UNAIDS/WHO Working Group
on Global HIV/AIDS and STI Surveillance

Guiding principles on Ethical issues in HIV surveillance

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Global surveillance of HIV and sexually transmitted infections is a joint effort of the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS). The UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance was initiated in November 1996, and provides technical guidance on conducting HIV and STI surveillance at national, regional and global levels. Its mandate is to improve the quality of data available for informed decision-making and planning at the national, regional and global levels.

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Preface

Second generation HIV surveillance grew out of the complexity inherent in measuring the full spectrum of populations' experiences with HIV infection. To fully understand the HIV epidemic, national programmes needed to understand the modes of transmission using behavioural data, the prevalence using HIV test data, and the prevalence of other sexually transmitted infections. Collection and use of these data constitute second generation surveillance. With the rise in treatment availability, additional data collection systems have arisen and merged with traditional second generation surveillance. Treatment availability has also changed the ethical dynamic between surveillance practitioner and respondent. This document addresses that changing dynamic.

The World Health Organization (WHO)/Joint United nations Programme on HIV/AIDS (UNAIDS) Surveillance Working Group publish a guidelines series describing best practices for implementation of the various components of second generation HIV surveillance systems. This guide complements that series.

Over the past decade, the global effort to monitor the spread of HIV led to an expansion of data collection systems to enable health professionals to better track the epidemic and behaviours that mitigate or contribute to its spread. Some of the new data collection systems raise new questions related to protecting respondents as human research subjects, while other systems, long in use, must be reviewed in this age of wider treatment availability. These changes underscore a heightened need for renewed attention to ethical issues in HIV surveillance.

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 with linked or unlinked HIV testing, testing for sexually transmitted infections, as well as behavioural surveys on sexual behaviours or illicit injecting. This document briefly reviews the main ethical issues to be considered in implementing second generation surveillance, gives a brief background on past ethical considerations and then provides specific guidance points to address these issues. The discussions build on the purpose and history of HIV surveillance and its conduct. The document considers the links between the technical and ethical aspects of HIV surveillance and ensuring protection for human subjects, and then tries to formulate guidelines that account for the context in which the surveillance systems are implemented.

Ethical questions can vary depending on the context of the epidemic; attention is given to the different types of epidemics – generalized, concentrated and low-level – which have implications for the strategies for collecting and disseminating data. While historical discussions of trade-offs between disclosure and privacy were partly shaped by poor availability of treatment, increased availability of medicines to treat HIV has changed ideas about the responsibilities of surveillance practitioners to provide care to respondents newly identified as being HIV-infected.

An important point of this publication is that ethical review should consider technical and programmatic needs from the field, and include inputs from affected individuals and communities. This complexity of issues, globally, underscores the need to provide leeway for adapting ethical guidance to local circumstances. Future capacity-building in bioethics should include considerations of second generation HIV surveillance systems.

These guidelines were commissioned to two public health ethics experts, Amy L. Fairchild, PhD, MPH, and Ronald Bayer, PhD. The specific tasks assigned to them were to:

- review the reports of recent international consultations on the ethics of HIV surveillance (2008, 2009);
- review any relevant published literature produced in the last five years, since the last Guidance Points document;

- review HIV surveillance guidelines produced in the last five years, since the last Guidance Points document;
- revise the guidance points document to reflect more accurately the discussions, and where extant, conclusions of the recent consultations.

These guidelines considered the most recent relevant publications by CIOMS, the 1991 and 2002 versions of *International ethical guidelines for biomedical research involving human subjects.* The CIOMS guidelines are both dated and ill-suited to inform HIV surveillance activities. Public health surveillance, including for HIV, is a routine public health function and not technically biomedical research.

Additionally, a special consultation to address the ethics of unlinked anonymous HIV testing for surveillance purposes was held in February 10-12, 2009 in Geneva. This meeting convened implementers, both non-governmental and governmental, and country-based ethicists from all WHO regions; the consultation report formed the basis for the guidance points contained herein. One author (RB) participated in the consultation prior to receiving the commission to write this document.

The independent review of the final document was performed by technical experts from WHO regional offices and the UNAIDS/WHO Global Surveillance Working Group for HIV/AIDS and STI surveillance. Therefore these guidelines present a global consensus on the main ethical issues that need to be address when conducting HIV surveillance. These guidelines do NOT prescribe specific findings regarding the ethical conduct of HIV surveillance, only the issues to be addressed and the ethical considerations for deciding those issues.

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.

Contents

Acronyms and abbreviations

ANC	antenatal clinic
CDC	Centres for Disease Control and Prevention
CIOMS	Council for International Organizations of Medical Sciences
DHHS	(US) Department of Health and Human Services
GPA	(WHO's) Global Programme on AIDS
IDU	injecting drug user
MSM	men who have sex with men
NBAC	National Bioethics Advisory Commission
NGO	nongovernmental organization
OPRR	Office for Protection of Research Risks (USA)
PEPFAR	US President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother-to-child transmission (of HIV)
STI	sexually transmitted infection
UAT	unlinked anonymous testing
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNHCHR	United Nations High Commission for Human Rights
WHO	World Health Organization
WMA	World Medical Association

Summary of the guiding principles

A. Notification: name-based surveillance

Guidance 1. Name-based HIV case reporting (as contrasted with anonymous or coded reporting) can be justified only if data can be maintained in a confidential manner. The data should be used only for purposes related to public health (and not for discrimination or criminalization). **Public health registries must be governed by the strictest rules of data protection and confidentiality.**

Guidance 2. Data should be shared with other public health agencies only if adequate security measures are in place and the reason is justified by a legitimate public health purpose. **When there are different confidentiality measures between the agencies sharing the data, the more stringent privacy standard should be applied.**

B. Informed consent

Guidance 3. All surveillance classified as research should be reviewed by ethical review boards (or human subjects' research oversight committees) to ensure that the consent process fully informs potential participants about:

- the public health goals of the study,
- their freedom to decline to participate,
- the need to ask sensitive questions about sex and other behaviours linked to HIV transmission,
- the nature of the risks and benefits of participation,
- the availability of services to assist the individual with any negative consequence of participation,
- the extent to which HIV testing and counselling services are available, and
- the confidentiality protections in place.

Guidance 4. The principles of **informed consent** described in guideline 3 **should also be respected in surveillance activities classified as public health practice** (activities to improve the health of the patient). Because public health practice usually does not undergo ethical review, systems should be created to ensure that these principles are respected. These systems should be developed through consultation with all relevant stakeholders.

Guidance 5. While there may be circumstances when survey opt-out[1] standards are ethically justifiable – studies involving biological specimens or records, for example – this is not the case when individuals will be asked to participate in studies where there is a face-to-face encounter. In other words, if consent or interviews are administered face to face, the opt-out procedure is not ethically justifiable.

Guidance 6. All surveillance, whether categorized as research or as public health practice, should involve the community. Consulting the community is important for ethical and logistical purposes. Such consultation often improves the chances that individuals in the community will participate.[2] However, a community consultation does not take the place of individual consent.

1 Opt-out refers to informing a participant that they will be in the survey unless they explicitly say they do not wish to participate.

2 The Kenya AIDS Indicator Survey sought community consultation in every cluster sampled. In clusters where consultation lagged behind or abutted the survey start date, participation rates were lower.

C. Vulnerable populations

Guidance 7. Understanding the patterns of sexual and drug-using behaviour among adolescents justifies **studies involving adolescents**. However, they must understand the risks and benefits of participating in surveillance activities. Explaining the risks and benefits is often possible among those aged 15–18 years.[3] Children below the age of 15 years, who lack the capacity to understand the risks and benefits of participation, can only participate with parental consent. Such studies should provide, through referral,

- psychological and social support services, if needed, and
- services that could assist with changing the risk-taking behaviours.

When studies are conducted in communities where such intervention services are not available, those responsible for ethical oversight should be made aware of the situation.

Guidance 8. The **rights of individuals to choose not to participate** in surveillance must be respected. Those with less autonomy (or independence), such as prisoners, patients at clinics, or individuals who are unable to read a consent form should be provided with additional protection. Special efforts must be made to ensure that patients understand that their decisions about whether to participate in clinic-based research will not change their access to and quality of medical care. Ethical review committees should make sure no coercion is involved in the consent process. For example, they may stipulate that persons not directly involved in patient care conduct the consent process. Prisoners and other detainees, too, may be vulnerable to coercion. Ethical review committees must give special attention to the question of whether prisoners have a truly voluntary choice to participate in the surveillance activity.

Guidance 9. Surveillance involving **persons who are most at risk for HIV** is necessary in the context of the HIV epidemic. However, the surveillance activities must meet appropriate ethical review. The review should ensure that the surveillance activity does not result in new burdens on the most-at-risk population. It is especially important that:

- consent is informed and voluntary,
- confidentiality protections are enforceable, and
- inducements to participate do not constitute coercive offers.

Any limits to confidentiality must be made clear to all potential participants.

Guidance 10. Just as a community leader may not give consent for participation on behalf of their community, **a husband, father or head of household may not provide the sole consent** for a woman to participate in surveillance. In some situations, a woman may choose to consult with and obtain the approval of her husband or father. However, her individual informed consent is required before participating in surveillance activities. Participation should never be excluded because no male approval is available.

Guidance 11. Investigators and ethical review committees must protect the confidentiality of participants in surveillance activities. This can be done by making the data anonymous (removing all identifying information). Where this is not possible, records should be locked up or secured to prevent access by unauthorized persons. **Only the minimal amount of identifiable information should be collected.**

Guidance 12. In some settings, the authorities will require researchers to alert them of any behaviour that are illegal or those that place others at risk. If such a law is in place, the researchers must be sure that participants understand this law. In some settings, the researchers will have received an exemption from this law. If they do not have such an exemption, **researchers have a duty to inform participants of the limits of confidentiality.**

3 In many jurisdictions, youth can be considered emancipated from the age of 15 years and may therefore legally provide informed consent

D. Unlinked anonymous testing (UAT)

Guidance 13. Unlinked anonymous testing (UAT) occurs when persons are tested for HIV but the test and results are not linked to any identifying information. The participants are not provided with their results. UAT is often done without informed consent. It should be used for surveillance only when data from clinical settings and other studies cannot provide the information necessary for surveillance. All study proposals using UAT should be reviewed by committees capable of evaluating both the epidemiological and ethical issues involved. **Those who conduct UAT must demonstrate that clinical data are not adequate for the purpose of public health surveillance.**

Guidance 14. Where both epidemiological evidence and ethical review suggest that UAT is justified as a strategy for HIV surveillance, the **communities where it will be conducted should be notified** that blood samples drawn for clinical purposes may be anonymously tested for HIV. In the case of pregnant women attending antenatal care clinics (ANCs), all women must also be referred to prevention of mother-to-child transmission (PMTCT) programmes for HIV testing, counselling and treatment, if needed.

