

# Unlinked anonymous HIV study of hospital patients and general practice attenders in Glasgow, 1991-1997

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## Abstract

**Aim**—To determine whether HIV is spreading from injecting drug users and homosexual/bisexual males into lower risk heterosexual populations in Glasgow, Scotland, and to pilot a method of monitoring HIV prevalence which involves testing routine biochemistry specimens.

**Methods**—An unlinked anonymous HIV testing study of hospital patients and general practice attenders was conducted during January 1992 to December 1997. Testing was performed on routine biochemistry specimens from patients aged 16-49 years attending two hospitals with catchment areas covering the north and the east of the city.

**Results**—78 260 specimens were tested in the study period and no patient objected to their samples being tested anonymously. HIV prevalence rates among male and female subjects were 0.63% and 0.01%, respectively; the large difference in prevalence resulted, in part, from the inclusion of HIV infected haemophiliac patients who attended one of the hospitals. Prevalence among male general practice patients ranged between 0.1% and 0.2%, while that for male patients attending surgical or surgically related specialties was 0.1%.

**Conclusions**—The prevalence data indicate that HIV has not seeded from the high risk groups into the wider heterosexual population, and that the risk of a surgeon acquiring HIV occupationally is extremely low in a city which has an HIV prevalence similar to or greater than that seen in most other parts of the United Kingdom. Large numbers of residual specimens from busy biochemistry laboratories can be processed for unlinked anonymous testing without interfering with the laboratories' routine functions. This survey approach might be best suited to monitoring HIV trends in developing countries with relatively high prevalence rates and where transmission is principally heterosexual.

(*J Clin Pathol* 2000;53:117-121)

Keywords: HIV prevalence; routine biochemistry; anonymous testing

In January 1990, the United Kingdom Departments of Health approved the concept of unlinked anonymous HIV testing<sup>1</sup> and thereaf-

ter the Communicable Disease Surveillance Centre for England and Wales and the Scottish Centre for Infection and Environmental Health (SCIEH) for Scotland established a programme of surveys designed to monitor the prevalence of HIV infection among high and low risk group populations.<sup>2,3</sup> Included in this programme was the testing of dried blood spots from neonatal metabolic screening (Guthrie) cards and syphilis serology specimens from attenders at genitourinary medicine clinics; the former study would enable HIV prevalence to be monitored in a general population group of childbearing women, while the latter would do so in the higher risk groups of male and female heterosexuals and male homosexuals/bisexuals who had presented with a sexually transmitted disease problem.

In Scotland, the HIV epidemic had been characterised by large numbers of male and female injecting drug users in Edinburgh and Dundee becoming HIV infected during the early to mid-1980s,<sup>4</sup> and prevalence rates of 51%<sup>5</sup> and 39%,<sup>6</sup> respectively, had been recorded in each city. By 1990, there was evidence of increasing numbers of infections in non-injecting heterosexuals who had had injecting sexual partners, and thus HIV appeared to be spreading into the more general population.<sup>7</sup> The unlinked anonymous programme would monitor the extent of this spread. To determine whether HIV was seeding into the lower risk male heterosexual population in particular, it was decided to perform unlinked anonymous HIV testing of specimens from hospital patients and general practice attenders. The study would be piloted in Glasgow, which had experienced less HIV spread than that seen in the east of Scotland,<sup>4</sup> and if successful would be extended to other centres.

## Methods

### SETTING, SAMPLING, AND ELIGIBILITY CRITERIA

From January 1992, unlinked anonymous HIV testing was performed on residual sera from specimens sent for routine urea and electrolyte biochemistry testing to laboratories at the Glasgow Royal Infirmary (GRI) and Stobhill General Hospital (STOB), which cover a 500 000 population in the northern and eastern sectors of Glasgow. GRI is also the west of Scotland centre for the care of haemophiliacs and a specialist centre for cardiac surgery, including transplantation. Both hospitals provided a comprehensive range of services for

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Accepted for publication 6 July 1999

adults attending as inpatients and outpatients, and both laboratories served all general practices in the catchment population. The hospitals were chosen because HIV was more prevalent in their catchment areas than elsewhere in Glasgow and as both laboratories had the necessary computing facilities and expertise to carry out the study successfully.

