possible advance in cancer care but more cautious in the spending of public money. Since well conducted studies give such little support for neutron therapy as a superior or even equal treatment to conventional radiotherapy there cannot be any further justification for continuing with this ill advised venture.

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Regular Review

Monitoring the prevalence of HIV

Foundations for a programme of unlinked anonymous testing in England and Wales

This month the Department of Health has announced plans for extensive testing for HIV of unlinked anonymous blood samples taken from patients in England and Wales. This review sets out the scientific, legal, and ethical basis for such a programme.

In England and Wales by the end of October 1989 some 2717 cases of AIDS had been reported confidentially by clinicians directly to the Public Health Laboratory Service AIDS centre and 1422 of these patients were known to have died (Public Health Laboratory Service, Communicable Disease Report 1989/44). The number of persons estimated to be infected with HIV at the end of 1987 was between 20 000 and 50 000; among these another 16 000 to 40 000 will probably develop AIDS in the next 10 to 15 years.[1]

Indirect evidence suggests that the rate of HIV transmission in behaviourally vulnerable groups such as homosexual or bisexual men[2] and intravenous drug users[3] may have declined. Though transmission of HIV through heterosexual contact is probably increasing (ON Gill *et al*, International Conference on AIDS, Montreal, 1989), it is uncertain whether transmission solely by such contact will produce a self sustaining HIV epidemic throughout the whole or parts of heterosexually active society in England and Wales.[4] Such uncertainties about a major epidemic of largely fatal infection make it imperative that surveillance methods be reviewed regularly.

Present methods

At present in England and Wales serosurveillance for HIV infection relies on aggregating data collected as a byproduct of case finding by using either the named[3 5-9] or mandatory[10] test methods (table). The informed consent of the patient is required in all but the most exceptional circumstances before testing a named specimen for HIV in all but the most exceptional circumstances (General Medical Council statement "HIV infection and AIDS: the ethical considerations," May, 1988). The mandatory tests of blood donors are also named, but donors can choose not to give blood and people at special risk behaviourally have since 1983 been encouraged not to donate (National Blood Transfusion Service leaflet "AIDS and how it concerns blood donors").

Serosurveillance for HIV should aim at obtaining unbiased estimates of the change in the prevalence of infection with time and by age, sex, place, and exposure category. Two forms of bias affect the interpretation of this type of case finding data.[18] Firstly, participation bias occurs when members of the study population differ in an important way from non-participants; for example, it affects universal named case-finding programmes.[9] Secondly, selection bias occurs when the study population is not representative of the population for which conclusions from the study are to be drawn; mandatory screening of blood donors is particularly

Approaches to HIV serosurveillance

Objective	Methods	Bias		Examples
		Participation	Selection	
Case finding*	Selective named	+	±	Laboratory reports of HIV infection,[3 5 6] ad hoc studies,[7] PHLS collaborative laboratory study of HIV tests[8]
	Universal named	++	±	PHLS collaborative study of patients attending clinics for sexually transmitted diseases[9]
	Linked anonymous	++	±	Alternative site HIV testing programme[11] (J C Grabau *et al*, International Conference on AIDS, Stockholm, 1988)
	Mandatory		++	Blood donor screening[10]
Prevalence monitoring	Unlinked anonymous		±	Studies conducted in London[12-16] (R S Tedder *et al*, International conference on AIDS, Montreal, 1989)
	Unlinked anonymous: voluntary**	±	±	Needle exchange project in central London[17]

* All case finding methods are voluntary.
** If a special specimen is collected (for example, saliva) then the study method must be voluntary.

prone to selection bias if used to infer the situation in the total population.[10] Therefore currently available serological data are flawed and potentially highly misleading. Scientists have repeatedly called for the introduction of an "unlinked anonymous" serosurveillance programme in England and Wales[1 19-21] comparable with that in the United States.[23 24]

The case for the unlinked anonymous method

Unlinked anonymous testing for HIV refers to the further sampling of sera from blood specimens voluntarily collected from patients for necessary laboratory tests. Personal identifiers are irreversibly removed from the sample and it is then tested for HIV infection without the consent of the patient from whom the material originated being sought.[24] When a survey design requires that a specimen be collected specifically for HIV testing, such as saliva from intravenous drug users,[17] then the voluntary variant of the unlinked anonymous test method is used, whereby the consent of the person is sought. In either case the patient's identity is unlinked from the specimen and the patient can never be identified by either the scientists conducting the HIV tests or the epidemiologists appraising the aggregate results.

