Informed consent: care for the recruitment of vulnerable populations

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Abstract
Research with vulnerable populations has shown a common concern among researchers worldwide. Protocols to conduct research with vulnerable populations emerge, which differ from those already existing due to concerns on the understanding of the study objectives and withholding of information throughout the research period. Protocols present videos, audio tapes, flipcharts, interviews with community counselors, techniques that seek to inform participants on key points of research, in addition to contraindications to treatment. In spite of these new techniques for withholding information and maximizing understanding, they are not sufficient to transform the consent in a continuous process. Local community support is crucial for the success of research with vulnerable populations. Ultimately, informed consent comprises, sell, voluntariness and the consent itself.
Key words: Vulnerable populations. Bioethics. Informed consent.

Resumo
Consentimento informado: cuidados no recrutamento de populações vulneráveis
Pesquisas com populações vulneráveis têm se mostrado preocupação comum entre pesquisadores em todo o mundo. Surgem protocolos para a realização de pesquisas com populações vulneráveis, que se diferenciam das já existentes pela preocupação com a compreensão dos objetivos do estudo e retenção das informações durante todo o período da pesquisa. Os protocolos apresentam vídeos, áudios, gravuras informativas e entrevistas com conselheiros comunitários, técnicas que buscam informar os participantes sobre pontos-chave da pesquisa e contra-indicações do tratamento. Apesar das novas técnicas para a retenção de informações e maximização da compreensão, estas não são suficientes para transformar o consentimento em um processo contínuo. O apoio da comunidade local é vital para o sucesso das pesquisas com populações vulneráveis. Em última instância, o consentimento informado contempla, ainda, a voluntariedade e o consentimento em si.
Palavras-chave: Populações vulneráveis. Bioética. Consentimento livre e esclarecido.

Resumen
Consentimiento informado: cuidado para el reclutamiento de las poblaciones vulnerables
Investigaciones con poblaciones vulnerables han representado una preocupación común entre investigadores en todo el mundo. Surgen protocolos para la realización de investigaciones con poblaciones vulnerables, que difieren de las ya existentes debido a la preocupación con la comprensión de los objetivos del estudio y retención de las informaciones durante todo el periodo de la investigación. Los protocolos presentan vídeos, audios, imágenes informativas y entrevistas con consejeros comunitarios, técnicas que tratan de informar a los participantes sobre aspectos fundamentales de la investigación y contraindicaciones del tratamiento. A pesar de las nuevas técnicas para la retención de informaciones y maximización de la comprensión, éstas no son suficientes para transformar el consentimiento en un proceso continuado. El apoyo de la comunidad local es fundamental para el éxito de las investigaciones con poblaciones vulnerables. En última instancia, el consentimiento informado incluye, asimismo, la voluntariedad y el consentimiento por si mismo.
Palabras-clave: Poblaciones vulnerables. Bioética. Consentimiento informado.

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The process of informed consent in research emerged in the early 20th century, in an official document from Prussia[1]. Later in the Nuremberg Code, included in the physicians' trial in 1947 [2], and in the Declaration of Helsinki of 1964, it was insufficient to guide research involving vulnerable populations. Until then, children, the elderly, pregnant women and the mentally ill had deserved some consideration at the individual level. Still, when we talk about ethics, we are increasingly convinced that the last word has not been written [3].

In the 1980s, Brazilian researchers have proposed the Code of Health Rights for Communities [4] - the first document to address the issue of consent in the community perspective. As a result, an item dedicated to underdeveloped populations was included in the new CIOMS (Council for International Organizations of Medical Sciences), published in 1993 [5].

The understanding and ability to retain information about the research in which vulnerable individuals will be inserted is strongly influenced by factors such as illiteracy, the language barrier, both in terms of vocabulary, structure, understanding the concept of probability and the nature of adverse events as well as the different socio-cultural perspectives of illness and health [6].

There is a need to consider the informed consent as a very important process throughout the research and not just as an activity in its starting point. From this premise, there is growing concern about individuals from vulnerable populations who participate in research, which is reflected in the development of different approaches to the process of continuing and appropriate consent to those circumstances.

The informed consent process is still under crescent investigation not only with regard to the theoretical aspects, but in its practical application, which may be inadequate, especially in its consequences [7]. For informed consent to be valid, it must include four elements: provision of information, understanding, voluntariness and the consent itself [8].

