and politicized¹¹.

Vaccines and ethics: uncertainty, controversy and conflict

Anywhere in the world, it is extremely unlikely, nowadays, to find someone who has never been touched by the issue of vaccination, especially vaccination promoted or imposed by the state. Thus, the ethical conflicts of vaccines associated with its universal form and compulsory administration demonstrate the difficulties of having an absolute judgment on the rational foundations of vaccination and the interrelationship between the human sciences and biomedical.

The world has undergone profound techno-scientific, cultural and ethical changes. It is in this perspective that can be found several particular factors to establish a moral analysis of vaccination, for example, the unpredictability of its effect on the human body in the long term, the emergence of universal declarations of human rights protection, the modification of the relationship doctor-patient, con-

temporary moral pluralism and the individual and collective conflict of interest.

The discovery of vaccines has crucial importance in the history of medical ethics. In the late eighteenth century, in the midst of an epidemic of smallpox, the English physician Edward Jenner in a revolutionary experiment, inoculated lymph lesions of a milkmaid in a boy, James Phillip. After some time, Jenner inoculated him over the fluid extracted from a smallpox lesion. The boy resisted and did not have the disease, proving the effectiveness of his thesis about the technique of immunization¹². This experience from Jenner, although it seems unethical in current perspective, it did not raise any moral dilemma at the time¹³ as the terror smallpox was widespread, being considered the most dreaded disease of the eighteenth century, which decimated entire populations.

These events occurred with the discovery of vaccines lead us to questions about the context in which they have been tested and accepted by the population in the past and how they are considered and used in the present. The bioethical analysis of vaccination allows a magnified view of a complex reality and, going beyond reduced and discipline analysis, making it more interesting and also more exciting. As stressed Moulin¹⁴, this approach is important not as a control mechanism, but it can also serve as an answer to a medical procedure that can be fallible or incompletely validated, applied untimely and often poorly explained and commented.

It is necessary to counterbalance the vaccination's triumphalist history as medical science and technology with the careful and thorough examination of its impact and its future consequences in the human subject as a moral being. Although this recognized and incontestable glory has been achieved over time, vaccines are also considered as one of the most controversial biomedical techniques, raising heated scientific and ethical debates. The efficacy and safety of vaccines, as well as immunization programs implemented by governments, and the injustices of unequal access to the benefits and costs of vaccination were intertwined throughout the history of vaccines and remain controversial to this day¹⁵.

The current global health condition achieves success and credibility to vaccines. However, according to Bazin¹⁶, eradication of diseases such as smallpox, and probably soon, polio, was and will be due to hygiene associated with vaccination in developed countries, but only by vaccination in poor countries that do not have access to drinking water and can not eliminate their waste properly. This the-

sis seems to be true when we consider that some diseases for which there are no vaccines, such as cholera, dengue, Chagas disease, only exist in the poorest countries that have poor sanitary conditions. For Holland¹⁷, the mass vaccination programs are controversial because their justification depends on which health direction is at stake.

One of the controversial issues and with respect to vaccine safety refers to the presence of preservatives and additives in their composition, which are used to reduce the economic cost of the pharmaceutical industry, since the adjuvant allows the use of less antigen in each dose and preservatives are used to prevent bacterial and fungal contamination in multidose presentations since manufacturing vaccines in monodoses is more costly due to the need of multiple packages, in addition to other problems related to storage, preservation and delivery to the application sites.

Uncertainties and controversies about the safety of vaccines had global repercussions after publication of article of Wakefield¹⁸ in the Lancet magazine, postulating that vaccination against measles, mumps and rubella (MMR) could be casually linked to autism because of the temporal association between the age at which children are vaccinated and the age at which begins the emergence of this disease. Wakefield's article was discredited (including by engaging scientific fraud) and removed from the list of articles published by Lancet (retracted). Despite this, it served to several researchers to initiate studies to evaluate the effect of preservatives and adjuvants in vaccines - which so far have shown there is no scientific evidence for this association¹⁹⁻²³.

