

## **Ethical issues to be considered in second generation surveillance**

April 28, 2004--Final

### **Preface**

In recent years, efforts to monitor the spread of HIV have translated into an increase in activities designed to collect data that enable health professionals to track the epidemic and the behaviour that contributes to spreading it or protecting against it. Second generation surveillance refers to the strengthened systems being put in place in an increasing number of settings to monitor the biological and behavioural indicators of the epidemic. The activities involved in collecting the necessary data raise several questions relating to protecting human subjects and hence underscore the need for attention to ethical issues.

The guidance points presented here do not represent strict prescriptions but rather analyse the ethical issues that need to be considered when conducting second generation surveillance. They cover activities such as serological surveys on HIV or sexually transmitted infections as well as behavioural surveys about unprotected sex or unsafe injections. The approach is to briefly review the main issues that need to be considered in implementing second generation surveillance, give a brief background on past efforts and then provide specific guidance points to address them. The publication builds on knowledge of what surveillance is and how it functions, underscores the links between the technical and the ethical aspects of the process of ensuring protection and tries to formulate guidelines that take into account the context in which the guidelines are to be implemented.

An effort is made throughout the publication to keep in mind the specific situation of mostly low- and middle-income countries. Because the ethical questions vary depending on the context of the epidemic, attention is given to the different types of epidemics – generalized, concentrated and low-level – which also have implications for strategies for collecting and disseminating data. In addition, although discussions of the trade-offs between disclosure and privacy have been shaped by earlier situations in which treatment was not available, the increased availability of medicines to treat HIV has changed ideas about the responsibilities of those involved in surveillance, and the issue of care is now difficult or even impossible to avoid entirely even in surveillance activities.

An important point of this publication is that ethical review and discussions need to build on information about the situation in the field and to include inputs from

individuals and communities. This underscores the need for capacity-building, and it also leaves some leeway for adapting ethical guidance to local circumstances.

This publication provides guidance on the ethical issues that emerge in the context of surveillance. It was commissioned by the WHO/UNAIDS Surveillance Working Group to complement the discussions that take place with country staff in the course of training on second generation surveillance. The potential audience is therefore the epidemiologists and programme managers who are responsible for surveillance activities. The issues discussed here are, however, of interest to all health professionals concerned with the ethics of research on HIV.

This publication is not an official document of WHO nor UNAIDS, nor does it necessarily reflect WHO or UNAIDS policy. Rather, the authors of this publication, who have considerable experience in the field of HIV, identify issues with ethical implications that arise in the course of planning or conducting surveillance activities. Having identified important issues, the authors provide discussion and useful guidance. While the WHO/UNAIDS Surveillance Working Group has found this document extremely valuable, the views expressed in the report are those of the authors.

## 1. Introduction

### 1.1 What is second generation surveillance and why is ethical guidance needed?

In 2000, the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) published guidelines for second generation HIV surveillance (1). Second generation surveillance promotes a more comprehensive approach to developing a solid HIV surveillance system. The guidelines were designed to remedy the deficiencies and limitations of earlier surveillance efforts. The existing systems of surveillance had helped to generate a response to the HIV epidemic and had contributed to monitoring the successes and failures of national responses to HIV/AIDS, but they were insufficient to meet the evolving challenges of the epidemic. Second generation surveillance should be built on the strengths of earlier efforts and be adapted to the needs. To achieve this goal, second generation surveillance seeks to integrate a wide range of resources including: HIV and AIDS case reports, sentinel surveillance, analyses of trends in sexually transmitted infections and, most critically, studies of the sexual behaviour of individuals at risk of acquiring and transmitting HIV. These guidelines summarize the “core” (essential) surveillance activities and “additional” (useful) surveillance activities for determining HIV prevalence, according to the state of the country’s epidemic. In low-level epidemics (in which HIV infection exists in low levels in some populations whose behaviour poses a high risk of contracting or transmitting HIV but infection is not widespread in the general population) and in concentrated epidemics (in which relatively high rates of HIV infection exist in selected subpopulations), the goals of surveillance are to understand the behaviour that exposes certain groups to risk, the prospect of increased infection in these groups and the probability that HIV will spread to the broader population. In generalized epidemics, with over 1% of pregnant women infected, HIV is already established in the sexually active population. Although heterosexual transmission is always the dominant mode by which HIV is transmitted in generalized epidemics, HIV may also be overrepresented in some groups, whose behaviour places them at increased risk for acquiring and transmitting HIV. In such epidemics, the goal of surveillance is to understand the behavioural dynamics that account for trends in HIV prevalence and the relative effectiveness of interventions designed to reduce the level of incident infection (1).

Virtually all discussions of the ethics of research involving human subjects, including this report, focus on the obligation to protect participants from harm and on the duty

to ensure that those who participate in research share in the benefits that may follow. Little attention is given to the question of whether there is an affirmative duty to undertake research and the full range of surveillance activities. No effort to control the HIV/AIDS epidemic and to direct resources towards those most at need can be effective without an accurate understanding of the incidence, prevalence and dynamics of HIV and HIV-related risk behaviour in a given community. WHO has defined surveillance as ongoing, systematic collection of health data, with analysis, evaluation and interpretation of these data and prompt dissemination of the findings to public health officials and others who need to know how to help shape public health intervention, planning and prevention. Surveillance is indeed the radar of public health (2,3). There is, therefore, an ethical obligation to undertake the studies and engage in the practices most likely to prevent disease and death. This obligation must be understood within the context of the resources available within countries and communities. In some situations, the issues posed by acquiring and transmitting HIV may touch upon matters of cultural sensitivity. The behaviour involved may be considered morally unacceptable or illegal. These views should not provide a justification for inhibiting crucially important surveillance efforts.

National and international guidelines, discussed below, typically share a common set of ethical principles that guide the discussion of research ethics. They were first formally articulated in the United States in 1979 in the Belmont report (4) of the United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Respect for people necessitates respecting the choices of competent individuals and protecting vulnerable people. The right of informed consent derives from this principle. Beneficence (the charge to do good) and its counterpart nonmaleficence (the admonition to do no harm) necessitate maximizing benefits and minimizing research harms. Justice requires equal treatment and, in the research context, refers to fairly distributing benefits and burdens (5–8). These ethical principles, which were first articulated to guide the conduct of medical research, were inevitably applied to epidemiological, behavioural and psychosocial investigations as well (9). The impulse of research ethics has been to enhance autonomy.

In the context of research ethics and medical ethics more broadly, concern for autonomy has had a pre-eminent role. In the context of public health, such priority is in tension with the population-based commitment to public wellbeing. Indeed, the entire history of public health can be understood as involving an effort to resolve the tension between the claims of individual rights and the needs of the community. In the last part of the 20th century, especially in the context of the AIDS epidemic, it became clear that respecting such rights could, in many ways, enhance the public health.

Adequately discussing the principles that must govern second generation surveillance means also considering a recent concept derived from human rights that is intimately related to the concept of respect for people: transparency. The principle of transparency is linked in important ways to that of autonomy but is not equivalent to autonomy. In the context of public health, transparency requires that individuals understand that they may be subject to surveillance. Transparency also requires an open process of decision-making that permits consultation and facilitates the exchange of information. It does not necessarily give individuals the right to refuse to participate in the efforts that emerge from such open processes.

The ethical principles governing second generation surveillance cannot be ordered hierarchically. Invariably, tension exists among them. Thus, for example, just as beneficence and justice may require collecting data to limit the threat of HIV infection, the public health mandate to conduct surveillance may be in tension with these very principles, which would seek to minimize the burdens of stigma that may emerge when vulnerable populations are identified as being at increased risk for AIDS. Nevertheless, these very populations, in the name of beneficence and justice,

benefit as a result of being identified as bearing a disproportionate burden of disease.

Ethical sensitivity necessitates an open discussion of how such tensions can be resolved fairly. Achieving the promise of second generation surveillance to contribute to reducing HIV-related morbidity and mortality requires confronting a series of ethical challenges.

- What role should individual consent and community approval play in surveillance activities?
- Do the requirements of consent change when surveillance is thought of in terms of research rather than public health practice?
- Are there circumstances under which the benefits of surveillance justify measures that may intrude on privacy?
- How should the benefits of surveillance among those most at risk be balanced against the risk that such efforts will increase the social burden of those already marginalized?
- How should the confidentiality of data obtained be ensured? When the confidentiality of such data cannot be guaranteed, what should be the impact on surveillance activities?
- How do the prospects of effectively utilizing surveillance data affect the ethics of acquiring and disseminating data?

Because the context within which surveillance occurs – the stage of the epidemic, the existing regimen for the protection of research subjects and the state of development of the capacity for public health surveillance – ultimately affects the course to be followed, the guidance points in this publication can only provide direction at the most general level. At times, they seek to make clear the issues that need to be addressed to maximize the prospect that the rights of individuals and communities and the control of the epidemic are given appropriate attention. These guidance points and discussion are addressed to public health policy-makers, those charged with the responsibility of conducting surveillance activities, researchers conducting behavioural studies, nongovernmental organizations that will be involved in consultations regarding surveillance, community advisory boards and ethical review committees. Ultimately, however, although nongovernmental organizations can undertake surveillance, they do not have a right to privileged information. All surveillance undertaken by private agencies must be regarded as research and governed accordingly; the state's surveillance efforts, however, must be regarded as practice and subject to different guidance. Health officials therefore have ethical responsibility for second generation surveillance.

## 1.2 Overview of national and international ethical guidelines governing research involving human subjects

The modern era of medical ethics began with the promulgation of the Nuremberg Code in 1947. Nuremberg marked the first of three major phases in the evolution of medical ethics. The first two decades following 1947 marked the articulation of ethical principles governing research, with less effort given to developing the means to enforce these principles. During the second phase of evolution, in the wake of scandals such as the Tuskegee syphilis study in the United States described later, new emphasis was placed on creating oversight mechanisms. Finally, since the 1990s, concerns about research in the developing world represent a third phase of evolution – especially concerns about the power relationships between researcher–sponsors in the industrialized world and study populations in developing countries in the light of controversies such as the trials on preventing the mother-to-child transmission of HIV that occurred in the context of the AIDS epidemic.

The Nuremberg Code was set forth by judges from the United States prosecuting the Nazi physicians as a standard against which to judge them (10). In the light of medical experiments in which concentration camp prisoners were subjected to conditions often intended to result in their deaths, the first principle of the Code was the centrality of the voluntary participation of subjects with their informed consent. Nevertheless, the principles of voluntary participation and informed consent, which stood at the heart of the code, received little attention from the mass media or physicians and did not necessarily alter research in countries such as the United States and United Kingdom following the Second World War. The Nazi atrocities seemed to be precisely that: acts of deranged politics rather than the ordinary practice of science; accordingly, self-monitoring continued to prevail (11).

