

1. HIV prevalence in South Africa

South Africa has the largest number of people living with HIV/AIDS in the world. In a recently publicised study using a linked, anonymous HIV testing of oral fluids in the general population, the Nelson Mandela/HSRC study of HIV/AIDS (2002) reported an estimated HIV prevalence of 11.4 per cent (or 4.5 million people) among persons aged two years and older. The HIV prevalence was higher among females (12.8 per cent) than males (9.5 per cent). Although HIV was found to have generalised in the population leaving no specific racial group or location type unaffected, the prevalence was highest among Africans (12.9 per cent), followed by whites (6.2 per cent), coloureds (6.1 per cent) and Indians (1.6 per cent).

The epidemic has also reached unacceptable levels among youth and older South Africans. The Nelson Mandela/HSRC study found that in 2002, 9.3 per cent of the youth and 7 per cent of persons aged 55 years and older, were living with HIV/AIDS. Those living in informal settlements were disproportionately affected by the virus, with 21.3 per cent living with HIV/AIDS. This prevalence is very high when compared to those who live in formal urban areas (12.1 per cent), tribal authority areas (8.7 per cent), and farms (7.9 per cent). The provinces were also not equally affected (as shown in Figure 1). Free State, Gauteng and Mpumalanga provinces were reported to have the highest HIV prevalence, while Eastern Cape and Northern Cape had the lowest prevalence. However the confidence intervals (CI) overlap, suggesting that the differences are not statistically different.

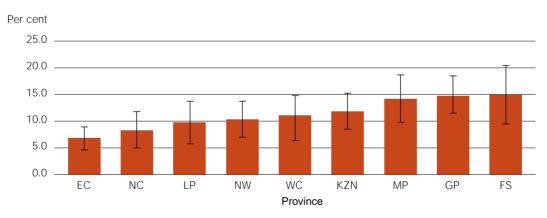


Figure 1: HIV prevalence by province, South Africa 2002

Source: The Nelson Mandela/HSRC Study of HIV/AIDS: South African National HIV Prevalence, Behavioural Risks and Mass Media Household Survey 2002, HSRC. The lines in the bars are 95% confidence intervals around the prevalence estimates.

2. Impact of HIV/AIDS

The high prevalence of HIV/AIDS (4.5 million citizens older than two years living with HIV/AIDS) has serious implications for South Africa:

• HIV/AIDS causes an enormous burden to society through high morbidity and mortality. Those killed by AIDS are frequently family breadwinners, and the loss of an income earner is exacerbated by the extra costs of caring for those who are ill.

Families are often forced to divert financial resources from basic foods, education and other necessities, to pay for health care. When people die, the cost of funerals is an additional financial burden to families without sufficient resources. Furthermore, premature mortality attributable to AIDS causes children to be orphaned. Thus the epidemic is causing the social disruption of families and society at large.

HIV increases the patient load at health facilities. This burden has been estimated in small studies that involved testing for HIV. A prospective, linked, anonymous cross-sectional study conducted over a four-week period at a tertiary level academic hospital in South Africa (Pillay, 2001), found that 60 per cent of all children admitted were HIV positive. Most of these children were younger than 12 months old. Of these infants, nearly 70 per cent were living with HIV/AIDS. HIV has also been found to be prevalent in adult medical wards at a tertiary hospital in Durban. Colvin et al. (2001) found that of 507 patients, 54 per cent were living with HIV.

• HIV compromises the patient's immunity and thus opportunistic infections proliferate in people living with the virus. Oral thrush and diarrhoea are two of the most important indicators of HIV/AIDS. Other opportunistic infections are pneumonia, pneumocystis carinii and cryptococcal meningitis. The high proportion of patients admitted to hospitals with the HI virus is evidence of the advanced stage of the HIV/AIDS epidemic in South Africa, as people living with HIV/AIDS who suffer from these opportunistic infections make use of the health services in an attempt to get relief.

Tuberculosis is a major opportunistic infection associated with HIV. Annual admissions in a rural South African hospital increased by 81 per cent between 1991 and 1998 – from a total of 6 562 patients to 11 872 – with much of that increase reportedly due to AIDS patients infected with TB. At times the increase in admissions to the TB ward was as high as 360 per cent (Floyd, Reid, Wilkinson & Gilks, 1999). As HIV/AIDS increases the demand for health services in developing countries, HIV negative patients may be crowded out of hospitals by those who are HIV positive. In Thailand, Uganda, Congo, Rwanda, Burundi and Kenya, the percentage of beds occupied by HIV positive patients in 1997 ranged between 39 per cent and 70 per cent (World Bank, 1997). Priority for health care tends to be given to those who are HIV positive and this overcrowding of hospitals due to AIDS needs to be managed.

