Ethical Principles applied to epidemiology. International Guidelines for the Ethical Assessment of Epidemiological Studies

CIOMS

Informed Consent

Individual Consent

1. When individuals will take part as subjects in an epidemiological research, normally an informed consent is assured to be obtained. In the case of epidemiological studies that use personally identifiable private data, the rules for informed consent vary, as it will be further analyzed. A consent is considered to be informed when it is granted by a person who understands the purpose and the nature of the study, what he/she should do and the risk that he/she must face by participating in the study, and which benefits are wished to be accomplish as a result of the study.

2. A researcher that suggests not requesting the informed consent has the obligation of explaining the ethical assessment committee the way in which the study will adjust to the ethical principles without having such consent: it can be impractical to locate people whose medical record should be examined, or the aim of some studies would be frustrated if, for example, the possible participants –when being informed- will modify the behavior that is intended to be studied, or could cause an unnecessary concern by knowing that they are participating in the study. The researcher will guarantee that severe measures will be maintained to protect the confidentiality and that the study has the aim to protect or promote health. Another justification not to request informed consent may be to inform through public announcements that it is usual to use personal data for epidemiological studies purposes.

3. An ethical problem may arise when occupational records are used, the medical records, the tissue samples, etc. with purposes for which consent was not granted, even though the study does not entail any risk or damage.

Generally, it must be communicated to people or their public representatives that their data might be used for epidemiological studies, and they should be informed of the measures that will be taken in order to protect confidentiality. Consent is not required for the use of public knowledge, if countries and communities differ when it comes to defining which type of information about citizens is considered public. However, when such information must be used, it is perfectly understood that researchers will reduce to a minimum the diffusion of delicate information from the personal point of view.
4. Some governmental organizations and agencies employ epidemiologists, who by law or by job contracts are allowed to have access to information without consent of people. These epidemiologists must then consider if it is ethical on their behalf, in a determined case, to use that personal access to information power. From the ethical viewpoint, it might still be necessary for them to obtain consent from the involved people or to justify their access to information without such consent. This access may be ethical for reasons such as minimum risk or damage to which people is exposed, the public benefit that will be achieved or the protection that researchers will give to the confidentiality of people whose data will be examined.

Consent of the community

5. When it is not possible to obtain the informed consent of each person involved in the study, the approval of a community or group representative may be requested; however, such representative must be chosen according to the nature, traditions and political philosophy of the community or group. The approval given by a community representative must be coherent with the general ethical principles. When researchers work with communities, they must take into account the rights and protection of the community in the same way they would in the case of the rights and protection of individual persons. In communities where it is usual to make decisions collectively, the community leader may express the collective will. However, the refusal of people to participate in a certain study must be respected: a leader may express approval on behalf of a community, but an individual’s refusal to personally participate is predominant over such approval.

6. When people are appointed by organizations that are external to a group, like in the case of a governmental agency, the researchers and ethical assessment committees must consider how authentically these people represent and speak on behalf of their group, and, if necessary, to assure the approval of other representatives. The representatives of a community or group may be involved sometimes in the preparation of the study and its ethical assessment.

7. The definition of a community or group for epidemiological studies purposes might be subject of ethical concern. When the members of a community are naturally conscious of their activities as communities and believe that they have common interests with other members, that means that the community does exist, independently from the study. The researchers must consider how a community is constituted or the way it is self-defined, and respect the rights of disadvantaged groups.

8. For the purposes of an epidemiological study, researchers may define groups that consist of people linked for statistical, geographical reasons or another type, and that do not interact socially. When these groups are artificially created for a scientific study, its members may not be clearly identifiable as leaders or representatives, and it cannot be
expected that people risk being in disadvantage for the benefit of others. Therefore, it will be more difficult to assure the representation of the group and more importantly, to obtain the free and informed consent of the people that will take part on it.

Selective diffusion of information

9. In epidemiology, an acceptable study technique entails the selective diffusion of information, which appears to contradict the principle of informed consent. In the case of certain epidemiological studies the non-diffusion is permitted, and it is even fundamental, to not influence the spontaneous behavior that is being surveyed, and to avoid obtaining responses aimed to please the researcher. Selective diffusion may be favorable and ethically permissible, as long as it does not induce people to do what they wouldn’t consent on doing in any other way. An ethical assessment committee can only allow diffusing selected information when it is justifiable.

Undue influence.

10. The possible participants might not feel free to refuse requests from those who have power or influence over them. Therefore, the identity of the researcher or another person in charge of inviting people to participate must be revealed. Researchers must explain the ethical assessment committee the way in which they plan to neutralize that apparent influence. From the ethical point of view, it is questionable that participants are selected from groups being unduly influenced by people with authority over them or community leaders, if the study can be carried out with participants that do not belong to this category.

Inducement to participate

11. People or communities should not be induced to take part in a study. Nonetheless, it might be difficult to clearly establish the difference between putting pressure and offering appropriate incentives, on one hand, and on the other hand, to create a legitimate motivation.