The information component of the agreement is researcher's responsibility. It is him who should provide essential information to the person being invited to participate. Understanding depends on the characteristics of each individual, education and understanding features of the presented proposal. The voluntariness is exercised by capable people. The freedom to choose to participate or not in the research is influenced not only by individual characteristics, such as autonomy, but by the relationship between the people involved. This relationship can generate coercive behaviors that reduce the voluntariness, even in autonomous persons. The agreement itself is the result of this process; it is the culmination of an appropriate interrelationship. The act of consent is to accept the invitation and authorize the execution of procedures presented by the researcher [9].

Researches related to HIV and AIDS were excellent field for this kind of study, given the need to discover new agents and strategies for its prevention and treatment. Those who most need protection and access to the benefits of new technologies are also the most likely to be exploited [4]. Desperate and vulnerable subjects are likely to mask the potential risks and maximize the benefits of research using different criteria and values when compared with less vulnerable subjects [6].

In a study in which researchers were interviewed and asked to define vulnerable populations in clinical trials in HIV/AIDS, they have recognized significant barriers in conducting research on pregnant women, children and prisoners, for which there are regulations with additional protection [10].

Due to its multiple facets, the area of HIV/AIDS has caused the very concept of vulnerability to be redefined. The distinction between personal vulnerability and social vulnerability, and these in relation to programmatic vulnerability was essential to adequate the understanding of the issue.

Personal vulnerability is based on the individual's ability, ie, his autonomy and self-determination. Social vulnerability refers to the social support networks of which this individual is part. Finally, programmatic vulnerability refers to the policies for education, health and justice available to society - that can reduce or increase personal vulnerability [11,12].

The fragile situation in which potential participants are approached can make them even more vulnerable, either from personal, social or programmatic points of view. In addition, other factors may further expand vulnerability, through biased presentation of the benefits associated with participation, such as differentiated access to drugs and health services. In this context, the adequacy of informed consent should be cautious and an understanding of the concepts, the administration process and the implications of the process should be sought [13].

Research and vulnerability

In the field of study on AIDS, the notion of vulnerability is briefly defined as a set of individual and collective aspects related to the degree and mode of HIV exposure or illness by it and to the more or less access to adequate resources to protect themselves from both [12]. Individuals who are very poor, illiterate or with rudimentary functional literacy, children, people with reduced capacity (including psychiatric), prisoners, fetuses, pregnant women, terminally ill patients, students, staff, comatose patients, tribal people and elders are examples of vulnerable population [14].

As specified, in the area of research, the notion of vulnerability can be classified into three dimensions: individual, social and programmatic [11,12]. The individual vulnerability was the first to be considered. The exclusion of children, pregnant women and older people in research projects was described in the Prussia document from the early 20th century [1]. Later, other documents included fetuses, psychiatric and comatose patients. In all of them, the emphasis has been the absence or reduced ability of the individual related to their autonomy and self-determination.

Social vulnerability was being incorporated as social networks, in which individuals insert themselves, were being recognized as a weakening factor in the decision making process. These groups included the poor, students, research institutions' employees, or persons related to structures with strong hierarchy, such as the military and members of religious orders, as well as members of traditional communities, such as indigenous peoples.

Programmatic vulnerability, still devoid of a better definition in the research area includes all people who lack formal support policies in the areas of education, health and justice. The lack of education, expressed by illiteracy or rudimentary literacy (functional), makes difficult the access to and understanding the information shared between the researcher and potential participants in the process of obtaining informed consent. This feature is often seen as personal vulnerability, when in fact it derives from a lack of social policies.

Also the lack of access to health care can lead an individual to maximize the benefits of participating in a survey, when they are offered different treatments for their health condition. Likewise, individuals under-served by the health policy can minimize, for the same reason, the risks associated with their participation in research.

The sick individual may be considered in isolation, as a bearer of personal vulnerability, but the lack of services also makes him vulnerable from a programmatic point of view. In the area of Justice, inmates may be included in this situation, when the system itself weakens them beyond the simple restriction of individual freedom. This group, for this feature, could be included in social vulnerability, but the set of all other conditions imposed on it generate this programmatic framework [11,12].

In many countries, HIV infection and AIDS most commonly affect vulnerable populations, poor, uneducated individuals and, therefore, with less ability to make decisions. These people may have also limited understanding regarding the disease and the perception of their problem [15].

When considering a vulnerable person, we are referring to someone who is unaware of the possibility of becoming infected by HIV or becoming ill with AIDS. Even when aware, these people are not able to develop (and program) effective and efficient strategies for coping with the disease or preventing infection [6]. HIV disproportionately affects vulnerable populations.