Another argument is that routine childhood vaccination with thimerosal-containing vaccines (TCV), which have mercury-based preservative and are administered soon after birth, could expose infants to unsafe levels of ethylmercury^{24,25}. Despite the consensus between the World Health Organization (WHO) and the American Academy of Pediatrics as a negligible risk of thimerosal in vaccines on the amount present, studies to evaluate the toxicity of mercury in the form of thimerosal²⁶⁻³¹ do not consider the relationship between iatrogenic mercury exposure through vaccines to dietary exposure, as in the breast milk or fish, which has been researched by groups in Brazil and other countries. As a precaution, some countries, like the United States of America (USA), no longer use thimerosal in their vaccines. Chile has a bill in the Senate to remove it³². The most challenging dose of compulsory immunization

programs is that due to the small body mass of babies, the impact of mercury administered by some vaccines, such as hepatitis B in the first 12 hours of life, is equivalent to twice the dose of DTP and hepatitis B added together, received at six months of age. Thus, a substantial number of children worldwide are getting through vaccines, doses of mercury above the limit considered safe. But countries like Hungary, Japan, Netherlands, Sweden, Switzerland and England do not use hepatitis B vaccine in their infant immunization schedules³³.

As a result of these uncertainties, the fact is that the monovalent or multivalent vaccines used in the U.S. and Europe in their childhood vaccination programs are free of thimerosal since 2004³⁴. However, most countries are still using VCT into their childhood immunization programs by WHO recommendation³⁵, including Brazil. Thus, the populations of the "peripheral countries" do not receive the same vaccines used in countries with better enforcement or more refined private services. Whereas the universal vaccination is a global practice and infectious agents that affect the world population are the same, why is there a difference between the types of vaccines administered between rich and poor countries?

There is no doubt that in a highly immunized population the risk of getting a particular disease is extremely low. However, for some diseases, such as polio, the expected occurrence of paralysis associated with the vaccine virus has expected and assumed risk by the global polio eradication program³⁶. For the Advisory Committee on Poliomyelitis Eradication (ACPE)³⁷, continuing the reintroduction of poliovirus attenuated through vaccines in a polio-free world results in cases of poliomyelitis caused by vaccination. This risk is not only disturbing as it requires extensive discussion and knowledge on the part of society and governments that adopt these strategies. The presence of cases of paralysis caused by the same vaccine policy that aims to eradicate constitutes the main technical and ethical dilemma of post-polio elimination³⁸. Brazil has demonstrated progress in relation to vaccination against polio, as included in the childhood vaccination schedule in 2012 the injectable inactivated polio vaccine³⁹, which will be replaced by the attenuated oral vaccine, used in the U.S. since 2000⁴⁰.

Another issue that has a strong ethical dilemma regarding the use of vaccines in the schedule of mandatory vaccinations for certain diseases for a specific age group or a particular exposed risk group⁴¹⁻⁴³. In the U.S., the introduction of compulsory vaccina-

tion against human papilloma virus (HPV) in children 11-12 years has been the subject of many ethical debates, since the vaccine's efficacy is greater in people who are not yet sexually active⁴⁴. Compel immunization of whole populations that are not under the same risk of acquiring or transmitting diseases is an ethical nonsense. In this case, one of the main arguments against this practice is that the risk of exposure and/or to acquire certain types of disease are different, as they are influenced by several factors, and in the case of common diseases there is no reason to assume any risk level of any adverse effects of the vaccine⁴⁵.

It is a fact that the risks of vaccines are known since the early days of its use in the health context of that era whose epidemics still decimated populations. However, in developing countries, such as Brazil, these issues have not had the same attention given by developed countries, since the focus of the government particularly focuses on maintaining high levels of vaccination coverage or on issues related to persistent social exclusion, distribution of income and access to basic health services - which are still part of the list of demands of the majority population.

Vaccination and principlialist bioethics

Recently, there has been great interest of ethics for public health issues based on a social responsibility to protect and promote the health of the population as a whole⁴⁶. However, especially in questions of health, public health and preventive medicine have been neglected areas in bioethics, which has more focus on the collective interests, rights and obligations than in the individual values and interests⁴⁷.

In the field of so-called applied ethics, bioethics emerged to account for the moral conflicts and ethical problems arising in the context of actions in health and the biomedical sciences. Thus, it is understood that at first, bioethics can be regarded as a legitimate and efficient tool for critical analysis of the morality of contemporary vaccination practices and as an aid to decision making, ethically justified, by health actions that ensure equitable distribution of both the benefits and possible risks of vaccination.

The principlialist current that became classic, focuses mainly on some moral principles whose application supposedly leads to the solution of ethical dilemmas in health care: autonomy, beneficence and justice. These four principles work, roughly, as

prima facie obligation. As it is not uncommon that they conflict, especially in the context of collective actions, the moral analysis of an action that considers the different values and interests must be counterbalanced so that moral agents eventually be able to reach a conclusion on how they should act⁹.

