At the cutting edge of HIV/AIDS research: A review of the Perinatal HIV Research Unit, University of the Witwatersrand, 1996-2005
vision

The Perinatal HIV Research Unit will reduce the impact of the HIV epidemic on South Africans in collaboration with the community and other key stakeholders.

mission

Our vision is achieved through leading, innovative, high quality and relevant inter-disciplinary research in a dynamic environment, making a positive contribution to people and policy debates.

This research will be conducted under the highest ethical standards respecting the rights of people and communities.

The unit is committed to integrity and the professional development of employees, with an emphasis on the empowerment of people previously or currently disadvantaged.
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Preface

This report details the achievements of the Perinatal HIV Research Unit’s (PHRU) comprehensive HIV/AIDS research programme over the past ten years. The report focuses on recent achievements but also provides a brief overview of the earlier days.

The PHRU concentrates on four broad areas of research: prevention, care, treatment and HIV-related research that includes investigating the medical, social, economic and anthropological impact of HIV/AIDS on the South African population.

This report is divided into three main sections. The first discusses the research studies in each of the above research areas. A brief description of the research is given, with key findings where available.

The second section gives an overview of HIVSA, a non-governmental organisation that works closely with the PHRU. HIVSA is primarily a psychosocial support organisation, providing HIV/AIDS education and support to PHRU clients, and many others infected with and affected by HIV/AIDS in greater Soweto and the Bohlabela district.

The third section of the report outlines an overview of the PHRU, including its operations, management and infrastructure. It describes the growth of the PHRU and the various research support entities.

Acknowledgements are due to Sheila Clapp who did a significant amount of work on this report in its early stages, Helen Struthers who compiled the final version and all the PHRU’s syndicate heads who provided detailed information on their areas of work.
“As more affordable ways to prevent transmission were found, the PHRU was one of the first institutions to respond to the situation and begin implementing treatment and care strategies for women and children attending public antenatal clinics in Soweto.”
The Perinatal HIV Research Unit (PHRU) has come a long way since our earliest days offering HIV testing and support services to pregnant women visiting Baragwanath Hospital in Soweto in 1991.

Although HIV/AIDS was already well documented in other African countries, Europe and North America, the epidemic was only just unfolding in South Africa at this time. It was clear to us that HIV/AIDS was going to spread rapidly among the South African population and would have devastating effects on our society and we realised that women would be disproportionately affected, simply because of their disadvantaged social and economic stature. While we knew that HIV could be transmitted from mother to child, we had no successful strategies at that stage to prevent this, until the first results from the ACTG 076 study in 1994. This catalysed research to find feasible and sustainable solutions for less resourced settings and the PHRU has led the way in this field for the last decade. As more affordable ways to prevent transmission were found, the PHRU was one of the first institutions to respond to the situation and begin implementing treatment and care strategies for women and children attending public antenatal clinics in Soweto.
Over the past decade, we have witnessed first-hand the rapid expansion of the HIV/AIDS epidemic in this country. The situation is critical – HIV prevalence is increasing steadily every year and now reaches almost 12 percent of the population – and the PHRU continues its efforts to provide quality treatment and prevention research.

From the very beginning, we at the PHRU concerned ourselves with developing appropriate and affordable treatments for HIV-infected people. Although women and children with HIV/AIDS will continue to be a focus, in our efforts to implement effective treatment protocols, the PHRU is also increasingly investigating the support and treatment needs of men infected with HIV. Men are critical vectors for HIV transmission, but many do not access HIV prevention messages or treatment opportunities, and the PHRU hopes to redress this.

Although we are primarily a clinical research and treatment facility, we have also become involved in developing more comprehensive responses to the epidemic, knowing that HIV/AIDS affects individuals, families and communities in many different and multifaceted ways. It is for this reason that we have encouraged research into the socio-economic impact of HIV/AIDS, and also took the lead in establishing a partner organisation – HIVSA – which provides comprehensive psychosocial support to people living with AIDS.

HIV prevention remains a crucial activity. Prevention efforts have not shown much success to date in curbing the epidemic and we need to find strategies that work. The PHRU is leading the way – with the first HIV vaccine trials to be undertaken in South Africa and innovative research on new prevention technologies and approaches.

The PHRU has also participated in policy-making, supporting the South African national and provincial government departments and international bodies such as World Health Organisation to develop far-reaching treatment protocols for PMTCT and antiretroviral therapies. We believe it is important to lend our expertise and translate the experiences of our clinical practice into workable policy frameworks for government. In addition, we have also challenged government, where necessary, and added our voice to advocacy calls for better HIV/AIDS treatment.

We are grateful to our dedicated staff, now numbering almost 400, who continue to serve the PHRU and the broader fight against HIV/AIDS with such professionalism, vision and integrity. We are fortunate in our ability to attract and retain highly qualified staff, and pleased that we are able to play a role in developing the skills and research capacity of previously disadvantaged South Africans. In an era when some of the African continent’s best scientists tend to leave for the well-resourced shores of the northern hemisphere, we are proud of the PHRU’s stature as a truly world-class research and treatment institution.

We are also extremely grateful to the many donors and partners who support the PHRU in our work. We have been fortunate in the solid relations we have formed with some of the largest global role players in the HIV/AIDS sector and we look forward to continued financial and collegial support in the future.

The PHRU has expanded our activities and range dramatically since 1991, and we hope to persist in our efforts to respond to the HIV/AIDS pandemic in the years to come. Through our research, treatment and care programmes, we will continue to strive for excellence and have a positive impact in the lives of our patients and clients.
The PHRU is housed in a world-class research facility — comprising a clinic, pharmacy, laboratory, counselling and training centre, and administrative offices — at the Chris Hani Baragwanath Hospital (known affectionately as “Bara”) in Soweto.
The PHRU aims to mitigate the impact of HIV/AIDS through relevant and appropriate research, which is conducted and shared with other key stakeholders including communities, government, academics, service organisations and activists. The unit utilises various research methodologies in order to maximise the interaction between biomedical, behavioural, sociological, statistical and operational research and support the development and implementation of high quality HIV/AIDS programmes and interventions.

The PHRU is housed in a world-class research facility – comprising a clinic, pharmacy, laboratory, counselling and training centre, and administrative offices – at the Chris Hani Baragwanath Hospital (known affectionately as “Bara”) in Soweto. The organisation has achieved recognition, both locally and internationally, for its research and service work.

Starting out as one of the country’s first dedicated HIV clinics at Bara’s maternity section in 1991, the PHRU has grown enormously in its scope and reach. In 1993, the unit began research into the prevention of mother-to-child transmission of HIV (PMTCT) and has since developed into a comprehensive, multi-disciplinary research centre. The unit currently employs more than 400 professional and support staff.
The PHRU was established under the auspices of the University of the Witwatersrand and was accorded research entity status by the university in 2000. The PHRU also collaborates with various partners, including universities and research institutes, government departments, non-governmental organisations and community groups, both nationally and internationally.

A close relationship has been established with HIVSA, a non-profit organisation providing support to people living with HIV/AIDS, also based at Bara. In addition, the PHRU has set up rural site partnerships in Limpopo province, together with the Rural AIDS and Development Action Research Programme (RADAR) and the University of Limpopo.
Soweto

Soweto (an acronym for South Western Township) is one of the most populous black urban residential areas in South Africa. It is situated 15 kilometres south west of Johannesburg in Gauteng province, the country’s economic centre.

Klipspruit (now called Pimville) was the first suburb to be established in 1904 after the outbreak of bubonic plague. The township later expanded to house migrant black labourers who came to work on the mines and in industry. Initially temporary iron structures were erected but, as Johannesburg became more industrialised, permanent homes were developed. Soweto was declared a township reserved for Africans under apartheid, with suburbs separated on the basis of language groups.

Soweto was the centre of political campaigns and unrest aimed at the overthrow of the apartheid state. Since the 1940s, Soweto residents have been campaigning for better living conditions and improved human rights. These included the early squatter movements. In 1976, students campaigning against the forced use of Afrikaans as the medium of instruction in schools were fired upon by police – the subsequent Soweto riots were a turning point in the struggle against apartheid and led to the infamous countrywide defiance campaigns of the 1980s.

Today, Soweto is a densely populated urban area. It comprises 78 km² and hosts complex social networks and a range of socio-economic strata. The poorest residents live in informal settlements and single-sex hostels. Middle class residents occupy the council houses which were formally leased to the occupants by the council but can now be owned. Private sector houses are also being built for the increasingly affluent middle class.

It is estimated that 1.2 million people live in Soweto itself, with about three million in the greater Soweto area. Soweto is populated by all ethnic and racial groups, mostly African, with a variety of activities and lifestyles. Unemployment is high, with 66 percent of people of working age unemployed, most of whom are women.

Gauteng has one of the highest HIV prevalence rates in the country and HIV/AIDS is a major concern in Soweto. Prevalence amongst pregnant women attending the antenatal clinics in Soweto is 30 percent. Stigma remains a problem, with very few men volunteering to test. Thus secrecy and non-disclosure persist.

Public health care facilities are easily accessible and efficient in Soweto. The Chris Hani Baragwanath Hospital was built as a military hospital with 1,544 beds and was officially opened by Field Marshal Jan Smuts in September 1942 to provide medical care for imperial troops. The hospital became a civilian hospital in 1948 and now serves the greater Soweto area. By 2001, the hospital had expanded to 2,964 beds and a staff of around 5,000 in 429 buildings. It is now the largest acute hospital in the world. In addition, there are about 60 local government and provincial healthcare clinics or mobile units in Soweto which are easily accessible to the residents.

Sources:
• www.joburg.org.za/soweto
• www.chrishanibaragwanathhospital.co.za
An overview of HIV/AIDS in South Africa

The HIV/AIDS epidemic in South Africa is one of the largest in the world and it shows little sign of abating. In 2002, the HSRC/Nelson Mandela survey estimated that the national prevalence of HIV amongst people two years and older was 11.4 percent – 9.5 percent for men and 12.8 percent for women. Out of an estimated population of four million people, about six million are infected with HIV and between 500,000 and 700,000 people require antiretroviral treatment.

Regionally, the Free State province had the highest prevalence at 14.9 percent, with Gauteng following at a rate of 14.7 percent. Limpopo had the third lowest prevalence at 9.8 percent. The survey found an increased likelihood of being HIV positive in urban areas (21.3 percent) compared to rural areas (7.9 percent). The national prevalence in children (aged 2 to 14 years) was 5.6 percent, youth (15 to 24 years) 9.3 percent and adults (25 and older) 15.5 percent.

HIV/AIDS is a highly politicised issue in South Africa and has been characterised by a persistent denial of the causal link between HIV and AIDS on the part of President Thabo Mbeki and the ruling African National Congress. Although the Presidential Partnership against AIDS, comprising government and a broad range of stakeholders, was established in 1998, government’s HIV/AIDS strategies have been slow off the mark.

Initially, the government focused almost all its efforts on HIV prevention but these have not proved effective. Indeed, prevalence rates in women attending antenatal clinics continued to rise, from one percent in 1990 to 20 percent in 1998 and 30 percent in 2004. Although the epidemic is lagging behind other countries, deaths among people older than 15 years increased by 62 percent from 1997-2002, with AIDS being the major contributory factor.

Prevention of mother-to-child transmission of HIV programmes were first proposed in 1999 once effective and affordable treatment options became available. However, it took a further four years, consistent lobbying from non-governmental advocacy groups and a Constitutional Court ruling to ensure that a programme was instituted in the public health sector.

An antiretroviral treatment programme and strategy was announced by government in November 2003 and since April 2004, treatment is available in a limited number of public hospitals in each province. This treatment programme is progressive but access to antiretroviral treatment and prophylaxis remains restricted. In 2004, of 33,000 pregnant women testing HIV- positive, only 18,857 received antiretroviral prophylaxis. Latest estimates of people on treatment indicate that 70,000 people are in government programmes and 70-80,000 in the private sector. UNAIDS estimates that 85 percent of those South Africans needing ARV are not yet receiving them.

Sources:
Part I: HIV/AIDS RESEARCH
HIV prevention

Preventing the spread of HIV infection is crucial to curbing the epidemic globally. In South Africa, HIV prevalence is at its highest ever level, with almost 30 percent of pregnant women testing positive in antenatal clinics in 2004. Although there have been several comprehensive and high-profile HIV/AIDS prevention campaigns in the last decade or so, the rates of HIV are increasing each year. This means that conventional prevention strategies are clearly not having as much impact as hoped, and there is an urgent need for critical and creative thinking around these issues.

The PHRU is engaged in a number of research projects investigating different approaches to prevention, as part of its mission towards turning the tide of HIV infections.

Voluntary counselling and testing

Voluntary counselling and testing (VCT) is a process to determine HIV status privately and confidentially, with the informed consent of the client. The process starts with pre-test counselling to inform and prepare the client for testing. Thereafter, a rapid test for HIV is usually performed which takes a few minutes and post-test counselling follows.

VCT is an important entry point to all HIV/AIDS treatment programmes and ongoing counselling and support is required for those on treatment. It is apparent that more information is needed to determine how effective counselling and psychosocial services should be structured. It is also necessary to evaluate the quality and effectiveness of such services, from the perspectives of counsellors, facilitators and clients.
Two studies have been conducted by the PHRU on counselling. The first dealt with support groups run by HIVSA, while the second examined the risk-reduction training given in some PHRU counselling sites. The PHRU is now revamping its entire counselling training programme to provide one that will be certified by the South African Qualifications Authority (SAQA) and will provide a best-practice model to other organisations.

The **Tshwarisanang Couples Centre**

The Tshwarisanang Couples Centre is an innovative programme providing education, counselling, HIV testing and support, focusing specifically on couples.

Most VCT programmes operating in public health facilities target pregnant women, people with sexually transmitted infections or tuberculosis, and people with other illnesses. Other programmes target high-risk groups such as sex workers, long-distance truck drivers and migrant workers. Although the counsellor may encourage the client to bring in their partner, this seldom happens. Instead, these programmes leave the patient to disclose their results to their partner with little support.

The PHRU opened the centre in June 2004, the first exclusive provider of couples HIV counselling and testing (CHCT) in South Africa. Specially trained counsellors create a contained, supportive environment in which constructive discussion can take place and couples are counselled, tested and receive their results together. This process better enables couples to mutually negotiate changes in their sexual behaviour.

At the end of November 2005, 1,247 couples had tested and 387 (31 percent) discordant couples were identified. Sixty-nine percent were concordant, 48 percent HIV-concordant negative and 21 percent HIV-concordant positive. The discordant couples identified in the clinic could potentially participate in clinical trials aimed at addressing this priority area.

This programme works in conjunction with the Partners in Prevention study (see below), as well as other research projects. The first is a study examining what factors facilitate or prohibit couples from jointly participating in CHCT. This information will feed back to the centre’s counselling practice, enabling the design of counselling sessions that appeal to couples and encouraging them to attend CHCT. This will provide more couples with an opportunity to discuss their HIV status, as well as learn about risk reduction in a neutral environment.

*Tshwarisanang* means “supporting each other” in Sotho.
The second research project is a couples-based HIV prevention study, run in association with the Centre for AIDS Prevention Studies at the University of California, San Francisco (UCSF). This is investigating communication about sex among heterosexual couples in Soweto. Very little is known about how partners talk about sexual risk for HIV/AIDS, which may be present from primary partners.

In addition, although CHCT has been demonstrated to be a useful intervention strategy, it is under-utilised. The study will investigate barriers and facilitators of utilising CHCT, even though it is readily available. This study entails qualitative data analysis to examine these issues via individual interviews with 60 adult participants.

