REPRODUCTIVE HEALTH AND HIV RESEARCH UNIT

RHRU

Reproductive Health & HIV Research Unit
of the University of the Witwatersrand, South Africa.

PROGRAMME REVIEW 2003 / 2004

RHRU CREDO

The Reproductive Health & HIV Research Unit is a South African academic research and training center working in the field of sexual and reproductive health (SRH). We believe that the activities we undertake should reflect our commitment to Improving the sexual and reproductive health of all people, particularly those marginalised in Society; and to bridging the gap between SRH policy, research, and service delivery.

We strive to be at the forefront of new ideas that inform scientific understanding, policy, practice and debates in sexual and reproductive health on a national, regional, and international level.

We strive to deliver the highest quality of research and training, by designing, implementing and participating in programmes and interventions that are aligned with the RHRU's strategic approach, which are ethical, and adhere to good clinical practice.

We will monitor and evaluate our work against the goals and objectives initially set out and agreed to at the outset of each programme.

We aim to document our research findings and recommendations and disseminate these to relevant stakeholders, to achieve maximum impact, and to empower stakeholders to make informed decisions.

Our research and training activities in communities will adopt a participatory approach which addresses the needs of the targeted communities and facilitates their involvement in the planning, development and implementation of any new programmes.

We will adhere to ethical practices when working with communities to ensure that we treat our research participants as partners.

We will explain the purpose and value of our work; demonstrate respect for privacy and informed consent; and provide the appropriate feedback to participants and communities.

We believe that our staff are the real assets of our organisation.

We embrace the diversity of culture, ethnicity and backgrounds in our country.

We are committed to transformation within the country and strive to reflect this throughout the organisation.

We believe our goals will be achieved through good teamwork with a focus on building the capacity of all staff and ensuring that staff are backed up by visionary leadership and effective management.

We strive to create an atmosphere of open expression underpinned by loyalty, mutual respect and tolerance and encourage a work ethic based on reliability, innovation, professionalism, and productivity.

We strive to strengthen partner and donor collaborations to ensure good working relationships, best practices, and harnessing resources both nationally and internationally to complement and further our work.

We will be accountable to all our stakeholders, partners, donors and communities, give regular feedback on all our activities, and will operate with integrity.

We will ensure that our relationships with staff, donors and stakeholders, including the communities within which we work, are based on trust, loyalty, confidentiality, and respect, as we strive to maintain the mission and vision of the Reproductive Health Research Unit.

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Executive Statement

Prof. Helen Rees

Executive Statement

Recent developments

In the year RHRU turned a decade old, South Africans saw the beginning of the national rollout of anti-retrovirals (ARVs) in April 2004. The rollout highlighted more than ever the ongoing clinical and research work done by RHRU and re-inforced the challenges posed by the epidemic for the sexual and reproductive health of women. Strengthening the South African health sector to deliver STI and HIV services, by supporting health workers whose training had not previously included HIV care and treatment, is an ongoing challenge as the rollout scales up. Our partnership with Johannesburg Hospital's ARV clinic and our own Esselen Street Clinic have involved extensive research and training in HIV care and treatment; feedback from these sites allows us to develop models of best practice in the public service delivery of appropriate care and treatment. Researching the links between STIs and HIV acquisition, RHRU has various ongoing trials which aim to contribute to the prevention of further HIV transmission through both treating and preventing STIs. This focus on prevention is in keeping with RHRU's commitment to provide research and develop methods that will put a woman's sexual life in her own hands. RHRU's work on microbicides, diaphragms, female condoms and emergency contraception aims to make these self-initiated barriers to HIV acquisition feasible and acceptable among the female population in order to giver her control over her own health and wellbeing. In addition, prevention efforts will have to focus on young people, who represent one of the biggest high-risk groups for HIV infection. One of the most exciting initiatives in the past two years has been the HIV seroprevalence and behavourial survey conducted in collaboration with loveLife among 15 to 24 year old South Africans. The first extensive survey of its kind, it was completed in 2003 and the report was released in 2004. Its findings will pave the way for future research in this vulnerable group. The last two years have seen the RHRU complete ongoing work, identify new areas that need to be researched and consolidated the unit as an institution undertaking some of the most significant sexual and reproductive health, and HIV research and training programmes in the region.

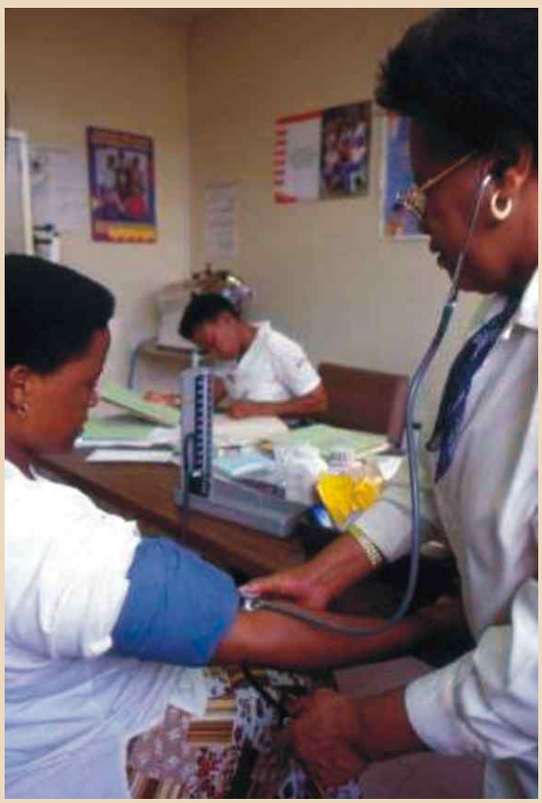
Collaborations

The RHRU plays a unique role in the South African public health sector by working in close partnership with the government on a national and provincial level, in the field of policy and programme development, research, training, and the implementation of new policies. From its inception, RHRU has also formed strong relationships with international organisations, resulting in many collaborative research and training programmes linked to international policies and recommendations. Foremost among these partners are the World Health Organisation (WHO), the Population Council, Family Health International (FHI), the Programme for Appropriate Technology in Health (PATH), the London School of Hygiene and Tropical Medicine, the Wellcome Trust, the University of North Carolina, the National Institutes of Health, the UK Medicines Research Council, the Gates Foundation, CONRAD and the International Planned Parenthood Federation (IPPF).

RHRU staff

RHRU's expansion is testimony to its proven clinical and research work, which has been made possible through a committed and growing staff. The unit has prioritised the training and development of previously disadvantaged groups with a particular focus on black women, and a number of staff have now successfully completed degrees, Masters programmes and PhDs while working at the RHRU. As a dynamic, progressive young organisation, the RHRU has prioritised institutional development, and has adopted a management style and philosophy that is associated with leading successful business practice. The following Programme Review is testimony to that investment.

Stakeholder Acknowledgements



Stakeholder Acknowledgements

FUNDERS

Atlantic Philanthropies
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Division of AIDS (National Institutes of Health) (DAIDS)
Department for International Development (DfID)
Duke University
European Commission
Ford Foundation
Henry J Kaiser Family Foundation
Johannesburg Development Agency (JDA)
Johnnic Communications
London School of Hygiene and Tropical Medicine
Mellon Foundation
National Department of Health, South Africa
National Health Laboratory Services (CDC Surveillance) (NHLS)
President's Emergency Plan for AIDS Relief (PEPFAR)
Programme for Appropriate Technology in Health (PATH)
The Global Fund to Fight AIDS, TB and Malaria
United States Agency for International Development (USAID)
Wellcome Trust
University of North Carolina
University of Washington (Seattle)

INTERNATIONAL COLLABORATORS

Centre for Training in Reproductive Health Technologies (France)
Contraceptive Research and Development (CONRAD)
Development Research Africa (DRA)
ECafrique
Family Health International (FHI)
Gynuity Health Project
Health and Development Africa (HDA)
Institute of Health Care Improvement (IHI) at the University of North Carolina
International Partnership for Microbicides (IPM)
International Planned Parenthood Federation (IPPF)
Ibis Reproductive Health
INSERMV430 (France)
London School of Hygiene and Tropical Medicine
National Abortion Federation
Mozambique Ministry of Health
Population Council
Population Services International (PSI)
HIV Prevention Trials Network (HPTN)
Programme for Appropriate Technology in Health (PATH)
UK Medical Research Council (MRC)
University of North Carolina
University of Washington (Seattle)
World Health Organisation (WHO)

NATIONAL COLLABORATORS

Centre for HIV/AIDS Networking
Chris Hani Baragwanath Hospital
City of Johannesburg
Clinical HIV Research Unit
Department of Medicine
Department of Microbiology, University of Natal
eThekwini Municipality Health Department
Health Systems Trust
Helen Joseph Hospital
Johannesburg Hospital
loveLife
Maternal, Child and Women's Health and Nutrition Cluster
National Bargaining Council
National Brands
National Department of Health
National Department of Social Welfare
National Directorate of STI&HIV Prevention
National Health Laboratory Services (NHLS)
Provincial Departments of Health
Provincial Department of Maternal, Child and Women's Health, KwaZulu-Natal
Provincial STI Directorate, KwaZulu-Natal
Road Freight Association
Sex Worker Education and Advocacy Taskforce (SWEAT)
Sisonke Sex Worker Project (Cape Town)
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Directors

RHRU Introduction

Rationale

The Reproductive Health and HIV Research Unit (RHRU) is part of the Department of Obstetrics and Gynaecology at the University of the Witwatersrand in Johannesburg. Established in 1994 under the leadership of Professor Helen Rees, the unit has evolved into the largest research and training unit of its kind in sub-Saharan Africa; and is committed to providing some of the most significant HIV and sexual and reproductive health research and training in Africa. Its head office is based at the world's largest hospital, the Chris Hani Baragwanath Hospital in Soweto, with a satellite office in Durban and associated research sites and clinics in Hillbrow, Orange Farm and Yeoville. In the past decade, RHRU has grown from a staff of five to two hundred people: a group of doctors, nurses and research scientists from clinical and social sciences who manage more than forty research and training programmes, many supported by national and international networks. Its unique role was recognised by the World Health Organisation when the unit was awarded the status of a WHO Collaborating Centre in 2002.

Research

RHRU's research agenda includes studies on microbicides, barrier methods (including diaphragms, female and male condoms), HIV and sexually transmitted infections (including herpes, HIV and syphilis), contraception, adolescent health, voluntary counselling and testing, mobile populations, acute HIV seroconversion (including anti-retroviral interventions), aspects of unsafe abortion and maternal health interventions. The RHRU is strategically linked with national, regional and international organisations and is strongly committed to collaborating with other stakeholders and partners to increase HIV and sexual and reproductive health research, and programme development. Funding is derived from a diverse range of local and international sources, a funding base which is expanding due to the relevance and significant impact of its programme directive. RHRU has been instrumental in expanding and strengthening government programmes dealing with sexually transmitted infections and female condoms and is the recipient of one of the largest HIV treatment training support grants from the US government, enabling it to support the Department of Health in rolling out anti-retrovirals in three of South Africa's nine provinces.

Hillbrow Health Precinct

One of RHRU's most innovative collaborations, this is a community responsibility programme which will provide one of the most comprehensive packages of HIV services in the world. As noted in the Programme Review, the health precinct will deliver essential services to disadvantaged groups within inner city Johannesburg by integrating services through key partnerships. It is part of the City of Johannesburg's urban regeneration programme.

