THE NEW ZEALAND MEDICAL JOURNAL

11 August 1993
Volume 106
No 961

Unlinked anonymous monitoring of HIV prevalence at sexually transmitted disease clinics

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Abstract

Aim. To determine the prevalence of HIV infection among patients attending the four sexually transmitted disease (STD) clinics in two metropolitan areas of New Zealand.

Methods. The population studied comprised everyone who attended between August 1991 and August 1992 because of concern about a possible new episode of an STD and who had a blood specimen taken for hepatitis B (or syphilis) serology. The study involved unlinked anonymous testing of left-over blood specimens, following ethical guidelines that have been proposed internationally.

Results. Among 8478 specimens tested, 23 (2.7 per 1000) were found to be HIV positive. The seroprevalence rates per 1000 among women, heterosexual men, and homosexual or bisexual men were 1.1, 1.3, and 44, respectively. All but five of the infected people were either known to be HIV positive or had an identifiable test during their clinic attendance.

Conclusions. The seroprevalence rates are similar to those reported from STD clinics in England, and suggest that heterosexual transmission of HIV infection has not yet been extensive in New Zealand.

NZ Med J 1993;106: 325-7

From a global perspective, the HIV/AIDS pandemic is predominantly affecting heterosexually active people and their children.[1] In New Zealand as in many other developed countries, however, the pattern has been different with the majority of people with AIDS being men who have had sex with men.[2] Up to 30 September 1992, 304 (87%) of the 348 people notified were known to be in this category (seven of these had also injected drugs).[3] In monitoring the epidemic, it is vital to determine the extent to which HIV infection is spreading to other groups such as heterosexuals and injecting drug users. For this purpose the registering of AIDS cases is of limited value, because there is usually a long delay (median about 10 years) between infection with HIV and development of AIDS.[4]

The very low overall prevalence of HIV infection in the community means that it is necessary to study sentinel populations into which HIV might be expected to spread early. Informed consent is required if blood specimens from identifiable individuals are to be tested for HIV. Numerous studies have shown that surveillance based on identifiable testing with informed consent gives a misleading picture, because people who agree to participate generally have a lower prevalence of infection than those who decline.[5-7] The World Health Organisation has therefore recommended unlinked anonymous monitoring of HIV prevalence using left-over blood specimens collected for other purposes.[8] The present study is the first such survey in New Zealand, conducted in sexually transmitted disease (STD) clinics whose clients are likely to have been practising sexual behaviours that might put them at risk of HIV infection. The main aims were to assess the suitability of STD clinics for sentinel surveillance in New Zealand, and to obtain baseline results for comparison with future surveys.

Methods

The project involved the three STD clinics in the Auckland region (Auckland City, Manukau City, and West Auckland) and the one in Christchurch. The population studied comprised all patients who attended between 12 August 1991 and 11 August 1992 because of concern about a possible new episode of an STD and who had a blood specimen taken for hepatitis B (or syphilis) serology. Patients were excluded if they were attending solely for HIV testing, or if they had already had blood taken for hepatitis B (or syphilis) serology at the same clinic during the survey period. Thus each person was eligible for inclusion only once. Patients attending the clinics were offered voluntary HIV testing, with appropriate counselling, but this was entirely separate from the unlinked anonymous monitoring.

The research nurse in each clinic identified potentially eligible subjects and attached data collection forms to their notes. Each form included a unique number, printed on the form and on a detachable self-adhesive label. The numbers were completely obscured by silver scratch-off material (as used on some lottery tickets). When blood was taken, the specimens required for clinical purposes were placed in the appropriate tubes and a residual aliquot of up to 2mL was placed in a separate tube for HIV serology. (In Christchurch this was done by the research nurse, whereas in Auckland it was done on receipt of the specimen at the laboratory which was also performing the hepatitis B serology.) The bottom part of the data collection form, which carried only the detachable self-adhesive label (with number still obscured), was sent with the blood specimen to the laboratory in Auckland. The remainder of the form was used for recording coded information about gender, ethnic origin, age group, sexual behaviour as reported by subjects (including any history among males of ever having sex with men), any history of ever having injected drugs, any history of ever having sexual contact overseas, whether the subject was known to be HIV positive, whether an identifiable test for HIV infection was carried out, and the diagnostic groups. Up to four diagnoses could be coded. All of this information was already being recorded in the notes for clinical purposes, and the research nurse abstracted it after the consultation. The information was collected in broad categories so that it would not be possible for the identity of individuals to be deduced. The completed data collection forms were sent to the coordinating centre in Dunedin, with their numbers still obscured.