The Tshwarisanang Couples Centre has also provided training in couples counselling to more than 100 local counsellors who work in different counselling venues, including clinics and government facilities. This partnership with local clinics has demonstrated how the PHRU and public sector support each other.

**Partners in Prevention study**

The Partners in Prevention study is a multi-centre Phase III randomised placebo-controlled trial of Herpes Simplex Virus (HSV) suppression to prevent HIV transmission among HIV-discordant couples. Observational data indicates that persons co-infected with HIV and HSV may be at a greater risk of transmitting HIV to an uninfected partner. The intervention being tested is acyclovir, an antiviral drug with activity against herpes viruses.

The study will enrol 3,000 heterosexual discordant couples across participating sites in South Africa, Botswana, Uganda, Kenya, Zambia, Tanzania and Rwanda. The PHRU was the first site to enrol participants into the study in November 2004 and over 80 discordant couples have joined the study to date. The majority of HIV-infected persons tested were HSV seropositive (86 percent) and approximately 75 percent of the HIV-infected partners enrolled were women. Follow-up will continue to 2007.

The Partners in Prevention study is funded by the Bill and Melinda Gates Foundation.

**Focusing on men for HIV prevention**

Many HIV prevention strategies have targeted women, specifically through PMTCT programmes. Men sometimes report that clinics are typically "feminine" environments, dominated by female staff and clients – men are uncomfortable coming in for HIV tests and reluctant to discuss their sexual behaviours in such places.

The PHRU has identified this as an important gap in prevention efforts and has proactively engaged in research on male sexuality, including men who have sex with men (MSM). The unit supports the Imbizo Male Health Centre Project in Soweto, an innovative programme in partnership with HIVSA that provides men-friendly health advice and HIV testing.

These projects are funded by USAID and PEPFAR under Grant Numbers 674-0320-G-00-5053 and 674-A-00-05-00003-00.

The PHRU also is working with partners at UCSF on one of the few MSM outreach programmes in Africa.
Project Accept

Project Accept (HPTN 043) is a National Institute of Mental Health (NIMH) Phase III community-based randomised trial, which tests the effectiveness of community-based voluntary testing and counselling (CBVCT), as compared to standard VCT services.

Standard VCT services are offered in public health clinics and through some NGOs. On the other hand CBVCT programmes go into a community, saturating them with advertising about VCT and offering accessible VCT through mobile units (in caravans), in addition to the standard services.

This multi-country study is being conducted in two South African sites (Soweto, Gauteng province and Vulindlela, KwaZulu-Natal province) and in Tanzania, Zimbabwe and Thailand.

The PHRU is responsible for the Soweto study in which eight communities have been randomised into either intervention or control groups. In the intervention group, three key elements will be delivered: CBVCT; community mobilisation; and post-test support services.

Preparations for this study have included detailed geographical mapping of the study communities to inform their selection, extensive stakeholder consultation, liaison with local and provincial health authorities, and community mapping ethnography in order to better understand the communities.

A mobile VCT intervention has been pilot tested in Diepkloof Zone One, an area of Soweto, to assess the logistics of providing mobile VCT. A baseline household survey has been conducted to assess levels of stigma, uptake of HIV testing, sexual risk behaviours, alcohol and drug abuse, and the availability of antiretroviral therapy in the study communities.

It is significant that, unlike other conventional VCT programmes, Project Accept has been able to attract men. During the four-month mobile VCT pilot study, a total of 654 clients have undergone VCT including 252 (39 percent) women and 402 (61 percent) men.

During the intervention, qualitative research will be conducted to monitor changes and a post-intervention survey will be conducted to assess any changes.

This project is funded by the NIMH, through a co-operative agreement with the University of California, Los Angeles (UCLA) under Grant Number 1U01-MH066701-O1A1.
New prevention methods

Methods for Improving Reproductive Health in Africa

The Methods for Improving Reproductive Health in Africa (MIRA) study is a multi-site randomised controlled trial that will measure the effectiveness of the latex diaphragm and lubricant gel (Replens®) in preventing heterosexual acquisition of HIV infection among women. The PHRU has enrolled 1,100 sexually active women in South Africa and will follow them for 12-24 months.

Among women entering the study, the prevalence of risky sexual behaviours is high, with only 50 percent of women reporting condom use with all partners in the last three months. In addition, 24 percent had two or more partners in the last three months and 10 percent report knowing of a previous partner who had tested positive for HIV. Fourteen percent of these women have evidence of a sexually transmitted infection at entry to the study. The preliminary HIV incidence in this cohort is approximately 4.2 per 100 women years (95 percent CI 2.0 – 7.8 cases/100 women years)\(^3\).

The study is financed by a grant from the Bill and Melinda Gates Foundation.

\(^3\)PHRU, unpublished data.
HIV vaccine research

The need for a safe, effective and affordable HIV vaccine is paramount to combat the spread of HIV. The PHRU was the first site to initiate a HIV vaccine trial in South Africa in October 2003. Since then, the unit has successfully initiated five phase I/II HIV vaccine trials and will be involved in preliminary efficacy trials and therapeutic vaccine trials in 2006-7.

Established in 2001, under the leadership of Glenda Gray, James McIntyre and Eftyhia Vardas with funding from the International AIDS Vaccine Initiative (IAVI), the South African AIDS Vaccine Initiative (SAAVI) and later, the US National Institutes for Health HIV Vaccine Trials Network (HVTN), the site is regarded as a leading centre for vaccine trials.

Investigators Glenda Gray, Eftyhia Vardas and Guy de Bruyn, are leading vaccine development teams within the HVTN. In particular, the team is leading the clinical development of South Africa’s own vaccines: the SAAVI DNA.C multi-gene vaccine and the SAAVI DNA.C multi-gene recombinant MVA vaccine. It is hoped that these will be tested in South Africa and the US in 2007.

With seed funding from SAAVI and the Paediatric AIDS Clinical Trial Group (PACTG), the unit also launched an adolescent vaccine preparedness programme in 2005.

HIV vaccine trials

The first two human trials of HIV vaccines in South Africa, which started in October-November 2003 (IAVI 011 and HVTN 040), are now complete, with a total of 45 enrolled volunteers. Preliminary results have been encouraging, with both these candidate vaccines being found to be extremely safe with very few adverse events reported during the respective studies. Two additional phase I HIV vaccine studies have already started (HVTN 050 and HVTN 059) and a phase II study (IAVI A002) is starting at the end of 2005.

An exciting new development, scheduled to start in 2006, is a phase II study to test a therapeutic candidate HIV vaccine. This has already been tested in phase I in Europe in HIV-infected individuals and has shown excellent preliminary results.

Theoretically, a therapeutic HIV vaccine can be used in people already infected with HIV, in order to help maintain their control of viral replication (viral load), thus preventing decline of their immune systems and CD4 counts. It is most likely that this type of vaccine will be used in conjunction with various antiretrovirals, with the advantage that the doses and numbers of drugs (and ultimately the side effects) may be decreased.

In 2005, the PHRU also completed enrolment into a phase III Human Papilloma Virus (HPV) vaccine trial, testing a quadric-valent vaccine produced by Merck. A total of 104 men between 16-24 years enrolled into this study, thereby demonstrating that the PHRU is able to enrol adolescents into vaccine trials.

The PHRU received funding from the AIDS Vaccine Integrated Programme (AVIP), supported by the European Union, to conduct the necessary field work (including HIV incidence measures, HIV genotyping and HLA characterisation) to better inform future HIV vaccine research. This testing will take place in Soweto, as well as in a planned rural site in Limpopo province, in collaboration with the Medical Research Council (MRC) and Wits Rural Public Health and Health Transitions Unit (School of Public Health, University of the Witwatersrand). The site, known as the Agincourt Field site, is situated 500 km north east of Johannesburg with a population of approximately 60,000 people.
Preparing HIV-negative participants for vaccine trials

The PHRU offers extensive, free VCT services. All HIV-negative clients are offered an opportunity to join a structured programme, which includes intensive information-sharing sessions called vaccine discussion groups (VDG). Participants learn about the risks and benefits of participating in an HIV vaccine trial and, after completion of this programme, may enrol into the medical component of the trial. In these clinical sessions, general health and sexual risk are also assessed.

During 2005, the centre provided VCT to approximately 400 clients a month, of whom almost 53 percent were HIV-negative. Over the past three years, 245 participants, of whom 46.6 percent are women, have successfully graduated from the programme and are ready to participate in phase I/II trials.

Monitoring HIV-1 diversity in preparation for phase III vaccine trials

HIV diversity remains one of the greatest challenges for developing an effective HIV vaccine. Viruses belonging to the same sub-type can vary up to 15 percent in certain regions of the genome, compared with 35 percent variation seen between sub-types. It is not yet understood how viral diversity will impact on vaccine efficacy.

The purpose of the monitoring HIV diversity study is to provide a comprehensive analysis of sub-type distribution and genetic diversity in vaccine trials sites in South Africa. The study aims to define regions under selection in natural infection and will contribute data to future investigations on the impact of vaccine immune pressure on sequence diversity in vaccine trial “breakthrough” infections. The PHRU site will enrol 200 participants to this study.

The study is supported by funding from SAAVI.

Adolescents

The PHRU has been funded by the PACTG to undertake an adolescent HIV prevention and vaccine preparedness programme in Soweto. An adolescent community advisory board was established in September 2005 and enrolment into the preparedness programme has begun, in collaboration with HIVSA and Camp Sizanani.
“The PHRU has been involved in research in methods to prevent mother-to-child transmission of HIV (PMTCT) since the mid 1990s and established one of South Africa’s first PMTCT programmes in Soweto, in partnership with the Gauteng Department of Health.”
The South African government began implementing its antiretroviral (ARV) treatment programme in 2004. In Gauteng, from April 2004 to September 2005, a total of 25,619 people started treatment and, although access to ARVs has improved, many people with AIDS are still waiting for treatment.

The PHRU has been involved in research in methods to prevent mother-to-child transmission of HIV (PMTCT) since the mid 1990s and established one of South Africa’s first PMTCT programmes in Soweto, in partnership with the Gauteng Department of Health.

The PHRU also started treating people with antiretrovirals in 1996 through clinical trials and in 2001, established a treatment access programme that enabled people to receive ARVs before these were available in the public sector. The PHRU has well-established adult and paediatric treatment programmes.

The PHRU embraces a comprehensive approach to treatment that includes psycho-social support. Clients receive counselling on the importance of adherence and are educated about all aspects of treatment, including drug resistance, side-effects, nutrition, prevention and disclosure amongst others. Once on treatment, clients are encouraged to go to adherence support groups when they collect their medication. Adherence is monitored through pill-counts and discussions with the pharmacists and health workers.

All treatment programmes at the PHRU have a research aspect. Research areas include drug resistance, pharmacokinetic studies and new drugs. The PHRU also collaborates with a number of international networks.
Comprehensive International Programme of Research on AIDS in South Africa

The Comprehensive International Programme of Research on AIDS (CIPRA) is a programme sponsored by the US National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS). It is one of the first programmes sponsored by the US National Institutes of Health (NIH) that funds foreign institutions directly.

The CIPRA aims to provide long-term support to developing countries to plan and implement a comprehensive HIV/AIDS prevention and treatment research agenda, which is relevant to their populations. The programme also aims to enhance the infrastructure necessary to conduct such research.

The CIPRA-SA “Safeguard the Household” programme, comprising seven organisations from Johannesburg and Cape Town, received the largest award to date – US$21.3 million for the five year programme – in mid 2003. Professor James McIntyre is the principal investigator.

The CIPRA-SA programme brings together South Africa’s leading HIV researchers in an innovative programme of work which addresses challenges in HIV care. The research programme includes five research projects:

- A household approach to antiretroviral treatment at primary healthcare level, comparing nurse- versus doctor-monitored treatment;
- The effects of early antiretroviral treatment in children (CHER);
- The efficacy of pneumococcal vaccines in HIV-infected children;
- The impact of the introduction of antiretroviral treatment on TB in a community; and
- The evaluation of affordable and feasible methods for HIV diagnosis and monitoring.

In addition, there are three supporting core structures: administrative, laboratory and training. The administrative core is based at the PHRU and provides all the programme’s administrative, project management, statistics and data management needs, financial oversight, quality assurance, safety and regulatory requirements. The PHRU data and statistics centre has developed a state-of-the-art facility to accomplish these objectives.

PHRU researchers are leading the paediatric project and part of the laboratory-based research. Patient enrolment started in 2005.

This programme is funded by US NIH DAIDS under Grant Number 1U19 AI53217-01. Further information is available at www.cipra-sa.co.za.
Prevention of Mother-to-Child Transmission

The PHRU has been at the forefront of PMTCT research for the past ten years. The unit was one of the first African sites to move into the operational application of the MTCT research results, with the Demonstration of Antiretroviral Treatment (DART) programme in Soweto, together with the Gauteng Department of Health. This programme has been one of the largest and most successful African PMTCT programmes to date.

The unit continues to undertake PMTCT research to improve the efficacy and safety of PMTCT prevention regimens. The development of nevirapine (NVP) resistant strains of the virus following a single dose of NVP is a particular concern, particularly with the increasing availability of antiretroviral treatment. The PHRU is engaged in research to determine the impact of resistance on future treatment options and methods to reduce resistance.

The PHRU has collaborated on several significant multi-centre research projects which have all contributed greatly to knowledge in this field, including:

- The UNAIDS PETRA (Perinatal transmission) trial, a placebo-controlled trial that investigated three different short-course regimens for PMTCT.
- The South African Intrapartum Nevirapine Trial (SAINT) which looked at the efficacy of an NVP-based regimen versus a short course of AZT and 3TC in the peripartum period.
- The Post-Exposure Prophylaxis (PEP) trial which studied two different post-partum regimens: single dose NVP versus AZT for six weeks in infants born to mothers who did not have access to ARV therapy during pregnancy.
- The Bristol Myers Squibb (BMS) AI455-094 study that evaluated the efficacy, safety, tolerability and pharmacokinetics of short-course regimens of nucleoside analogues for the prevention of MTCT of HIV-1. This study involved intensive pharmacokinetic sampling in very young infants.
- The BMS AI455-120, which is a follow-up study looking at late outcomes in infants exposed to ddI/ d4T in pregnancy. It is an observational protocol following a cohort of 148 children from birth to 16 years of age. Five years of follow up have recently been completed.
The PHRU also participated in a pregnancy pharmacokinetic study of the drug MKC-442, was the single site for the HIVNET 025 study of chlorhexidine washes, and undertook an NIH funded study on T-helper responses to HIV-1 in cord blood of HIV-1 exposed infants.

The PHRU has played a central role in the development of national and international guidelines on PMTCT, working over the last decade with the South African government, the World Health Organisation (WHO), UNAIDS and the United Nations Children’s Fund (UNICEF). Professor James McIntyre was the chairperson of the WHO PMTCT guideline committee in 2004 and co-chair in 2005.

The unit has also provided a great deal of training on MTCT, including a regional training course in collaboration with the Regional AIDS Training Network (RATN).

### Treatment implementation programmes

#### Demonstration of antiretroviral treatment and care

Soweto has one of the longest established PMTCT services in the country and VCT services have been offered in the antenatal clinics since 1987.

In October 2000, the PHRU started the Demonstration of Antiretroviral Treatment (DART) project, with funding from the Elizabeth Glaser Paediatric AIDS Foundation’s (EGPAF) Call to Action Programme. HIV-infected women are currently given a single dose, intrapartum NVP-regimen to reduce the risk of mother-to-child transmission of HIV, with one dose to infants. The programme operates in all 13 antenatal clinics providing VCT for pregnant women and nevirapine for HIV-positive mothers and their infants.

Support groups, infant feeding information and subsidised milk formula are also offered. Infant milk formula is now available for HIV-positive mothers who choose to use it, free of charge for six months, through the government’s provincial authorities.

