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Concepts of human vulnerability and individual integrity in bioethics

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Abstract

This article consists of a literature review of the meanings and concepts of vulnerability and integrity contained in the most significant international documents on bioethics, and aims to describe the categories most commonly used to classify vulnerabilities. Technological advances and the increase in clinical research studies in the 20th century have given rise to new forms of vulnerability, and have emphasized the vulnerabilities caused by social, political and environmental determinants, or in other words, social vulnerability. The intervention bioethics can be used by peripheral countries to address the problem of social exclusion through the use of prudence, prevention, precaution and protection. Latin American bioethics have been important for the expansion and politicization of moral conflicts in health care, allowing the construction of a global bioethics, in which vulnerability can be tackled by adding different perspectives to solve common problems.

Keywords: Bioethics. Ethical relativism. Principle-based ethics. Health vulnerability. Social vulnerability.

Resumo

Conceitos de vulnerabilidade humana e integridade individual para a bioética

Este artigo consiste em revisão bibliográfica dos significados e conceitos de vulnerabilidade e integridade nos documentos internacionais mais significativos para a bioética. Também é objetivo deste artigo apresentar as categorias de classificação de vulnerabilidades mais utilizadas. Avanços tecnológicos e a multiplicação de pesquisas clínicas no século XX suscitaram novas formas de vulnerabilidade e deixaram mais evidentes aquelas causadas por determinantes sociais, políticos e ambientais, isto é, a vulnerabilidade social. A bioética de intervenção é proposta que pode ser utilizada por países periféricos para enfrentar o problema dos excluídos sociais mediante prudência, prevenção, precaução e proteção. A bioética latino-americana foi importante para ampliar a compreensão sobre conflitos morais em saúde e gerar politização, possibilitando a construção de uma bioética global, na qual a vulnerabilidade pode ser trabalhada agregando diferentes perspectivas para enfrentar problemas comuns.

Palavras-chave: Bioética. Relativismo ético. Ética baseada em princípios. Vulnerabilidade em saúde. Vulnerabilidade social.

Resumen

Los conceptos de vulnerabilidad humana y la Integridad individual para la bioética

Este artículo consiste en una revisión bibliográfica de los significados y conceptos de vulnerabilidad e integridad en los documentos internacionales más importantes para la bioética. También este artículo tiene como objetivo presentar las categorías de clasificación de vulnerabilidad más utilizadas. Los avances tecnológicos y la multiplicación de la investigación clínica en el siglo XX plantearon nuevas formas de vulnerabilidad e hicieron más evidentes las vulnerabilidades causadas por determinantes sociales, políticos y ambientales, o sea, la vulnerabilidad social. La bioética de intervención es una propuesta que puede ser utilizada por los países periféricos para enfrentar el problema de la exclusión social por medio de la prudencia, la prevención, la precaución y la protección. La bioética de América Latina fue importante para ampliar la comprensión de los conflictos morales en salud y generar politización, lo cual posibilita la construcción de una bioética global, en la cual la vulnerabilidad puede trabajarse agregando diferentes perspectivas para enfrentar problemas comunes.

Palabras clave: Bioética. Relativismo ético. Ética basada en principios. Vulnerabilidad en salud. Vulnerabilidad social.

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Scientific development has provoked innumerable changes in social relations, raising ethical dilemmas of every scale, especially regarding the deteriorating socioeconomic disparities in peripheral countries. When the diverse socio-cultural contexts in which bioethics is discussed and applied are considered, the issue of vulnerability becomes an even greater challenge. In this context, Article 8 of the *Universal Declaration on Bioethics and Human Rights* (UDBHR) states:

*In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected*¹.

The word “vulnerability” is of Latin origin, derived from *vulnerabilis*, meaning “something that causes injury”². It is, in this context, the susceptibility to be injured, or wounded. In philosophical vocabulary it is the human condition inherent to its existence in its finitude and frailty, which cannot be overcome or eliminated. By recognizing themselves as vulnerable, people understand the vulnerability of others, as well as the need for care, responsibility and solidarity, as opposed to the exploitation of this condition by others³.