Marking the beginning of a new era, the World Medical Association adopted the Declaration of Helsinki in 1964. The Declaration built on the Nuremberg Code, adding a distinction between therapeutic and nontherapeutic research, a call for institutional review mechanisms and a provision for family members to consent for the subject when the subject could not consent. When the World Medical Association issued its revised Declaration of Helsinki in 2000, it reflected the deepening appreciation of the many elements included in fully informed consent (12).

In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's

freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

As it had in 1964, the Declaration of Helsinki in 2000 made clear the critical importance of ethical review by a committee independent of the researcher.

Empirical investigations have sparked concerns about the extent to which researchers adhere to the multiple aspects of consent. These investigations repeatedly demonstrate that, although subjects involved in studies have apparently consented as reflected in signed forms, many subjects, especially those involved in research sponsored by wealthy countries and conducted in less developed host countries, do not fully appreciate the nature of the projects with which they will be involved, their right not to participate or their right to withdraw when they so decide. The United States National Bioethics Advisory Committee devoted considerable attention to how the consent “process” might be enhanced. Among the critical aspects of its analysis were the necessity of communicating in a culturally appropriate manner and of adopting measures to determine whether potential participants have fully understood what they have been told. In achieving a more fully informed consent process, the Committee underscored the importance of involving community representatives – also emphasized by the Nuffield Council on Bioethics (13) – who might effectively guide investigators in shaping the informed consent in a way that reflects both the spirit and letter of the ethical obligations that have been universally recognized.

These principles were emphasized further in 2002 when the Council for International Organizations of Medical Sciences (CIOMS) published a revision of its *International ethical guidelines for biomedical research involving human subjects* (14). Given the increased concern about the exploitation of research populations in less developed countries by investigators from sponsoring wealthy countries, the CIOMS guidelines gave sustained attention to the steps necessary to prevent exploitation and to ensure culturally sensitive informed consent. Further, the guidelines underscore the obligation of investigators to protect the confidentiality of the information they obtained from research participants (14): “The investigation must establish secure safeguards of the confidentiality of subjects’ research data. Subjects should be told the limits, legal or otherwise, to the investigators’ ability to safeguard confidentiality and the possible consequences of breaches of confidentiality.” Specifically referring to HIV/AIDS, the guidelines noted the special importance of efforts to protect confidentiality given the social discrimination or harm to which participants might be subject. In commenting on this guidelines, CIOMS noted that the strategies investigators might adopt include techniques that make linking identifiable individuals to the information they had provided difficult by, for example, making the data anonymous.

Although competent adults or parents or guardians (who may consent for their children in all international guidelines on research) emphasize informed voluntary consent, exceptions have been recognized for investigations involving the examination of existing records and biological specimens, reflecting the balance between privacy and consent on the one hand and socially important epidemiological investigations on the other. The next section discusses the ethical issues posed by the examination of existing records. Section 2.3 discusses studies involving biological specimens and unlinked seroprevalence studies.

### 1.3 Medical ethics and the ethics of epidemiological research: a review of the literature and international guidelines

The ethical principles for the protection of human subjects articulated in Nuremberg and Helsinki and the initial national legislation governing research were based on a common set of principles stressing the absolute need to give priority to the rights of the individual over that of society (15). Thus, there could be no exceptions to voluntary participation and informed consent (15). Nuremberg and Helsinki and the first efforts to adopt national guidelines on research ethics were, after all, rooted in a distinct historical period of revelations of great harm and injustice perpetrated on vulnerable populations. Although they affirmed the need to prevent research abuses, the guidelines, as Levine (16) argues, “were not addressed to the entire field of research involving human subjects as that field is currently understood.”

Accordingly, epidemiologists and ethicists began to discuss whether the principle of informed consent extended to the use of records and whether the insistence on individual consent with large numbers of individuals, many of whom would be difficult or impossible to locate, would render epidemiological research virtually impossible (7,17–22). Last (5) noted: “The clash between the privacy rights of persons and the need for access to and disclosure of personal health-related information is the most frequent ethical dilemma to confront epidemiologists.” In the United States, the Department of Health and Human Services regulations from 1981 for the protection of human subjects explicitly exempted epidemiological research involving already existing data from informed consent requirements provided that the risk to subjects was minimal, the research did not record data in a way that was individually identifiable and the research could not otherwise be conducted.

Other industrialized countries confronted the tension between the claims of individual informed consent and the demands imposed by record-based epidemiological research. How these tensions were resolved reflected the extent to which the rights of the individual were given priority, judgements about how significant a burden would be entailed by insisting on consent and the social value accorded to such retrospective record-based studies. The Australian National Health and Medical Research Council,

for example, required ethical review of all epidemiological studies and the consent of subjects unless such a requirement would render it impossible to conduct the study. In 1991, the European Union likewise proposed that all studies must undergo ethical review (23). The proposed directive gave such priority to privacy and consent that epidemiologists expressed alarm over the future of their efforts. In response to arguments that the directive would make epidemiological research unfeasible, a 1995 directive made provisions for research without consent when confidentiality was adequately protected, obtaining consent was impracticable and the research was of sufficient importance. France and Germany passed similar provisions a year before the European Union approved its final directive, but concerns remained in the late 1990s, especially in the United Kingdom (23).

CIOMS also addressed the issues imposed by the use of existing clinical records as part of its broader analysis of the ethical issues posed by epidemiological studies. In its 1991 report, CIOMS (8) acknowledged that prior efforts to provide ethical guidance for biomedical research focused on “patients and individual subjects” were not sufficient for studies involving “groups” of people. Thus, while emphasizing the importance of the principles of research ethics first stated in the Belmont report (4) from the United States, CIOMS recognized that applying them in epidemiology would require flexibility.

Most important, the CIOMS epidemiological guidelines, like those from countries that had addressed these issues before, noted that individual informed consent was not always practical in epidemiological studies. Although CIOMS asserted (Guideline 3) that individuals and their representatives should “normally” be told that their medical records or stored tissue samples might be used for future epidemiological studies (8), CIOMS acknowledged that such notification might not always have occurred. In the end (Guideline 2), researchers who sought to undertake such record-based studies had “to explain to an ethical review committee how the study would be ethical in [the absence of consent]: it may be impractical to local subjects whose records are to be examined ...” (8).

In lieu of individual consent, CIOMS suggested that the agreement of a representative of the community or group in which the proposed study would occur could be important. It recognized (Guideline 8), however, that identifying and selecting such representatives might pose difficulties, especially if the investigators created the “group” under study (8).

The CIOMS guidelines focused on matters of consent, protecting confidentiality, the role of review by ethics committees, the nature of ethical review in studies sponsored by typically wealthy countries but conducted in a typically less-developed host country and the importance of representation of communities to be studied on ethical

review panels. In addition, the guidelines gave great attention to how research findings were to be communicated. More attention is devoted to this issue below, but the guidelines (Guidelines 19 and 21) reflected considerable concern about how the results of epidemiological studies could result in “suffering, stigmatization, prejudice, loss of prestige or self-esteem, or economic loss” (8). Thus (Guideline 22), “conflict may appear between, on the one hand, doing no harm and on the other, telling the truth and openly discussing scientific findings” (8).

Finally, in its brief discussion of the ambiguous border between research and programme evaluation and in its conclusion that the former but not the latter be subject to ethical review, CIOMS (Guideline 52) touched upon the relationship between public health research and practice, which is discussed below (8).

The guidance points in this publication assume that all activities referred to in terms of research – whether publicly funded or not and whether initiated domestically or through international cooperation – are reviewed by duly constituted ethics committees. Studies that originate in sponsoring countries but are carried out in host countries must be reviewed by ethics committees in both settings. Within host countries, the relationships may vary between ethics review committees at the national level that may set national standards for the conduct of research and review committees at the local level that review protocols involving local residents. No single principle can account for how countries may choose to allocate such responsibilities. Whether these responsibilities are mainly centralized or devolved, review committees must reflect the broad constituencies affected by research. Most importantly, people who represent and can speak on behalf of the participants in research are critically important.

Lack of experience and training may impede the capacity for ethical review at the local level. Countries that play a central role in sponsoring research in less-developed countries and the international organizations that have addressed the question of research have given considerable attention to the necessity for enhancing the capacity for ethical review in host countries. Both the Declaration of Helsinki and the 2002 CIOMS guidelines (14) emphasize the obligation of sponsors to enhance such capacity.

## **1.4 Public health and mandatory notification**

The focus so far has been on the ethical challenges posed by research related to public health. Nevertheless, research is not the sole source of data relevant to understanding patterns of morbidity and mortality or to evaluating efforts designed to limit the impact of disease outbreaks and epidemics. Indeed, many countries have a long history of governmentally mandated and conducted public health surveillance

that has been the primary source of such data. Where such surveillance exists as a matter of law or official regulation, it typically requires specified individuals – generally health care workers or institutions – to report information about identifiable people to public health registries. There is variation in the extent of the information to be reported, whether it is linked to individuals by the use of names and whether such information is regarded as confidential and, if so, how it is protected from disclosure as a matter of law or practice. If notification is required, those who report and those about whom they must report have no choice. The principles of consent that may otherwise prevail in the management of public health–related research do not apply under such circumstances. Because the people who have been required to report have sometimes believed that such notification entailed an unacceptable intrusion into the privileged nature of clinical communications, the history of public health surveillance has been marked by resistance that has taken a number of forms: most notably simple failure to comply with legal requirements.

The collection of vital statistics – the registration of births and deaths – has been a legally established function of nation–states for centuries, considered important as the periodic conduct of population censuses. By definition, birth and death registries involve names. Early death certificates were not very precise, in part because of the difficulty until the modern era of correctly diagnosing disease and of establishing a commonly accepted nomenclature. Even when diagnostic accuracy improved, records could be inaccurate because of the concern about the stigma associated with various conditions: tuberculosis at one moment and cancer at another. Contributing to these concerns was the fact that death certificates are treated as public documents in many countries, suggesting that, even as greater attention was given to privacy in the 20th century, such rights were not thought to survive the demise of individuals.

