Ethics in epidemiological research

A ética na pesquisa epidemiológica

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Abstract *This text focus, on a series of author's opinions, on the difficulties that the current system of regulation of ethics in research represents for the practice of the epidemiological research, in the Country. It introduces a few understandings concerning the present subject in the international literature, pointing out some of the most relevant themes and problems. It also examines part of the difficulties faced by Brazilian epidemiologists. The main topic developed in the article is the specificity of the science's reasoning that guides acting of the public health and epidemiology with repercussions for the practice of scientific research in this field, plenty different from the science's reasoning that preside medical practice and biomedical research. Hence the inadequacy of the ethical recommendations in force, all of them based on biomedical research, particularly at that with experimental design. It concludes with the indication that procedures adopted by the system of the ethics in research should be reviewed, adapting such procedures to the characteristics of different kinds of research.*

Key words *Epidemiological research ethic, Epidemiological research, CEP-CONEP system*

Resumo *Este artigo reúne uma série de opiniões do autor sobre as dificuldades que o atual sistema de controle da ética em pesquisa representa para a prática da pesquisa epidemiológica no país. São apresentadas algumas posições referentes ao assunto presentes na literatura internacional, apontados alguns dos temas e problemas mais relevantes e discutidas algumas das dificuldades enfrentadas pelos epidemiologistas brasileiros. O argumento principal desenvolvido no artigo é a especificidade da lógica de atuação da saúde pública e da epidemiologia em seu interior com repercussões para a prática da pesquisa científica nesse campo, bastante diferente da lógica que preside a prática médica e a pesquisa biomédica. Daí a inadequação das recomendações éticas vigentes, todas elas baseadas na pesquisa biomédica, em particular, naquelas com desenho experimental. Conclui-se com a indicação da necessidade de revisão dos procedimentos adotados pelo sistema de revisão da ética em pesquisa adaptando-os às características dos diferentes tipos de pesquisa.*

Palavras-chave *Ética em pesquisa epidemiológica, Ética principalista, Pesquisa epidemiológica, Sistema CEP-CONEP*

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Introduction

Since 1991, when the Council for International Organizations of Medical Sciences (CIOMS) published the guidelines for ethical analysis of epidemiological studies, it has become clear that the characteristics of research carried out in epidemiology are different from those present in biomedical research, thus calling for another set of normative procedures[1].

However, in this first set of norms, CIOMS representatives considered that the same ethical principles used as guidance for ethics in research with human beings in the biomedical area could be employed to population research. Therefore, by following the guideline of the principalist ethics, used to regulate biomedical research, they established that (1) respect to people, (2) beneficence, (3) nonmaleficence, and (4) justice were the basic principles for the ethical judgments of epidemiological pieces of research[1].

The last decade of the twentieth century was a scenario for the challenge of theoretical and methodological concepts in epidemiology. This, however, was mostly seen in the commitment of this subject of study to the Public Health field. Along the lines of debates initiated by the "epistemological crisis" one can see the appearance of the first criticism regarding the adoption of conflicting principles as regards the notion and practice of public health.

Kass, in a paper written in 2001, calls our attention for the shortfall of prioritizing the defense of individual autonomy in the Public Health practice, when its foremost obligations are with the improvement of health of the public and the reduction of social inequities – often objects seen in clash with the protection of individual autonomy[2].

At the same time that individualist principles do not apply to public health, they do not apply to the process of research in the epidemiological field – which clearly shows the need for norms of conduct that take into account the specificities of groups and populations.

In 2000, the American College of Epidemiology launches their proposal for the ethical conduct of epidemiologists. The Ethics Decalogue in epidemiological research combines concerns with research participants and with the community. The following are considered researchers' obligations: (1) minimizing the risks to participants; (2) maximizing the benefits to the participants and the community; (3) weighing and equitably distributing damages and benefits; (4) protecting participants' privacy and confidentiality; (5) obtaining informed consent, taking care to avoid all forms of manipulation or coercion; (6) submitting research projects to ethical review; (7) maintaining public trust in research results, adopting high scientific standards and incorporating representatives from the community into the team; (8) avoiding conflicts of interest; (9) guaranteeing ethical conduct of the other team members; and (10) adhering to the commitments made with the community, including the need to report research results; advocating so as to ensure that benefits achieved can be extended to the community, besides keeping respect for cultural diversities[3].

Practically the same items can be seen in the proposal presented by the Center for Diseases Control and Prevention (CDC). Ethical precepts for research conduct are grouped into five topics: risk minimization and benefit provision, conflicts of interest explicitation, obligations for the communities; informed consent, and privacy and confidentiality[4].

In terms of damage reduction and benefit extension, Coughlin[4] calls our attention to the commitment that epidemiologists must have with the acquisition and application of scientific knowledge with a view to maintaining and restoring public health, while respecting individual rights. Minimization of damages and maximization of benefits are particularly important in epidemiological studies involving vulnerable populations.