Uptake in this programme increased dramatically in the first two years and by 2002, 96.8 percent of all women coming to antenatal clinics for their first visit accepted HIV testing. Over 30,000 women are now participating in the programme annually. Since inception, a total of 130,564 women were offered testing, 124,518 (95.4 percent) agreed to be tested and 111,492 (89.5 percent) received post-test counselling. Thirty percent (37,369) tested positive and nevirapine was given to 31,221 (83.5 percent) of their women.
The programme falls in line with the continuum of care approach adopted by the PHRU. Recent government-mandated standards of practice further provide for CD4 cell count evaluations of pregnant women and early HIV Polymerase Chain Reaction (PCR) testing of their babies. These have been incorporated into the model. Pregnant women with CD4 < 200/mm³ are referred to the government treatment sites for triple therapy and the PHRU is actively involved in supporting pregnant women at these sites. There is active follow-up of children to perform early testing and infant diagnosis.

Provisional data from January to June 2005 indicated that 20-25 percent of pregnant women had a CD4 cell count of <200/mm³; these women have been offered HAART since March 2005. Currently, HIV PCR testing at six weeks of age is performed on 100 children per month, with the vertical transmission rate averaging 10 percent. As the programme becomes more established, it is anticipated that the number of children tested will increase to 400 per month.

The DART project has received funding from the Gauteng Department of Health, EGPAF, Fonds de Solidarité Thérapeutique Internationale (FSTI) and Axios International. Currently, the Department of Health supplies the test kits, nevirapine and infant feeding formula.

Since 2002, USAID has supported the programme and is now fully funded the programme through USAID (PEPFAR) under Grant Number 674-A-00-05-00003-00.
Post-partum voluntary counselling and testing

The Post-Exposure Prophylaxis (PEP) study conducted from 2000-2003 was a randomised trial of two post-exposure prophylaxis regimens to reduce mother-to-child HIV transmission in infants of untreated mothers. In total, 1,051 infants were enrolled into the trial which compared single dose NVP (sdNVP) to six weeks of zidovudine in reducing MTCT. The trial showed that sdNVP given to infants offers protection against HIV infection and was at least as good as six weeks of zidovudine. Further analysis showed that the zidovudine regimen did not appear to be as effective as sdNVP in reducing postnatal transmission.

In 2003, the Post-Partum VCT programme (PPVCT) operationalised this research at Bara Hospital, where annually over 18,000 pregnant women from Soweto give birth. Although the uptake of PMTCT in Soweto is very high, some women may not have accessed PMTCT programmes during their pregnancy or may not have a test result available when they go into labour. The PPVCT programme provides a safety net for these mothers. If the HIV status of a woman in the labour ward at not known, she is offered VCT soon after the birth of the baby. If the mother is found to be positive, she is offered nevirapine for her baby, which the PEP study showed reduces the risk of infection.

From January 2003 to October 2005, a total of 50,430 births were recorded at Bara. Of these, 9,759 (19 percent) women presented with an unknown HIV status. In the past three years, the number of women presenting with unknown status has decreased from 25 percent in 2003 to 14 percent in 2005, an indication of the success of the Soweto PMTCT (DART) programme. Tests were offered to 7,426 (76 percent) women and 5,575 (75 percent) were tested.

Those women not offered tests were mainly those who had still births or abortions (78 percent), who were not well (seven percent) or were not found in the ward (11 percent). Of those tested, 1,748 (31.4 percent) women were found to be HIV infected, and 1,693 (97 percent) accepted NVP for their infants.

This programme is funded by USAID and PEPFAR under Grant Numbers 674-0320-G-00-5053 and 674-A-00-05-00003-00.

Soweto PPVCT statistics

**PMTCT research**

**Nevirapine use in PMTCT**

The PHRU has particular expertise in researching the problems experienced by women living with HIV. Researchers are investigating the epidemiology, as well as new techniques of measurement and strategies to avoid non-nucleoside reverse transcriptase inhibitor (NNRTI)-resistance following single-dose nevirapine for PMTCT. There has been increasing concern about the high rate of detectable nevirapine resistance variants following its use in PMTCT programmes, which may have the potential to impact future pregnancies and future treatment options.

**The prevalence of nevirapine resistance**

A prevalence of nevirapine resistance study started in May 2002 at the PHRU and King Edward Hospital in Durban. The primary objective was to determine the prevalence of nevirapine resistance at six weeks, post-delivery. A total of 623 women enrolled onto this study, with follow-up available for 420 of these.

Results presented at the 11th Conference on Retroviruses and Opportunistic Infections (CROI) in San Francisco in February 2004 demonstrated that 39 percent of women and 42 percent of infants had detectable NNRTI-resistant virus seven weeks post-delivery. In addition, 10 percent of the participants had received at least two doses of nevirapine prior to delivery and these were more likely to develop resistance. The implications of these results need to be considered in the context of triple therapy becoming available to a larger number of HIV-positive people and the potential long-term effects of single dose nevirapine treatment. Furthermore, data on persistence of NNRTI resistance genotypes have shown that K103N is the most likely to persist. Resistance in approximately 50 percent of women is not detected when using standard assays.

Maternal and infant resistance at 6 weeks and 6 months

![Resistance Chart](chart.png)

Samples from this study were shared with two groups of US collaborators developing highly sensitive methods of detecting NNRTI resistance in minority populations. Both groups showed almost 40 percent greater levels of NNRTI resistance than detected by conventional sequencing methods. However, the implications of resistance on the maternal and child’s eventual wellbeing when treated with ARVs are not clear. The PHRU is collaborating with Johns Hopkins University assessing the prevalence of NNRTI resistance in the latent reservoir of women who have previously been exposed to sdNVP. This study was funded by the South African Department of Health and Boehringer-Ingelheim.

**Treatment Options Preservation Study**

The objective of the Boehringer-Ingelheim funded multi-centre Treatment Options Preservation Study (TOPS) (BI 1100.1413) is to assess ways of reducing the resistance induced by single dose NVP administered to pregnant mothers and their newborn infants. The idea is to cover the long half-life of NVP with two other ARVs, thus providing an ultra-short course of triple ARV therapy.

The study provided groundbreaking information on a strategy to reduce the risk of selection of NVP resistance following its use for PMTCT. The preliminary results show a dramatic difference between the rates of resistance in mothers who received sdNVP only (60 percent) and the mothers receiving four or seven days of combivir with NVP (10-12 percent).

Because preliminary results showed a very strong effect, the trial endpoints were achieved and the arm with sdNVP only was stopped. However, the arms comparing four days with seven days of combivir were continued and final results will be available in 2006.

The World Health Organisation has recommended the addition of this postpartum cover as one of the options for PMTCT regimens.

**Nevirapine II**

The nevirapine II study is an investigator-initiated study, led by Dr Neil Martinson in collaboration with Professor Lynn Morris from NICD. The study aims to assess the effectiveness of sdNVP when used by women who had received sdNVP to prevent MTCT in a prior pregnancy. The study started in May 2003 with an enrolment target of 360 participants: 240 who have nevirapine for the first time and 120 who receive nevirapine a second time. Preliminary results were presented at the 12th CROI in Boston, 2005. Enrolment is complete and final results should be available in 2006.

The study did find that women who transmitted HIV in their previous pregnancy did not necessarily transmit in their subsequent pregnancy in the presence of sdNVP.

This programme is funded by USAID and PEPFAR under Grant Numbers 674-0320-G-00-5053 and 674-A-00-05-00003-00.

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Antiretroviral treatment after nevirapine exposure

The A5208/Optimal Combination Treatment after Nevirapine Exposure (OCTANE) trial, funded by NIH, will compare the use of either a non-nucleoside reverse transcriptase (NNRTI) containing regimen to a protease inhibitor regimen for ongoing treatment in both nevirapine exposed and unexposed women. This will be conducted at multiple sites in Africa, in collaboration with the Adult AIDS Clinical Trials Group (AACTG).

The PHRU is also one of three sites for the BI 1100.1414 study, which is an open-label study of nevirapine plus combivir (AZT+3TC) treatment in women who have previously received sdNVP for the PMTCT. Most women are now completing 48 weeks follow-up.

Oral HIV/AIDS Research Alliance

In collaboration with the University of the Witwatersrand’s Department of Community Dentistry, the PHRU funded a post-graduate student to assess the prevalence of oral lesions in HIV-infected pregnant women attending the PMTCT programme. The study showed oral candidiasis and angular cheilitis were the most commonly seen oral lesions in these patients with a frequency of 78 (61 percent) and 51 (40 percent) respectively. Oral ulceration was seen in 35 (27 percent) of the patients. Thirty-three women (26 percent) presented with necrotising ulcerative gingivitis, six (five percent) had necrotising ulcerative periodontitis and six (five percent) had linear gingival erythema. Less than three percent of the patients presented with herpes, which was mainly extra-oral. No other HIV-associated oral lesions were seen in these patients.
**Adult treatment**

The PHRU has been at the forefront of treatment in South Africa since the first antiretroviral therapy trials in 1996. The unit established a treatment access programme (PTAP) in 2001 for clients who had completed a trial (with and without follow-up drugs) and for clients failing screening for trials to enable them to access ART.

CIPRA-SA Project One, is a randomised controlled trial that will assess nurse-based versus doctor-based treatment delivery using standard ARV regimens supplied by the Department of Health. This project aims to prove that antiretroviral therapy can be implemented in a resource-poor setting at a primary care facility, with trained primary health care personnel rather than doctors. This trial is being run at two sites: the PHRU in Johannesburg in collaboration with the Wits Clinical HIV Research Unit (CHRU) and at Masiphumelele township in Cape Town.

The specific aims of the project include:

- Comparing the percentage of patients with undetectable viral load at 36 months of treatment, using two different schedules of three treatment regimens of ART in adults (over 16 years) and children over the age of one year;
- Addressing the cost and economic impact on families and society of the implementation of a predetermined schedule of antiretroviral therapy to “Safeguard the Household”;
- Describing the treatment outcomes in terms of morbidity, opportunistic and endemic infections and mortality of ART in a resource-poor setting; and
- Evaluating the contributing factors to treatment failure in a resource-poor setting, including (but not limited to) toxicity, resistance, compliance and treatment interruption due to concomitant medication and intercurrent medical conditions.

As from 2005, the PHRU is an Adults AIDS Clinical Trial Group (AACTG) site. The AACTG is a co-operative clinical trials network funded by the National Institute of Allergy and Infectious Diseases (NIAID). The network evaluates clinical interventions, the efficacy of drugs and drug combinations for treating HIV infection and HIV-associated illnesses.

The Antiretroviral Therapy in Lower Income Countries (ART-LINC) collaboration, a network of HIV/AIDS treatment programmes and cohorts in Africa, South America and Asia was set up in 2003 to address questions around “what works, what does not work, and why” with regard to antiretroviral treatment. The PHRU is a founding member of ART-LINC and will be part of a new collaborative group OASIS, which will expand the work of ART-LINC in the future. The information that can be obtained from these unique programmes will be extremely valuable in designing and scaling up ARV programmes.

**PHRU treatment access programme**

The PHRU’s treatment access programme (PTAP) provides access to antiretroviral treatment. PTAP serves to complement the South African government’s antiretroviral treatment programme providing care and treatment to HIV-infected adults and children. The programme provides antiretroviral therapy, monitoring and support for HIV-1 infected adults and children living in Soweto who meet the country guidelines for treatment, as well as those whose funding for treatment in other programmes or clinical trials in the unit has ended.
Access programmes started in 2001, when the French-based International Solidarity Fund for Treatment (ITSF)/Fonds de Solidarité Thérapeutique Internationale (FSTI) partnered with the PHRU for one of the first antiretroviral treatment access programmes in South Africa. This programme, Operational Research on Antiretrovirals (OPERA), provided drug access for 100 people in need of ARVs to combat their disease progression.

The Doris Duke Charitable Foundation / Pangaea Global AIDS Foundation drug access programme (DDPan) started in mid 2003 and was funded to mid 2005. The original goal was to place 35 people onto antiretroviral therapy for two years. With savings made on reduced drug prices, the PHRU was able to increase this to 40 people on therapy.

The PHRU was awarded supplementary funding to the CIPRA-SA Safeguard the Household grant to establish an antiretroviral treatment access programme (PTAP) to provide HIV care and treatment to HIV-infected adults and children seen in the unit. The PTAP programme has incorporated the participants from the OPERA and DDPan access programmes and a total of 811 people are now on ART through this programme.

The programme is funded through NIH by funding from PEPFAR, thereby assisting PEPFAR in meeting its global goals to treat two million HIV-infected individuals with antiretroviral therapy, to prevent seven million new infections and care for 10 million HIV-infected individuals and those orphaned by HIV/AIDS, in 15 focus countries over a five-year period.
Clinical trials

The PHRU adult pharmaceutical trial division was established in 1996 with a phase III study sponsored by Upjohn Pharmaceuticals. It has extensive experience in industry-sponsored trials, many of which were multi-centre. To date, more than 20 adult pharmaceutical trials have been conducted, four are ongoing and nine are providing post-protocol treatment access (PTAP).

PTAP is available for people who were previously enrolled in clinical trials and continue to receive treatment and follow-up care in the unit. In most cases, the trial sponsors continue to provide antiretroviral drugs and some laboratory monitoring after the clinical trial ends. However, for the trials where this is not the case, the unit has to find the funds to keep the patients in care and, in some cases, provide the antiretroviral drugs. Fortunately, the PHRU is now also able to refer to the government ARV programme for post-trial treatment access.

The ongoing clinical trials in partnership with industry sponsors are:

- GlaxoSmithKlein which is sponsoring a trial assessing the long-term safety profile of one of its investigational drug-containing regimens in HIV-infected subjects;
- Pfizer Pharmaceuticals is conducting a randomised, double-blind, comparative trial of a novel CCR5 antagonist, in combination with zidovudine/lamivudine versus efavirenz in combination with zidovudine/lamivudine for the treatment of antiretroviral-naive HIV-1 infected subjects; and
- Johnson and Johnson conducting a phase IIb randomised, partially blinded, dose-finding trial of TMC278 in antiretroviral naïve HIV-1 infected subjects.

PHRU’s partnership with the pharmaceutical industry and involvement in clinical trials continues to grow and the unit has recently been selected to participate in more trials with GlaxoSmithKline and Johnson and Johnson.

In addition, the unit will be a site for the AACTG OCTANE clinical trial, and future ACTG trials.
Paediatric treatment

The PHRU has been at the forefront of paediatric treatment in South Africa since the first trials in 1996. The Paediatric Treatment Division is headed up by Dr Avy Violari, a deputy director of PHRU and a specialist HIV paediatrician. The PHRU has contributed significantly to trials investigating safe and appropriate paediatric dosing, which lead to the registration of new ARV drugs for children. The unit established a treatment access programme (PTAP) in 2001 for clients completing trials and for clients failing screening for trials.

The PHRU is a current Paediatric AIDS Clinical Trial Group (PACTG) site. The PACTG aims “to evaluate clinical interventions, including the efficacy of drugs and drug combinations for treating HIV infection and HIV-associated illnesses in infants, children, adolescents and pregnant women”. The unit is also collaborating with “KIDS ART-LINC” a programme undertaking multi-site analysis on paediatric issues.

The PHRU clinic is child-friendly, with a fenced children’s playground, an immunisation facility, early infant testing and developmental testing services. A social worker is on hand to assist with child-related problems too.

HIVSA provides education and support groups for patients, parents and caregivers, and children. Pre-treatment and adherence therapy counselling is provided to caregivers and children and clients are encouraged to attend adherence support groups at every visit. The Camp Sizanani children’s programme is available for HIV-infected and HIV-affected children through HIVSA.