Guidance 15. In household surveys or in clinical or non-clinical settings, **where blood is drawn** exclusively for the purposes of unlinked anonymous surveillance, the informed consent of each **individual participant must be obtained.** Individuals must understand their freedom to decline to participate, the nature of the risks and benefits of participation, and the nature of UAT.

Guidance 16. In household surveys or in clinical or non-clinical settings that involve HIV testing, participants must be **given the opportunity to be informed of their test results.** Test results may be provided by the surveillance team or by referral to surveillance-sponsored mobile testing units. Alternatively, participants may be referred to local and accessible clinics where testing and counselling are available.

E. Data use

Guidance 17. Surveillance efforts can be **justified** only if they will help prevent the spread of HIV or will be used for directing resources to those already infected. When there is resistance to effective interventions or resources are scarce, surveillance may be used as a basis for advocacy and empowering the most vulnerable populations.

Guidance 18. The results of surveillance must always be **communicated** to stakeholders and the community. Any censoring of surveillance data must be challenged. Community advisory boards, ethics review committees and other oversight bodies charged with ethical review of public health practice should consider how the results will be used and shared.

Guidance 19. When the communication of surveillance data may injure the population it is intended to serve, every effort must be made to **minimize such risks**. Discussions with representatives of the community about how the results can best be presented may avoid some unnecessary harm.

Guidance 20. Prior to undertaking surveillance studies, investigators, in consultation with community advisory boards and ethics review committees, should make clear what, if any, direct role they intend to play in advocating for the provision of **prevention and treatment services** in the post-surveillance period.

Guidance 21. Surveillance projects should ensure that persons placing themselves at risk are referred to **appropriate services.** If no referrals are possible, the project itself should advocate for services. This should be done in consultation with community advisory boards, ethical review committees and other bodies charged with the ethical oversight of public health practice.

1. Introduction

A. Why do we need ethical guidelines for second generation surveillance?

In 2000, the World Health Organization (WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS) published the *Guidelines for second generation HIV surveillance.(1)* The guidelines are a series of modules released over the past decade, designed to address the complexity of different HIV epidemic contexts and meet the planning needs of national programmes. The earlier surveillance systems were focused on strategies for determining the prevalence of both asymptomatic and symptomatic HIV infection. While they helped to generate a response to the HIV epidemic and served to monitor the successes and failures of national responses to HIV, they were inadequate to meet the evolving challenges of the epidemic. Second generation surveillance aims to build on the strengths of earlier efforts but with more focus on the importance of providing early warning signs of the spread of HIV. To achieve this goal, second generation surveillance seeks to integrate a wide range of resources including: HIV and advanced HIV (AIDS) case reports, serological studies of the prevalence of HIV infection, analyses of trends in sexually transmitted infections (STIs), general morbidity and mortality reports and, most critically, studies of the behaviour of individuals most at risk for acquiring and transmitting HIV. To ensure that surveillance efforts would make effective contributions to the control of the spread of HIV and the provision of services to those already infected, second generation surveillance distinguishes among the efforts necessary to control the spread of HIV in countries at very different epidemic stages.

Low-level epidemics are those in which HIV infection exists at low levels in some populations whose social circumstances increase the likelihood of behaviours that carry a high risk of contracting or transmitting HIV, but in which infection is not widespread in the general population. In concentrated epidemics, relatively high levels of infections exist in selected subpopulations. The goals of surveillance are to understand the social and structural factors shaping behaviours that expose certain groups to risk, the prospect of increased infection in those groups, and the probability of the spread of HIV to the broader population. In generalized epidemics, HIV is already established in the population of sexually active adults with >1% of pregnant women infected. While heterosexual transmission is always the dominant mode of HIV spread in generalized epidemics, HIV may also be overrepresented in some groups whose position in society and behaviour places them at increased risk for acquiring and transmitting HIV. In such epidemics, the goal of surveillance is to understand both the sociostructural and behavioural dynamics that account for trends in HIV prevalence and the impact of interventions designed to reduce the level of incident infection.1

Virtually all discussions of the ethics of research on human subjects and, increasingly, of surveillance, note the obligation to protect participants from harm and the duty to ensure that those who participate in such activities 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. It is critical to remedy this state of affairs. No effort to control the HIV epidemic and direct resources to those most at need can be effective without an accurate understanding of the incidence, prevalence and dynamics of HIV, and HIV-related risk behaviours, and the cultural and structural influences on those behaviours in a given community. Surveillance is defined by WHO as the on going, 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 thus the radar of public health;*(2,3)* it is a routine activity, integral to a government's role to protect the health of its citizens. There is, therefore, an ethical obligation to undertake those studies and engage in those practices most likely to prevent disease and death. That obligation must be understood within the context of the resources available within nations and communities.

In some situations, the issues posed by HIV acquisition and transmission may touch upon matters of cultural sensitivity. The behaviours involved may be viewed as morally unacceptable or illegal. These views should not provide a justification for inhibiting crucially important surveillance efforts. They do, however, signal the importance of creating protective regimes for those who may be made vulnerable, however inadvertently, by research and surveillance activities.

National and international research guidelines, discussed below, typically share a common set of ethical principles that guide the discussions of research ethics. They were first formally articulated in the United States in the 1979 Belmont report.*(4)* Respect for persons necessitates respect for the choices of competent individuals and protection of vulnerable persons. The right of informed consent derives from this principle. Beneficence (the charge to do good) and its counterpart no maleficence (the admonition to do no harm) necessitate maximizing benefits and minimizing research harms. Justice demands equal treatment and, in the research context, refers to fairly distributing benefits and burdens.*(5,6,7,8)* These ethical principles, which were first articulated to guide the conduct of medical research, were inevitably brought to bear on epidemiological, behavioural and psychosocial investigations as well.*(9)* It may be said that the first impulse of research ethics has been autonomy-enhancing.

In the context of research ethics, and medical ethics more broadly, concern for autonomy has maintained this pre-eminent role. In the context of both public health research and surveillance-related practices, such priority may be in conflict with the population-based commitment to public well-being. Indeed, a central theme in the history of public health can be understood as involving an effort to resolve the dilemma between the claims of individual rights and the needs of the community. In the last part of the twentieth century, especially in the context of the AIDS epidemic, it became clear that respecting such rights could, in many ways, enhance public health. In epidemiological research that serves the goals of public health, consent remains the prime consideration. Nonetheless, there are carefully circumscribed instances, involving the examination of existing records and biological specimens, where consent may be waived after approval by an ethics review board. In the context of public health surveillance, however, individuals do not necessarily have a right to refuse to participate in efforts that emerge from transparent, ethically sound, processes.

Finally, to adequately discuss the principles that must govern second generation surveillance, we must also consider a recent concept derived from human rights, which is intimately related to the concept of respect for persons: transparency. The principle of transparency is linked in important ways to that of autonomy but is not its equivalent. In the context of public health, transparency requires that individuals understand that they may be the subject of surveillance. Transparency also requires an open process of decision-making that permits consultation and facilitates the exchange of information.

It is important to bear in mind that the ethical principles governing second generation surveillance are not hierarchically ordered. Invariably, tension exists among them. Thus, for example, just as beneficence and justice may require the collection of data to limit the threat of HIV infection, the public health mandate to conduct surveillance may be in conflict with those 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. Nonetheless, it is those very populations that, 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 on how such conflicts can be fairly resolved. The promise of second generation surveillance to contribute to the reduction of HIV-related morbidity and mortality requires us to confront a series of ethical challenges.

Among them are the following:

- What role should individual consent and community approval play in surveillance activities?
- What right do individuals have to know that they have been the subject of public health surveillance?
- What circumstances justify surveillance measures that will intrude upon privacy?
- How ought 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 assured and, when the confidentiality of such data cannot be guaranteed, what ought to be the impact on surveillance activities?
- How can the ethical challenges posed by the duties to disseminate data be met?
- What lessons and insights can be drawn from the history of the ethical review of research for the potential role of ethical oversight of the practice of public health surveillance?

Because the context within which surveillance occurs – the stage of the epidemic, the existing regime for the protection of research subjects, the state of development of the capacity for public health surveillance – will ultimately affect the course to be followed, these guidelines can only provide direction at the most general level. At times, they will seek to make clear the issues that need to be addressed in order to maximize

the prospect that the rights of individuals and communities and the control of the epidemic are given appropriate attention.

These guidelines represent an update of those first posted by WHO in 2004,*(10)* and reflect the evolving international discussion of the ethical challenges posed by HIV surveillance. They are addressed to public health policy-makers, those charged with the responsibility of conducting surveillance activities, researchers conducting behavioural studies, nongovernmental organizations (NGOs) that will be involved in consultations regarding surveillance, community advisory boards, ethical review committees, and those entities that may be created to provide ethical oversight for surveillance efforts that are classified as practice rather than as research.

B. Overview of national and international ethical guidelines on surveillance

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 twenty years or so after Nuremberg marked the articulation of ethical principles governing research, with less effort given to developing the means to enforce those principles. During the second phase of evolution, in the wake of scandals such as the Tuskegee syphilis study in the United States, a new emphasis was placed on creating oversight mechanisms. Since the 1990s, concerns about research in the developing world represents a third phase of evolution, particularly concerns about the power relationships between researcher–sponsors and study populations in host-developing nations in light of controversies such as the maternal–fetal HIV transmission prevention trials that occurred in the context of the AIDS epidemic.

The Nuremberg Code was set forth by American judges prosecuting Germany for war crimes as a standard against which to judge Nazi doctors.*(11)* Reacting to medical experiments in which concentration camp prisoners were subjected to conditions often intended to result in their deaths, the first principle of that code was the centrality of the voluntary participation of subjects with their informed consent. But the principles of voluntary participation and informed consent, which stood at the heart of the code, received little media or medical attention and did not necessarily alter research in countries such as the USA and Great Britain following the war. The Nazi atrocities seemed to be precisely that – acts of deranged and exceptional politics rather than the ordinary practice of science; accordingly, self-monitoring continued to prevail in the research enterprise at large.*(12)*

Marking the beginning of a new era, the Declaration of Helsinki, adopted in 1964 by the World Medical Association (WMA), built on Nuremberg, adding a distinction between therapeutic and non-therapeutic research, a call for institutional review mechanisms, and a provision for family members to consent for the subject when the subject could not. Thirty-six years later, when the WMA issued its revised Declaration of Helsinki in 2000, it provided a formulation that reflected the deepening appreciation of the many elements that went into a fully informed consent: "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."*(13)* As it had in its earlier document, the Declaration of Helsinki, 2000 made clear the critical importance of ethical review by a committee independent of the researcher.