Regional Development Programmes

Annually, RHRU runs a Research Methods Training Course to build research capacity in Africa and encourage localised studies, and has trained more than two hundred scientists from seventeen African countries in the last nine years. In addition, the RHRU runs the internationally acclaimed Priorities Conference in Sexual and Reproductive Health and HIV (now bi-annually), which attracts researchers and programme managers from all over the world. It is the co-ordinator of WHO's Regional Reproductive Health Research Task Force and is a lead partner for the upcoming Microbicides Conference in Cape Town in March 2006.

RHRU DIRECTORS

2003 - 2004 Directors

Rees, Helen	Executive Director
Beksinska, Matgorzata	Deputy Executive Director
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Delany, Sinead	Director Research
Ndondo, Noziquu	Director Training
Smit, Jennifer	Director Programme
Van Blerk, Linda	Director Ukwenza
Pleaner, Melanie	Director NAFCI Training
Ramkissoon, Arthi	Director Programme
Pettifor, Audrey	Director Programme
Grenville Grey, Thulani	Director Programme
Venter, Francois	Director Clinical

Microbicides Programme

Microbicides Programme

The goal of RHRU's microbicide programme is to develop a female controlled HIV prevention method that functions either as a non-contraceptive microbicide or as a dual action microbicide to prevent pregnancy in addition to preventing infection.

Microbicides are inserted vaginally before sex to prevent or decrease HIV transmission and the transmission of other sexually transmitted infections (STIs). These topical gels or creams offer women an urgently needed HIV prevention option, which could be hidden from a male partner should a woman need to do so.

Microbicide development is a major focus of the RHRU and a variety of studies are ongoing in both Johannesburg and Durban, with more planned.

The Microbicides Development Programme (MDP): feasibility study, pilot study of placebo gel and Phase III trial of PRO 2000 0.5% and 2.0%

The Microbicide Development Programme (MDP) feasibility study is conducted in partnership with the United Kingdom's Medical Research Council (MRC) and is funded by its Department for International Development (DfID). RHRU is one of 3 South African centres participating in this multi-centred research along with other African sites, including Tanzania, Zambia, Uganda and Cameroon.

The feasibility component of this study is near completion, having enrolled 755 women over 2 years with participants followed up over 1 year. In addition, a pilot study enrolled 50 women with un-blinded use of a placebo gel to run trial procedures and assess acceptability of the gel and applicator. The feasibility study also has a large social science component focusing on extensive research within the study cohort on sexual behaviour, vaginal hygiene, microbicide acceptability and study experiences, and a community participation component through the formation of a Community Advisory Group.

At the Soweto site of the feasibility study an estimate of HIV incidence in the study cohort found incidence to be 4.5%; and condom use was estimated through case report forms, focus group discussions and in-depth interviews.
The MDP 301 pilot study enrolled 50 women and followed them up over 1 month. Retention rates were in excess of 90% and the trial procedures were tested. A clinic pharmacy was set up and a pharmacist joined the team to manage the study drug. The pilot study also saw the introduction of a new access-based database and the expansion of the data management team.

Plans are underway for the start of the MDP 301 trial of PRO 2000 0.5% and PRO 2000 2.0%. The trial will commence in March 2005. RHRU will run two sites for the trial, one in Orange Farm and one at Chris Hani Baragwanath Hospital in Soweto, Johannesburg.

Standards of care for referral of HIV positive women and seroconvertors have been explored extensively through the MDP studies. Women found to be HIV positive during screening are referred for psycho-social support to various non-governmental organisations (NGOs). With the start of the anti-retroviral (ARV) rollout programme, participants are also given guidance on how to access ARV services. RHRU clinicians are providing support to several of the main ARV rollout sites in Johannesburg, so that the study staff not only support government facilities, but also provide a link for women requiring referral for ARV therapy.

Short Pulse HIV Anti-retroviral Treatment at Conversion (SPARTAC) study to evaluate early HIV treatment with different short-course ARV regimens

In the course of the MDP study and during the provision of clinical services, people who are newly infected with HIV are being identified. This provides an opportunity to evaluate the impact of short and long courses of ARVs on the progression of HIV infection, something that has never been correctly evaluated in developing countries. The SPARTAC study will look at the treatment of primary HIV infections with two different ARV regimens and the effect of these on disease progression, as well as the acceptability of and adherence to these drugs. Preparation for the SPARTAC study started in 2004, and recruitment will begin in early 2005.

Phase II diaphragm and ACIDFORM study

The ACIDFORM study is a safety and acceptability study funded by CONRAD. The ACIDFORM gel or a placebo gel is used in conjunction with a conventional latex diaphragm. The ACIDFORM study began in 2003 and enrolled 70 of the 120 participants in 2004. Anecdotally, the women in the study seem to really enjoy using the diaphragm.

International Partnership for Microbicides (IPM) TMC 120 gel Phase II trial

The International Partnership for Microbicides (IPM) is supported by the Bill and Melinda Gates Foundation and is tasked with rapidly bringing microbicides through the early phases of drug development and into clinical trials.

The Johannesburg site is one of two African sites, in addition to one European site. Second generation microbicides will be evaluated. Preparation has begun for a Phase II study of TMC 120 gel, which will be conducted in RHRU's Yeoville site beginning in mid-2005. TMC 120 gel is part of a new generation of microbicides containing ARVs. It will progress to Phase III at the same site, if found to be successful.

Microbicide applicators: perspectives of women from Durban, South Africa

The applicator, as a delivery mechanism for the microbicide, will play a central role in factors such as cost, acceptability, dose delivery, dose effectiveness and overall product safety. Understanding women's needs and preferences as they relate to microbicide applicators is critical to ensuring high levels of uptake and long-term use of microbicide products.

This study was supported by the Programme for Appropriate Technology in Health (PATH), which is developing new applicators for microbicides. The purpose was to characterise the preferences for applicator attributes as determined by potential microbicide users in South Africa and the Dominican Republic, and to explore how these preferences differed, based on socio-economic characteristics such as income, marital status and perceived HIV risk.

Structured surveys were administered to 452 women in 3 primary health care centres in and around Durban. The vast majority of women were concerned about spreading germs with a re-usable applicator (94%) or about the effect of a re-usable applicator on their own vaginal hygiene (89%). A single-use design was the most strongly preferred attribute, and low-cost products are perceived to provide reduced effectiveness, with many respondents voicing the need for "free" products. These perceptions, as well as the preferences for specific applicator attributes, should be considered for microbicide product design and introduction.

Publication

Mayer KH, Abdool Karim S, Kelly C, Maslankowski L, Rees H, Prof AT, Day J, Welch J, Rosenberg Z, for the HIV Prevention Trials Network (HPTN) 020 Protocol Team. *Safety and tolerability of vaginal PRO 2000 gel in sexually active HIV-uninfected and abstinent HIV-infected women*. AIDS 2003; 17: 321-329.

Herpes Simplex Virus Type 2 and HIV Research Programme

Herpes Simplex Virus Type 2 and HIV Research Programme

Herpes Simplex Virus type 2 (HSV-2) has been identified as an important co-factor in HIV transmission. In South Africa, HSV-2 is a common infection that is widespread. In several centres throughout the country, seroprevalence of >50% has been observed in women attending public sector services. There is an urgent need to identify interventions to prevent HIV acquisition in those that are uninfected.

One of the focal areas of the RHRU's STI/HIV research programme is the relationship between HSV-2 and HIV. A number of projects were initiated in 2003 to lay the foundation for 3 large randomised-controlled intervention trials of treatment for HSV-2 infection to prevent HIV acquisition, shedding and transmission.

A comparison of the sensitivity and specificity of Focus HerpeSelect and Kalon HSV-2 ELISA in a South African population

A key concern in trials is the choice of serological assay used to identify true positive HSV-2 cases. Recent reports suggest that high rates of false positivity have been observed in cohorts from eastern and southern Africa when using some of the newer HSV-2 specific ELISAs. This study aimed to compare the sensitivity and specificity of these tests when compared to a gold standard Western Blot, involving investigators from RHRU and funded by the National Health Laboratory Services, the London School of Hygiene and Tropical Medicine, and the University of Washington in Seattle.

The study was completed in December 2003 and involved a total of 210 family planning clients. HSV-2 seroprevalence ranged from 66% to 80% depending on the test used. Focus HerpeSelect was the more sensitive test (98%) when compared with Kalon (85%), but the specificity was poor (61% versus 85%). Specificity was improved by increasing the cut-off of the Focus HerpeSelect. The best results were achieved by a two-test algorithm using Focus HerpeSelect (higher cut-off) to identify all positives. Equivocal tests were then re-tested with Kalon to identify additional positive specimens. This resulted in a sensitivity of 92% and a specificity of 93%.

Factors which influence treatment adherence in clinical trials

One of the key concerns when planning an intervention trial is the expected level of adherence to study treatment in the study population. The aim of this study was to determine hypothetical as well as actual factors that might influence treatment adherence in a population in inner city Johannesburg. (Three trials are planned to determine the impact on HIV acquisition or transmission of twice daily suppressive therapy for HSV-2.)

Female participants were interviewed in a series of focus groups about factors they thought might influence their ability to take tablets twice daily for an extended period of time. These participants were then asked to take multivitamins twice a day for a period of 1 month and record their daily treatment adherence in a diary.

Factors associated with increased adherence to treatment included using an alarm clock as a reminder, identifying a support person to remind the participant about treatment, taking treatment during other routine activities such as brushing teeth and using support groups. Barriers to treatment adherence included a change in routine, travelling away from home and myths regarding the effects of treatment.

A Phase III randomised, double-blind, placebo-controlled trial of acyclovir to prevent HIV acquisition in high-risk HIV seronegative HSV-2 seropositive individuals

This multi-country study aims to determine the effectiveness of twice daily suppressive therapy with acyclovir on HIV acquisition in HIV seronegative individuals: men who have sex with men in the United States and South America, and women who have sex with men in Africa. RHRU is 1 of 3 trial sites in southern Africa. The trial aims to recruit a total of 2,700 to 3,600 HIV seronegative HSV-2 seropositive participants over a 2-year period. Participants will be followed over 18 months; and the main outcome of interest is HIV incidence. RHRU will contribute approximately 400 to 450 female participants to the study.

The HIV prevalence in the population being tested is about 30% and HSV-2 seroprevalence is 60%. Among those enrolled, adherence to study treatment appears to be high, with >95% of doses reported as taken. Cohort retention also appears to be high with 95% retention after 3 months of the study.

Prospective cohort study of HPTN 039 seroconverters: the effect of HSV-2 suppression on HIV-1 viral set point

The purpose of this study is to determine the effect of HSV-2 suppression, with twice daily acyclovir during the first 6 months after HIV acquisition, on HIV viral set point and CD4 count. In addition, the study aims to describe the incidence and severity of clinical HSV re-activation, as detected during visits or reported by participants, during early HIV infection. Women enrolled in the randomised-controlled trial of acyclovir's role in the reduction of HIV acquisition (HPTN 039) who are identified as HIV-positive during follow-up, will be included in this study.

The South African site will contribute an estimated 20 women. Study participants identified as HIV-positive during HPTN 039 follow-up will continue taking, in blinded manner, either oral acyclovir 400 mg twice daily or matching oral placebo twice daily, for 6 months after their first HIV positive confirmation visit. Measurements of HIV viral load will be collected at month 1, 3, 5 and 6. This study will provide important information on the effect of treatment for HSV-2 on HIV plasma viral load set point and subsequent prognosis for HIV infection. The study will start in 2005.