The PHRU collaborates with the Respiratory and Meningeal Pathogens Research Unit (RMPRU) which has played a lead role in defining the epidemiology of respiratory-related infections in HIV infected children, and determining the potential for their prevention, and participates in the WHO working-group forums addressing prevention and management regimens for childhood pneumonia in African countries affected by HIV/AIDS.

Paediatric ART Access Programme

In total, over 500 children attend the Paediatric Wellness programme and 141 children are now on ART. Many of these children are post-trial and are accessing post-trial drugs. Those who are unable to access post-trial drugs or fail screening for a trial, are accessing treatment through funding from USAID and PEPFAR under Grant Number 674-A-00-05-00003-00, or are referred to government treatment sites.
**MTCT-Plus**

MTCT programmes have traditionally focused on reducing the transmission of HIV from mother to child. The MTCT-Plus programme adopts a family-centred approach, providing care and treatment to the entire family. Created in response to the United Nations Secretary General’s Call to Action on AIDS and co-ordinated by the Mailman School of Public Health at Columbia University, the MTCT-Plus initiative supports the provision of specialised care to HIV-infected women, their partners and their children identified in PMTCT programmes.

By providing a continuum of services, from patient education to HIV-specific treatment, MTCT-Plus builds on the experiences of successful PMTCT programmes to create sites where prevention services and high-quality care are linked. HIV-infected patients on the programme have access to diagnostic testing, prophylaxis and treatment of opportunistic infections and antiretroviral therapy. The care team is multi-disciplinary: psychosocial support, patient education and counselling is available at each visit.

The PHRU is one of several sites included in the first round of MTCT-Plus sites. The ongoing programme is led by Dr Avy Violari and started in September 2003. To date, 669 adults and 607 children have enrolled in the programme and 223 adults and 56 children are on ART. The purpose of the programme is to use the PMTCT programme as an entry point to provide treatment and care to the entire household.

The patients are assessed to determine the stage of HIV disease. Those requiring ARV treatment are provided treatment; others are provided good medical care and psychosocial support and continue to be monitored in the clinic. The programme provides life-long treatment. During the course of the participants’ follow-up, if at any time they need to begin ARV treatment, they do, and are provided this treatment for life.

USAID is now contributing towards treatment of those enrolled, through funding from PEPFAR under Grant Number 674-A-00-05-00003-00.

**NIH/DIADS funded multi-centre paediatric trials**

The PHRU is currently enrolling into the following trials:

- **PACTG 1041 (phase II/III)**. A placebo-controlled study evaluating the efficacy of isoniazid in preventing TB in HIV-infected children and mycobacterium tuberculosis infection in HIV-exposed uninfected children.

- **PACTG 1020 (phase I/II)**. The study aims to establish the dose and safety of a new protease inhibitor (atazanavir) in infants, children and adolescents.

- **Preventing serious neonatal and maternal peripartum infections in developing country settings with a high prevalence of HIV infection (phase III)**. A CDC/NICHD-funded study recruiting 8,000 women (including 2,500 HIV-infected). The objectives of the study include determining whether HIV exposure is a risk factor for neonatal sepsis as well as defining whether intravaginal chlorhexidine washes during labour are able to reduce peri-partum maternal sepsis and early-onset neonatal sepsis.

The NIH also sponsors the CIPRA-SA paediatric trials:

- **CHER (CIPRA-SA Project Two) (phase III)**. The primary goal of this innovative study is to determine whether initiating antiretrovirals for a limited period during the acute
phase of infection in children will delay disease progression. It is a novel approach to the treatment of paediatric HIV infection. The study sites are the PHRU and University of Stellenbosch in the Western Cape. The study started in 2005 – the unit will enrol 250 participants and will conduct follow-up visits for three years after enrolment.

- **The Paediatric Immune Correlates of Early Anti-HIV Therapy study.** This is an immunological study (RO1 AI062512) linked to CHER, in collaboration with the Wistar Institute, Philadelphia. It will characterise immune correlates of early treatment in HIV-infected infants in relation to disease progression and identify the correlates of delayed disease progression and targets for immunotherapy.

- **CIPRA-SA Project Four (phase III)** evaluates safety and the quantitative and qualitative antibody responses to two bacterial conjugate vaccines (streptococcus pneumoniae and haemophilus influenza type B conjugate vaccines) in HIV-exposed uninfected and HIV-infected children. The project is a collaboration with the RMPRU.

### Pharmaceutical sponsored clinical paediatric trials

The PHRU is involved in a number of paediatric clinical trials sponsored by pharmaceutical companies. Trials in progress are investigating interventions to prevent morbidity and improve the health of HIV-infected children and of the large number of HIV-exposed, uninfected children and to find ways to preserve the immune system with reduced exposure to ARVs.

The unit has conducted 10 clinical trials in MTCT and paediatric treatment. The following studies are currently ongoing:

- **BI 1100.1368** is re-evaluating nevirapine dosing, tolerability and efficacy with two different dosing regimens of NVP in infants, children and adolescents. This is funded by Boehringer Ingelheim.

- **FTC-203** is evaluating the pharmacokinetics, safety and tolerability of a new nucleoside (FTC) in children. This is funded by Gilead Sciences Inc (previously Triangle Pharmaceuticals).

- **M98-940 ABT 378/rit.** This pivotal paediatric phase I/II study to assess the safety and efficacy of lopinavir/ritonavir, in combination with two nucleosides in children between three months and 12 years contributed to a dramatic expansion of therapeutic options for children. This is funded by Abbott Pharmaceuticals.

- **MKC-442.** This study allowed triple therapy for HIV-infected children and continued for 58 weeks. This was the first known triple therapy ART study in South African children. This was funded by Triangle Pharmaceuticals.

- **BMS AI455-094** aimed to treat infants who participated in the PHRU’s BMS-funded AI455-094 PMTCT trial of D4T and ddi. Infected infants in this study, identified by positive DNA PCR, were offered early treatment, initiated between eight weeks and six months of age. Twenty-five of the 27 infants who received early therapy continue to receive ART in the unit. This is funded by Bristol Myers Squibb.

### Multi-centre pharmacokinetic studies

The PHRU has conducted eight pharmacokinetic studies, five as part of paediatric ART treatment protocols, two as part of MTCT trials, and the FTC-116 study, an intensive phase I pharmacokinetic study in HIV-1 exposed negative infants initiated in the first week of life.
“The rollout of ARVs is not restricted to prescribing drugs alone but includes a comprehensive package of care and services”
Once a person is identified as HIV-positive, they may require care for several years before needing antiretroviral treatment. There are a number of interventions that benefit HIV-positive people, such as cotrimoxazole prophylaxis for a range of opportunistic infections, screening for active TB, isoniazid preventive treatment for latent TB infection, screening for syphilis and other STIs, screening for cervical cancer, and appropriate referrals for treatment.

The PHRU offers a package of care that is based on these interventions which are aligned with recommendations by the Department of Health. In addition, cervical smears have been included as the incidence of abnormal smears has been found to be higher in HIV-positive women. Depression is also being investigated.

The rollout of ARVs is not restricted to prescribing drugs alone but includes a comprehensive package of care and services. Currently, ARVs are prescribed in hospitals but the primary healthcare centres and clinics have an important role to play in supporting treatment programmes with supplementary services. Large hospitals benefit from well-functioning care systems in the primary health facilities located within their catchment areas and good co-operation between them is crucial for successful ARV rollout.

TB is a major cause of death amongst people living with HIV/AIDS. The increased number of HIV-positive people could also fuel the TB epidemic. The PHRU is investigating the intersection of TB and HIV through research into new TB treatment regimens, TB prevalence, TB related deaths and exploring the use of GIS to improve follow-up of clients.

A model of palliative care is being implemented in Soweto too, thereby ensuring that a full continuum of services and care is available to people infected with and affected by HIV/AIDS.
The Wellness Programme

The Wellness Programme provides comprehensive care and support for HIV-positive clients before they require ART. The Wellness Programme was first piloted in Soweto and has subsequently been rolled-out to two rural sites in Limpopo province, the poorest province in South Africa.

The programme provides medical care in wellness clinics following the Department of Health and international guidelines. Clients are seen by primary health care nurses, with support from a doctor. Dispensing takes place in consulting rooms or in the clinic. Psychological and social support is provided to clients through a network of support groups and referrals to relevant services.

The programme began in Soweto in 2003 at the PHRU clinic. The Tshisimane Wellness Clinic operates five days a week as a primary health care (PHC) clinic run by PHC nurses and a part-time doctor. By November 2005, over 4,600 clients had attended the clinic, which shows an average of 550 clinic visits monthly. Support is provided by HIVSA through support groups, counselling and education programmes.

A wellness programme was also set up in a local government clinic serving an informal settlement at Weiler’s Farm, 20 kilometres south of Soweto with an estimated population of 26,000 people. The clinic and support groups operate one day a week. For the first time, residents in this area with HIV/AIDS have access to a comprehensive service.

In the Bohlabela district of Limpopo, the wellness programme runs at the Rixile Clinic in Tintswalo hospital. This site is managed by the PHRU’s partner, the Rural AIDS Development and Action Research programme (RADAR). Support is provided by HIVSA’s Ha Swikota support programme, which is a district-wide programme operating in all the primary care clinics. This facility has recently received government accreditation to provide ART.

In addition, the Khutso-Khurhula Wellness Programme is being implemented in the greater Tzaneen Health District in Limpopo. The PHRU is collaborating with the University of Limpopo’s Department of Family Medicine on this project.

Over 4,500 people have accessed these services at these four sites and the PHRU is currently performing an audit to determine how many of these clients are presently active. Statistics show that the median CD4 count of all attendees is 210, of whom 16 percent are less than 50. Although rural attendees are slightly older, surprisingly, CD4 counts at entry are almost the same. At the Soweto site, approximately 80 percent of clients have disclosed their HIV status, whereas only 56 percent of people at the Tintswalo site have done so. Thirty-two percent of women who had a cervical smear were found to have cervical lesions which could progress to cancer; of these about one third were found to have high-grade lesions.

Over the past year, the wellness programme has been instrumental in training numerous primary health care nurses in HIV care and, more recently, has developed a mental health training course specifically directed at nurses involved in the care of people living with HIV/AIDS.

The PHRU intends to continue expanding its wellness programmes, increasing the number of sites in future. To date, approximately 1,000 wellness participants have been transitioned onto ARVs, either through the government ARV initiative or through funds from USAID and the PEPFAR programme under grant numbers 674-0320-G-00-5053 and 674-A-00-05-00003-00.

11 “Tshisimane” means fountain in Sotho.
12 “Rixile” means “the sun will rise” in Shangaan.
Limpopo Province

Limpopo province is one of the poorest provinces in South Africa. In 2001, the province had an estimated unemployment rate of 50 percent and the highest percentage of people in the country without any education (33.4 percent). The provincial HIV-prevalence is 9.8 percent and 19.3 percent in the antenatal clinics, one of the lowest in South Africa.

In Limpopo, the PHRU has partnered with RADAR and the University of Limpopo, Department of Family Medicine in two health districts: Bohlabela and the greater Tzaneen sub-district.

The Bohalabela district (formerly Bushbuckridge), has approximately 800,000 inhabitants and is served by four hospitals. There are two large public hospitals: Tintswalo (450 beds) and Mapulaneng (350 beds), as well as Sekororo (100 beds) and a public-private Life Care facility, Matikwana (150 beds). There are 45 PHC clinics in the district, including two health centres. This district borders on Mpumalanga province which has the third highest HIV-prevalence.

Tintswalo Hospital is situated in Acornhoek and located approximately 250km from the provincial capital of Polokwane. The hospital is located in a rural, environmentally degraded area where the main sources of income come from migrant remittances, social grants and the informal sector. The people in this area have been negatively affected by forced relocations, gross neglect and divisive administrative planning during the apartheid years, and there are many long-term refugees from Mozambique. The hospital serves a population of about 400,000 with an adult HIV seroprevalence of 22 percent.

The Greater Tzaneen sub-district is an area situated in Limpopo with a population of around 400,000. Primary health care services in the Greater Tzaneen sub-district are rendered by two district hospitals and 31 clinics or health centres. Virtually all primary healthcare facilities are managed by staff with a qualification of professional nurse or higher. The majority of facilities are open five days per week, on average nine hours per day, with most of them providing a 24-hour emergency service.

According to the Limpopo Department of Health, the ARV rollout in this area started at Letaba Hospital, with CN Pathudi Hospital following in November 2005.

Sources:
• Department of Health, 2005, National HIV and Syphilis Antenatal Sero-prevalence Survey in South Africa 2004
HIV in surgical cases

A collaborative study with the Department of Surgery at Bara enrolled 1,000 adults from general surgical wards from April to December 2003, approximately half of whom agreed to be tested for HIV. The primary research questions were:

- What is the HIV prevalence in trauma and non-trauma patients?
- Does an HIV-positive person have a longer stay in the hospital?

Overall prevalence of HIV in adult surgical patients was 32 percent. Prevalence rates were very high in women aged 25-30, where over 50 percent of those tested were HIV-positive. There was no major difference in prevalence between trauma and non-trauma patients.

Overall, there was no significant difference in the length of stay or operative procedures between HIV-infected and uninfected patients. However, HIV-positive patients that entered the hospital for non-trauma procedures had a shorter hospital stay than those non-trauma uninfected patients. This could possibly be due to their younger age, easier hospital course or potential bias from the doctors.

Preliminary results were presented to the South African Surgical Research Society’s annual meeting in April 2004 and have been submitted for publication.

This programme was funded by USAID, under grant number 674-0320-G-00-5053.

Depression and HIV

International literature indicates that the prevalence of depression and other neuropsychiatric disorders in HIV-positive individuals is higher than in the uninfected population. Dr Rita Thom of the Psychiatry Department at the University of the Witwatersrand is investigating the occurrence of depression and anxiety in HIV-infected individuals. A total of 300 HIV-positive people have been interviewed and assessed so far. This study will be completed in 2006.

This study is funded by USAID and PEPFAR under grant number 674-A-00-05-00003-00.

HIV/TB clinical epidemiology

Like most sub-Saharan Africa settings, South Africa has high and rising tuberculosis (TB) incidence rates, estimated at 526/100,000. Chris Hani Baragwanath Hospital admits about 300 adults per month with a diagnosis of TB, of whom about 80 percent are HIV-infected. About 30 percent of these die during their admission. The scale of TB prevalence makes assessing interventions to prevent morbidity and mortality in co-infected patients relatively easy.

In 2000, the PHRU entered into a formal partnership with the Johns Hopkins School of Medicine to investigate TB and its impact on the Soweto Community. Since that time the director of this division, Dr Neil Martinson, has developed several projects in the TB and HIV area.
Novel Tuberculosis prevention regimens for HIV-infected adults

Adherence to treatment is a major concern for clinicians treating people with HIV and TB. Novel TB prevention regimens for HIV-infected adults could potentially reduce the duration of treatment and the total number of doses, thereby enhancing adherence.

In September 2002, a randomised controlled trial of three novel preventive treatment regimens was started. The study enrolment of 1,150 participants has been completed and is now in the follow-up phase, with loss to follow-up after 34 months less than 15 percent. Results from this study are expected in late 2006.

The PHRU hopes to obtain supplementary funding from the NIH to allow additional follow-up for a further two and a half years. This programme is funded by the NIH through Johns Hopkins University, under grant number AI48526-01.

TB incidence in HIV-infected children

This retrospective cohort study assesses whether children who receive HAART have a lower incidence of active TB than HIV-infected children not treated with HAART. The study includes data on 1,000 children from four South African sites and will provide important information on a relatively neglected area: TB and HIV co-infection in children.

