Editorial review

The American, British and Dutch responses to unlinked anonymous HIV seroprevalence studies: an international comparison

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Introduction

With the identification of HIV as the etiological agent of AIDS in 1984, it became clear that an understanding of the dimensions of the epidemic would require more than a careful detailing of the incidence and prevalence of overt symptoms of the disease. To enable public health authorities to target and evaluate preventive interventions and plan for the health care service that would be required in the future as the infected progressed to symptomatic conditions, knowledge of the incidence and prevalence of HIV infection was critically needed.

The importance of developing monitoring systems for HIV infection was succinctly summarized by the Committee on AIDS Research and the Behavioral, Social, and the Statistical Sciences of the US National Research Council.

> Counts of AIDS cases are out-of-date indicators of the present state of the epidemic. There is a long, asymptomatic latency period between HIV infection and the development of AIDS (in most persons). Consequently the statistics on *new* cases reflect *old* cases of HIV infection. . . . Persons whose life spans are significantly shortened by HIV infection do not always manifest sufficient symptoms to be captured by the AIDS reporting system. . . . HIV-infected persons without overt AIDS symptoms can transmit the virus to others. The future magnitude of the AIDS epidemic will be determined primarily by the current extent and future spread of HIV infection in the population [1].

Now that the focus of clinical intervention has shifted to the earliest stages of the spectrum of HIV disease, the importance of distinguishing between surveillance to detect the *prevalence* of infection and case finding that seeks to identify *individuals* who might benefit from treatment is all the more important.

For epidemiologists and public health officials concerned with the surveillance of the HIV epidemic it became clear soon after antibody testing became possible that data based on volunteer studies involving only consenting individuals drawn from high-risk groups, such as homosexual men, intravenous drug users (IVDUs), visitors to sexually transmitted disease (STD) clinics , or from low-risk groups such as pregnant women and blood donors were not adequate to the challenge of monitoring the incidence and prevalence of HIV infection because of selection and participation bias. Some investigators reported that the prevalence of HIV infection among those who refused to participate in volunteer studies was likely to be much higher than the prevalence of HIV among participants [2,3]. Studies of volunteers were thus perceived as unreliable. They could not be extrapolated to estimate accurately the HIV seroprevalence levels of the populations being studied. Furthermore, it was clearly necessary to undertake additional investigations to establish the incidence and prevalence of HIV in the general population [4].

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Anonymous, blinded, or unlinked screening emerged as the method of choice for epidemiologists who sought to overcome the inadequacies of volunteer studies. Such studies would involve the screening of blood specimens collected for purposes other than HIV testing under conditions that permanently stripped such samples of personal identifiers. As an epidemiological tool, blinded studies had been used on other occasions to establish vaccination levels in populations and for reference purposes in hospital laboratories.

Because anonymous surveys would be conducted without the knowledge and agreement of the test subjects and would detect infection without being able to inform individuals of the risks they might pose for others, it was natural that questions about their legality and ethical acceptability would arise. Matters of informed consent, privacy and the clinical duty to counsel the infected were raised by the very design of blinded studies. Indeed, in Europe, controversies centering on these issues have delayed or thwarted efforts to undertake such studies despite their widespread use in the United States and their endorsement by the World Health Organization Global Programme on AIDS [5].

In this review we wish to describe the responses to proposals for blinded seroprevalence studies in the United States, the United Kingdom, and the Netherlands in order to provide background for those nations where the debate has still to be resolved. The responses differed in these three countries. In the United States, such studies aroused little debate and were implemented with relative ease. In the United Kingdom, the issue was the subject of heated debate and was resolved finally in favour of unlinked studies with an 'opt out' provision. In the Netherlands, the issue has provoked great controversy and has yet to be settled. Such an examination is especially critical now that the efficacy of early intervention to inhibit the progression of HIV disease has been demonstrated. The clinical significance of identifying infected individuals may place strains on the alliances that have supported blinded studies and may create potent ethical challenges to their further use.

