Vision

To tackle Africa’s health challenges through science and innovation.

Mission

As an internationally renowned African academic Institute and an agent of social change, our mission is to lead the way in the field of HIV, sexual & reproductive health and related conditions, and to be recognised for:

- Outstanding pioneering research
- Responsive technical support and quality innovative services
- Evidence-based policy development and advocacy
- Teaching and capacity-building
- Partnership with communities and stakeholders
- Commitment to our staff and creating a sustainable institute
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Message from the Dean: Faculty of Health Sciences

The primary aim of the Faculty of Health Sciences of the University of the Witwatersrand is to improve the provision of health care for every individual. The vision of Wits Reproductive Health and HIV Institute (Wits RHI) reflects this, as is evident from its long history of sterling work in the field of sexual and reproductive health and infectious diseases. RHI contributes extensively to strengthening health systems, working at various levels to ensure that patients receive high-quality care. Its comprehensive training and capacity-building activities support and complement the reputation for excellent undergraduate and postgraduate teaching that we at the Faculty of Health Sciences have long cultivated. We strive to train our health care professionals to be responsive to the needs of our society, a challenging task in a complex public health landscape. RHI’s programmatic and research activities are structured around tackling the issues faced by South African communities and the impact of these activities, for example in the Johannesburg inner city where the Hillbrow Health Precinct is located, is evident.

Health Sciences is a research-intensive Faculty which produces highly skilled postgraduate students and contributes significantly to the body of knowledge in many important fields. Wits RHI, with its broad and prolific research agenda, participates in a large number of clinical trials and research studies and this is highly valued by the University. In 2013, RHI initiated an in-depth research capacity-building programme, and we commend its efforts to invest in staff and strengthen the competency of researchers. We know that this exercise will bear fruit in the form of increased research publications and an even greater number of graduated masters and PhD students. We would like to congratulate the RHI staff members who graduated in 2013 and 2014 and wish the many employees currently enrolled in postgraduate studies the best of luck.

An organisation is only as strong as its people and RHI consists of people who are truly passionate about the work that they do. We would like to acknowledge the hard work, energy and enthusiasm that fuels the outstanding work produced year after year. RHI is driven by a visionary leader, Professor Helen Rees, who founded the Institute in 1994 with the goal of making sexual and reproductive health accessible to all. With Professor Rees at the helm as the Executive Director, RHI has grown considerably in size and focus since then, a testament to her dedication and unfailingly high standards. Professor Rees gives her time to many international organisations as a technical expert, including the Global Alliance on Vaccines and Immunisation, the HIV Vaccine Advisory Committee and the HPV Vaccine expert committee of the World Health Organization, the Population Council and the US National Institutes of Health. Her contribution to the fields of reproductive health, infectious diseases and vaccinology is internationally acclaimed and she has received numerous awards recognising her service to medicine and research.

We congratulate Wits RHI on its 20th anniversary, and we look forward to the continued growth of the Institute and wish Professor Rees and RHI staff every success as they work towards their goal of tackling Africa’s health challenges through science and innovation.

Professor Martin Veller

Dean: Faculty of Health Sciences
Message from the Wits Health Consortium

Wits Health Consortium (WHC) proudly supports the Faculty of Health Sciences in financial, operational and legal matters. Wits RHI has gone from strength to strength, becoming one of the largest divisions within the WHC. Through its considerable networks and collaborations within South Africa and internationally, its pioneering research and its commitment to working with communities and facilities where it is most needed, RHI fully embodies the Faculty’s overall mandate to make health care accessible to all who need it. RHI has a reputation for academic rigour and excellence, and thus another aspect of RHI is its work in teaching and mentoring students and young researchers, ensuring that a new generation of health care workers and researchers is better equipped to work in the field of sexual and reproductive health and make a concrete difference. We congratulate Professor Rees and her team at Wits RHI for their tireless work and dedication and wish the Institute every success in the future.

Alf Farrell

CEO, Wits Health Consortium
Foreword from Executive Director

In 2013-2014 RHI achieved many milestones as it grew its research footprint and continued to support key global and national policies. RHI’s areas of expertise cover HIV, reproductive health, maternal health and vaccine-preventable diseases. Some of RHI’s research has explored the interface between these key areas. With a focus on HIV prevention, RHI continues to be a global player in microbicide research. RHI’s treatment optimisation agenda strengthened its emphasis on improving first- and second-line treatment for adults and children. The reproductive health agenda concentrated on HPV and its interaction with HIV, and supported the National Department of Health as it rolled out HPV vaccines across South Africa. The maternal health agenda shifted towards pre-conception services addressing conception in the context of HIV.