Systematic morbidity notification dates to the 19th century and had become a staple feature of nation–states by the 20th century. Although the establishment of notification requirements was often controversial, when they were instituted they almost universally required the names of the people who had been diagnosed. In several countries sexually transmitted infections were an exception that permitted the use of various types of coded mechanisms. Unlike birth and death registration, however, morbidity reports have typically been treated as confidential and have been protected against disclosure as a matter of law, regulation and practice. Nevertheless, concerns about the privacy of health information have made morbidity notification problematic. One method developed to short-circuit resistance among clinicians has been the adoption of laboratory-based reporting. Another has involved active surveillance, in which public health officials are authorized to review medical records in physicians’ offices, clinics and hospitals or to use other methods to solicit information from the providers to identify cases of disease that would otherwise go

unreported (24). Both instances reflect the priority of public health over the claims of privacy.

Finally, not all efforts to monitor morbidity and mortality entail formal notification of individual cases. Even in countries with very well developed systems, a simpler form of enumeration is used in some situations involving rapidly evolving epidemics. For example, annual influenza outbreaks have historically been tracked by the number of cases rather than by name.

Remarkably, although the ethics of research and especially the ethics of epidemiological research received increasing attention after the Second World War, the ethics of public health surveillance was given little attention until the AIDS epidemic. This is all the more striking, since much of public health surveillance involves ongoing efforts that may resemble activities that are called epidemiological research. The 2002 CIOMS guidelines (14) used a relatively narrow definition – informed by the threat of emergency – of public health surveillance to justify exceptions to the requirement for ethical review (Guideline 33). “An exception is justified when epidemiologists must investigate outbreaks of acute communicable diseases. Then they must proceed without delay to identify and control health risks. They cannot be expected to await the formal approval of an ethical review committee.” Such a definition would cover neither ongoing case-reporting requirements in non-emergency situations nor the follow-up by public health interviewers that is typically provoked by disease notification, especially when efforts to understand epidemiological dynamics are at stake. Left unresolved in the CIOMS formulation is whether such public health practices should, in general, be subject to ethical review and whether all “emergency” situations warrant an exception to the necessity for review.

The complexity of the issues involved is illustrated by the typical relationship between cancer notification requirements in many countries and research based on such surveillance. Hence, although reporting to tumour registries may be mandated by law as a matter of public health practice and is therefore exempt from requirements for consent and external ethical review, studies drawing on these very registries typically require both consent and review by an ethics committee. Indeed, some individuals with cancer are unaware of the existence of tumour registries until they are contacted by researchers seeking their consent to participate in studies of their disease.

The existence of disease registries may be subject to controversy despite exacting confidentiality protection. Thus, for example, registries of mental disorders that had long served as the basis for important epidemiological studies have been challenged in some countries. As a result, both the registries and the research based on them have

been ended in some settings.

## 1.5 Research versus public health practice: the ethical implications

The Declaration of Helsinki (1964) drew “a fundamental distinction ... between medical research for which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research” (25,26).<sup>1</sup> It was, however, the Belmont report (4) that sought to lay bare the ethical implications of the difficult distinguishing boundary separating research from practice.<sup>2</sup> The Belmont report (4) stated: “The distinction between research and practice is blurred partly because both often occur together.” A central person in the development of contemporary medical ethics who served on the Commission described this task as “the most difficult and complex problem facing the Commission” (26). The Commission concluded, however, that practice “refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success.” Research, in contrast (4):

designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to knowledge that can be generalized (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

Subsequent to resolving the controversies over epidemiological research, in the early 1990s, the Office for Protection from Research Risks (now the Office of Human Research Protections) of the United States Department of Health and Human Services began to advance the notion that all surveillance was research. To the United States Centers for Disease Control and Prevention, this was more than a bureaucratic

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<sup>1</sup> This distinction, which was subject to substantial criticism, persisted virtually unchanged until the 2000 revision (12), when it was substantially modified (26). In 2000, the Declaration of Helsinki (12) provided principles governing all medical research, with special principles for research combined with care. It is also in 2000 that references to “physicians” were completely replaced by references to “investigators” or “researchers”.

<sup>2</sup> The United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created to make recommendations to the United States Department of Health and Human Services on the regulation of research involving human subjects. It also made recommendations to the President and Congress (26).

consideration: if public health surveillance activities were designated research, the United States Centers for Disease Control and Prevention feared that “people with TB could prevent their names from being reported to the health department or refuse to provide information about their contacts” (27). The more profound implications, however, have been for behavioural surveillance. Here the complexity of distinguishing between research and practice even within a single country is stark. For example, the United States Centers for Disease Control and Prevention has determined that behavioural surveillance constitutes research requiring oversight by an institutional review board, whereas many state health departments have determined that such surveys constitute part of the practice of public health and are therefore exempt from such review.

The significance of the effort to distinguish between research and practice in large measure hinges on the practical implications. To the extent that an activity is called research, both international and national guidelines almost universally now require review by ethics review committees and require that this review be guided by a set of ethical principles that emerged in the research context. Mechanisms to review the ethics of activities termed public health practice, of which surveillance is clearly a part, are extremely rare. CIOMS (Guideline 33) stressed that, even in the context of surveillance, investigators “as far as possible” were still obligated to respect individual rights, freedom, privacy and confidentiality, but it left open the question of what rules should govern surveillance more broadly understood (8). The guidelines stated: “Practice and research may overlap, as for example, when both routine surveillance of cancer and original research on cancer are conducted by professional staff of a population-based cancer registry.” (8).

The guidance points in this publication discuss a set of principles that ought to govern second generation surveillance of HIV whether or not it is determined that it constitutes research or practice. If such surveillance is considered practice, mechanisms need to be created to ensure that these ethical guidance points are applied.

## **2. Data collection for second generation surveillance of the HIV epidemic**

### **2.1. Public health surveillance: the role of mandatory notification**

Despite their limitations, mortality reports – whether or not they involve official death certificates – can serve as a potentially useful index of the impact of the AIDS epidemic, whether as a result of the explicit recording of AIDS-defining diagnoses on death certificates or because of the increase in conditions such as lymphoma or tuberculosis. Vital statistics are nearly universal in industrialized countries, whereas

the completeness of reporting in less-developed countries is far lower and thus the utility of such reports for surveillance must remain an empirical question. As noted above, whether such information should remain in the public domain and what the public nature of death reports suggests about the issue of the rights of privacy after death remain unresolved.

Morbidity reports may also play a role in second generation HIV surveillance. Most less-developed countries have limited capacity to impose HIV/AIDS notification requirements. Public health officials, however, can use active surveillance to identify AIDS cases or HIV-related opportunistic infections that may serve a role in an overall surveillance effort.

Where the capacity for HIV/AIDS surveillance is in place, the question remains whether such notification ought to involve the use of people's names. The debate on the use of names or coded identifiers for cases of HIV reflects, in some respects, an earlier debate in western Europe and the United States about whether sexually transmitted infections should be reported by name. As noted above, for much of the 20th century, in some countries, such as the United States, sexually transmitted infections were reported through the use of serial numbers, reflecting the concerns of physicians about the confidentiality of their private patients. The practice surrounding notification of sexually transmitted infections sharply contrasts with the prevailing practice of using names in disease notification systems. The discussion of HIV reporting assumes an exceptionalist quality in relation to this common practice. The unique constellation of social, psychological and political factors surrounding the AIDS epidemic and especially concerns about stigma and of driving those most at risk away from contact with the health care system led many countries to avoid reporting HIV by people's names.

Because of concerns about privacy and confidentiality, most European countries have not conducted name-based notification. An unpublished study by the European Centre for the Epidemiological Monitoring of AIDS in 1998 found that 36 countries of 51 in the WHO European Region, including 9 European Union countries, had nationwide HIV reporting systems. Reporting was mandatory in 27. Notification was by name in 10 countries, by code in 20 and without unique identifiers in 6. Similar to the United States, AIDS-related organizations in Europe have increasingly tended to support coded HIV reporting but have opposed the use of people's names as a threat to privacy and human rights more broadly.

Records of HIV infection may often not be kept by name, but other records such as tuberculosis or reports of sexually transmitted infections are also critical elements of second generation surveillance. These may be reported by name. At stake, then, is the core issue of whether the goals of public health that are to be served by requiring

clinicians to breach confidentiality in making name-based reports – even to surveillance registries that are secured against unwarranted disclosure – justify overriding the claims of medical privacy. Emphasizing the importance of unbiased disease notification, Verity & Nicoll (28) warned that “if explicit consent for sharing data had to be obtained the completeness and timeliness of reporting would be dangerously disrupted”.

Although the issue of public health notification received virtually no attention prior to the AIDS epidemic, the unique social context of the epidemic set the stage for a searching discussion of the implications of name-based disease reporting for ethics and human rights. The Office of the United Nations High Commissioner for Human Rights and UNAIDS have provided broad principles to guide consideration of this issue (29). The guidelines reflecting the 1984 Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights – adopted by a group of international law experts to clarify the Covenant (30) – acknowledge that states “may impose restrictions on some rights, in narrowly defined circumstances, if such restrictions are necessary to achieve overriding goals, such as public health [or to protect] the rights of others ... [and] the general welfare ...” (29). For such restrictions to be justified, however, they must be “proportional to [the] interest and [constitute] the least intrusive and least restrictive measure available ...”, be carried out in accordance with the law and be imposed in a way that is not arbitrary (29). Unfortunately, the extremely limited reference to the issues raised by reporting in these guidelines merely states: “Public health legislation should ensure that HIV and AIDS cases reported to public health authorities for epidemiological purposes are subject to strict rules of data protection and confidentiality.” (29). The reference is thus permissive with regard to reporting, stipulating only the most limited and basic of protective conditions. The guidelines do not confront the question of whether the use of names is justifiable or how tradeoffs between epidemiological requirements and privacy concerns should be addressed.

More helpful is the observation of Gostin et al. (31) in laying out the general principles that should guide public health authorities in acquiring data:

Public health authorities must substantiate the need for a named identifier when collecting information. If they could achieve the public health good as well, or better, without personal identifiers, the collection of non-identifiable or aggregate data is preferable. These data collection principles recognize that government authority to acquire sensitive personal information ought to be justified by substantial public health good that cannot be achieved by means that are less invasive of individual privacy.

The international guidelines (29) implicitly require and the discussion of Gostin et al. (31) more directly requires a series of complex empirical questions to be answered as

a precondition for ethical analysis. Does effective surveillance require the reporting of AIDS cases or cases of HIV infection? Does achieving the goals of surveillance require collecting names? What consequences will follow for the willingness of individuals to be tested for HIV and to undergo counselling to enter care if their names are reported in contrast with anonymous reporting? Do other public health functions such as voluntary partner notification, ensuring adequate counselling and providing care require the use of names? What level of inaccuracy will using code-based versus name-based reports produce and how would this level of inaccuracy affect the purposes for which reporting was initiated? What mechanism exists for protecting the confidentiality of names if they are reported, and what is known about their effectiveness? These critical questions have no definitive answers that are universally applicable. The answers appropriate in one country at a given moment may not be appropriate in the same country at a different juncture or in other countries. Much depends on the state of the epidemic, the infrastructural capacity of the public health and clinical care systems, the availability of resources to manage and secure notification systems and the general political culture. In the face of uncertainty, dispute thrives.