Although patients with opportunistic infections have higher rates of hospitalisation and stay longer in hospitals, this need not be the case. In industrialised countries, progress in medical care has reduced the length of stay in hospital for AIDS patients. In a London hospital, the average length of stay decreased from 16 days in 1992, to 11 days in 1997, and similar changes were reported from other hospitals in industrialised countries (Mocroft et al., 1999). Major causes of the decrease in length of stay were the introduction of prophylactic treatment for pneumocystis carinii pneumonia (PCP) in 1989, dual antiretroviral therapy (in approximately 1994), and highly active antiretroviral therapy (HAART) in 1996.

The latter decreased the utilisation of hospital services significantly (Mouton et al., 1997). While there has been a decrease in the length of stay in hospital for AIDS

patients in developed countries, there is no clarity on the frequency of admissions. In some studies, authors report a decrease in the frequency of admissions, while in others an increase is reported. While these reports seem contradictory, such increases and decreases are probably due to a number of factors including medical progress, improved access to treatment, and policies regarding admission or treatment.

There were sharp declines in the mortality of AIDS patients in those developed countries that had introduced HAART between 1994 and 1997. The patients in these countries have obviously benefited from medical progress. In contrast, developing countries continue to experience an increased burden due to HIV/AIDS mortality. In middle-income countries such as Brazil and Thailand, decreases in hospital utilisation have been a direct result of policies that promote outpatient services instead of hospital-based care (Buvé, 1997). In addition, Brazil and Thailand manufacture antiretroviral drugs and have introduced HAART for patients. Hence, there has been a corresponding decrease in rates of opportunistic infections, and subsequently, in health care utilisation. In Brazil, the annual number of AIDS deaths has been halved nearly, and opportunistic infections have decreased by between 60 per cent and 80 per cent (UNAIDS, 2000). This intervention clearly has an impact on hospital admission and discharge rates, on the length of stay in hospital, and on the cost of providing health services.

In addition to the suffering and loss of human life caused, HIV/AIDS is expected to have a profound effect on the labour market as HIV affects many individuals in their economically productive years. In the 1999 national study of workers in heavy industry in South Africa, the prevalence of HIV was estimated at 8.8 per cent among agricultural workers, but in KwaZulu-Natal the rate was 22 per cent (Rosen et al., 2001). From an employer's perspective, the direct impact of HIV/AIDS may result in increased costs and lower profits due to the loss of labour. Direct costs include increased benefit payments, insurance premiums, recruitment and training, overtime and casual wages. Indirect costs include reduced on-the-job productivity, increased absenteeism, supervisory time management burden, production disruptions, loss of workforce cohesion and experience, and labour disputes.

Given the overall impact of HIV/AIDS on South African society and the need to make policies on the management of those living with the disease, it is critical that studies are undertaken to provide data on the impact of HIV/AIDS on the health system. This has become urgent because, having started in the early 1990s, the epidemic is maturing. More people are expected to become ill and therefore the patient load is expected to increase. For this reason, South Africa needs data to assess the impact of HIV/AIDS on the health system to aid decision makers and programme planners to make policies to mitigate this impact.

3. Objectives of this report

The HSRC and the National School of Public Health (NSPH) at MEDUNSA responded to Tender No GES 38/2000–2001 called for by the DoH to achieve the following specific objectives:

- Determine the current status and projected morbidity and mortality among South African health workers;
- Estimate the number of persons with AIDS utilising public health services in South Africa and determine the demographic profile of these patients;
- Identify the health services most severely affected by HIV/AIDS, estimate and project important health service indicators such as drug utilisation, bed occupancy and length of stay in hospital;
- Determine the impact of HIV/AIDS on human resources by focusing on training, staff morale, workload, working hours and absenteeism; and
- Estimate the total cost of administering preventive therapy to newborns and pregnant women at different levels of the health care system.

The first two objectives were later extended to include the private sector as well. This report does not include mortality among South African health workers.

From a literature review we know that in depth assessments of the impact on health systems are a useful contribution to understanding the nature of the interaction between HIV/AIDS and health systems (WHO, 2000). However, such assessments are usually complex and expensive to implement. As a result, we proposed to the DoH to conduct a series of studies that would permit rapid assessment and generate empirical data that could be used for planning and management of HIV/AIDS. These studies will answer the following three broad questions:

- To what extent does HIV/AIDS affect the health system?
- What aspects or subsystems are most highly affected?
- How is the impact going to progress over time?

In our response to the tender we indicated that we would not conduct a study of orphanhood and dependants of health workers because of the complexity and time required to do justice to this issue. We also indicated that we planned to conduct a survey in two phases. Phase 1 would take place in Gauteng for the first four objectives outlined above, while Phase 2 would cover the other eight provinces for all objectives. The last objective is a longitudinal study conducted during Phases 1 and 2. Phase 1 is now complete and the results of the analysis of the survey in Gauteng have already been reported to the DoH. The purpose of Phase 1 was to identify any methodological problems or areas for improvement, to inform the main, national survey.