In tackling the challenge of rolling out ARVs to the six million people requiring them in South Africa, RHI developed three core activities. Firstly, through the health systems strengthening activities, models of care were developed for vulnerable populations including those in rural areas, sex workers and adolescents, as well as retention strategies for patients established on antiretrovirals. The mHealth agenda tackled linkage and retention in care, adherence strategies for clients on ART and participants in clinical trials, and support to the National Department of Health’s MCH programmes through MAMA and MomConnect. RHI clinical staff supported the Department of Health in the development of new policies for PMTCT, adult HIV and TB treatment and paediatric treatment. In 2014, in recognition of RHI’s contribution to the field of HIV, the Institute was made a UNAIDS Collaborating Centre.

The HIV treatment optimisation research agenda explored new and better ARVs and improved dosing and regimens. The stavudine dose-reduction study is nearing completion, and new proposals for improved first- and second-line regimens will soon be starting. At the Shandukani research facility a number of Phase I/II studies were conducted to evaluate new antiretroviral drugs for children and infants as part of the IMPAACT group, as well as the complex PROMISE study that aims to optimise the prevention of mother-to-child
transmission. The paediatric group is developing a new focus on childhood vaccines, starting with TB vaccine use among infants.

With global ongoing efforts to identify better HIV prevention technologies, RHI led the FACTS 001 study which explored the efficacy of vaginal tenofovir 1% gel in preventing HIV and HSV-2 infection. RHI also contributes to the leadership of the ASPIRE study which is investigating the efficacy of the Dapivirine ring in preventing HIV infection in women. In the pipeline are studies to evaluate the uptake and effectiveness of using ARVs for pre-exposure prophylaxis among sex worker populations and among young women as part of a broader combination prevention package. This package includes interventions to address gender-based violence. One such intervention tackling gender-based violence among pregnant women is also underway, as are other interventions that evaluate innovations designed to influence the structural drivers of HIV.

South Africa’s National Strategic Plan for HIV, TB and STIs stresses the importance of working with key populations who are particularly vulnerable to HIV infection. RHI’s long history of working with the sex worker population in Johannesburg’s inner city has been expanded across the country and neighbouring borders, to create a network of roadside wellness clinics out of shipping containers. Additionally, in partnership with the Gauteng Department of Health, RHI established an adolescent programme providing services and innovation for HIV-positive and negative adolescents.

Building on the span of its geographical footprint and research expertise, the Institute adopted a new approach to the development of population cohorts which will allow it to build a future research agenda around them, including young women, adolescents, pregnant women and sex workers.

An ongoing challenge for post-apartheid South Africa is transformation. The Institute has developed a comprehensive research capacity-building strategy that aligns with Wits University’s vision and with national developmental priorities. The aim is to develop a new generation of passionate young South African and African academics who will take up the mantle of solving the country’s and the continent’s many public health challenges.

South Africa and the region have recently made many strides in improving the health of all citizens but more needs to be done and RHI is excited about developing a research agenda, a policy support role and a capacity-building infrastructure that facilitates this.

Professor Helen Rees

Executive Director
Chapter One: Health Systems Optimisation – Helping to build a stronger health system for South Africa

“We will not be successful in our efforts to end deaths from AIDS, malaria, and tuberculosis unless we do more to improve the health systems around the world.” – Barack Obama

To care for patients in a comprehensive and effective way, the public health care system needs to be well run, efficiently managed and constantly evaluated for opportunities to address needs and close gaps. The National Department of Health (NDoH) has committed to the re-engineering of Primary Health Care and the National Strategic Plan for HIV, STIs and TB. Wits RHI supports the Department of Health at the national, provincial, district and facility levels through targeted and intensive technical assistance and capacity-building to strengthen the systems that provide health care to millions of South Africans.

Wits RHI’s work in strengthening health systems

Wits RHI has twenty years of experience in providing technical assistance, training and mentorship. This experience capitalises on both the academic rigour of a university-based research institute, and the on-the-ground knowledge of the complexities of health service delivery in both urban and rural environments in South Africa. The Health Systems Strengthening (HSS) project leverages this experience and RHI’s strong relationships with government at all levels to support the NDoH in the delivery of high-quality health services that result in better prevention of HIV/TB and improved management of those infected.

