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An ethical framework for drug epidemiology: identifying the issues

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ABSTRACT

The Global Workshop on Drug Information Systems: Activities, Methods and Future Opportunities, held in Vienna from 3 to 5 December 2001, highlighted the need for an ethical framework for drug epidemiology. The present article suggests some first steps that could be taken towards developing such a framework by identifying some of the key issues for consideration. The scope of drug epidemiology is defined and attention is drawn to the current dearth of scholarship and lack of specific guidelines on the ethical issues raised by such research. The importance of ethics in drug epidemiology is explained and it is argued that a guiding framework would be helpful in promoting an understanding of some of the prominent ethical challenges in this field (for example, obtaining free and informed consent to participation, the use of inducements to recruit subjects, the protection of interviewees from violations of privacy and the risk of prosecution, and the safety of field research staff). The traditional principles of biomedical ethics are outlined and their limitations in enabling an understanding of ethical issues in drug epidemiology are considered. The utility of practical case-based approaches to ethical analysis is also discussed. The article concludes with broad recommendations for an ethical framework for drug epidemiology that can be refined in further discussion on those important issues.

Keywords: ethics; epidemiology; drug use; public health.

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Introduction

The idea for the present article grew from the first author's participation in the Global Workshop on Drug Information Systems: Activities, Methods and Future Opportunities, organized by the United Nations International Drug Control Programme and held in Vienna from 3 to 5 December 2001. The purpose of the workshop was to discuss global trends in illicit drug use and to reflect on the utility of epidemiological methods in monitoring such trends. At the workshop some common practical challenges of drug epidemiology research were highlighted, such as issues of study design, subject recruitment, data collection and analysis, reporting, the secondary uses of data, many of which raised ethical challenges, or at least signalled issues that ought to be the subject of explicit ethical analysis.

At the workshop it became clear that there was currently no ethical framework to guide investigators in planning and conducting epidemiological studies of illicit drug use or to assist ethics committees and funding bodies in appraising research proposals and identifying ways to resolve those issues. The purpose of the present article, therefore, is to discuss some of the first steps that could be taken towards developing such a framework.

Public health, epidemiology and ethics

The mortality and morbidity associated with the misuse of alcohol and illicit drugs represent a significant challenge to public health [1, 2]. A key feature of the modern public health response to such drug problems has been the use of epidemiological research methods to define at-risk populations, identify opportunities for intervention and evaluate the effects of different policies.

A consensus has slowly emerged that epidemiological research raises a unique set of ethical challenges [3-5], including questions of data-sharing, confidentiality, privacy and the role of epidemiology in public health advocacy. Although a number of ethics guidelines have been proposed for epidemiologists, the thinking on the ethics of epidemiology is still in its infancy and little attention has been given to defining its core values [5].

More generally, there is a lack of ethics literacy in the public health field [6-8] and no agreed framework in public health for analysing ethical dilemmas [9]. There is a similar scarcity of critical discussion of either the ethical underpinnings of addiction research or how to deal with its day-to-day ethical challenges [10]. In addition, the increasing application of drug information systems and rapid assessment methods to the study of drug epidemiology has occurred in a theoretical vacuum [11]. A salient example of this lack of analysis has been the failure to develop an ethical framework for drug epidemiology.

The boundaries of epidemiological research on drug addiction are not sharply defined. Drug epidemiology includes surveys of patterns of licit and illicit drug use in the community that define populations at risk [12]. It also encompasses longitudinal studies of the personal and social factors that predict the course of drug

use [12, 13]. Drug epidemiology also includes studies of the prevalence and correlates of drug dependence in the general population using standardized diagnostic interviews [14]. Observational studies of treated populations are also employed to examine rates of mortality, morbidity and abstinence among drug-dependent persons [15].