A series of five sub-reports are presented separately in this document. These are:

- HIV/AIDS prevalence amongst South African health workers and patients, 2002 (Study No 1);
- The impact of HIV/AIDS on the South African health workers (Study No 2);
- The impact of HIV/AIDS on health services (Study No 3);
- The total cost of administering prophylaxis therapy to pregnant women and newborns to different levels of health care in a peri-urban setting following the Nevirapine and Zidovudine Protocols (Study No 4: the abstract only is presented here; the work is ongoing and an interim report has been presented to the DoH.); and
- AIDS-attributable mortality amongst South African health workers.

4. Methods

4.1 Sampling frames

A stratified cluster sample of 222 health facilities representative of the public and private health sector in South Africa was drawn from the National DoH's database on health facilities (1996). The sample was designed to obtain a nationwide representative sample of:

- Medical professionals i.e., specialists and doctors;
- Nursing professionals and other nursing staff;
- Other health professionals such as social workers and physiotherapists;
- Non-professional health workers such as ward attendants and cleaners; and
- Adult and child patients.

The target population consisted of two separate sampling frames, that is:

- A list of all public clinics in the country (excluding mobile, satellite, part-time and specialised clinics); and
- A list of all hospitals (public and private) and private clinics with an indication of the number of beds available in each of these health facilities.

From these sampling frames, a representative probability sample of 2 000 patients was obtained as well as a representative probability sample of 2 000 health workers who were in contact with patients undergoing treatment at these health facilities.

4.1.1 Sampling frame of public clinics

A random sample of 1 000 patients, 500 nursing personnel and 111 non-professional health workers was obtained. A nationwide representative sample of 167 clinics was drawn, and at each drawn clinic an average of three nursing personnel, six patients and 0.67 non-professional personnel were drawn at random. Information on the number of employees per occupational category, as well as the number of patients undergoing treatment at the day of our visit, were obtained for the calculation of record weights. (See also Appendix 3 for more information on sample design, drawing and weighting.)

4.1.2 Sampling frame of public and private hospitals

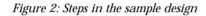
At hospitals, the following numbers of persons were obtained in the sample: Public hospitals

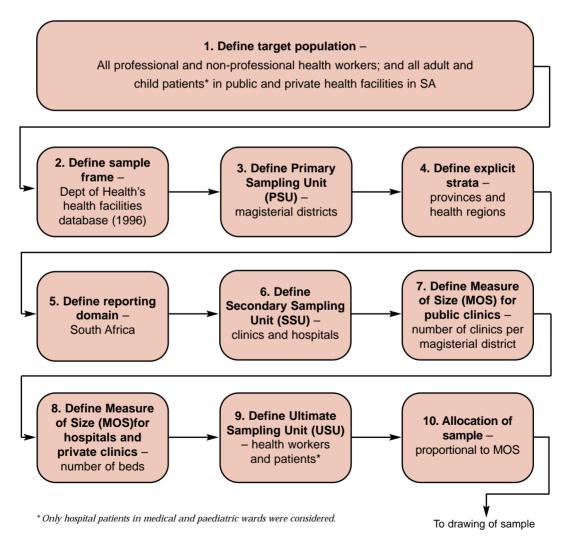
- 667 patients;
- 333 nurses (all categories);
- 200 medical practitioners;
- 67 other health professionals eg. social workers, psychologists; and
- 222 non-professionals eg. cleaners.
- Private hospitals
- 333 patients;
- 167 nurses (all categories);
- 100 medical practitioners;
- 33 other health professionals eg. social workers, psychologists; and
- 167 non-professionals eg. cleaners.

Information on the number of employees per occupational category, as well as the number of patients undergoing treatment in medical and paediatric wards at the time of our visit, was obtained for the calculation of record weights. The process of drawing the sample is shown in Figure 2.

4.2 Sample drawing at health facilities

Within each province, the two sampling frames were ordered according to health regions, and within each health region according to magisterial district. Statistics South Africa's (Stats SA) numerical numbering system of magisterial districts was used to obtain a geographical spread of magisterial districts in the systematically drawn sample over the health regions.





4.2.1 Sample of public clinics

Provinces were considered as the primary stratification variable, and the health regions as the secondary stratification variable. The 167 clinics that were drawn were allocated disproportionately (see Table 1). In other words, proportionately more clinics were allocated to the provinces with the smaller number of clinics and proportionately fewer clinics to the provinces with the greater number of clinics. This was done to obtain sufficient representation of the smaller provinces in the sample so that the results of each province could be reported separately.