The effect of anti-herpetic suppressive therapy on HIV shedding in South African women who are seropositive for HIV and HSV-2: a randomised-controlled trial

This study aims to measure the effect of twice daily suppressive therapy with acyclovir on the frequency and quantity of HIV shedding in 300 women who are co-infected with HIV and HSV-2. In this study it is hypothesised that the suppression of HSV-2 re-activation will, through the biological interactions between these two viruses, lead to a reduction in HIV replication. The main outcome of interest in this study is whether there is a reduction in the frequency and quantity of HIV shedding in the genital tract after 3 months of suppressive therapy.

Participants will be recruited from women not eligible for the HPTN 039 trial because they are HIV- positive. Women who consent to participate in the trial will be randomised to receive either acyclovir or a placebo twice daily and followed up monthly over a period of 3 months. At each monthly visit, women will be interviewed regarding their sexual behaviour, condom use, symptoms and adherence to therapy. Genital specimens will be collected by means of cervico-vaginal lavage and tested for the presence and quantity of both HIV and HSV-2.

This is a collaborative project between RHRU, the London School of Hygiene and Tropical Medicine, and laboratory colleagues from INSERM U430 in Paris. It is funded by a grant from the Wellcome Trust. The project will begin in 2005.

The validation of four methods used to collect genital secretions for the detection and quantification of HIV-1 RNA and HSV-2 DNA in a South African female population

This study aimed to compare 4 methods used for the collection of genital secretions (cervico-vaginal lavage, cervical swab, "enriched" cervico-vaginal lavage and vaginal tampons) to detect and quantify HSV-2 and HIV-1 genital shedding in HSV-2 seropositive South African women who are co-infected with HIV. In addition, it aimed to assess the acceptability or ease of use of each method by research participants and clinical staff. This study was conducted in preparation for the randomised trial described above.

HIV and HSV-2 seropositive women were enrolled in the study and followed up weekly over a period of 3 weeks for a total of 4 visits. At each visit they were interviewed regarding their health, sexual behaviour and symptoms. They were examined and all 4 methods described above were used to collect specimens. Each week the order of specimen collection was changed so as to determine the effect that

order had on the performance of these tests. Preliminary results show that genital HIV shedding was detected by at least one method in 50% to 60% of women at each visit. Analysis regarding the comparative performance of each test is ongoing.

Partners in Prevention: a Phase III randomised placebo-controlled trial of HSV-2 suppression to prevent HIV transmission among HIV-discordant couples

This study, funded by the Bill & Melinda Gates Foundation, aims to determine the effectiveness of twice daily suppressive therapy with acyclovir in reducing HIV transmission between HIV serodiscordant couples, where the HIV-infected partner is also HSV-2 seropositive and has a CD4 count >250 (and therefore is not eligible for ARVs). It will involve 3,600 serodiscordant couples at several sites in Africa.

It is expected that 12,000 couples will need to be counselled and tested for HIV at the South African site in Orange Farm south of Johannesburg to identify 400 HIV serodiscordant couples. On its own, the counselling and testing of so many couples represents a huge public health intervention for HIV prevention in this community. Activities to date have focused on community consultation and preparation prior to the start of the project in April 2005.

Expected outcomes of the HSV/HIV research programme

Although these studies are proof of concept trials, they may provide evidence for important public health interventions to prevent HIV transmission in selected populations. While it may not be possible to introduce widespread use of acyclovir for HIV prevention, it may become possible to recommend the use of acyclovir, for example, in young women with a first episode of genital herpes to prevent HIV acquisition, or in serodiscordant couples not yet eligible for ARVs to prevent HIV transmission. The RHRU has already co-hosted a meeting with the National Department of Health on the need to revise the guidelines for the management of genital herpes.

As part of the collaboration with the London School of Hygiene and Tropical Medicine, the data from this site will be used to inform the development of mathematical models which can be used to predict the introduction of HSV-2 prevention interventions on HIV transmission at a population level. A mathematical model of HIV transmission dynamics within the population that is serviced by the Esselen Street Clinic has been developed and has been used to demonstrate the impact of introducing other technologies like rapid STI diagnostic tests or a microbicide into the population.

Sexual Practices
Contraception and Barrier Methods

Sexual Practices
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Sexual Practices

Perceptions of the value and the use of external drying agents in sexual practice

Funded by the Ford Foundation, this study is being undertaken by RHRU with the Centre for HIV/AIDS Networking. It forms part of a larger multi-country study under the auspices of the World Health Organisation (WHO) on gender, sexuality and vaginal practices involving comparative research in southern Africa and South East Asia. The project seeks to document commonly practised vaginal & dry sex practices in selected urban and rural sites in KwaZulu-Natal, and to explore the social, cultural and historical meanings attributed to these practices both by those who engage in them and by those who resist or reject them. This formative work will lay the foundation for a subsequent quantitative prevalence study using survey methods.

Contraception and Barrier Methods

RHRU has established itself in several areas of contraceptive and barrier method research and policy development that are regionally relevant and aim to answer priority issues. The programme has established links with international organisations including WHO, PATH, Family Health International (FHI), Ibis Reproductive Health, Contraceptive Research and Development (CONRAD), the Population Council and universities in South Africa and around the world. At the national level, RHRU has established a Contraceptive Programme Network that brings together South African institutions that work in complementary areas in a range of disciplines. RHRU has been involved in the development of the National Contraception Policy and service delivery guidelines since 2001 and has orientated over 300 health care workers from all 9 provinces in South Africa on the guidelines. RHRU's main areas of contraceptive and barrier methods research and policy development are outlined below.

BARRIER METHODS PROGRAMME

One of the focal areas of the contraception programme is barrier methods. A number of diverse research projects are underway, with the programme focusing on the female condom, new female barrier method prototypes and the diaphragm. The female condom remains the only female-initiated barrier method available to women. The comparatively high cost of the female condom has limited its availability, particularly in developing countries where it is arguably most needed.

Technical support and evaluation of the National Female Condom Rollout Programme in the public sector

Since 1998 the RHRU has provided technical support to the Department of Health's Female Condom Programme. This has included training, evaluation and research. Research components have involved follow-up surveys among users, non-users and discontinuers of the female condom, and providers who were involved in the early distribution phase. By 2003, 184 new distribution sites throughout the country had been established. These sites include primary health care services, hospitals, services for high-risk women, truck stops, workplaces, NGOs, HIV/AIDS support centres, tertiary institutions and youth centres.

Draft Report

Mqhayi M, Beksinska M, Smit J, Rees H, Nutley T, Hatzell T, Wesson J, Marumo E. *Introduction of the Female Condom in South Africa: Programme Activities and Performance 1998-2001*. Draft Report, 2004.

A non-randomised comparative trial to determine the contraceptive effectiveness of female and male condoms, and their efficacy against STI transmission

Evidence of the effectiveness of the female condom is limited; this was the first comparative study on the contraceptive effectiveness of the female condom. The study was a multi-national, non-randomised prospective follow-up trial conducted in 4 sites: South Africa, China, Nigeria and Panama. The study was completed at the end of 2004. It is hoped this trial will provide real evidence of the contraceptive

effectiveness of the female condom in a setting where it is directly compared with the male condom. A study aimed at developing a new technique to evaluate the efficacy of the female and male condom in the prevention of STIs was piloted at RHRU's Research and Training Centre in Hillbrow, inner city Johannesburg. This was done in partnership with WHO; and a larger study utilising this novel approach to STI efficacy evaluation is now being considered.

Evaluating the effect of female condom distribution on use of dual protection

This is a randomised-controlled cluster design study undertaken in 24 KwaZulu-Natal health facilities randomly assigned to intervention and control sites. The study involves a baseline survey of clients attending family planning, STI, well-baby, ante-natal and post-natal care facilities. On completion of baseline data collection, providers are trained in dual protection promotion and counselling, and the intervention sites receive female condoms for distribution. The intervention sites are being monitored for 9 months, after which a follow-up survey will be conducted in 2005.

The development of new female condom prototypes

Some acceptability trials have reported a positive response to the female condom, while other studies have reported a mixed reaction. RHRU has been working with PATH since 2000 on developing an acceptable female condom. The South African project is one of several international sites carrying out the same work. The study involves women and their partners using the various prototype designs and giving feedback on fit, comfort and ease of insertion. The information collected is continuously reviewed; and after each phase the prototype is developed further in the light of comments from the different sites. A final design will be evaluated in 2005. In addition, RHRU assisted PATH in developing a future introduction strategy for their final design.

Technical Report

Mabude Z, Beksinska M, Smit J, Mqhayi M. *Development of an Introduction Strategy for PATH's Women's Condom in South Africa*. Technical Report, 2003.

Performance and acceptability of the Reality® Polyurethane female condom and a synthetic latex prototype: a randomised cross-over trial among South African women

RHRU has completed a performance and acceptability study of a new prototype synthetic latex female condom design. This device can be produced at a lower cost and could potentially decrease programmatic costs significantly. A small pilot study was successfully completed in 2003 and the main acceptability study was completed at the end of 2004.

The analysis and report of the study will be available in 2005. It is hoped that the findings of both these projects and prototype revisions will contribute to a new design. This may lead to a wider range of female condoms being made available, which will provide women with a greater choice of barrier methods.

Female condom use among South African students

This study over 5 years will develop and test a two-session, culture-specific, group-based female condom negotiation and insertion skills intervention, versus a one-session standard information-only intervention on a South African university campus, where the female condom is already available.

In the preparatory research phase, formative qualitative work and a representative, campus-wide, cross-sectional interview survey of 1,000 students will be conducted to understand the social context, characterise the target population, formulate appropriate intervention messages and stimulate interest in the female condom trial. The trial phase will test the effectiveness of a cognitive-behavioural skills intervention against an information-only control condition on short- and long-term use of the female condom and discontinuation of use among 280 women. In-depth interviews with 70 female trial participants and their male partners will augment data provided by women participants to increase understanding of the contextual factors that influence initial adoption, long-term use and discontinued use of the female condom.

DIAPHRAGM PROJECTS

There is a great need for additional female-initiated barrier methods that are safe, easy-to-use and acceptable. Cervical barrier methods including diaphragms and cervical caps are among the oldest known contraceptives. Although many cervical methods are approved for use as family planning methods, their use is limited and the provision in the South African public sector was discontinued many years ago. In addition to pregnancy prevention, there is now renewed interest in these devices in relation to protection against STIs and HIV. The physical barrier to the cervix can contribute to protection from STIs and HIV since the endo-cervical tissue is thought to be a susceptible site of infection. Low uptake of the traditional "ORTHO" diaphragm has been attributed to several characteristics that complicate use. These factors include availability, the need for provider fitting, the variation in size and problems with insertion.

RHRU is involved in a series of studies examining the acceptability of new diaphragm prototypes as well as their efficacy. One such study is described under the microbicide section of this review ('Phase II diaphragm and ACIDFORM study').

SILCS diaphragm: use acceptability of a single-size, re-usable cervical barrier by South African couples

PATH has worked since 1994 to develop an improved diaphragm that better meets users' needs. The SILCS diaphragm is designed to be easier to insert and use, more comfortable for both partners and easier to remove than the standard diaphragm. It is a one-size device designed to fit women who would wear a range of diaphragm sizes (65mm to 80mm).

RHRU was involved in assessing the acceptability of the SILCS Prototype 6 diaphragm after multiple uses by couples in Durban. The unit conducted a non-blinded, non-randomised, non-significant risk study among 21 couples to evaluate acceptability (fit, ease-of-use, comfort) of the SILCS diaphragm used with water-based lubricant gel.

Results indicate that the SILCS diaphragm was acceptable to men and women, fits women who represent a range of standard diaphragm sizes and who have varied body mass index and parity. Women reported that the diaphragm was easy to insert and easy to remove.