***Guidance point 1.*** HIV/AIDS notification may play a role in second generation surveillance. The breach in confidentiality represented by mandatory notification can only be justified if systems are in place that can ensure that reported data will be used solely for public health purposes. If name-based reporting (versus anonymous or coded reporting) is determined to be a critical aspect of second generation surveillance, the registries to which individuals are reported must be protected by strict confidentiality regimens. This is to preclude disclosure for purposes unrelated to public health and discrimination or deprivation of liberty. Public health registries must, from this perspective, be governed by the strictest rules of data protection and confidentiality.

## 2.2 Behavioural surveillance

### 2.2.1 Individuals, the local context and the consent process

A central feature of second generation surveillance is the incorporation of behavioural studies designed to improve understanding of the dynamics of the epidemic in low-level, concentrated and generalized states. In each instance the goal is to understand who is at risk for infection, which factors explain the vulnerability and the prospect of further transmission and which interventions have been effective and which ineffective in stemming the spread of HIV.

Behavioural surveillance studies typically focus on groups at differing levels of risk: adults, youth, female sex workers, men who have sex with men and injecting drug

users. Family Health International is based in the United States and has been an important partner in recent efforts to standardize data indicators for HIV-related risk behaviour, underscoring that the standard information collected is extremely intimate and sensitive. In all instances it includes: the individual's knowledge of HIV transmission and prevention methods; exposure to intervention; voluntary testing behaviour and information about the number of sex partners an individual has had; and the individual's sexual practices, including condom use, unprotected sex, commercial sex and sex with higher-risk partners. Standardized key indicators for surveys of youth behaviour add questions on the age at which the individual had sex for the first time. Behavioural surveillance seeks additional information on condom use and drug injection among female sex workers. The extent of anal sex with multiple partners as well as risky sex with both men and women is also queried among men who have sex with men. Among injecting drug users, behavioural surveillance seeks data regarding equipment sharing, access to sterile needles and selling sex (32).

Individuals are selected for such behavioural studies in different ways. Some may come to the attention of researchers because of retrospective case reviews in clinics and others because they have been reported through disease notification systems. Convenience samples may also play a role. The principle of justice requires that those selected – especially if they are already socially vulnerable – not bear the undue burden that may be associated with participation in surveillance. Here good ethics depends on good epidemiology. Selecting subjects for research that cannot be epidemiologically justified is unethical. Regardless of how such individuals are recruited, all such studies require fully informed consent to ensure that participants fully appreciate the right not to participate, the nature of the mental stress to which interviews may subject them, the extent to which participation in such studies may expose them to the risk of stigma, the protection that will be in place to secure the confidentiality of the data they provide and the limits of this very protection.

The most exacting standard of informed consent requires that individuals affirmatively agree to participate based on a process that fully explains the risks and benefits of participation and the extent to which such a decision will not compromise access to care or services to which the individual would otherwise be entitled. The “opt-in” standard is especially important if subjects are recruited in clinical contexts in which the unspoken expectations of those responsible for clinical care may enhance the pressure to participate. As Fitzgerald et al. (33) noted, “in developing countries, where many participants cannot read or write and are unfamiliar with the concept of a consent form,” individuals “may be likely to sign any paper that a person wearing a white coat places in front of them.” Conversely, some individuals may be “reluctant to put their signatures on documents because of suspicion based on

historical injustices that have occurred to them as a result of such signatures, for example, the signing away of land rights” (33). Obtaining informed consent therefore also requires understanding the local language and local concepts of disease causality and requires giving thought to how to document that volunteers were truly informed.

A second factor that may invalidate the capacity to choose to participate may be the offer of benefits otherwise unavailable. The ways in which such inducements may affect informed consent are discussed below.

A less exacting standard of consent is commonly referred to as opt-out. Under opt-out provisions – sometimes referred to as informed right of refusal – individuals are told that, unless they explicitly choose to exclude themselves from a proposed study, they will be assumed to have agreed to participate. Opt-out provisions, especially in clinical contexts, typically yield higher rates of participation, in large measure because of the difficulty of saying no. Although opt-out standards may be ethically justifiable in some circumstances – such as studies involving biological specimens or records – this approach to consent is generally viewed as compromising the ability of potential surveillance participants to choose freely.

**Guidance point 2.** All behavioural studies should be reviewed by ethics committees to ensure that the consent process fully informs potential participants about their freedom to decline to participate, the nature of the risks and benefits of participation, the availability of services to assist the individual with any negative consequence of participation and the nature of the confidentiality protection in place.

### 2.2.2 Role of the community in the consent process

Researchers are conventionally obligated to protect the rights of individual subjects through a process of informed consent. Research must also pay attention to the communal context of investigations. In many instances surveillance cannot occur before local leaders have approved such efforts. This becomes all the more critical when the issues under investigation are sensitive, as they are in HIV surveillance. Obtaining such permission may not only be necessary as a practical matter but also reflects respect for local community institutions. Such respect may play a critical role in securing the confidence of the people to be involved in surveillance activities. Although obtaining permission from local leaders thus represents an important first step, it should not be confused with the ultimate obligation to obtain the consent of those who may be interviewed in surveillance activities. The 1991 CIOMS guidelines (8), for example, state (Guideline 5) that informed consent must be sought as a matter of principle. Nevertheless, CIOMS distinguishes between “individual consent” and “community agreement”. The guidelines note that “for communities in which collective decision-making is customary, communal leaders can express the collective

will” (8).

Both for surveillance involving contact with individuals as well as the investigation of existing records, as discussed above, an additional step proves vital: consultation with those who may represent the community at large. The Nuffield Council on Bioethics (13) noted that some countries require such community consultation by law . In addressing this issue, the United States National Bioethics Advisory Committee (34) stated:

One mechanism for addressing problems in a culturally sensitive way – without compromising ethical standards for obtaining voluntary informed consent – is to work collaboratively with the community in which the research will be carried out. Informing and educating the local community before the research begins can be helpful in recruiting volunteers and ensuring that their recruitment is noncoercive. Community education and consultation are important in protecting the rights of potential participants during recruitment, in promoting their understanding of the research, and in providing additional information about the study when relevant and necessary.

One mechanism for ensuring that such consultation occurs is creating specially constituted community advisory boards. How such boards are selected and how representative they are of those most at risk or most vulnerable determines their ultimate effectiveness and contribution to the ethical conduct of surveillance. No simple formulas can ensure that such consultation will allow true representativity. However, involving only those with formal or informal authority is clearly insufficient. The difficulties were recognized in the 1991 CIOMS guidelines (8). Speaking of the representation of socially vulnerable or marginalized groups, Guideline 8 stated: “When such groups are artificially created for scientific study, group members may not readily be identifiable as leaders or representatives, and individuals may not be expected to risk disadvantage for the benefit of others. Accordingly, it will be more difficult to ensure group representation, and all the more important to obtain a subject’s free and informed consent to participate.”

***Guidance point 3.*** All second generation surveillance for HIV, whether formally designated as research or as public health practice, ought to involve a process of community consultation. Such consultation is important as a matter of ethical principle and for pragmatic reasons as well. Consultation may enhance the prospect of the voluntary informed cooperation of participants. When surveillance involves direct contact with individuals, such community consultation may not be taken as a substitute for individual consent. All efforts should be made to avoid transforming such consultation into a subtle form of coercion that serves to compel individual participation.

### 2.2.3 Unique issues of consent with minors and the role of parents in the consent process

The very basic principles of research ethics, which seek to protect the right of individuals to choose not to participate in investigations, also require the protection of vulnerable individuals who may not have the psychological or legal capacity to choose. The definition of when an individual reaches the legal age of majority may differ among countries, but where that threshold has not been passed, parents routinely are required to consent to their children participating. Such consent does not automatically guarantee that children will participate. Depending on the nature of the research and the age of the child, the child's consent is also often required.

This set of basic premises raises significant problems in second generation surveillance, where interviewing adolescents about their sexual behaviour may clearly be critically important. Parents may not want their children to participate, and parents who are informed that their children have chosen to participate may view such a decision as indicative of disapproved behaviour involving either sex or drugs.

CIOMS recognized these problems in Guideline 69 from 2002 (14). Given the central importance of studies involving sex and drugs, an exception from the principle of parental involvement with the permission of an ethics review committee was explicitly provided for.

Some studies involve investigation of adolescents' beliefs and behaviour regarding sexuality or use of recreational drugs; other research addresses domestic violence or child abuse. For studies on these topics, ethical review committees may waive parental permission if, for example, parental knowledge of the subject matter may place the adolescents at some risk of questioning or even intimidation by their parents.

Community advisory boards and ethical review committees need to consider such issues as the extent to which participation in studies involving sexuality and drug use may provoke mental distress and a sense of shame and increased vulnerability. Under these circumstances, the availability of social support mechanisms will be a crucial element in determining whether such investigations should go forward.

**Guidance point 4.** The pre-eminent importance of understanding patterns of sexual and drug-using behaviour among adolescents justifies studies involving adolescents who are able to understand the risks and benefits of participating without parental consent. Children who lack the capacity to understand the risks and benefits of participation can only participate with parental consent. Such studies should only occur with the approval of ethics review committees and should demonstrate the availability, through referral, to psychological and social support services that participation may necessitate and to intervention services that will assist at-risk

adolescents in modifying their behaviour.

#### 2.2.4 Impact of the social context on the capacity to consent: prisons and clinical settings

A natural setting for second generation surveillance is the settings in which individuals receive clinical care: prenatal clinics, sexually transmitted infection clinics, tuberculosis treatment centres and hospitals. Inevitably, people receiving clinical care who are recruited to studies may believe that they have no alternative but to agree to participate. They may feel that their treatment will be compromised or interrupted if they choose not to participate in second generation surveillance studies or if they choose to withdraw from studies that they have agreed to join. Even when they do not feel that their treatment is threatened, they may believe that they have a duty to their caregivers to agree to participate. Evidence shows that, even when potential participants are explicitly told that they have a right not to participate and that such a decision will not influence their care, they feel coerced into cooperation (35). Such instances underscore the importance of community consultation, which may enhance the prospect for ensuring voluntary consent.