The United States

At the US Centers for Disease Control (CDC) the importance of undertaking blinded seroprevalence studies was recognized early in the fall of 1985, just 6 months after the licensure of the enzyme-linked immunosorbent assay (ELISA) antibody test. Selected institutions—sentinel hospitals—across the nation would be chosen to provide sera for HIV testing. To Timothy Donero, Chief of the surveillance and evaluation branch at the CDC's AIDS program, and his colleagues, it was clear that only such screening could reflect regional as well as national prevalence trends, could provide prevalence and trends by age and sex, and would be consistent with the ethical requirements governing research involving human subjects. Such studies would avoid the inevitable distortions associated with volunteer studies and would, because they involved samples drawn for other purposes that were stripped of identifiers, preclude the requirements of informed consent and the follow-up and counseling of those found to be infected (TJ Dondero, unpublished data).

Federal regulations governing human subjects research explicitly exempted 'research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects' from the requirements of informed consent [6]. This provision was noted by advocates of blinded studies as they sought to develop the scientific, legal and ethical arguments for their proposed investigations.

The initial CDC proposal for blinded studies also addressed a matter that would represent a source of concern and, as such, surveillance became the subject of debate in the United States and in Europe. By stripping sera of identifiers it would not be possible to inform and counsel the infected. This was an especially critical point since the Food and Drug Administration (FDA) had ruled earlier that, when blood banks began to screen donations in mid-1985, notification of the infected would be required and could not be waived even at the request of the donor. Hence the very element of the proposed studies that appeared to permit testing without violation of the principle of informed consent and without an invasion of privacy, raised problems for public health and seemed to represent a breach of the ethical duty to inform individuals about clinical findings germane to their well-being. When the prospects for early clinical intervention improved, 4 years later in 1989, this question would take on new significance. But in 1985 it was the limitation of the possibility of acting in accordance with the preventive demands of the public health that was to draw attention. To those concerns CDC officials responded that since the sera to be tested 'were about to be discarded', the data to be produced would not have been available to those from whom the blood had been drawn. More importantly, no person whose blood was to be tested would be denied an opportunity to obtain testing and counseling in a manner that would be fully informative. Finally, the discovery of an unexpected level of infection in a community 'would spur both an epidemiologic investigation and the development of community public health resources for serologic testing, follow-up and counseling'. Given the overriding public health goal of preventing the further spread of infection, a balance had to be struck between the importance of identifying and counseling HIV-infected people and obtaining an accurate epidemiological understanding of the patterns of infection in society. Implicit in the argument for blinded studies was the determination that, whatever the social costs involved in losing the capacity to warn specific individuals,

they would be more than compensated for by the acquisition of otherwise unobtainable socially critical data.

Neither those federal officials responsible for assuring the ethical conduct of research, nor others outside government whose professional concerns centered on the ethics of human subjects research, raised objection to the proposed studies. The Office for the Protection from Research Risks declared that 'since patient identifying information will not be linked to HIV test results, informed consent will not be required' [7]. A working group made up of philosophers, lawyers, social scientists, public health officials, gay rights advocates, and representatives of civil liberties organizations at the Hastings Center— a research institute devoted to the study of medical ethics—that was considering the ethics of HIV screening, was explicitly asked by the Chief of Infectious Diseases of California's State Health Department to exempt blinded studies from the ethical requirement that tested individuals be informed of their results. While many matters considered by the working group produced divisive reactions, no such response greeted this request. And so the Center's ethical guidelines for HIV screening, which appeared in the *Journal of the American Medical Association*, raised no objection to blinded studies [8]. Perhaps more pertinent, neither civil liberties groups nor gay rights organizations opposed blinded seroprevalence studies. Some went further and urged their expeditious implementation under stringent safeguards. Indeed when the press first became aware of the CDC's plans to undertake blinded studies, reporters were surprised at the absence of what they had anticipated would be an outcry from groups that monitored all public health moves that could place those infected at any risk of violation of privacy.

