

## Communication in environmental epidemiological studies

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### Abstract

Communication in public health has been, since the Fifties, the object of debates and ethical reflection. In more recent years it has received particular attention, due to the increased diffusion of information and requests for an increased participatory approach in our societies.

The purpose of this paper is to illustrate the process of communication in two environmental epidemiology investigations; along with a discussion of ethical principles and guidelines.

The first case-study is an epidemiological study about a resident population close to a power line, exposed to high levels of 50 Hz magnetic fields. A relationship between the investigators and community has been in existence since the very beginning of the study, with communication occurring at both the individual and group levels and at different times during the study: it is an example of "participatory research".

The other example is an epidemiological study concerning the health impact of waste management in a part of the region of Campania, defined as a site of national interest for environmental reclamation, due to the illegal practice of waste management, including dumping of toxic wastes. In this case, communicating with the population turned out to be quite difficult, and a specific communication program remains necessary.

Environmental epidemiological studies, such as the aforementioned examples, and in general public health studies, require a conceded effort from the very beginning by researchers to communicate with the interested communities, creating *in itinere* moments of individual and group communication. The relationship between the community and the investigators must be characterized by mutual listening, transparency and respect for self-autonomy.

*Key words: ethic principles, ethic virtues, communication, participatory research, community involvement, environmental epidemiology*

### Introduction

The purpose of the present paper is to describe the communication strategies adopted in two environmental epidemiology investigations in order to hold dialogues with the study's populations. Some of the thinking behind the ethical values underlying the approaches followed by our research group will be given, taking into account the on-going discussion on these still open issues.

#### Ethical principles and codes: an overview

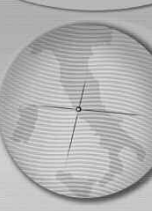
Four principles derived from the Hippocratic Oath, which are of interest to everyone working in public health, have recently been the object of renewed ethical consideration when communicating with populations of epidemiological studies: autonomy, beneficence, non-maleficence, and equity.

According to the foundations of biomedical ethics, these principles provide guidance to medical practice, but they require, as it had

already been stated by Aristotle, the evaluation of every single situation, and the generation of an adequate response: both of these depend on the "virtue" of the individual physician. There is, thus, a complementary role of virtues and principles: the first need to be guided by rules and principles, the latter needs virtues in order to be applied [1].

This is the framework in which the International Codes of Medical Practice has been placed, as it provides directions on the application of principles and rules in order to guide and integrate the individual physicians' virtues [2].

As far as biomedical research is concerned, the first code of reference is the Nuremberg Code of 1947. Some basic concepts are introduced here for the first time in the practice of professional medical ethics: individual consent of subjects involved in research; non-maleficence of the experiment; obligation to terminate the experiment in as much as non-maleficence may not be adequately ensured.



Subsequently, starting from the mid-Sixties, guidelines for biomedical research on human subjects have been developed (Helsinki Declaration, 1964). The second Helsinki declaration of 1975 was taken as a basis for the 1982 WHO guidelines [3]. The latter introduced the requirement for an external committee for the evaluation of compliance with set ethical principles in order to publish research findings, and it emphasizes the notion of "informed consent", implying the awareness of study subjects, and their involvement, even in the case of research on entire communities.

In 1991 WHO published the first guidelines for epidemiologic studies, which focused especially on the investigations of epidemics like HIV/AIDS [4]. Peculiar problems which arose when dealing with groups of subjects, rather than individuals, were specifically addressed in this document, namely conflicts between individual rights and the needs of the community. The following principles were considered: respect, and thus autonomy of all study participants, as well as their protection; beneficence; non-maleficence and distributive justice. The distinction between microethics (individual level) and macroethics (community level) was introduced, so that any procedure that appeared to be non-ethical on one level, could not be regarded as being ethical on another.

Informed consent may not necessarily be requested in the case of community studies, if data banks of individual records are used for the greater public interest, while safeguarding an individual's privacy. Individual consent may in some cases be substituted by Community Agreement, in other words by the consent of community representatives, warranting, individual choices. In the absence of the latter, an external ethics committee will also have to take a standpoint on the possible need for compensation [5, 6].

As far as environmental epidemiology is concerned, the object of the present paper is the ISEE-WHO guidelines which were presented in 1994 [7] and subsequently revisited by Soskolne [8]. Community involvement, from the study design to interpretation and dissemination of findings, while taking in consideration the privacy of individual subjects, is obligatory for investigators. Obligations to colleagues include the process of a qualified peer-review before the study is published.

Following this debate, some national contributions highlight the peculiarities of the Italian context [9, 10]. The authors stressed that the basic request for the ethicacy of a study is its scientific soundness. The investigator is supposed

to be honest and aware of the moral value of the choices he is making about the population to be studied and the adopted methodology for causal inference. Since "collective goods" are dealt with, it seems appropriate to apply procedures that take into account an equitable distribution of risks and benefits.

In the framework of the aforementioned discussion, that obviously goes beyond the aims of the present paper, emphasis will be given to the application of ethical principles and virtues to the issue of communications with study populations in environmental epidemiology.