PROVINCE	TOTAL	CLINICS		TOTAL		
	CLINICS	IN SAMPLE	Professional	Non-professional	Patients	INTERVIEWS
			health workers	health workers		
	n	n	n	n	n	n
Eastern Cape	781	33	99	22	198	319
Free State	280	15	45	10	90	145
Gauteng	461	22	66	15	132	213
KwaZulu-Natal	420	20	60	13	120	193
Mpumalanga	188	11	33	7	66	106
North West	327	17	51	11	102	164
Northern Cape	221	13	39	9	78	126
Limpopo	330	17	51	11	102	164
Western Cape	379	19	57	13	114	184
TOTAL	3 387	167	501	111	1 002	1 614

Table 1: The provincial allocation of public clinics and interviews

The sample number of clinics within each province was allocated approximately proportionately to the number of clinics within the health regions in the province. Magisterial districts were considered as primary sampling units (PSUs) within each health region. Because two clinics were drawn per magisterial district, districts with only one clinic were combined with a geographically adjacent magisterial district.

A measure of size (MOS) (as defined below) was used i.e.:

- If the number of clinics is two or less, and not more than four, then the PSU_MOS = 1;
- If the number of clinics is between five and ten, then the PSU_MOS = 2; and
- If the number of clinics is more than ten, the PSU_MOS = 3.

This definition of the PSU_MOS was used to avoid an imbalance between large (in terms of number of clinics) and small magisterial districts in the sample.

4.2.2 Drawing of the sample

The SAS version 8.2 procedure '*Surveyselect*' was used to draw the samples. This procedure calculated also the final sampling weight of the drawn clinics within each explicit stratum (viz. health region within province). The final sampling weight of a selected clinic is equal to the sampling weight of the relevant PSU (i.e. magisterial district), times the sampling weight of the selected clinic within the PSU.

The sampling weight of a drawn PSU within an explicit stratum was calculated as:

(the sum of the MOS of all PSUs within the stratum)

(the number of PSUs drawn within the stratum) x (the MOS of the drawn PSU).

The sampling weight of a drawn clinic within a drawn PSU was calculated as:

(the number of clinics within the PSU)

(the number of clinics drawn).

4.2.3 Sample of public and private hospitals

Public and private sector hospitals and clinics were separated before the sample was drawn. The number of health facilities allocated to provinces was calculated proportionately to the sum of the MOS, and not proportionately to the number of beds or to the number of facilities. One-third of the sample was drawn from private health facilities and two-thirds from public health facilities. An adjusted MOS, based on the number of beds (hosp_MOS), was developed and used for the allocation of health facilities to the provinces as well as for determining the different sample sizes, i.e.:

- If the number of beds is less than 30, then the hosp_MOS = 1;
- If the number of beds is between 31 and 80, then the hosp_MOS = 2;
- If the number of beds is between 81 and 150, then the hosp MOS = 3;
- If the number of beds is between 151 and 300, then the hosp_MOS = 4; and
- If number of beds is greater than 300, then the hosp_MOS = 5.

The hosp_MOS was applied to avoid the concentration of health personnel to a few large hospitals, and to expand the sample across hospitals and clinics of all sizes. Tables 2 and 3 show the allocation of public and private hospitals to the provinces as well as the number of interviews per occupational category.

PROVINCE	NO. OF	NO. IN	_	IN	ITERVIEW	/S		TOTAL
I	HOSPITALS	SPITALS THE SAMPLE		Nursing staff	Prof health workers	Non-prof health workers	Patients	INTERVIEWS
Eastern Cape	72	6	38	64	13	43	129	287
Free State	35	3	16	26	5	17	52	116
Gauteng	28	3	19	31	6	21	62	139
KwaZulu-Nata	al 64	6	41	68	14	45	136	304
Mpumalanga	28	2	13	22	4	15	44	98
North West	33	3	17	28	6	19	56	126
NorthernCape	e 26	2	7	12	2	8	23	52
Limpopo	44	4	26	44	9	29	89	197
Western Cape	e 47	4	23	38	8	25	76	170
TOTAL	377	33	200	333	67	222	667	1 489

Table 2: The provincial allocation of public hospitals and interviews

Table 3: The provincial allocation of private hospitals/clinics and interviews

PROVINCE	TOTAL	HOSPITALS	8	IN	ITERVIEV	VS		TOTAL
	HOSPITAL	S IN SAMPLE	Doctors	Nursing staff	Prof health workers	Non-prof health workers	Patients	INTERVIEWS
Eastern Cape	40	3	12	20	4	20	36	92
Free State	19	2	7	12	2	12	24	57
Gauteng	112	8	43	72	14	72	145	346
KwaZulu-Nata	l 44	3	18	30	6	30	60	144
Mpumalanga	13	1	4	7	1	7	14	33
North West	19	2	6	10	2	10	20	48
Northern Cape	e 20	2	5	8	2	8	16	39
Limpopo	2	0	0	0	0	0	3	3
Western Cape	16	1	5	8	2	8	15	38
TOTAL	285	22	100	167	33	167	333	800

The actual determination of the numbers of each of the categories of staff and patients to be interviewed at a drawn hospital is direct and can be described as follows.