The evidence shows that whenever HIV is present the prevalence found by unlinked anonymous testing tends to be much greater than that shown by named testing of the same population. In 1987 a New Mexico clinic for sexually transmitted diseases evaluated a universal named HIV case finding programme; four fifths of patients accepted named testing, and unlinked anonymous tests were conducted on the remainder.[25] The prevalence of HIV in those who had a named test was 0·7%; this was five times lower than the 3·8% prevalence in the remainder. In homosexual men in London the prevalence of infection found in a named testing programme was less than half of the 25% found in the same population when studied unlinked and anonymously.[12-14] In the United States unlinked anonymous sentinel hospital study of people admitted to hospital for reasons unrelated to HIV infection the prevalence of HIV infection in the first 18 809 tests was 0·3%[26]; in the same, mostly midwestern cities the rate in military recruitment applicants was between a quarter and a third of that in the hospital patients. Of 73 infections found in four unlinked anonymous studies in New York and New Jersey of pregnant women, only 20 were identified in concurrent named case finding programmes (R Sperling *et al*, E Conor *et al*, International Conference on AIDS, Stockholm, 1988).[27 28]

The unlinked anonymous technique overcomes the problem of participation bias except when the survey design requires that the voluntary variant be used (table). The extent of selection bias with the unlinked anonymous approach depends on the target population chosen and the population groups to which the results are applied. Furthermore, if the intention is to monitor accurately prevalence of HIV in a vulnerable sentinel group and not to extrapolate directly to the total population then the problem of selection bias can be minimised.

Future measurement of change in the proportions infected with HIV in particular subgroups of the total population, when the rate of change may be small, requires that the monitoring surveys must be sufficiently large, sustained, and unbiased to provide a robust estimate of the change. If the necessary HIV surveys use the universal named case finding method they will be complex, expensive, and subject to participation bias. They may cause considerable and avoidable distress in populations with very low prevalence.[29] On the other hand the unlinked anonymous method will provide unbiased results over many years, may be introduced relatively cheaply, and may be extended geographically as the HIV epidemic unfolds.

Principles of the method

Increasing experience of unlinked anonymous surveys in both North America[30-32] and England (R S Tedder *et al*, International Conference on AIDS, Montreal 1989)[12-16] has established some principles as vital (box). The blood specimens that are used must have been taken with the patient's consent for clinically necessary laboratory tests unconnected with HIV. Only the usual amount of blood should have been collected, and the satisfactory conduct of the original laboratory test should not have been compromised in any way. Personal identifiers must be irreversibly removed before the specimens are tested for HIV.

Principles of the unlinked anonymous method

- Necessary clinical specimens of usual amount
- Original clinical test not compromised
- Unlinked and made anonymous before HIV test
- Restricted data set to prevent indirect identification
- Access to named HIV testing for target population
- Valid study design

Information such as sex and exposure category (if known) may accompany the unlinked anonymous specimen, but the possibility of indirectly identifying people infected with HIV must be eliminated by ensuring that this information is not too discriminating—for example, an age group should be used rather than specific age in years. In this way even the smallest data cells will contain sufficient people to make the likelihood of finding all with particular characteristics to be infected extremely remote. In the family of surveys coordinated by the Centers for Disease Control in the United States, over 200 000 specimens have been tested in 31 states by using the unlinked anonymous method by the end of September 1989 without a single report of results being indirectly linked to individuals (T J Dondero, personal communication).

Members of the target population must also have ready access to a named HIV testing service that includes proper counselling before and after testing. Such a service exists throughout England and Wales. Finally, the survey design must be capable of achieving the stated objectives: in particular, if the objective is to monitor prevalence then the survey must be sufficiently large and sustained to provide a reliable answer.

