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Ethical Considerations for Drug Abuse Epidemiologic Research

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1. EPIDEMIOLOGY, DRUGS AND ETHICS

The mortality and morbidity caused by alcohol, tobacco and illicit drug misuse represents a significant public health burden (Ezzati et al., 2002). A key part of the public health response is the collection of epidemiological and social science data to define at-risk populations to identify opportunities for intervention and to evaluate the effectiveness of policies in preventing or treating drug misuse and drug-related harm. The systematic use of epidemiological and social science research methods to study illicit drug use is barely 40 years old in the United States and United Kingdom, which have pioneered this approach. Because of the sensitive nature of epidemiological research on illicit drug use a unique set of ethical challenges need to be explicitly addressed by the field. Although ethics guidelines have been proposed (Council for International Organizations of Medical Sciences, 1991), scholarship on the ethics of epidemiology is scant, and consensus on core values not yet achieved (Coughlin, 2000).

1.1. The Nature of Epidemiological Research on Drug Use

Epidemiological research on drug use includes: community surveys of licit and illicit drug use patterns that define populations at risk (Bachman et al., 1997); longitudinal studies of personal and social factors that predict the course of drug use (Bachman et al., 1997; Kandel and Chen, 2000; Wills et al., herein); studies of the prevalence and correlates of drug dependence in the general population using standardized diagnostic interviews (Anthony and Helzer, 1991); and observational studies of treated populations using administrative and health record systems to examine mortality, morbidity and abstinence rates among drug dependent persons (Hser et al., 2001). In the past decade drug epidemiology has increasingly applied a mix of quantitative and qualitative social research methods (see Rhodes et al., 2000). Methods developed by ethnographers have also been employed successfully in epidemiological studies of drug use (e.g. Agar, 1996; Maher et al., 1998).

Epidemiological drug research occurs in a variety of settings (e.g. schools, work place, public settings, prisons, drug treatment facilities etc), and includes diverse target groups (e.g. youth, sex workers, homeless people, homosexual men,

indigenous peoples etc). The development of epidemiological research methods to study drug use has largely occurred in industrialized societies that have had substantial problems with illicit drug use in large cities and the societal resources to devote to studying this phenomenon. As the morbidity and mortality associated with illicit drug use has become internationally recognized, so too the application of epidemiological research methods has become increasingly global, extending frequently to developing countries.

The spread of such research beyond the settings in which it originated has in turn raised questions about the possible role of ethical frameworks that differ from those that have grown from the Western biomedical tradition. Resolving such questions will be important for successful international collaborations in drug epidemiology. For epidemiologists, an awareness of "alternative ethical arguments has become as important as knowing the advantages and disadvantages of different epidemiological techniques" (Roberts and Reich, 2002 p. 1059).

1.2. Why is Ethics Important in Drug Use Epidemiology?

Since the end of the Second World War, the world has witnessed the adverse effects of unethical experimentation on vulnerable groups using invasive medical interventions (Nazi medical experimentation, the Tuskegee syphilis study, clinical trial deaths etc) (Brody, 1998). These events prompted the development of international ethics guidelines for medical research with humans. Institutional ethics committee frameworks for the oversight and regulation of such research have also emerged in most developed countries to protect the rights of participants in medical research. These are enforced through obligatory compliance with the World Medical Association Declaration of Helsinki (see http://www.wma.net), or local frameworks that are consistent with the Helsinki principles.

The conduct of drug use epidemiology differs from traditional biomedical research in that it rarely involves invasive medical interventions that may directly harm or benefit study participants. Rather, it typically involves collection of sensitive personal information on drug use and illegal activities from study participants, where the principal potential harms arise if this information becomes known to third parties and used to the detriment of research participants (e.g. workplace discrimination, criminal prosecution). Participants in epidemiological research need to be protected from these outcomes. Discussions about the ethics of drug epidemiology connect closely with civil liberties, human rights and justice.

There are also compelling non-ethical reasons for protecting the confidentiality of drug research participants. Those who do participate in studies where confidentiality and other risks exist may be less forthcoming or even deliberately misleading about their drug use and related issues. Reliable and valid data on drug

use requires well-designed epidemiological research that is conducted in accordance with accepted ethical standards.