The project works at facility level in three health districts: Region F in the City of Johannesburg and the Dr Kenneth Kaunda and Dr Ruth Segomotsi Mompati Districts in the North West Province. The work done in these facilities strengthens district and sub-district structures through a Quality Improvement approach; this approach introduces sustainable methods to increase the efficiency and effectiveness of facility processes and improve clinical practices. Ultimately this will result in improved health outcomes in the facilities.

Since 2013, the HSS project has used a strategic approach to target facilities and activities for impact. The project established prioritisation criteria based on facility HIV burden, and re-designed its technical assistance strategy to provide more intensive support for a defined period. The project utilised ‘graduation’ criteria that were agreed with district Departments of Health, and worked with Local Health Area managers to support their clusters of facilities in the achievement of the criteria.

The process is intensive and focused. In the selected facilities, a comprehensive assessment is carried out together with facility staff. Challenges and issues are identified and a plan of action is agreed. “Learning Collaboratives” are convened within the sub-district and the Local Health Area to share successes and challenges.
across facilities. While RHI Quality Improvement specialists work in the facilities, the Wits RHI Training Team works across the sub-district to support improved management practices through training and mentoring programmes that reinforce the facility-level work. Emphasis is placed on accountability and managerial support, creating an organised system that enables people to work efficiently and create change. Facilities are periodically re-assessed to ensure they are making progress towards meeting the graduation criteria. This practice of ‘graduating’ facilities is unique to RHI, which is the only PEPFAR-supported partner that works in this way.

This cycle of intensive technical support draws on the skills of both district staff, with expertise in quality improvement and health service delivery, and technical experts at central level who guide the activity prioritisation related to Adult TB and HIV, Child TB and HIV, Women’s Health, and Psychosocial Support for people affected by HIV.

The HSS team also provides expert technical advice and input to the NDoH through continued involvement in a range of national and provincial technical committees and working groups. There, our technical experts draw on both the most recent scientific evidence and practical on-the-ground knowledge of implementation to advise the government. Members of the team sit on national advisory boards, guidelines committees and technical working groups; these groups inform and help to shape policy and its implementation on issues such as treatment and prevention of HIV and TB, contraception and family planning, cervical cancer and prevention of mother-to-child-transmission of HIV (PMTCT).

“Our strategic approach of prioritising clusters of high-burden facilities in which we can have the greatest impact, and leveraging the co-ordination and accountability mechanisms of sub-district management, has been incredibly successful. We will continue to monitor these facilities after ‘graduation’ to assess sustainability of these efforts.” – Karen Kelley, Technical Head, Health Programmes

Adult TB and HIV

“Today we are calling on the world to recognise that we cannot fight AIDS unless we do much more to fight TB as well.” – Nelson Mandela

Within the South African context, TB and HIV are inextricably linked. The immunosuppression caused by HIV increases the risk of TB co-infection in people living with HIV, and changes the clinical pattern of the disease, whilst TB can accelerate the course of HIV. Integrating TB and HIV care is crucial, something which has been acknowledged and strongly supported by the NDoH. However, the process of combining HIV and TB diagnosis and treatment procedures at a facility level across South Africa requires changes in the health care delivery systems. Wits RHI staff, through involvement in NDoH policy development and through their first-hand understanding of factors that influence adoption of these policies at facility level, have helped to bridge the policy/implementation gap.

For example, in 2014 the TB programme assessment tools were found to be inadequate for the new TB programme guidelines, which include the use of new diagnostic tools and the integration of TB/HIV care. The team developed an updated assessment tool and piloted it. Implementing solutions to the challenges documented with the new tool had major impacts in the district, in programme areas such as the retention of patients who had previously been lost to follow-up, and in the total number of people reached. The tool was subsequently presented to the NDoH, and is being further refined in collaboration with multiple stakeholders, for use as a
Drug-resistant tuberculosis

The number of cases of multi- and extremely drug-resistant TB in South Africa is increasing. NDoH figures indicate that the number of laboratory-confirmed multi-drug-resistant TB (MDR-TB) cases doubled between 2007 and 2012 and continues to rise. Only half of all MDR patients receive treatment, due to inadequate data centralisation which results in patients not being followed up or traced. Additionally, treatment delays can result in patient morbidity and mortality as well as the spread of MDR-TB.