Empirical investigations have repeatedly demonstrated that, despite the existence of apparent consent as reflected on signed forms, many subjects involved in studies, especially those which are sponsored by wealthy nations and conducted in less-developed host nations, 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. In the United States, the National Bioethics Advisory Commission (NBAC) devoted considerable attention to how the consent process might be enhanced. Among the critical aspects of its analysis was the necessity of communicating in a culturally appropriate manner and the adoption of measures to determine whether potential participants had fully understood what had been disclosed to them. In achieving a more

fully informed consent process, NBAC underscored the importance of involving community representatives, a matter given emphasis by the Nuffield Council on Bioethics as well,*(14)* who might effectively guide investigators in shaping the informed consent in a way that reflected both the spirit and letter of the universally recognized ethical obligations.

These principles received further emphasis in 2002 when the Council for International Organizations of Medical Sciences (CIOMS) promulgated a revision of its *International ethical guidelines for biomedical research involving human subjects.* Against the backdrop of increased concern about exploitation of research populations in less-developed countries by investigators from sponsoring wealthy nations, the CIOMS guidelines gave sustained attention to the steps necessary to prevent exploitation and to ensure culturally sensitive informed consent. Furthermore, the guidelines underscored the obligation of investigators to protect the confidentiality of the information they obtained from research participants: "The investigation must establish secure safeguards for 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."*(15)* Specifically referring to HIV, the guidelines highlighted the special importance of efforts to protect confidentiality, given the social discrimination or harm to which participants might be subject. In commenting on this guideline, CIOMS noted that among the strategies investigators might adopt were techniques that made it difficult to link individuals to the information they had provided by, for example, removing any linkage that enabled identification of specific individuals, thus rendering the data anonymous.

Despite the emphasis placed on informed voluntary consent by competent adults or by parents or guardians who may assent for their children in all international guidelines on research, 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 ethical issues posed by the examination of existing records will be discussed in the next section. The ethics of studies involving biological specimens will be discussed in the section on unlinked seroprevalence studies below.

C. Medical ethics and the ethics of epidemiological research: a literature review

The ethical principles for the protection of human subjects articulated in Nuremberg and Helsinki, as we have noted, were based on a common set of principles, stressing the absolute need to prioritize the rights of the individual over that of society.*(16)* Thus, there could be no exceptions to voluntary participation and informed consent.*(16)* 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. But while affirming the need to prevent research abuse, the guidelines "were not addressed to the entire field of research involving human subjects as that field is currently understood".*(17)*

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 of large numbers of individuals, many of whom would be difficult or impossible to locate, would render epidemiological research virtually impossible.*(7,18,19,20,21,22,23)* "The clash between the privacy rights of persons and the need for access to and disclosure of personal health-related information", noted one observer, "is the most frequent ethical dilemma to confront epidemiologists."*(5)* In 1981 in the United States, the Department of Health and Human Services (DHHS) regulations for the protection of human subjects explicitly exempted epidemiological research involving already existing data from informed consent requirements provided 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.

The conflict between the claims of individual informed consent and the demands imposed by records-based epidemiological research was also confronted in other economically advanced democratic nations. How these conflicts 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 upon 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 that all studies must undergo ethical review.*(24)* 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 in instances where 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, though at the end of the 1990s, concerns remained, especially in Great Britain.

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, it acknowledged that prior efforts to provide ethical guidance for biomedical research were focused on "patients and individual subjects" and were not sufficient for studies involving "groups" of people. Thus, while emphasizing the importance of the principles of research ethics first propounded in the US Belmont Report, it recognized that their application in the epidemiological context would require flexibility.

Most important, the CIOMS epidemiological guidelines, like those from nations that had addressed these issues earlier, noted that individual informed consent was not always practical in epidemiological studies. *(26)* While asserting that individuals and their representatives should "normally" be told that their medical records or stored tissue samples might be used for future epidemiological studies, CIOMS acknowledged that such notification might not have always been undertaken. In the end, it was the duty of researchers who sought to undertake such records-based studies "to explain to an ethical review committee how the study would be ethical in [the absence of consent]: it may be impractical to locate subjects whose records are to be examined…." *(27)*

In lieu of individual consent, CIOMS suggested that the agreement of a representative of the community or group in which the proposed study would be conducted could be important. It recognized, however, that the identification and selection of such representatives might pose difficulties, especially if the "group" under study was, in fact, created by the investigators.*(28)*

In 2009, after an extended process of consultation, CIOMS proposed revised guidelines for epidemiological research. In a fundamental way, they confirmed the analysis issued two decades earlier about the conditions under which epidemiological studies could be conducted in the absence of individual informed consent. Furthermore, they re-emphasized the critically important role of community consultation in such instances.*(29)*

In addition to matters of consent, the protection of confidentiality, the role of review by ethics committees, the nature of ethical review in studies sponsored by typically wealthy nations but conducted in a typically less-developed host nation, and the importance of representation of communities to be studied on ethical review panels, the CIOMS guidelines give great attention to how research findings should be communicated. We will devote more attention to this issue below, but here it should be underscored that the guidelines reflect considerable concern about how the results of epidemiological studies could injure the "interests of communities, societies, or racially or ethnically defined groups". Such concerns led CIOMS to urge that ethical review committees weigh the potential harms and benefits that could result from publication of research findings. They suggested that in "certain exceptional circumstances" a decision against publication could be made.28

These revised guidelines are predicated on the assumption that all activities referred to in terms of research – whether publicly funded or not, whether initiated within a country or through international cooperation – will be subject to the review of duly constituted ethics committees. Studies that originate in sponsoring nations but are carried out in host nations must be reviewed by ethics committees in both settings. Within host nations, the relationship will vary between ethics review committees at the national level, which may set national standards for the conduct of research, and review committees at the local level, which will review protocols involving local residents. No single principle can account for the way in which countries may choose to allocate responsibilities in this regard. Irrespective of whether those responsibilities are primarily centralized or devolved, review committees must reflect the broad constituencies affected by the research. Most importantly, the participation in ethical review of those who represent and can speak on behalf of the research participants is critically important.

The capacity for ethical review at the local level may be impeded by lack of experience and training. Within nations that play a central role in sponsoring research in less-developed countries as well as within those international organizations that have addressed the question of research, considerable attention has been given to the necessity for enhancing the capacity for ethical review in host nations. Both the Declaration of Helsinki and the 2002 CIOMS *International ethical guidelines for biomedical research involving human subjects* emphasize the obligation of sponsors to enhance such capacities.*(30)*

D. Research, practice and surveillance

With so much attention devoted to the standards that ought to govern medical research and to the mechanisms that could best ensure ethical oversight, it was deemed crucial to distinguish that domain of clinical practice which was not subject to the same regulatory norms.

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".*(31,32)*[1] It was, however, a 1979 report of the United States National Commission for the Protection of Research Subjects of Biomedical and Behaviour Research known as the *Belmont report* that sought to lay bare the ethical implications of the difficult-to-distinguish boundary separating research from practice.*(33)*[2] The Belmont report stated, "The distinction between research and practice is blurred partly because both often occur together."*(34)* A central figure in the development of contemporary medical ethics who served on the committee described this task as "the most difficult and complex problem facing the Commission".*(35)* The committee 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, "designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (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."*(34)*

Subsequent to resolving the controversies over epidemiological research, in the early 1990s, the United States DHHS's Office for Protection of Research Risks (OPRR) began to advance the notion that *all* surveillance activities undertaken by public health departments qualified as research. To the United States Centres for Disease Control and Prevention (CDC), this was more than a bureaucratic consideration: if public health surveillance activities were designated research, the CDC feared that "people with TB could prevent their names from being reported to the health department or refuse to provide information about their contacts".*(36)* The more profound implications, however, were for behavioural surveillance.*(37)* Here the complexity of distinguishing between research and practice even within a single nation can be stark. At one juncture, the CDC determined that behavioural surveillance constituted research requiring oversight by an institutional review board, while at the same time many state health departments maintained that such surveys constituted part of the practice of public health and were therefore exempt from review.

In commenting on this issue in 2009, the CIOMS *Guidelines on epidemiological studies* stated that while the effort to distinguish research from practice, in terms of where the goal was to produce "generalizable knowledge" worked well in medical and behavioural studies, it worked less well in distinguishing between research and practice in epidemiology: "Many studies using the tools of epidemiology, which are performed on a regular basis by public health agencies, are currently viewed as 'practice' even though the information produced may contribute to generalizable knowledge." In the end, CIOMS asserted that careful judgement was necessary in handling such cases. It is in this ambiguous realm of surveillance-related activities that ethical guidelines are necessary. Notably, the CIOMS guidelines provide only passing discussion of the ethical norms that ought to govern surveillance activities.*(38,39)*

1 This distinction – the subject of substantial criticism – would persist virtually unchanged until the 2000 revision of the code, when it was substantially modified. In 2000, the Declaration of Helsinki provided principles governing all of medical research with special principles for research combined with care. It is also in this year that references to "physicians" are completely replaced by references to "investigators" or "researchers."

2 The National Commission was created to make recommendations to the US Department of Health and Human Services on the regulation of human subjects' research. Some, as Levine notes, also made recommendations to the President and Congress.

There may be occasions when NGOs undertake activities that fall within the domain of public health surveillance. When this is the case, important questions are raised about the extent to which they ought to be given access to otherwise privileged information. In any event, such efforts must be regarded as research and governed accordingly; the State's surveillance efforts, however, must be regarded as practice, and subject to different guidance. The ultimate responsibility for ensuring that appropriate ethical oversight occurs in both the domains of research and practice must be borne by government health officials.*(40)* This does not imply, however, that any surveillance activity undertaken by governments is per se ethical.

The significance of the effort to distinguish between research and practice has both practical and ethical implications. To the extent that an activity is designated as research, both international and national guidelines almost universally now require review by ethics review committees and that those reviews are guided by a set of ethical principles that emerged in the research context. It is extremely rare for mechanisms to exist to review the ethics of activities termed public health practice, of which surveillance is clearly a part.

In these revised guidelines, we discuss a set of principles that ought to govern second generation surveillance, whether or not a distinction is made that they constitute research or practice. We are mindful of the fact that if such surveillance is considered practice, it will be necessary to create mechanisms to ensure that these ethical guidelines are brought to bear.