The outcome of the public hospital sample in the Eastern Cape (EC) as indicated in Table 4 is used as an example. Six public hospitals were drawn, with hosp_MOS = 4, 2, 5, 5, 3 and 5, with sum (hosp_MOS) = 24. On average three nursing personnel had to be drawn per hosp_ MOS value, which implied in total the drawing of 72 (i.e. 3×24) nursing personnel in the EC.

According to Table 2 only 64 nurses should be drawn, necessitating the application of a correction factor of 64/72=0.89 to all sample sizes given for the EC in that table. Table 4 indicates the outcome of the correction process in the EC.

HOSPITAL	HOSPITAL		NO. OF				
	MOS			of other professionals	of non- professionals	PATIENTS	
1	4	11	6	2	7	22	
2	2	5	3	1	4	11	
3	5	13	8	3	9	27	
4	5	13	8	3	9	27	
5	3	8	5	1	5	16	
6	5	14	8	3	9	26	
TOTAL	24	64	38	13	43	129	

Table 4: The correction of given sample sizes for public hospitals in the Eastern Cape

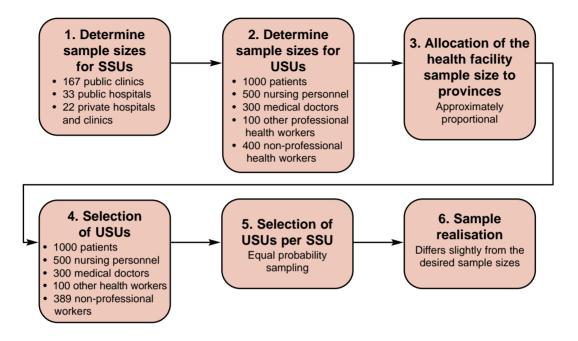
This scaling down or scaling up process was applied to all provinces after the initial sample size had been determined. A similar correction procedure was applied to private hospitals in the sample. The process is summarised in Figure 3.

Table 5: Public hosp.	tal sample for	r the Eastern	Cape
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SECTO	R NAME OF HOSPITAL	MAGISTERIAL DISTRICT (MD)	MD NO.	NUMBER OF BEDS	HOSPITAL MOS	HOSPITAL WEIGHT
Public	Dora Nginza Hospital	Port Elizabeth	240	220	4	10.2917
Public	Burgersdorp Hospital	Albert	201	57	2	20.5833
Public	Komani Hospital	Queenstown	215	850	5	8.2333
Public	Madwaleni Hospital	Elliotdale	252	347	5	8.2333
Public	Isilimela Hospital	Port St Johns	266	143	3	13.7222
Public	St Patrick's Hospital	Bizana	250	310	5	8.2333

4.3 Drawing of the sample of health facilities

Figure 3: Steps in the drawing of the sample.



Within each explicit stratum (viz. province by nature of the health facility), the health facilities were ordered according to health region, magisterial district number and type of health facility to make the sample more representative. Health facilities were drawn systematically within each explicit stratum with probability proportional to its hosp_MOS as indicated above.

The SAS version 8.2 procedure '*Surveyselect*' was used to draw the samples. This procedure also calculated the sampling weight of the drawn health facility within each explicit stratum. The sampling weight of a drawn health facility within an explicit stratum was calculated as:

(the sum of the MOS of all health facilities within the stratum)

(the number of health facilities drawn within the stratum) x (the MOS of the drawn health facility)

4.4 The drawing of the sample of health workers

The drawing of the allocated numbers of health personnel, other personnel and patients in the drawn health facilities, can be explained as follows.

4.4.1 Health workers in clinics

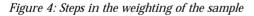
In the case of incorrect information or refusal to participate, a clinic was replaced by another clinic in the same stratum. In clinics, the following broad categories were considered, namely health professionals, non-professional workers whose duties brought them in contact with patients, and patients coming to the clinic at the day of the field work.

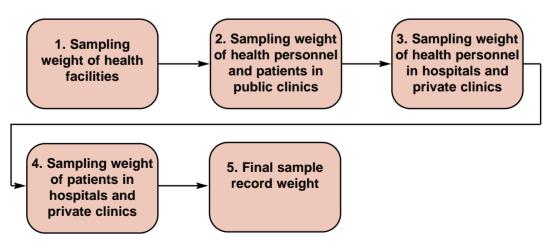
The final sampling weight of any person drawn in the clinic sample is then equal to the sampling weight of the relevant clinic multiplied by the total number of persons in a category at a clinic divided by the number of persons drawn in that category.