Field-testing and adaptation of a WHO decision-making tool for family planning clients and providers

RHRU assisted WHO to field-test their decision-making tool for family planning clients and providers. This tool, in the form of a flipchart, provides technical information on available family planning methods and facilitates key elements of the clientprovider interaction during the provision of family planning services. The information provided in the flipchart is consistent with the National Contraceptive Policy and Service Delivery Guidelines. The first phase of field-testing the tool involved trial use and feedback from family planning providers, programme managers and experts in counselling, communication and family planning service delivery. Similar procedures were followed in Indonesia and Mexico. RHRU adapted the tool for use in South African family planning clinics and the process was documented. The adapted tool will now be field-tested among family planning providers, trainers and clients.

EMERGENCY CONTRACEPTION (EC)

Availability of emergency contraception (EC) in South Africa is important because rates of unplanned pregnancy and teenage pregnancy remain high. South Africans are increasingly advised to use condoms to prevent sexually transmitted infections. EC is the only contraceptive that can be used after unprotected intercourse, and its role as a back-up method to prevent pregnancy when condom failure occurs should be highlighted. EC is available at South African public sector clinics and over-the-counter at pharmacies. RHRU has been involved in a number of EC research and programmatic activities.

A South African multi-centre situation analysis of EC provision

This analysis was undertaken in 1999 and 2000 at public sector primary health care facilities in response to the lack of information on the availability, provision and use of EC in South Africa. Interviews were held with 89 managers, 197 providers and 1,068 clients in 89 public sector primary health care facilities in 2 urban (Gauteng and Western Cape) and 2 rural (KwaZulu-Natal and Western Cape) areas. In addition, 165 simulated client visits were conducted at health facilities and private sector pharmacies at 2 of the study sites (Gauteng and KwaZulu-Natal). Findings indicate that if women knew about EC, where to get it and how soon to take it, they would use it if needed.

A carefully designed intervention programme to promote EC awareness is needed. Training for providers should focus on accurate information about mode of action, dosing interval, safety and efficacy. The importance of EC as a contingency to condom failure should be emphasised, and providers should use every opportunity to counsel clients about the dual risk of pregnancy and STIs, including HIV. Findings have been extensively disseminated to study participants, service providers and stakeholders.

An educational intervention trial conducted in private sector pharmacies

In 2002 and 2003, a study was undertaken to measure the availability of EC in private sector pharmacies in the Durban metropolitan area and evaluate an educational intervention programme developed for pharmacists to promote access to EC. The study also determined if pharmacists provided appropriate counselling on STI and HIV risk after unprotected sex. A randomised-controlled study design was employed and the intervention was delivered at 30 of 60 randomly selected pharmacies.

Data was collected on the availability of EC and on pharmacists' knowledge of EC. An evaluation of the intervention was undertaken by means of interviews with pharmacists and by simulated client visits to each pharmacy. Data analysis is in progress.

Promotion of EC

Training of public sector service providers in sexual and reproductive health, including EC, is ongoing. In addition, RHRU became a founder member of ECafrique, an Africa-wide forum dedicated to introducing, delivering and mainstreaming quality EC services in Africa.

HORMONAL CONTRACEPTIVES

Injectable progestin contraceptive use and risk of HIV infection in a South African family planning population

A number of studies have sought to investigate the possible association between the use of hormonal contraceptives and HIV transmission; however, the evidence remains uncertain. Use of long-acting injectable progestin contraceptives is widespread in South Africa, as is infection with HIV among women. A prospective study was undertaken to investigate whether the incidence of HIV infection is higher among sexually active women using progestin (DMPA or NET-EN) injections for contraception than among women using non-hormonal or no contraception.

Five hundred and fifty-one initially HIV-negative women using one of the progestin injectable methods, or not using any hormonal contraceptive, were followed up for a total of 491 person years. Participants were seen at 3 monthly intervals, at which they were interviewed, counselled, examined, tested for HIV, syphilis, chlamydia, gonorrhoea, trichomonas and bacterial vaginosis, and treated syndromically. The data are currently being analysed.

The effect of hormonal contraceptives on bone density

Osteoporosis is a major cause of ill-health in post-menopausal women. It is important to know which factors affect peak bone mass in pre-menopausal women. Given the casual association between oestrogen deficiency and rate of bone loss, many studies have tried to establish whether a relationship exists between hormonal contraceptives and bone density. Work carried out thus far has not provided

consistent answers, nor have study groups included all categories of women who could be affected, such as young women and pre-menopausal women using injectable progestin contraceptives. In South Africa many women use injectable progestin contraceptives; and RHRU is conducting a study to investigate the effect of injectable and oral hormonal contraceptives on bone mineral density in a large family planning clinic in central Durban.

Almost 1,000 women are being followed up over 5 years. This study aims to assess the relationship between bone density and hormonal contraceptive users among women aged 15-19 years and 40-49 years. The results of investigation into the older women (aged 40-49 years) with at least 12 months of current use of DMPA, NET-EN and COCs found there was no significant difference in bone mineral density between the 4 contraceptive user groups. This study suggests that long-term use of DMPA and NET-EN in older women does not affect bone mineral density in this population.

Findings will be used to make policy recommendations related to the use of these methods in the two age groups. The study is funded by WHO.

Detection of menopause in hormonal injectable users

In older women it may be difficult to distinguish between amenorrhoea associated with approaching menopause and the side effects of the contraceptive method. There is limited information on whether measurement of the FSH hormone can be used reliably to indicate approaching menopause in older long-term users of Depo-Provera and Nur-isterate and it has been documented that this hormone is suppressed in users of these products.

Initial study findings reveal that a raised level of FSH can be detected well within the 3-month injection cycle and, potentially, could be used as a menopause indicator in this group of contraceptive users.

Determination of medroxyprogesterone acetate (MPA) serum levels of new and repeat users of Depo-Provera at the end of the dosing interval

The study was undertaken at 3 family planning clinics in Durban. Medroxyprogesterone acetate (MPA) levels were measured in 96 women returning between 11 and 14 weeks after their last injection. Despite the widespread use of Depo-Provera, this is the first study to examine MPA levels in South African users. The first ever population pharmacokinetic analysis of MPA was undertaken and the pharmacokinetic parameters' apparent volume of distribution and clearance were determined for the first time. It is intended that findings from these and future studies will be used to inform public health policy and protocols governing the provision of these widely used contraceptives.

Research and Interventions in Vulnerable Populations

Research and Interventions in Vulnerable Populations

MOBILE POPULATIONS PROGRAMME

The RHRU Mobile Populations Programme has been running since 2002. The programme now consists of the truckers project TRIPS and an inner city hostel and informal settlement project called Mpilonhle-Mpilonde, which means 'Quality of Life - Long Life'. Those involved in both projects are challenged daily with the problem of access and the need to establish trusting partnerships with these highly mobile target communities.

Hostels & informal settlements: the Mpilonhle-Mpilonde project

This 3-year project seeks to address risks of HIV transmission among men living in inner city hostels and women living in informal settlements. Its primary focus is on increasing male involvement in health and wellbeing as a strategy for empowering communities around sexual and reproductive health.

This operations research project uses baseline data to develop a targeted intervention for community residents, including the health facilities (biomedical and traditional) serving this population. The intervention will aim to improve the quality of life of residents in these communities through Quality of Life Clubs, and improve the quality of care provided in the health facilities they use.

Accessing this highly underserved population for both a survey and an intervention was challenging. Extensive formative work, negotiations with traditional leadership and careful research design that engaged the community in the research process were required. The behavioural and prevalence survey of a random sample of 2,000 men and 1,000 women between the ages of 18 and 55 years, who had lived in the community for over 3 months, has been completed. A quality of care assessment of 9 urban public health facilities in addition to the pharmacies, private practices and traditional healers practising in the area is also underway. Technical and Community Advisory Groups have been established as a way of staying attuned to the ongoing government and NGO activities.

The data collected are currently being used to design a cost-effective, innovative and sustainable intervention focused on improving the health and wellbeing of the 24,000 men living in 6 single sex hostels and 10,000 women living in the surrounding informal settlements over the course of 3 years.

The intervention has 3 components: a health sector component, consisting of attitude adjustment and competency training for public, private and traditional practitioners; an integration component that fosters collaboration and prevents duplication through the Technical and Community Advisory Groups; and a community component built upon Quality of Life Clubs. Through a structured participation approach, the Quality of Life Clubs intend to place the tools for change in the hands of residents, forging stronger ties between residents and government services, ensuring that issues relating to rights, participatory decision-making and citizenship are addressed, while engaging the communities through interactive training around ideas of wellness such as nutrition and sanitation.

The aim is to address HIV/AIDS with the club members, who after a few months of affecting change in other areas of their lives, will be receptive to discussions around behaviour-change, specifically relating to HIV prevention, testing, treatment access and wellbeing.

TRIPS: The study on truckers

There are few data on the trucking industry and its role in HIV prevention and transmission. There are a number of features of the road transport industry that contribute to the vulnerability of truck drivers to STIs and HIV. The nature of the industry requires truck drivers to be away from home, and their regular social networks and sexual partners, for long periods of time, thus rendering them susceptible to engaging in casual sexual relations. In addition, long-distance truck drivers have less access to regular health care services because they are frequently on the road. Due to concerns about the transmission of HIV within the road transport industry, the South African Department of Health, together with the Road Freight Association and the National Bargaining Council, established a project known as "Focus on AIDS".

As part of a large grant aimed at strengthening sexual and reproductive health services in South Africa, and because of RHRU's expertise in the area of interventions in mobile populations, the unit was requested by the Department of Health to provide technical support to the "Focus on AIDS" project.

More specifically, RHRU was asked to provide support to improve the quality of care provided at 6 roadside clinics, as well as to evaluate the impact of this approach on increasing access to STI/HIV prevention services for truckers. The evaluation component of this operations research project has involved a prevalence and behavioural survey among 1,900 long-distance truck drivers from depots across the country. Ongoing analysis of the data will determine levels of access to STI/HIV prevention services, prevalence of STIs and HIV, condom use and health-seeking behaviour among truck drivers within the Road Freight Association.

Baseline behavioural sentinel surveillance (BSS) in high transmission groups

The National STI Initiative has conducted baseline behavioural sentinel surveillance (BSS) in high transmission populations (migrants, commercial sex workers, male STI clients) over a 3-year period. The data was collected from 2000 to 2003 and provide trends in sexual risk behaviour, and substance and condom use among South African male migrant workers.