Specimens eligible for HIV testing were from hospital inpatients, outpatients, and general practice attenders aged 16–49 years. While it was recognised that data on the prevalence of HIV among the lower risk female population were already being obtained through the anonymous HIV testing of neonates, the investigators decided to include female patients during the early stages of the study at least. Repeat specimens submitted within 90 days of receiving the initial sample were excluded and specimens were ineligible for testing if the accompanying laboratory request form indicated that the patient had either objected to unlinked anonymous testing, or was confused or in a coma. Such decisions not to allow testing were made possible by ensuring that patients in all appropriate clinical settings were aware of the survey through the distribution of posters and leaflets. Also excluded were specimens from the accident and emergency departments (insufficient details to identify repeat samples), local prisons (small numbers), genitourinary clinics (studies on this group already being performed), and biochemistry studies/clinical trials (consent having been given for study purposes only). Ethical permission was obtained from each hospital's ethics committee.

#### SELECTION OF SAMPLES AND INFORMATION COLLECTED

From an archive file on the GRI laboratory's mainframe, records on patients aged 16–49 years and of known sex were selected. A search on the clinical history field of each record was performed so that records corresponding to patients who had objected to HIV testing or who were unable to object owing to confusion or coma could be excluded. If the clinical history field indicated that the patient was HIV positive, this information was also recorded. From the file, selected data items from each record were transferred to a database held on a personal computer; these data comprised the laboratory number of the specimen, name (first four characters of surname plus initial of forename), date of birth, sex, source of sample (that is, clinical specialty grouping, see below), and the date the sample was taken from the patient. A search based on the patient's name, sex, and date of birth was performed on records to eliminate repeat specimens submitted over a rolling 90 day period.

A seven digit code indicating five year age band, sex, hospital, and source of sample, plus the year and the calendar quarter in which the specimen was taken, was derived for each sample. By restricting the amount of data which would be linked to an HIV test result, patient anonymity was ensured and any possibility of deducing the identity of the original specimen

was eliminated. Unfortunately, it was not possible to collect risk category information as this was not recorded routinely on the patient's request form. At the STOB laboratory, the mainframe computer was capable of performing all the processing up to this point.

A sheet of labels was generated in laboratory number order, listing the code adjacent to the corresponding number. In each laboratory, the selected samples had been analysed by the instruments which measured urea and electrolytes, bone biochemistry, liver function tests, and cardiac enzymes. Once the residual specimens were located, an aliquot of serum from each specimen was decanted into a 2.5 ml Sarstedt vial, on to which the appropriate coded label was transferred. Vials containing sera from patients known to be HIV positive were marked with a pen. The sheets bearing the laboratory numbers were then shredded and the samples were boxed randomly. A worksheet of codes, not in any sequential laboratory number order, was sent with the samples to the Regional Virus Laboratory and a file of codes was sent on disk to SCIEH for subsequent linkage with HIV antibody test results from the Regional Virus Laboratory.

#### SOURCE OF SAMPLE (CLINICAL SPECIALTY)

As information on clinical diagnosis was unreliable, data were linked to the clinical specialty to which the patient belonged when the specimen was taken. The following specialty groupings were identified: (a) cardiology/cardiac and other vascular surgery; (b) general surgery/ENT/plastic surgery; (c) general medical inpatients; (d) general medical outpatients; (e) general practice patients; (f) haematology, oncology; dermatology, and respiratory medicine; (g) psychiatry; (h) renal medicine/urology; and (i) rheumatology/orthopaedics.

All groups except (c), (d), and (e) included both inpatients and outpatients. Group (f) comprised specialties in which the investigators considered that HIV infected persons might present for treatment. Otherwise, the categorisation was based on connections between specialties and on the numbers of specimens generated by each specialty. Haemophiliacs comprised an appreciable number of patients in the general medical inpatient and outpatient groups.

#### HIV ANTIBODY TESTING

Serum specimens were sent to the Regional Virus Laboratory, where they were screened for HIV antibodies using a modified particle agglutination test<sup>8</sup> (Serodia, Fujirebio MAST Diagnostics). Reactive specimens were retested with an HIV-1+2 enzyme linked immunosorbent assay (ELISA) (Abbott 3rd Generation); results were confirmed using western blot (Cambridge Biotech, Organon).

#### DATA ANALYSIS

Data were analysed using Dataease software, and specimens were classified on testing as negative, known positive, unknown positive, or indeterminate (see below).

