Guidelines on Ethics for Epidemiologists

The International Epidemiological Association (IEA) organized a workshop on Ethics, Health Policy and Epidemiology, as a side activity of its last worldwide meeting on August 3–5, 1990 in Los Angeles. During this workshop, many comments and suggestions were made on the previous draft of the IEA Guidelines and submitted to Professor John Last (Ottawa), in charge of their successive revisions.
In a letter of September 20, 1990 to his many correspondants within and outside the IEA, he wrote: «This revision is being circulated to all who attended that workshop whose names and addresses are known, ad to those who reacted to earlier versions that were circulated at intervals beginning in December 1987».
At an other international meeting on the same topic, I had a chance to ask his permission to have the latest interim version of these Guidelines published in «Sozial- und Präventivmedizin / Médecine Sociale et Préventive».

Professor F. Paccaud and myself thank therefore our Canadian colleague for this opportunity of making these Guidelines available to our readers, at a time when epidemiological research is growing rapidly here and when researchers are faced with many ethical concerns which are only partly addressed by the existing variety of Guidelines on ethics in biomedical research.

O. Jeanneret, Genève

Proposed Ethics Guidelines for Epidemiologists

1. Definition and purposes of epidemiology
1.1 Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems.
1.2 The practice of epidemiology – health surveillance and disease control in populations – is integral to public health pratice. As a research method, epidemiology is used to test hypotheses about causes of disease, to measure health risks, and to conduct experiments to investigate the efficacy of preventive diagnostic or therapeutic regimes or procedures.
1.3 The purposes of epidemiology are to enlarge our understanding of factors that influence health-related states or events, so that the health of populations and individuals can be enhanced, protected or restored; to provide information and analyses to guide decisions affecting community health; to evaluate measures taken to enhance, protect or restore health; and to respond to community concerns regarding health.
1.4.1 Epidemiology can be conducted with national or regional populations, with samples, or with subsets of the population such as patients or high-risk groups; it may have broad aims or focus on specialized themes.
1.4.2 These guidelines apply to all aspects of epidemiology and to all kinds of health professionals who practice epidemiology. They are intended primarily to help in identifying ethical issues that arise in epidemiological practice and research, and to promote procedures to deal with these issues. The guidelines should help epidemiologists, ethics review committees, and members of the public such as consumer groups concerned about ethical conduct of health surveillance and research.

2. The nature and values of epidemiology
2.1 Epidemiology is a science, an aspect of public health practice, and the source of facts to aid in advocacy.
2.2 Epidemiology is a basic science of public health and of clinical medicine. We, who practice epidemiology are concerned with the health of all population groups. Our role is to identify interventions likely to restore, maintain and improve health. We apply our skills and knowledge from diverse educational and experiential backgrounds. We recognize that other health professionals share the same goals, and we collaborate fully with all others in achieving these goals.
2.3 Our professional activity as scientists focuses on improving the state of knowledge that provides the basis for inferences about causes and levels of risks to which individuals and population groups have been exposed; and the basis for decisions concerning, for example, efficaceous preventive and therapeutic interventions, health goals and resource allocation.
2.4 As public health professionals, we have an obligation to communities rather than to individuals. We are sensitive to the cultural norms of communities and groups that we study. We have specific professional skills relevant to solving the health problems of communities. Our obligation to these communities and our professional skills place us at the interface of science and public health policy. As public health professionals we provide information for the rational use of resources, and we may also advocate specific solutions to health problems.
2.5 We distinguish between our role as scientists and our role as advocates, and ensure that those with whom we are dealing are also aware of this distinction.

3. Basic principles of biomedical ethics
3.1 Ethics is the branch of philosophy concerned with the distinction between right and wrong, with moral choices, duties and obligations.
3.2 Four principles of biomedical ethics are commonly defined. These are respect for autonomy (human rights, dignity and freedom), non-maleficence, beneficence and justice. Non-maleficence, the principle of not harming, applies in such contexts as not allowing information collected to harm persons or groups providing it. Beneficence is the principle of doing good; it encompasses truth-telling, a tenet of epidemiology. Justice is the principle concerned with equity and fairness.
3.3 Though we strive to observe all these principles, they are occasionally in conflict, as when we have to sacrifice autonomy in the interest of justice.
3.4 These principles are the basis for codes of professional conduct such as the Helsinki Declaration and its revisions. All health professionals in contact with human subjects are expected to abide by the Helsinki Declaration.