The widescale political support for blinded studies is underscored by the relative ease with which legislative and administrative modifications were made to remove roadblocks that might have precluded such efforts. In California where stringent confidentiality legislation had been enacted in 1985 [9] to protect individuals from unconsented testing and wrongful disclosures of test results, the architect of the enactment—who had the support of public health officials, those identified as political liberals, gay rights organizations and civil liberties groups—pressed for an amendment to the statute when the state's chief health officer interpreted the law in a way that would have prohibited blinded studies [10]. In Minnesota, which was among the first states to make HIV infection notifiable, it was necessary to amend the law to permit blinded testing so as to preclude reporting of those found to be infected to the state health department's registry of infected persons. No protest emerged from the legislature. (Michael Osterholm, personal communication, 1989). In New York, which in 1988 enacted very carefully crafted legislation to protect individuals from unconsented HIV antibody testing and which sought, under penalty of the law, to assure the confidentiality of test results, the statute explicitly carved out an exception for blinded studies [11]. Many other states have followed suit, enacting exemptions for blinded studies in their consent laws [12].

The virtual absence of protest against blinded studies in the United States is all the more noteworthy given the legislative and administrative provisions for the monitoring of all research involving human subjects, the pervasive influence of those concerned with medical ethics and the volatile politics that have surrounded the AIDS epidemic. In one case—involving the study of infection rates among prisoners in New York—strong organizational opposition was raised to blinded studies. In this instance the Prisoners Rights Project of the Legal Aid Society, an organization that provides legal defense for impoverished prisoners, asserted that the discovery of high levels of infection among inmates would result in further stigmatization of a population already subject to discrimination and that, therefore, such studies would be unacceptably burdensome [13]. This response was quite atypical. Somewhat more common has been the opposition from those individuals—a marginal few—who take an absolutist position with regard to the principles of privacy and informed consent and from local public health officials—few in number as well—who have insisted that a full list of infected individuals is an essential component of the overarching goal of preventing the further spread of HIV infection. With almost no political opposition, and in the absence of ethical and legal objections from those who might have put forth such claims, epidemiological surveillance of HIV infection through blinded studies has been undertaken not only in the original sentinel hospitals but in clinics that treat sexually transmitted disease, tuberculosis, drug abuse, and women of reproductive age. Forty-three states have undertaken blinded studies of newborns, thus providing an extraordinary data set on infection among women of childbearing age. (T.J. Dondero, personal communication, 1989).

It was only in mid-1989, under circumstances marked by rapid developments in the clinical picture surrounding HIV infection, that some began to challenge the ethical justification for blinded studies. It was only then that proposals emerged to develop protocols which might permit the 'unblinding' of studies so that, for example, women found to be infected as a result of newborn screening might be expeditiously warned [14]. Such proposals reflected a tension between the ethics of epidemiological research and the ethics of clinical intervention, a confusion between the public health function of surveillance and the task of case finding.

The straightforward resolution in the United States of the ethical, legal and public health questions posed when blinded studies were first considered was not repeated in Great Britain. There, proposals to undertake such studies provoked an extended controversy, lasting almost 2 years. More striking was the fact that the alliance that supported such studies in the United States failed to materialize, and that the most vocal British exponents of medical ethics challenged the very conclusions that had appeared virtually beyond question.

Great Britain

In January 1987, Sir Richard Doll, chair of the Subcommittee on Epidemiology of the Medical Research Council's Working Party on AIDS, made public in a letter to the *British Medical Journal* the opposition with which the proposal for blinded seroprevalence studies had been greeted in Great Britain [15]. For more than 6 months, he reported, he had sought support to undertake studies similar to those being planned in the United States, but to no avail, The objections to such investigations on grounds of ethics, law and public health, were, he argued, without foundation. Like officials at the CDC he argued that since all samples would be stripped of identifiers, no invasion of privacy would be involved. And, like his American counterparts, he asserted that if the condition for conducting such unconsented testing was the elimination of the possibility of informing the infected, then that was a price that had to be paid.

Two months later, Raanan Gillon, Editor of the *Journal of Medical Ethics* responded to Doll's challenge in the *British Medical Journal* [16]. Citing the World Medical Association's 1983 Declaration of Helsinki, Gillon warned that the proposed studies would entail an unwarranted breach of the principles that should guide research. Unlike the epidemiologists who asserted that blinded studies would provide invaluable data on the prevalence of infection, Gillon argued—as would all opponents of the proposed research—that the findings 'would not accurately show HIV prevalence in the general population but will give only rough guides from unrepresentative samples'. Unless overriding and compelling reasons were provided, obtaining the consent of individuals for research was imperative. 'In the case proposed I see no such powerful arguments and am not at all clear why adequate consent should be unobtainable'. Finally, Gillon raised an alarm about the very design of the blinded study that would preclude notification of those who were infected. 'We trade on a deceit—a minor deceit but undoubtedly 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 or not they would wish to know it and so organized matters that we cannot pass it on even if they did wish to know.'