The term “integrity” is also Latin in origin, from the roots of the adjective *integer*, which means “untouched, integral” and the noun *integritas*, meaning “totality, wholeness”. The noun “integrity” evokes a state in which all parts are maintained, in addition to the quality of something that has not been altered, thus also generating the adjective “integral”³.

In the *Declaration of Helsinki*⁴, integrity appears as an attribute of the inviolability of the research subject, which cannot be disrespected. The researcher must then take as many precautions as possible to protect the research participant from potential physical, mental and social harm. In the biomedical framework, integrity presents itself as a negative right to which all persons are entitled, that is, it refers to the non-interference of one in the private sphere of the other. In the UDBHR, integrity refers to the totality of the individual and to the fundamental aspects of human life that must be respected. Therefore, it is not related to virtue, honesty, moral character or good behavior of an individual⁵.

Article 8 of the UDBHR was strategically placed after articles 6 and 7, which deal respectively

with consent and individuals without the capacity to consent, to cover situations where these two principles prove to be insufficient⁶. Individuals without the capacity to consent are those who are in principle autonomous and have the capacity to consent, but are under the influence of factors that impede their independence in terms of any type of control⁷.

This article aims to analyze the different meanings of the concepts of vulnerability and integrity in the most significant international documents on bioethics, especially in the context of technological advances and the increase in clinical research in the 20th century. A further objective of the article is to present the most commonly used categories for the classification of vulnerability.

History

Integrity was associated with the protection of the body from harm by third parties in Article 5 of the *Universal Declaration on Human Rights*⁶, which states that *No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment*⁸.

Article 7 of the *International Covenant on Civil and Political Rights* (ICCPR) states: *No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation*⁹. The *Pact of San José, Costa Rica* adopted a broader vision in its article 5: *every person has the right to have his physical, mental, and moral integrity respected*¹⁰.

Vulnerability was introduced in the context of human research as a characteristic attributed to certain categories of the population who are considered more exposed and less able to defend themselves against abuse and ill-treatment by others. History has made clear the need for such protection, as the number of clinical trials undertaken grew enormously in the first half of the twentieth century, involving unprotected or institutionalized groups of people. Orphans, prisoners, the elderly and, later, ethnic groups considered to be inferior, like the Jews and Chinese, were compromised. Ethnic minorities, socially disadvantaged women and women were also identified as vulnerable³.

The Belmont Report of 1978, which provided ethical principles and guidelines on the protection of human subjects, addressed the vulnerability of individuals in a particular and relative (voluntary in character) manner, and of the population through

the evaluation of risk and benefit¹¹. Beauchamp and Childress, in *"Principles of biomedical ethics"*¹², reinforced the importance of protecting individuals or groups through the broad and rigorous requirement of informed consent. This implied the fulfillment of the principle of autonomy, understood as a capacity for self-determination, and rejecting paternalistic protectionism¹².

Vulnerability was not present in the original version of the *Declaration of Helsinki*⁴ of 1964. Only in the 1996 version did it appear to classify research subjects in private and relative terms, stating the need for their proper protection. The *Universal Declaration on the Human Genome and Human Rights*¹³ and the *International Declaration on Human Genetic Data*¹⁴ refer to integrity in a deontological sense. In other words, the statements describe vulnerable groups, individuals and families as deserving of special attention through the responsibility, virtue or morality of the researcher when faced with issues relating to the ethical and social implications of genetic research. Society must demand the fulfillment of morality and ethics on the part of the different actors, guaranteeing integrity, or in other words, acting correctly in the performance of the research^{13,14}.

In the *Declaration of Barcelona*¹⁵ of 1998, which contained four fundamental principles (autonomy, dignity, integrity and vulnerability) for a joint European policy on bioethics and biolaw, vulnerability was presented as an object to be developed by bioethics and a principle to be respected¹⁵. The *International Ethical Guidelines for Biomedical Research Involving Human Beings*¹⁶ of the Council of International Organizations of Medical Sciences in collaboration with the World Health Organization also refers to vulnerability, describing it as a category of individuals, subjects, people, groups, populations or communities unable to protect their own interests, restricted to the field of human experimentation¹⁶.