E. Public health and mandatory notification

In many nations, there is a long history of governmentally mandated and conducted public health surveillance that has been the primary source of data relevant to the understanding of patterns of morbidity and mortality, or the evaluation of efforts designed to limit the impact of disease outbreaks and epidemics. Where such surveillance exists as a matter of law or official regulation, it typically imposes on specified individuals (generally health-care workers) or institutions the duty to report information about identifiable persons to public health registries. The extent of the information to be reported differs, depending on whether it is linked to individuals by the use of names, whether such information is regarded as confidential and, if confidential, how as a matter of law or practice it is protected from disclosure. But where notification is required, those who report and those about whom they must report have no choice in the matter. Whatever principles of consent may otherwise prevail in the management of public health-related research, they do not apply under such circumstances. Because those who have been required to report have at times believed that such notification entailed an unacceptable intrusion upon the privileged nature of clinical communications, the history of public health surveillance has been punctuated by instances of resistance that have taken a number of forms, most notably, simple failures to comply with legal requirements.*(41)*

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

Systematic disease notification dates back to the nineteenth century and, by the twentieth century, had become a staple feature of nation states. While controversy often surrounded the establishment of notification requirements, when they were instituted they almost universally required the names of those who had been diagnosed. In a number of nations, STIs were an exception, permitting the use of various types of coded mechanisms. However, unlike birth and death registration, 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 medical privacy have made morbidity notification problematic. One

method developed to short-circuit clinician resistance 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 to solicit information from such providers in order to identify cases of disease that would otherwise go unreported.*(42)* Both instances reflect the priority of public health over the claims of privacy.

Finally, it should be noted that not all efforts to monitor morbidity and mortality entail formal notification of individual cases. Even in nations where well-developed systems exist, in some situations involving a rapidly evolving epidemic, a simpler form of enumeration is relied upon. For example, annual influenza outbreaks have historically been tracked by the number of cases rather than by name.

Remarkably, despite the increasing attention paid to the ethics of research in the post-World War II period and to the ethics of epidemiological research more recently, little attention was given to the ethics of public health surveillance until the AIDS epidemic. This is all the more striking since much of public health surveillance involves on going efforts that may resemble activities that are designated as epidemiological research. In the 1991 CIOMS *International guidelines for ethical review of epidemiological studies*, informed by the threat of emergency, a relatively narrow definition of public health surveillance was employed to justify exceptions to the requirement of ethical review. "An exception is justified", the guidelines stated, "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."*(43)* Such a definition covered neither on going case-reporting requirements in non-emergency situations nor the follow up by public health interviewers, which is typically provoked by disease notification, especially when efforts to understand epidemiological dynamics were at stake.

The 2009 revision of the CIOMS guidelines addresses the issue more directly. They provide support for case-based public health surveillance on an on going basis. "Several considerations support the common practice of requiring that all practitioners submit relevant data [to public health registries]: the importance of having comprehensive information…about an entire population, the scientific need to include all cases in order to avoid undetectable selection bias and the general ethical principle that burdens and benefits should be distributed equitably across the population."*(29)*

This position echoed the analysis provided by the Nuffield Council on Bioethics in Great Britain in 2007. Going beyond the ethical acceptability of the collection of anonymized data without individual consent for public health purposes, the Council stated, "The avoidance of significant harm to others…may outweigh the consideration of personal privacy or confidentiality and on that basis it can be ethically justified to collect non-anonymized data about individuals for purposes of implementing control measures." On the matter of consent, the Council warned about the potential for adverse consequences for public health if individuals were given the opportunity to opt out or decline to have data about their conditions reported to public health registries. "We are aware of several examples [where] consent requirements have or could have had serious negative consequences…." Despite this endorsement of mandatory nominal case reporting, the Council underscored the inevitability of making ethical judgements about when such breaches of consent should occur. In particular circumstances, as is clear from the context of HIV, profound disagreements about how to draw the lines would surface internationally. *(44)*

2. Data collection for HIV surveillance

A. Public health surveillance: the role of mandatory notification

Surveillance was the foundation on which the new public health was built, not only in the United States but also in Europe. The move toward the reporting of disease by name to health officials in the United States was paralleled in Europe, driven in part by the cholera epidemics of the nineteenth century. As disease notification began to emerge as a tool for epidemic control, it was bolstered by the more well-established reporting of vital statistics, the registration of births, marriages and deaths. While vital statistics were treated as reform tools capable of exposing the damage that urbanization wrought on health,*(45,46,47)* disease notification was a tool for direct intervention with individuals.*(48)*[1]

Graham Mooney, in recounting the history of surveillance in Great Britain, argues that "notification was the crucial policy development in the move toward the individualization of public health strategies in the later nineteenth century". Intervention "would not have been possible without it".*(49)* Peter Baldwin's analysis of the State and contagious disease in England and the continent underscores the linkage of disease notification and what he terms the "neoquarantinist system"—inspection, isolation, disinfection and surveillance. In 1889, a parliamentary act gave localities the authority to require notification. By the early 1890s, such provisions covered more than 80% of the English population. In 1899, the Notification of Diseases Act was passed requiring reporting throughout the country. Thus, not only did notification make intervention possible, such intervention provided the justification for notification.*(50)*

In the current era, despite their limitations, mortality reports – whether or not they involve official death certificates – have served as useful measures 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.

While vital statistics are nearly universal in developed countries, 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 understanding of the rights of privacy after death remain unresolved matters.

Morbidity reports may also play a role in second generation HIV surveillance. In the first decade of the AIDS epidemic, notification of AIDS cases was a central feature of public health surveillance in developed nations. However, beginning in the mid-1990s, the introduction of antiretroviral therapy made AIDS case reports an increasingly unreliable source for monitoring the current state of the epidemic. A report of surveillance in WHO's European Region noted, "With the introduction of the widespread use of highly active antiretroviral treatment the number of AIDS diagnoses has become less reflective of trends in the HIV epidemic." Indeed, a 2005 survey of the European Region underscored that the notification of HIV cases was progressively replacing AIDS reporting as the approach to monitoring the epidemic.*(51)* The picture is even more complex in less-developed nations, where the capacity to conduct systematic case-based surveillance for either AIDS or HIV infection is limited. It is, however, possible that, through active surveillance, public health officials can identify AIDS cases or HIV-related opportunistic infections that may play a role in an overall surveillance effort.

Where the capacity for HIV surveillance is in place, there remains the question of whether such notification ought to involve the use of names. The debate over the use of names or coded identifiers for cases of HIV

1 Prevention and control of disease was described as the "primary raison d'etre of health organizations," necessitating the conference of "vast powers" on boards of health.

mirrors, in some respects, an early twentieth century debate in Western Europe and the United States about whether STIs should be reported by name. As we noted above, for much of the twentieth century, in some countries, the United States, for example, STIs were reported through the use of serial numbers, reflecting the concerns of physicians who wanted to protect the confidentiality of their private patients. The practice surrounding STI notification stood in sharp contrast to the prevailing practice of using names in disease notification systems. It is against that common practice that the discussion around HIV reporting assumes an exceptional quality.

To be sure, not all acts of surveillance elicit public debate. For example, the "shoe leather epidemiology" involved in investigating outbreaks of acute communicable diseases or common source outbreaks such as meningitis or salmonellosis inevitably requires the collection of names and follow up of cases.*(52,53)* This vital part of the day-to-day practice of public health surveillance has virtually never provoked concerns. *(54,55,56,57)* Plague surveillance in India, birth defects and immunization registration in the US, the Census in Germany: all have provided instances in which the value of privacy or the legitimacy of the uses to which surveillance data may be put have sometimes fostered pitched battles. Just as often, people have demanded to be counted, as in the instance of occupational disease and cancer surveillance.*(41)*

Yet despite public debates, the practice of surveillance received no ethical attention until the AIDS epidemic. The unique social context of the epidemic set the stage for a searching discussion of the ethical and human rights implications of nominal disease reporting. A set of broad principles to guide consideration of this issue were provided by the Office of the United Nations High Commission for Human Rights (UNHCHR) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) in *HIV and human rights: international guidelines.(58)* The guidelines reflect the 1984 Siracusa principles, adopted by a group of international law experts in order to clarify the International Covenant on Civil and Political Rights.*(59)* They acknowledged that States "may impose restrictions on some rights, in narrowly defined circumstances, if such restrictions are necessary to achieve overriding goods, such as public health [or to protect] the rights of others ... [and] the general welfare...." *(60)* But for such restrictions to be justified they must be "proportional to [the] interest and constitu[te] 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.*(60)* Unfortunately, the reference to the issues raised by disease notification in the guidelines were extremely limited and stated merely, "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." *(61)* The reference was thus permissive with regard to reporting, stipulating the necessity of only the most limited and basic of protective conditions. The question of whether the use of names was justifiable or how trade-offs between epidemiological requirements and privacy concerns should be addressed was not confronted.

More helpful was the observation of Gostin and colleagues in laying out the general principles that should guide the acquisition of data by public health authorities: "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 less invasive of individual privacy." *(62)*

Implicit in the international guidelines published by the UNHCHR and UNAIDS and, more directly in Gostin's discussion, was the necessity of answering a series of complex empirical questions as a precondition for ethical analyses: Does effective surveillance require the reporting of AIDS cases or instances of HIV infections? Can the goals of surveillance be achieved only by collection of names? What will be the consequences of the willingness of individuals to be tested for HIV and to undergo counselling to enter care if named, as contrasted with adopting anonymous testing? Do other public health functions such as voluntary partner notification, the assurance of adequate counselling, provision of care require the use of names? What level of inaccuracy will be produced by the use of coded versus named reports and how would that level of inaccuracy affects the purposes for which reporting was initiated? What mechanism exists for protecting the confidentiality of reported names, if they are used, and what is known about the effectiveness of such mechanisms? Most critically, what principles and practices will govern the sharing of notifiable data? What assurances exist that case reports of HIV or AIDS, especially if identifiable, will be used solely for public health purposes?*(63)* To these critical questions there are no definitive answers that are

universally applicable. The answers appropriate in one nation at a given moment may not be appropriate for the same nation at a different juncture or in other nations. Much depends on the state of the epidemic, the infrastructural capacity of the public health and medical systems, the availability of resources to manage and secure notification systems, and the general political culture.

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 nations to avoid name reporting for HIV. Because of concerns about privacy and confidentiality, most European countries have not conducted name-based notification. In 2006, 28 nations in WHO's European Region used coded identifiers for HIV case reports. In 11 countries, so great were the concerns about potential breaches of privacy that the codes contained no name-related elements. Only 12 nations used full names for HIV notification, 10 of which were in Eastern Europe or the former Soviet Union. The exceptions were Iceland and Israel.*(51,64,65)* In contrast, in the United States, opposition to name-based reporting from AIDS-related organizations has all but vanished.

While records of HIV infection often do not include names, other case records do, for example, STI records. STIs are now commonly 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.