### Ethics in communication

**Autonomy** implies respect of the right of each person to self determination. This requires that the subject receives all of the information that he may be interested in, because he is regarded as being able to make his own decisions. The role of the researcher is not to ensure that each person makes the "correct" decisions, but rather to provide correct and understandable information so that anyone can make an informed and autonomous decision [11].

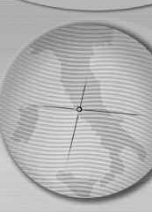
**Beneficence:** according to this principle, the researcher must inform the subject about health risks in order to enable him to adopt preventive behaviours or, if applicable, have access to early detection and treatment.

**Non-maleficence:** this principle may be summarized as "do more good than harm". It requires care in the communication of results: if the latter are not well presented, the person may not make the best decision. Following this principle, some researchers believe it is not prudent to communicate the study findings, when the relationship between exposure and health effects is not ascertained. Not all researchers agree with this option though, and the reasons for their disagreement will be mentioned later.

**Equity.** This principle implies that all subjects be treated with the same respect. The right of each person to be aware of adverse environmental exposures is stated by law and in ethical guidelines [12]. This has implications for the communication of both individual and group research findings.

When a study collects information on a series of individual subjects, different times for individual and group information are requested [13].

When the relationship between a given exposure and the occurrence of adverse health effects is not ascertained, there may be a conflict between the principles of non-maleficence and autonomy.



Epidemiology tends to rely on the notion of “probability”, rather than on “certainty”. The amount of time required in order to reach a reasonable level of certainty may be too long with respect to the time span of individual lives (with their need to take decisions on personal behaviours like diet, smoking, and access to health care) and of populations (with their need to take decisions on public policies such as transport, urban planning and location of industrial sites). Taking into account the abovementioned principles, it can be argued that epidemiologists should be able to communicate the notion and the degree of “uncertainty”. Individual subjects and society as a whole will take their decisions, giving different weight to the results of the epidemiological investigation with respect to the evaluation of economical, social and other aspects [14].

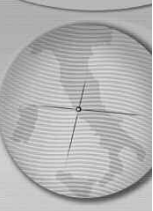
In this framework, the guidelines of the Health Investigations Communication Work Group of the Agency for Toxic Substances and Disease Registry [15] may be taken as a standard, since communication is regarded as a significant component of the Agency’s activities. The following three main points should be considered in particular:

1. To develop a relationship with the communities being investigated. This point subsumes the clarification of two concepts: who are the subjects included in the study (and what are the criteria for their enrolment), and what members of the community will have the role of discussing with the investigators the various areas of common concern. Communities are not always homogeneous, and environmental activists do not always represent all community members: it is necessary therefore to know the “silent community voice”. The active involvement of part of the community, may help in establishing a relationship with the other subjects. This leads to a wider involvement, a higher response rate and, finally, a greater credibility of the study findings. An actively involved community can produce valuable knowledge for the implementation of the study [16]. The frequency of contacts between investigators and population is of the utmost importance. A long time may elapse between study design and the production of the final results, and thus communication in progress is needed, not necessarily in plenary, but at least with the population’s representatives [13].
2. To clarify the study objectives. The judgement of a community on a study, in general, depends on whether the study succeeds in providing the scientific basis for political interventions. On the

other hand, investigators evaluate the quality of a study according to scientific requirements: study design, validity issues as well as controlling of bias and confounding. Clinical tests performed by the investigators may not be interpretable at the individual level, but only at population level; this may cause a lengthening of the requested time in order to have final results. Regardless, it is necessary to be explicit from the outset of the study regarding the meaning of technical terms such as “expected cases” or “statistical significance”, the amount of time requested and the methodology being utilized. The population’s expectations concerning the study may in some instances be quite remarkable. Investigators should be explicit about what conclusions can be and can’t be reached by the study itself. Researchers, finally, must pay attention to the population’s expectations and ensure that the study can respond to these expectations, without losing its validity. Respect of the community’s autonomy should always be pursued [17].

3. To communicate research findings. Communities, in general, do not endorse studies whose findings don’t detect increased risks. On the other hand, people are not likely to feel cheated, even in the circumstance of a negative study, inasmuch as all stages of the investigation have been clearly presented, while explicitly mentioning their limitations. Establishing causal connections between exposure and disease can be difficult. This issue should be stated openly, together with indications for future *ad hoc* studies, and for the types of public health actions to be adopted meanwhile. Investigators should also inform both the population and administrators about the degree of uncertainty of the association of interest, in order to provide the rationale for decision making processes [14]. If possible, study results should be discussed with concerned communities, before public meetings, and in those circumstances consensus between investigators and community should be checked. This is particularly important when individual data has been collected, and thus answers must be in the first place given to the individual subject, and then to the group level [13].

In conclusion, the efficacy of the communication process largely depends on the amount of time devoted by investigators to establishing a relationship with the population during the course of the study. The main issues to deal with are the needs of the population, practical value and limitations of the study,



adopted procedures, required time-scale and the possibility that the results will differ from the public's expectations.