Table 1 Specimens tested by year (male subjects only)

Year	Tested (n)	Unknown positive		Known positive		Total positive	
		n	%	n	%	n	%
<b>Glasgow Royal Infirmary</b>							
1992	6304	10	0.16	77	1.22	87	1.38
1993	6332	14	0.22	49	0.77	63	0.99
1994	6951	20	0.29	46	0.66	66	0.95
1995	6721	32	0.48	21	0.31	53	0.79
1996	6737	17	0.25	29	0.43	46	0.68
1997	7152	13	0.18	36	0.50	49	0.69
<b>Total</b>	<b>40 197</b>	<b>106</b>	<b>0.26</b>	<b>258</b>	<b>0.64</b>	<b>364</b>	<b>0.91</b>
<b>Stobhill Hospital</b>							
1992	4356	4	0.09	2	0.05	6	0.14
1993	3084	2	0.06	1	0.03	3	0.10
1994	3411	2	0.06	0	0.00	2	0.06
1995	3261	3	0.09	2	0.06	5	0.15
1996	2504	3	0.12	0	0.00	3	0.12
1997	4258	2	0.05	2	0.05	4	0.09
<b>Total</b>	<b>20 874</b>	<b>16</b>	<b>0.08</b>	<b>7</b>	<b>0.03</b>	<b>23</b>	<b>0.11</b>

*Indeterminate samples*

Early on in the study, 13 specimens reacted strongly on Serodia and ELISA screening but western blot patterns were atypical: few bands developed and their colour intensities were weak. Either these specimens arose from individuals who were undergoing early HIV seroconversion or they were the result of serum being contaminated. The reactive specimens were predominantly from female patients, a finding which did not correspond with expected HIV prevalence based on knowledge acquired from other surveys. Accordingly, serum carry over on autoanalyser probes from antibody positive to antibody negative sera was considered a major possibility; this phenomenon has long been recognised by the blood transfusion service and in biochemistry laboratories when single probe analysers are used (Follett EAC, personal communication). To test this hypothesis, 14 sets of sera, each comprising an initial sample known to be HIV antibody positive followed by five samples each known to be antibody negative, were placed in the single probe analyser and subjected to biochemical analysis. Subsequent HIV antibody

testing of these sera showed that in 12 of the 14 sets carry over was detected in the first of the five sequential sera known to be antibody negative, and in one of the remaining two sets carry over was detected in the first and second samples known to be negative.

Four months into the study both biochemistry laboratories upgraded their analysers from Technicon SMAC continuous flow analysers to Olympus AU5200 discreet analysers. The additional washing procedure on these instruments reduced carry over to a single cup in three sets from a further 14 sets of six sequential wells, set up as before. Despite further testing of the "atypical" specimens, five (three of which related to the period when the original analysers were used) could not be categorised as positive or negative and were designated indeterminate. As these were most likely to have resulted from serum carry over, these results were excluded from the final analysis.

**Results**

During January 1992 to December 1997, 62 274 specimens from male subjects were selected for HIV antibody testing. Testing of specimens from female subjects was discontinued after 18 months owing to the extremely low HIV prevalence in this group; thus only 17 502 specimens were selected up to June 1993. Of the 79 776 specimens, 1516 yielded insufficient serum for antibody testing and the majority of these were collected early on in the study; thereafter, a smaller volume of serum was used and insufficient samples were encountered infrequently. Throughout the study period not a single objection to anonymous HIV testing was recorded on a request form.

HIV prevalence among female patients was 0.012% (2/17 189) while among male patients it was 0.91% (364/40 197) at GRI and 0.11% (23/20 874) at STOB.

Tables 1 and 2 present the HIV prevalence results for male subjects by clinical specialty grouping and year of specimen, respectively.

Table 2 Specimens tested by clinical specialty grouping (male subjects only)