In lieu of blinded studies, which he found so morally troubling, Gillon proposed that individuals in groups selected for prevalence studies be informed that 'spare blood' in excess of that which had been used for tests done for their own benefit would be screened for HIV antibody. Permission for such testing would be assumed unless it was explicitly withheld. Each individual who agreed to testing would then be given the option of being informed of the results. Such an approach to seroprevalence studies would neither violate the principle of consent, not would it deprive those who were tested of information critical to their own life plans.

The controversy that was thus joined in the pages of the *British Medical Journal* was but a prelude to that which was played out before the Social Services Committee of the House of Commons in its hearing on the problems associated with AIDS. Among those supporting blinded studies were the British Medical Association, the Medical Research Council and the Trades Union Congress. The Terrence Higgins Trust, a gay rights organization, asserted that if confidentiality could be guaranteed it would support 'fairly aggressive' surveillance. Opposed to blinded studies were the Royal College of Obstetrics and Gynaecology, Professor Ian Kennedy of the Centre of Medical Law and Ethics at Kings College, London, Sir Donald Acheson, Chief Medical officer in the Department of Health and Social Security, and Dr IS MacDonald, Chief Medical Officer of Scotland.

Professor Kennedy [17], like his colleague, Raanan Gillon, argued that the proposed studies would represent poor science and mistaken public health ethics. Because there would be little information—other than the barest demographic facts—about the individuals whose blood was being tested, the findings would tell nothing about the central epidemiological question, i.e., the spread of HIV infection from high-risk groups to the general population. On those grounds alone the research was ethically tarnished. 'If it is bad scientifically, then it is bad ethically because you are doing something which *prima facie* invades the privacy of someone else for no good reason'. Secondly, the construction of studies that would prevent notification about infection would represent an injury to the social interest in preventing the further spread of HIV infection.

However important those arguments were, they were clearly subsidiary to the main thrust of Kennedy's statement before the Committee which centered on the profound moral wrong that would be entailed in 'conscripting' individuals into research studies. 'There may be some things which one wants to know but if the only route toward knowing them is an impermissible route one may not know them. One may either have to try to find desperately another route or simply operate somewhat in the blind. I know that is an unhappy position for those who have to make policy, but it is after all the heritage that we have acquired from Nuremberg and afterwards. . . ' The force of Kennedy's presentation was a critical factor in swaying committee members and in setting political limits to views that could be expressed publicly by health officials. (A. Pinching, personal communication, 1989).

Unlike the situation that prevailed in United States, where those centrally responsible for public health had not only embraced blinded studies but had been their major proponents, the Chief Medical officer was unable to testify as to their social utility. In his testimony before the Social Services Committee, Sir Donald Acheson noted both the advantages and disadvantages of blinded studies from a public health and planning perspective but seemed extraordinarily sensitive to the ethical and legal challenges that had been raised [18] Although he appeared to bow to those who gave voice to such concerns, it was in fact the authority of this highest ranking medical official that

gave force to the dissenting voices of the medical ethicists.

It is thus unsurprising that when the Social Services Committee issued its report in May 1987 it was, on scientific and ethical grounds, 'unable to recommend the general use of anonymized screening at this stage' [19]. The Committee reached this decision although it acknowledged that such testing was commonplace, being used to detect antibodies to diseases such as measles, rubella, diphtheria, tetanus and poliomyelitis. What made this conclusion all the more stunning was that it was taken despite the broad array of professional associations that had argued in favor of blinded studies and despite the admission by the Committee that 'almost all doctors we spoke to argued that in ethical terms anonymized screening was better than no screening at all'.