4.4.2 Health workers in hospitals

If a hospital refused to co-operate it was replaced by another hospital in the same stratum, although a private hospital could not always be replaced. In hospitals, the following occupational categories were considered: medical practitioners (general practitioners and specialists), nurses (all categories), other health professionals (eg. social workers and psychologists) and non-professional health workers whose duties brought them in contact with patients. Patients were selected from people occupying the medical and paediatric wards of the hospital. If there were no medical and paediatric wards at a drawn hospital, all patients occupying beds at the hospital were considered. No day patients were considered.

The final sampling weight of any person drawn in the hospital sample is then equal to the sampling weight of the relevant hospital multiplied by the total number of persons in a category at a hospital divided by the number of persons drawn in that category. This is illustrated in Figure 4.





4.5 Development of questionnaires

Existing data sources such as articles, dissertations and news reports were explored to establish a broad background against which the interviews could be planned and structured. Information was collected from members of the management team, health workers and patients, during interviews as well as from focus group discussions, to gain an understanding of the following:

- Hospital/clinic environment;
- Impact of the disease on health personnel; and
- Impact of the disease on patients.

The health facility questionnaire was adapted from that developed by Family Health International.

4.6 Training of data collection staff

Training of fieldworkers for the pilot study was done in August 2001, and for the national study, in April and May 2002. Thirteen fieldwork co-ordinators (FWCs) and 53 fieldworkers were trained during two-day training workshops presented in Pretoria, Cape Town, Kimberley, Durban, Bloemfontein, Umtata and Pietersburg. The workshop included the selection of candidates as fieldworkers. A survey planner and two assistants were appointed to assist with the planning of the survey and the training.

Professional nurses were appointed as fieldworkers and they were trained to conduct face-to-face interviews with health workers and patients at health facilities by means of three separate questionnaires. Where applicable they were also taught how to obtain oral fluid specimens from respondents. The FWCs conducted interviews with the superintendents/managers of health facilities by using the health facility questionnaire. They were also trained to select the respondents to be interviewed (see Appendix 1: Instructions to fieldworkers), and to do administration and quality control.

Fieldwork teams consisting of a FWC and \pm four fieldworkers conducted fieldwork during 23 'tours' over a period of two months across SA. The survey planners developed a travel plan for each tour, contacted the facilities for appointments and made the necessary travel and accommodation arrangements. At least one day was spent at a facility and each tour took from one to three weeks to complete.

4.7 HIV testing

Oral fluid specimens were obtained from participants by means of the Orasure oral fluid collection device. All aspects of specimen collection, transport and storage were done according to the 'Standard Operating Procedures for collecting, storing and transporting oral fluid using the OraSure® HIV-1 Oral Specimen Collection Device' (see Appendices 4 and 5).

For all of the selected health workers in Mpumalanga, KwaZulu-Natal, Free State and North West, the Orasure/Vironostika combination was used so that the same methodology was applied to ensure comparability across provinces. Testing was anonymous, but the

results of the HIV test could be matched to the data through a bar code.By separating the questionnaires from the consent forms, anonymity was ensured. Individual's names and unique identifying information was not collected and therefore could not be linked to an individual's HIV test results. While this ensures the confidentiality of the HIV test, it also means that HIV results cannot be returned to individuals who wish to know their HIV status. However, individuals wanting to know their HIV status could enquire at the health facility whether they can undergo voluntary counselling and testing (VCT), which includes providing new specimens to be tested.

For all of the health workers and patients, the collection of the oral fluid specimen using Orasure was done at the time of the interview. As the test is non-invasive and only requires individuals to stick a pad between their cheek and gum for two to five minutes, the logistics of this procedure was simple. Furthermore, as the Orasure is a specimen collection device, the specimen is sent to the laboratory for analysis and therefore the individual and the interviewer had no way of knowing the tested individual's HIV status, making the acceptability of the test higher.

4.8 Quality control

The principal investigator prepared detailed protocols for Phase 2 of the study. Since the project comprised five objectives, various researchers were allocated responsibilities to develop questionnaires for their respective objectives. Draft questionnaires were brought before a special project committee for assessment and reconstruction. This was intended to ensure the quality of questionnaires.

Final draft questionnaires, study protocols and informed consent forms were subjected to the ethics review processes of the NSPH at MEDUNSA. After this process, the project manager drafted training manuals for field supervisors and fieldworkers.

Training manuals included final questionnaires, maps of field work routes, instructions on access to health care facilities, administrative forms to record daily activities and for other administrative activities, and instruction on safe keeping of completed questionnaires. Information generated from the Gauteng Phase I survey was used to design questionnaires for the national study and to retrain staff accordingly.