Specialty	Tested (n)	Unknown positive		Known positive		Total positive	
		n	%	n	%	n	%
<b>Glasgow Royal Infirmary</b>							
(a) Cardiology/ cardiothoracic	4323	1	0.02	3	0.07	4	0.09
(b) ENT, general, and plastic surgery	3955	4	0.10	4	0.10	8	0.20
(c) General medical inpatients	3963	14	0.35	17	0.43	31	0.78
(d) General medical outpatients	4862	58	1.19	220	4.52	278	5.72
(e) General practice patients	8416	10	0.12	4	0.05	14	0.17
(f) Haematology, dermatology, oncology, respiratory medicine	4149	13	0.31	7	0.17	20	0.48
(g) Psychiatric	1484	3	0.20	1	0.07	4	0.27
(h) Renal/urology	5294	0	0.00	0	0.00	0	0.00
(i) Rheumatology/ orthopaedic	3751	3	0.08	2	0.05	5	0.13
<b>Total</b>	<b>40 197</b>	<b>106</b>	<b>0.26</b>	<b>258</b>	<b>0.64</b>	<b>364</b>	<b>0.91</b>
<b>Stobhill Hospital</b>							
(a) Cardiology	1848	1	0.05	0	0.00	1	0.05
(b) ENT, general surgery	2504	2	0.08	1	0.04	3	0.12
(c) General medical inpatients	3578	4	0.11	4	0.11	8	0.22
(d) General medical outpatients	1248	0	0.00	1	0.08	1	0.08
(e) General practice patients	7540	7	0.09	1	0.01	8	0.11
(f) Haematology, dermatology, oncology, respiratory medicine	921	0	0.00	0	0.00	0	0.00
(g) Psychiatric	379	0	0.00	0	0.00	0	0.00
(h) Renal/urology	2082	2	0.10	0	0.00	2	0.10
(i) Rheumatology/ orthopaedic	774	0	0.00	0	0.00	0	0.00
<b>Total</b>	<b>20 874</b>	<b>16</b>	<b>0.08</b>	<b>7</b>	<b>0.03</b>	<b>23</b>	<b>0.11</b>

At GRI, the outstanding prevalence rate was that recorded among general medical outpatients (5.72%). In all the other specialty groupings, prevalence ranged from 0% among renal/urology patients to 0.78% among general medical inpatients. Among general practice patients, prevalence was 0.17% and among patients in the four specialty groupings which included surgical patients (groups (a), (b), (h), and (i)) the prevalence was 0.10% (17/17 323). The great majority of HIV positive specimens from general medical inpatients and outpatients (76.7%) had originally been accompanied by request forms that indicated known positivity. In contrast, the proportion of known positives among specimens from patients in the other specialty groupings was 38.2%. The annual prevalence of "unknown" HIV infection remained between 0.16% and 0.29% throughout the six year period except for that in 1995, when it peaked at 0.48%. The prevalence of "known" infection declined from an annual average of 0.88% during 1992–94 to 0.41% during 1995–97.

At STOB, prevalence ranged from 0% in three of the specialty groupings to 0.22% in general medical inpatients. Prevalence among general practice patients was 0.11%, while that among patients in the four specialty groupings which included surgical patients was 0.08% (6/7208). Only a minority of the 23 HIV positive specimens (30.4%) were accompanied by request forms indicating known positivity. No trends in prevalence were seen over the six year period with annual rates fluctuating around the 0.1% level.

### Discussion

In this study we showed that large numbers of residual specimens from busy biochemistry laboratories can be processed for unlinked anonymous HIV testing without interfering with the laboratories' routine functions. The only laboratory hitch was the occurrence of HIV antibody contamination of sera owing to "carry over" on the autoanalyser probe. However, this problem was resolved when new autoanalysers with improved washing facilities to clean the probe were introduced.

From the outset, the investigators were aware that the absence of risk category information might render the data difficult to interpret. Furthermore, it was appreciated that haemophiliac patients, many of whom were HIV positive, attended the GRI on a regular basis. This factor almost certainly accounted for the extraordinarily high HIV prevalence (5.72%) observed among male general medical outpatients in this hospital. Thirty HIV positive haemophiliacs were known to attend outpatients, usually at three monthly intervals, and blood samples would be obtained for urea and electrolyte analysis. By 1997, only 16 were alive and this decrease could explain the decline in overall HIV prevalence among male GRI patients during the six year period of study. Generally, the HIV status of these cases would be recorded on the request form but during early 1995 this measure was not under-

taken and this explains why, in that year only, the majority of infected patients at GRI were "unknown" to be HIV positive.

Despite the haemophiliac issue, much of the data have improved our understanding of the dynamics of HIV spread in Glasgow. The exceptionally low 0.012% prevalence of HIV among 17 189 female subjects aged 16–49 years was consistent with prevalence rates recorded in other female populations over the same period; accordingly, we felt justified in excluding specimens from female patients after the initial 18 month period of the study. During 1992–94, 0.09% (3/32 783)<sup>9 10</sup> of childbearing women throughout Greater Glasgow Health Board and 0.026% (2/7664) of non-pregnant women attending Glasgow's main family planning centre were HIV positive.<sup>11</sup> The HIV prevalence among non-injecting female attenders at the city's genitourinary medicine clinic between 1991 and 1995 was 0.09% (7/7500)<sup>12</sup> and the prevalence of HIV among city-wide samples of female injecting drug users during 1990–94 was 1%.<sup>13 14</sup> Since the female population is not affected by haemophiliac and male homosexual associated HIV infection, prevalence of HIV within it is a gauge of either injecting drug use or heterosexual risk. The log differences in HIV prevalence which separate the injectors (1 in 100) from the group presenting with a sexually transmitted disease problem (1 in 1000) and the more general population groups including hospital patients (1 in 10 000) indicate that heterosexual transmission of HIV is rare in Glasgow.