Ethical challenges in drug epidemiology

In many developed countries, there are institutional research ethics committees that oversee the ethical conduct of human research. These committees typically apply broad ethical principles in advising on the ethical conduct of biomedical, clinical and social research. There are reasonable concerns about the applicability of such principles and standards to new and emerging specialized fields of research, such as drug epidemiology. General ethical principles often fail to provide specific guidance in dealing with the complexities and ambiguities of ethical challenges that arise in everyday practice [16]. There are also questions about how such standards and guidelines, which have been developed in a specific cultural context, may be applied in developing countries that may have either very different or no research traditions and may not have an established institutional ethics committee system.

Epidemiological research on drug addiction exemplifies many of these concerns. The present article includes an examination of some of the major challenges in drug epidemiology that also have important ethical aspects. Many of these ethical challenges remain unresolved, leaving open the possibility of serious ethical breaches.

Free and informed consent

The adequacy of informed consent is commonly assessed in terms of the level of information provided to participants about research procedures, risks, benefits and safeguards; the types of information delivery when literacy levels and preferred communication modes are considered; the opportunities for participants to voice concerns and ask questions; the extent to which consent is free from duress, undue influence or intimidation; and who provides consent in accordance with local traditions.

Free and informed consent to participate in epidemiological research does not present any special problems for adults who can understand the nature of their participation and can freely decide whether or not they wish to participate. It presents more of an ethical issue for epidemiological studies of adolescents; such studies are increasingly being conducted because adolescence is when drug use often begins [17]. The participation of adolescents in any form of research usually requires parental consent and adolescent assent [4]. Obtaining such consent can be cumbersome in school-based surveys of drug use, which are an efficient

way of doing surveys of drug use. Low response rates and the underrepresentation of minority groups have prompted researchers to use a method of "passive parental consent", in which parents are informed that a survey is to be done in a circular that invites them to object to their child's participation. It is then assumed that the absence of parental objection means that the child can be included in school surveys. This approach requires more ethical justification and discussion.

The issue of informed consent also arises in the case of research involving participants who may be intoxicated, or who may have a psychiatric condition requiring medication [18]. There has been little discussion in the addictions literature of the implications for consent, autonomy and voluntariness of recruiting intoxicated persons for drug research. Few records are kept as to the intoxicated state of research participants in drug epidemiology studies, though we note from experience that it is not unusual in illicit drug research for a small proportion of participants to be intoxicated to some degree at interview. The College on Problems of Drug Dependence based in the United States of America, has suggested that informed consent should not be obtained when prospective participants are intoxicated, in withdrawal or cognitively impaired [19]. However, it is unclear how these states may be reliably determined. Some important ethical questions to be explored are whether intoxication should be an absolute exclusion criterion, how participants who are intoxicated but lucid should be dealt with, how researchers should judge the extent of impairment and how reliable such judgements would be.

The payment of research participants may also raise issues of consent in studies of drug users. In Australia, for example, it has been common practice since 1984 for drug researchers to provide monetary payment to drug users who participate in research interviews. It has proved to be a successful way of recruiting illicit drug users for a variety of studies. It is also standard practice in drug research in the United States [19]. While the bioethics literature has explored the ethics of paying research participants [20-23], it has not yet considered the special issues that exist in relation to reimbursing drug users for research involvement. Critics of the practice are concerned that cash payments could serve as an inducement and be used by drug users to buy drugs [17]. Non-cash reimbursement has been suggested as more appropriate for this group. Advocates of cash payment claim that payment for research participation is an ethical practice, as it reflects the ethical principles of respect and dignity [20, 24], and that non-cash methods may reflect negative drug user stereotypes ("they only participate in research for the money") and a paternalistic view of the capacity and rights of users to make their own choices. That issue is controversial and remains unresolved in the drug research setting. Issues requiring further attention include the suitability of various ethical frameworks for understanding research participant motivation; the relative weight placed upon various motivators for determining research involvement; definitions of inducement; the quantification of the value of time and out-of-pocket expenses; the mechanisms for reimbursement; and analysis of the risks and harm that may arise from reimbursement practices.