2. ETHICAL PRINCIPLES

There is little consensus among ethicists on the most appropriate approach to use in deciding how we should act in difficult cases (Beauchamp and Childress, 2001; Rachels, 1993). Among the competing ethical theories is "utilitarianism" which judges individual actions or moral rules according to their consequences (e.g. Singer, 1993), and "deontological" or duty-based ethical theories that propose that our actions should be guided by broad ethical principles or duties (e.g. Rawls, 1971). For a review of ethical theories refer to LaFollette (2001).

A number of ethical principles have been suggested as a form of common moral ground that can be accepted by most people. These include autonomy, beneficence and others that are discussed below. These principles alert us to the existence of important ethical issues but they alone do not solve our ethical problems or necessarily tell us how to behave. Making decisions about what is ethical behavior or processes requires more than simply following accepted prescriptions and principles (Jonsen, 1998). If we are to take a rule-based approach to ethics, these principles must be applied and tested in specific cases by a process of debate and discussion. This approach to applied ethical analysis is a useful starting point to develop ethical standards in drug epidemiology.

2.1. Autonomy, Non-Maleficence, Beneficence, Justice

An influential set of moral principles has emerged from ethical analyses of biomedical research in the US (grounded in a Judaeo-Christian tradition of rule-based morality). These are the principles of autonomy, non-maleficence, beneficence, and justice (Beauchamp and Childress, 2001) that were originally derived from internationally recognized guidelines for the ethical conduct of medical research with humans (Brody, 1998; Beauchamp and Childress, 2001) but have been increasingly applied to all types of research with humans, including social and behavioral and epidemiological research.

Respect for autonomy means that we respect and not interfere with the actions of rational persons, persons who are assumed to be able to freely decide upon a course of action without being coerced or forced. In biomedical research, respect for autonomy requires that research participants give informed and voluntary consent to participate in research; that assurances are provided that the confidentiality and privacy of any personal information that they provide will be respected, and that researchers will be truthful about risks that may arise from their study participation (Beauchamp and Childress, 2001).

Non-maleficence simply means, "do no harm", and requires us to refrain from causing harm or injury, or from placing others at risk of harm or injury. In biomedical research, the principle requires researchers to minimize the risks of research participation (Brody, 1998; Beauchamp and Childress, 2001). Truth telling is also relevant to the principle of non-maleficence. Beneficence requires that research studies have a reasonable chance of producing benefits, and that the benefits of research outweigh any burdens or risks of participation. In biomedical research, this means not only that the benefits of the research to society outweigh the risks but also that the risks for individual participants are outweighed by the benefits of their participation.

The principle of distributive justice requires a fair and equitable distribution of the burdens and the benefits of research participation (Brody, 1998). This requires: that the risks of research participation were not unfairly distributed (e.g. confined to the poor and indigent); and that any benefits of research participation (e.g. access to promising new treatments) were fairly shared between all who potentially may benefit from it.

2.2. Ethical Requirements of Human Biomedical Research

Debate over the past half century about the applied ethics of medical research has produced a consensus on basic requirements for ethical biomedical research with human subjects (Brody, 1998; Jonsen, 1998). While conditions for ethical approval may differ in detail from country to country, the following basic set of ethical requirements or rules is found in most national guidelines (Brody, 1998).

2.2.1. Independent Ethical Review of Risks and Benefits

Before any human research proceeds, investigators must obtain ethical approval from an independent committee of ethical review. This is usually an Institutional Ethics Committee, although terminology differs between countries (e.g. Institutional Review Boards in the US, Human Research Ethics Committees in Australia etc), as do the ways in which these committees are constituted and how they operate. Their major aim is to provide an external and independent assessment of whether the benefits of proposed research outweigh risks to participants (Brody, 1998).