At the laboratory, tubes with obscured numbers attached were stored in boxes of at least 20 specimens. Before testing, each tube was labelled with a laboratory number and the detachable label

(with number still obscured) was stuck to a reporting sheet, alongside a duplicate of the laboratory number. Laboratory staff were instructed not to test a sample if any of the scratch-off material had been removed, and they signed each reporting sheet to confirm this.

Serum was separated under a laminar flow hood using aseptic procedures. The serum specimens were frozen at below -20°C before being tested in batches. They were screened for HIV-1 and HIV-2 on automated equipment, using a recombinant HIV-1/HIV-2 enzyme immunoassay (Abbott Diagnostic Division). Those found to be reactive were re-tested twice using the same kit. If either of the repeat tests was again reactive, the sample was sent for confirmatory testing using the Western blot technique.

The test results were written on the reporting sheets, which were sent to the coordinating centre in Dunedin (where it was again checked that no numbers had been revealed). At the coordinating centre, the scratch-off material was removed from both the data collection forms and the laboratory reporting sheets. The data were entered into separate files on a microcomputer, which were analysed after matching the study numbers.

Ethical considerations. Ethical approval was received from the Auckland and Canterbury Area Health Board ethics committees. All procedures were carefully designed to guarantee that individuals with positive test results could not be identified. Any patient who spontaneously objected was not to be tested. The protocol provided for a notice to be displayed in each clinic, informing people that unlinked anonymous testing was being performed. One of the ethics committees recommended against such a notice, on ethical grounds. In their view, because no harm could be done to any individual and because the public good required full participation, any measure that might decrease participation was counter-productive. After a few months this decision attracted criticism in the news media; since experience in the other centre had shown that the displaying of a notice did not reduce participation, the ethics committee agreed to reverse its earlier decision and signs were displayed. Before the study commenced, information about it was disseminated through the news media and the ethical issues were discussed on radio and in newspapers.

Results

Data collection forms were completed for 8592 eligible patients. Only one person spontaneously objected to the blood test, and this was at the clinic which was not displaying a notice at the time. Six blood samples were not tested because the study number had been partly revealed by the time the specimen reached the laboratory. In another 107 cases, blood was not tested because there was insufficient serum (92) or because the tube was broken (3) or mislabelled (12). Thus results were available for 8478 people. Analysis of the demographic and behavioural information showed no significant difference between the people who were not tested and the remainder.

The sex and age groups of the 8478 people tested are shown in Table 1. The patients had a wide variety of clinical diagnoses, with the commonest being genital warts (in 17.4% of patients), nonspecific urethritis or cervicitis (11.9%), and chlamydial infection (11.7%).

In 40 cases, the initial and repeat screens for HIV were positive, so confirmatory tests were performed. The results were positive for HIV in 23 cases and indeterminate in one. The latter subject was classified as seronegative, so the overall number of people found to be HIV positive was 23 out of 8 478 (2.7 per 1000; 95% confidence interval (CI) 1.7 - 4.1). In 22 cases, the antibody detected was to HIV-1, but in one case it was to HIV-2. In Auckland the number seropositive was 20 out of 6 371 (3.1 per 1000), while in Christchurch it was 3 out of 2 087 (1.4 per 1000). These seroprevalence rates were not significantly different (χ^2 = 1.66; p = 0.2).