4. Obligations to individuals
4.1 When interventions into people's autonomy are planned, their informed consent to the intervention is a necessary prerequisite. This requires that knowledge and understanding of the nature and consequences of the intervention are communicated, that the subjects of the intervention give free and voluntary consent to the intervention and that they retain the right to withdraw. In some situations such as studies involving large data files, it may be impractical to obtain the informed consent of individuals to whom the records relate.
4.2 Epidemiologists respect personal privacy and avoid violation of confidentiality. It is a sine qua non of epidemiological surveillance and research that privacy and confidentiality of individuals, and in some circumstances, of groups or communities, should be preserved. This is important because epidemiology requires collection of information that is private, personal and sometimes potentially harmful to the interest of individuals if divulged. Such information can only be publicly disseminated as statistical tables or displays that do not reveal identities.
4.3 Sometimes the health, safety or wellbeing of others may require that information possessed by epidemiologists is communicated to responsible health authorities, and perhaps to family members or other contacts of persons with communicable diseases that are under surveillance. This has long been a requirement in control of many communicable diseases; it has the support of laws or regulations in many jurisdictions. In these circumstances, privacy can be invaded, confidentiality violated. An example is notifying and counselling partners of persons with sexually transmitted diseases; if possible the epidemiologist should obtain the informed consent of such persons to this necessary loss of their privacy and confidentiality.
4.4 The interventions in both surveillance and research should not harm human subjects. However, as in other aspects of health care, epidemiological studies may sometimes involve painful or even hazardous procedures or regimens. The balance of benefits and risks must always be carefully weighed.
4.5 Epidemiologists may not be able to resolve ethical dilemmas unaided or by seeking advice from colleagues. Therefore means must be developed to allow a broader scrutiny of the issues by all interested parties. Ethical review committees are one mechanism to accomplish this.

5. Obligations to communities

5.1 Epidemiology is primarily concerned with providing service to communities. Epidemiologists have an obligation to communicate with communities directly or through community representatives to explain what they are doing and why, to transmit the results of their studies, to explain their significance, and to suggest appropriate action.

5.2 Health workers including epidemiologists have an obligation to ensure the provision of health care for communities and individuals found to be in need of care. Epidemiologists do not themselves usually provide the care, but in some circumstances, e.g. in developing countries where no other source of care is available, they may have to do so. When they are involved in providing health care, the roles of care-giver and epidemiologist must be distinguished.

5.3 Identification of problems to be studie, and their priority for study, should take into account the perceived importance of the problem to the people living in a community. Notwithstanding this, epidemiologists may perceive that a health problem exists but is being ignored or its existence denied by the people in a community. Examples include the health problems identified in the 1950s as attributable to tobacco addiction, and occupational health problems that workers and their families do not want to be ameliorated because they fear economic repercussions or loss of employment. Epidemiologists are frequently drawn to the problems of disempowered communities, and may require unusual sensitivity in dealing with them, because it can be difficult for people in these communities to clearly articulate their needs.

5.4 Epidemiologists do not conduct studies aimed at protecting the interests of one group in a community at the expense of or to the detriment of others.

6. Access to information

6.1 Concern for personal privacy has led to measures intended to improve the security of information stored in health records; in some countries, this has limited the usefulness of health information systems such as linked medical records. However, the public interest in identifying the causes and control of health problems indicates a need to preserve and enhance the efficacy of health information systems. A conflict may arise between a legitimate desire to enhance personal privacy and the societal benefits of access to personal information for surveillance and research purposes, although this conflict is often more apparent than real. Epidemiologists may need to emphasize to community and political leaders that adequate safeguards of individual interests can almost always be developed in ways that protect research interests as well. Epidemiologists have an obligation not to use health information systems for improper purposes.

6.2 The results of epidemiological studies should generally enter the public domain by publication or dissemination in other ways. Moreover, the raw data and protocols used in epidemiological study should be accessible and available to other epidemiologists in order that findings can be replicated. Clear understanding of this basic principle of good scientific conduct facilitates collegiality and reduces the chance of adversarial or confrontational relationships. Unfettered access to data, protocols and findings applies to all, including special interest groups that may seek to withhold, selectively release or manipulate data in ways that are not in the public interest.

7. Scientific integrity

7.1 Ethical issues arise in the choice of research topics and research methods. Epidemiologists have an obligation to serve community and global needs in exercising these choices.