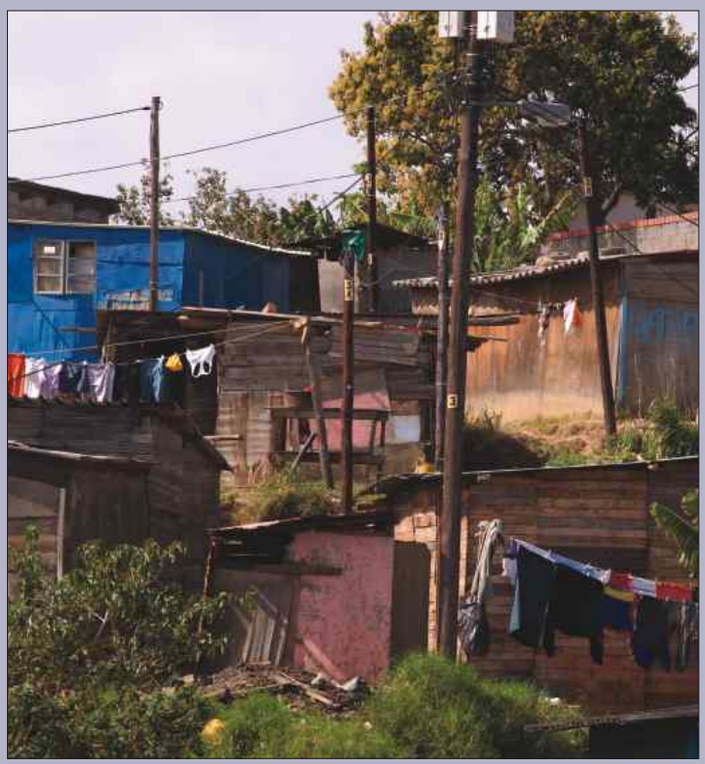
Migrant workers from a health district in rural KwaZulu-Natal participated in this study. A key result was that there was no significant change in sexual risk behaviour noted between 2000 and 2003. Over this period, increased accessibility and availability of condoms was reported; and the proportion of respondents who reported using a condom with any partner increased from 48% to 59% (P=0.013). Abstinence and consistent condom use were most frequently cited by respondents as methods of STI/HIV prevention; the proportion that reported using a method to prevent infection increased slightly from 19% to 22% between 2000 and 2003. In conclusion, high-risk sexual and substance-related behaviours are prevalent among male migrant workers in South Africa and may contribute to STI/HIV transmission. There is an urgent need to promote condom use for the prevention of pregnancies in order to increase acceptability of condom use with 'main' sexual partners.

Studies on service delivery for high-risk women

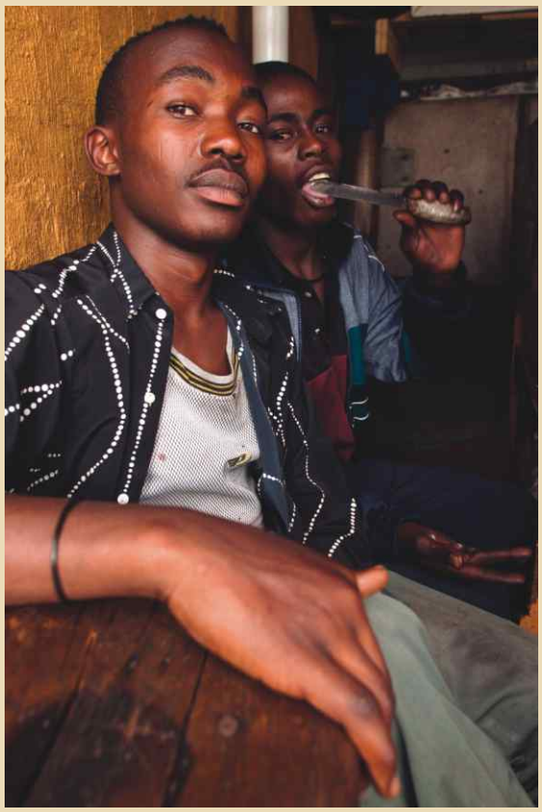
RHRU has undertaken two studies evaluating different approaches to the delivery of services for high-risk women in 2 different areas in inner city Johannesburg and Durban. Research into appropriate STI treatment services for commercial sex workers has been completed. During 2004 an evaluation of STI care provided by traditional health practitioners and general practitioners was conducted. In Johannesburg, 6 hotels which house a sex worker population of about 5,000 women were randomised to receive outreach health services which either provided periodic presumptive treatment and syndromic STI treatment, or syndromic STI treatment alone.

Publication

Vickerman P, Terris-Prestholt F, Delany S, Kumaranayake L, Rees H, Watts C. *Are targeted HIV prevention activities still cost-effective in high prevalence settings? Results from an STI treatment intervention for sex workers in South Africa*. Accepted, Sexually Transmitted Infections.



Adolescent Health Research



Adolescent Health Research

RHRU's adolescent health research division has undertaken a number of large epidemiological and health systems studies all aimed at better understanding the HIV epidemic among young people and evaluating which interventions positively impact on behaviour and diminuish HIV risk. A major focus of this evaluation has been the loveLife campaign, which is the largest HIV prevention and positive lifestyle programme for youth currently being undertaken anywhere in the developing world. During 2003 and 2004 in particular, the division focused on 5 key areas:

1) a nationally representative HIV seroprevalence household survey of youth between the ages of 15 and 24;
2) a community-based household survey comparing communities with either the National Adolescent Friendly Clinic Intervention (NAFCI), a loveLife Y Centre or with standard public sector health services;
3) research on particular loveLife programmes;
4) monitoring of ongoing loveLife programmes; and
5) development of research ideas around youth voluntary counselling and testing.

National HIV seroprevalence and behavioural survey of 15-24 year olds

RHRU's Adolescent Health Division conducted a nationally representative household survey of young people between the ages of 15 and 24 from March to August 2003. The objectives of the survey were to describe the prevalence of HIV and related risk behaviours among young people in South Africa, and to determine levels of exposure to the loveLife programme. One young person was randomly selected per household. A questionnaire was administered and an oral fluid sample was collected using Orasure to test anonymously for HIV infection. A total of 11,904 young people took part in the survey. Field-work was undertaken by Development Research Africa (DRA). The national survey report was released in April 2004.

National Survey

Pettifor AE, Rees H, Steffenson A, Hlongwa-Madikizela L, MacPhail C, Vermaak K, Kleinschmidt I. *HIV and sexual behaviour among young South Africans: A national survey of 15-24 year olds*. RHRU, University of the Witwatersrand, 2004.

Community-based survey comparing three different approaches to the provision of health services and HIV prevention among youth

A quasi experimental, community-based survey was designed and implemented to assess the effect of key loveLife programmes on the transmission of HIV/STIs and related risk behaviours among young people. The study was conducted in 33 communities from all 9 provinces in South Africa. Communities were grouped into 'triplets' based on the type of loveLife programmes they had; each triplet was in the same health district. In total there were 11 'triplets' of interventions (each triplet constituted a Y-Centre, a NAFCI clinic and a comparison public clinic). One young person per household living within a 2km radius of the service delivery point was randomly sampled. The selected participants were anonymously tested for HIV using the Orasure ® device and were asked to provide a urine specimen that was tested for chlamydia and gonorrhoea at a central, accredited laboratory. They were also asked to respond to a questionnaire administered by an interviewer.

The main aim of the study was to determine if young people between the ages of 15 and 24 living in communities that have loveLife NAFCI clinics or Y-Centres have a lower prevalence of HIV, STIs, pregnancy and risk behaviours compared to those communities without these interventions.

The aim of the baseline survey was to describe the prevalence of HIV, gonorrhoea, chlamydia, self reported pregnancy, key sexual risk behaviours, socio-demographics and exposure to loveLife at the time of the baseline survey in each type of community (with a NAFCI, a Y-Centre or comparison public clinic). Secondary objectives included determining if there were any significant differences between sites on key outcomes at baseline.

The survey took place in 2003. In total 8,749 young people between the ages of 15 to 24 were interviewed. This is an ongoing study; the next surveys are planned for 2005 and 2007. Copies of the baseline report are available from RHRU.

Focused adolescent research

Two focused research projects were undertaken to better understand and measure the effects of participation in the loveLife motivation programme. At the individual level, learners in Mandeni were interviewed in 2003 to establish the relationship between participation in the motivation programme and levels of self-efficacy, school marks and knowledge of HIV.

Integral to the loveLife initiative are the groundBREAKERS. Approximately 800 young people between the ages of 18 and 24 have been selected by their communities to be trained as peer educators and motivators of their younger peers. Some initial research on loveLife groundBREAKERS was conducted to evaluate the impact of the groundBREAKER programme. This research has been continued in 2004 with a before and after design to better establish whether behaviour changes occur and can be attributed to the groundBREAKER programme.

An evaluation of the loveLife Games was conducted in 2003. Data were collected from learners and teachers at 6 provincial Games. Analysis indicated that learners and teachers were mostly satisfied with the Games but would like to see the involvement of more schools in future Games. A report is available from loveLife or from the RHRU website.

Monitoring of the loveLife Initiative

Monitoring a campaign of the scope and diversity of loveLife is an enormous challenge. A report synthesising the 2002 loveLife activities was produced with Health and Development Africa (HDA) and was released in August 2003. This report is available on the loveLife website and from RHRU. One key activity is the development of a database system to improve the quality of monitoring information captured for loveLife's outreach activities at franchises, Y-Centres and NAFCI clinics. More recently the monitoring team focused on the development of monitoring tools for loveLife's loveLifestyle approach launched in 2004. An annual report documenting the monitoring activities of all loveLife programmes (outreach and NAFCI) is available from the loveLife offices.

Youth Voluntary Counselling and Testing

As ARVs become increasingly available in the national rollout and youth remain the largest group vulnerable to HIV acquisition, special consideration must be given to the provision of voluntary counselling and testing (VCT) services for young people. RHRU's adolescent research team undertook formative research to inform a VCT intervention for young people. Attitudes and beliefs around VCT for HIV among adolescents were discussed. The results of this formative research are being used for further research projects.

A further research project on VCT is currently underway with the collaboration of RHRU's STI/HIV Research Division and staff at the Esselen Street Clinic. The objectives of the research are to obtain a profile of people accessing VCT at this facility; better understand reasons for testing; examine the role of stigma; assess attitudes towards testing in the light of free access to ARVs; and reveal attitudes about couples testing together. Based on this work, funding has been secured from National Brands to develop a youth-friendly model of VCT at Esselen Street Clinic.

Publication

Pettifor A, Measham D, Rees H, Padian N. *Sexual power and HIV risk among young women in South Africa*. Accepted, Emerging Infectious Diseases, 2004

National Adolescent-Friendly Clinic Initiative (NAFCI)

With the majority of new HIV infections occurring in young people under the age of 24, it is imperative that new ways are found to influence the behaviour of this age group. Such initiatives must include accessible public sector health services. NAFCI is a partnership between RHRU and the Maternal, Child and Women's Health and Nutrition Cluster in the South African Department of Health and is an integral component of loveLife, the largest South African youth HIV prevention programme. The programme aims to make public health services accessible and acceptable to adolescents, establish national standards and criteria for adolescent health care in clinics throughout the country and

build the capacity of health care workers to provide quality adolescent health services. Successful clinics are then awarded a bronze, silver or gold status according to their success in the implementation of the programme.

NAFCI is currently working across all 9 South African provinces in 260 clinics; this will be increased to 350 clinics in 2005. NAFCI's quality improvement programme includes a strong skills development and capacitybuilding process for health care providers at the NAFCI sites.

A key part of the NAFCI programme is peer community outreach to encourage young people to take advantage of clinic services. Using loveLife groundBREAKERS based at NAFCI sites, educational programmes are run at the clinics and in the schools. This programme has become so successful that 3 provinces have now requested the introduction of the programme into their public education sector.

An ambitious programme such as NAFCI requires rigorous evaluation and monitoring to quantify its progress and success. Monitoring results from 2004 are beginning to show a significant impact of the programme on youth utilisation of clinic services.