Prisons may provide a unique environment for second generation surveillance because the people who are especially vulnerable to HIV infection may be drawn from the populations most at risk for incarceration. This very epidemiological fact makes such populations especially useful for second generation surveillance. Prisoners are at increased risk for believing that their failure to cooperate with research studies will result in punitive responses. In addition, given the conditions under which most prison populations live, relatively small benefits that may accrue as a result of participation may assume the proportions of undue inducements.

The history of exploitation of prison populations in biomedical research and the way in which the context of incarceration produced an inherently coercive context for choice resulted in many countries prohibiting research involving prisoners. In the context of the AIDS epidemic, these restrictions are being reconsidered.

**Guidance point 5.** Respecting the autonomy of individuals to make choices is a reflection of respect for people, which also requires that those who have diminished autonomy or are dependent or vulnerable be afforded special protection. Special efforts must be made to ensure that patients understand that their decisions about whether to participate in clinic-based research will not compromise their clinical care. Review committees should include people who can ensure that the approach to patients avoids coercive elements. For example, they may determine that the consent process be undertaken by people who are not directly involved in patient care.

Prisoners, too, may be vulnerable to overt or covert coercion. Although they

should not be denied the right to participate in surveillance if they so choose, ethical review committees must give special attention to the question of whether the coercive context of choice has been sufficiently addressed to ensure that consent is truly voluntary.

### 2.2.5 Unique issues of consent among vulnerable populations

The problem of the coercive impact of undue inducements extends beyond prison populations. In poor or marginalized populations, small offers or payments to potential subjects of second generation surveillance may be hard to refuse. In relatively wealthy countries, this is an issue that affects impoverished and marginalized minorities. In countries in which poverty is widespread, offers by external sponsoring researchers with access to resources may produce, however inadvertently, pressure to participate in surveillance that undercuts the principle of voluntary consent. The 2002 CIOMS guidelines (14) thus recommend (Guideline 45) that “payments should not be so large ... or the medical services so extensive as to induce prospective subjects to consent to participate in research against their better judgement.” Both CIOMS and the Nuffield Council on Bioethics underscore that, given the variability and contextual nature of what might constitute an “undue inducement” that all payments for participation in research be reviewed by local ethics committees. Fitzgerald et al. (33) note that, even a local institutional review board, “acutely aware of the poverty in the host country and wanting to protect the well-being of potential volunteers, may encourage generous financial reimbursements and free medical care”. Thus, ongoing communication between researchers, institutional review boards and communities is critical.

Because of the prospect of exploitation, research ethics precludes using especially vulnerable populations in investigations when the question under study could be answered through the involvement of those who are not marginalized. In second generation surveillance, on the other hand, understanding the dynamics of the effects of the HIV epidemic on the effectiveness of behavioural interventions and the necessity for enhanced funding of prevention services may necessitate involving populations that, because of ethnicity or behaviour, may be viewed as especially vulnerable. Due care must be taken under such circumstances to avoid recruitment processes that capitalize on such vulnerability, thus creating a coercive context within which individuals must decide whether or not to participate. This is especially the case when the subject of the investigation may involve illegal behaviour. In commenting on these issues, CIOMS (14) noted (Guideline 64): “Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied.”

Confidentiality, which is so central to the ethical conduct of second generation surveillance, is especially important with such populations. The consent process must explicitly make clear how the data obtained will be protected and the extent to which material gathered from those who are interviewed may, either as a matter of law or practice, be subject to discovery by those involved with social control or law enforcement. Even when surveillance does not rely on personal identifiers, the existence of signed consent may open individuals to risk if participation is predicated on involvement with behaviour deemed socially unacceptable or illegal.

Community resistance may sometimes, at least initially, thwart second generation surveillance involving drug use, commercial sex work or hidden sexual behaviour and violence. Such opposition could make surveillance – which would serve the interests of the most vulnerable people – difficult to undertake. No simple solution to such tensions exists, especially given a commitment to the process of community consultation. Efforts may be required to demonstrate how, in the long term, the community is best served by surveillance that enables behaviour increasing the risk of HIV transmission to be reduced among vulnerable and socially marginalized populations.

***Guidance point 6.*** With appropriate ethical review, surveillance involving especially vulnerable populations is not only acceptable but necessary in the context of the HIV epidemic. Such review should give due attention to efforts to limiting the imposition of new burdens on vulnerable people as a result of their participation. Especially important is ensuring that consent is informed and voluntary, that confidentiality protection is enforceable and that inducements to participate do not constitute coercive offers.

### 2.2.6 Issues of consent unique to women

The 2002 CIOMS guidelines (14) maintained that a husband or head of household may not consent on behalf of women. Nevertheless, in many societies the father, husband or family head is expected to make all decisions regarding sensitive family issues. Women and other family members who fail to submit to male authority are subject to domestic violence, divorce or social ostracism. Refusing to involve women in studies because of such cultural constraints could thwart investigations crucial to women's interests. The United States National Bioethics Advisory Committee (34) thus maintained that the resultant prospects of denying substantial informational and medical benefits to women “calls for a narrow exception to the requirement that researchers use the same procedures in the consent process for women as for men, one that would allow for obtaining the permission of a man in addition to the woman's own consent”. A woman's informed consent may be supplemented by consent from a man under the following conditions (34): “a) it would be impossible

to conduct the research without obtaining such supplemental permission; and b) failure to conduct this research could deny its potential benefits to women in the host country; and c) measures to respect the woman's autonomy to consent to research are undertaken to the greatest extent possible." Like CIOMS, however, the United States National Bioethics Advisory Committee (34) ultimately recommended that "In no case may a competent adult woman be enrolled in research solely upon the consent of another person; her individual consent is always required."

The Nuffield Council on Bioethics (13) further recognized that the status of women and their right to make decisions without the intrusion of others is not static: the AIDS epidemic has sparked many changes in the role and attitude of women in many industrialized countries. Thus, their guidelines on research in developing countries stress that "cultures are not fixed" and underscore the obligation of researchers and health officials to foster discussion about context and cultural norms as they affect the rights of women.

**Guidance point 7.** Just as a community leader may not consent on behalf of an individual to participate in surveillance, a husband, father or head of household may not provide the sole consent for a woman to participate in surveillance. Although there may be circumstances in which a woman may need to consult with and get the approval of her husband or father, her individual informed consent remains imperative before she is enrolled in behavioural surveillance studies.

### 2.2.7 Confidentiality

In general, behavioural surveillance studies do not require that data be recorded in a manner that links them to identifiable individuals. Research should be conducted in a way that makes sensitive records anonymous when this can be done without compromising the investigation. However, identifiable records may be required in some circumstances, such as in longitudinal studies, which seek to track changes in behaviour over time, or if linkage to other data sources is essential for the investigation. Under these circumstances, every effort must be made to protect the confidentiality of research records. For example, coded identifiers could be appended to each research record and the link between that code and a given individual kept in a highly secure file.

Although researchers are obligated to report their findings in a way that protects the anonymity of their research subjects, a very different problem arises when studies conducted in small communities would clearly identify individuals despite the effort to make research records anonymous. Thus, anonymous records cannot be regarded as strictly confidential in all circumstances.

As noted in the first section of this report, the 2002 CIOMS guidelines (14) obligate

investigators to safeguard the confidentiality of subjects' research data. The Nuffield Council on Bioethics (13) also emphasizes protecting the security and confidentiality of data. Confidentiality is protected in two ways in research. On a pragmatic level, the failure to ensure confidentiality will inhibit the willingness of individuals to discuss precisely the intimate matters of sex and drug use that bear on the dynamics of the HIV epidemic. A study of mother-to-child transmission of HIV conducted in the Ivory Coast, for example, found that women were reluctant to be tested for HIV because they feared that family members, especially husbands, would learn of positive test results. It was the requirement of informed consent that alarmed women about the possibility of their confidentiality being breached; this concern reduced participation rates (36). The ethical underpinnings of confidentiality are as important as its pragmatic basis. The principle of beneficence requires that researchers maximize benefits and minimize harm. The principle of nonmaleficence obligates researchers to avoid inflicting harm. For both reasons, protecting confidentiality is crucial, especially in the context of a socially stigmatized epidemic such as HIV/AIDS.

But confidentiality is not an absolute. As discussed below, researchers conducting behavioural studies related to sexual behaviour and drug use may encounter information suggesting that a given participant has placed himself or herself at risk – especially adolescents – or may be engaged in practices placing others at risk, such as unsuspecting sexual partners. The obligation of researchers under such circumstances varies depending on the law in various countries. In some countries, researchers may have an affirmative duty to notify the relevant authorities so that appropriate intervention can take place. If such limits to the principle of confidentiality exist, the researcher is obligated to notify potential participants of that fact, even if such notification may inhibit participants from fully disclosing their behaviour. It is precisely because of the conflict of interest that may arise under these circumstances that this issue must be subjected to careful ethics review.

A second circumstance in which the principle of absolute confidentiality may be compromised is when records created during a behavioural study may be made available to other researchers. Under certain circumstances, such secondary use may be the subject of a requirement for specific consent. On the other hand, such consent may be impossible in a large-scale retrospective epidemiological review based on records and may be waived with the appropriate approval of an ethics review committee. Section 1.3 discusses this issue more fully.

**Guidance point 8.** Researchers and ethical review committees are obligated to protect the confidentiality of people recruited to behavioural studies. Such an obligation may be met by recording the data anonymously. If this is not possible, every effort must

be made to secure records to prevent unwarranted disclosure. Legal or ethical limits on confidentiality should be disclosed to research participants as part of the informed consent process. The minimum identifiable information necessary to conduct a study should be collected.

### 2.3 Anonymous unlinked surveillance

When HIV was identified in 1984, it became clear that understanding the dimensions of the AIDS epidemic would require more than carefully detailing the incidence and prevalence of overt symptoms of disease. The prevalence of HIV infection had to be determined to enable public health authorities in countries with well developed public health and health care systems to target and evaluate preventive interventions and plan for the health care services that would be required in the future as people infected with HIV progressed to symptomatic conditions. Data based on volunteer studies involving only consenting individuals drawn from groups at increased risk such as men who have sex with men, intravenous drug users or attendees at sexually transmitted infection clinics were not adequate to the challenge of monitoring the epidemic because of selection and participation bias. To meet the challenge, epidemiologists quickly agreed that anonymous, blinded or unlinked serosurveillance was necessary. Such unlinked surveillance would involve screening blood specimens collected for purposes other than HIV testing under conditions that permanently stripped the samples of personal identifiers.

Unlinked anonymous serosurveillance has provided a unique vantage on epidemics, and those opposed to name-based HIV notification have therefore viewed it as a superior epidemiological tool (37). Second generation surveillance recognizes these potential contributions while underscoring the need to locate anonymous unlinked studies in a much broader surveillance framework. Since such efforts will continue to play a role, acknowledging their methodological limitations and the ethical challenges they pose is important.