2.2.2. Free and Informed Consent

Informed consent is an essential condition of ethical research, and involves asking potential participants to consent to their participation after a detailed description of events that will occur in the course of the study (including description of possible risks and adverse events), and an opportunity to ask questions (Brody,

1998). The participation of persons under the age of 18 years may require the consent of a parent or guardian, along with the *assent* of the young person, though this will vary across jurisdictions. Any uncertainty about participation risks must be accurately communicated to potential participants along with close monitoring of adverse events that may occur, and remedial action where necessary.

All forms of consent must be given after participants are informed of what involvement in the research will require. Ideally, the consent process would include an independent witness to ensure the integrity of the process, and participants must be allowed to withdraw at any time (along with data collected). A participant's decision to withdraw must be respected and be free of consequences, such as incurred costs or refusal of future care (Brody, 1998).

The conditions under which persons are recruited into a study should be free from coercion or excessive inducement to participate (Brody, 1998). In recent years, it has become more common to reimburse study participants (i.e., via cash payment, vouchers, movie tickets, travel costs etc). However, cash payments may be interpreted by potential study participants as rewards for potential risks or harm. Under these circumstances, vouchers and money may serve as inducements for participation rather than as acceptable reimbursements for time and travel costs (Ashcroft, 2001).

2.2.3. Privacy and Confidentiality

Participant privacy is another ethical obligation that should be respected in any research. The privacy question refers to the extent to which a research study collects, uses or discloses identified or potentially identifiable information without individual consent. It encompasses 'confidentiality' (non disclosure of information and/or identity) and 'anonymity' (protection of participant identity). The basic accepted standard is that personal information must not be disclosed to any individual or group without participant consent, and participant identity should not be identifiable from the published results of the study (Brody, 1998).

2.2.4. Vulnerable Research Participants

Research involving persons who are cognitively or physically impaired or in a dependent relationship with investigators (e.g. as clients or students) requires special consideration (Brody, 1998). The most widely discussed issue is whether vulnerable persons are capable of providing informed consent in that they are able to: (1) understand the rationale for a research study; (2) understand what is required of them and why; and (3) provide free and informed consent to participate in the study (National Bioethics Advisory Commission, 1999). The scientific community hold differing views on the ability of vulnerable persons to give informed consent to research participation. A generally accepted model of practice is one

that strives to protect special needs and minimize potential research harms (Brody, 1998).

3. ETHICAL ISSUES IN DRUG EPIDEMIOLOGICAL RESEARCH

3.1. Ethical Challenges in Drug Use Epidemiology

In most developed countries the institutional research ethics committees that oversee human research typically adhere to the broad ethical principles outlined above. However, questions exist about the applicability of such principles and standards to new and emerging fields of research. General ethical principles often fail to provide specific guidance in dealing with the complexities and ambiguities of ethical challenges that arise in everyday practice (Witkin, 2000). There are also concerns about how ethical standards and processes developed in one cultural context apply in settings where different research traditions may exist, or where morality and ethics are not institutionalized. We illustrate some of these concerns by considering some major unresolved ethical challenges in drug epidemiological research. Our aim is to highlight significant ethical challenges, rather than provide exhaustive analysis or solutions.

3.1.1. Free and Informed Consent

The adequacy of informed consent is commonly assessed in relation to questions about: the level of information provided to participants about research procedures, risks, benefits and safeguards; types of information delivery when considering literacy levels and preferred communication modes; opportunities for participants to voice concerns and ask questions; the extent to which consent is free from duress, undue influence or intimidation; and who has authority to provide consent.

Free and informed consent to participate in epidemiological research does not present any special problems for autonomous adults who can understand the nature of their participation and can freely decide to be involved or not. It presents more of an ethical issue for epidemiological studies of persons under the age of consent (Brody and Waldron, 2000), particularly when jurisdictional regulations differ. Obtaining consent can be cumbersome in school-based surveys of drug use (an efficient way of doing surveys of drug use). Typically low response rates and under-representation of minority groups has prompted researchers to use a method of "passive parental consent", in which a circular or letter informs parents that a survey is to be conducted and 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 further ethical justification and discussion.