Blurred boundaries between beneficence and non-maleficence of mass vaccination

Several preventive actions of routine use, such as vaccination, involve some degree of risk to patients. In the context of principlist bioethics, it is necessary to respect the principle of non-maleficence, given that health workers have the ethical principle of not causing harm to their patients (*primum non nocere*). In parallel, as preventive activities aimed in the first instance, to protect people against infectious diseases, we assume that the vaccination procedure also complies with the principle of beneficence. In this case, considering that it is morally undesirable to cause harm to people, either by exposure to the risks of adverse effects of vaccination or by exposure to diseases due to lack of immunization, which moral principle should be considered when the risks and benefits of vaccination are distributed unevenly among the population?

In many practical situations it makes no sense the balance between very different principles because many principles or values are incomparable. This occurs in cases where a particular action is the best in some relevant context, while another is better over another relevant context, but there is no obvious truth about how they should be compared considering all relevant contexts - in this circumstance, the actions are "on par" or in parity⁴⁸. As an example, the vaccine against pandemic influenza, whose morals or values related to its administration are disparate. In this case, why should we believe that protecting children from the risk of getting the flu is more important than protecting them from the risk of being affected with any adverse effects of the vaccine?⁴⁹.

Since vaccines are not 100% effective⁵⁰, one can not say with absolute certainty that an individual did not acquire certain disease due to acquired immunity by vaccination or due to collective immunity, since there are several factors that influence the achievement of this immunity. Meanwhile, when a healthy child is vaccinated the aim is to initially protect him/her against a certain disease. However, considering that vaccines are not 100% safe, adverse events following immunization (AEFI) may occur. In this case, an initial action aimed at fulfilling the principle of beneficence started not to

meet the principle of non-maleficence. The existing moral dilemma would be that to not vaccinate means, on the one hand, not subjecting children to the risks of AEFI, but on the other, subjecting them to the risk of acquiring vaccine-preventable diseases. Thus, conflicts arise between principles because a certain ethical principle is defined based on the desired outcomes of an action, without considering the possible effects resulting from it.

Individual freedom versus the collective responsibility

The issue of patient autonomy is already part of the internal discussion of medical ethics in various countries. The principle of autonomy has been accepted by doctors, because they are considered essential to the free and informed consent, which, in turn, is the basis of the existing ethics codes and resolutions pertaining to research on human beings⁵². Unlike clinical practice, whose notion of autonomy is invoked to express the freedom of the individual to consent or refuse a proposed treatment by a physician in the field of public health, particularly in cases of mass vaccination in epidemic situations, the autonomy of subject is in conflict with the interest of collective protection, as the violation of individual autonomy does not imply a real risk to the community⁵³. In such circumstances, what is the value of autonomy when the health of the community is at risk?

In many situations, where a common good is at stake, the collective interest shall have priority over individual interest, as, for example, in cases of epidemics, whose rigid restriction of individual freedom can be legitimate, using the principle of protection the 'social body' against threats of individuals and groups that can harm it⁵⁴. However, Fine⁵⁵ counter-argues that collective protection through compulsory vaccination has ethical and legal consequences because it provides indirect protection to people who were not vaccinated and exposure to vaccine's risks, even if small, to a few individuals for the benefit of others. This may have several implications, which differ in different cultural, ethical and legal issues regarding the accountability of government to the circumstances facing the adverse effects of vaccines. From this perspective, it appears that the indirect protection, the basis of collective immunity, raises important ethical issues about individual and collective values.

The right to self-determination is correlative to the obligation not to harm others. Respect for autonomy has, therefore, prima facie validity and can

be overridden by competing moral considerations. The obligation to respect autonomy, although extensive, does not apply to non-autonomous people because they are immature, ignorant, coerced or exploited. As examples of children and patients with mental disabilities, who have diminished competence. Thus, autonomy is not limited to the patient, but extends to his family⁵⁶. In this case, the lexical priority of autonomy of an individual or his parents to refuse vaccination is not necessarily worth and can give way to the principle of beneficence to the individual and the collective.

According to Bradley⁵⁷, particularly for childhood vaccination there is no need to talk about autonomy, but rights. The author questions whether a rights-based approach would solve the dilemma of compulsory vaccination in childhood, since it is not easy to prioritize the rights of children to receive health care with the rights of parents to educate their children according to their own convictions and the right of the population to be protected against infectious diseases preventable by vaccines. Thus, if adequate levels of protection can be acquired by other means, compulsory vaccination against the wishes of the parents may not be justified if the benefit to the child is insignificant.