On methodological grounds, blinded seroprevalence studies are not as easy to design and interpret as is sometimes believed. Surveillance sites must be carefully selected to ensure that the populations that come into contact with them are representative of the larger population. In countries in which significant proportions of the population are treated in the “traditional” sector, this requirement may pose insuperable obstacles. Finally, without an epidemiological model of local epidemics, the significance of prevalence at any given moment is not easily interpretable. For example, unchanged prevalence may reflect a dramatic decline in incidence or may simply reflect continued high incidence combined with high mortality. Consequently, accurate HIV/AIDS morbidity and mortality figures remain key to interpreting sentinel surveillance data.

In the United States, such surveillance became a central feature of the public health response to the HIV epidemic in the mid-1980s. Nevertheless, such efforts had to address a set of ethical questions. Issues of consent and the right to know were foremost because anonymous surveys would be conducted without the knowledge and agreement of those who were tested and would detect infection without being able to inform individuals. In considering these issues, the United States Centers for Disease Control and Prevention concluded that unlinked anonymous surveillance is ethical because no person whose blood was to be tested would be denied an opportunity to obtain testing and counselling in a manner that could reveal his or her HIV status. Further, since the tested samples were anonymous, no individual's HIV status would be determined without consent; the social and psychological risks of being identified as infected were precluded by irrevocably unlinking the test results and specific individuals. Finally, from a public health viewpoint, discovering unexpected levels of infection in a community could spur both further epidemiological investigations and the targeting of necessary public health resources for testing, follow-up and counselling. The social costs involved in losing the capacity to warn specific individuals that they were infected would be compensated for by the public health benefit that involved only a minimal violation of the rights of informed consent and privacy. When a working group comprised of ethicists, lawyers, advocates of civil liberties, proponents of gay and lesbian rights and public health officials met in 1985 to discuss the issue of unlinked anonymous HIV surveillance at the Hastings Center, a research institute devoted to the study of ethical questions in medicine, no objection was raised to such efforts. Unlinked surveillance was extended beyond the initial sentinel hospital settings and, most importantly, was extended to childbearing women in 44 of the 50 states of the United States with virtually no opposition and much support.

In 1989, WHO issued *Unlinked anonymous screening for public health surveillance for HIV infections: proposed international guidelines* (38). This stated that one of the primary objectives of public health surveillance of HIV infection was to obtain information on the prevalence and incidence of infection in selected populations in a way that was as free as possible from participation and selection bias. To ensure this goal, WHO endorsed the use of unlinked anonymous surveillance and concluded that this could be used “without endangering or compromising the broad principles of public health and human rights”.

Despite consensus in the United States and the endorsement of UNAIDS, unlinked anonymous surveillance provoked controversy in other industrialized countries. Most notably, resistance in the United Kingdom, the Netherlands and Denmark resulted in a delay of several years before such surveillance could be undertaken. The remarks of two leading British ethicists who challenged the fundamental premises of such

surveillance indicate the level of concern. Raanan Gillon, editor of the *Journal of Medical Ethics*, wrote of such studies (39):

We trade on a deceit ... if without either explicit or implicit permission we start using our patients for the benefit of others. The deceit is compounded if in so using our patients we discover important information that they may wish to know and we have deliberately both failed to find out whether they would wish to know it and so organized matters that we cannot pass it on even if they wish to know.

Ian Kennedy acknowledged that the ethical challenge to unlinked anonymous surveillance might preclude obtaining information critically important to public health: "There may be some things which one wants to know but if the only route toward knowing them is an impermissible route one may not know them .... This is after all the heritage that we have acquired from Nuremberg and afterwards." (40). Summarizing the objections, one expert on the ethics of human subjects research from the United States said: "The fundamental issue for these critics is that such programmes conscript research efforts that they may not want to be part of." (23). This was, therefore, a challenge rooted in the very fundamentals of bioethics after the Second World War.

When the United Kingdom finally adopted a system of unlinked anonymous surveillance, it sought to achieve the benefits of such efforts while acknowledging the importance of respecting the right of individuals not to be the objects of study. The public was to be notified that, whenever blood was taken for testing, some quantity might be used for unlinked anonymous surveillance and the right of refusal to such testing would be respected if expressed in a "spontaneous refusal" (41). The Canadian guidelines on unlinked surveillance (42) also acknowledged the right to such spontaneous refusal. In other respects, the Canadian guidelines were enthusiastic about the ethical and public health justifications for epidemiological methods that avoided the problems of selection and participation bias.

The early history and debate surrounding unlinked anonymous surveillance occurred under conditions of radical therapeutic limits. With virtually no effective treatment available for those with asymptomatic HIV infection, knowledge of infection had little relevance to the kind of clinical care one would receive. As the prospects for intervention in HIV infection increased, the immediate interests of people with HIV infection to know that fact increased as well. Although voluntary counselling and testing were available, some began to believe that the ethical foundations of unlinked surveillance were becoming more questionable. This issue became acute in the very country that pioneered the wide-scale use of unlinked surveillance: the United States. When clinical trial ACTG 076 in 1994 revealed that providing zidovudine to pregnant women could reduce the risk of vertical transmission by two thirds, pressure

mounted to ensure that all women who might benefit were identified. Ironically, opposition to unlinked surveillance of pregnant women came from two radically distinct sources: those who believed that pregnant women should be subject to mandatory testing and those who believed that anonymous surveillance, which precluded notifying pregnant women, was the equivalent of the infamous Tuskegee syphilis experiment, in which African-American men with syphilis were not informed of their infections – indeed, deceived about their infections – and systematically denied treatment for about 40 years (43). Faced with such pressure, the United States Centers for Disease Control and Prevention ultimately interrupted the massive and important serosurveillance of childbearing women.

In the wake of efforts to discover less costly regimens to interrupt mother-to-child transmission of HIV and given increased international efforts to provide either short-course zidovudine or nevirapine, ethical questions that first arose in industrialized countries have now begun to surface in less-developed countries as well.

The CIOMS 1991 epidemiological guidelines (8) make only passing and approving reference to unlinked anonymous seroprevalence studies, suggesting only (Guideline 13) that, “where feasible”, they be conducted parallel with voluntary HIV testing with informed consent accompanied by pre- and post-test counselling and ensuring confidentiality. More than a decade later, the 2002 CIOMS guidelines (14) were much more exacting in their strictures, suggesting (Guideline 36) that individuals retain the right to refuse to have their stored records and specimens used for such studies.

Patients have a right to know that their records of specimens may be used for research. Refusal or reluctance of individuals to agree to participate would not be evidence of impracticability sufficient to warrant waiving informed consent. Records and specimens of individuals who have specifically rejected such uses in the past may be used only in the case of public health emergencies.

The potential effect this recognition might have on the epidemiological validity of serosurveillance and whether this would undercut the unique solution to the problem of participation bias remains an empirical question. Where the right to participate is recognized to subvert the goals of unlinked anonymous surveillance, ethics review committees will have to assess whether the public health benefits outweigh the limited violation of the right of informed consent and whether only emergencies should provide a warrant for such surveillance.

### 2.3.1 Individual consent to blood drawn for other purposes

In summary, no country requires the most exacting standard of informed consent for participation in unlinked anonymous surveillance in which individuals affirmatively

agree to participate based on a process that fully explains the risks and benefits of participation. Further, no international ethical guidelines require such consent. Some countries do notify the public that, whenever blood is drawn for testing for some purpose other than HIV testing, some portion might be used for unlinked anonymous surveillance; these countries grant individuals the right to “spontaneous refusal”.

***Guidance point 9.*** Communities should be broadly notified that blood collected for one purpose may be anonymously tested for HIV. Although fully informed consent is not required for unlinked anonymous surveillance, the wishes of individuals wishing to opt out of such surveillance should be respected where possible. If the numbers of individuals opting out or spontaneously refusing to participate threaten the validity of surveillance efforts, ethics review committees will have to determine whether the public health significance of the studies warrants overriding the right to refuse to participate.

### 2.3.2 Individual consent to blood drawn specifically for HIV surveillance

Unlinked anonymous surveillance need not be coupled with drawing blood for other purposes: it may be designed specifically to test for HIV. For example, WHO has considered whether unlinked anonymous surveillance can be conducted among tuberculosis patients, whose blood is not routinely collected. Since such testing must involve the informed consent of participants, the rate of refusal may compromise the initial rationale of unlinked anonymous surveillance: the elimination of participation bias.

During the debates over unlinked anonymous surveillance in the United States in the wake of trial ACTG 076, some opponents of such surveillance pressed for measures that would have given childbearing women the ability to have their test results relinked with their names. The possibility of “relinking” fundamentally alters the ethical foundations of an approach to surveillance predicated on the irreversibility of the decoupling of names from test results. Individuals may wish to know their HIV test results as a result of learning about unlinked anonymous surveillance, but the appropriate route for individuals to learn of their HIV status is through confidential HIV testing and counselling, in which they can be fully informed of the meaning of the test and therapeutic options and referred to counselling or other clinical or support services. Participants must understand that they cannot be informed of their HIV status and that the absence of this information does not mean that they are HIV negative.

Similar to behavioural surveillance conducted in clinical settings, the people responsible for clinical care may apply unspoken pressure to participate or the people receiving care may fear that continued care depends on participation. Ethics

committees reviewing such surveillance protocols must consider such pressure.

**Guidance point 10.** When blood is drawn exclusively for the purpose of unlinked anonymous surveillance, the informed consent of each individual subject must be obtained. Individuals must understand their right to decline to participate, the nature of the risks and benefits of participation, the nature of unlinked anonymous testing and the availability of voluntary testing and counselling services.

### 2.3.3 Community consent

Communities should be broadly notified of such surveillance and efforts should be made to gain their acceptance and cooperation. When blood is drawn for other purposes, communities should be broadly informed of the possibility that any individual's blood might be used to undertake unlinked anonymous surveillance. Community consent cannot serve as a substitute for individual informed consent when which blood is drawn specifically for purposes of unlinked anonymous surveillance.

**Guidance point 11.** Unlinked anonymous surveillance ought to involve a process of community consultation to enhance the prospect of voluntary informed cooperation of participants. Such community consultation may not be taken as a substitute for individual consent in instances where blood is drawn exclusively for the purpose of unlinked anonymous surveillance.