The benefits of a study, for example, major or new knowledge are appropriate incentives. However, when people or communities lack the basic health services or money, the possibility of being compensated with goods, services or payment in cash may induce their participation. To determine the ethical suitability of such incentives, these must be evaluated in light of cultural traditions.

12. The risks that carry the participation should be acceptable for the participants, even if no incentive is presented. It is acceptable that all the expenses are refunded, for example, during trips. Similarly, the promises of compensation and medical care for damage, injury or loss of income should not be regarded as an inducement to participate.

Ensure maximum benefit
Communication about the Study Results

13. Part of the benefit that communities, groups and individuals can reasonably expect from their participation in such studies is that they will be informed of the findings and conclusions regarding their health. In cases in which the results are translated into public health measures for the benefit of the community, they should be communicated to the health authorities. By informing people about the findings and how these are related to their health, it is necessary to take into account their ability to read and write, and their understanding level. Research protocols should include provisions in order to communicate such information to the communities and the individuals.

The results of a research and the information provided to the community should be published by any appropriate and available mean. When studies on HIV prevalence are conducted by unlinked and anonymous selection, whatever is needed must be available, whenever it is possible, in order to make voluntary HIV antibody tests under informed consent conditions, with pre- and post-test assessment, and confidentiality guarantee.

Impossibility to communicate the study results

14. It should be informed to all the epidemiologic test participants that it could be impossible to inform them about the findings regarding their health, but this should not be interpreted as being free of the sickness or illness; even though it is the object of the study. Often, it may not be feasible to extract from the general results the information concerning the individuals and their families, but when the results indicate the need for medical care, the affected people should be advised on how to get a diagnosis and personal counseling.

When the epidemiologic data is not linked, a disadvantage for the participants could be that whoever is in danger could not be informed about any useful finding or any result concerning their health, which derives from such studies. When it is not possible to personally advise those people to get medical care, the ethical duty of doing good to others could be achieved by offering the communities advice for the corresponding medical care.

Disclosure of the Study Results

15. Researchers may be unable to compel the disclosure of information held by government or commercial entities; however, as health professionals, they have an ethical obligation to advocate for the disclosure of information that is of public interest.

Research sponsors may put pressure on researchers to present their findings in order to promote special interests, for example, to demonstrate that a product or process is or is not
harmful for health. Sponsors should not present interpretations or inferences, or theories and hypothesis, as if they were real truths.

Medical Care for a Community Subject to a Study

16. An epidemiological project carried out in a developing country can create the expectation in the community that it will provide health care, at least while researchers are present. Such expectation should not be frustrated and, when people need medical care, measures should be taken in order to offer them treatment or they should be referred to a local health service that can provide the required need.

Training for Local Health-Care Personnel

17. While performing the studies, especially in developing countries, there is a great opportunity to train local health-care personnel in specialties and techniques that could be used to improve health services. For example, while training them to handle measurement mechanisms and calculating machines, researchers will provide a valuable tool, such as the ability to keep track of morbidity or mortality.

Reduce Risk to its Minimum

Cause damage or do something inappropriate

18. Researchers who design studies should recognize the risk of causing any damage, i.e. creating any situation of disadvantage, and the risk of doing something inappropriate, i.e. to transgress the values of the people. Damage can be caused, for example, when the limited health-care personnel is deviated from their routine duties to meet the needs of a study, or when, without informing the community, the priorities are modified in relation to the health-care offer. It is improper to consider community members as impersonal objects only to carry out a study, even if they are not going to be injured.

19. Ethical assessment must always determine the risk that participants or groups could suffer as a result of taking part in a study, such as stigmatization, prejudice, loss of self-esteem or prestige, or economic harm. Researchers should inform the ethical assessment Committees and potential participants about the perceived risks and proposals to avoid or mitigate them. Researchers should be able to demonstrate that the importance of benefits outweighs the risks, whether they are dealing with individuals or groups. A thorough analysis must be carried out in order to determine who would be at risk and who would benefit from the study. It is unethical to expose people to avoidable risks that do not have any proportion regarding the expected benefits, or to allow that a recognized risk subsists, if it can be avoided or at least minimized.
20. When a healthy person is a member of a population or subgroup with a high level of risk and engages in high-risk activities, it is unethical not to carry out measures to protect the population or subgroup.

Avoid Group Damage

21. Epidemiological studies may expose groups and individuals to damage without being noticed, such as economic loss, stigmatization, censure or denial of access to services. Researchers, who obtain sensitive information that may subject a group to a risk of unfavorable criticism or treatment must be discreet in communicating and explaining their results or conclusions.

When the location or circumstances of a study are important to understand the results, researchers will explain what measures are proposed to protect the group from any damage or disadvantage. Said measures include provisions concerning confidentiality and the use of a language that does not involve a moral criticism of the participants’ behavior.