Table 1 - Characteristics of the 8 478 people tested

Age group (years)	Male	Female	Sex not recorded	Total
<15	11	42	-	53
15- 19	684	1084	-	1768
20- 24	1486	1093	-	2579
25 - 29	1066	572	1	1639
30- 39	1010	618	-	1628
40 - 49	365	190	-	555
50- 59	186	59	-	245
Not recorded	-	2	9	11
Total	4808	3660	10	8478

Women. Of 3660 females tested, four were HIV positive. The seroprevalence rate was 1.1 per 1000 (95% confidence interval 0.30 - 2.8). All of the affected women described themselves as heterosexual. Three denied ever having injected drugs, while such information was not available for the other woman. Thus none of the 151 women known to have injected drugs was infected.

Ethnic origin was coded in four categories: European (2 819 women), Maori (442), Pacific Islander (201), and other (183). Three of the infected women were in the last category, while the remaining case was one of 15 women for whom the ethnic group was not recorded. Hence none of the women known to be of European, Maori, or Pacific Island origin was found to be infected. All four of the infected women had had sexual contact overseas at some time.

Heterosexual men. Of 4486 males who described themselves as heterosexual, six were HIV positive. The seroprevalence rate was 1.3 per 1000 (95% CI 0.49 - 2.9). Two of these six men reported homosexual activity at some time in the past, and one of the two had also injected drugs. Altogether two of 208 heterosexual men who were known to have injected drugs were infected.

The six heterosexual men included three of European origin and three in the other category (ie. not Maori or Pacific Islanders). Four had had sexual contact overseas (including both of the injecting drug users).

Homosexual and bisexual men. Of 295 males who described themselves as homosexual or bisexual, 13 were HIV positive. The seroprevalence rate was 44 per 1000 (95% CI 23.5 - 75.4). One of the infected men reported having injected drugs (out of a total of 20 homosexual or bisexual men in this category).

Twelve of the infected men were of European origin, while one was Maori. Among 125 homosexual or bisexual men who reported having had sexual contact overseas at some time, six (48 per 1000) were infected; the corresponding number among 155 men who had had no such contact was five (32 per 1000). These seroprevalence rates were not significantly different (χ^2 = 0.45; p = 0.5). For the other two infected men, this information was not available.

Remaining subjects. For 10 samples the gender of the subject was not recorded, and for 27 men their sexual behaviour was not categorised. None of these people was found to be infected.

Discussion

Unlinked anonymous monitoring of the prevalence of HIV infection is not directed to the individual, but has as its objective the public health surveillance of HIV infection.[8] It is an epidemiological approach for determining HIV prevalence in selected populations with the minimum of participation bias. This is now regarded as the method of choice for HIV serological surveillance, which can provide information essential for monitoring the epidemic, for designing and evaluating preventive programmes, and for planning and obtaining adequate resources for health care and social services.[9]

There has been extensive experience with unlinked anonymous monitoring in the United States since 1986,[10] and in Britain since 1988.[5] Groups surveyed have included people attending STD clinics, injecting drug users, women attending antenatal clinics, newborn infants, hospital patients, university students, and prisoners.[11] Whereas the approach was quickly accepted as an appropriate and necessary tool for assisting control of the epidemic in the United States, widespread implementation in Britain was initially delayed while the scientific, ethical, and legal issues were debated. A consensus emerged and in November 1988 the British government concluded that there was no legal or ethical objection to unlinked

anonymous surveys.[5] In recommending the approach, the World Health Organisation advised that it was consistent with existing global guidelines on human rights in biomedical research.[8] This conclusion has been confirmed in international guidelines for ethical review of epidemiological studies.[12]