Expliciting conflicts of interest, when they exist, is part of the concern with maintenance of public trust.

Observational studies, designs that are more frequently used in epidemiological researches, present a number of possible damages to participants – which may be classified as of minimum risk. Authors state that some potential damages to participants may include: loss of privacy, time spent with interviews and exams, adverse psychological effects resulting from anxiety facing anticipation of negative results or in consequence of false positive results[4].

The most sensitive aspect in observational studies and in those based on the use of population record data pertains to the preservation of privacy or protection of confidentiality. There are a number of resources that researchers may use for this: blocking records; limiting access to them; deleting personal identification information from databases whenever possible; training the team as to the importance of protecting privacy and confidentiality; using codes or cryptographic data; limiting case locating data to the minimum

necessary; suppress the cells which have little data so as to avoid the possibility of isolating them[4].

In intervention studies, the most debated point has been the protection of vulnerable populations, especially in pieces of research that are financed and carried out by researchers from developed countries in under-developed countries. Bhutta[5] states that it is in the public health field that the use of ethical principles is more distanced from individual ethics, but these aspects are not sufficiently covered by the existing recommendations. Besides this, the debates along the problems presented by researches carried out with international financial support focus more often on individual rights than on the issues of public health.

Buchanan and Miller[6] present another extremely unsettled issue. The authors discuss situations in which intervention studies would be justified on the basis of testing cheaper – even if less effective – procedures. According to the authors, in public health, the need to make the extension of benefits viable to a large portion of the population would justify the fulfillment of cheaper intervention tests that are potentially applicable in a broad sense, even if they do not seem as effective as other, more expensive, procedures that are not broadly applicable.

The conditions that would ethically justify such experiments would be the need to apply the intervention to a large number of people so as to reach broad coverage, and obtain the expected health effects; the existence of a more effective solution – though excessively expensive – the existence of political or economical disquiet that might impede the broad coverage with the Standard intervention; and the high probability of broadly implementing the cheaper intervention[6].

According to these authors, the situations described are distinct from those in which drugs or other medical inputs are tested with no population coverage in mind.

In Brazil, the first attempt to institutionalize ethics in research involving human beings was made by the Comissão Intersetorial de Ciência e Tecnologia do Conselho Nacional de Saúde [Intersector Commission of Science and Technology of the National Health Council], in 1992. CIOMS's recommendations were translated into Portuguese and broadly published. A series of initiatives were taken in the sense of regulating the research conducted in the country by foreign researchers, in consonance with the Agência Brasileira de Cooperação do Itamarati [Itamaraty Brazilian Agency of Cooperation]. However, it was only with the creation of the Comissão Nacional de Ética em Pesquisa (CONEP) [National Commission for Ethics in Research] and the approval of Resolution 196, on the 10th October 1996, that the creation of a network of Ethic Research Committees was effectively founded, and the ethical judgment of health researches in the country was institutionalized[7].

In the last 10 years, it is undeniable that there has been progress in the area of implementation of mechanisms of ethical control in Brazilian researches. The funding agencies and the main scientific journals have started to require the project approval by the ethics committees, thus reinforcing the roles that these committees had assumed. There is increasing awareness among researchers as to the need to follow regulations of ethical issues, despite their being broadly based on a consensus of moral values negotiated between researchers and the organized civil society, since the resolutions have no legal force, nor presume sanctions for those who do not follow them.

Going from a situation of total lack of mechanisms for ethical regulation into another of regulation and control has generated some problems that point to the need for a review of procedures. For the purpose of this discussion, these problems can be divided into two major groups: problems of a general category, pertaining to the implementation of the system, and specific problems resulting from the characteristics of epidemiological studies.

Among those relating to the implementation of the system, one can cite the unwarrantable use of ethics committees to bargain research authorship in exchange for the approval of projects, the multiplicity and superposition of judgments for one single project, the lack of clarity of the actual role that should be played by the committees, and the little grounding, on the part of committee members, with which to competently exercise their role of social control.

What frequently happens is that, even if lacking background and experience in the conduct of research, the committees mistake their judgment attribution of ethical aspects for the assessment of the scientific merit of the research – thus generating great resistance from the part of the researchers when facing what they consider unacceptable and undue evaluation reports. In order to solve this difficulty, it would be necessary to have an evaluating process initiated by the judgment of merit – which would be carried out by the researcher's peers – followed by the judgment of ethical aspects, which would

be carried out by a group of representatives from the society, and whose mission would be to corroborate the work of the scientists according to socially accepted values.

Judgment superposition for the same project could easily be solved by institutionalizing acceptance norms for reading evaluation in each duly registered committee by the other committees – thus avoiding bureaucratization of the process, as well as avoiding object digression.