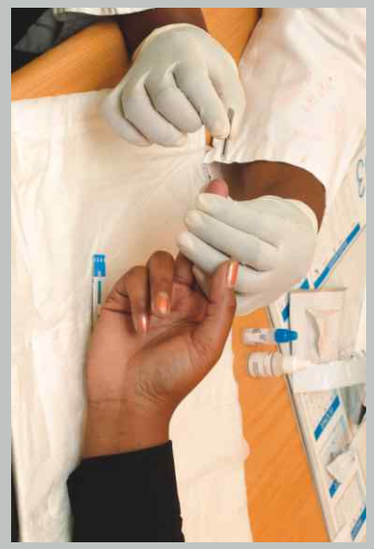
NAFCI External Assessment Results

In the past 2 years there have been additional benefits derived from the partnership with the Department of Health. Policy guidelines for youth and adolescents have been developed and disseminated through a series of jointly implemented workshops. As the needs of health services continuously change, a new NAFCI co-ordinators manual was developed and the Going for Gold manual, which is the blueprint for clinics to implement adolescent friendly services, were both updated. In 2005 NAFCI will work together with 32 loveLife regional campaign teams around the country, and will shift its focus from individual clinics to District Management Teams to increase reach and impact. A more strategic approach to involving communities is planned through working with District Management Teams, youth-serving & religious organisations as well as schools.

Publications

NAFCI Co-ordinators Handbook (unpublished Internal NAFCI Staff Resource). RHRU, 2003.
Melanie Pleaner (Contributing Author). *WHO Child and Adolescent Health Job Aid Caring for Adolescents*. WHO, 2003.
Melanie Pleaner (Contributing Author). *WHO Child and Adolescent Health Job Aid Caring for Adolescents Training and Dissemination Handbook*. WHO, 2003.

Strengthening the South African Health Sector[i]



Strengthening the South African Health Sector in the Delivery of STI and HIV Services

Since 1998 the RHRU has worked with the Department of Health on a series of initiatives aimed at strengthening STI and HIV service delivery in both the public and private sector, supported by USAID and the Kaiser Family Foundation. Between 2001 and 2004, USAID funded RHRU to run a joint programme with the National Directorate of STI & HIV Prevention, aimed at improving the quality of STI management in South Africa, and supporting the national barrier method programme.

At the end of 2004, RHRU was awarded funding from PEPFAR, the United States' President's Emergency Programme For Aids Relief. This funding has allowed the unit to give direct support to sites providing ARV treatment in the public health sector. PEPFAR activities are centred in 3 provinces: Gauteng, North West and KwaZulu-Natal. The PEPFAR grant was signed during a ceremony at the Addington Hospital ARV Clinic in Durban in December 2004. The ceremony was attended by national and provincial representatives of the HIV/AIDS directorate hospital management and the Global AIDS Co-ordinators office. It is anticipated that the number of sites supported by RHRU in the provision of ARV treatment will expand in 2005.

Esselen Street Clinic Development, Johannesburg Hospital & the Hillbrow Health Precinct Project

For the RHRU, the development of the Esselen Street Clinic site represents an expansion of capacity to undertake training and research in a unique area. In the heart of the inner city of Johannesburg is an old, well-established primary health care clinic, which is run by the local health authority and provides basic STI care, family planning and tuberculosis (TB) services. It also runs a busy HIV VCT site.

In 2000, planning began to extend the scope of Esselen Street Clinic, in co-operation with the City Health Department. The mayor, Mr. Amos Masondo, gave his full backing to the Hillbrow Health Precinct Project, which would be located in and around the grounds of the old Hillbrow Hospital site, with the development of a reproductive health focused "Centre of Excellence" in the Esselen Street Clinic and the newly renovated Community Health Centre as its cornerstone.

The Hillbrow Health Precinct Vision

The inner city Health Precinct is an innovative project that uses the precinct model of urban regeneration to comprehensively respond to the HIV/AIDS epidemic. This HIV-themed urban regeneration project in Johannesburg will include strengthening existing primary health care services for all aspects of HIV, establishing new and novel HIV prevention and treatment services, and facilitating non-governmental, academic and private organisations in support roles.

The Hillbrow Health Precinct allows easy access to an extremely densely populated area with high HIV infection rates and low levels of support services. HIV-negative individuals are highly vulnerable to infection and urgently need access to appropriate prevention strategies to minimise transmission. Hillbrow is a major entry point for migrants and refugees from the rest of Africa, giving this project the opportunity to learn from, treat, inform and reduce stigma among an extremely diverse and deprived population with an extraordinary range of needs. This microcosm of Africa, contained in a single area, has unique relevance to the needs of an entire continent.

The Health Precinct will provide one of the most comprehensive packages of HIV support services in the world, by gathering a large number of clinical and non-clinical service providers dedicated to HIV/AIDS in one location. The strong emphasis on innovation and service improvement will enable the generation of best practice models that will be disseminated widely in southern Africa, improving knowledge and service provision well beyond the borders of the Health Precinct.

The RHRU's Research & Training Centre is due to open in the precinct in February 2005. RHRU has been successful in receiving grants from PEPFAR and Johnnic Communications this year; these will contribute to the activities conducted from this site. The Johnnic Communications award will enable Community AIDS Response (CARE), in partnership with RHRU, to set up a Wellness Centre in the Research & Training Centre.

Esselen Street Sex Worker Outreach Project

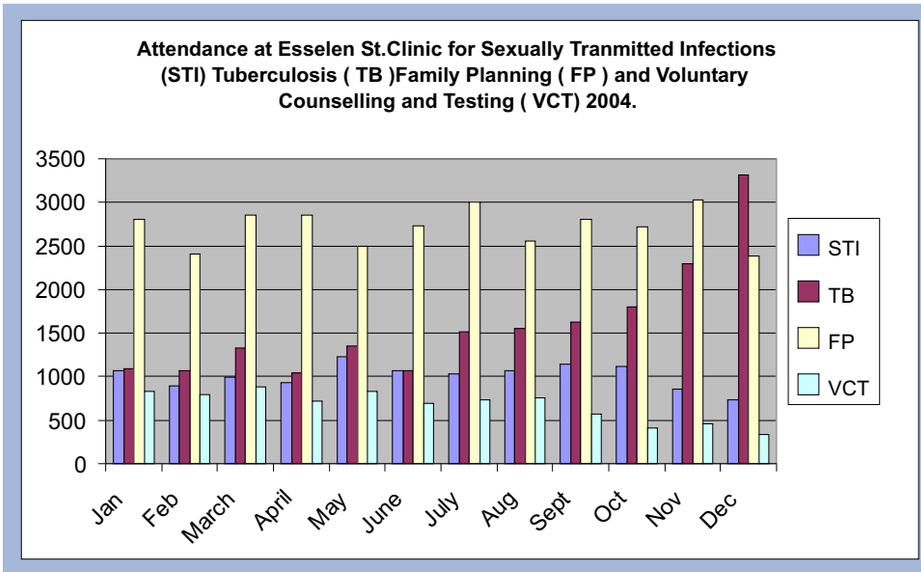
RHRU has been working with sex workers since 1996. Sex workers were found not to access mainstream STI services despite being at high risk. Campaigns, workshops and collaborations continue to develop most notably with the Sisonke sex worker project in Cape Town, the Sex Workers Education and Advocacy Taskforce (SWEAT) and Wits University. A research proposal to evaluate the outreach services aimed at improving the health of sex workers has been completed. Hillbrow sex workers contributed to the discussion on the Sexual Offences Bill at Constitution Hill in August 2004. The project has been profiled on the SABC, BBC, KAYA fm, JOZI fm and in the Mail and Guardian and The Star newspapers, a United Nations publication and True Love magazine.

Training at Esselen Street Clinic and Johannesburg Hospital

Special attention has been focused on improving and developing training abilities through the continuing development of professional staff. The training team continues to foster good relationships and maintain links with training institutions such as the Department of Health, nursing schools and universities by providing a variety of programmes to students according to their objectives and learning needs. Staff from RHRU's Esselen Street Clinic were involved in training all categories of health care workers in the intensive HIV care and ARV rollout. Training occurred in Gauteng, North West and Limpopo provinces on behalf of the National Department of Health.

Training participants included: graduate entry medical students, 6th year medical students, community health workers, NAFCI co-ordinators, business leaders, nurses (including palliative care nurses) and advanced midwifery students. All programmes included information on the connection between STIs and HIV: diagnosis, management, treatment, prevention and referrals.

Atlantic Philanthropies awarded a grant to RHRU to develop and implement various HIV care and treatment training courses for health care workers in the public sector. Many members of the RHRU team have supported the training programme through curriculum development, facilitation and evaluation. A total of 1,563 health professionals have been trained.



Esselen Street Clinical Services

Research at Esselen Street Clinic

Urethritis study: aims to determine the etiology of symptomatic, persistent and asymptomatic urethrits in an inner city region of Johannesburg. The study will be completed in 2005 and is being conducted in collaboration with the National Health Laboratory Services.

Acute HIV/seroconversion study: aims to document the incidence of acute HIV (i.e. individuals in the 'window period' between infection and the ability to detect the infection with a test) in different risk groups at the Esselen Street Clinic.

Patterns of death at an urban hospital: analyses the impact of HIV on mortality patterns at Helen Joseph Hospital in Johannesburg. The study, funded by University of North Carolina's Centre for AIDS Research (CFAR) and conducted in collaboration with the Clinical HIV Research Unit, has been completed.

Prisoners study: looks at outcomes among prisoners on ARVs versus the general population of HIV-positive males accessing ARVs, and assesses barriers to the provision of optimal care. Recommendations will be made to the Correctional Services and the Department of Health.

HIV nephropathy study: assesses the prevalence of early and late nephropathy among HIV-positive patients at different stages of immunosuppression attending clinical services. The project will be a pilot for a larger study to assess the impact of ARVs on the progression of nephropathy.

Pregnancy and HIV study: describes the experiences of pregnant women after starting ARVs on the Department of Health programme, in terms of toxicity, viral suppression and immunological and foetal outcomes.

Assessment of ARV provision at Johannesburg Hospital: a retrospective study of the first 10 months of the ARV rollout, including demographics, efficacy, toxicity and overall outcomes.

Comparison of outcomes between a rural and urban ARV site: compares demographics, efficacy, toxicity and overall outcomes between Johannesburg Hospital's and Taung Hospital's first 300 patients on ARV treatment.

Qualitative experiences of health care workers in Johannesburg Hospital's ARV Clinic's first 10 weeks: this interview-based study assesses experiences and suggestions for changes from community health workers involved in the ARV rollout in the first 10 weeks of the programme.

Post Exposure Prophylaxis (PEP) in sexual assault survivors: assesses the efficacy of PEP in sexual assault survivors, with an in-depth retrospective chart review. The study is internally funded and is being conducted in collaboration with WHO and Adrinne Wulfsohn.

IRIS (Immune Reconstitution Syndrome) study: plans to prospectively study the incidence and clinical and laboratory characteristics of IRIS in HIV-positive patients starting ARVs in South Africa. The project will be funded through UNC / Duke (why put together like this? Co-funded by University of North Caroline and Duke University?) and conducted in collaboration with these institutions and the National Health Laboratory Services/Department of Medicine (why put together like this, they are separate institutions).

Adrenal function in patients with TB on rifampicin-containing regimens: looks at the impact of conventional TB therapy on adrenal function. The study was conducted in collaboration with the Department of Medicine and has been completed.

A comparison of four methods used to collect genital secretions for quantification of HIV-1 and HSV-2: compares 4 methods of genital fluid collection for detection of HIV-1 and HSV-2.

A randomised-controlled trial of the use of acyclovir for the reduction of HIV acquisition among high-risk HSV-2+ HIV individuals (HPTNO39) This multi-centre, multi-national trial of the HIV Prevention Trials Network (HPTN 039) aims to determine the effectiveness of twice daily suppressive therapy with acyclovir on HIV acquisition in HIV seronegative individuals: men who have sex with men in the United States and South America, and women who have sex with men in Africa.