The ethical issues have also been analysed by a New Zealand bioethicist, who concluded that anonymous surveillance (without consent) is ethical in that there is no potential harm to the individual and the knowledge gained will be beneficial to the community.[13,14] The plans for this study were widely publicised and attracted little criticism. Only one person spontaneously objected to being included. After a few months, however, there was some criticism of the study in the news media - particularly in regard to the recommendation of one ethics committee that notices should not be displayed in clinics. This controversy prompted a further review of the issues by a medico-legal expert who concluded that, provided appropriate precautions were in place to ensure that the study was truly anonymous, it would be most unfortunate if a potentially valuable epidemiological survey were to be frustrated by ill-founded ethical and legal concerns.[15] The methods were in fact carefully designed to guarantee anonymity, in the light of international guidelines proposed for this kind of surveillance.[8]

Sexually transmitted diseases are known to be important cofactors for HIV transmission.[16] The main reason for choosing STD clinics as the setting for this first New Zealand survey, however, was that their clients are likely to have been practising sexual behaviours that might put them at risk of HIV infection. In particular, surveillance in STD clinics should give an early warning of heterosexual transmission. In this respect, the most important group to study are women - since one can be certain that they have not practised male homosexual behaviours. The estimated prevalence among women attending Auckland or Christchurch STD clinics (1.1 per 1000; 95% confidence interval 0.29 - 2.8), was not significantly different from that reported for women attending STD clinics in London (2.3 per 1000) or outside London (0.49 per 1000) in 1990.[17] The prevalence was similar among heterosexual men, but much higher (44 per 1000) among men known to be homosexual or bisexual. The latter finding may be compared with the prevalence among homosexual or bisexual men attending STD clinics in London (206 per 1 000) or outside London (35 per 1000).[17]

The appreciable number of screening tests that were found on confirmatory testing to be false positive results would be expected in a population where the prevalence of infection is low. The relatively low prevalence among women and heterosexual men suggests that heterosexual transmission of HIV infection has not yet been extensive in New Zealand. This conclusion is strengthened by the observation that all four of the infected women reported sexual contact overseas, and at least three were not of European, Maori, or Pacific Island origin. While our results are encouraging, it could be tragic if they led to complacency. Surveillance in STD clinics might be expected to miss the group of New Zealand women who are most likely to have been infected so far - the partners of bisexual men. Heterosexual transmission is now rampant in a number of countries with which New Zealand has close links, particularly Thailand.[18] Consideration of the transmission dynamics of HIV infection suggests that it is still too early to predict whether a significant heterosexual epidemic could occur in countries like New Zealand.[19] A survey of sexual behaviour in New Zealand 18 year olds found numbers of sexual partners that could be consistent with development of a self sustaining heterosexual epidemic among young people.[20]

Apart from their public health significance, surveys of this kind are clinically useful in assessing both the need for identifiable testing and the adequacy of current practice in this respect. Among the 8592 patients for whom data collection forms were completed, 1882 (22%) were recorded as having an identifiable HIV test. Of the 23 found to be infected in our survey, all but five were either known to be HIV positive or had an identifiable test during their clinic attendance. The five who apparently would have been missed were all men who denied having injected drugs: three were recorded as homosexual or bisexual, while one of the other two reported homosexual activity in the past.

This study has shown that STD clinics are a suitable setting for sentinel surveillance of HIV infection in New Zealand. The AIDS epidemiology group has also been conducting surveillance among injecting drug users in six cities: because these people do not routinely have blood taken for other purposes, it has been necessary to use voluntary saliva testing which is more likely to be affected by participation bias. Consideration has also been given to unlinked anonymous monitoring among other groups, such as pregnant women or newborn babies (using the dried blood spots collected for neonatal screening).[21] While pregnant women should continue to be counselled and tested as appropriate, we do not believe that unlinked anonymous monitoring of these groups would be warranted in New Zealand until the HIV prevalence among women attending STD clinics becomes more appreciable. Our results should provide a good baseline for future surveys, and we recommend that this study should be repeated (perhaps with inclusion of further centres) within three years.

Acknowledgements. This study was supported by the Health Research Council of New Zealand. We thank Colette Noordanus and Anne Wintle for their work in the clinics, all of the other clinic staff, and Marjorie Bridle, Warren Kertell, and Denis Yep for laboratory work.
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