Confidentiality, privacy and legal hazard

Protecting the privacy of participants and the confidentiality of the information that they provide is critical in drug epidemiological research. The use of certain drugs, such as cannabis, cocaine and heroin, is illegal, as is the use of alcohol by persons who are under the minimum legal drinking age. Drug use surveys may also ask about other illegal acts, such as driving while intoxicated, selling illegal drugs or engaging in theft, fraud or violence to finance drug use. If such data were linked to individuals and provided to the police, criminal charges could be brought. In the United States, certificates of confidentiality, which provide subjects with an assurance that this will not happen, can be obtained by researchers. The situation in most other countries is much less clear [25, 26].

Assuring the confidentiality of information is less of a problem when data are collected in a single cross-sectional interview and no information identifying subjects, such as their names, is obtained. Confidentiality may become much more of an issue in longitudinal studies, during which multiple contact details may be collected to allow individuals to be contacted again for additional interviews. Standard precautions are to store separately and securely names and identifiers and the survey data. This could become a major issue if biological samples from which deoxyribonucleic acid (DNA) samples can be derived (blood, for example) were taken. Such a DNA sample would provide a unique identifier for all individuals (except identical twins) that could, if linked with questionnaire or interview data, permit named persons to be linked to self-reported illegal acts. Special legal protection and research precautions would be necessary to protect privacy in such cases. The implications for drug epidemiology of recent changes to health privacy and data protection legislation in a number of jurisdictions will require careful monitoring [27].

Safety issues

Interviews with illicit drug users are often thought of as potentially dangerous [28]. In order to protect the confidentiality of participants when conducting face-to-face survey work with illicit drug users in the field, interviews are often conducted in settings that are out of the public view. Interviews may be held outside of normal business hours, at night, at the participant's residence, in settings where researcher safety cannot necessarily be guaranteed. In drug research, topics of enquiry are often sensitive and may cause feelings of anxiety and discomfort for participants. The issue of safety arises in connection with interview locations and timing; interview content; the level of support, backup and researcher training; the response to crises that require confidentiality to be broken; and the carrying of valuable personal and research items. Safety is a concern for the researcher, the participant and third parties. Although broad safety protocols for social research are starting to emerge [29-31], they may need to be adapted for use in drug epidemiology.

Other challenges

Another issue is the practice of integrating questions ("piggy-backing") on certain aspects of illicit drug abuse into studies designed for other purposes. This approach may be indicated where more in-depth research is neither feasible nor funded and where investigators are seeking to minimize the burden of similar studies on particular target groups. However, experience suggests that there are often trade-offs to such an approach [31]. Careful consideration should be given to issues such as the likely impact on reliability and validity of reports obtained from participants; researcher training; the potential for confusion created around informed consent and confidentiality assurances for qualitatively different studies; and the ethicality of participant payment if reimbursement is for multiple studies.

Ethical concerns also arise in connection with the use of the findings of drug epidemiological research to inform policy development and decision-making. Given the varying degrees of empirical uncertainty, the values that underpin the choice of research topics and the utilization of findings have ethical implications that should be explored [7].

Challenges for drug epidemiological research in developing countries

Recent discussion has highlighted the ethical challenges posed by conducting comparative epidemiological studies of drug use across different cultures [3, 4], particularly in developing countries that have no research tradition. This work, which is still in its infancy, needs to be given priority. In addition to the application of broad bioethical principles, a focus on the significant practical challenges that exist for drug epidemiology research in developing countries may highlight issues that ought to be the subject of ethical analysis and oversight. It cannot be assumed that the notions of informed consent, confidentiality and privacy that have arisen out of ethical debates in developed countries can be straightforwardly applied in all cultures and societies.

For example, there are aspects of informed consent that are particular to the conduct of drug epidemiology in developing countries. As it is a relatively recent development in research ethics, there are still many unanswered questions about the requirements of informed consent in these settings [32]. The relevance of certain issues, such as participant vulnerability, levels of awareness of and expectations about rights, communication difficulties, documentation issues and the rules of obtaining consent in hierarchical societies, is still contested [33].