When concerns about the potential misuse of surveillance data were at their peak in the United States, some advocates challenged the prerogative of public health officials to share data within the same agency or with public health agencies in other disricts even where there were strong interconnections, e.g. the linking of HIV, TB and STI data. Not only community-based advocates but also some programme officials objected to the sharing of highly sensitive data. For example, some HIV surveillance programmes maintained that data could be used only for epidemiological monitoring purposes. They asserted that data could never be shared outside HIV surveillance programmes even *within* the same public health agency and that they should never be used for public health interventions such as partner notification or case management. Indeed, some agencies erected protective walls around HIV registries and prohibited the linkage of HIV data with TB data.

These controversies, however they were resolved over time, reflected the profound concerns over whether shared data would be given the strictest privacy protections. For example, HIV data are often afforded higher levels of protection than other data. If those data are cross-matched with TB or STI data, would they receive the same level of privacy protection? Privacy afforded to one database must extend to those databases to which it will be linked.

Guidance 1. Name-based HIV case reporting (as contrasted with anonymous or coded reporting) can be justified only if data can be maintained in a confidential manner. The data should be used only for purposes related to public health (and not for discrimination or criminalization). Public health registries must be governed by the strictest rules of data protection and confidentiality.

Guidance 2. Data should be shared with other public health agencies only if adequate security measures are in place and the reason is justified by a legitimate public health purpose. When there are different confidentiality measures between the agencies sharing the data, the more stringent privacy standard should be applied.

B. Integrated biological and behavioural surveillance

Individuals, local context and the consent process

A central feature of second generation surveillance is the incorporation of behavioural studies designed to provide a better understanding of dynamics of the epidemic in low-level, concentrated and generalized states.*(66)* In each instance, the goal is to understand who is at risk for infection; what social, cultural and structural factors explain the vulnerability and the prospect of further transmission; what interventions have been effective or ineffective in stemming the spread of HIV.

Behavioural surveillance studies typically focus on groups at differing levels of risk: general population adults, youth, female sex workers, men who have sex with men (MSM) and injecting drug users (IDUs). The US-based Family Health International, which has been an important partner in efforts to standardize data indicators for HIV-related risk behaviour, has underscored that the standard information collected is of the most intimate, sensitive nature. For example, surveys often include respondents' knowledge of HIV transmission and prevention methods, exposure to interventions, voluntary testing behaviour, as well as information about the number of sex partners, and specific sexual practices, including but not limited to condom use, age at first sex, history of unprotected sex, commercial sex and sex with high-risk partners. In the case of female sex workers, behavioural surveillance seeks additional information on condom use and drug injection. Information on the extent of anal sex with multiple partners as well as risky sex with both men and women is additionally sought from MSM. In the case of IDUs, behavioural surveillance seeks data regarding equipment sharing, access to sterile needles and selling sex.*(67)* Finally, population-based household surveys, which do not select those thought to be at increased risk but which, on the contrary, attempt to study individuals most like the broader community, have emerged as a critical element in the expanded approach to HIV surveillance.*(68)*

How individuals or communities are selected for such behavioural studies will differ. Some may come to the attention of investigators because of retrospective case reviews in clinics, others because they have been reported through disease notification systems. It is in this instance that the complex relationship between surveillance as a public health practice and epidemiological research that serves the ends of public health is underscored. Convenience samples may also play a role. The principle of justice requires that those selected – especially if they are already socially vulnerable – do not bear the undue burden that may be associated with participation in surveillance. Here, good ethics is dependent upon good epidemiology. Selection of subjects for research that cannot be epidemiologically justified is unethical. However such individuals are recruited, all such studies require fully informed consent to ensure that participants truly appreciate the right not to participate. In this regard, such investigations, whether formally designated research or public health practices, are clearly different from case-based reporting and other forms of surveillance where consent may not be necessary because they do not require direct contact with investigators and subjects. Since consent is integral to such studies, it is necessary that potential participants be informed not only of the possible public health benefits that may result from the inquiry, but also about the nature of the psychological stress to which interviews may subject them, the extent to which participation in such studies may expose them to the risk of stigma, the protections that will be in place to secure the confidentiality of the data they provide, and the limits of those very protections.

The standard of informed consent requires that individuals affirmatively agree to participate. They must be assured that their decisions will not compromise access to care or services to which the individual would otherwise be entitled. The "opt-in" standard is especially important if recruitment occurs in clinical contexts where the pressure to participate may include unspoken expectations on the part of those responsible for the patient's care. 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".*(69)* Therefore, obtaining informed consent also requires an understanding of the local language, local concepts of disease causality, and even local and national history. Further, it requires giving thought to how to document that volunteers were truly informed.
A second factor that may vitiate 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, it will be assumed that they have agreed to participate. Less protective opt-out standards do not ensure that individuals are provided with information regarding their right of refusal. Whether or not they provide patients with full information or create subtle barriers to opting out, such provisions, especially in clinical contexts, typically yield higher rates of participation, in large measure because of the difficulty of saying no. Because of the potential for high rates of refusal, opt-out is typically regarded as a threat that compromises the validity of surveillance data. Therefore, it is important to weigh carefully the ethical justifications for allowing individuals to opt-out of surveillance efforts against the public health need for 100% ascertainment of the data.

Guidance 3. All surveillance classified as research should be reviewed by ethical review boards (or human subjects' research oversight committees) to ensure that the consent process fully informs potential participants about:

- the public health goals of the study,
- their freedom to decline to participate,
- the need to ask sensitive questions about sex and other behaviours linked to HIV transmission,
- the nature of the risks and benefits of participation,
- the availability of services to assist the individual with any negative consequence of participation,
- the extent to which HIV testing and counselling services are available, and
- the confidentiality protections in place.

Guidance 4. The principles of informed consent described in guideline 3 should also be respected in surveillance activities classified as public health practice (activities to improve the health of the patient). Because public health practice usually does not undergo ethical review, systems should be created to ensure that these principles are respected. This system should be developed through consultation with all relevant stakeholders.

Guidance 5. While there may be circumstances when survey opt-out[2] standards are ethically justifiable – studies involving biological specimens or records, for example – this is not the case when individuals will be asked to participate in studies where there is a face-to-face encounter. In other words, if consent or interviews are administered face to face, the opt-out procedure is not ethically justifiable.

Role of community consultation in the consent process

As noted, researchers are obliged to protect the rights of *individual* subjects through an informed consent process. Both for surveillance involving contact with individuals as well as the investigation of already existing records, as discussed above, an additional step will prove vital: consultation with those who may represent the community at large. In its report *The ethics of research related to health care in developing countries*, the Nuffield Council on Bioethics noted that in some nations such community consultation is required as a matter of law. In addressing this issue, the US NBAC 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 non-coercive. 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." While 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.

One mechanism for ensuring that such consultation occurs is the creation of specially constituted community advisory boards. How such boards are selected and how representative they are of those most at risk or most vulnerable will determine their ultimate effectiveness and contribution to the ethical conduct of surveillance. There are no simple formulas that can ensure that such consultation will permit true representativeness. In 1991, CIOMS noted that "for communities in which collective decision-making are customary, communal leaders can express the collective will".*(72)* In 2009, it made clear, however, that involving only those with formal or informal authority is insufficient. Underscoring the importance of ethical oversight in this process, the 2009 guidelines stipulate that the plans for community review be laid out in the research protocol so that they might be subject to appropriate ethical oversight.*(73)*

Guidance 6. All surveillance, whether categorized as research or as public health practice, should involve the community. Consulting the community is important for ethical and logistical purposes. Such consultation often improves the chances that individuals in the community will participate.[3] However, a community consultation does not take the place of individual consent.

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2 Opt-out refers to informing a participant that they will be in the survey unless they explicitly say they do not wish to participate.

3 The Kenya AIDS Indicator Survey sought community consultation in every cluster sampled. In clusters where consultation lagged behind or abutted the survey start date, participation rates were lower.

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 not participate in investigations if that is their choice, 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 nations, but where that threshold has not been passed, parents are routinely required to give consent for the participation of their children. 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 assent is also often required.

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

These problems were recognized by CIOMS in the 2002 *International ethical guidelines for biomedical research involving human subjects*. Given the central importance of studies involving sex and drugs, CIOMS provided a "carve out" from the principle of parental involvement with the permission of an ethics review committee: "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." *(74)*

Reacting to what they viewed as unduly restrictive regulations regarding the participation of adolescents in non-therapeutic research, Singh et al. in South Africa argued, "The need to protect adolescents from harm in research needs to be carefully balanced with the need to undertake research in this population…. To this end, rigid legislation and/or ethical guidelines that pertain to adolescent participation in research and their uncritical application are counterproductive." *(75)*

Among the issues that community advisory boards and ethical review committees will need to consider when adolescents are involved are the extent to which participation in studies involving sexuality and drug use may provoke psychological distress and a sense of shame and increased vulnerability. Under those circumstances, the availability of social support mechanisms will be a crucial element in determining whether such investigations should go forward.

Guidance 7. Understanding the patterns of sexual and drug-using behaviour among adolescents justifies studies involving adolescents. However, they must understand the risks and benefits of participating in surveillance activities. Explaining the risks and benefits is often possible among those aged 15–18 years.[4] Children below the age of 15 years, who lack the capacity to understand the risks and benefits of participation, can only participate with parental consent. Such studies should provide, through referral,

- psychological and social support services, if needed, and
- services that could assist with changing the risk-taking behaviours.

When studies occur in communities where such intervention services are not available, those responsible for ethical oversight should be made aware of the situation.

Impact of social context on the capacity for consent: prisons and clinical settings

Settings in which individuals receive medical care, such as prenatal clinics, STI clinics, TB treatment centres and hospitals, provide a natural context for second generation surveillance. Inevitably, patients 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 to not participate in second generation surveillance studies or if they choose to withdraw from studies after agreeing to join. As one research team noted, "in developing countries, where many participants cannot read or write, are unfamiliar with the concept of a consent form", individuals "may be likely to sign any paper that a person wearing a white coat

4 In many jurisdictions, youth can be considered emancipated from the age of 15 years and may therefore legally provide informed consent.

places in front of them".*(69)* Even when they do not feel that their treatment is threatened, they may believe they have a duty to their caregivers to agree to participate.*(76)* Such instances underscore the importance of community consultations, which may enhance the prospect of ensuring voluntary consent.

Prisoners are also 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, the relatively small benefits that may accrue as a result of participation may assume the proportions of undue inducements.

It was because of 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 that, in some countries, research involving prisoners was prohibited. In the context of the AIDS epidemic, those restrictions have become subject to reconsideration. Prisons may provide a unique environment for second generation surveillance because those especially vulnerable to HIV infection may be drawn from the populations most at risk for incarceration.