Proposed programme

The Medical Research Council has proposed a range of unlinked anonymous HIV serosurveys appropriate for both the current stage of the epidemic and the pattern of health care delivery in England and Wales (box). These surveys are to be coordinated by the Public Health Laboratory Service AIDS centre and the academic department of genitourinary medicine, University College and Middlesex School of Medicine, which together form the Medical Research Council

Unlinked anonymous monitoring of HIV prevalence, 1990 onwards

Vulnerable sentinel groups

- Attenders at genitourinary clinics
- Injecting drug users

Less vulnerable groups

- General hospital inpatients and attenders (in selected diagnostic categories)
- Women undergoing termination of pregnancy
- Pregnant women and newborn infants

United Kingdom centres for coordinating epidemiological studies of AIDS and HIV.

The aim of the proposed programme is to provide estimates of the prevalence of HIV infection in the population and in particular the rate of change of the prevalence estimates over time. The value of such information is twofold: firstly, to identify the sections of the population in which appreciable transmission is taking place, better to target primary prevention campaigns; and secondly, to improve the accuracy with which predictions can be made of the future course of the epidemic[1] and so of the need for health care resources. For both purposes the value of the monitoring programme will be enhanced if changing prevalence is estimated within behaviourally vulnerable groups of the population. The programme therefore aims to determine the rate of transmission among homosexual or bisexual men, among injecting drug users, and by means of heterosexual contact as well as providing an overall range for the number of people infected with HIV in the population. There is also great geographical variation in the extent of the HIV epidemic, which the prevalence monitoring programme is designed to capture. In the initial phases geographical stratification will be limited to inner London, outer London, the rest of the four Thames regions, and the rest of England and Wales.

To interpret trends in the prevalence of HIV in patients attending genitourinary medicine clinics data on supplementary risk factors will be needed. A study design has been developed that does not compromise the unlinked anonymous method and that will allow critical pieces of information to be retained, such as age group, sex, sexual orientation, use of drugs by injection, and broad clinical diagnosis. Saliva or urine specimens, or both, and limited risk factor data will be collected voluntarily from injecting drug users in a variety of settings such as drug dependency units, needle exchange centres, and street agencies, then unlinked and made anonymous.

Because those already infected with HIV develop clinical illness and attend hospital in increasing numbers, testing all hospital patients will become of limited value for monitoring prevalence in the community. Therefore tests will be limited to specimens from an age weighted sample of patients in certain diagnostic categories not associated with HIV infection and from women undergoing termination of pregnancy.

Pregnant women are a stable subgroup of the total heterosexually active population, and the trend in HIV infection in pregnant women should mirror that in the heterosexual population. For an interim period two approaches will be used to study this. Antenatal specimens drawn for rubella serology[33,34] and dried blood spots from Guthrie card specimens collected from newborn infants (R S Tedder *et al*, International Conference on AIDS, Montreal, 1989) will be unlinked, made anonymous, and tested for HIV.

Available data suggests that the prevalence of HIV infection in heterosexual women in inner London may be between 0·1% and 0·5% (R S Tedder *et al*, International Conference on AIDS, Montreal, 1989).[8,9,12-16,35] If the observed prevalence were 0·1% in a sample of 30 000 then the 95% confidence interval would be 0·06% to 0·14%. Furthermore, if the same sample size were studied the following year the minimum prevalence that could be said confidently to represent a real increase from 0·1% would be 0·18%—almost double. Outside London the prevalence of HIV infection in heterosexual women may well be 0·01% or lower. It follows that monitoring HIV infection in populations with low prevalence will require very many specimens and a multicentre effort.