### Two case-studies

Two case-studies may illustrate the abovementioned principles. Both studies have been performed with colleagues of the Environmental Epidemiology Unit of Istituto Superiore di Sanità.

The first one is an example of "participatory research", as defined by Cornwall and Jewkles (1995) [16]. This is an epidemiological study on a population exposed to high levels of 50 Hz magnetic fields.

Since the beginning, the study had the characteristics described by Cornwall and Jewkles: a sequential process of reflections and actions developed in partnership with the local population. A bottom-up approach, "collegiate" type, has been followed, with focus on local priorities and expectations, mutual listening with the community; while at the same time pursuing the autonomy of the researchers and community.

In the specific case, the first contact of the investigators was with an activist group which reported a peculiar environmental exposure pattern due to the presence of a distribution power line close to the dwellings, that was subsequently verified with magnetic field measurements. This group of concerned citizens favoured the setting up of a relationship between the population and the investigators. This enabled the systematic collection of information aimed at reconstructing the cohort of all subjects resident in the area since the foundation of the district in the Fifties, in the absence of official records because of the lack of authorization when the district was originally built [18]. A cross-sectional health survey is currently on going in the area, and the response rate is quite high.

Several meetings have been organized in order to ensure *in itinere*, exchanges of information between investigators and the population; these meetings are characterized by transparency and respect of the different roles of each party. Presentation and discussion in the community of the preliminary mortality results have enabled the subsequent building of a positive relationship with politicians, local health authorities, the mass-media and other stakeholders, even when conflicting messages arrived from external institutions and subjects.

Even if this approach turns out to be quite successful in this particular experience, it can be very complex and difficult to follow. Difficulties

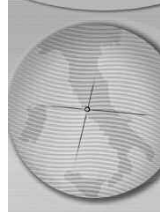
are particularly relevant when the community under study is not well defined and localized, as in the previous case, but a high number of subjects live in large areas affected by widespread environmental pollution. This situation is typical of polluted sites of national interest for environmental reclamation [19]. This is the case of the epidemiological study on the health impact of the waste cycle in Campania, an Italian region characterized by illegal practices of waste management, including dumping of toxic wastes. For this reason the Region has been ruled by a Commissioner appointed by the National Government, as far as waste management is concerned, and part of the territory of two provinces is defined, as a site of national interest for environmental reclamation.

The first epidemiological study in this area dealt with three municipalities whose critical environmental situation was reported by an environmental organization (Legambiente). Increased cancer mortality in the area was then detected by the investigators [20]. The connection between investigators and environmental activists made it easy to communicate the research findings to the resident population and to the local health professionals.

Subsequently, the Department of Civil Defence of the Italian Government, commissioned the same investigators to carry out an epidemiological study, aimed at assessing cause specific mortality in the entire territory of the two provinces affected by the toxic waste dumping practices, which was 196 municipalities altogether [21]. In this case, communicating with the population turned out to be quite difficult for several different reasons. The community was not homogeneous and did not recognize one or few representatives. Furthermore, the scientific community had delivered conflicting messages [22]: this should be absolutely avoided [13].

The Commissioner for waste management emergency, had decided to install a waste incinerator in this area, without any consultation with the local community, and without the consent of most of the population. This issue hampered the credibility of the independent investigators in charge of the epidemiological study. Epidemiological studies in polluted sites should be performed before decision making processes on territorial planning takes place.

In this case, the role of the epidemiological study is to identify areas representing priorities in terms of public health action or environmental reclamation: the results of the environmental and health studies with emphasis on the illegal waste



dumping practices will thus be the objects of an *ad hoc* communication program.

### Conclusions

There is widespread agreement within the scientific community and among public health professionals that the right-to-know should influence all aspects of environmental health practice. The awareness of this dates back to the circumstances of major chemical accidents, like the Bhopal event in India. Communication of health risks between providers and the general public should be based on mutual autonomy and respect [23]. The need to involve local communities resident in polluted sites in all stages of environmental epidemiologic investigations is largely acknowledged at the international level, as witnessed for instance by the U.S. Agency for Toxic Substances and Disease Registries, that has embodied this issue in its work procedures [15].

Both a participatory approach and a systematic consultation of the population unavoidably adds further complexity and may imply some degree of concern and even nuisance, but, if properly implemented, they represent a great added value [24]. This requires, of course, high levels professional skills both in the conduct of the study and in the communication of its findings, and strict compliance with deontological principles of epidemiologic research. In the absence of these requirements, the whole process not only may not be beneficial to the concerned community, but it may even turn out to be harmful.

Environmental epidemiological studies, like those reported in the aforementioned examples, and in general public health studies, require a conceded effort by researchers in order to communicate with the interested communities, from the very outset, creating *in itinere* moments of individual and group communication.

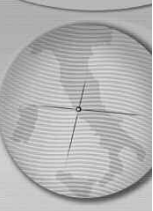
The relation between community and investigators must be characterized by mutual listening, transparency and respect for self autonomy.

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