Guidance 8. The rights of individuals to choose not to participate in surveillance must be respected. Those with less autonomy (or independence), such as prisoners, patients at clinics or individuals who are unable to read a consent form should be provided with additional protection. Special efforts must be made to ensure that patients understand that their decisions about whether to participate in clinic-based research will not change their access to and quality of medical care. Ethical review committees should make sure that no coercion is involved in the consent process. For example, they may stipulate that persons not directly involved in patient care conduct the consent process. Prisoners and other detainees, too, may be vulnerable to coercion. Ethical review committees must give special attention to the question of whether prisoners have a truly voluntary choice to participate in the surveillance activity.

Unique issues of consent with 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 participants in second generation surveillance may be hard to refuse. In relatively wealthy countries, this is an issue that affects the impoverished and marginalized minorities. In nations where poverty is widespread, offers by external investigators with access to resources may produce, however inadvertently, pressures to participate in surveillance, which undermine the principle of voluntary consent. The 2002 CIOMS *International ethical guidelines for biomedical research involving human subjects* thus recommended 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".*(77)* This position was reiterated in the 2009 CIOMS Guidelines on epidemiological research.*(78)* Given the complexity of the socioeconomic and cultural issues involved, the guidelines go on to underscore that all payments for participation in research be the subject of review by local ethics committees. However, ethics committees do not necessarily represent a failsafe mechanism. One set of commentators notes that even a local ethics committee, "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".*(69)*

Because of the prospect of exploitation, long-established ethical standards governing the conduct of research deemed it unacceptable to use especially vulnerable populations in investigations when the question under study could be answered through the involvement of those who are not marginalized. In the context of second generation surveillance, on the other hand, an understanding of the dynamics of the HIV epidemic on the effectiveness of behavioural interventions and the necessity for enhanced funding of prevention services may necessitate involving populations which, 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 will make decisions about whether or not to participate. This is especially the case where the subject of investigation may involve illegal behaviours. In commenting on these issues, CIOMS noted, "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."*(79)*

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

There may be circumstances where, at least initially, community resistance may thwart second generation surveillance involving drug use, commercial sex work, or hidden sexual behaviours and violence. Such opposition could render surveillance that would serve the interests of the most vulnerable difficult to undertake. No simple solution to such problems exists, especially given a commitment to the process of community consultation. Efforts may be required to demonstrate how, in the long run, the community is best served by surveillance that makes possible the reduction of HIV risk behaviours among vulnerable and socially marginalized populations.

Guidance 9. Surveillance involving persons who are most at risk for HIV is necessary in the context of the HIV epidemic. However, the surveillance activities must meet appropriate ethical review. The review should ensure that the surveillance activity does not result in new burdens on the most-at-risk population. It is especially important that:

- consent is informed and voluntary,
- confidentiality protections are enforceable, and
- inducements to participate do not constitute coercive offers.

Any limits to confidentiality must be made clear to all potential participants.

Unique issues of consent with women

The 2002 CIOMS *International ethical guidelines for biomedical research involving human subjects* maintained that husbands or heads of households may not consent on behalf of women. Nonetheless, 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 may be subject to domestic violence, divorce or social ostracism. The refusal to involve women in studies because of such cultural constraints could thwart investigations crucial to women's interests. In the United States, the NBAC 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: "a) it would be impossible to conduct the research without obtaining such supplemental permission; d 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, NBAC 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." *(80)* The Nuffield Council on Bioethics 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 roles and attitudes of women in many developed nations. Thus, their guidelines on research in developing countries set into relief the obligation of researchers and health officials to foster discussion about context and changing cultural norms as they affect the rights of women.*(81)* The 2009 CIOMS *Guidelines on epidemiological research* highlighted the importance of respecting a woman's right to volunteer for studies regardless of the preference of her father, husband or head of family: "If women wish to consult with their husbands or partners or seek voluntarily to obtain their permission before deciding to enrol in research, that is not only ethically permissible but in some contexts highly desirable. A strict requirement of authorization of a spouse or partner, however, violates the substantive principle of respect for persons." *(82)*

Guidance 10. Just as a community leader may not give consent for participation on behalf of their community, a husband, father or head of household may not provide the sole consent for a woman to participate in surveillance. In some situations, a woman may choose to consult with and obtain the approval of her husband or father. However, her individual informed consent is required before participating in surveillance activities. Participation should never be excluded because no male approval is available.

Confidentiality

As noted, CIOMS, in its 2002 revision of *International ethical guidelines for biomedical research involving human subjects*, established an obligation on the part of investigators to safeguard the confidentiality of subjects' research data. The Nuffield Council on Bioethics also emphasized protecting the security and confidentiality of data.*(83)* So too do the 2009 CIOMS *Guidelines on epidemiological research.*

The protection of confidentiality in the context of research and other surveillance-related investigations has two sources. On a pragmatic level, the failure to provide such assurances will inhibit the willingness of individuals to discuss precisely those intimate matters of sex and drug use that bear on the dynamics of the HIV epidemic. A study of maternal–fetal HIV transmission conducted in the Ivory Coast, for example, found that women were reluctant to be tested for HIV due to fear that family members, particularly husbands, would learn of positive test results. The point here is not whether this was research or practice, but the fact that it was the informed consent process itself that alarmed women because it raised concerns about the possibility of their confidentiality being breached; this concern lowered participation rates.*(84)* As important as the pragmatic bases of confidentiality are its ethical underpinnings, which include respect for persons, beneficence and non-maleficence. On ethical grounds, the protection of confidentiality, especially in the context of a socially stigmatized epidemic such as HIV, is crucial.

In general, behavioural surveillance studies, including those that collect biological specimens, do not require that data be recorded in a manner that links them to identifiable individuals. There may, however, be circumstances where identifiable records are necessary, such as longitudinal studies, which seek to track changes in behaviour over time, for example, or where linkage to other data sources is essential for investigation.*(85)* Under those 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. Note that Guideline 2 referred to record linkages from different registries such as TB and HIV. It is not intended to bear on the issue of linking behavioural surveillance and registry data.

While there is no doubt that investigators have an obligation 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 might result in the identification of individuals, despite the effort to keep the records anonymous. Thus, anonymous records cannot be regarded as strictly confidential in all circumstances.

However, confidentiality is not an absolute. During the course of behavioural surveillance, it may be discovered that individuals have placed other potentially unsuspecting parties at risk for HIV infection because of sexual activity or sharing of drug-use equipment. Those conducting surveillance activities may also learn the identities of individuals who have placed survey participants at risk. How such behaviour is viewed as a legal matter differs among nations. The availability of services such as partner notification also varies. These contexts will inevitably affect both the legal and ethical obligations of those involved in behavioural surveillance studies. There may be a fundamental conflict between the goals of surveillance to uncover risky behaviour and the impulse to intervene, even involving the notification of legal authorities. Much will depend on the nature of the discovered threat, 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 whatever legal requirements exist when investigators discover that participants are engaging in behaviour that may threaten the welfare of others. In the absence of such exemptions, there will be an inevitable impact on the willingness of participants to speak candidly. On the other hand, somedisricts require the reporting of certain illegal behaviours if uncovered. In the absence of an exemption, such information should not be collected.

Some disricts have laws that could place interviewers of persons engaging in illegal behaviours, e.g. sodomy, in legal jeopardy. The local laws that may cause harm to surveillance staff should be fully understood and the staff should understand the risk.

A second circumstance where 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, where a large-scale retrospective epidemiological review based on records may be undertaken, such consent may be impossible and may be waived with the appropriate approval of an ethics review committee. *(86)* This issue is discussed more fully above.

Guidance 11. Investigators and ethical review committees must protect the confidentiality of participants in surveillance activities. This can be done by making the data anonymous (removing all identifying information). Where this is not possible, records should be locked up or secured to prevent access by unauthorized persons. Only the minimal amount of identifiable information should be collected.

Guidance 12. In some settings, the authorities will require researchers to alert them of any behaviour that are illegal or those that place others at risk. If such a law is in place, the researchers must make sure that participants understand this law. In some settings, the researchers will have received an exemption from this law. If they do not have such an exemption, researchers have a duty to inform participants of the limits of confidentiality.

C. Anonymous unlinked surveillance

With the identification of HIV in 1984, it became clear that an understanding of the dimensions of the AIDS epidemic would require more than a careful detailing of the incidence and prevalence of overt symptoms of the disease. To enable public health authorities in nations 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 those with infection progressed to symptomatic conditions, knowledge of the prevalence of HIV infection was necessary. Data based on volunteer studies involving only consenting individuals drawn from groups at increased risk such as MSM, IDUs or attendees at STI clinics were not adequate for the task of monitoring the epidemic because of selection and participation bias. To meet the challenge, epidemiologists quickly came to agree that anonymous, blinded or unlinked serosurveillance was necessary. Such unlinked surveillance would involve the screening of blood specimens collected for purposes other than HIV testing under conditions that permanently stripped the samples of personal identifiers. This method became the backbone of surveillance in generalized epidemics in low-income countries.

Historically, UAT provided a unique vantage on epidemics and as a consequence was initially viewed by those opposed to nominal HIV notification as a superior epidemiological tool.*(87)* However, on methodological grounds, blinded seroprevalence studies were not as easy to design and interpret as was sometimes believed. Surveillance sites had to be carefully selected to ensure that the populations which came into contact with them were representative of the larger population. In nations where considerable proportions of the population were treated in the nongovernment clinic sector, this requirement could pose insuperable obstacles.

UAT has been the subject of an on going and evolving international ethical discussion. It is important to understand this evolution in order to appreciate this revised set of guidelines. In the United States, UAT became a central feature of the public health response to the HIV epidemic in the mid-1980s. Such efforts had to address a set of ethical questions. 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 of the results, issues of consent and the right to know were foremost. In considering these issues, the US CDC concluded that UAT was in fact 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. Furthermore, since the tested samples were anonymized, no identifiable 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 particular individuals. Finally, from a public health point of view, the discovery of unexpected levels of infection in a community could spur both further epidemiological investigations and the direction of public health resources necessary for testing, follow up and counselling. Whatever 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 intrusion on the rights of informed consent and privacy.

When a working group comprising ethicists, lawyers, civil liberties advocates, gay rights proponents and public health officials met in 1985 to discuss the issue of unlinked anonymous HIV surveillance at the Hastings Centre, a research institute devoted to the study of ethical questions in medicine, no objection was raised to such efforts. UAT was extended beyond the initial sentinel hospital settings and, most importantly, was extended to childbearing women in virtually all US states with no opposition and much support.