Not surprisingly the report met with a strong rebuke from those who believed that Great Britain's ability to track the spread of the HIV epidemic was being hobbled. In a letter to the *The Lancet* signed by nine prominent figures in the medical research community including the present and former Presidents of the Royal College of Physicians, and the President of the Royal Statistical Society, the report was criticized as neither scientifically nor ethically coherent [20]. Nevertheless, a year later, in May 1988, the Working Group on the Monitoring and Surveillance of HIV infection and AIDS, established in 1987 to advise the Chief Medical Officer at the Department of Health and Social Security on how best to track the AIDS epidemic, also rejected blinded seroprevalence studies, although on this occasion in less categorical terms [21]. Such surveillance, the report asserted, might well become necessary 'in the light of the response to, and the results of, voluntary testing and the scale of the infection'. Instead, a widely expanded program of voluntary testing for epidemiological purposes was proposed. In a suggestion reminiscent of that made by Raanan Gillon, those who refused named testing would be offered the option of anonymous testing as well as the right to refuse any testing.

Aware that this report, like its predecessor, would provoke a storm of protest from those who were increasingly dismayed by the refusal of Britain to follow the course dictated by the exigencies of the epidemic, the Minister of Health called for further debate and formal comment [22]. Within 6 months a remarkable about-face took place. By November 1988, Sir Donald Acheson, who had been so unwilling to support blinded studies, appeared before the General Medical Council arguing that it give its approval to unconsented anonymized testing. A legal opinion of the Department of Health stated that 'the Government sees no legal obstacles to such testing' [25]. In that month the government provided funds to the Medical Research Council to conduct such studies in a variety of settings [24]. A number of factors clearly contributed to this change. Data presented at the Fourth International Conference on AIDS, in Stockholm, in June 1988, provided empirical grounds for the claim that participation bias in voluntary studies fundamentally subverted the utility of such epidemiological investigations of HIV infection [2]. More importantly, the rapidly accumulating evidence of the social utility of blinded studies had made the refusal of the British authorities more difficult to justify.

In an apparent political concession to those who believed that the new studies would represent a threat to the norms that ought to govern the ethical conduct of research, the government proposed that in future studies individuals be given the right to refuse to have their blood tested for HIV, although consent for testing would not be sought. There were, however, lingering concerns that an 'opt out' provision in the context of blinded screening, which would not make explicit the right of refusal would, in fact, subvert the principle of informed consent. This position was most forcefully put by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting which declared that prior to the initiation of blinded surveillance the public be made widely aware that such studies would be undertaken and that individuals retained the right to state their blood should not be used for such purposes [23]. In the period following the government's announced intention to support blinded studies, these objections were met head on [25]. Under the proposed program, the public would be informed that whenever blood was taken for testing, some quantity might be used for anonymous HIV testing, and that the right of refusal to such testing would be respected if expressed in a 'spontaneous refusal'. As plans for widescale anonymous testing in England and Wales in genitourinary medicine clinics, among injecting drug users, hospital patients, pregnant women and newborn infants were announced in November 1989, the Department of Health prepared materials including a poster in several languages and leaflets explaining the new surveillance program. Whether such efforts will, in fact, meet the exacting demands of those who believe that no testing for HIV ought to be undertaken without a truly informed consent remains to be seen. Furthermore, only time will tell whether the provision of the right to 'spontaneous refusal' will subvert the fundamental goal of blinded studies: the elimination of participation bias in the surveillance of HIV infection.

The Netherlands

The question of whether to conduct anonymous HIV seroprevalence studies remains a matter of controversy in the Netherlands.

In February 1989, after 10 months of deliberation, the Dutch Health Council's Standing Committee on AIDS issued a recommendation to proceed with such studies [26]. The Council is an expert body empowered by statute to advise the government on matters of health. Its authority is generally undisputed, and it is widely regarded as the primary advisory body to the government on medical matters. The standing Committee on AIDS recommended that blood samples available from preg-

nant women or newborns, selected hospitals, STD clinics, and clinics for IVDUs be tested for HIV on a blinded basis and without prior informed consent. Such testing would be repeated at regular intervals.

The Committee's decision was, however, not unanimously arrived at. The majority, made up of representatives from various clinical and public health specialities (virology, immunology, internal medicine, and epidemiology) strongly favored blinded testing, citing the need to obtain data bearing on future decisions regarding the AIDS epidemic, the spread of HIV infection beyond groups already defined as high risk, and the targeting of interventions aimed at behavior change.