Initially, Article 8 of the UDBHR was not part of the preliminary plans of the International Bioethics Committee, and was only accepted in the final session of the intergovernmental meeting of technical committees. The *Declaration* sees integrity as the unity of a person comprised in the plurality of his or her dimensions (physical, psychological, social and spiritual) which cannot be harmed. The duty of respect for individual integrity affirms the obligation to consider the inherent vulnerability of all human beings, as well as to prioritize vulnerable individuals and groups³. The patient's understanding

of his or her own life, disease, and choices must be respected.

Article 24 of the UDBHR, in dealing with international cooperation among states, advises that special attention should be paid to individuals, families, groups and communities who have become vulnerable due to illness, incapacity or other conditions, whether individual, social or environmental. The Declaration also emphasizes the specific needs of developing countries and indigenous communities for international cooperation¹.

The report of the International Bioethics Committee of the United Nations Educational, Scientific and Cultural Organization¹⁷, published in 2013, recognized two fundamental categories of specific vulnerabilities: the special and the social. The former may be temporary or permanent, caused by the incapacities, illnesses, or limitations of the stages of life. The second, based on political and environmental determinants, appears through culture, economy, power relations or natural disasters¹⁷.

Theoretical references

For bioethics, the concept of vulnerability is not self-evident. The concept is applied to the existential condition of individuals and population groups in certain circumstances of abandonment. In citing Rendtorff and Kemp, Solbakk¹⁸ discusses the complexity of the principle of respect for vulnerability by pointing out its broad and narrow conceptions. The broad conceptions refer to the recognition of the principle as the basis of all ethics, considering it as the most important element of bioethics for ontologically expressing the finitude of the human condition. That is, vulnerability as an inherent aspect of the human being.

In being able to bring together moral strangers in a plural society, the concept must be seen as the core biopolitical principle of the modern welfare state. The critique of this overly general conception is the exhaustion of its moral force. On the other hand, restricted conceptions can be based on consent or harm. They create the problem of not covering the entire field of vulnerability in medical research and clinical practice, as well as creating stereotypes, as there is no distinction between which people in a group should and should not have special characteristics taken into account¹⁸.

However, Schramm¹⁹ and Kottow²⁰ differentiate the concepts of vulnerable and violated. The former

points to the universal characteristic of any organism, seen as potentiality, frailty, and a non-state of harm. This vulnerability is reduced by respecting basic human rights in a just social order. It requires negative actions by the state, aimed at the equitable protection of individuals against harm to prevent their vulnerability from being transformed into an injury to their integrity^{19,20}.

Violated refers to an actual situation and a current harm that has relevant consequences at the time of decision making. In view of the damage suffered, these violations require special care by organized social institutions. That is, it is necessary for society to install therapeutic and protective services, such as those of health, welfare, and education, among others, to reduce and remove harm, in order to empower the disadvantaged. It requires from the state affirmative and reparative actions that interfere in the autonomy, integrity and dignity of the violated^{19,20}.

Neves²¹ identified the different notions of vulnerability used in bioethics based on adjective, substantive and principlist functions. The narrowest notion refers to the adjective function. It is presented in a descriptive plane, denoting the expression of values that qualify certain groups and people. Thus, its characteristic is *particular and relative, contingent and provisional, of restricted use to the plane of human experimentation*²².

The substantive function refers to the anthropological perspective of ethics based on Lévinas and Jonas, cited by Neves²¹. They describe vulnerability as a reality common to human beings (constitutive of the human) and to the existing whole (not specific to man), imposing ethical reflection on the animal, environmental and vegetal plane, recognizing the principle as the basis of all ethics.