In 1989, WHO's Global Programme on AIDS (GPA) issued its report *Unlinked anonymous screening for the public health surveillance of HIV infections: proposed international guidelines.* It 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 that goal, the GPA endorsed the use of unlinked anonymous surveillance and concluded that they could be used "without endangering or compromising the broad principles of public health and human rights".*(88)*

Despite consensus in the United States and the endorsement of WHO, unlinked anonymous surveillance did provoke controversy in other economically developed nations. Resistance in the United Kingdom, the Netherlands and Denmark resulted in a delay of several years before such surveillance could be undertaken. Indicative of the level of concern were the remarks of two leading British ethicists, who challenged the fundamental premises of such surveillance. Dr Raanan Gillon, editor of the *Journal of Medical Ethics*, wrote of such studies, "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." Professor Ian Kennedy acknowledged that the ethical challenge to UAT 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 and one may not know them….. This is after all the heritage that we have acquired from Nuremberg and afterwards."*(89,90)* Summarizing the objections, one US expert on the ethics of research on human subjects stated, "The fundamental issue for these critics is that such programs conscript research efforts that they may not want to be part of."*(91)* This was, therefore, a challenge rooted in the very fundamentals of post-World War II bioethics.

When at last the United Kingdom 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 to not 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".*(92)* The right to such spontaneous refusal was also acknowledged by the Canadian guidelines on unlinked surveillance, which were in other respects enthusiastic about the ethical and public health justifications for epidemiological methods that avoided the problems of selection and participation bias.*(93)*

An important turning point occurred in 1994. Clinical trial ACTG 076 revealed that zidovudine could reduce by two-thirds the risk of vertical HIV transmission from mother to fetus, and pressure mounted in the US to unblind the newborn screening serosurveys to ascertain the notification of all women who might benefit from such knowledge. In that year, the US CDC ended its support for UAT among childbearing women. The advent and widespread availability of antiretroviral therapy in well-resourced nations contributed further to growing discomfort with an approach to surveillance which, by definition, precluded the notification of HIV status to individuals who could benefit from therapeutic intervention. In Europe, UAT subsequently fell out of favour in all but a few nations.*(51)*

UAT continued, however, in antenatal clinics in Africa, Asia, and Latin America and the Caribbean where neither HIV testing nor antiretroviral therapy was widely available. Nevertheless, as an approach to HIV surveillance, UAT became the subject of on going dispute, fuelled in large measure by the slow but marked extension of clinical HIV testing, prophylaxis against maternal–fetal transmission and antiretroviral therapy. Two central questions emerged: as the benefits of clinical intervention became more salient, was it ethical to employ a surveillance strategy that made notification of those in need of care impossible? How extensive did PMTCT programmes need to be for data generated in such clinical settings to serve surveillance needs?

UAT retained support, on both epidemiological and ethical grounds, from proponents who believed that ANCs did not yet yield data adequate for public health "advocacy, resources allocation, and targeting of interventions".*(94)* It was in this context that evidence from Thailand, where more than 90% of births occurred in hospitals and uptake of HIV testing in ANCs exceeded 95%, suggested what might be possible in the future. Indeed, the experience of Thailand indicated to some that clinical data could provide "greater coverage and representation than UAT". Thus, the evidence pointed to the real possibility that the benefits of surveillance need not come at the expense of a woman's right to know her HIV status.*(95)*

After more than a decade of discussion, in which ethical concerns and epidemiological evidence were brought to bear, a new global consensus that cast doubt upon the future of UAT had begun to emerge by 2008 and 2009. On the long-debated question of the role of UAT in ANCs, ethicists had come to agree that periodic review was necessary "to determine whether [circumstances] warranted testing without providing results to the individuals tested". The burden of proof, it was increasingly asserted, should now fall on those who held that the necessities of surveillance justified an approach first crafted in a period defined by profound therapeutic limits.

The massive US global commitment to provide treatment funds via the US President's Emergency Plan for AIDS Relief (PEPFAR) created an impetus to provide clear guidance for surveillance efforts. In mid-2009, relevant US agencies reviewed the implications of the consultations that had addressed the ethics of UAT in the previous year and provided an example of the kind of specificity that might be required for UAT to continue. US agencies concluded that where PMTCT programmes or stand-alone testing services were available in less than 75% of ANC sites and where uptake of testing in these clinics was less than 90%, "a waiver should be submitted to conduct UAT surveillance". The default position of the US agencies became non-UAT-based surveillance.[5]*(97,98)* However, most countries qualify for the waiver under these parameters.

On 23 and 24 February 2009, the UNAIDS/WHO "Ethics consultation to review ethical issues associated with HIV testing in the context of surveillance surveys" included epidemiologists, ethicists and public health specialists, who convened at WHO in Geneva, Switzerland. The meeting's principal objective was to obtain an updated external ethical review of HIV surveillance methods and include an overview of improved coverage and currently available methods. In particular, the meeting reviewed two key methods: the use of UAT in the ANC setting without informed consent and using leftover blood when the participant was unaware of being tested; and UAT with informed consent such as population-based HIV household surveys when the results of testing are not returned to participants. Outcomes from the consultation will support updates to current surveillance guidelines to ensure that ethical practices are considered when developing and conducting HIV surveillance. The meeting report can be found at the WHO web site http://www.who.int/hiv/en/.

Guidance 13. UAT occurs when persons are tested for HIV but the test and results are not linked to any identifying information. The participants are not provided with their results. UAT is often done without informed consent. It should be used for surveillance only when data from clinical settings and other studies cannot provide the necessary information. All study proposals using UAT should be reviewed by committees capable of evaluating both the epidemiological and ethical issues involved. Those who conduct UAT must demonstrate that clinical data are not adequate for the purpose of public health surveillance.

Guidance 14. Where both epidemiological evidence and ethical review suggest that UAT is justified as a strategy for HIV surveillance, the communities where it will be conducted should be notified that blood samples drawn for clinical purposes may be anonymously tested for HIV. In the case of pregnant women attending ANCs, all women must also be referred to PMTCT programmes for HIV testing, counselling and treatment, if needed.

5 Summary of ethical consultations held in New York (2008) and Geneva (2009). HIV testing in surveillance and survey protocols. 14 July 2009:1,3. (Unpublished report)

Individual consent to blood drawn specifically for HIV surveillance

While much of the discussion on UAT had focused on ANCs and the needs and claims of women, there was also increasing uncertainty about the ethics of UAT in population-based household surveys. Despite the importance of studies drawn from ANCs, there was growing concern that they might not, in fact, provide the most accurate characterization of the prevalence of HIV infection in the population at large. They certainly did not permit the linkage of behavioural data with serostatus. Household surveys drawn from sample populations, although very expensive and complex, were thus deemed necessary. In such contexts, blood samples for HIV testing could be obtained only after informed consent. Direct contact with study participants is a defining feature of household surveys. In such surveys, the essential question was not whether those who conducted the surveillance had an obligation to ensure that those who were tested were given an opportunity to learn their results but how such knowledge should be provided. Indeed, in the earliest discussions of the issue, some argued that the most challenging question was whether participants should be *required* to receive their test results and, if so, how this might affect the willingness to participate in such surveys.

Strikingly, in the first major UNAIDS/WHO report on the conduct and potential role of household surveys, *Guidelines for measuring national HIV prevalence in population-based surveys*, the strictures governing epidemiological research rather than public health surveillance provided the framework for addressing a host of issues. To meet the ethical requirement that *"study participants*[6] should share in the benefits of the research", it was essential to explicitly define how they would be informed of their HIV status.*(99)* Two options were available: the study itself could provide the test results and the necessary counselling (prior to delinking serostatus results from personal identifiers); or participants could be referred to ancillary mobile testing and counselling sites or to readily accessible community-based services. The report noted that, if the former approach was adopted, it would be necessary to modify the testing protocol since the level of specificity necessary in surveillance activities was not typically the equivalent of that necessary for clinical diagnosis.*(100)* Further, they voiced concern about how home-based notification might place individuals at risk for stigmatization and violence.

The guidelines, however, offered no preference for either option, and sharp debate characterized ensuing discussions. For some, the community referral option represented a failure to meet the central ethical responsibility to provide appropriate care to survey participants. Others, while acknowledging a duty to make efforts to ensure that study participants were tested in the community or via mobile services, worried that surveillance personnel were not qualified to provide test results directly to participants.

It is clear that consensus has emerged: investigators have an obligation to participants in epidemiological studies, in particular, in general and household surveys, to ensure that they may learn the test results that are clinically relevant to their individual health. The 2009 CIOMS guidelines observed that while it had not been common practice for epidemiologists to assume the burden of notification, this was no longer acceptable as a general practice: "In light of contemporary standards for informed consent, however, epidemiologists should make subjects aware of findings that are clinically relevant to their individual health." Exceptions could be approved by review committees when the scale of a study would effectively prohibit notification. Nonetheless, it was imperative that, as part of the consent process, participants clearly understand what they would be told and not told.*(101)*

Guidance 15. In household surveys or in clinical or non-clinical settings, where blood is drawn exclusively for the purposes of unlinked anonymous surveillance, the informed consent of each individual participant must be obtained. Individuals must understand their freedom to decline to participate, the nature of the risks and benefits of participation, and the nature of UAT.

Guidance 16. In household surveys or in clinical or non-clinical settings that involve HIV testing, participants must be given the opportunity to be informed of their test results. Test results may be provided by the surveillance team or by referral to surveillance-sponsored mobile testing units. Alternatively, participants may be referred to local and accessible clinics where testing and counselling are available.

6 Emphasis added

3. Use of collected data

A. Obligation to use data

There is now international consensus that research in a given population is justified only if the results of studies will provide benefit to the populations from which participants are drawn. Surveillance activities have *always* been justified in terms of the population-level benefits that would follow. In the 2000 revision of the Declaration of Helsinki, the WMA 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."*(102)* The 2002 CIOMS *International ethical guidelines for biomedical research involving human* subjects gave great emphasis to this point and in a commentary assert 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."*(103)*

It is the responsibility of ethics review committees to focus on the question of how surveillance-related evidence will be used after studies are completed. The significance of the absence of formal ethical review processes for on going governmental surveillance activities that may not be characterized as research is underscored here.

Guidance 17. Surveillance efforts can be justified only if they will help prevent the spread of HIV or will be used for directing resources to those already infected. When there is resistance to effective interventions or resources are scarce, surveillance may be used as a basis for advocacy and empowering the most vulnerable populations.