Further, issues of race, culture and gender may impact upon researcher safety, in particular when the research context is developing countries [30]. Non-indigenous researchers may find it particularly difficult to conduct fieldwork in such settings. The issues may also have implications for research participants and third parties to the research, especially in small communities where the participation of a person in research is more difficult to disguise than it is in larger cities. Another issue is that of monitoring the conduct of drug epidemiological research

in developing countries. Consideration should be given to the special needs that exist in jurisdictions that lack the local institutional ethics committee infrastructure to support such ethical oversight.

In considering the ethics of research in developing countries, the need for drug epidemiologists to understand the social, economic and political context in which their work is conducted is clear [34]. This will require a commitment to including the views of all stakeholders and engaging in discussion about local ethics.

Ethics discussion in epidemiology and public health has emerged from philosophical ethics, bioethics and the writings of public health practitioners reflecting upon everyday ethical challenges in professional practice (for example, advocacy, coercion, scientific misconduct, privacy, conflicts of interest and the rights of vulnerable communities) [35]. The discussion below draws from each of these sources, beginning with a brief description of bioethical approaches to the analysis of ethical issues in biomedical research.

Ethical analysis

There are a bewildering array of competing ethical theories that seek to rationalize moral rules and allow decisions to be made on what conduct is right or good in problematical cases [36, 37]. These include principle-based deontological ethics; situational ethics; utilitarian ethics; consequentialist ethics; casuist case-based ethics; narrative ethics; feminist ethics; hermeneutical ethics; and virtue ethics [38]. All of these theories capture some aspects of ethical reasoning, but none commands universal assent among ethicists [37].

Over the past three decades, an influential set of moral principles has emerged in the Anglo-American analyses of the ethics of biomedical research [4, 37, 39]. "Principlism", as it has been called, appeals to the principles of autonomy, non-maleficence, beneficence and justice. Some variants of these principles have also been included in influential international statements of ethical principles for medical research, such as the World Medical Association Declaration of Helsinki and the statements of United Nations organizations [4]. These principles have their limitations, but they provide a useful beginning for ethical discussion.

The principles of biomedical ethics: autonomy, non-maleficence, beneficence and justice

Respecting autonomy means respecting and not interfering with the action of rational persons who have a capacity for autonomous action, that is, adults who are able to decide freely upon a course of action without influence, coercion or force [37]. In the context of biomedical research, the principle of respect for autonomy is usually taken to require informed consent to treatment or research participation, voluntariness in research participation and the maintenance of confidentiality and privacy of information provided to a researcher.

The principle of non-maleficence is simply the duty to do no harm [37]. Following the principle of non-maleficence requires refraining from causing harm or injury or from placing others at risk of harm or injury. In the biomedical research context, the principle of non-maleficence requires researchers to minimize the risks of research participation [4, 39].

Beauchamp and Childress have identified "positive beneficence" and "utility" as two elements of the principle of beneficence [37]. Positive beneficence requires researchers to perform actions that result in a benefit. Utility requires them to ensure that the benefits of their actions outweigh the burdens that they impose upon others. The principle of beneficence therefore requires that an action produces benefits and that its benefits outweigh its burdens. In the context of biomedical research, this means that the benefits of the research to society should outweigh its risks to participants and also that, in the case of individual participants, the benefits of participation exceed the risks.

Justice is probably the most controversial of the four moral principles. For the purpose of this discussion, "justice" refers to "distributive justice" rather than retributive (criminal) or rectificatory (compensatory) justice [37]. In bioethics, the principle of distributive justice has been central to debates about how to ensure equitable access to health care and reduce unequal health outcomes. In the case of research, the principle of distributive justice refers to the equitable distribution of the risks, as well as the benefits of research participation [4]. A fair and just research policy would aim to achieve a distribution of the benefits and burdens of research participation that is as fair and equitable as possible.

The limitations of biomedical ethics

Concerns have been raised as to whether biomedical ethics is an appropriate model for public health, given the tension between the individualistic orientation of bioethics and the societal focus of public health. Callahan and Jennings also note that, in a pluralistic society, numerous ethical perspectives coexist on matters of widespread interest and importance and that one or more might be appropriate for any particular ethical problem [7].