Hence the importance of Article 17 of the UDBHR for the protection of the environment, biosphere and biodiversity in the access to and use of resources that compromise the conditions of life on our planet¹. However, the ethical dimension remains anthropocentric both because of the difficulty in instituting the moral value of nature, and the power of man to destroy the existing whole, emphasizing man's moral duty to ensure respect for vulnerability and integrity. The articulation of previous functions raised the notion of vulnerability as a principle. It establishes the obligation of moral action, which:

Exceeds the preponderant logic of claiming the rights that care for people and announces the logic of the solicitude of duties that apply to all, aiming at the

*complementarity between a consolidated ethics of rights, established in the freedom of the individual and developed by the reinforcement of autonomy, and an urgent ethics of duties, established in the responsibility of the other and developed by the reinforcement of solidarity*²³.

Thus, with a conditional and temporary characteristic, vulnerability became a universal, permanent condition. From a factor of differentiation if not discrimination between populations and individuals, it has become a factor of equality. Of prime consideration in the field of experimentation with humans, it has gained constant attention from the fields of clinical care and health policies. From the demand for autonomy and the practice of informed consent, it has come to demand responsibility and solidarity³.

In this way, the UDBHR has become the first global step in creating a concept of morally sustainable vulnerability. Respect for vulnerability appears as a proposal for global bioethics, in which there is little consensus on the moral pluralism of most of today's democracies¹⁸. Cunha and Garrafa²⁴, analyzing concepts of vulnerability through five regional perspectives on bioethics (the United States, Europe, Latin America, Africa and Asia) s, concluded that vulnerability is a fundamental principle for global bioethics.

It must, however, be founded on a continuing process of dialogue between different regional perspectives of bioethics, based on the mutual commitment to overcome conditions that make certain individuals and groups across the globe more susceptible to injury than others. It has been observed that these approaches, although different, are able to complement rather than contradict each other.

By addressing individual, social or environmental conditions that make individuals, groups or people vulnerable, the UDBHR directs the focus of bioethical discussion to the link between vulnerability and relations of power, given technological advances in the modern context.

Anjos²⁵ states that asymmetrical power relations stand out when vulnerability is hidden. This is because, by hiding vulnerability, its social causes are also hidden, hence the significant appreciation of autonomy as an expression of power. However, it is understood that power is not the same as autonomy. Therefore:

The attempt to conceal the causes of vulnerability leads to the making from autonomy a discourse of blaming the victims for their own wounds. On a

political scale, we see this discourse of autonomy delivering social groups and entire nations into their own conditions of poverty and being held accountable for it²⁶.

The author also exemplifies three scenarios of the relationship between vulnerability and power. The first scenario addresses the difficulties or non-recognition of the limits of vulnerabilities due to the remarkable developments of science, which makes us a “society of risks”. The second scenario calls attention to the concentration of power (both of consumption and production), that structures a society without ethical reflection, legitimizing iniquity. And finally, the frailty and vulnerability of power are seen in wars, in terrorism, in economic and political disputes between nations, and in the structuring of social inequities²⁵.

Schramm¹⁹ addresses the moral conflicts of bioethics experienced in the practices of public health. Paradoxically, these practices can lead to forms of both inclusion and exclusion through the exercise of biopolitics (a new form of exercise of power, called biopower). Biopolitics controls epidemiological indicators, endemics, epidemics, events that affect the safety and functioning of societies, environmental aspects, welfare policies and social welfare, among other factors. Thus, the author describes the two faces of biopolitics: the protective and the discriminatory.

The first is revealed when the “health imperative” of public health is based on the prevention of “risk behaviors” and the promotion of healthier attitudes. These protective attitudes foster paternalism and authoritarianism, reducing the possibilities for legitimate action by citizens by limiting their autonomy. The second concerns the new form of discrimination of people with genetic diseases or people with habits considered to be harmful to their personal health (alcohol consumption, smoking, physical inactivity, among others).

However, this supposed guarantee of the health and well-being of the social body is justified by the “society of risks”, which, in reality, masks the regime of capitalist production and exploitation. The political economy in the globalized world imposes *intervention strategies on the entire social body, based on criteria of effectiveness, of economic and financial maximization*²⁷. In the light of the above, the threat is to base biopower on evidence that is presented as unique or superior, coming from the moral imperialism of central countries that

appropriate natural and human resources from peripheral countries.