### 2.3.4 Access to voluntary testing and counselling

Ethical guidelines for all industrialized countries have stipulated that the conduct of unlinked anonymous surveillance must coexist with the availability of access to voluntary testing and counselling. Thus, the acceptability of such surveillance depends on individuals having other avenues to learn of their HIV status. In less-developed countries, confidential voluntary testing and counselling services are not universally available. Indeed, the purpose of such surveillance may be to determine the need for such services.

**Guidance point 12.** Unlinked anonymous surveillance may be imperative for establishing the need for and the provision of testing and counselling programmes. Not knowing the levels of infection in either the general population or subgroups at potentially high risk may result in inadequate planning for the HIV epidemic and may preclude effective advocacy for the necessary preventive and clinical services. The possibility of such advocacy provides the basis for an exception to the requirement that unlinked surveillance be undertaken only if access to voluntary testing and counselling is available.

## 3. Data use and dissemination

In the 2000 revision of the Declaration of Helsinki (12), the World Medical Association declared: “Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.” The 2002 CIOMS guidelines (14) strongly emphasize this point and assert (Guideline 10) that “it is not sufficient simply to determine that a disease is prevalent in the population and that new or further research is needed. The ethical requirement of ‘responsiveness’ can be fulfilled only if successful interventions or other kinds of benefits are made available to the population.”

Both the Declaration of Helsinki and the CIOMS guidelines focused on medical interventions that might follow clinical research, but the relevance of their discussion to surveillance is clear. The goal of surveillance is to gather knowledge in the service of public health. Public health surveillance is the ongoing, systematic collection of health data followed by analysis, evaluation and interpretation of these data and prompt dissemination of the findings to public health officials and others who need to know how to help shape public health intervention, planning and prevention (2,3). If acquiring knowledge and public health activity are not linked, the ethical foundation for surveillance – especially that most intrusive on privacy and the principles of consent – may be subverted. What obligations do those who conduct surveillance have to the populations they have studied? Ensuring that surveillance data will lead to new efforts at prevention or the provision of services may not be possible. What is required is some commitment to make use of such knowledge to benefit the population studied. Such efforts may include advocacy within government institutions and between less-developed countries and international aid agencies. This also may include the empowerment, through knowledge, of vulnerable populations. Vague promissory notes however, may risk becoming a pretext for inaction.

Ethics review committees are responsible for focusing on how surveillance-related evidence will be used after studies are completed. The significance of the absence of formal ethical review processes for ongoing government surveillance activities that may not be characterized as research is hereby underscored.

In stressing the imperative for researchers from industrialized countries to make good-faith efforts to ensure that participants in a clinical trial have access to the products shown to be effective in completed research, the United States National Bioethics Advisory Committee stressed the importance of communicating results to the communities in which investigations take place. As Fitzgerald et al. (33) note, “At a minimum, if researchers collect data in a country they have a responsibility to share the results with the people in the country.” In the absence of such data dissemination, researchers might rightly be accused of exploiting vulnerable populations. The

Nuffield Council on Bioethics (13) concluded that the obligation to disseminate data included a duty to explain “the implication of the results for future healthcare” and for “prevention of disease in the community”. The ideal form of such information dissemination could vary, but the form chosen would need to ensure that researchers answered all the questions of participants and the community. The Council added a pragmatic reason for attending to such communication: failure to disseminate results contributes to low participation rates in subsequent research.

The 1991 CIOMS guidelines (8) also stress the importance of communicating study results (or advocating the release of such results when controlled by either governments or private entities) to individuals and communities when possible and of informing participants when conveying individual health information will not be possible. CIOMS also emphasizes fulfilling the expectations for health care that may be created by epidemiological research and improving the training of local health personnel as part of such research. The guidelines (8) note (Guideline 13) that “In informing individuals of their findings and their pertinence to health, their level of literacy and comprehension must be considered. Research protocols should include provision for communicating such information to communities and individuals.” Finally, Canadian guidelines for unlinked anonymous seroprevalence surveillance (42) recommend that, at a minimum, “Communication with the public should be clear and balanced” and that a variety of media should be considered for information dissemination: physicians being informed of surveillance results, mass mailings, videotapes, toll-free information hotlines, newspapers, seminars and public meetings are all potential tools for conveying surveillance information to the public.

The communication of knowledge is a double-edged sword: knowledge may empower but may also harm. Thus, the 1991 CIOMS guidelines (8) note the possibility that releasing information may cause harm, especially to stigmatized, marginalized or vulnerable groups. Guidelines 19, 21 and 22 state that, in addition to always assessing the potential risks of “stigmatization, prejudice, loss of prestige or self-esteem, or economic loss as a result of taking part in a study” and demonstrating that the risks outweigh the benefits, “Investigators who find sensitive information that may put a group at risk of adverse criticism or treatment should be discreet in communicating and explaining their findings.” The guidelines continue: “Harm may be mitigated by interpreting data in a way that protects the interests of those at risk, and is at the same time consistent with scientific integrity.” The guidelines further require investigators to explain how they will protect groups and communities from harm, which must include confidentiality provisions.

In the end, vulnerable populations may unavoidably experience some communication as harmful. Only the commitment to utilizing second generation surveillance to

benefit such vulnerable groups can justify such short-term harm.

## 3.1 Feedback and empowerment

The following guidance points must be read with the understanding that the obligation to use and disseminate data and the goal of empowering vulnerable groups may be in tension with the obligation of the 1991 CIOMS guidelines (Guidelines 19 and 21) to protect these very groups from short-term “suffering, stigmatization, prejudice, loss of prestige or self-esteem, or economic loss” (8).

### 3.1.1 Obligation to use data

**Guidance point 13.** Second generation surveillance efforts can only be justified if they will enhance the capacity to prevent the spread of HIV infection or direct resources to people already infected. When such surveillance occurs under conditions characterized by resistance to effective intervention or scarce resources, which may impede programmatic change, it may be used as a basis for advocacy and empowering the most vulnerable people.

### 3.1.2 Obligation to disseminate data

**Guidance point 14.** The results of second generation surveillance must be communicated to stakeholders in all cases. Efforts to inhibit such communication must be challenged. Community advisory boards and ethics review committees should examine surveillance efforts with an eye to plans for post-surveillance interventions.

### 3.1.3 Duty to protect vulnerable groups (including women, young people, sex workers and injecting drug users) from stigmatization

**Guidance point 15.** When communicating surveillance data may harm the vulnerable populations intended to be served, every effort must be made to minimize such risks. Consultation with representatives of vulnerable communities may play a critical role in maximizing the prospect of communication without harm.

## 3.2 Behavioural surveillance

### 3.2.1 Obligation to intervene at the individual level

In behavioural surveillance, a researcher administering a questionnaire may become aware during the interview that the participant is placing himself or herself at risk because he or she does not know how HIV is acquired and transmitted, has limited access to preventive services or has psychosocial stressors. Individuals may also reveal that they are being placed at risk because of the coercive or threatening behaviour of their own sexual partners. Intervening to protect such people may be beyond the

immediate role of the researcher, but such situations require considering referring such people to appropriate services if they are available. A much more difficult issue is posed when referral is not practical or possible. Referrals to socially or geographically inaccessible services cannot be an acceptable resolution to this problem and, indeed, may only serve further to disempower people who are already vulnerable. If referral is impossible, surveillance projects may have to assume responsibility that would otherwise be beyond the normal scope of their activities. Community advisory boards and ethical review committees may serve as the appropriate fora for discussing these matters before they emerge.

**Guidance point 16.** Surveillance projects are obligated to ensure that people who are placing themselves at risk are referred to appropriate services. If such referral is not possible, the project itself is obligated to advocate for appropriate intervention in consultation with community advisory boards and ethics review committees.

### 3.2.2 Obligation to third parties

During the course of behavioural surveillance, researchers may further discover that individuals have placed other potentially unsuspecting people at risk for HIV infection because of sexual activity or sharing drug use equipment. They may also learn the identities of individuals who have placed research participants at risk. How such behaviour is viewed legally varies between countries, as does the availability of services such as partner notification. These contexts inevitably affect both the legal and ethical obligation of those involved in behavioural surveillance studies. There may be a fundamental tension between the goals of research to uncover risky behaviour and the impulse to intervene, even involving notifying legal authorities. Much depends on the nature of the threat discovered, its immediacy, the capacity of those at risk to protect themselves and the extent to which they may be thought to have placed themselves at risk voluntarily. The successful conduct of such surveillance may require explicit exemption from any standard legal requirements when researchers discover that participants are engaging in behaviour that may threaten the welfare of others. The absence of such exemptions will inevitably influence the willingness of participants to speak candidly.

**Guidance point 17.** Prior to undertaking behavioural surveillance, participants should clearly understand the legal obligation to inform authorities about behaviour that may place others at risk. If the researchers are not exempt from notifying the authorities, the researchers have a duty to inform participants of the limits of confidentiality. See also Guidance points 2, 6 and 8. Individuals placing others at risk should be referred to appropriate services in accordance with Guidance point 16.

### 3.2.3 Obligation to intervene at the community level

Researchers and others who conduct surveillance may not be able to ensure that vulnerable communities have access to the services – such as condoms, supportive services for women or needle exchange programmes – that surveillance reveals would be helpful in preventing the spread of HIV. One function of pre-surveillance consultation with community advisory boards and ethics review committees would be to delineate the shared understanding of the obligations, if any, of those who conduct surveillance at the end of the study period. In this regard, the issues raised are not radically dissimilar from those involving biomedical research, in which consultation is necessary about access to therapies that may prove to be effective.

**Guidance point 18.** Prior to undertaking behavioural studies, researchers, in consultation with community advisory boards and ethics review committees, should make clear what, if any, direct role they would intend to play in advocating for providing prevention services after surveillance.

### 3.3 Serosurveillance

In some instances, such as unlinked anonymous surveillance, subjects cannot, by definition, be informed of their HIV status. As noted previously, this was one major objection to such studies from the onset. With the enhanced prospect for therapeutic intervention, debate surrounding this matter has only intensified, since individuals now have an immediate interest in knowing their HIV status. The justification for unlinked anonymous surveillance has always been that the epidemiological results would be pertinent to determining the services needed within given communities. The possibility of clinical intervention to slow the onset of HIV-related disease has sparked demands that such therapy be made widely available. The most notable cases have surrounded pregnant women, to benefit both the child and the mother herself. In the poorest of less-developed countries, access to such therapy remains extremely limited. In other countries, the prospects are much different. In Brazil, for example, all HIV-infected individuals are entitled to antiretroviral therapy. Where resources are limited or where public policies preclude access to antiretroviral therapy, unlinked anonymous surveillance data may serve as a basis for advocacy on the part of vulnerable groups as they seek to convince their own governments about the need for care and may serve the interests of poor countries as they seek to obtain resources from the international community.