However, others have observed that the prescriptive use of key ethical principles may discourage consideration of alternative ethical perspectives, such as those emphasizing collective rather than individual responsibilities. Witkin has warned that ethical principles may therefore be seen as instruments of control rather than as moral guides for research [16]. An increasingly popular alternative approach is to view ethics as a discourse rather than as a system of rules and to encourage narrative accounts of actual ethical situations that, for example, drug epidemiological researchers face.

Moral positions are historical rather than timeless and subject to revision and augmentation. Witkin argues that by ignoring alternative ethical perspectives, people limit their capacity to assess the limits of their own belief systems and so engage in ethical discussions only within the boundaries of the "taken-for-granted" [16]. An ethical framework for drug epidemiology might usefully transcend

those boundaries by adopting a more proactive approach that breaks with the reactive research ethics traditions of the past [34].

In the absence of consensus on a universal theory of ethics, the ethical analyses of public policy cannot be a matter of deducing moral rulings from categorical imperatives or applying a utilitarian calculus to all the possible courses of action. Ethical analysis does not always achieve consensus, but the range of morally acceptable behaviour is often narrowed by ethical debate. A dialectical discovery process can identify common moral rules and shared justifications for morally acceptable courses of action. This has been described by Rawls as the method of "reflective equilibrium" [40]. It involves testing ethical principles (that may be derived from one or more ethical theories) against widely shared moral rules and judgements that have been called the "common morality" [37]. People aim to reduce the discrepancies between their moral principles and their understanding of the "common morality" and, by iterative adjustment, work towards an equilibrium between their principles and their shared moral rules and judgements.

A more recent variation of this form of pluralism has been called "pluralistic casuistry". Brody argues that, in contrast to the monistic ethical theories that attempt to reduce morality to a single value or set of principles, pluralistic casuistry reflects the reality of how people engage in moral reasoning [4]. Casuistry or case-based ethics is a method of practical ethical reasoning emphasizing the value of moral intuitions about particular cases over theories or principles [35]. Pluralistic casuistry recognizes that multiple moral values may coexist and are modifiable with reflection on more cases. Casuistry is also sympathetic to communitarian ethics, in which morality is also seen as contextual and where divergent ethical values of different communities are respected. A common theme in pluralistic approaches to ethical analysis is the key role of public discussion in achieving a balance between competing ethical values [41, 42].

Conclusions

Biomedical ethics is crucial to biomedical, clinical and social research efforts. It prescribes the boundaries of ethical research conduct by identifying core principles. However, those principles do not provide guidance in relation to the day-to-day ethical challenges that researchers encounter, in particular in specialized areas such as drug epidemiology. Furthermore, such guidelines quickly become dated, with advances in modern science occurring "much faster than either ethics, law or social and public policy" ([38], pp. 279-280).

Making decisions about what is ethical involves more than just following accepted prescriptions and principles [34]. The main virtue of ethical principles such as autonomy and beneficence is that they alert us to important ethical issues; they do not solve ethical problems. Such principles must be applied and tested in the analysis of specific cases by a process of open debate and discussion if they are to be interpreted at the practical or applied level. This approach to ethical analysis needs to inform discussions of ethical issues that arise in undertaking drug epidemiological research in developing countries.

A useful way to bridge the gap that exists between the principles of ethical research and the special challenges of drug epidemiology is through the development of an ethical framework specific to drug epidemiology. A casuistic social analysis of ethics also has utility if one is committed to sharing the decision-making in this developmental process and also interested in practical outcomes.

As drug epidemiological research becomes more global, the ability to consider the potential role of ethical systems that differ from those that have grown in the biomedical tradition will be critical for successful international collaboration. Taking a collaborative and open approach to ethics will also allow for particular ethical challenges to be viewed through many lenses, the result of which should be improved ethics problem-solving. Roberts and Reich have noted recently that for epidemiologists, an awareness of "alternative ethical arguments has become as important as knowing the advantages and disadvantages of different epidemiological techniques" ([9], p. 1059).