This work is funded by the PHRU.
TB prevalence in HIV-infected pregnant women

The primary objective of this study was to determine the prevalence of active TB in HIV-positive pregnant women at the time of antenatal counselling and testing. The study closed in mid-2003, with 370 women enrolled.

It was found that two percent of HIV-infected pregnant women had previously undiagnosed, active TB which had not been picked up with a TB smear, the most common method used for diagnosing TB in this type of setting. The implications of these results are that TB cultures would be required to detect TB early in pregnant HIV-positive women. The expense of this is likely to be prohibitive, although this type of symptomatic screening can be done by lay counsellors without adding too much additional time to the counselling session.

This programme was funded by USAID under grant number 674-0320-G-00-5053.

TB autopsy study

In collaboration with internists from Bara and Johannesburg Hospital, the autopsy study attempted to unravel the immediate, contributory and underlying causes of high early mortality in patients admitted with an ante-mortem clinical diagnosis of TB. Several studies have documented the impact of HIV infection on mortality in patients with TB, but very little data exists on the autopsy confirmed cause of death in patients who die soon after being diagnosed with TB. Preliminary, unpublished results from this study show cytomegalovirus, pneumocystis and salmonella infections are important co-morbidities.

This programme is funded by AIDS Care Research in Africa (ACRI-A).

A follow-up study, in conjunction with the Partners AIDS Research Centre at Harvard, is planned to identify easily collected risk factors of mortality in TB patients, facilitating the development of a scoring system similar to those developed for community-acquired pneumonia.

TB and GIS study

This study was a proof of concept study assessing whether a handheld personal digital assistant (PDA) (or "digital diary") could be combined with GIS technology and be used to assist the follow up of TB patients. This study was conducted in collaboration with the University of Witwatersrand’s Department of Electrical Engineering. Two settings were chosen to test the PDA: Alexandra, a dense urban township in Johannesburg and Wheiler’s Farm, a semi-rural informal settlement, south of Soweto. All data has been collected and preliminary results show that the handheld PDA can save considerable time in finding a person’s residence, especially in areas where no reliable street addresses exist.

This study was funded by the Wits AIDS Research Institute and the Carnegie Foundation.
Palliative care

Palliative care is the provision of pain and symptom relief. The PHRU partnered with the Department of Medicine at the University of the Witwatersrand to develop and run a model of palliative care in Soweto from 2002-2005.

The objectives of this programme included:

- Improving the quality of care for terminally ill AIDS and cancer patients, by providing pain relief, symptom relief and related care;
- Piloting a model of home- and community-based care in Soweto; and
- Addressing the lack of linkages and referrals between home-based care activities and the public health sector.

In addition, the programme provided training, developed nurse-led care services in Soweto and facilitated the Soweto Care-Givers’ Forum. From 2005, this programme runs as a separate syndicate within the Wits Health Consortium.

This programme was funded by Development Co-operation Ireland.
“Much of the research focus at the PHRU and elsewhere has been on women but the PHRU is developing expertise in new, previously ignored areas such as men and men who have sex with men.”
HIV/AIDS-related research

The PHRU is committed to mitigating the impact of HIV/AIDS in South Africa. Although it is primarily a medical research organisation, HIV/AIDS-related issues provide critical contextual information to inform the comprehensive approach taken at the PHRU. The PHRU has partnered with many organisations and academic institutions in this research.

The PHRU has engaged in a number of surveys in its primary research locations of Soweto and Boheitenla, to provide important information on the study population and health-related issues, such as health-seeking behaviour.

Much of the research focus at the PHRU and elsewhere has been on women but the PHRU is developing expertise in new, previously ignored areas such as men and men who have sex with men.

As antiretroviral treatment expands in South Africa, new issues will develop. Adherence to treatment is a concern, particularly in relation to resistant viruses. Treatment is a long-term commitment and the PHRU has researched and contributed towards the development of training and other materials that will improve adherence rates.

Death rates continue to increase and the anthropological research conducted by the PHRU gives a unique insight into the impact on families, communities and health practitioners.

Effective counselling programmes in resource-limited settings are a challenge. The PHRU is engaged in research to improve the support given to HIV-positive people and their families.

The PHRU is also committed to disseminating information, research findings and accurate information through the media. The HIV/AIDS and the media fellowship projects is a novel approach to improving HIV/AIDS reporting in the news media.
Household surveys investigating the social and economic impact of HIV

Impact of HIV/AIDS on household vulnerability and child wellbeing

In 2002, research revealed that Gauteng province had a provincial HIV-prevalence rate of 14.7 percent\(^1\), with a sero-prevalence of around 30 percent in the antenatal clinics in Soweto\(^2\). These rates are amongst the highest in South Africa. The impact of HIV on adult morbidity and mortality, the effect on households and wellbeing of children is not known. The aim of this study was to investigate these effects. Although the HIV/AIDS epidemic affects all sectors of society, low-income households carry the greatest burden of disease, experience the most negative impacts and have the least reserves available to cope.

A cross-sectional survey of 4,912 households in 226 census enumerator areas of Soweto was conducted in May 2002. The design was a stratified, two-stage cluster sample. In the first phase, 4,501 households containing children under the age of 16 were surveyed; in the second, 411 households with no children were surveyed. The stratification was based on household type, including private sector housing, council housing, backyard dwellings, hostels and informal settlements. The sample included detailed information on 22,724 individuals, of whom 8,523 were children.

The survey was completed in early 2003 and has provided an invaluable database on the Soweto population. A report titled “The Effects of Adult Morbidity and Mortality on Household Welfare and the Wellbeing of Children in Soweto” has been completed and can be downloaded from the website www.phru.co.za. The analysis for this report was conducted by Helen Struthers, Veni Naidu and Ronelle Van Niekerk.

The household study was funded by USAID under grant number 674-0320-G-00-5053. The fieldwork was conducted by Progressus cc.

Economic impact of HIV/AIDS on households in Soweto

This longitudinal study examined the impact of HIV/AIDS on economic wellbeing at the household level. The study was conducted in collaboration with Dr Veni Naidu who developed this research project for her doctoral thesis. A household survey focused on identifying operational support systems within the community; on identifying at-risk children and households; and on developing strategies to improve social networking and support for these households. The analysis focused on assessing the impact of HIV/AIDS and households’ responses to it, as well as its effects on the survival, vulnerability, and education of children.

This household survey was conducted by the PHRU, in collaboration with the Economic Policy Research Unit of the University of Cape Town and the University of KwaZulu-Natal, Durban.

The research was sponsored by USAID, the Department for International Development (DFID) and Australian International Aid (AUSAID), and was administered by the Joint Economic AIDS and Poverty Programme (JEAPP).


\(^{17}\)PHRU unpublished PMTCT data
Masculinity and men’s sexual behaviour

There has been little research in South Africa on factors affecting sexuality and sexual behaviour in men, and how these impact on the HIV epidemic. The PHRU has started to work in some of these areas, to develop an understanding of effective prevention measures. This work is underway in two areas:

Male sexuality in Soweto. An ethnographic study of masculinity was undertaken by Sakhumzi Mfecane among heterosexual men in Soweto, which has given some insight into male sexuality and examined a male perspective on relationships and sexual engagement. These results have been published in a book chapter.

Men who have sex with men (MSM). Sexual risk behaviours for HIV transmission among black urban MSM in South Africa have not been well described. The majority of HIV infections in South Africa occur via heterosexual intercourse and the HIV prevention and testing needs of MSM have received little attention. A qualitative study on 48 men was conducted on MSM in Soweto and Hillbrow. Robin Hamilton designed the study, while Tim Lane and Helen Struthers analysed the data. This preliminary study explored sexual practices, sexual identities, risk behaviours and health-seeking behaviours. The study results were presented at the XV International AIDS Conference, Bangkok, in 2004.

These results suggest that MSM are at high risk for HIV infection and have few targeted prevention or sexual health services available to them. Interventions to improve the quality of health care for MSM are urgently needed. Research and intervention strategies must recognise the diversity of sexual and gender identities among MSM: targeting “gay” men will not reach all MSM. There is a need for further ethnographic research in this field, and the PHRU is partnering with researchers from UCSF to take this important research further.

Adherence to antiretroviral treatment

As the roll-out of ART treatment takes place, issues of adherence will become more critical, especially in view of the implications of drug and cross-drug resistance. It is essential that barriers to adherence are understood.

Adherence to ARV therapy is largely unexplored in South Africa since so few people have been on treatment until recently. Poor adherence to complicated ARV drug regimens is one of the most pressing behavioural problems in the clinical management of HIV-infected persons. Stigma and lack of disclosure are hypothesised as some of the barriers to adherence. In-depth understanding of factors that impede or facilitate adherence is essential as South Africa gears up for broader ART distribution.

The unit has conducted a number of studies on adherence. Focus groups, a qualitative survey and an ethnographic study were used to explore the issue and provide information for health-care practitioners and counsellors. Outcomes include:

- A video on adherence made by a student from Yale University;
- Adherence support groups; and
- An adherence resource pack and kit for running support groups.


An ethnographic study carried out by the PHRU’s anthropologist and senior researcher, Nokuthula Skosana, was an exploration into the everyday experiences of taking ARV treatment among a cohort involved in various pilot studies in Soweto. Its aim was to understand the link between stigma and disclosure, and ARV adherence. Through semi-structured, in-depth interviews, participants were encouraged to explore emotions and everyday challenges. The study was not intended to measure adherence but to understand its dynamics. It was funded by USAID under grant number 674-0320-G-00-5053.

Adherence support groups are now run regularly by HIVSA. Four educational pamphlets on treatment and adherence were produced as part of the Therapeutic Counselling Project (funded by Glaxo Smith Kline Foundation).

The Adherence Networking Group (ANG) is a collaboration between the PHRU, the Centre for the Study of AIDS at the University of Pretoria, Community AIDS Response, Reproductive Health Research Unit, Aurum Health (Anglo American Corporation), private consultants and others. The ANG has developed the Adherence Resource Pack that includes material for training adherence counsellors. The PHRU will pilot monitoring and evaluation mechanisms for training and counselling. A very successful day-long symposium “Sticking with the programme” on adherence was held by ANG, in November 2005, and funded by the PHRU through the USAID PEPFAR grant number 674-A-00-05-00003-00.

Living with HIV and dying of AIDS

The Medical Research Council report on adult mortality in South Africa shows an alarming increase in deaths due to HIV/AIDS, but little research has been conducted on death in this context. This ethnographic study aims to gain a better understanding of the emotions of those infected and affected by someone dying of HIV/AIDS, the support structures and community responses to this situation, and finally how people confront death. The PHRU partnered with the Department of Anthropology, University of the Witwatersrand.
In total of 59 individual interviews and seven focus group discussions were conducted over three months. Due to ethical constraints, this study focused on adults and did not investigate children's perspective on issues affecting them.

The study found that HIV/AIDS has infiltrated all aspects of life. Family relationships are taking strain from the spectre of AIDS – stigma, discrimination, financial burdens and a lack of emotional support all impact negatively. Traditional networks of support are being eroded, with new ones forming. Health care workers are under stress and burnout is a major issue. Traditional healers are fighting to gain status within the health care system. Faith-based organisations are only just beginning to play an active role, while health, welfare and community-based service organisations are stretched financially and logistically.

The conclusions of the study showed that there is a need for systematic planning and co-ordination of services to maximise the levels of care for those infected and affected by HIV/AIDS, particularly in a resource-poor setting. Communication between various levels of service providers needs to be optimised for quality health and welfare services delivery. Community-based organisations play an increasingly active role in the care of people with AIDS and need to be empowered as partners in the care of patients and their families.

**HIV/AIDS and the media**

The PHRU has always been in the forefront of advocacy, education and training on the issue of HIV/AIDS. A collaborative project with the School of Journalism at Wits University on HIV/AIDS and the media was initiated in 2003. This innovative programme has provided opportunities for working journalists to research aspects of HIV/AIDS coverage in the media, backed up by the expertise of the PHRU.

The first two fellowships were awarded in 2003. Alan Findlay undertook a comparative study of media coverage of HIV in the three months from March to May 2002 with the same period in 2003. A comprehensive survey of all printed media was performed to assess changes in the way the HIV/AIDS was covered as well as what events were reported on in the two time periods. It was found that conflict between government and civil society was the main driver of HIV and AIDS-related news during these periods.

Ida Jooste, a TV journalist, engaged with a poor disadvantaged community in an informal settlement – Cato Manor (near Durban, KwaZulu-Natal) to assess audience reception of HIV/AIDS related messages. Results showed that the residents wanted more personal stories about ordinary people affected by HIV/AIDS and challenged the notion of news fatigue.

In 2004, the focus was on PMTCT. Phillipa Garson did in-depth interviews with women who had accessed PMTCT services in Soweto. Nicola Spurr analysed media coverage of PMTCT.

The focus for 2005 is on orphans and vulnerable children. The project also hosts and updates the Journ-Aids website where journalists can access information and key documents on HIV/AIDS in South Africa.

The findings have been presented at joint symposia held with the Nelson Mandela Foundation. Other organisations contributing to the project include the Centre for AIDS Development, Research and Evaluation (CADRE), the South African National Editors Forum (SANEF) and the Media Monitoring Project (MMP).

This project is funded by USAID (grant number 674-0320-G-00-5053), with subsequent funding from Johns Hopkins University.
Part II:
A STRATEGIC PARTNERSHIP BETWEEN THE PHRU AND HIVSA
**IMBIZO men’s health project**

Men are reluctant to test for HIV or, if HIV-positive, do not find it easy to access services and support. The Imbizo project broadens access to HIV/AIDS information and services to include men. Two drop-in centres have been set up in the community of Soweto, giving men an opportunity to engage with each other in a male-friendly environment. All project staff members are male and the project co-ordinator is a professional male nurse.

Men are encouraged by fieldworkers to come in for HIV/AIDS information, VCT and support. In the first ten months of the programme, on average over 300 men came to the centre monthly and 916 tested for HIV.

Information and discussion is also facilitated on a range of issues, including fatherhood, men as partners of HIV-positive women, women’s rights and men having sex with men. Referrals are often made to auxiliary services. A media launch was used to promote the project including a weekly radio talk show around men’s health issues. A toll-free helpline is also available.

This programme is funded by USAID and PEPFAR under grant numbers 674-0320-G-00-5053 and 674-A-00-05-00003-00.

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23 An “imbizo” refers to a traditional gathering of men.
Camp Sizanani

The presence of HIV/AIDS in the family deprives vulnerable children in disadvantaged communities of many of the resources needed for normal development. Camp Sizanani provides vulnerable children with essential life skills and a sound knowledge of HIV/AIDS through a 10-day residential camp programme. This is achieved by the use of play and experiential activities teaching social skills and coping mechanisms. A follow-up Community Kids Club strengthens learning gained at the camp and encourages the community to participate.

More than 2,000 children have attended Camp Sizanani to date, with excellent results. Social workers have reported that many of the children in their care are communicating their needs and difficulties more openly and seem better equipped to deal with their problems. In addition, the voluntary camp counsellors (who are also drawn from the community) have grown and continue to be actively and enthusiastically involved. A challenge faced by this programme is the restriction on the number of children reached, due to the costs involved.

It is HIVSA’s aim to acquire a permanent site to extend the services to vulnerable children.

This programme is funded by World Camps Inc and the Elton John AIDS Foundation.

Aha Tshepo food gardens and nursery

Nutrition and food security are two very important needs in the lives of people affected by HIV/AIDS. HIVSA’s Aha Tshepo food garden project aims to meet these needs, with a demonstration and training garden Bara Hospital and 10 food gardens at local clinics in Soweto.