In recognition of these problems and in collaboration with the Gauteng provincial Department of Health the HSS team implemented a new filing and data storage system at the two decentralised drug-resistant TB sites it supports. These systems allow for improved linkages between in-patient TB care and out-patient treatment, and allow for the tracking of both initial and secondary loss to follow-up of drug-resistant clients. The team has representation on the Gauteng Province Drug-resistant TB committee, the NDoH MDR data committee, and the NDoH TB think tank. Training in the field of HIV and TB is provided to local medical undergraduates and postgraduates and the Cuban-trained doctors and health associates at the University of the Witwatersrand.

Psychosocial support for patients and providers

Both patients and health care workers face psychosocial challenges that can affect the strength of the health care system. Health care workers experience burnout from high workloads and pressure, while the psychosocial context of patients can influence their ability to adhere to treatment or attend regular follow-up visits. HIV-positive patients are at an increased risk of experiencing common mental health problems, such as anxiety and depression, and often live in difficult socio-economic circumstances which can exacerbate care and treatment challenges such as adherence, disclosure and retention in care. Through targeted technical support and training, Wits RHI’s psychosocial team capacitates public health care workers to provide mental health support throughout the cycle of care, from testing and diagnosis through the treatment cascade. Capacity-building includes the development of counselling skills and enhanced understanding of the mental health impact on people affected by HIV.

The psychosocial team led the development and piloting of a tool to assess the quality of counselling services at prioritised facilities, and to identify factors that support and hinder provision of quality counselling at the facility. These assessments uncovered barriers that were easy to fix, such as ensuring that notes from counsellors are part of the medical record and inform appropriate disease management, and others that are more complex, such as lack of counselling space in clinics or inadequate training regarding HIV testing. They also uncovered good practices that were then shared across facilities through sub-district management mechanisms.

A structural driver of HIV that requires a nuanced approach to care and treatment includes Gender-Based Violence (GBV). The psychosocial team addressed the need to integrate care with two ten-day training courses for the Gauteng Provincial Department of Health’s Clinical Forensic Department which oversees services at Thuthuzela Centres and Medico-Legal Clinics.

The team also contributed to a number of national guidelines, including the national disclosure guidelines for children and adolescents; guidelines around the management of mental health disorders in people living with HIV; a guide to integrated access to care and treatment for adolescents; and a counselling resource guide. The team was active in training undergraduate clinical associates and social workers at the University of the Witwatersrand and the University of Johannesburg.
Child TB and HIV

HIV and TB in children remains a challenging issue. Children have limited options with regards to HIV and TB medication, and disease progression is often different to that of adults. According to the Elizabeth Glaser Pediatric AIDS Foundation, children with HIV are 20 times more likely to contract TB and UNAIDS estimates that 700 children worldwide become infected each day, and that almost half of them will die before their second birthday without ARV therapy. Diagnosis of infant HIV and subsequent initiation onto ART is thus imperative to prevent disease progression and mortality.

This is one of the major objectives of the paediatric team, which is working to strengthen health systems to better identify and care for children living with HIV and TB. In 2013 and 2014 the team provided technical assistance, training and mentorship to facilities within the three districts where RHI operates, to increase their capacity to treat HIV-infected children and adolescents in a holistic manner. Focus areas included testing of larger numbers of children, earlier access to ART, treating co-morbidities and ensuring efficient referral networks. The team trained NiMART nurses, giving them specifically developed paper-based test cases in order to increase their exposure to practical examples, which is a requirement to be certified as a NiMART nurse. The team also worked with clinicians within and from outside RHI and provided mentorship to nurses and doctors around paediatric ART initiation. Undergraduate training included the University of the Witwatersrand Clinical Associate and Graduate Entry Medical Programme students.

Strategically, the team supported the NDoH with the drafting of paediatric and adolescent HIV guidelines, as well as with technical assistance on a number of child-focused projects. The team’s research agenda included the investigation of options for optimised care, from both a clinical and operational perspective.

Women & maternal health

Wits RHI’s women and maternal health programme provides extensive support to the South African government in its efforts to reduce infant mortality and improve maternal health, in line with Millennium
Development Goals Four and Five. In 2013 the team worked closely with the National Department of Health to prepare for and implement the roll-out of the 2014 National Contraception and Fertility Planning Policy and Service Delivery Guidelines. RHI provided significant technical guidance around the development of policy and RHI’s Executive Director Professor Helen Rees chaired the Policy Revision Task Team, while RHI staff members also sat on the various working groups and functioned as specialist technical contributors. RHI also assisted with training doctors and nurses on the new policy. RHI wrote the 2013 and 2014 PMTCT guideline drafts for the NDoH and took the technical lead in the development of these guidelines.