#### 3.3.1 Access to test results and treatment

**Guidance point 19.** Unlinked anonymous surveillance cannot provide individuals with access to their own HIV test results. They can, however, provide communities and officials with an understanding of the prevalence of infection. People who conduct surveillance are obligated to ensure that such results are effectively

communicated to the communities within which unlinked anonymous studies take place. See also guidance points 9 and 10.

**Guidance point 20.** Serosurveillance provides a measure of the need for clinical intervention. People who conduct unlinked anonymous surveillance cannot ensure that this need will be met. Data can serve as a foundation for people who advocate the provision of increased clinical resources for those infected with HIV.

#### 4. Summary and conclusions: ethical implications of the type of epidemic

Several themes have been salient throughout the discussion and in the guidance points that have emerged from it. Because of the nature of the HIV epidemic and how it is linked to sexual and drug-using behaviour, people thought to be at risk or who are in fact at risk have been subject to stigmatization, discrimination and violence. As a result, confidentiality, which is a central ethical principle governing research, has assumed critical importance in the conduct of surveillance. Unless confidentiality is ensured, those most at risk for HIV infection would have every reason to avoid cooperation with those undertaking surveillance activities. This is true not only of individuals who may be engaged in behavioural surveillance but of clinicians who may, under notification requirements, be expected to report cases of HIV, AIDS-related infections or AIDS itself. In addition, consent – the first principle of research ethics enunciated in the Nuremberg Code – has clearly been crucial in HIV surveillance. The importance of ensuring that people who participate in surveillance understand both the risks and benefits has been underscored precisely because of concerns about stigmatization, the risks associated with breaches of confidentiality and potentially threatening social environments. The emphasis on consent does not come without costs, as demonstrated by the challenges to unlinked anonymous surveillance and in the unwillingness of individuals to consider standard disease notification practices in HIV – which have a long history in public health.

Despite the emphasis on the importance of protecting the rights of individuals in surveillance and the limits such concerns may have for surveillance as an activity, there is an ethical obligation to undertake surveillance precisely because of the potential for the prevention of disease, suffering and death. This is where the link between surveillance as a data-gathering activity and surveillance as a public health undertaking designed to limit morbidity and mortality becomes clear. The moral foundations of surveillance activity vanish without a commitment to using surveillance findings to benefit vulnerable people.

The broad general themes that emerge have been discussed so far independently of the stage of the epidemic. One of the key achievements of second generation

surveillance is that it recognizes that low-level, concentrated and generalized epidemics impose different demands on public health and surveillance activities. Table 1 locates the various guidance points developed in this publication in the context of the surveillance methods appropriate for different stages of the epidemic. Concerns about stigma, confidentiality, consent and data use play out differently in different epidemic stages.

In low-level epidemics and concentrated epidemics, the risk of stigmatization is greatest because HIV infection may be viewed as involving marginalized populations engaged in behaviour considered to be immoral or illicit. Identifying the groups that are just beginning to show signs of HIV infection, as in low-level epidemics, or among whom HIV infection has already made a significant appearance, as in concentrated epidemics, is especially risky because the groups themselves feel threatened. Creating an atmosphere of trust and securing the commitment to confidentiality and emphasizing the importance of consent are crucial. Most problematic, especially in low-level epidemics, is the ability to link surveillance findings to enhanced public health activities designed to inhibit the development of an epidemic that is not yet viewed as a threat. In concentrated epidemics, the location of HIV infection among marginalized populations may permit decision-makers to ignore the human costs of the disease because it afflicts solely marginalized people or because decision-makers refuse to acknowledge that bridging populations may provide an opportunity for HIV infection to extend into the broader population. The ethical obligation to ensure that surveillance efforts shape public policies may necessitate unexpected relationships between researchers and people who advocate on behalf of the most vulnerable.

In generalized epidemics, the threat of stigmatization, discrimination and violence would be expected to diminish, and yet this is not always the case. The capacity for denial may create contexts within which those with symptomatic HIV disease become the objects of opprobrium and even violence although they represent the tip of a vast iceberg. Under such circumstances, a key function of surveillance is to underscore how widespread infection is. One important task in getting societies with generalized epidemics to acknowledge the actual state of affairs is to create a context within which those with HIV infection, whether symptomatic or not, feel free to go public with their illness. The importance of breaking the silence cannot be overstated. Nevertheless, it is precisely the importance of uncovering the presence of HIV that may threaten the ethical principle of confidentiality such that it is viewed as being no different from socially harmful secrecy. Because generalized epidemics are heterosexual by definition, they always involve childbearing women and their infants. Protecting the rights of women to consent to medical intervention and, indeed, protecting their privacy becomes central.

Generalized epidemics almost always represent a failure of prior efforts to interrupt the spread of HIV infection or indicate neglect that permitted HIV infection to spread without the impact of public health efforts. Surveillance activities that underscore these failures thus inevitably represent a challenge to the people in positions of authority. Acknowledging past failures but also redirecting efforts in a way that reflects the dynamics of HIV transmission will be a challenge.

**Table 1. Ethical guidance points relevant to various activities and levels of the epidemic within second generation surveillance for HIV**

**Low-level epidemics**

<b>Key epidemiological questions</b>	<b>Core surveillance</b>	<b>Relevant guidance points</b>	<b>Additional studies</b>	<b>Relevant guidance points</b>
Are there groups with risk behaviour?	Formative research and mapping of groups with potential risk behaviour	3, 15	Mapping to cover a larger geographical area and to be conducted more frequently	
	Analysis of available surveillance data on sexually transmitted infections		Estimate the size of groups with potential risk behaviour	15
What are the main types of risk behaviour?	Risk behaviour surveys in groups considered at high risk for HIV infection	2, 3, 4, 5, 6, 8, 15, 16, 17, 18	Increased geographical coverage of risk behaviour surveys	2, 3, 5, 8, 16, 17, 18
			Studies of the prevalence and incidence of sexually transmitted infections in groups with risk behaviour	3, 4, 9, 10, 15
How much HIV infection is there?	HIV serosurveillance in identified groups with risk behaviour	3, 4, 6, 9, 10, 11, 12, 15, 19, 20	Larger coverage and increased frequency of HIV serosurveillance among identified groups with risk behaviour	3, 4, 9, 10, 11, 12, 15, 19, 20
	Analysis of available data on HIV screening among blood donors	3, 9	HIV sentinel serosurveillance among pregnant women in urban areas	3, 7, 9, 10, 11, 12, 15, 19, 20
Who else might be infected and to what extent?	AIDS case reporting	1, 15	Risk behaviour surveys focused on potential bridging populations	2, 3, 4, 5, 6, 8, 16, 17, 18
	HIV case reporting	1, 15		

**Concentrated epidemics**

<b>Key epidemiological questions</b>	<b>Core surveillance</b>	<b>Relevant guidance points</b>	<b>Additional studies</b>	<b>Relevant guidance points</b>
How much HIV infection is there?	HIV serosurveillance in identified groups with risk behaviour	3, 9, 10, 11, 12, 15, 19, 20	Wider geographical coverage and increased frequency of HIV serosurveillance among identified groups with risk behaviour	3, 4, 9, 10, 11, 12, 15, 19, 20
	Annual HIV sentinel serosurveillance among pregnant women in urban areas and areas with high exposure	3, 7, 9, 10, 11, 12, 15, 19, 20	HIV serosurveillance among bridging populations and pregnant women	3, 4, 7, 9, 10, 11, 12, 15, 19, 20
	Analysis of available data on HIV screening among blood donors	9		

What are the main types of risk behaviour and how do they change over time?	Repeated risk behaviour surveys among groups with risk behaviour	2, 3, 4, 5, 6, 8, 15, 16, 17, 18	Wider geographical coverage and increased frequency of repeated behavioural surveys among groups with risk behaviour and bridging populations	2, 3, 4, 5, 6, 8, 15, 16, 17, 18
	Repeated risk behaviour surveys among groups with risk behaviour Analysis of data on sexually transmitted infections among groups with risk behaviour and bridging populations	2, 3, 4, 5, 6, 8, 15, 16, 17, 18 9, 10, 15	Surveys of health-seeking behaviour for sexually transmitted infections	3, 4, 6, 8, 15
Who else might be affected and to what extent?	Repeated risk behaviour surveys in the general population in urban areas and areas with high exposure	2, 3, 5, 6, 8, 16, 17, 18	Repeated risk behaviour surveys among the general population in all areas	2, 3, 5, 8, 16, 17, 18
	AIDS case reporting	1, 15	HIV case reporting	1, 15

### Generalized epidemics

Key epidemiological questions	Core surveillance	Relevant guidance points	Additional studies	Relevant guidance points
What are the trends in HIV infection?	Annual HIV sentinel serosurveillance among pregnant women in urban and rural areas	3, 7, 9, 10, 11, 12, 15, 19, 20	HIV sentinel serosurveillance among pregnant women in a larger number of sentinel sites	3, 7, 9, 10, 11, 12, 15, 19, 20
	Increased sample size in high-volume sites to enable analysis by age groups		HIV serosurveillance among groups considered at high risk (such as sex workers and their clients)	3, 9, 10, 15, 19, 20
	AIDS case reporting	15	Population-based HIV prevalence studies to validate surveillance data	3
Is behaviour changing?	Repeated behavioural surveys among groups considered at high risk of HIV infection	2, 3, 4, 5, 6, 8, 16, 17, 18	Larger coverage of behaviour surveys	3, 4, 5, 8, 16, 17, 18
Do the recorded changes help explain trends in HIV infection?	Analysis of surveillance data on sexually transmitted infections among groups considered at high risk of HIV infection	9, 10, 15		
	Repeated risk behaviour surveys among the general population with a focus on young people	2, 3, 4, 5, 6, 8, 15, 16, 17, 18		
	Analysis of surveillance data on sexually transmitted infections among the general population	9, 10		
What is the impact of HIV?	Vital registration data		Other health data (census and studies)	
	Surveillance of tuberculosis and other illnesses related to HIV/AIDS	15	Studies of access to care	3

Source: adopted from step-by-step summary in *Second generation surveillance for*

*HIV: the next decade (1)*, pp. 37–39.

Some guidance points are not listed because they span all categories of surveillance and serve more as justifying ethical principles for any such efforts, such as guidance points 13 and 14. Guidance point 7 is listed only in instances where surveillance is targeted at women, but clearly it applies in any instance in which women may need to consult with or seek the approval of a husband or father. This table is intended as a general guide; the ethical conduct of second generation surveillance requires reading and understanding the guidance points as a whole.

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#### Annex

The annex needs to be created using the absolutely final versions of the guidance points.