However, perhaps the main problem in the Resolution 196 is the fact that, differently from the international CIOMS recommendations, the former has been built with a focus on situations of controlled clinical essays only, i.e., on specific aspects of experimental studies, generalizing these conditions to all the other types of researches – to which they are evidently inadequate.

It is comprehensible that the resolution has chosen to initiate the ethical revision by the kind of research that gathers the greater potential for participant damage. Ten years later, it is time to establish different resolutions for different types of research, and not only for different themes – as has been the tradition of the work carried out at CONEP.

Epidemiological researches designed as observation studies have particularly been the focus of several hindrances, as a result of the attempt to submit to the application of the same principles adopted for experimental studies.

As an example, one can cite the difficulties pertaining to the use of the informed consent in population surveys, with no biological material collection; the restrictions to the maintenance and use of biological material banks; the accomplishment of studies of case-control in hospital settings and the carrying out of data generation in large databases.

The institutionalized informed consent aims mostly at the preservation of the individual's autonomy, and at the guarantee that there will be no exploitation of subjects. Evidently, every research involving human beings must consider obtaining participants' consents after their full clarification of the research procedures. However, in home surveys, the mere consent to carry out interviews should suffice. In countries where there are low levels of literacy among the population – as is the case of the Brazilian population – people are afraid of signing papers. Besides facing the relatively low level of functional literacy that jeopardizes the adequate understanding of the written word, people are afraid of signing documents that might be unduly used. The requirement of signed consent represents a reason for broadening the rates of refusal, and could even jeopardize the precision of the estimate obtained in the study.

According to the American College of Epidemiology guidelines, researchers running investigations that present only minimum risks – as in the case of observational studies – could be exempted of the need to have the signed informed consent. The document is considered surplus in studies that involve information linkage in large databases, in surveys with no biological data collection, case-control and cohort study with data collection by means of interviews, investigations of outbreaks, program evaluations, routine actions and surveillance[3].

Restrictions to the use of biological material conditioned in banks such as serum stocks or histological plate collection, among others, could mean the impossibility of later discovering the origin of emerging diseases or of diagnosing situations that may put the health of the population at risk. In the case of the aids epidemics, for example, the possibility of analyzing and testing the serum of thousands of homosexuals belonging to the study cohort of hepatitis B in San Francisco was extremely important for the conduction of the researches that led to the clarification of the etiology, besides indicating possible mechanisms of transmission by analogy and similarity.

Studies of case-control, hospital-based, with the inclusion of information from records of patients seen in a great number of health services are practically unfeasible in the country. The need to submit the same project to the appreciation of dozens or hundreds of research ethics committees simply to obtain the permission to consult the records of patients seen in one of these health services makes the research extremely long and subject to the scarcely ethical behavior of some committees.

Finally, the use of data which is regularly recorded in great national databases – such as the system of birth information, the system of death information, the national system of disease reports or the system of hospital-based information - has also been generating some problems. In order to preserve privacy and confidentiality, some governmental bodies responsible for the maintenance of these systems issue Draconian norms that, in practice, represent privatization of public information and interference, even censorship of the researcher's work.

These, as well as other problems that have not been discussed in this paper, are indicating the need for a revision of the procedures and res-

olutions for the ethical evaluation of researches in epidemiology and public health.

Rodolfo Saracci[8], ex-president of the International Association of Epidemiology (IEA) states that when the epidemiologist uses the population only aiming at science, restraining themselves from any direct or indirect involvement with public health, they are deviating from the Kantian ethical imperative – which prohibits using people as a means for an end. Besides, when acting like that they will be perpetuating the stereotype of the sterile scientist, only committed with the search for truth. According to the author, this stereotype can be naïve, but is not innocent, since it stimulates the position of scientists that do not "get their hands dirty" with political decisions, when, actually, the position of alleged neutrality favors the action of non-declared moral values and political interests (conflict of interests). Finally, this position jeopardizes the case for more resources in researches in public health and epidemiology under the allegation that the research in the health field would more rapidly be beneficial to the society than research in the biomedical area.

According to Saracci, the classicist view of epidemiological research, uncommitted to public health, can supply a comfortable excusing rhetoric, though based on frail arguments, as well as on debatable ethics – to say the least. He also adds that there are two twin objectives in the scientific work of engaged epidemiologists who work in public health: the search for the truth and for social justice[7].

To fully accomplish the commitments assumed with public health, respecting rights pertaining to individuality, without missing the focus of improving the health of the population and the reduction of social inequities, the enhancement of ethical regulations established for research in public health is fundamental.

Reviewing the system of procedures for ethical control of the work of scientists cannot, and must not be seen as a threat of the advances already achieved. It must be seen as a further step towards excellence in the Brazilian research, congregating academic merit, social relevance and commitment with life.

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