Through this project, HIVSA teaches people to grow sustainable, organic and highly nutritious foods. In partnership with Garden Africa, the principles of permaculture food gardening have been adopted, with very positive results. Community involvement is an essential aspect and volunteers are trained in permaculture and good nutrition, medicinal herbs, setting up a nursery and food preparation.

This programme is funded by Garden Africa, with additional support from Seeds for Africa and the Belgium Technical Co-operation South Africa.

24 “Sizanani” means “to help each other” in Zulu.
25 “Aha Tshepo” means “to create hope” in Southern Sotho.
PART II: A STRATEGIC PARTNERSHIP BETWEEN THE PHRU AND HIVSA

Johnson and Johnson palliative care support programme

Home-based care is a crucial aspect of support for the terminally ill but many caregivers lack basic materials to assist them. HIVSA has developed a best-practice model for home-based care organisations and, in collaboration with Johnson and Johnson pharmaceuticals, distributes quality home-based care kits. These kits include lotions, earbuds, mouthwash, talcum powder and oil that greatly benefit bed-ridden and weak patients.

Approximately 350 volunteer caregivers reach about 3,500 patients through this programme and more than 2,000 packs are distributed monthly. Most caregivers also attend a weekly support group run by HIVSA and a social worker is available to families in crisis. This programme has now been expanded into a rural area in the Mpumalanga province.

Aha Tshepo halfway house

The Aha Tshepo halfway house was opened in October 2004 for displaced HIV-positive women and their children. Because of the stigma surrounding HIV/AIDS, many people who disclose their HIV status publicly are ostracised by their families and communities. This safe house is located on the outskirts of Soweto. Run by a full-time housemother, it can accommodate up to 20 women and their pre-school children.

Residents of the house are given support and counselling, enabling them to come to terms with their HIV status and work through any family issues. They are taught beading, sewing and food gardening, and are able to earn money while resident at Aha Tshepo. A HIVSA social worker helps them to access welfare grants and medical services.

HIVSA staff members also bring families together to educate them about HIV/AIDS and create support networks to enable women to return to their families or partners. Residents typically stay at the house for four to six months. While there, they take turns to clean and maintain the house, manage their own food garden and care for the children.

The Aha Tshepo halfway house is funded by the Orange Babies Project and the residence is provided by the Johannesburg City Council.
Aha Tshepo milk formula project

The Aha Tshepo milk formula project provides support to the PMTCT programme in Soweto. HIVSA distributes government-funded formula for six months to HIV-positive women who choose not to breastfeed in order to reduce the risk of mother-to-child transmission of HIV.

In addition, destitute HIV-positive mothers are given free formula for the 6-12 month period required for safe infant feeding, through funding from the Orange Babies Project in the Netherlands. The Milk Room also supplies nutritional supplements such as E-pap, a maize meal porridge enriched with soya, vitamins and minerals.

Aha Tshepo income-generating projects

Poor families find their resources even more stretched when a member becomes HIV-infected. Medical insurance is rare and these benefits may not extend to HIV/AIDS cover. Also, the cost of treatment, healthy food and transport to access services may be prohibitive and economically productive family members may have to leave their jobs to care for sick relatives. Overall, there is less money available for food, transport, school fees and other expenses.

Through the Aha Tshepo income-generating projects, HIVSA attempts to help people generate earnings for their families as part of its comprehensive approach to HIV/AIDS care and support. HIVSA clients are trained to produce high-quality beadwork and African jewellery. Beaded AIDS ribbons and shopper bags are also produced on order for corporate and NGO events. Some of these products are created by women living at the Aha Tshepo Halfway House, helping them to earn a living and develop a sense of achievement. The Aha Tshepo trading store is located at Bara Hospital where a full-time employee sells snacks and refreshments to local staff and visitors. This small business is self-sufficient.
Aha Tshepo feeding scheme and kitchen

People living with HIV/AIDS need good nutrition in order to remain healthy and enhance their immune systems. However, many impoverished HIV-positive people simply cannot afford good food and scores of HIVSA clients are actually malnourished. Nutrition is therefore a vital piece of a comprehensive care package for people with HIV/AIDS and is something which HIVSA takes very seriously.

All HIVSA and PHRU clients and their children are provided with a free, nutritious meal when they visit the clinic at Bara hospital by the Aha Tshepo feeding scheme and kitchen. Many people leave home early without eating and HIVSA feeds up to 200 people every weekday. HIVSA also provides nutritious food parcels to clients in need. In addition, those people who prepare meals are paid for their work.

This programme is currently under review due to the lack of funding. Past support was from the South African Catholic Bishops Conference Fund.

Areiketsetse le Bana programme

The aim of the Areiketsetse le Bana programme is to mitigate the effects of HIV/AIDS on orphans and vulnerable children in the community. Street guardians, recruited from the community, interact with community committees who identify children’s needs in their respective areas. Access to child grants, health and nutrition, school fees and uniforms are some of the current needs identified. An important part of this programme is to develop an effective and user-friendly referral system within the community.

This programme is supported by Save the Children Norway / Zimbabwe.

“Areiketsetse le bana” means “let’s do it for ourselves and our children” in Sotha.
Support and education programme

HIVSA believes that knowledge is critical to empower a person to make important decisions regarding their life. Education plays an important part of HIVSA’s programmes and there is an enormous need for people to be educated and informed about HIV/AIDS. It is also important that people test their HIV status and make informed choices about safe sex and positive living.

The support and education programme provides a range of activities to people infected and affected by HIV/AIDS. This programme runs at Bara Hospital and at clinics in Soweto.

HIVSA offers pre- and post-test counselling and support. “Info hour” sessions run daily for any person interested in learning more about HIV/AIDS.

A resource pack for support group facilitators has been developed, as well as a range of education tools around HIV/AIDS. Training adherence counsellors and support group facilitators is an important aspect of HIVSA’s work.

For people starting antiretroviral treatment, adherence counselling and support groups are provided. These are a valuable mechanism to empower and educate people living with HIV/AIDS. Support groups are a cost-effective way of disseminating information about HIV/AIDS to communities in urban and rural areas in a safe, confidential, welcoming space where people feel comfortable expressing their fears, thoughts and concerns.

HIVSA runs support groups for various categories of people affected by HIV/AIDS. At present approximately 500 people attend every month and this number continues to rise. Support groups for children are also being developed.

Some clients coming through the support groups are also referred for individual counselling sessions with a HIVSA social worker funded by the American Jewish World Service. These clients may require help in accessing government grants for housing or welfare support, or may have other psychological needs that are best addressed individually.

HIVSA’s education and support group programmes are funded by USAID and PEPFAR under grant numbers 674-0320-G-00-5053 and 674-A-00-05-00003-00.
Ha Swikota rural support programme

Ha Swikota⁷ is HIVSA’s rural support and education programme in the Bohabelo district of Limpopo province.

HIVSA, through its partnership with the PHRU and the Rural AIDS Development Action Research programme (RADAR), has extended its psychosocial support model to one of the country’s poorest regions. The Ha Swikota project supports 45 primary healthcare facilities and three healthcare centres in Bohabelo. Through more than 130 trained counsellors and fieldworkers, support groups are facilitated for people with HIV/AIDS and information about HIV/AIDS is widely disseminated. HIV/AIDS education and awareness are promoted through community awareness days, a local stakeholders’ forum, youth meetings and door-to-door campaigning. Thousands of people have been reached in this manner. Ha Swikota volunteers wear bright orange t-shirts, giving them a sense of identity that also boosts their motivation.

This programme is funded by USAID and PEPFAR under grant numbers 674-0320-G-00-5053 and 674-A-00-05-00003-00.

HIVSA is also supporting the development of the Khutso-Kurhula programme in Tzaneen, Limpopo province.

¹⁷ “Ha Swikota” means “we care” in Shangaan.
Part III: PHRU OPERATIONS AND INFRASTRUCTURE
Establishing and maintaining these support structures to enable researchers and administrative personnel to effectively execute their duties is an integral function of the unit. The PHRU has proven that it has the expertise to influence and support research in South Africa at a time when commitment and professionalism is a priority.

**Governance and conduct**

The PHRU operates as a division of the Wits Health Consortium, a wholly owned subsidiary of the University of the Witwatersrand in Johannesburg. This means that the unit is subject to the university’s management and financial controls.

The PHRU executive team is committed to effective governance and continually evaluates both the contribution of management and the development of appropriate processes and procedures. The directors lead the unit in conjunction with an executive committee which meets regularly to review decisions and actions. This structure affords the PHRU independent, insightful and objective contributions on major decision-making processes and standards of conduct.

The PHRU’s leadership recognises that adherence to the principles of sound scientific research and codes of conduct are of paramount importance.

**PHRU operations and infrastructure**

The PHRU has faced many challenges in recent years in its efforts to maintain its position as one of the world’s leading HIV research organisations. The unit has increased its programmes dramatically, resulting in a significant increase in staff. This has meant a need for extra office and clinical space, as well as additional IT, network and data support essential for maintaining the correct levels of confidentiality required when running complex pharmaceutical and vaccine trials.
Internal and financial controls

The PHRU’s systems of internal and financial control are designed to provide reasonable assurance as to the integrity and reliability of the financial information and to safeguard, verify and maintain accountability of revenue and assets. These controls are implemented and managed by skilled operational personnel, and monitored by the directors according to industry-standard internal control norms.

The PHRU has also implemented a system of personal performance appraisal which contributes towards the way in which internal controls are measured and regular management reviews conducted.

Code of ethics

Each and every PHRU employee is expected to maintain the highest level of ethical standards, ensuring that the unit’s work and practices are conducted in an exemplary manner. The directors continually strive to set an example for the organisation to conduct its programmes and projects with absolute integrity and transparency towards all stakeholders.

Research support

Data management

Over the past year, the data management department has focused on refining the DataFax system in order to accommodate the increase in staffing. DataFax is an industry-standard clinical trials management software solution that has been incorporated in order to adhere to the strict regulatory requirements for DAIDS and other US government-sponsored research. There are currently 20 protocols managed within DataFax, with 12 data managers trained to use this software system effectively.

A DAIDS-sponsored audit of the data management centre included a review of operating systems and documentation, training systems, work practices, adherence to regulatory standards, and all CIPRA-related database development and validation work by an internationally recognised expert in the clinical research industry. The auditor concluded that the PHRU operates at a level comparable to, or even better than, the industry standard in the US and Europe. DAIDS subsequently granted approval for the initiation of the CIPRA projects based on this superb review.

DAIDS has awarded the data centre a US$100,000 training grant as part of the AIDS International Training and Research Programme (AITRP). This grant has enabled targeted training opportunities within data management and statistics that have been critical in the ongoing development of the department.

The Clintech system, developed in-house, currently supports the information needs for the entire PHRU clinic system. The team has integrated a fingerprint scanning solution in each of the clinics in order to better identify research participants, and to expedite the check-in process. Clintech is an important software tool which centralises patient and visit information across all syndicates. A laboratory module also allows the PHRU laboratory to report on test results. The PHRU hopes to add a pharmacy module in the near future that will allow dispensing and adherence information to be linked to the patient database.

Staffing in the department continues to grow, with a total staff body of 65 by the end of 2005.
Statistics

The statistics department is currently staffed by three Master’s level statisticians who provide statistical support for the PHRU staff. These statisticians are involved in the development of study protocols, calculating sample sizes and planning the statistical methods to be used in any research analysis. They are involved in statistical programming and statistical analysis of data sets generated in the unit, and they assist with the interpretation of results, thus contributing to the unit’s formidable research output. They are also involved in developing standard documentation and procedural guidelines for the unit.

In South Africa, industry experience and technical training for statisticians is very limited. To address this, the PHRU has actively sourced international training and staff development opportunities. Two biostatisticians were funded by the Fogarty International Training Programme to attend the Johns Hopkins University summer programme in epidemiology and biostatistics while two others received training in applied regression analysis at Universitat Zurich. Another significant opportunity was the three-month placement in the PHRU of a senior biostatistician sponsored by Pfizer, who provided mentoring and training for staff.

Through ongoing research projects, the staff has the opportunity for mentoring exchanges with experienced foreign biostatisticians. With CIPRA, for instance, staff members have worked closely with US- and UK-based statisticians to develop analysis plans, study reporting plans, safety monitoring plans, and terms of reference for the Data Safety Monitoring Board (DSMB).

In due course, the PHRU biostatisticians will take over the lead role in the ongoing responsibilities of these research protocols, with additional support from the foreign mentors as required.
Information technology
The PHRU has grown exponentially in recent years and there are now over 200 staff members requiring information technology (IT) services. A major overhaul of the unit’s IT infrastructure has ensured that excellent security and backup systems are now in place. Access to the PHRU network and data are fully protected and restricted, with effective backup measures in place in the event of loss or disaster.

The IT department has further implemented new telephone management software to allow billing to syndicates by users. The PABX has been expanded and a revamped physical security system has been implemented.

The server room has been upgraded to allow better security and access control. The PHRU is in line with international regulatory standards, including environmental monitoring equipment, a state-of-the-art fire detection and fire suppression system, back-up power systems and automated phone alerts in any instance of out-of-range temperature or humidity reading.

Expansion of internet and email access has been contracted to CMC Networks. Sentech continues to sponsor an internet satellite link that is used by most network users, while designated critical staff members use the CMC link for high-speed internet access.

The IT department is staffed by seven personnel, with the addition of a part-time specialised IT contractor focused on technical improvements and refining departmental documentation. Continued staff development has been possible through training opportunities provided by the AITRP grant.
Finance

The PHRU was awarded recognition as a university research unit in 2000. At that time, no financial support was requested, and the unit has not received salary or other financial support from the university to date.

Two finance teams are responsible for the management of the PHRU’s financial needs. Lead by the Chief Financial Officer and four other staff, the unit’s internal finance department is funded through the PHRU syndicates. Their primary responsibility is to prepare and manage donor-funded budgets, including submitting financial reports as required. They are also responsible for daily financial management and management of the PHRU’s central accounts.

The Wits Health Consortium’s finance team is funded out of a management fee income. Their responsibilities include payment processing, cashbook processing, general ledger maintenance and reconciliation, management of bank accounts and audits, both for the WHC and specific donors.

Revenue Stream (SA Rands)

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Top Three Funders (SA Rands)

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<td>82,281,982</td>
<td>85,708,604</td>
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</table>
Human resources

The PHRU now employs over 400 staff in its various projects and programmes. The human resources department (HR) forms part of the management provided to the unit by the Wits Health Consortium. The on-site HR department provides input into performance management, payroll, the HIV/AIDS management programme, provident fund and employee communication through Essential Elements, a monthly newsletter. The PHRU and WHC are committed to improving leadership, skills development and employment equity in the workplace.

Empowerment

The PHRU is an equal opportunity employer, committed to a working environment that is free from any racial or gender-based discrimination. The PHRU continually evaluates its development of the skills and abilities of its employees.

Professional development

In 2005, the PHRU had 11 staff members pursuing further education and the unit supports them to ensure that their personal goals are met while employed at the PHRU. Employees pursuing post-graduate education have access to a considerable amount of data for developing and completing their research in an area that is tremendously important to the South African community. Professor James McIntyre and Dr Glenda Gray have acted as supervisors for higher degree candidates and examiners for higher degrees at Wits, as well as the Universities of Natal and Pretoria, and Imperial College, London.

In addition, three medical doctors have left the PHRU to pursue degree courses at the London School of Tropical Health and Hygiene, in some cases using data from their work at the unit for research purposes there.

Fellowships, interns and volunteers

The PHRU has been very successful in developing programmes that attract new, exciting talent and in sending employees to other institutions to acquire new skills. Due to the number of requests from people wanting to volunteer or conduct independent research projects through the PHRU, a formal internship and volunteer programme has been established.