3.1.1.a. Impaired Consent. A special issue for epidemiological research on drug use and addiction is whether persons who are drug dependent have an impaired capacity to consent to participation in research. It has become an issue in the context of experimental and clinical research involving the administration of drugs of dependence (Charland, 2002; Cohen, 2002; College on Problems of Drug Dependence, 1995; Gorelick et al., 1999; Hall et al., 2003). Some (e.g. Charland, 2002; Cohen, 2002) have argued that the nature of addiction precludes an informed decision as to participation in experiments where a drug of dependence will be administered. It is uncertain how applicable these arguments are to epidemiological drug research, but the question of consent and impairment is clearly important.

Informed consent issues also arise for research participants who may be intoxicated, or who may have an acute drug induced psychiatric condition (Tarter et al., 1995). The College on Problems of Drug Dependence (1995) has suggested that informed consent should not be obtained when prospective participants are intoxicated, in withdrawal or cognitively impaired. However, it is unclear how a state of intoxication or impairment (of comprehension or performance) may be reliably determined. A key ethical consideration is the potential risks people may be exposed to because of their participation (e.g. increased intoxication and risk of overdose).

3.1.1.b. Research Participant Payment. Participant payment in epidemiological research on drug use raises questions about voluntary consent. In Australia and the US for example, it has been common practice since the 1980s for researchers to pay illicit drug users for involvement in research (College on Problems of Drug Dependence, 1995). While the bioethics literature has explored research payment ethics (Grady, 2001; Macklin, 1981; McNeill, 1997; Wilkinson and Moore, 1997) it has not yet considered the special issues raised by paying drug users for research involvement. Critics of this practice are concerned that cash payments will serve as an inducement because they may be used to purchase drugs (Brody and Waldron, 2000). Non-cash payments (e.g. vouchers, prize draws, food and refreshments) have been suggested as more appropriate for this reason. Advocates of cash payments argue that payment for research participation is an ethical practice in that it reflects the ethical principles of respect and dignity (Grady, 2001; Ritter et al., 2003). Non-cash methods, they argue, reinforce negative drug user stereotypes and reflect a paternalistic view of the capacity and rights of users to make their own choices.

A key consideration is the potential for payments to increase risks to participants. Drug dependent persons may be vulnerable to coercion and inducement to participate in research when they are intoxicated or when they are experiencing

acute withdrawal (College on Problems of Drug Dependence, 1995; Gorelick et al., 1999). In such cases, monetary payments may be seen as an inducement to participate because these enable the person to fund (even if only partially) the purchase of drugs to alleviate their withdrawal symptoms. Persons in this predicament may ignore any risks that participation entails that would in other circumstances discourage study entry.

To avoid these problems researchers may need to consider screening participants for withdrawal symptoms when assessing suitability and obtaining informed consent (College on Problems of Drug Dependence, 1995; Gorelick et al., 1999). Other strategies to consider include not advertising cash payments when recruiting participants or providing cash payment immediately after informed consent has been obtained and prior to interview/survey commencement (to minimise coercive impact of payment). This issue is controversial and remains unresolved in epidemiological drug research (Fry and Hall, 2003).

3.1.2. Privacy, Confidentiality and Legal Hazard

Some types of drugs (e.g. cocaine and heroin) are illegal in any context and the use of some drugs is illegal in some age groups (e.g. alcohol use by persons under the minimum legal age). Drug use surveys may also ask about illegal and stigmatized acts, such as driving while intoxicated, selling illegal drugs or engaging in theft, fraud or violence to finance drug use. If law enforcement officials have access to such data and it can be linked to individuals then study participants could face criminal charges. In the US, researchers can obtain certificates of confidentiality in order to provide participants with an assurance that this will not happen. The situation in other countries is less clear (Fitzgerald and Hamilton, 1996; Loxley et al., 1996).

Participant privacy is a critical concern in drug epidemiological research. As stated previously, this encompasses protection of confidentiality and anonymity (i.e. non disclosure of information and/or identity without consent). Protecting the confidentiality of sensitive information collected through research is less of a problem when identifying information is not obtained (such as person's name or other unique identifiers) and anonymity thereby preserved. Ensuring confidentiality becomes more of an ethical issue in longitudinal studies where multiple contact details may be collected to allow individuals to be recontacted for follow-up interviews, months or even years later. Standard precautions are to store names and identifiers and the survey data separately and securely.