7.2 Honesty and impartiality are essential components of all sciences, including epidemiology; it is professional misconduct to distort the truth, whether by manipulating data, applying inappropriate methods of analysis, withholding part of the evidence, or by crimes such as misrepresentation or fraud.

7.3 At times, epidemiologists may find themselves in situations where there is a conflict of interest. For example, an employing or research-funding agency may seek to influence the presentation of results of epidemiological study, by manipulating the data, by slanted interpretation or by requiring that some findings be withheld. In such situations, epidemiologists have an obligation to uphold the public interest in full unbiased disclosure, rather than supporting narrow or special interests such as those of pressure groups that may seek to distort the truth. Any conflict of interest must be disclosed.

7.4 Epidemiologists often discover hazards to health that demand correction; they may therefore choose to become advocates. Advocacy for health does not preclude scientific impartiality but is incompatible with neutrality between the interests of health and other, often competing interests. Value-laden statements made and actions taken in the role of advocate should therefore be clearly distinguished from those deriving from the role as scientist. Neverthele even purely scientific interpretations of factual evidence in epidemiology, as in other sciences, are rarely value-free.

7.5 Such conflicts as those described above are more likely to be resolved in a constructive way by collective rather than individual judgements. It thus becomes an opportunity and an obligation of professional associations, editorial boards, ethics review committees and the like, to provide a forum for presentation and evaluation of these conflicts.

8. Professional standards

8.1 Epidemiologists interact with free-living healthy people, patients, colleagues in their own field and other health professionals, students and others learning epidemiology, health policy makers, research funding agencies, the media, special interest groups of many kinds, and usually an employer. Respect for the dignity, integrity and motivation of other participants in all these interactions is a professional obligation.

8.2 Interactions with the public, clients and patients have been discussed above. Interactions with other epidemiologists should be collegial. Discussion of disagreements about methods, procedures or scientific findings, should be objective and restrained, not confrontational or destructive of reputations. Interactions with the media should clearly distinguish among statements of facts, opinions and advocacy. Any conflict of interest should be disclosed.

8.3 The education and training requirements of epidemiologists are ill-defined; nonetheless, epidemiologists responsible for educating and training entrants to the discipline should communicate to students and demonstrate by example their commitment to the highest possible standards of professional conduct. Education and training of epidemiologists should include discussion of ethical issues.

9. Cultural variations in values

9.1 Epidemiologists may encounter difficulty in acting in accordance with moral values other than their own. It is necessary to respect moral values other than one's own, but without sacrificing basic scientific or ethical principles. Values differ among the major cultures and religious groups, e g among Christian, Hindu, Orthodox Islamic societies. The concept of autonomy is different in some communities, such as some tribal communities and some religious sects, where individuals perceive hemselves as part of a collective in which essential decisions are taken on their behalf by a tribal headman or religious leader. In some countries and cultures, patients consider that they delegate to their doctor all responsibility for decision- making, including decisions requiring informed consent. However, as much as possible, consent of community or family leaders should not be a substitute for or override consent or choice on the part of individuals.

9.2 Epidemiologists must be cognizant of cultural variations, but may have to face difficult choices if their studies disclose culturally determined hazards to health that can be corrected only by changing behaviors that are deeply rooted in custom or tradition. In such situations, as in all others where the moral and ethical choices are difficult, careful consideration of all the options in discussion with appropriately qualified experts is the correct procedure. Opinions vary about the extent to which western values may be imposed upon other cultures.

10. Conclusion

These guidelines on ethics for epidemiologists are not a formal code of conduct; rather, this document is a starting point for discussions among epidemiologists and other concerned parties who encounter moral or ethical dilemmas in practice or research that uses epidemiological methods and procedures.

Congrès annuel de la Société française de santé publique Nancy-Vandœuvre, 14–16 novembre 1990

Largement ouvert aux professionnels de la santé comme aux responsable sociaux, ce Congrès a réuni 300 personnes, dont une quinzaine de Belges, de Québecois, de Suisses et quelques journalistes scientifiques.

«Les examens de santé: leur place dans une politique de prévention», le thème général choisi cette année, a donné lieu

- à une série imposante d'exposés, de posters et d'échanges informels,
- à une discussion «en conclave» d'une trentaine d'experts dont il sera question plus bas.

En même temps que ce conclave se tenait une Assemblée générale chargée d'approuver de nouveaux statuts, destinés à restructurer cette Société, en fonction de nouveaux besoins et de nouvelles demandes.