According to Garrafa and Lorenzo²⁸, moral imperialism is intended to impose, through different forms of coercion, the moral standards of certain cultures, geopolitical regions and countries onto other cultures, regions or countries. The pharmaceutical industries, for example, test their medicines on populations that are afflicted by poverty in peripheral countries in order to maximize profits in the treatment and commercialization of these supplies in central countries that have greater purchasing power and where the diseases studied are more prevalent and relevant.

The latest changes to the *Declaration of Helsinki*, made in 2008, reveal the moral imperialism of developed nations in adopting different ethical criteria (or *double standards*) in clinical research when compared to developing nations. These changes deal with issues such as ensuring access to the best available treatment methods, which makes it possible to employ the double standard, as well as the non-obligatory nature of the responsibility of sponsors for research subjects after the end of their studies.

The *Declaration* relativizes the vulnerability of the peoples and peripheral countries, justifying the use of differentiated methodologies of clinical research that may depend on the sanitary and health circumstances of the countries. That is, they reduce the requirements of internationally accepted ethical standards in conducting clinical studies and, consequently, the costs of research, claiming urgency of cure^{29,30}.

Therefore, populations of peripheral countries are in situations of vulnerability, not necessarily through biological but by economic factors, since poverty and inequities in low-income countries make them attractive for research. This is the so-called “social vulnerability” that negatively interferes with the self-determination of individuals or peoples³¹. In this sense, Garrafa states:

*Social vulnerability is related to the structure of people’s daily lives. Among the situations that generate social vulnerability in research in peripheral countries are the following: the low research capacity of the country; socioeconomic disparities among the population; the low educational level of people; an inaccessibility to specific health services and vulnerabilities related to women, as well as racial and ethnic issues, among others*³².

Intervention bioethics (IB) has established concepts necessary to guide concrete actions when tackling this question. It *assumes a commitment to dispense special attention to vulnerable and disempowered individuals*³³, aimed at reducing social inequality through hard interventive practices in the social field^{34,35}.

These practices also commit to the public ideal and the environmental balance by exercising the four “P’s”: prudence in the face of advances; prevention of possible damage and iatrogenesis; precaution against the unknown; and the protection of the socially excluded, the most vulnerable and the neglected³⁶. *The recognition of one’s own vulnerability is a starting point for a larger construction*³⁷ making it possible to overcome one’s frailties²⁵.

As such, IB offers an alternative thinking by and for countries with historical, cultural and social particularities that display contrasting realities arising from scientific progress observed through the persistent and emerging problems of bioethics.

Discussion

The welfare state adopts a utilitarian approach that aims to prioritize the majority of the population. However, this does not mean that minorities should be excluded; instead, distributive justice is required in order to provide equal access to opportunities for citizens, by developing their capacities. In this context, equality, justice and equity are fundamental values for the promotion of public policies focused on social justice.

Daniels and Sabin³⁸, applying John Rawls’ theory of distributive justice in the area of health, explain why we should use the moral principle of the protection of equal opportunity. According to the authors, our health is affected by social determinants. Thus, diseases and disabilities impair the normal functioning of individuals, restricting their range of opportunities. This causes negative impacts, as health preserves people’s abilities to be participatory citizens in society’s social, political and economic life.

It is clear that this complex problem requires the implementation of sociopolitical measures, especially affirmative action, prioritizing opportunities for those who have few or none because they are socially excluded from the benefits of global development. The context of exploitation and the damage caused by a breach of integrity

justify the differentiated and positive treatment of sectors affected by vulnerability, thus prohibiting discriminatory barriers to redressing the effects of inequalities. This includes, in addition to health care, the provision of public education and other interventions to generate opportunities beginning from early childhood³⁸.