Suggestions that emerge from the research ethics committees (REC) are innovative and explore the suitability, feasibility and effectiveness of new methods of conveying information - videotapes and informative sessions with counselors, for example. These approaches can improve the understanding of the study among subjects invited to participate [8]. Affective relationships play an important role in the decision-making process, especially those related to family [16-19].

It is opportune to remember that the Declaration of Helsinki itself ensures that medical research involving a vulnerable or needy population or community is only justified if the research is responsive to the health needs and priorities of that population or community and if there is a reasonable likelihood that this population or community can benefit from the results of the survey [20]. In parallel, it should signal that the complexity of research carried out in developing countries is exacerbated by a number of unique ethical concerns. Eager for seeking answers to research problems, some issues, especially related to testing safety, were not fully exploited [21].

Examples of new approaches to vulnerable populations

During the assessment of key issues of informed consent about HIV/AIDS administered to pregnant women in India, it was found that even after counseling and education of the group in relation to the study, only 38% of women understood six of the eight key issues [22]. Research conducted in the Republic of Congo sought the reasons for people's participation in the study for research into a vaccine for HIV. The in-depth interviews revealed that the most common motivation was personal concern about health and the impact of the epidemic on families and the country [23].

The community, as well as the individuals, has to be carefully addressed in HIV vaccine studies. In preparation for the study of this vaccine, conducted in southwestern Uganda, 95% of the studied community wanted to participate in a survey for this purpose. However, some prerequisites for inclusion were associated with reduced capacity for participation, as the need to delay pregnancy or the chance to receive a placebo instead of the vaccine itself [24]. The stigma left by the disease is a mark that can repeal survey participants [22-25].

To ensure that even the illiterate and people with less education may volunteer to study and understand the major issues, the use of educational videos and explanatory drawings seems to be the way that researchers have been taking [6,15-24]. While some studies show concern for understanding the information pertinent to the study, others apply methods that provide information retention throughout the participation in the study. It must be said that both the understanding and the retention of information is of great value to the consent of the volunteer. However, one should not confuse these two variables with the consent itself.

What the research seems to provide to the subjects is repeated meetings to reinforce the key points, such as, how to use the medicine/when to stop using the medicine.

In the study carried out in Mzwanza, Tanzania, it was tested the efficacy of a continuous process of informed consent during phase III study of a vaginal microbicide that would prevent HIV infection. The women, after selected, were guided through drawings and informational audiotapes on the instructions and the key messages about the research. A check-list for understanding was applied by the team already in the screening and repeated after 12, 24, 40 and 50 weeks.

To investigate women's perceptions about the study and evaluate the internalization and retention of key messages, a random subsample of 102 women was invited to participate in in-depth interviews, after 4, 24 and 52 weeks. The result indicates increased levels of comprehension and retention of the message, being possible to say that it was understood satisfactorily. In parallel, we cannot state that the consent was evaluated during these weeks [6].

Studies to assess the feasibility for conducting research on vaccines for AIDS are important precursors for testing candidate vaccines against the virus [25,26]. During the preparation of tests for AIDS vaccines in India, the country's own government strived to highlight that the successful research and ethics required the active participation and support of the local community.

Unethical research conducted in the past has generated mistrust, ignorance, stigma and discrimination on HIV/AIDS, and these situations may be responsible for difficulties in recruiting volunteers for clinical trials. The key to the success of clinical trials in India is due to specific training for screening team members [27].

Final thoughts

Research seeking an informed consent process has resulted in individuals who better understand and retain the messages relevant to the study. Studies that seek to develop new approaches to understanding and retaining information about the survey by participants are not necessarily developing a new way of consent.

The central question of the current proposed approach to research with vulnerable populations is to make the research subject aware of the key issues, providing him with enough information about the study, to understand it at all stages. Informed consent, however, also includes the voluntariness and consent itself. These two variables should not be at the margin of the continuous informed consent process.

Besides those responsible for the research, to make the research subjects aware of the objectives of the study to which they volunteer means to better qualify them as to the assessment of the risks and benefits they will undergo.

Community involvement in research is extremely

important to establish a trusted environment for the individuals who participate in it. In addressing vulnerable populations, it is not up to the researcher to provide a team composed of members of their trust, but those who are trusted by community where the clinical trial, study or interview is being proposed.

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Authors' participation

Aletheia Bajotto was responsible for devising the article, literature review and drafting. Jose Goldim was responsible for devising and reviewing the article.

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