RHRU provision of services at Esselen Street Clinic and Johannesburg Hospital

During 2004, RHRU staff from the Esselen Street Clinic and the Johannesburg HIV Referral Clinic provided services to a total of 11,950 patients. Close to 10,000 clients presenting with an STI were correctly treated and managed following the Syndromic Management Guidelines at Esselen Street Clinic; and 1,400 clients were seen at the Johannesburg General HIV Referral Clinic for management and treatment of HIV/AIDS.

Mobile clinical support teams

These expert technical assistance task teams assist government rollout sites in the North West Province and Gauteng with the specific brief of building local capacity. Training includes adherence counselling, treatment literacy, bedside training in TB, ARV treatment, HIV staging, baseline assessments, debriefing strategies, classes of ARV, dosing and drug interactions of ARVs.

Unstructured bedside training continues with the registrars, medical officers and interns at the ARV clinic at Johannesburg Hospital. In-service training of adherence counsellors on treatment literacy is planned for 2005. Monitoring and evaluation tools for site assessments have been developed.

In October, RHRU, in conjunction with Professor Pierre Barker from the University of North Carolina, Institute of Healthcare Improvement (IHI), piloted a Patient Management Tool that will drastically improve and rationalise the management of patient information at the clinic. The tool has been partially integrated into the patient visit process and will be fully integrated by May 2005.

Publications

Hudspeth J, Venter WDF, Van Rie A, Wing J, Feldman C. *Access to and early outcomes of a public South African adult anti-retroviral clinic*. South African Journal of Epidemiological Infections 2004; 19: 48-51.

Barker P, McCannon J, Venter WDF, Mmbara NW. *Managing HIV as a chronic disease: Using interactive data collection to improve clinical care*. The Southern African Journal of HIV Medicine, December 2004.

Morris L, Pillay C, Chezzi C, Lupondwana P, Ntsala M, Levin L, Venter F, Martinson N, Gray G, McIntyre J. *Low frequency of the V106M mutation among HIV-1 subtype C infected pregnant women exposed to nevirapine*. AIDS 2003; 17: 1698-1700.

Venter WDF. *Fungal Infections in the ICU* in Feldman, C et al. Infection in the ICU, in press 2005.

Venter WDF, Sanne IM. *The cardiovascular consequences of HIV and anti-retroviral therapy*. Cardiovascular Journal of South Africa 2003 14 (5): 225-229.

Venter WDF, Wilson D. *Thai me up, Thai me down: The 15th IAS Conference in Bangkok*. The Southern African Journal of HIV Medicine, in press 2004 to 2005.

Conradie F, Sannie I, Venter WDF, Eron J. *Failure of lopinavir-ritonavir (Kaletra)containing regimen in an anti-retroviral-naive patient*. AIDS 2004 Apr 30; 18(7): 1084-5.

Motloung T, Myers M, Venter FDF, Delany S, Rees H, Stevens W. *Identifying acute HIV infection - a major new public health challenge*. South African Medical Journal, July 2004; 94(7): 531.

MacPhail C. *Challenging dominant norms of masculinity for HIV prevention*'. African Journal of AIDS Research 2003; 2: 141-149.

NATIONAL STI INITIATIVE

The National STI Initiative is funded by the Henry J Kaiser Family Foundation and involves collaboration between RHRU, the Health Systems Trust and the National Department of Health. The STI Initiative has attempted to strengthen STI control in both the public and private health sectors by focusing on training and capacity building of primary health care service providers, development of training resources and monitoring and evaluation tools, and by providing on-site technical support to districts.

Strengthening public sector STI management and prevention services

The STI Initiative identified and developed STI working groups to co-ordinate training and supervision and to address constraints hindering appropriate care in districts. In addition, the initiative has developed and conducted training in comprehensive STI management.

Various training modules and materials were developed and distributed nationally in 2003 and 2004.

The booklet *Guidelines for Improving Quality of STI Care at District Level* is based on lessons learnt through the STI Initiative and draws on case studies from the initiative at district level. The STI Initiative is also involved in facilitating the development and implementation of the National STI Surveillance System.

One of the programme's highlights has been the introduction of the District STI Quality of Care Assessment (DISCA) tool for monitoring and evaluation at primary health care level. The use of DISCA as a tool has extended to districts and facilities other than STI Initiative sites. The National Department of Health is in the process of developing an electronic version of DISCA for use at district level.

Strengthening private sector STI services

The STI Initiative has co-ordinated the activities of 4 task teams that were formed to develop strategies for improving quality of STI care in the private sector through training, public-private partnerships (PPPs), research and surveillance. Situational analyses of existing PPPs and training programmes for private sector clinicians were undertaken. Dissemination of results occurred through 2 national symposia organised by the STI Initiative which brought role players together to discuss key national issues in STI care. A symposium on STI management in the private sector was held in Johannesburg in April 2003. In addition, the 2nd National Symposium for the Promotion of Public-Private Partnerships to Improve STI/HIV/AIDS Quality of Care & Control in South Africa was held in Johannesburg in May 2003.

Publication

Ramkissoon A. *Proceedings of 2nd National Symposium for the Promotion of Public-Private Partnerships to improve STI/HIV/AIDS Quality of Care & Control in South Africa in Johanesburg*. Health System Trust, 16 May, 2003.

Feasibility study on the production and distribution of home-based care kits

The South African Government and NGOs are making efforts to provide community-based care for people living with HIV and AIDS (PLWHA). However, there is a need to increase access to and availability of home-based care (HBC), a component of which is the provision of HBC kits.

PATH contracted RHRU to conduct a feasibility study for the production and distribution of HBC kits in the country. Data were collected from HBC organisations in South Africa's 9 provinces. In addition, key informant interviews were conducted with a number of HBC organisations, provincial community HBC co-ordinators and representatives from companies that were distributing or supplying HBC kits.

Findings from this feasibility study show that kit availability was highly variable. Most organisations were using lay kits and received their HBC supplies from the Department of Health; however, replenishment was reported as problematic and supplies sourced from clinics were always limited. The demand for HBC kits is high and many organisations expressed frustration at not being able to meet their clients' needs.

Publication

Mabude Z, Beksinska M, Ramkissoon A, Mdlalose N, Wood S, Folsom M. *Feasibility Study of the Production and Distribution of Home-Based Care Kits in South Africa*. Technical Report, 2005.

The impact study for home- or community-based care and support projects supported through the National Integrated Plan

The study is aimed at evaluating the impact of the community home-based care services offered to selected communities in KwaZulu-Natal. This is a 6-month study ending in April 2005. Funding for the study was received from the Department of Social Welfare. The study is being conducted in 4 drop-in centres in KwaZulu-Natal: Emoyeni, Bhamayi, Ndumo and Nseleni. These sites received funding from the Departments of Health and Social Welfare for provision of care and support services for orphans and vulnerable children, and are due for

a review. To date, all data have been collected in all 4 sites. Data analysis will commence soon.

THE USAID PROGRAMME AIMED AT IMPROVING THE QUALITY OF CARE IN STI SERVICES

The programme comprised several components aimed at increased capacity of the National Department of Health in the delivery and reach of high quality STI services, including provision of technical assistance, training and intervention-linked research. Major accomplishments during 2003 include completion of a national STI baseline survey, implementation of the Provincial Project Facilitators Project and expansion of on-site syphilis testing. There has been a high level of collaboration and support from both the Provincial and National Departments of Health. This, together with the extension of funding for the programme, demonstrates its valuable contribution to raising the quality of STI care in South Africa.

Baseline survey of public sector STI services

In association with the National Department of Health, RHRU conducted a comprehensive national baseline survey of STI and HIV prevention and management services at 962 primary health care facilities. This involved data collection on a range of indicators such as correct drug treatment of STIs, number of STI clients, numbers of male and female condoms distributed, drug stockouts and condom stockouts. Data will inform STI programme direction, policy review, interventions and the selection of indicators for ongoing monitoring and evaluation. Survey results were disseminated at a national launch in February 2004 and were presented at the XV International AIDS Conference in Bangkok in July 2004. The report is available on the RHRU website.

Publications

Ramkissoon A, Kleinschmidt I, Beksinska M, Smit J, Hlazo J, Mabude Z. *National Baseline Assessment of Sexually Transmitted Infection and HIV services in South African public sector health facilities*. Summary Report. RHRU, 2004.

Ramkissoon A, Kleinschmidt I, Beksinska M, Smit J, Hlazo J, Mabude Z. *STI Baseline Survey* in Ijumba P, Day C, Ntuli A (editors). South African Health Review, 2003/4. Durban Health Systems Trust 2004

Provincial Project Facilitator Project

The project was launched in May 2003 to provide technical support to provincial STI co-ordinators in implementation of STI services, integrated STI/HIV barrier methods training, monitoring and evaluation and other activities. Specific roles have included facilitation of training for master trainers, mentoring of district trainers, supporting implementation of the national clinical STI sentinel surveillance programme and an audit of high transmission areas. Facilitators have received training in project management and the District Health Information System (DHIS) and the facilitators play an important role in provincial STI programmes, and are also involved in VCT and prevention of mother to child transmission (PMTCT) programmes.

Regional STI/HIV Training and Referral Centre

During 2003, the eThekwini Municipality Health Department requested technical assistance from RHRU to address limited and overburdened STI/HIV referral systems as well as a need for comprehensive STI and HIV training. A dedicated local health facility in Durban has been identified and is being developed in partnership with RHRU to offer specialised on-site training and capacity-building around comprehensive STI and HIV management. In addition, RHRU has facilitated the provision of televised health education programmes in waiting areas of the clinic through which 150,000 clients pass annually.

Information, Education and Communication (IEC)

A range of IEC materials (leaflets, reports, posters) have been developed in collaboration with the National Department of Health and the Provincial Departments of Health. About 50,000 leaflets on dual protection, condom quality, and STI signs, symptoms and treatment, were developed in local languages and distributed nationally during 2003 and 2004.

Abstinence project

RHRU staff have been involved in the implementation of a community outreach prevention programme that is primarily abstinence focused. 'Generation Vuka' is targeted at female youth. To date it is estimated that over 500 people have been reached with this programme to promote abstinence and faithfulness.

Training of health service providers

RHRU staff have been intrinsically involved in training in integrated STI management, including barrier methods and dual protection, at the Department of Health and other sites in South Africa's 9 provinces.

Assessment of STI project in Mozambique

During 2004, RHRU staff from Durban conducted a rapid assessment of an STI prevention and treatment programme operating in 200 health facilities across all provinces in Mozambique. The programme was implemented by Population Services International (PSI) in collaboration with the Mozambique Ministry of Health and funded by DfID. The objectives of the assessment were:

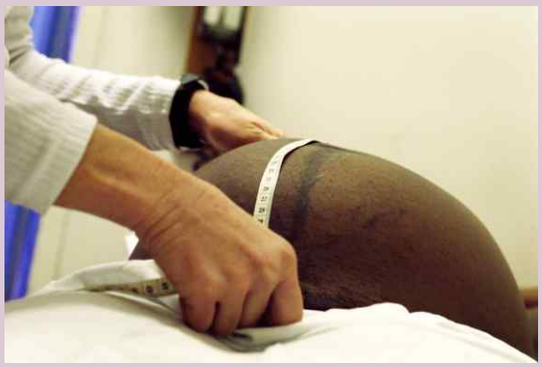
- to improve the quality of STI consultations;
- to increase informed demand for STI services; and
- to improve the capacity of health workers to collect and analyse STI-related data.