The minority, two out of the 10 voting members of the Committee, vigorously dissented. Reflecting the views of some lawyers and ethicists in the Netherlands regarding the absolute nature of the prohibition on the unconsented use of bodily parts, including discarded tissue samples, they asserted that in the absence of informed consent seroprevalence studies would be illegal and unethical. Citing two articles of the Dutch constitution, Article 10 which protects privacy and Article 11 which declares, 'All individuals are entitled to integrity of the human body, conditional of specific statutory exemptions', they have argued that such studies would violate rights guaranteed under Dutch fundamental law.

Professor Henriette Roscam Abbing, a Dutch health lawyer who was not a member of the Standing Committee on AIDS, has given articulate expression to the concerns of those opposed to blinded studies [27]. Citing Dutch constitutional law, the European Convention (Article 8) and the UN Covenant on Civil and Political Rights (Article 17) (Roscam Abbing to James Chin, personal communication, March 1989), she, like Ian Kennedy in Great Britain, has taken the position that under *no* circumstances can blood samples be tested without informed consent.

Precisely because of the gravity of the issues involved, Roscam Abbing—who also opposes the international guidelines on unlinked anonymous screening proposed by the World Health Organization's Global Programme on AIDS—has demanded that the proposed research meet a very high standard of social utility. And on those grounds she, like the early opponents of blinded studies in Great Britain, has not been persuaded. Indeed both Roscam Abbing and her colleagues have gone so far as to dispute the medical and scientific need for large-scale blinded HIV surveys, claiming that the spread of the epidemic was already adequately documented by existing counts of AIDS and HIV-infection levels from blood donor data. They have questioned whether in fact new data would bring about any change in existing policies regarding prevention. Furthermore, they have claimed that since anonymous screening could not document behavioral risk factors, no meaningful conclusions could be drawn from such efforts. Finally, they have warned that the proposed studies could prove counterproductive. Should such studies demonstrate low levels of HIV infection among young people, for example, they might discredit warnings about the importance of modifying sexual practices.

Three days after the issuance of the Committee's report, the Secretary of Health declared that he was not yet convinced that the recommendations of the Committee should be implemented [28].

The hesitation of the Secretary of Health to accept the recommendation of the Standing Committee on AIDS took place against a background of professional and popular support for blinded studies [29]. The Dutch National Institute of Public Health and Environmental Protection (Rijksinstituut voor Volksgezondheid en Milieuhygiene; RIVM), a division within the Ministry of Health, has advocated such studies [30]. A public opinion poll conducted just days after the committee issued its report indicated public support for such efforts by a margin of two to one. Finally, members of parliament had endorsed such investigations.

After the national elections in September 1989, the question of blinded studies was addressed by the new government. In its opinion, the information already available was adequate for the purpose of AIDS policy. Hence there was no apparent need for anonymous studies at present [31]. The National Committee Against AIDS (Nationale Commissie AIDS Bestrijding) a citizen's advisory body for AIDS policy, had earlier taken the same position [32].

The Dutch disagreement over anonymous testing must be understood in the context of public health policy in the Netherlands where public health authorities have traditionally rejected compulsory measures as overly coercive and unwarranted, preferring voluntary compliance [33]. Physicians are not, for example, required by law to report cases of AIDS. For some, the screening of existing blood samples for HIV infection without informed consent would represent an unwarranted departure from this well-accepted tradition. Furthermore, unlike the situation that prevails in United States, there are no explicit statutory provisions for blinded testing without informed consent. Indeed, there are no statutory provisions for HIV testing in any form. But the absence of statutory authorization does not mean that blinded studies without informed consent have not taken place in the Netherlands. In the past, screening of sera for epidemiologic surveillance, for example, to determine vaccination coverage in school children, or to establish levels of industrial pollutants and trace elements in population samples have been undertaken. Those studies have never aroused public debate. Nor has there been debate when available sera in hospitals were tested without informed consent to establish laboratory reference values. Opposition to blinded studies is now undoubtedly the consequence, and understandably so, of the heightened political, legal and ethical sensitivity provoked by AIDS. It is that sensitivity that has forced a confrontation between the need to obtain critically important data bearing on the public health and a public health tradition which favors voluntary compliance to obtain reliable data from medical practitioners.