The women and maternal health team worked within the overall strategic approach of the HSS programme to identify facilities in targeted geographical clusters that required assistance with regards to quality improvement. Training was provided to improve the number of antenatal HIV tests conducted, to assist with the roll-out of the new prevention of mother-to-child transmission guidelines and algorithm, and to pioneer the concept of the mother-infant pair, helping health care workers to see mother and child as a unit that needs to be treated holistically. RHI developed the PMTCT training material and trained the trainers.

In 2013 the team also contributed to a number of training initiatives. The 2013 North West Province Midwifery Symposium was fully sponsored by Wits RHI, reaching over 200 midwives on topics related to maternal and infant care. Additionally a district specialist team was convened by RHI at the Symposium to discuss strategies for the reduction of maternal mortality. The team re-established CPD meetings at the Hillbrow Community Health Centre as a means of providing doctors with ongoing clinical updates and contributed to undergraduate education at the University of the Witwatersrand, running a module for final year medical students on clinical risk management.

The maternal and child health team also supported the development of a specialist colposcopy clinic at Shandukani in Hillbrow. This dual purpose clinic provides a critical women’s health service, helping to cut down on the unacceptably high waiting period for a Pap smear result, which is currently in excess of nine months, while training family physicians in colposcopy. The team worked to build relationships with the Gynaecology and Oncology Departments at Charlotte Maxeke Johannesburg Academic Hospital and the groundwork was laid in 2013 to begin renovating and equipping the clinic, which opened in 2014. RHI provided training in colposcopy to DoH staff.

Finally, in 2014 Wits RHI established a ‘safer conception services’ clinic. Senior technical staff represented RHI at a World Health Organization meeting on the topic and RHI is becoming recognised for its expertise in this field.

2nd & 3rd line treatment

As more people are initiated on antiretroviral treatment in South Africa, we see more patients failing their first-line drug therapy. Patients who do not take their ARV medication consistently develop drug-resistant strains of HIV that no longer respond to the initial ART regimen provided. Thus, it has become a priority for second- and third-line regimens to be developed and made accessible to those who need it. These patients need to be handled with care to ensure that their already limited treatment options are not compromised. Their
complex medical conditions must be managed in conjunction with any psychosocial problems that may have caused their initial non-adherence.

In 2014 Wits RHI had two representatives on the national third-line committee, one of the largest programmes in Africa. Every single third-line patient is managed by the committee, which is composed of very experienced clinicians. By the end of 2014, the committee had assessed almost 250 third-line therapy applications. In addition, Wits RHI is well represented on the National Department of Health HIV Guidelines Committee which provides technical advice and assists in training and roll-out of new ART guidelines across South Africa.

mHealth

mHealth is an exciting innovation in health care which uses the ubiquity of mobile phones, even in resource-poor and rural areas, to bring health information directly into people’s hands. It is estimated that in South Africa currently, there are more SIM cards than people. mHealth technology has the potential to reach a very large proportion of people across the country, and recognising an opportunity to address some of the challenges within maternal health and HIV, Wits RHI is working on several mHealth projects.

The mHealth team was extremely active in 2013 and 2014, attending and presenting at a number of local, national and international conferences and forums. The team also provided technical support to other organisations who are implementing mHealth initiatives, such as the ANOVA Health Institute. Support was also given to the NDoH to help develop a mobile phone-based electronic data collection tool for the National Health Insurance Scheme. The team worked with the Praekelt Foundation on their Young Africa Live (YAL) initiative, a mobile platform for young people, as well as on the YAL “Chommie” service, which sends anyone who signs up free ARV-support messages every week for a year.

MAMA

Educating mothers has a direct impact on the number of children...
dying each year. A global analysis published in the Lancet found that maternal education was responsible for half of the reduction in child deaths over the last 40 years. The Mobile Alliance for Maternal Action (MAMA) is a global initiative that is giving mothers health information through text and voice messaging to prevent child and maternal deaths. Founded in 2011, MAMA is already beginning to see measured improvements in outcomes such as the number of women attending clinics for care before and after birth.

South Africa is particularly in need of innovative solutions to address the high rates of maternal and child mortality. The maternal mortality ratio in South Africa has more than quadrupled over the past decade and the UN estimates that 4500 women die each year due to preventable pregnancy- or childbirth-related causes. The mortality rate of children under five years of age also remains unacceptably high, with over 50 000 children dying each year, many of preventable causes.