The ethical analysis of epidemiological research on drug use is an underdeveloped field, even in developed societies with a tradition of drug research and ethical protection of human participants in medical research. The authors hope to have demonstrated the need for drug researchers to address those issues in a more systematic way. The urgency of doing so is increased by recent efforts to expand epidemiological research on drug use to cultures and societies with little tradition of drug research and often less experience in the ethical oversight of human medical research. Given the role of international organizations such as the United Nations International Drug Control Programme and the World Health Organization in sponsoring and encouraging such research, such organizations may consider facilitating discussions on ethical issues from which an ethical framework may emerge. This suggestion should not discourage drug researchers in developed countries from initiating their own discussions of those issues.

The present article is intended as a first step towards developing an ethical framework for drug epidemiology. It is hoped that it will serve as a useful beginning for future debate on the ethical challenges involved in conducting drug epidemiology research and in doing so will assist in raising the profile of research ethics considerations for the addictions specialty in public health.

References

1. D. J. Collins and H. M. Lapsley, *The Social Costs of Alcohol and Drug Use* (Canberra, Australian Government Publishing Service, 1996).
2. C. J. Murray and A. D. Lopez, "Evidence-based health policy: lessons from the Global Burden of Disease Study", *Science*, vol. 274, 1996, pp. 1593-1594.
3. Council for International Organizations of Medical Sciences, *International Guidelines for Ethical Review of Epidemiological Studies* (Geneva, World Health Organization, 1991).
4. B. Brody, *The Ethics of Biomedical Research: an International Perspective* (Oxford, Oxford University Press, 1998).

5. S. S. Coughlin, "Ethics in epidemiology at the end of the twentieth century: ethics, values and mission statements", *Epidemiologic Review*, vol. 22, 2000, pp. 169-175.
6. N. Kass, "An ethics framework for public health", *American Journal of Public Health*, vol. 91, 2001, pp. 1776-1782.
7. D. Callahan and B. Jennings, "Ethics and public health: forging a strong relationship", *American Journal of Public Health*, vol. 92, 2002, pp. 169-176.
8. B. W. Levin and A. R. Fleischman, "Public health and bioethics: the benefits of collaboration", *American Journal of Public Health*, vol. 92, 2002, pp. 165-167.
9. M. J. Roberts and M. R. Reich, "Ethical analysis in public health", *The Lancet*, vol. 359, 2002, pp. 1055-1059.
10. C. Fry, "Raising the profile of human research ethics in addictions research: a key role for addictions journals", *Addiction*, vol. 97, 2002, pp. 229-230.
11. P. Griffiths and others, "Drug information systems, early warning and new drug trends: can drug trend monitoring systems become more sensitive to emerging trends in drug consumption?", *Substance Use and Misuse*, vol. 35, 2002, pp. 811-844.
12. J. G. Bachman and others, *Smoking, Drinking and Drug Use in Young Adulthood: the Impacts of New Freedoms and Responsibilities* (Mahwah, New Jersey, Lawrence Erlbaum, 1997).
13. D. B. Kandel and K. Chen, "Types of marijuana users by longitudinal course", *Journal of Studies on Alcohol*, vol. 61, 2000, pp. 367-378.
14. J. C. Anthony and J. Helzer, "Syndromes of drug abuse and dependence", *Psychiatric Disorders in America*, L. N. Robins and D. A. Regier, eds. (New York, Academic Press, 1991), pp. 116-154.
15. Y. I. Hser and others, "A 33-year follow up of narcotic addicts", *Archives of General Psychiatry*, vol. 58, 2001, pp. 503-508.
16. S. L. Witkin, "Ethics-R-Us", *Social Work*, vol. 45, 2000, pp. 197-200.
17. J. L. Brody and H. B. Waldron, "Ethical issues in research on the treatment of adolescent substance abuse disorders", *Addictive Behaviors*, vol. 25, 2002, pp. 217-228.
18. R. E. Tarter and others, "Cognitive capacity in female adolescent substance abusers", *Drug and Alcohol Dependence*, vol. 39, 1995, pp. 15-21.
19. College on Problems of Drug Dependence, "Human subject issues in drug abuse research", *Drug and Alcohol Dependence*, vol. 37, 1995, pp. 167-175.
20. C. Grady, "Money for research participation: does it jeopardize informed consent?", *American Journal of Bioethics*, vol. 1, 2001, pp. 41-44.
21. R. Macklin, "'Due' and 'undue' inducements: on paying money to research subjects", *A Review of Human Subjects Research*, vol. 3 (Institutional Review Board, 1981), pp. 1-6.
22. P. McNeill, "Paying people to participate in research: why not?", *Bioethics*, vol. 11, 1997, pp. 390-396.
23. M. Wilkinson and A. Moore, "Inducement in research", *Bioethics*, vol. 11, 1997, pp. 373-389.
24. A. J. Ritter, C. Fry and A. Swan, "The ethics of reimbursing injecting drug users for public health research interviews: what price are we prepared to pay?", *International Journal of Drug Policy* (forthcoming).