Legal and ethical basis

The World Health Organisation's global programme on AIDS considers unlinked anonymous surveys both to be "consistent with existing global guidelines on human rights in biomedical research" and to be a useful technique for providing accurate HIV surveillance data.[18] In the United States the Government Office for Protection from Research Risks has determined that "the public health interest in obtaining valuable epidemiological data can best be served by the anonymous testing methods that do not retain individual identifiers" (C R McCarthy, memorandum to Public Health Service AIDS Coordinator, 6 February 1988), and a comprehensive range of unlinked anonymous HIV serosurveys[22,23] is under way.[30-32] The National Gay and Lesbian Task Force in Washington supports this programme.[36]

In November 1988 the British government stated that it saw no legal or ethical objection to unlinked anonymous surveys (Department of Health, press release "Government announces new steps to monitor the spread of HIV infection," 23 November 1988). The legal advice given to the Department of Health is that provided the patient's blood is used for the original test for which consent was obtained it is unnecessary to tell patients (either individually or through a public notice in a clinic) that any blood residue might be tested unlinked and anonymously. This is also the view of medical defence societies in Britain (Defence Societies Joint Coordinating Committee, correspondence with Public Health Laboratory Service AIDS centre, 1989).

Should a patient spontaneously object to the possibility of his or her blood specimen residue being tested in this way that wish must be respected, and survey protocols will make provision for this eventuality. Some of the surveys in the United States were also designed to respect spontaneous objections, particularly in clinics for university students, but a negligible number of patients have exercised this right (T J Dondero, personal communication). Furthermore, refusal of a named HIV test after pretest counselling as part of a case finding programme does not legally equate with spontaneously objecting to an unlinked anonymous test.

The Association of British Insurers has provided the reassurance that there is no need when completing life assurance forms for proposers to speculate whether the residue of a blood specimen of theirs was ever unlinked and anonymously tested for HIV (Association of British Insurers, correspondence with the Public Health Laboratory Service AIDS centre, 1989).

No fundamental ethical principle is breached by unlinked anonymous HIV testing, according to the standards committee of the General Medical Council (Standards Committee, General Medical Council, correspondence with Medical

Research Council, 1989). The Medical Research Council considers unlinked anonymous HIV testing to be ethically justifiable, and the BMA has consistently supported this approach to monitoring HIV prevalence.[37] Public health physicians welcomed the government announcement that anonymous testing was to begin on a mass scale (Faculty of Community Medicine of the Royal Colleges of Physicians, press statement, December 1988) and the Health Education Authority believes that such an HIV serosurveillance programme is the most acceptable way to meet the current public health need (Health Education Authority, position statement on testing and screening for HIV infection, October 1988).

Each of the published unlinked anonymous HIV prevalence studies in England successfully obtained ethical committee approval before beginning (R S Tedder *et al*, International Conference on AIDS, Montreal, 1989),[12-16] some as early as 1984.[12-14] Since the government announcement in November 1988 several district ethical committees have been approached (as part of the pilot phase of the HIV prevalence monitoring programme) and have given approval to the proposals.

After careful consideration and critical examination of the proposals both the United Kingdom Central Council for Nursing, Midwifery, and Health Visiting and the Royal College of Midwives have supported the current plans. The United Kingdom Central Council recently issued specific advice and guidance (United Kingdom Central Council for Nursing, Midwifery, and Health Visiting, "Annonymous testing for the prevalence of the human immunodeficiency virus," October 1989). Central to the consensus that has been reached is the acceptance that members of the public must be made aware that, whenever they have a blood sample taken, any leftover blood may be used for unlinked anonymous HIV testing. Patients must also know that the survey designs include the requirement to respect the wishes of those who spontaneously object to this test method. Accordingly the Department of Health has prepared material, including a poster in different languages and explanatory leaflets, directed at both the general public and health professionals, and these will be made available widely after a national launch in November 1989. Results presented at regular intervals will serve as a reminder of the progress of the programme.

Conclusion

The implementation of an HIV prevalence monitoring programme with the unlinked anonymous test method will be an important step towards improving our understanding of the evolving epidemic in England and Wales. More accurate knowledge of the rate of progress of the epidemic in the total population and in subgroups will allow preventive resources to be targeted more effectively and efficiently. As the benefits of actively managing asymptomatic HIV infection become clearer[38-41] the need for unlinked anonymous surveys, which show the total numbers who could benefit, becomes greater. Doctors can support the programme by thoroughly understanding the unlinked anonymous test method and by providing reassurance about the programme to their patients when the need arises.

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