Internship programme

From December 2004 to November 2005, 11 interns have come to the unit for stays ranging from several days to three months. Projects and activities included working in the clinic, involvement with the PMTCT programme, and developing laboratory assays with the on-site research laboratory. Interns and volunteers have also worked in administration; teaching and assisting with statistical expertise; developing materials; literature searches; data analysis; computer training; and work with HIVSA at its halfway house or children’s camps.

Over the last year, links for internship training have been forged with the University of Rochester, New York state, and the International Health Division at the University of Washington, Seattle.

Most of these interns and volunteers funded themselves.
Awards

Two prestigious awards have been given to the PHRU Directors, Dr Glenda Gray and Professor James McIntyre. In 2002, they were jointly awarded the Nelson Mandela Award for Health and Human Rights, for “outstanding contributions to advancing scientific understanding and practical application of medical techniques for prevention transmission of HIV/AIDS from mothers to newborn”. In 2003, they received the International Association for Physicians in AIDS Care (IAPAC) “Heroes in Medicine Award” in recognition of their work.

Pfizer fellowship

The PHRU has recently instituted a programme with Pfizer Pharmaceuticals and the Global Health Fellowship Programme. The PHRU (along with other organisations worldwide) submits a request and job description to the International Philanthropy Division at Pfizer’s headquarters in New York. Once both the candidate and the unit have agreed upon a match, a Pfizer employee is seconded to the PHRU for either three or six months in order to transfer skills.

The first Pfizer fellow Veronique Raimond, a manager of pricing and reimbursement strategy at Pfizer Inc in Paris, France, worked at the PHRU for three months in early 2004. She was trained as a health economist and assisted the PHRU in analyzing the Soweto household vulnerability and health database. Together with Sangeetha Madhavan, a demographer based at the Wits Department of Sociology, Veronique examined the role of social factors, in particular socio-economic status, in influencing adult illness in Soweto.

The second Pfizer fellow was a statistician, Dr Nigel Brayshaw from Pfizer UK, who completed his fellowship in April 2005. He worked with several unit employees on reviewing statistical methods for the CIPRA studies, developing SAS code, developing and implementing a project management tool, and assisting with creation of departmental standard operating procedures. His main activities were teaching statistical methods to PHRU statisticians including theory and practical examples of the use of generalized estimating equations, Poisson regression, and sample size techniques. He also assisted in data analysis.
Population Leadership Programme

The Population Leadership Programme (PLP) is funded by USAID and administered by the Public Health Institute in Oakland, California. The PLP has three key result areas to meet the challenges of improving leadership, management and sustainability of family planning and reproductive health programmes worldwide. These areas are: recruitment and placement; professional development and support; and consultants focusing on USAID programmes.

The programme seeks out people interested in pursuing personal and professional development in their area of expertise, while at the same time building capacity, transferring skills and contributing effectively to their work environment.

Sheila Clapp a PLP fellow, was seconded to the PHRU in 2000 and worked as a senior manager and technical advisor to the directors for four years. Ms Clapp was instrumental in the CIPRA grant application, as well as organisational development and the development of standard operating procedures. She was also a director of HIVSA and assisted in that organisation’s start-up.

Johns Hopkins University courses

As part of the PHRU’s ongoing collaboration with Johns Hopkins University (JHU) in Baltimore, the unit can access Fogarty International AIDS Training and Research Programme (IATRP) funds to send staff to short academic courses. This is as an important part of capacity development and 11 staff members have attended courses at the JHU Bloomberg School of Public Health over the past three years.

Intense training has been offered in principles of epidemiology, biostatistics, survival analysis, regression analysis in public health research, multi-level models, application of case-control methods, methods and applications of cohort studies, ethics of human subjects research in developing countries, management of epidemiologic studies, epidemiology of HIV/AIDS, and pharmaco-epidemiology.

Each of these fellows has put their summer school education to good use when they returned to the unit, through effective contributions to study designs, proposal development and data analysis.
Twinning programme

In 2004 and 2005, the PHRU participated in a training programme linking the PHRU with the University of California, San Francisco (UCSF) and the University of Zimbabwe (UZim). The leaders of this programme were Dr Nancy Padian at UCSF, Dr James Hakim at UZim, and Dr Guy de Bruyn and Professor James McIntyre at the PHRU.

The key activities of the twinning trainings were clinical exchanges between the African sites and UCSF, and between the African sites, as well as training in monitoring and evaluation (M&E).

A PHRU staff member travelled to San Francisco in January 2005 to undergo M&E training. In February 2005, a PHRU clinician spent two weeks at UCSF participating in lecture-based teaching and clinical observation. In May 2005, four senior clinicians from UZim and other centres in Zimbabwe attended a week-long training at the PHRU, focusing on implementation issues. The last component of the programme was a two-day workshop in Harare, attended by all of the participants in the prior exchanges.

PHRU Research Centre

In 2002, the PHRU moved from a couple of small rooms in Bara’s maternity unit to new premises in the New Nurses Home of the hospital. This space was made available through an agreement with the hospital and the Gauteng Department of Health. The Gauteng provincial Minister for Health, Dr Gwen Ramokgopa, and the Archbishop of Cape Town, Njongonkulu Ndungane officially opened the new research centre. All renovation costs were covered by the PHRU and the unit is now housed in a world-class research centre.

The PHRU clinic has a separate paediatric section, while the main clinic comprises a reception area, two waiting areas, 11 consulting rooms, one phlebotomy room, three counselling rooms and a children’s play therapy area. The paediatric section has seven consulting rooms, a phlebotomy room, an immunisation room and two counselling rooms. All examination rooms are equipped with diagnostic and essential equipment, as well as examination couches. A fully-equipped emergency cart, with defibrillator and oxygen is maintained in the clinic. The clinic has over 5,000 client visits each month.

The PHRU pharmacy is registered with the South African Pharmacy Council and licensed by the Department of Health, under the ownership and responsibility of Fatima Mayat. It is subject to the conditions of Good Clinical Practice and conforms to the South African Medicines and Related Substances Act. The pharmacy staff comprises six pharmacists and one pharmacist assistant. At present, it is responsible for approximately 20 ongoing trials, 12 post-trial protocols and programmes, and the initiation process for another seven trials that are due to begin soon.

The pharmacists are responsible for ordering medication stock, as well as receiving, storing and dispensing drugs for study purposes, according to each study protocol, each of which has different procedures that must be adhered to. Their daily duties involve ensuring that clients understand how to take their drugs, drug accountability, adherence calculation using pill counts, and maintaining safety precautions when handling medication. On occasion, some drug destruction takes place according to protocol requirements.

The pharmacists are involved in developing unit-wide standard operating procedures and work practices for various studies. This team forms an integral part of the patient-oriented
health-care team at the PHRU and is involved in critical decision-making, staff training and education, and other protocol-related issues.

The PHRU laboratory is located on-site and consists of a receiving area, an open-plan office, serology, peripheral blood mononuclear cell (PBMC) extraction and preparation laboratories. There are separate rooms for lab kit preparation and autoclaving and a small repository of three -70˚C freezers and one -20˚C freezer.

Since opening in 1996, the laboratory has performed rapid HIV tests and acted as a repository for biological samples sent to contracted laboratories for further testing. The laboratory has increased its scope of work to include a number of new tests and services such as:

- Syphilis testing (rapid plasma reagin (RPR) and treponema pallidum haemagglutination (TPHA));
- Peripheral blood mononuclear cell extraction;
- Human papilloma virus PCR testing;
- Avidity index testing (HIV incidence);
- Wet mounts of vaginal swabs;
- Urine dipstick testing and rapid urine pregnancy testing;
- Low temperature storage facilities (-70°C, -20°C and 2-8°C);
- Storing dried blood spots;
- Tracking system for samples sent for testing to contracted laboratories;
- Processing of laboratory invoices for laboratory tests contracted out;
- Participating in the College of American Pathologists (CAP) QC programme for all tests performed in its laboratory and International Air Transport Association (IATA) certified for national and international shipment of biological samples;
- Monitoring all HIV testing performed at PMTCT clinics in Soweto; and
- Training lay HIV testers working at the PHRU.

The PHRU laboratory hopes to become accredited for selected tests with the South African National Accreditation Systems (SANAS).

The HIV/AIDS prevention studies area includes the Tshwarisanang Couples Centre, extensive counselling, consulting and research areas for the MIRA study and the HIV/AIDS Vaccine Centre, where VCT and vaccine trials take place.

In addition, various spaces have been renovated to house partner organisations, including HIVSA and Project Accept.

The training centre includes a newly renovated, 160-seater, raked auditorium, a fully equipped 40-seater boardroom, and one large and two small training rooms.

The PHRU has also renovated four floors for offices, housing management, administrative and research staff, and board rooms. The tenth floor houses our statistics and data management centre, equipped with state-of-the-art data processing equipment. All our offices are equipped with connections to the unit’s IT network and internet.
Conclusion

The PHRU has come a long way since its earliest inception. Its programmes, staff complement and infrastructure have grown incrementally and its multitude of research activities reflects the emerging complexity of the HIV/AIDS pandemic, with all its many facets.

The PHRU intends to continue collaborating with, and learning from, partner organisations and institutions, both within South Africa and globally. There is an enormous body of medical, sociological and psychological data being uncovered about HIV/AIDS all over the world. Indeed, the HIV/AIDS pandemic has resulted in possibly the most comprehensive and far-reaching research and societal support movements ever known, with thousands of scientists and researchers participating in a myriad of activities around the globe. The PHRU views itself as an important part of this broader process, and will continue to make its contribution as long as the need exists.

In South Africa, the dedicated staff of the PHRU will also continue their efforts to militate against the devastating effects of this widespread epidemic. By providing high-quality clinical and social support services to under-resourced communities, the PHRU plays a role in ensuring that the poor have access to good healthcare. The unit will also strive towards the highest standards of research excellence in order to find new ways of combating HIV/AIDS, and will work in partnership with the government and research institutions in this regard.
"The PHRU views itself as an important part of this broader process, and will continue to make its contribution as long as the need exists."
Appendix I:

Publications and presentations

Journal articles: 2005


McIntyre J. Preventing mother-to-child transmission of HIV: successes and challenges. BJOG. 2005 Sep;112(9):1196-203. Review.


Group publications


Submitted publications

Heyer AS, Ogunbanjo GA. Adherence to HIV Anti-retroviral Therapy Part I – Factors Related to Treatment Regimen. Submitted to SA Family Practice, received on 7 September 2005.

Journal articles: 2004


Group publications

Journal articles: 2003


Book chapters: 2005


Book chapters: 2004

Oral presentations: 2005


Dladla S, Robertson G. *Couple HIV counselling and testing as entry to treatment and care*. 1st Priorities in AIDS Care and Treatment conference, 2005.

Gray GE. *The current debate: Routine HIV screening or VCT?* (Plenary) 1st Conference on Priorities in AIDS Care and Treatment, Muldersdrift, Johannesburg, 19 – 22 April 2005


Jooste I, Struthers H. *Wanting more from the media: audiences in high HIV prevalence areas say news does not represent their reality*. 3rd African Conference for the Research on the Social Aspects of the HIV / AIDS, “Bridging the gap between policy, research and interventions”, Dakar, Senegal October 10th -14th 2005

Martinson N. *An integrated approach to primary HIV care*. 1st Conference on Priorities in AIDS Care and Treatment, Muldersdrift, Johannesburg, 19 – 22 April 2005


McIntyre JA. *Controversies in the use of nevirapine for the prevention of mother-to-child transmission of HIV*. (Plenary) 12th Conference on Retroviruses and Opportunistic Infections, Boston, February 22-2 5 2005

McIntyre JA. *New developments in the prevention of mother-to-child transmission of HIV*. (Plenary) 1st Conference on Priorities in AIDS Care and Treatment, Muldersdrift, Johannesburg, 19 – 22 April 2005

McIntyre JA. *Addition of short course Combivir (CBV) to single dose Viramune (sdNVP) for prevention of mother to child transmission (pMTCT) of HIV-1 can significantly decrease the subsequent development of maternal NNRTI-resistant virus*. 3rd IAS conference on HIV pathogenesis and Treatment, Rio de Janeiro, 24 – 27 July 2005

McIntyre JA. *New directions in the science of AIDS prevention*. (Plenary) University of the Witwatersrand Faculty of Health Sciences Research Day, 4 August 2005


McIntyre JA. *Antiretroviral treatment in South Africa. New approaches to HIV management*. Centes Garde Symposium, Beijing China, 3 – 6 December 2005

Modiba P. *VCT: The entry point to HIV care and treatment*. 1st Conference on Priorities in AIDS Care and Treatment, Muldersdrift, Johannesburg, 19 – 22 April 2005


Violari A. *ARV treatment in pregnancy*. 1st Conference on Priorities in AIDS Care and Treatment, Muldersdrift, Johannesburg, 19 – 22 April 2005
Oral presentations: 2004


McIntyre JA. Rolling out ART: issues and implications. CARE African Regional Conference, Rosebank, Johannesburg, April 26 2004

McIntyre JA. Maternal health and HIV. UNFPA Global Consultation on HIV/AIDS and Reproductive Health, New York, 10 May 2005

McIntyre JA. Will the HIV pandemic ever be conquered? (Keynote) British Congress of Obstetrics and Gynaecology, Glasgow, 7 – 9 July 2004

McIntyre JA. Impact of HIV AIDS for maternal and child health. (Plenary) South African Midwifess Conference, Johannesburg. 1 December 2004


Oral presentations: 2003

Dinat N, Russell A, Malebogo P. Putting medical care back into home based care -the N’doro model. Oral presentation at the 6th International HCC conference for people living with HIV/AIDS. Home Based Care conference Dakar, Dec 2003


Gray GE. MTCT update. 23rd International Conference of Chemotherapy, Durban, 8 – 10 June 2003


McIntyre JA. Mother-to-child transmission of HIV. PHRU and Regional AIDS Training Network Train the Trainer course on PMTCT, Rosebank Hotel, January 27–February 8 2003.


McIntyre JA. The relevance of nevirapine resistance after single dose PMTCT use. 23rd International Conference of Chemotherapy, Durban, 8 – 10 June 2003.


McIntyre JA. Family planning needs of HIV positive women. Elizabeth Glaser Pediatric AIDS Foundation International Call to Action Site meeting. Somerset West, 18 – 20 August 2003.


McIntyre JA. The Perinatal HIV Research Unit. SADC Health Ministers meeting, Chris Hani Baragwanath Hospital, 6 September 2003.


McIntyre JA. Introduction to HIV-related care. WHO Round Table on: HIV-related care, treatment and support in the context of preventing HIV infection in infants and young children & session chair. ICASA, Nairobi, 21 – 25 September 2003.


McIntyre JA. HIV in South Africa. St Francis House Hospice Annual meeting, Boksburg, 4 October 2003.


McIntyre JA. Preventing postnatal transmission of HIV. Ghent Working Group on mother-to-child transmission of HIV. Ghent, 11-13 December 2003


Violari A. Basic principles of antiretroviral therapy in children, HIV Clinician’s society meeting, Johannesburg, June 2003.


**Poster presentations: 2005**

Gray GE, McIntyre JA, Martinson N, Hopley M, Hall D, Mayers D for the Treatment Options (TOPS) Trial/1413 Investigator Team. **NNRTI-resistant mutations in HIV-infected infants following single dose nevirapine (sd-NVP) are reduced by the addition of short course zidovudine and 3TC.** 3rd Conference on HIV Pathogenesis and Treatment. 24-27 July 2005, Rio de Janeiro.