Harmful Advertising

22. Conflict may appear when taking a decision of not causing damage and tell the truth and openly disclose scientific results. The damage could be mitigated by interpreting data in a way that allows protecting the interests of those in a situation of risk and at the same time it should be consistent with the scientific integrity. Researchers should, whenever possible, anticipate and avoid any misinterpretation that could cause damage.

Respect for Social Costumes

23. Generally, disruption of social costumes is considered harmful. Although cultural values and social customs should be respected, it may be a specific target for an epidemiological study to stimulate the change of certain conventional habits or behaviors in order to culminate in healthy behaviors, for example, regarding a diet or a hazardous occupation.

24. While members of the community have the right not to allow other people to impose a non-requested "benefit", studies whose results are expected beneficial for the health are generally considered ethically acceptable and not detrimental. Ethical assessment Committees should consider the potential of a study to produce a beneficial change. However, researchers should not overestimate such benefits, if the willingness of a community to participate is wrongfully influenced by the expectation of better health services.

Sensitivity to Other Cultures
25. Epidemiologists often research cultural groups other than their own, inside or outside their own countries, and undertake studies initiated from outside their culture, community or country in which the study will be carried out. The sponsor and the host country may differ in how they understand and apply ethical values in their culture, for example, regarding the autonomy of individuals.

Researchers must respect the ethical standards of their own countries and the cultural expectations of the societies in which the epidemiological studies are conducted, unless it involves the violation of an important moral rule.

Researchers risk harming their reputation by performing tasks that host countries consider acceptable, but their own countries consider offensive. Similarly, they may transgress the cultural values of the host countries, when they uncritically adhere to the expectations of their own countries.

Confidentiality

26. The investigation may involve the collection of data related to individuals and groups, and these data, if disclosed to third parties, may cause harm or distress. Consequently, researchers should take measures to protect the confidentiality of such data, for example, leaving out information that might lead to the identification of specific individuals, or limiting the access to data, or any other means. In epidemiology, it is normal to aggregate numbers, to keep the identity of the participants hidden. When the group confidentiality cannot be kept or it is violated, researchers must take measures to maintain or restore the good name and prestige of a group. There are generally two types of information collected on participants:

Unrelated information, which cannot be linked, associated or connected with the person to whom it refers, i.e. when the researcher does not know this person; therefore, the confidentiality is not at risk and there is no problem of consent.

Linked information, which could be:

- Anonymous, when it cannot be linked to the person it refers, only through a code or other means known only by that person and the researcher is not able to identify the person;

- Not nominal, when the information can be linked to the person through a code (not including personal identification) known by the person and the researcher, or

- Nominal or nominative, when the information is linked to the person by means of personal identification, usually the name.

Epidemiologists discard personally identifiable information, when they consolidate data for statistical analysis purposes.
No personally identifiable information will be used when a study can be done without personal identification, for example, for blood samples tests, unlinked anonymous will be used to determine the presence of HIV.

When personal identification data is kept in the files used for a study, researchers must explain to the assessment Committees why this is necessary and how confidentiality should be protected. If, with the consent of the participants, researchers link different data sets relating to specific individuals, usually they will keep the confidentiality by adding individual data in tables or diagrams. In public management, the obligation to protect the confidentiality is often reinforced by the practice of making the employees to commit themselves to secrecy.

Incompatibility of Interests

Determination of the Interests Incompatibility

27. It is an ethical rule that researchers should not have incompatibility of undisclosed interests with their partners, sponsors or participants in the study. Researchers must disclose to the ethical assessment Committee any potential incompatibility of interests. The afore mentioned arises when a commercial sponsor or any other sponsor wishes to use the study results to promote a product or service, or when it may not be appropriate from a political standpoint to disclose the results of a study.

28. Epidemiological studies can be initiated or can be financially or in other form supported by government agencies or other agencies that hire researchers. In the fields of occupational health and environmental health, there may be conflicts of interest among various groups: shareholders, managers, employees, state regulatory agencies, advocacy groups for the public interests, among others. Epidemiological researchers can be employed by any of the said groups. It may be difficult to avoid the pressure derived from these conflicts of interest and from the resulting distorted interpretations of the conclusions drawn from the study. It is possible that similar conflicts of interest arise when carrying out studies on the effects of drugs and devices or medical equipment tests.

29. Researchers and ethical assessment Committees should be alert to the risk of conflict, and Committees generally should not approve proposals, in which incompatibility of interests are inherent. If for exceptional reasons the proposal is approved, the incompatibility of interests must be disclosed to potential participants and their communities.

30. It may seem that there is a conflict of interest when the participants do not want to modify their behavior and researchers consider that they should do it for the benefit of their health. However, it is possible that it is not really a conflict of interest, as researchers are motivated by the good health of the participants.
Scientific Objectivity and Interest Defense

31. Honesty and impartiality are essential to formulate and conduct studies, as well as to present and interpret the results. Data must not be retained, distorted or manipulated. Researchers can find health risks, which have to be corrected, and can advocate for protection forms and health restoration. In such case, their defense should be based in objective and scientific data.