Conclusions

There is carefully documented evidence about the potential contribution to the public health response to AIDS that might be made by the initiation of carefully designed, blinded seroprevalence studies [34]. Epidemiologists have spoken with virtual unanimity on the matter. Only in countries where blood samples are not collected as a routine measure will blinded seroprevalence studies have limited applicability. It is most striking that objections to the warrant for such studies have come almost exclusively from lawyers and ethicists who have, at times, sought to ground their objections on grounds of science. More pertinent are the considered objections that are based on ethical and legal principles.

In the post-World War II era, but especially over the past 2 decades, there has been a remarkable development in the area of legislative, administrative and moral standards governing the conduct scientific research on human subjects, reflecting the emergence not only of consensus within nations but within the international community as well. Although there are significant differences of emphasis among nations—even among those that share a common commitment to democratic government and liberal values designed to protect the individual—these are overshadowed by a consensus on the principle that the potential subjects of research be provided with the opportunity to refuse participation in studies that would entail some personal risk and invasion of privacy. In seeking to protect human subjects, nations have enacted codes restricting the conduct of scientists whose research undertakings might pose a threat to their rights. In some cases those codes may, because of historical accident, prohibit the conduct of blinded studies of specimens in the absence of informed consent. The exigencies of the AIDS epidemic have forced a confrontation with such restrictive codes.

The highest professional and moral commitments of public health officials in the face of the AIDS epidemic require that they undertake such measures–within the bounds dictated by reason and respect for personal dignity and integrity–that will strengthen the efforts undertaken to combat the further spread of HIV infections. It is in light of that responsibility that the contribution of blinded studies must be viewed.

But, those that propose to undertake such studies must be fully attentive to the claims now raised by the prospects for effective early intervention for those with HIV infection. It is no longer a matter of balancing the public health benefits of blinded studies against those that might be achieved in studies that would not preclude the notification of infected people. Those with HIV infection have a clear and immediate interest in knowing that fact. The ethical standards that impose upon clinicians a duty to inform their patients may increasingly seem to be in tension with the ethical and professional duty of public health officials to develop the most accurate epidemiological foundations for guiding both preventive interventions and organizing health care services. Under these circumstances it will be critically important to ensure that the subjects of blinded seroprevalence studies have access to voluntary confidential HIV antibody testing with appropriate clinical follow-up.

A model for the thorough examination of the ethical and legal issues posed by blinded studies is provided by the Federal Centre for AIDS in Canada which convened a multidisciplinary panel–the Working Group on Anonymous Unlinked HIV Seroprevalence Studies—in December 1988, comprised epidemiologists, clinicians, public health officials, lawyers, theologians, and philosophers [35]. Based upon its discussions, the Working Group recommended to the Centre that blinded seroprevalence studies be undertaken. In urging this course the report stressed that: those populations to be studied have access to individual voluntary testing under conditions of informed consent with appropriate pre- and post-test counseling; no sample size be so small as to risk the identification of individuals; research be subject to relevant review by institutional ethics committees, and the public be made aware of the research. Congnizant of the potential for stigmatization and misinformation about groups identified as being at increased risk by seroprevalence studies, the working group underscored the importance of involving, where possible, special interest groups in plans for the communication of 'potentially sensitive research results'. These are exemplary recommendations that ought to provide a sound ethical foundation for blinded studies, as European nations confront the administrative, legal and constitutional factors that will be involved in determining how to proceed with them.

The experience of those nations that have already confronted the issues posed by such research should be useful and instructive to those that have yet to resolve the problems that will inevitably arise. Thorough discussion within each nation is crucial. But the need for such discussions should not serve as a pretext for unnecessary delay. The time is long due for the full study of the epidemiology of the HIV epidemic that is so crucial to charting of effective public health strategies for controlling the AIDS epidemic and for mobilizing the clinical resources that will be necessary for treating symptomatic people as well as for the provision of prophylactic interventions for those in the early stages of the disease.

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