However, even when such protective measures are taken researchers in some countries may be compelled by courts to provide research records to law enforcement officials. Concerns around privacy also arise in the case of field research where face-to-face interviews may occur in public places such as the street, parks or cafes etc. In small communities this may create a potential risk to research

participants, particularly if the investigator is a known drug researcher or if the interview is overheard.

Confidentiality is a potentially major ethical issue if biological samples (e.g. blood) are taken from a participant. DNA that can be extracted from such samples provides a unique identifier for all individuals (except identical twins). It could, if linked with questionnaire or interview data, permit individuals to be linked with self-reported illegal acts. The same issues are raised by the use of case registers and clinical databases, such as, treatment registers, or registers that linked treatment, arrest and other reporting of people who use drugs.

The implications for drug epidemiology of recent changes in a number of jurisdictions to health privacy and data protection legislation will require careful monitoring, and drug use epidemiologists should be aware of these (Lawlor and Stone, 2001). In jurisdictions where legislation requires identification and tracking of drug users, assurances of confidentiality cannot be given to participants. In such cases, researchers might seriously consider the option of not conducting the research.

3.1.3. Safety Issues

Illicit drug research often occurs in settings that may be dangerous for researchers and participants (Wright et al., 1998). In order to protect participant privacy, illicit drug users are often interviewed in settings out of the public gaze. Interviews may occur late at night, in the participants' residence, and other settings in which researcher safety cannot be guaranteed. Personal safety is an ethical issue to the extent that it is the responsibility of the researcher to ensure that their research, and contact with research participants and their communities, does not cause harm to research participants, researchers or community members. Safety protocols emerging for social science research (Craig et al., 2002) have potential for addressing safety issues in drug epidemiology.

3.2. Drug Epidemiological Research Challenges in Developing Countries

The ethical challenges posed by epidemiological research on drug use are amplified in comparative epidemiological studies of drug use across cultures (Council for International Organizations of Medical Sciences, 1991; Brody, 1998). This is particularly true in developing countries with little or no tradition of doing such research, and no institutional infrastructure for research ethics oversight that is standard in many developed societies. The application of broad biomedical ethical principles to this research may be a starting point but significant practical challenges exist that should also be addressed, such as developing local mechanisms for ethical decision-making and protection of research participants, (see Strauss et al., 2001).

One cannot assume that the rules of informed consent, privacy and confidentiality that have arisen out of debates on ethical principles in developed countries can be applied across all cultures and societies. For example, as a relatively recent development in research ethics, there are still many unanswered questions about the requirements of informed consent in these settings (Ijsselmuiden and Faden, 1999). Further, the relevance of issues such as participant vulnerability, awareness and expectations about rights, communication difficulties, documentation issues, literacy and the rules of obtaining consent in hierarchical societies are all still contested and deserve further attention (Sánchez et al., 2001).

4. CONCLUSIONS AND A WAY FORWARD

Consideration of ethical issues is crucial to biomedical, clinical and social research effort. While principles and guidelines that have emerged from biomedical ethics can assist in defining the ethical boundaries of most research, they provide limited guidance in relation to the day-to-day challenges that researchers encounter, particularly in speciality areas such as drug epidemiology. One way ahead for drug abuse epidemiology is to strive to apply the intent of ethical principles such as autonomy and beneficence, and the rules that derive from these to the analysis of specific cases through a process of open debate and discussion. This approach could inform discussions of ethical issues that arise in research in developing countries. We have explored these issues (including discussion of a hierarchy of ethical review options) more fully elsewhere (Fry and Hall, 2002; 2004).

Where to from here? Ethical analysis of epidemiological research on drug use is an under-developed field, even in developed societies with a tradition of drug research and ethical protection of human participants in medical research. Drug researchers must start to address the issues that are unique to drug abuse epidemiology 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 no experience in the ethical oversight of human medical research. Given the role of international organizations such as WHO and UNODC in sponsoring such research, these organizations may also consider facilitating future discussion and debate about ethical issues from which an applied ethical framework and resources for international drug abuse epidemiology may emerge.

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