Field supervisors did 'over the shoulder' supervision of fieldworkers. At the end of each day, supervisors checked completed questionnaires to detect possible deviations from protocols and to offer corrective support where such deviations were observed. Regular supervision of data collection by fieldworkers is an important quality control measure.

To maintain the accuracy of questionnaires, the project manager regularly evaluated completed questionnaires as they arrived. Regular meetings with field supervisors were held to review issues arising out of completed questionnaires. In this way, quality assurance on data collection was maintained.

The process of data management started as soon as completed questionnaires were satisfactorily assessed. Coding lists were prepared for the pilot survey by researchers. For the main study, specialists were contracted to do this work. The database, set up

before the study began, was in the SPSS software format. The data-capturing unit of HSRC entered and cleaned the data with the assistance of the project manager and researchers. Statisticians were contracted to set up the data for analysis, including creating categorical variables from continuous variables and creating major variables of the study (such as Bangui indicators). Backups of data were made and stored safely for future use.

The statistical outputs were subjected to random checks by an independent statistical consultant to assess their accuracy. No statistical computation errors were found.

4.9 Data collection

The questionnaires in the study are listed in Table 6.

4.9.1 Pilot study

Individual and focus group interviews with health personnel and patients were conducted at both public and private health facilities in urban and rural areas of Gauteng and North West. Using this knowledge, two questionnaires were compiled, namely:

- A demographic and morbidity questionnaire for adult patients; and
- A demographic and morbidity questionnaire for children.

The questionnaires were pilot-tested during face-to-face interviews with two health workers, eight patients and members of management at three hospitals and one clinic. These health managers were interviewed to determine logistic information about administering the questionnaire, such as access to the facility, patients' files, how best to select patients, records of the patients, ensuring confidentiality, and the organisation of fieldworkers.

Once the questionnaires had been finalised, the adult and child questionnaires were translated from English into seven other languages, namely Northern Sotho, Southern Sotho, Tswana, Zulu, Xhosa, Shangaan and Venda.

4.9.2 Phase 1 study in Gauteng

Retired registered nurses were hired to visit health facilities in order to collect information using five different questionnaires. We developed a fieldworker manual that included the methodology for the selection of health workers and patients at health facilities. The retired nurses were then trained during a one-day workshop to conduct field work at hospitals and clinics.

The methodology was tested in Gauteng, prior to full implementation in the second and national phase. All interviews were confidential and non-compulsory, and respondents had to give their informed written consent before being interviewed.

4.9.3 Phase 2

The second objective of this survey was to estimate the number of persons with AIDS utilising public and private health services in South Africa, and to determine the demographic profile of these patients.

Table 6: Questionnaires and target groups

QUESTIONNAIRE	TARGET GROUP
1. The impact of HIV/AIDS on health services in South Africa (facility questionnaire)	Public hospitals, private hospitals/clinics
2.1. Demographic and morbidity questionnaire for adults	Adult patients (15–49 years) at health facilities.
2.2. Demographic and morbidity questionnaire for children	Child patients (below 15 years) at health facilities
3.1. Impact of HIV/AIDS on professional health workers in the health sector	Health professionals, i.e., doctors, nurses, other professionals.
3.2. Impact of HIV/AIDS on non-professional health workers in the health sector	Non-professionals who worked with patients such as ward attendants and cleaners.

The first three sections of the adult and child questionnaires are: section 1 - demographic, section 2 - morbidity, and section 3 - behavioural. This instrument primarily collected information on nine variables, each measured through numerous items. The first part of the instrument collected data on facilities, as well as on the biographical details of respondents. A fourth section was addressed to facilities and was intended to yield information on the distribution of AIDS cases in the private and public facilities.

In section 5 of the questionnaire, on health status, we enquired into the symptoms/ diseases that had prompted patients to seek medical and health care. Section 6 was intended to determine the presence or absence of major and minor AIDS symptoms according to the Bangui definition. In those few instances where the medical diagnosis of AIDS was stated on the medical record, the symptoms were clearly validated. Medical records were used as the gold standard to predict AIDS, given the symptoms. This was not possible for all cases, because of missing medical diagnoses on patients' records.

Section 7 of the questionnaire captured behavioural variables, because certain behaviours predispose one towards infection with HIV.

4.10 Informed consent process for adults, for health workers and for children

4.10.1 Informed consent for questionnaires

An informed consent form was attached to each questionnaire. All adults were requested to give informed consent and to sign the form in the presence of a witness. For child respondents who were too young to give consent, their parents or guardians were asked to give consent on their behalf. However, child respondents who were old enough to give consent were asked to sign an additional child consent form.