In the context of mass vaccination programs, the right to autonomy is based on the social recognition of respect for this principle. Considering that vaccines are not foolproof, respect for autonomy dictates that risks should not be imposed on individuals without their consent. In this case, there is a critical reason to evaluate the arguments for and against the right to consent or refuse, as this can seriously affect the health of people⁵⁸.

Restrictions on individual rights within the scope of vaccination programs are justified for two reasons: due to the benefit to oneself or in relation to the benefit to the community. Many countries have collective vaccination programs that have been implemented on the grounds of protecting the community against infectious diseases, considering the potential of people who have not been vaccinated for any reason and those who have been vaccinated, but were not properly protected.

The success of a mass vaccination program depends on the number of individuals immunized. Thus, the higher the coverage, the lower the probability of spread of the infectious agent, especially in vulnerable groups such as children and the elderly. In this context, the individual non-vaccination is undesirable because those individuals who have decided not to vaccinate hold higher risk

than those who opted for vaccination. In this case, where there is an obvious tension between individual and collective interests, autonomy loses value against the interests of the collective immunity. In the principlist perspective, meeting the principle of autonomy, which empowers the individual to take the vaccine or not, opposes to the principle of non-maleficence to endanger the community.

In the context of public health, vaccination policies may consider reasonable to assume that the protection of populations has lexical priority over the exercise of personal autonomy. However, there is an ethical conflict between individual autonomy and collective good, which makes the moral individual responsibility argument fragile in collective actions.

Principle of justice

What is the concept of justice in the context of mass vaccination programs? For Duran⁵⁹, in bioethics there is much talk of distributive justice, which concerns the fair distribution of burdens and benefits of social life. More so, means, on one hand, the equitable distribution of both the costs and the benefits on society and on the other, fair access to these resources.

In the context of vaccination policies, distributive justice means access for all children to safe and effective vaccines. Paradoxically, although there is equal access to vaccines, there is equitable distribution of costs of vaccination, given that in the collective vaccination is unlikely that a person will benefit more than the other, since the distribution of benefits can not be allocated unfairly. In parallel, there are situations in which groups of individuals would bear the full burden of vaccination in favor of another group that was not vaccinated^{60,61}. Although, in the collective context, it is considered that these small risks are balanced by the benefits of immunization of the general population, an individual occasionally carries the burden of occurrence of an AEFI for the benefit of the general population.

Several countries have AEFI compensation programs that are implemented irrespective of guilt "No-fault compensation"⁶². These programs are run within an administrative government instance, in order to ensure and promote equal treatment, transparency and justice to children affected with AEFI by vaccines used in collective vaccination programs⁶³. With this, it is removed the uncertainty of lawsuits that are a restricted and extensive paths,

often inaccessible to the majority of low-income individuals who take the vaccine ⁶⁴.

Brazil, despite having one of the most successful immunization programs in the world, has no initiative to make or answer differently to the children affected with AEFI, creating a "disadvantaged" group in the official system of public health leaving only the "Via Crucis" of the judiciary as the only alternative to the quest for justice ⁶⁵⁻⁶⁸. Even in cases of post-polio vaccine it can be found within the Brazilian jurisprudence, decisions that exclude the liability of the State - like the Civil Appeal 639645-5 6/69, rejecting a claim for moral and material damages against a child who had been vaccinated in the vaccination campaign against polio. To the court, post-vaccination reactions configure risking immunization itself, which is mandatory by virtue of national law, accented by health factors ⁶⁹.

With this, the current childhood immunization policies do not fully comply with the principles of equity, universality and comprehensiveness in health care, despite finding explicitly arranged as doctrinal principles of Organic Health Law (LOS) which regulates the Health System (SUS) in Brazil. Thus, in our context of analysis, we are convinced that the concept of distributive justice in principlist bioethics is not sufficient or capable of ensuring the equitable distribution of the burden of childhood vaccination policies.

Limitations of principlism and the new paradigm of bioethics

The principlist theory, reviewed by its own proponents in the fifth edition of the book *Principles of biomedical ethics*⁹, despite its recognized practicality and usefulness for the analysis of vaccination in the individual context, it is demonstrated insufficient for analysis in the context of public health actions. This limitation has been constantly debated by bioethicists in Latin America in the set of bioethical persistent large scale problems or problems that are daily faced by much of the population of countries with significant levels of social exclusion, such as Brazil and its Latin American neighbors ⁷⁰.