Les *praticiens* de ces examens de santé opèrent avant tout, en France, dans les services de protection maternelle et infantile (PMI), de santé scolaire et de santé universitaire, ainsi que dans les centres de bilans de santé; mais il peut s'agir aussi de médecins praticiens.

Ces examens de santé, bien qu'effectués sur une base légale et/ou règlementaire depuis plus d'un demi-siècle dans ce pays, sont actuellement remis en cause: leur utilité, leur efficacité, leur efficience, leurs publics- cible, leur contenu, voire leur légitimité font problème – selon le constat de départ des organisateurs du congrès –.

Au delà des opérations de *prévention secondaire* (dépistage), de nombreuses équipes s'attachent de plus en plus à faire de ces examens un instrument de *prévention primaire*: profitant d'un contact systématique et/ou périodique avec les populations desservies, ces équipes mettent en œuvre des programmes complémentaires d'information et d'éducation pour la santé souvent personnalisés. En outre, certaines les utilisent pour des recherches épidémiologiques différenciées. Enfin, beaucoup se préoccupent de plus en plus d'évaluation, mais sans disposer toujours des outils nécessaires.

D'où des décisions prises sur la base d'arguments tenant davantage compte des facteurs d'opportunité que de besoins de santé réels des populations ou d'une juste affectation des ressources. C'est dire l'intérêt majeur et la grande actualité du thème retenu.

Il n'est évidemment pas question ici de tenter une relation portant sur l'ensemble des présentations (orales ou affichées). Disons simplement que les points de vue plus objectifs exprimés par des universitaires ont alterné avec les prises de position plus subjectives venant des acteurs du terrain, les unes teintées d'un enthousiasme désintéressé pour la tâche à accomplir avec des moyens limités, les autres, d'un intérêt corporatiste moins désintéressé.

Revenons plutôt aux *prises de position du groupe d'«experts»* de tous horizons, dont le soussigné a eu le privilège de faire partie, lors de ce conclave très original d'une demi-journée.

Dûment renseignés à l'avance par quatre substanciels rapports d'un cabinet privé chargé d'étudier les structures citées plus haut (services de PMI, de santé scolaire, de santé universitaire, et centres de bilans de santé), ces experts ont été amenés à prendre position individuellement sur dix propositions rédigées de manière délibérément très concise, voire provocante. En voici trois exemples:

a) les examens de santé systématiques ne sont vraiment pertinents que pour les groupes à risque;
b) c'est en intégrant une dimension curative que les structures en charge des examens de santé systématiques peuvent devenir réellement crédibles pour la population (desservie);
c) la coupure d'avec le système de soins rend souvent difficile le suivi (individuel) de ces examens.

Les critères permettant aux experts de se déterminer n'étant pas définis – et chacun devant prendre position pour, contre, à la fois pour et contre ou s'abstenir – la justification de cette prise de position individuelle nécessitait un éclaircissement; d'où, sur chaque proposition, un échange de vue nourri qu'orchestrait un modérateur.

Rapportant en séance plénière finale sur cette expérience, deux des experts identifièrent habilement des questions pour les quelles un certain consensus avait pu être dégagé soit du côté favorable, soit du côté défavorable, et celles à propos desquelles les opinions des experts étaient restées plus ou moins fortement polarisées sur le oui et le non. En faveur de la pertinence d'une majorité des dix questions posées s'est dégagé le constat d'une faible proportion d'abstentions.

Mais de là à déboucher sur la formulation de propositions précises à l'intention des décideurs – ainsi que semblaient l'avoir espéré les organisateurs de cette réunion –, il est resté une large marge que seule une réflexion ultérieure prolongée devrait permettre de combler: c'est à cette tâche en particulier que devrait s'atteler l'un des nouveaux organes dont la Société s'est dotée en approuvant ses nouveaux statuts.

En bref, un congrès animé (par un thème mobilisateur), substanciel et instructif quant à son apport, précédé d'une évaluation externe et neutre des structures opérationnelles en place (à l'intention du groupe hétérogène d'élus désignés comme experts) et marqué d'une volonté évidente de renouveau. Tout bien pesé, l'observateur extérieur ne peut que se demander si, à l'avenir, ce n'est pas tant de la place des examens de santé dans la stratégie préventive dont il sera question, mais bien plutôt de cette stratégie elle-même!

(Les comptes rendus détaillés seront publiés dans «Santé publique», le périodique bimestriel de cette Société).

Olivier Jeanneret, Genève