To protect the identity of respondents, the covering sheet of the questionnaire was separated from the rest of the questionnaire because it contained identifying details of respondents. The separated pages were destroyed.

4.10.2 Informed consent for HIV testing

The procedure described in this section was applied to the four provinces where HIV testing was done. The process entailed describing the purpose of the project to all patients and obtaining the written or verbal (where respondent was illiterate) consent of those who agreed to participate. The nurses requested permission from parents and guardians of children under 15 years to give informed consent for including their children in the survey, and they obtained verbal consent from all children who gave a specimen for HIV testing. Nurses who collected data were trained to ensure that this procedure was done correctly.

To ensure compliance with ethical standards, we took the following measures:

- We did not record names of individuals on the questionnaires or on the oral fluid specimen. Instead we pasted bar codes with the same numbers on the questionnaires, the laboratory results sheet and the oral fluid specimen.
- We ensured that the specimens were sent by courier to the laboratories for HIV testing.
- We linked the HIV test results and the questionnaires electronically, making this a linked anonymous HIV testing survey. Because we designed the study to ensure anonymity, we did not give the participants their results. Patients who wished to know their HIV status could enquire from the health care facilities where they were being served at the time of the survey. They would first go through VCT, which was not available in this survey.

4.11 Approval of the ethics committee at the NSPH

The research proposal, data collection instruments, study protocol, and informed consent forms were brought before the Research and Ethics Review Committee of the NSPH at MEDUNSA. The Committee suggested some changes to documents prior to approval. The changes were then reviewed and approved.

The Research and Ethics Review Committee of the NSPH at MEDUNSA reviewed the study, and project number NSPH/FA/2002/01 was allocated after suggested changes to the protocol and informed consent forms were satisfactorily effected.

4.12 Administration of the HIV test

The HIV test was used in the public and private health care facilities. This HIV test has a shelf life of 22 days.

4.12.1 Collecting oral fluids

The following general steps were followed to collect a specimen:

- A specially treated absorbent pad attached to a plastic stick was used (details are presented in Appendix 3);
- The pad was placed in the person's mouth against the inner cheek for the length of time specified in the manufacturer's instructions. Then the pad was placed into a vial containing a preservative solution.

Due to the test complexity, oral fluid specimens collected for Enzyme immunoassays (EIAs) are sent to a national laboratory for analysis.

4.12.2 Storing oral fluids

Oral fluid specimens can be stored from 4° -37° C for a maximum of 21 days (including the time for shipping and testing). Oral specimens should be refrigerated during shipment. Specimens can be frozen (-20° C) for a limited time (approximately 6 weeks). Once thawed, they can be refrozen once. The test kit insert should be consulted prior to testing for more specific storage information.

Supervisors made sure that all envelopes were sealed and sent to the nearest courier depot before being dispatched twice a week.

4.12.3 Administration

Patients and health personnel were tested using the Oral fluid collection devices in Mpumalanga, KwaZulu-Natal, Free State and North West. Three testing sites participated in determining the HIV status. These are:

- The Department of Virology, University of Natal, Durban;
- Contract Lab Services (CLS), a joint venture unit of the WITS Health Consortium (Pty) Ltd and the National Health Laboratory Service; and
- The Medical University of Southern Africa (MEDUNSA).

The test results were linked electronically to the questionnaires prior to analysis.

5. Strengths and limitations of the study

Each research study has strengths and limitations. This study has the following strengths.

5.1 Strengths

- First, because five per cent of all health facilities were selected on a probability basis and using a stratified approach, the findings can be generalised. With respect to HIV prevalence amongst health workers and patients, the generalisation is limited to four South African provinces and not to the whole country.
- Second, the response rate in the study of the patients is very high, obviating the need to adjust for non-response bias.
- Third, the data allows for comparison of the public and private sectors in key areas of service delivery, identifying the strengths of each sector. Such information is necessary for planning the delivery of health services.

5.2 Limitations

- First, due to insufficient funds, we were not able to draw a sample large enough to allow for the production of provincial estimates, key demographic variables or to conduct HIV prevalence tests in all the five per cent of health care facilities sampled. The small sample size, in some cases, resulted in large confidence intervals around estimates and we were therefore unable to determine whether there were statistically significant differences between estimates even when the differences appeared substantial.
- Second, due to the poor medical record systems in health care facilities, some of the statistics may be subject to recall bias. For key indicators related to health services, most of the estimates were derived from medical records.
- Third, the poor medical record systems found in health facilities accounted for a lack of crucial information. For example, most health facilities did not keep statistics on key indicators such as the number of individual patients seen.
- Finally, because AIDS is not a notifiable disease, most health facilities did not keep statistics on the number of patients diagnosed with AIDS, hence our decision to use projections to estimate the number of patients with AIDS using the health care system.