B. Obligation to disseminate data

Dissemination of findings represents a benefit to which the participants in surveillance-related activities have an ethical claim. In stressing the imperative for researchers from developed 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 US NBAC stressed the importance of communicating results to the communities in which investigations take place. As one group of international researchers 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.*(69)* The Nuffield Council on Bioethics 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". While noting that the ideal form of such information dissemination could vary, the form chosen would need to ensure that investigators answered all the questions of participants and the community.*(104)* The Council added a pragmatic reason for attending to such communication: failure to disseminate results contributes to low participation rates in subsequent studies.

In an early commentary on the importance of communicating the results of UAT, which has relevance for the broader issue of the obligation to plan and undertake dissemination, Canadian health officials stated in 1990, "Communication with the public should be clear and balanced," and that a variety of media should be considered for information dissemination: physicians should be informed of surveillance results, and mass mailings, video tapes, toll-free information hotlines, newspapers, seminars and public meetings are all potential tools for conveying surveillance information to the public.*(93)* Finally, the 2009 CIOMS

Epidemiological guidelines also stressed the importance of communicating study results (or advocating for the release of such results when controlled by either governments or private entities) to individuals and communities when possible. Participants should be informed when this will not be possible.*(39,105)*[1]

The communication of knowledge, however, is double-edged: on the one hand, knowledge may clearly empower; on the other, it may injure. Thus, the CIOMS *Epidemiological guidelines* noted the possibility that releasing information may cause harm, particularly to stigmatized, marginalized or vulnerable groups. "Information might be published that could stigmatize a group or expose its members to discrimination." Consequently, CIOMS asserted that data should be published in a way "that is respectful of the interests of all concerned". In certain "exceptional circumstances" a decision to not publish data might be justified. But CIOMS warned that it was also necessary to consider "the harm that could result from foregoing the research or from failing to publish the results".*(106)*

In the end, there may be no way of avoiding the fact that some communication may be experienced as injurious by vulnerable populations. It is only the commitment to utilizing second generation surveillance to benefit such vulnerable groups that can justify potential short-term harms.

Guidance 18. The results of surveillance must always be communicated to stakeholders and the community. Any censoring of surveillance data must be challenged. Community advisory boards, ethics review committees and other oversight bodies charged with ethical review of public health practice should consider how the results will be used and shared.

Guidance 19. When the communication of surveillance data may injure the population it is intended to serve, every effort must be made to minimize such risks. Discussions with representatives of the community about how the results can best be presented may avoid some unnecessary harm.

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

Guidance 20. Prior to undertaking surveillance studies, investigators, 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 the provision of prevention and treatment services in the post-surveillance period.

D. Obligation to intervene at the individual level

Those conducting integrated behavioural and biological studies and surveillance activities may, during the course of the interview, become aware that a participant is placing himself or herself at risk because of a lack of information about how HIV is acquired and transmitted, limited access to preventive services or psychosocial stressors. Individuals may also reveal that they themselves are being placed at risk because of the coercive or threatening behaviour of their sexual partners. While it may be beyond the immediate role of the investigator to intervene to protect such individuals, such situations require consideration of referral to appropriate services, where they are available. A much more difficult issue is posed when

1 Additionally, CIOMS notes the importance of fulfilling expectations for health care that may be created by epidemiological research and improving the training of local health personnel as part of such research.

referrals are not practical or possible. Referrals to socially or geographically inaccessible services cannot be an acceptable resolution to this problem and, indeed, may only serve to further disempower those already vulnerable. Where referrals are impossible, it may be necessary for surveillance projects to assume responsibilities otherwise beyond the normal scope of their activities. Community advisory boards, ethical review committees, and other bodies charged with the ethical oversight of public health practice may serve as the appropriate forums for discussing these matters before they emerge.

Guidance 21. Surveillance projects should ensure that persons placing themselves at risk are referred to appropriate services. If no referrals are possible, the project itself should advocate for services. This should be done in consultation with community advisory boards, ethical review committees and other bodies charged with the ethical oversight of public health practice.

4. Summary and Conclusions: ethical implications of type of epidemic

Throughout this discussion, the consultations and in the guidelines that have emerged from it, a number of themes have been salient. Despite the emphasis on the importance of protecting the rights of individuals in the context of surveillance and the limits such concerns may have for surveillance as an activity, it is worth re-emphasizing that there is an ethical obligation to undertake surveillance precisely because of the potential for prevention of disease, suffering and death. It is here that the linkage between surveillance as a data-gathering activity and surveillance as a public health undertaking designed to limit morbidity and mortality becomes clear. In the absence of a commitment to using surveillance findings to benefit the vulnerable, the moral foundations of the activity vanish.

Among the most challenging features of the commitment to bringing ethical considerations to bear on the conduct of HIV surveillance will be the need to address the question of what mechanisms can best provide appropriate oversight. For decades, committees charged with the responsibility for ethical review have performed this function in the context of research on human subjects, both clinical and epidemiological. The effectiveness of such committees in meeting this obligation and the need to enhance the institutional capacity of such committees in poor nations has been the subject of on going international concern. If even the most basic forms of ethical oversight are to be brought to surveillance activities that are not classified as research, it will be necessary to provide sufficient resources to make such new initiatives possible. In some nations, efforts to systematically consider the ethics of surveillance in a sustained way are beginning. In most nations the process has yet to begin. Hence, a commitment to realizing the promise of ethical scrutiny of all surveillance activities will pose significant institutional challenges for the international community.

Because of the nature of the HIV epidemic and its linkage to sexual and drug-using behaviours, those thought to be at risk or 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. Without the assurance of confidentiality, those most at risk for HIV infection would have every reason to avoid cooperating 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 to secure public health registries.

It is clear from the analysis in this report that consent – the first principle of research ethics enunciated in the Nuremberg Code – has become increasingly important in the context of surveillance. It is precisely because of concerns about stigmatization, the risks associated with breaches of confidentiality and potentially threatening social environments that the importance of ensuring that those who participate in surveillance understand both the risks and benefits has been underscored. It is also noted, however, that there are clearly defined circumstances where the principle of consent may be subject to limitations in public health surveillance activities such as disease notification.

To this point, we have discussed the broad general themes that emerge regardless of epidemic state. It is one of the central achievements of second generation surveillance that it recognizes that low-level, concentrated and generalized epidemics impose different demands on public health and surveillance activities. Concerns about stigma, confidentiality, consent and data use play out differently at different stages of the epidemic.

In low-level and concentrated epidemics, the risk of stigmatization is greatest because HIV infection may be viewed as involving marginalized populations engaged in behaviours thought to be immoral or illicit. Identifying those 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, will be especially risky because they themselves will feel threatened. Creating an atmosphere of trust and securing the commitment to confidentiality, and emphasizing the importance of consent will be crucial. Most

problematic, especially in low-level epidemics, will be 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, there is the possibility that the location of HIV infection among marginalized populations will permit decision-makers to ignore the human costs of the disease because it afflicts solely the marginalized, or because they refuse to acknowledge the possibility 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, investigators involved in public health surveillance activities, and those who advocate on behalf of the most vulnerable.

In generalized epidemics, one would suspect that the threat of stigmatization, discrimination and violence toward HIV-infected persons would diminish, and yet that 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 despite the fact that they represent the tip of a vast iceberg. Under such circumstances, a central 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 would be 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. It is precisely the importance of uncovering the presence of HIV which necessitates that a distinction be made between the claims of confidentiality at the individual level and the need to challenge forms of secrecy that represent an expression of social denial, which may compel those with HIV infection to remain hidden. Because generalized epidemics are heterosexual by definition, they always involve the issue of childbearing women and their infants. Protecting the rights of women to consent for medical interventions and, indeed, protecting their privacy becomes central. Stigma, discrimination and violence towards other highly at-risk populations should not be overlooked in countries with generalized epidemics. Though heterosexual sex is the predominant mode of transmission, MSM, IDUs and sex workers often have an HIV prevalence at or above the national rate and their access to prevention, care and treatment may be hampered by their stigmatized position in society.

Generalized epidemics almost always represent a failure of prior efforts to interrupt the spread of HIV infection or are indicative of neglect that permitted HIV infection to spread without the impact of public health efforts. It is thus inevitable that surveillance activities which underscore these failures will represent a challenge to those in positions of authority. To acknowledge past failures will be a challenge but efforts must be redirected in a way that reflects the dynamics of HIV transmission.

Annex: List of guidelines from the WHO/ UNAIDS Working Group

Title	Year	Topic
HIV surveillance among hard to reach populations	2011	Update on methodologies for conducting HIV surveillance among most-at-risk populations.
Guidelines on Estimating the Size of Populations Most at Risk to HIV (UNAIDS/WHO)	2010	Update on methodologies for estimating the size of most-at-risk populations. http://www.globalhealthsciences.ucsf.edu/PPHG/surveillance/who_trainings.html
Testing Technologies in Surveillance: Selection, Evaluation, and Implementation: update 2009	2009	An update in guidance on selecting and utilizing appropriate HIV tests for surveillance purposes.
HIV Triangulation Guide: Synthesis of Results from Multiple Data Sources for Evaluation and Decision making	2009	Guidelines on conducting triangulation, users manual developed with examples from based on experiences in Africa. http://www.who.int/hiv/pub/surveillance/hiv_triangulation_guide.pdf
The pre-surveillance assessment: Guidelines for planning sero-surveillance of HIV, prevalence of sexually transmitted infections and behavioural components of second generation surveillance of HIV	2005	Tools for preparing to implement SGS including defining and selecting risk groups, sites, and feasibility of methods http://www.who.int/hiv/pub/surveillance/sti/en/index.html
Guidelines for measuring HIV prevalence in population based survey	2005	Guidelines for national population based survey with HIV testing http://data.unaids.org/pub/Manual/2005/20050101_GS_GuideMeasuringPopulation_en.pdf
Guidelines for HIV surveillance among TB patients	2004	How to conduct HIV surveillance among TB patients http://data.unaids.org/pub/Manual/2005/20050101_GS_GuideMeasuringPopulation_en.pdf
Guidelines for effective use of data from HIV surveillance systems	2004	Guidance on how to analyse, interpret, and present surveillance data http://data.unaids.org/Publications/IRC-pub06/JC1010-UsingData_en.pdf
Guidelines to HIV sentinel serosurveys among pregnant women and other groups	2003	Protocols for implementing ANC sentinel surveillance http://data.unaids.org/Publications/IRC-pub06/JC954-ANC-Serosurveys_Guidelines_en.pdf
Initiating Second Generation HIV Surveillance Systems: Practical Guidelines	2004	Suggested process for planning and getting consensus on design of a national SGS system http://www.who.int/hiv/pub/surveillance/en/isbn9291732192.pdf
Guidelines for Second Generation Surveillance	2000	Overview of principles of Second Generation Surveillance http://www.who.int/hiv/pub/surveillance/en/cds_edc_2000_5.pdf

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