Given the specificities of public health actions, questions arise whether it is adequate enough to adapt to the context of the collective model the four principles of principlist bioethics as a tool to understand and discuss the moral conflicts that occur in the collective actions ⁷¹. The inapplicability of the

principlist model for the analysis of mass childhood vaccination was evidenced by the occurrence of a tension between principles, as Schramm ⁷² points out.

With regard to issues related to the risks versus benefits of vaccines and their universal and compulsory use for the entire population, thus related to public health, it is important to note that the focus is on the relationship between the State, the individual and the collective. Consequently, it is necessary to define which conceptual tools could be used in the approach of these problems to provide positive impacts on the most vulnerable, violated and excluded - and consequently in their organizations and administrative policies.

Programs of mass immunization are ultimately aimed at the collective protection, the desirable effects on the individual does not have the same ethical value of the collective effects, leading to an imbalance between the individual cost/benefit in relation to the collective cost/benefit. Thus, considering the moral conflicts between the individual and the collective, the imbalance between the cost/benefit and the inability or failure of the principlist bioethics strictly applied, it is necessary to use other values and moral principles - as, for example, responsibility, solidarity and social justice - as a tool for reflection on ethical issues related to childhood vaccination programs.

In recent years, bioethics met an important development in the countries of South America with the consolidation of a contextualized and politicized perspective that could respond to the reality of the peripheral countries in the global context, setting up an effective tool to mediate emerging conflicts, and especially, the persistent ones, which continue marking so demeaning to the majority of society in these nations ⁷³.

Bioethics had great conceptual change when the United Nations Educational, Scientific and Cultural Organization (UNESCO) published in 2005, the Universal Declaration on Bioethics and Human Rights, incorporating and politicizing health, social and environmental issues in its context. Latin America played a key role in the consolidation of this document as a reference for international bioethics, whose negotiations were marked by a difficult path of discussion and persuasion, despite protests from more traditional and conservative sectors of bioethics ⁷⁴.

This new concept for bioethics emerged in Latin America as an anti-hegemonic epistemologi-

cal proposal to principlism that according to Botle and Porto ⁷⁵proposes a concrete alliance with the historically weaker side of society. This bioethics current aims to legitimize the field of study of moralities and the application of ethical values, a broad perspective involving the social aspects of disease production, contributing to building a critical bioethics that can be applied in the peripheral countries and especially in Brazil.

The protection concept inserted in this new approach to bioethics by Latin American researchers consider the moral problems involved by human vulnerability, i.e., the existential condition of humans who are not only subjected to risks of vulnerability, but the damage and concrete needs, observable by any rational and impartial observer. The moral principle of protection is implicit in government obligations, which should protect its citizens against disasters, wars etc., since all citizens are unable to protect themselves against all odds, may become susceptible and even violated in certain circumstances.

The child has a born condition of vulnerability which is a natural condition of any living being and therefore, a universal characteristic that can not be fully protected. When affected by an adverse reaction to the vaccine, it changed from vulnerable to vulnerably affected, i.e. directly affected. Therefore, as Schramm ⁷⁶ highlights, it should be distinguished the degrees of protection according to the existential condition of vulnerability and susceptibility, which could be considered in the development and implementation of public compensation policies.

Conclusions

It was demonstrated in this article that the principlist bioethics is not sufficient or adequate for the analysis of the ethical issues involved in individual actions that have significant impact on public health, such as childhood mass vaccination. The individual and collective conflict of interest, the unequal distribution of risk versus benefit and the vulnerable condition of the child open space for ethical reflection of current vaccination programs used by governments and creates an environment for reflection and reasoning for the improvement of public health policies.

The social and politicized approach of bioethics idealized by Latin American countries meets this theoretical reflection and practical need for action. This amplified bioethics view allows analyses of public and collective health actions, to also consider the social, environmental, economic and political issues. This will allow, for example, that the country progresses in discussions for the implementation of AEFI compensatory measures, like as is currently done in other countries and in Brazil, in the case of traffic accidents or environmental disasters.

In this sense, the analysis of mass vaccination programs in a broader perspective of bioethics, will be able to understand the complexity of the subject, the severity of prevention, the recognition of vulnerability and respect for otherness, referring to a notion of collective solidary responsibility which will serve as a prerequisite to the State for the implementation of compensatory measures to support children affected by reactions to vaccines compulsorily administered for the benefit of public health.

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