The HIV prevalence data on males, at STOB in particular, further support these observations. Overall prevalence was 0.11% among both hospital and general practice patients from an area in Glasgow which has more HIV infected injecting drug users than anywhere else in the city. It is easier for a male person to transmit HIV to a female through sexual intercourse than vice versa.<sup>15</sup> Thus, in view of the low female rates of HIV, it is extremely likely that very few of the infections among the males will have been acquired heterosexually. The HIV prevalence of homosexual/bisexual males attending genitourinary clinics in Glasgow is 5%,<sup>16</sup> and that among male injecting drug users throughout the city is 1%; it is thus highly probable that most of the male hospital and general practice patients who were HIV infected belonged to these and, in the GRI only, to the haemophiliac groupings.

The control of HIV transmission among Glasgow's injecting population (8500) and from injectors to their sexual partners explains the low HIV prevalence in the hospital patient and general practice population. There is considerable evidence that needle/syringe exchange which was implemented in the city during 1988–92 was responsible for this control.<sup>17 18</sup>

There has been much concern about the risk of healthcare workers, especially those performing exposure-prone procedures, acquiring HIV occupationally. Accordingly, the United Kingdom Departments of Health introduced guidelines in mid-1997 which recommended

that healthcare workers sustaining, in particular, a percutaneous injury from an instrument which had been used on a patient who was known, or highly suspected, to be HIV positive, should receive postexposure prophylaxis in the form of combination antiretroviral therapy.<sup>19</sup> It is reassuring that HIV prevalence among male patients in the four specialty groupings which included surgical patients was approximately 1/1000. The prevalence among female patients in these groupings was even lower, at 0.04% (3/7595). Sixty per cent of adults undergoing surgery in Glasgow are older than 49 years and are much less likely to be infected than younger patients. Accordingly, the average risk of contracting HIV through a single percutaneous injury is considerably less than the 1 in 300 000 risk, based on the product of a 0.1% chance of the source patient being HIV infected and a 0.32% probability of transmission if the source is infected.<sup>19</sup> Since the prevalence of HIV in Glasgow is comparable to that in most parts of the United Kingdom, the study data point to the occupational HIV risk for most surgeons who work in the United Kingdom being extremely low.

Similar surveys have been performed in London hospitals by the Communicable Disease Surveillance Centre.<sup>3</sup> The methods were almost identical to those adopted in Glasgow, though plasma from full blood count specimens was used instead of serum. Prevalences in male subjects always exceeded those in female subjects. Patients attending accident and emergency departments were included in these surveys and prevalence among attenders ranged between 0.4% and 1.9% during 1991–96. The Centers for Disease Control, Atlanta, also performed such surveys at 20 hospitals in 15 US cities, but were able to link HIV test results to patient diagnoses.<sup>20</sup>

In Glasgow, the survey was discontinued in December 1997 and was not extended to other centres in Scotland. This was because HIV prevalence had been shown to be low and stable among Glasgow patients, and elsewhere, surveys involving other groups were considered sufficient to monitor the spread of HIV in both high and lower risk populations. The principal deficiency of this unlinked anonymous HIV testing study was the absence of risk information. In centres where HIV transmission involves different risk groups and routes, prevalence data are extremely difficult to interpret. If, however, one route of transmission is predominant in an area, the absence of risk information poses less of a problem. This is the case in many developing countries where heterosexual intercourse is the principal route of HIV transmission.<sup>21</sup> The approach described

above is perhaps best suited to such circumstances.

We would like to thank the following people for their help in establishing the survey: A Brown, J Emslie, E Follett, R Skinner, A McLaughlin, L McDonald, F Pearson, M Rodger, and K Wilson. We are also grateful to the Medical Research Council for funding the survey during its first three years and to the Scottish Office Department of Health for funding it thereafter.

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*J Clin Pathol* 2000 53: 117-121  
doi: 10.1136/jcp.53.2.117

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