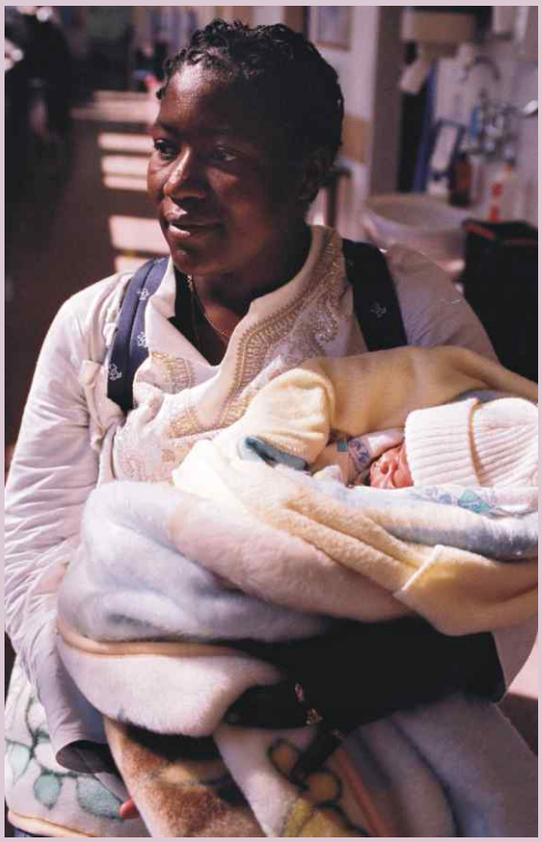
Methodologies used included a situational analysis; document review; site visits; observations of provider/client interactions and provider training sessions; key informant interviews with government officials, programme managers, health workers, clients and relevant donors. From assessment findings, a number of interventions were identified to strengthen STI/HIV management and prevention services in Mozambique. These included in-service training and transfer of skills to Ministry of Health service providers and the implementation of systems for monitoring and evaluation of key activities, for support and supervision, for improving drug access and for human resources management.

Publication

Marumo E, Hlazo J, Maloka A, Hamelmann C. *Managing and controlling STIs*. Focus on STIs, 2004; 48-50

Maternal Health





Maternal Health

Nationally the maternal mortality rate has increased from 188/100,000 in 1998 to 243/100,000 in 2001. Thirty eight percent of these deaths have been identified as non-pregnancy related infections, including AIDS. The 1998 South Africa Demographic and Health Survey reported high utilisation (94%) of ante-natal care by pregnant women. The ante-natal period is therefore an important opportunity to address a number or prevention issues in women. The prevention of mother to child transmission (PMTCT) programme has been implemented nationwide with considerable support in the form of counselling of all pregnant women by lay counsellors. There is an urgent need for men to be involved during pregnancy and to ensure that the messages and counselling that women are receiving is shared with men. RHRU is involved in a number of projects aimed at improving maternal health by supporting the National Department of Health and the KwaZulu-Natal Department of Health in their maternal health programmes. Key programmes are described below.

Men in Maternity

Recent research shows that, not only do women want their male partners to be more actively involved, the men themselves are more interested than previously believed. Men are becoming more aware of their critical role in reproductive health. The male involvement study was conducted in 8 urban and 4 rural clinics that fell in the catchment area of Prince Mshiyeni Memorial Hospital in KwaZulu-Natal between 2000 and 2003. The main aim of the study was to test an expanded ante-natal and post-partum care programme aimed at improving women's and men's reproductive health, particularly increasing the use of appropriate post-partum family planning and the prevention of STIs. The study was funded by and conducted in collaboration with the Population Council.

Although it was feasible to implement such an intervention in the clinic facilities, there were a number of challenges. These were cultural norms, health provider attitudes, few couples living together and men not being able to take time off from work. All these factors would need further consideration for the intervention to improve coverage and attendance. The counselling sessions provided an opportunity to introduce men to other services that were available, such as STI treatment, voluntary counselling and testing for HIV, family planning services and condoms. Men were encouraged to attend the clinic after counselling if they had any personal issues to discuss with nurses. Both men and women who were exposed to the intervention found it to be useful.

Publication

Kunene B, Beksinska M, Zondi S, Mthembu N, Mullick S, Ottolenghi E, Kleinschmidt I, Adamchak S, Janowits B, Cuthbertson C. *Involving Men in Maternity Care*. Technical Report, 2004. www.rhru.co.za.

Evaluation of rapid syphilis screening in pregnant women in KwaZulu-Natal

Syphilis poses a significant risk to pregnancy. Data from the 2002 national ante-natal survey showed that on average, 3.2% of women attending ante-natal care clinics were infected with syphilis. Although almost all facilities offer syphilis testing, getting results back to women timeously to ensure that positive women complete treatment before delivery has been problematic, particularly in rural areas. Delays may occur as transport is often unreliable and long distances are involved.

In 2001, a joint collaboration between the KwaZulu-Natal Department of Health, RHRU and the Population Council FRONTIERS programme embarked on a project to improve the ante-natal care package in the Ulundi district. This programme included the introduction of on-site RPR testing for syphilis in a number of clinics. With support from the University of Natal's Department of Microbiology, providers in 6 clinics were trained to implement the RPR test on site. An evaluation revealed that discrepancies arose in the reading of the test across clinics. Transport problems, although raised at various levels, persisted. Following this evaluation, the Department of Health concluded that the next step should be the introduction of the rapid syphilis thumb prick tests without the need for laboratory facilities.

Following implementation of the rapid test, an evaluation was conducted in 12 clinics in the Ulundi district. The information will be used to inform the province as to the benefits of wider introduction and replacement of the existing RPR test across the province.

Publications

Mullick S, Beksinska M, Msomi S. *Treatment for Syphilis in Ante-natal care: compliance with the three-dose standard treatment regimen*. Sexually Transmitted Infections, August 2004. In press.

Milluck S, Watson-Jones D, Beksinska M, Mabey D. *Sexually Transmitted Infections in Pregnancy: prevalence impact on pregnancy outcomes and approach to treatment in developing countries*. Sexually Transmitted Infection, accepted September 2004

Values clarification for health care workers in KwaZulu-Natal

Health care workers are key to the provision of sexual and reproductive health care information within the community. Dealing with programmes around HIV/AIDS such as PMTCT and ARV treatment is complex and there are many issues and dilemmas confronting health care workers. Positive interpersonal relations between health care workers and clients have been identified as critical factors for successful health care interventions. While positive attitudes and supportive behaviours may facilitate effective utilisation of health services, negative attitudes can act as a barrier to the use of these services.

This project aims to develop and implement a values clarification programme that will give health care providers a chance to examine their attitudes and change those attitudes that hinder service progress. This programme is funded by the Global Fund to fight AIDS, TB and Malaria through the KwaZulu-Natal Department of Health. Manual development was completed at the end of 2004 and workshops will begin in 2005.

Creating conditions for implementing a comprehensive, evidence-based ante-natal care package in KwaZulu-Natal: getting evidence into policy and guidelines

The Provincial Department of Maternal Child and Women's Health and the Provincial STI Directorate have recognised the need for an integrated and comprehensive ante-natal care package based on existing evidence. In collaboration with RHRU and the Population Council, the KwaZulu-Natal Department of Health is undertaking a systematic process aimed at ensuring that this evidence feeds into the development of provincial maternity care policies and guidelines. The policy will be completed by mid 2005.

Publication

Pattinson RC, Buchmann E, Mantel G, Schoon M, Rees H. '*Can enquiries into severe acute maternal morbidity act as a surrogate for maternal death enquiries?* BJOG: An International Journal of Obstetrics and Gynaecology, 2003; 110: 889-893.

TERMINATION OF PREGNANCY RESEARCH

Medical Abortion Research

Medical abortion offers the potential of increasing the access of women to termination of pregnancy (TOP) services. This method may be more easily decentralised as staff at primary health care clinics can prescribe and dispense the method, and may require less management support and equipment. It is also possible that providers may find it a more acceptable method, which gives them the required degree of distance from actually performing surgical abortions, but allows them to fulfill their obligations.

Medical abortion with mifepristone-misoprostol has been shown to be a safe, effective and acceptable alternative to surgical TOP in many countries. Many women, for a variety of reasons, prefer medical to surgical TOP, and access to medical abortion could potentially reduce morbidity since there is no need for instrumentation of the uterus. In South

Africa, current TOP services are overstretched due to resource constraints. Provision of medical abortion would not only increase women's options but could also increase access to TOP services.

A multi-centred double-blind randomised comparison of two misoprostol regimens for the termination of pregnancy in the second trimester

This study was funded by and conducted in collaboration with WHO. The study was carried out at Chris Hani Baragwanath Hospital in Johannesburg; South Africa was one of 11 sites.

This was a double-blind placebo-controlled trial comparing vaginal and sublingual regimens of misoprostol in the termination of pregnancies of 14 to 20 weeks' duration. A total of 140 women were recruited from women requesting legal second trimester (14 - 20 weeks) TOPs at the Gynaecology Outpatients Department in Chris Hani Baragwanath Hospital. The study was completed in 2004. Overall results are expected from WHO by 2005.

Comparison of two mifepristone doses and two intervals of misoprostol administration for termination of early pregnancy

This study was funded by and conducted in collaboration with WHO. South Africa was one of 13 international sites. This was a randomised, partly double-blind multi-centre trial to compare the efficacy of 100 mg and 200 mg of mifepristone followed 24 or 48 hours later by 0.8 mg vaginal misoprostol. In total, 150 women were recruited from among women = 63 days from last menses, requesting a legal termination at the Chiawelo TOP Clinic. The study was completed in 2004. Results will be available early in 2005.

Integrating mifepristone-misoprostol medical abortion into safe abortion services in six pilot sites in South Africa

This study was conducted in collaboration with Ibis Reproductive Health, the Women's Health Project (WHP) and the Women's Health Research Unit (WHRU) of the University of Cape Town. Sites included Gauteng, Northern Cape and the Western Cape. This research project aimed to provide operational information on offering medical abortion services, which will be used when medical abortion is introduced into South Africa's public health services. Medical abortion training was conducted for study staff by trainers from the National Abortion Federation, Gynuity Health Project and Centre for Training in Reproductive Health Technologies (France) in November 2003.

Safety and satisfaction of first trimester abortion performed by doctors and nurses using manual vacuum aspiration in South Africa and Vietnam

The Choice on Termination of Pregnancy Act (Act 92 of 1996) allows both nurses and doctors to perform abortions provided they have had appropriate training. The Women's Health Research Unit (WHRU) managed the study in Cape Town, while RHRU supervised the Durban site of the study. This study compared the safety and satisfaction of first trimester abortion performed by doctors and nurses using manual vacuum aspiration (MVA) in South Africa and Vietnam. A total of 1,400 women attending clinics for the first time in Durban and Cape Town were recruited and admitted to the randomised-controlled trial. Follow-ups were conducted between 7 and 14 days after the procedure, either upon return for a check-up or telephonically. Data collection was completed in mid 2004 and analysis is ongoing.

Publication

Brown HC, Jewkes R, Dickson-Tetteh K, Rees H. *Management of incomplete abortion in South African public hospitals*. BJOG: An International Journal of Obstetrics and Gynaecology 2003; 110: 371-377.

Dickson KE, Jewkes RK, Brown H, Levin J, Rees H, Mavuya L. *Abortion service provision in South Africa three years after liberalisation of the law*. Studies in Family Planning, 2003; 34: 277-284.

Smit J, Beksinska M, Ramkissoon A, Kunene B, Penn-Kekana L. *Reproductive Health* in Ijumba P, Day C, Ntuli A (editors). South African Health Review 2003/4. Durban: Health Systems Trust, 2004.

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