25. J. Fitzgerald and M. Hamilton, "Confidentiality, disseminated regulation and ethico-legal liabilities in research with hidden populations of illicit drug users", *Addiction*, vol. 92, 1996, pp. 1099-1107.
26. W. Loxley, D. Hawks and J. Bevan, "Protecting the interests of participants in research into illicit drug use: two case studies", *Addiction*, vol. 92, 1996, pp. 1081-1085.
27. D. A. Lawlor and T. Stone, "Public health and data protection: an inevitable collision or potential for a meeting of minds?", *International Journal of Epidemiology*, vol. 30, 2001, pp. 1221-1225.
28. S. Wright, H. Klee and P. Reid, "Interviewing illicit drug users: observations from the field", *Addiction Research*, vol. 6, 1998, pp. 517-535.
29. C. Day and others, "Interviewing/safety protocol for the National Drug and Alcohol Research Centre" (Sydney, National Drug and Alcohol Research Centre Safety Committee, 2001).
30. G. Craig, A. Corden and P. Thornton, "Safety in social research", *Social Research Update*, vol. 29, 2002, pp. 1-6.
31. World Health Organization, "Putting women first: ethical and safety recommendations for research on domestic violence against women", Department of Injuries and Violence Prevention, undated.
32. C. Ijsselmuiden and R. Faden, "Research and informed consent in Africa: another look", *Health and Human Rights: a Reader*, J. M. Mann and others, eds. (New York, Routledge, 1999), pp. 363-372.
33. S. Sánchez and others, "Informed consent procedures: responsibilities of researchers in developing countries", *Bioethics*, vol. 15, 2001, pp. 398-412.
34. S. R. Benatar and P. A. Singer, "A new look at international research ethics", *British Medical Journal*, vol. 321, 2000, pp. 824-826.
35. D. L. Weed and R. E. McKeown, "Ethics in epidemiology and public health: I. Technical terms", *Journal of Epidemiology and Community Health*, vol. 55, 2001, pp. 855-857.
36. J. Rachels, *The Elements of Moral Philosophy*, 2nd ed. (New York, McGraw-Hill, 1993).
37. T. L. Beauchamp and J. F. Childress, *Principles of Biomedical Ethics*, 5th ed. (Oxford, Oxford University Press, 2001).
38. M. Somerville, *The Ethical Canary: Science, Society and the Human Spirit* (Viking/Penguin Books, Australia, 2000).
39. A. R. Jonsen, *The Birth of Bioethics* (Oxford, Oxford University Press, 1999).
40. J. A. Rawls, *Theory of Justice* (Oxford, Oxford University Press, 1971).
41. S. Hampshire, "Morality and convention", *Utilitarianism and Beyond*, A. Sen and B. Williams, eds. (New York, Cambridge University Press, 1982).
42. M. Nussbaum, "Non-relative virtues: an Aristotelian approach", *The Quality of Life*, M. Nussbaum and A. Sen, eds. (New York, Oxford University Press, 1993).