Affirmative actions aim to guarantee social justice in a democratic manner. Hence the importance of article 14 of the UDBHR, which deals with the principle of social responsibility and health. It corresponds to one of the aspects of the responsibility - personal, political and social - to act in the promotion of health, considered as the fundamental right of every human being, through various actions shared with all sectors. It is the recognition that the states of health of individuals are the result of a social project that depends on the commitment of all, according to their possibilities^{1,38}.

The social control of any activity of public and collective interest must be a committed and participatory democratic process, passing through the legitimacy of the authorities in the choice of ethical standards of control and judgment. Taking clinical research as an example, it is essential to establish dialogue with the public in the formulation of ethical norms adapted to local contexts. In addition, it is vital to develop ethics committees that are capable of analyzing research in order to filter studies that are relevant to the population tested, minimize risks, treat injuries to participants, and maximize and distribute research benefits^{30,38}.

The versatility of the concept of vulnerability is capable of announcing the principle at a universal level, recognizing forms of vulnerability that can be overcome through specific measures of protection and forms that remain unchanged, that is, are inherent, prevented by actions based on rights and dignity that provide equitable protection by the state^{3,19}.

The more an individual is respected, the less vulnerable they are. This is because human rights are recognized and the need to guarantee the inherent dignity of the person, through the non-violation of his or her integrity, whether physical, psychic or moral, and by not exploiting their vulnerability, is intrinsic to every human being, or is caused by individual, social or environmental conditions.

Latin American bioethics has played an important role in this debate in recent years through the expansion and politicization of the moral conflicts that are approached in this field of knowledge from an international perspective. It has excelled through

working on reflections and actions that allow principles to be adapted to the realities and complexities of various scenarios beyond biomedical and biotechnology issues, from the respect and recognition of moral pluralism³². The reduction of social injustices is fundamental to the development of nations.

Final considerations

Technological advances have made clear the importance of bioethics as an instrument to guarantee fundamental rights and prevent or stop abuses against vulnerable populations or individuals. Some people are more susceptible to wrongdoing than others, giving rise to protections tailored to their specific needs. They should be protected against the damage or risk of participating in research simply because they are more “accessible” due to their illnesses/weaknesses or inferior economic conditions.

There is a close relationship between vulnerability and justice, requiring more ethical criteria and restrictions for the development of clinical research involving vulnerable individuals. The application of justice is also present in the elaboration of public policies and health care through affirmative actions capable of promoting social justice and equal access to opportunities for all.

It is imperative to recognize that vulnerability cannot be completely eliminated, as it is not merely circumstantial. The fact of exercising autonomy through free and informed consent does not suppress vulnerability, since there is always the risk of such consent being exploited. For example, there is the possibility of fraud, “sweetened” presentations on the benefits of the results, exaggerated medicalization in response to any kind of suffering, aggravated by the publicity material of sponsors.

For the reasons described, autonomy should not be narrowly understood through the US principlist approach (the ability to act freely according to one’s values and beliefs), but also from the effective creation of conditions that make a person capable of acting in an autonomous way. In other words, a liberated and empowered person who understands the power relations that influence self-determination and which, from this understanding, can act on determinant factors for health, reducing his or her situation of vulnerability.

Vulnerability is a concept with different regional perspectives, allowing dialogue for a global bioethics in the search for new approaches that include these perspectives within the commitment to tackle current and future bioethical problems.

The responsibility of health professionals to public health is relevant in the fight against health vulnerability and to preserve or restore the integrity of patients, above all by considering the duty to promote patients’ interests by strengthening their fundamental rights (based on human dignity and human rights) and respecting their options and life history.

Social responsibility in health requires much more than the accountability of states in the formulation of public policies, as in the *Política Nacional de Saúde Integral da População Negra* (National Policy for the Integral Health of the Afro-Brazilian Population)³⁹. It requires national and international social strategies that eliminate inequalities and promote the well-being of the vulnerable. It is inferred, therefore, that the individual is understood in his or her totality (no longer an object reduced to disease or incapacity) and is inserted in a bioethics of rights and duties. Vulnerability and integrity must be recognized as intrinsically human dimensions, as they are components of individual identity that must be taken into account in every function.

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