McIntyre J, Martinson N, Gray GE for the Treatment Options (TOPS) Trial/1413 Investigator Team. **Single dose nevirapine combined with a short course of combivir for prevention of mother to child transmission of HIV-1 can significantly decrease the subsequent development of maternal and infant resistant virus.** 3rd Conference on HIV Pathogenesis and Treatment. 24-27 July 2005, Rio de Janeiro.


**Poster presentations: 2004**


Middelw-Saayre D, Schramm D, Gray GE, Kuhn L, Tiemessen CT. Reduced ability of newborns to produce MIP-1α and MIP-1β is associated with an increased susceptibility to perinatal HIV-1 transmission. Abstract Number: MoPeA3051; XV International AIDS Conference Bangkok, Thailand, July 11-16, 2004.


**Poster presentations: 2003**


**Abstracts co-authored by PHRU staff (presented or accepted for presentation): 2005**


**Media Publications**


Ridgard N. “If you want to see me bright, touch on the question”: attitudes of health care workers to the PMTCT programme in a rural area. In Baby Steps: Reporting on the prevention of mother-to-child transmission in South Africa, 2005

Spurr N. *“Who is setting the PMTCT agenda?” A quantitative content analysis of media coverage of PMTCT in South Africa.* In Baby Steps. Reporting on the prevention of mother-to-child transmission in South Africa, 2005
Media articles: 2005

Garson P. It helps when you know you're not alone. Sunday Independent, 5 June 2005.
Garson P. Don't forget girls like to have sex, sometimes skin to skin. Sunday Independent, 12 June 2005.
Masango P. Ntombenhle's Story. HIV/AIDS Indaba, 1 April 2005.

Media articles: 2004

Finlay A. Media helped win the drugs fight. The Star, 6 January 2004.
Jooste I. The untold story of AIDS. SABC 2, Fokus, 2004

Media articles: 2003

Appendix II: Funders and partners

**Major funders**
- National Institutes of Health
- United States Agency for International Development – President’s Emergency Plan for AIDS Relief
- Bill and Melinda Gates Foundation

**International funders and partners**

**International donor agencies**
- Australian International Aid
- Department for International Development
- Development Co-operation Ireland
- United States Agency for International Development – President’s Emergency Plan for AIDS Relief
- International non-governmental organisations
- AIDS Care Research in Africa
- Axios International
- Bill and Melinda Gates Foundation
- Carnegie Foundation
- Doris Duke Charitable Foundation
- Elizabeth Glaser Paediatric AIDS Foundation
- EngenderHealth
- Fonds de Solidarité Thérapeutique Internationale (FSTI)
- Global Health Fellowship
- International Solidarity Fund for Treatment (ISFT)
- Pangea Global AIDS Foundation
- Population Leadership Programme
- Public Health Institute: Population Leadership Programme
- Wistar Institute

**US government institutions**
- Centres of Disease Control and prevention (CDC)
- United States National Institutes of Health (NIH)
  - National Institute of Allergy and Infectious Diseases (NIAID): Division of AIDS (DAIDS)
  - National Institute of Child Health and Development (NICHD)
  - National Institute of Mental Health (NIMH)

**International institutions**
- Joint United Nations Programme on HIV/AIDS (UNAIDS)
- Regional AIDS Training Network (RATN)
- World Health Organisation (WHO)
- United Nations Children’s Fund (UNICEF)

**International academic institutions**
- Harvard University: Partners AIDS Research Centre
- Johns Hopkins University:
  - Bloomberg School of Public Health
  - School of Medicine
  - Johns Hopkins Health and Education in South Africa (JH/HESA)
  - Fogarty International AIDS Training and Research Programme
- University of California, Los Angeles (UCLA)
- University of California, San Francisco: Centre for AIDS Prevention Studies (UCSF: CAPS)
- University of Columbia Mailman School of Public Health
- University of Rochester
- University of Washington
- University of Zimbabwe
- University of Zurich

**International research networks**
- AIDS Vaccine Integrated Programme (AVIP)
- HIV Vaccine Trials Network (HVTN)
- International AIDS Vaccine Initiative (IAVI)
- Paediatric AIDS Clinical Trial Group (PACTG)
- International AIDS Vaccine Initiative (AACTG)

**South African funders and partners**

**South African non-governmental organisations**
- AIDS Consortium
- Centre for AIDS Development, Research and Evaluation (Cadre)
- Community AIDS Response (Care)
- HIVSA
- Joint Economic AIDS and Poverty Programme (JEAPP)
- Media Monitoring Project (MMP)
- Nelson Mandela Foundation (NMF)
- South African National Editors Forum (Sanef)

**South African government departments**
- Gauteng Department of Health
- Limpopo Department of Health
- South African National Department of Health

**South African Hospitals**
- Chris Hani Baragwanath Hospital, Soweto (Bara)
- Johannesburg Hospital, Johannesburg
- King Edward Hospital, Durban
- Mapulaneng Hospital, Bushbuckridge
- Tintswalo Hospital, Acomhoek
South African academic institutions

University of Cape Town (UCT):
- Desmond Tutu HIV Foundation
- Economic Policy Research Unit

University of KwaZulu-Natal

University of Limpopo: Department of Family Medicine

University of Pretoria: Centre for the Study of AIDS (CSA)

University of Stellenbosch: Children’s Infectious Diseases Clinical Research Unit (KID-CRU)

University of the Witwatersrand:
- AIDS Research Institute (ARI)
- Clinical HIV Research Unit (CHRU)
- Contract Laboratory Services (CLS)
- Department of Anthropology
- Department of Community Dentistry
- Department of Electrical Engineering
- Department of Psychiatry
- Department of Sociology
- Reproductive Health and HIV Research Unit (RHRU)
- Respiratory and Meningeal Pathogens Research Unit (RMPRU)
- Rural AIDS Development Action Research (RADAR)
- School of Journalism
- School of Public Health
- Wits Rural Public Health and Health Transitions Unit

South African research institutions

Medical Research Council (MRC)
National Institute of Communicable Diseases (NICD)
South African AIDS Vaccine Initiative (SAAVI)

Pharmaceutical companies

Abbott
Boehringer-Ingelheim
Bristol Myers Squibb
Gilead Sciences Inc. (formally Triangle)
Glaxo Smith Klein
Johnson and Johnson
Pfizer Pharmaceuticals

South African industry

Aurum Health, Anglo American Corporation
Sentech

HIVSA’s funders and partners

American Jewish World Service
Belgium Technical Co-operation South Africa
Elton John AIDS Foundation
Garden Africa
Johannesburg City Council
Johnson and Johnson
Orange Babies Project
Peace Corps
Perinatal HIV Research Unit
Save the Children Norway / Zimbabwe
South African Catholic Bishops Conference Fund
United States Agency for International Development – President’s Emergency Plan for AIDS Relief
Voluntary Service Organisation
World Camps Inc
## Appendix III:

**Glossary of terms and acronyms**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
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</thead>
<tbody>
<tr>
<td>3TC</td>
<td>Lamivudine</td>
</tr>
<tr>
<td>AACTG</td>
<td>Adult AIDS Clinical Trials Group</td>
</tr>
<tr>
<td>AITRP</td>
<td>AIDS International Training and Research Programme</td>
</tr>
<tr>
<td>ANG</td>
<td>Adherence Networking Group</td>
</tr>
<tr>
<td>ART</td>
<td>Antiretroviral therapy</td>
</tr>
<tr>
<td>ART-LINC</td>
<td>Antiretroviral Therapy in Lower Income Countries</td>
</tr>
<tr>
<td>ARV</td>
<td>Antiretroviral drugs</td>
</tr>
<tr>
<td>AUSAID</td>
<td>Australian International Aid Programme</td>
</tr>
<tr>
<td>AVIP</td>
<td>AIDS Vaccine Integrated Programme</td>
</tr>
<tr>
<td>AZT</td>
<td>Zidovudine (INN) or azidothymidine</td>
</tr>
<tr>
<td>Bara</td>
<td>Chris Hani Baragwanath Hospital</td>
</tr>
<tr>
<td>BMS</td>
<td>Bristol Myers Squibb</td>
</tr>
<tr>
<td>CAP</td>
<td>College of American Pathologists</td>
</tr>
<tr>
<td>CBV</td>
<td>Combivir - combination of lamivudine (3TC) and zidovudine (AZT)</td>
</tr>
<tr>
<td>CBVCT</td>
<td>Community-based Voluntary Counselling and Testing</td>
</tr>
<tr>
<td>CHCT</td>
<td>Couples HIV counselling and testing</td>
</tr>
<tr>
<td>CHER</td>
<td>CIPRA – Project One</td>
</tr>
<tr>
<td>CHRU</td>
<td>Clinical HIV Research Unit</td>
</tr>
<tr>
<td>CIPRA</td>
<td>Comprehensive International Programme of Research on AIDS in South Africa</td>
</tr>
<tr>
<td>CROI</td>
<td>Conference on Retroviruses and Opportunistic Infections</td>
</tr>
<tr>
<td>DAIDS</td>
<td>Division of AIDS (National Institute of Allergy and Infectious Diseases, United States)</td>
</tr>
<tr>
<td>DART</td>
<td>Demonstration of Antiretroviral Treatment and care</td>
</tr>
<tr>
<td>d4T</td>
<td>Stavudine and Zerit</td>
</tr>
<tr>
<td>ddl</td>
<td>Dideoxyinosine (didanosine, Videx),</td>
</tr>
<tr>
<td>DDfan</td>
<td>Doris Duke Charitable Foundation/ Pangea Global AIDS Foundation drug access programme</td>
</tr>
<tr>
<td>DfID</td>
<td>Department for International Development</td>
</tr>
<tr>
<td>DTHF</td>
<td>Desmond Tutu HIV Foundation</td>
</tr>
<tr>
<td>EGPAF</td>
<td>Elizabeth Glaser Paediatric AIDS Foundation</td>
</tr>
<tr>
<td>FSTI</td>
<td>Fonds de Solidarité Thérapeutique Internationale</td>
</tr>
<tr>
<td>HAART</td>
<td>Highly Active Antiretroviral Therapy</td>
</tr>
<tr>
<td>HIVNET</td>
<td>HIV Network for Prevention Trials</td>
</tr>
<tr>
<td>HIVSA</td>
<td>HIVSA is a not for profit organisation, a collaborative partner of the PHRU</td>
</tr>
<tr>
<td>HR</td>
<td>Human Resources</td>
</tr>
<tr>
<td>HSV</td>
<td>Herpes Simplex Virus</td>
</tr>
<tr>
<td>HVTN</td>
<td>HIV Vaccines Trial Network, United States</td>
</tr>
<tr>
<td>IAPAC</td>
<td>International Association for Physicians in AIDS Care</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>IAVI</td>
<td>International AIDS Vaccine Initiative</td>
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<tr>
<td>ITSF</td>
<td>International Solidarity Fund for Treatment</td>
</tr>
<tr>
<td>IT</td>
<td>Information Technology</td>
</tr>
<tr>
<td>JEAPP</td>
<td>Joint Economic AIDS and Poverty Programme</td>
</tr>
<tr>
<td>JHU</td>
<td>Johns Hopkins University</td>
</tr>
<tr>
<td>KID-CRU</td>
<td>Children's Infectious Diseases: Clinical Research Unit</td>
</tr>
<tr>
<td>MCC</td>
<td>Medicines Control Council, the statutory body established in terms of the Medicines and Related Substances Control Act No 101 of 1965.</td>
</tr>
<tr>
<td>M&amp;E</td>
<td>Monitoring and Evaluation</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>MIRA</td>
<td>Methods for Improving Reproductive Health in Africa</td>
</tr>
<tr>
<td>MKC</td>
<td>Emivirine</td>
</tr>
<tr>
<td>MRC</td>
<td>Medical Research Council (South Africa)</td>
</tr>
<tr>
<td>MSM</td>
<td>Men who have sex with men</td>
</tr>
<tr>
<td>MTCT+</td>
<td>Mother-to-Child Transmission Plus</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-governmental Organisation</td>
</tr>
<tr>
<td>NHLS</td>
<td>National Health Laboratory Services</td>
</tr>
<tr>
<td>NIAID</td>
<td>National Institute of Allergy and Infectious Diseases (United States)</td>
</tr>
<tr>
<td>NICD</td>
<td>National Institute of Communicable Diseases (South Africa)</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health (United States)</td>
</tr>
<tr>
<td>NIMH</td>
<td>National Institute of Mental Health (United States)</td>
</tr>
<tr>
<td>NNRTI</td>
<td>non-nucleoside reverse transcriptase inhibitor</td>
</tr>
<tr>
<td>NVP</td>
<td>Nevirapine</td>
</tr>
<tr>
<td>OCTAN-E</td>
<td>Optimal Combination Treatment After Nevirapine Exposure</td>
</tr>
<tr>
<td>OI</td>
<td>Opportunistic Infection</td>
</tr>
<tr>
<td>OPERA</td>
<td>Operational Research on Antiretrovirals</td>
</tr>
<tr>
<td>PACTG</td>
<td>Paediatric AIDS Clinical Trial Group</td>
</tr>
<tr>
<td>PBMC</td>
<td>Peripheral blood mononuclear cell</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase Chain Reaction</td>
</tr>
<tr>
<td>PEP</td>
<td>Post-Exposure Prophylaxis</td>
</tr>
<tr>
<td>PEPFAR</td>
<td>President’s Emergency Plan for AIDS Relief</td>
</tr>
<tr>
<td>PETRA</td>
<td>Perinatal Transmission Trial</td>
</tr>
<tr>
<td>PHC</td>
<td>Primary Health Care</td>
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<tr>
<td>PHRU</td>
<td>Perinatal HIV Research Unit</td>
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<tr>
<td>PLP</td>
<td>Population Leadership Programme</td>
</tr>
<tr>
<td>PLWA</td>
<td>People Living With AIDS</td>
</tr>
<tr>
<td>PMTCT</td>
<td>Prevention of Mother-to-Child Transmission of HIV</td>
</tr>
<tr>
<td>PPVCT</td>
<td>Post-Partum Voluntary Counselling and Testing</td>
</tr>
<tr>
<td>PTAP</td>
<td>Perinatal HIV Research Unit’s Treatment Access Programme</td>
</tr>
<tr>
<td>RADAR</td>
<td>Rural AIDS and Development Action Research Programme</td>
</tr>
<tr>
<td>RATN</td>
<td>Regional AIDS Training Network</td>
</tr>
<tr>
<td>RHRU</td>
<td>Reproductive Health and HIV Research Unit</td>
</tr>
<tr>
<td>PMPRU</td>
<td>Respiratory and Meningeal Pathogens Research Unit</td>
</tr>
<tr>
<td>SAAVI</td>
<td>South African AIDS Vaccine Initiative</td>
</tr>
<tr>
<td>SANAS</td>
<td>South African National Accreditation Systems</td>
</tr>
<tr>
<td>SAQA</td>
<td>South African Qualifications Authority</td>
</tr>
<tr>
<td>SAINT</td>
<td>South African Intrapartum Nevirapine Trial</td>
</tr>
<tr>
<td>sdNVP</td>
<td>Single dose nevirapine</td>
</tr>
<tr>
<td>STI</td>
<td>Sexually transmitted infections</td>
</tr>
<tr>
<td>TOPS</td>
<td>Treatment Options Preservation Study</td>
</tr>
<tr>
<td>UCLA</td>
<td>University of California, Los Angeles</td>
</tr>
<tr>
<td>UCSF</td>
<td>University of California, San Francisco</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>VCT</td>
<td>Voluntary Counselling and Testing</td>
</tr>
<tr>
<td>VDG</td>
<td>Vaccine Discussion Group</td>
</tr>
<tr>
<td>WHC</td>
<td>Wits Health Consortium</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>Wits</td>
<td>University of the Witwatersrand</td>
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