Not all mamas, old and new, know how to take care of their babies or how to take care of themselves when they are pregnant or when they are about to deliver” – anonymous MAMA user

Wits RHI is a partner in a local consortium to bring MAMA to South Africa, joining two other countries, India and Bangladesh. Partnering with Vodacom, Cell-Life and the Praekelt Foundation, RHI is overseeing the clinical quality of the messages sent to mothers, reviewing all messages to ensure compliance with South African guidelines and management protocols. Additionally, RHI is conducting an ongoing study measuring the impact of the project on maternal and child health. The official launch of MAMA South Africa was held in 2013 at RHI’s Hillbrow offices, where local mothers, media, funders and other stakeholders, including MAMA Global Director Kirsten Gagnaire, were present. The launch marked the introduction of MAMA SA’s four channels through which women could access information and support through their mobile phones: the mobi site, text messaging and the USSD system. The mobi site is a web page specifically designed for cellular phones, which can be accessed by any phone that can connect to the internet. It gives mothers personalised information based on the stage of their pregnancy or the age of their child. The text message service sends out personalised messages to support mothers during their pregnancy and the first year of an infant’s life. The USSD system is an interactive system that provides text-based quizzes to educate mothers.

Not all mamas, old and new, know how to take care of their babies or how to take care of themselves when they are pregnant or when they are about to deliver” – anonymous MAMA user

“MAMA helps me to think about the upcoming birth and what I need to do to prepare for it. It also encourages me to think that I am not alone” – anonymous MAMA user

The MAMA project recruits women from clinics such as RHI’s Shandukani and Esselen Street facilities, with the aim of measuring the impact that the project has on maternal and child health outcomes. Focus groups conducted in 2013 shortly after the MAMA launch indicated that many women felt that the MAMA messages were beneficial in helping them care for their babies. By the end of 2014 the MAMA SA mobi site had over 510 000 unique users, 12 834 SMS users, more than 31 000 USSD users and just over 100 000 unique Mxit users.

MomConnect

During 2014 the RHI mHealth team supported the NDoH with the launch of MomConnect. RHI advised on planning, supported the implementation, and provided training and ongoing participation in the NDoH MomConnect Task Team through the conduct of operational research activities.
Vodacom mHealth project

This project offers people who test HIV-positive the option to receive text messages that encourage and support them, with the overall aim of retaining patients in care. The first message received notifies patients of their CD4 counts via text message. This is done within three days of testing, providing clients with early notification and facilitating their early initiation onto ART if necessary. They are then sent further messages, reminding them to attend counselling sessions and providing adherence support and positive living messages on a weekly basis. These messages educate patients and give them increased social support. Three appointment reminders are sent for every appointment to encourage patients to attend the clinic.

The project began sending messages in 2012. Informal feedback from users indicated that they found it very useful, and an initial evaluation showed that reminder messages increased the number of people who return to the clinic to be placed onto ART. Based on these results the team helped the Adolescent and Sex Worker projects to create their own support messages for clients. Both appointment reminders and supportive messages will be offered to these populations in 2015.

To monitor and evaluate the impact that this intervention is having on patient clinic attendance in more detail, Wits RHI is conducting a study in two Johannesburg clinics. The study is examining the effect of the messages on patients with regards to the number of clinic visits, ART adherence, psychosocial outcomes and quality-of-life outcomes. 2013 represented a planning phase for this study, which commenced in 2014, with results expected in 2015.

Mobile phone data collection

RHI is helping field workers and research teams who need to capture information rapidly and accurately to move away from pen and paper towards using mobile phones and tablets instead. The system, which was put into use in 2013, records information directly onto a central database. It was used to recruit patients for the above-mentioned messaging initiatives, allowing the research team to sign up patients immediately. This meant that patients did not have to sign up for the service by sending in their details via text message at their own cost.

In 2014 data collection using both smartphones and tablets was used in the RHI studies into Violence Against Women study and Retention in Care.

SmartLtC study

In 2014 Wits RHI received a grant from the World Bank and DFID to conduct a randomised controlled trial into linkage-to-care outcomes from a smartphone application providing HIV information and laboratory test results to HIV-positive individuals. The study will complete in 2016.

mHealth is a way to provide people with individualised information on a mass scale. It is a really powerful way to connect with people because we can send messages that are specific to them, and help them to feel supported on a more personal level.” – Jesse Coleman, Programme Manager, mHealth

mHealth is a way to provide people with individualised information on a mass scale. It is a really powerful way to connect with people because we can send messages that are specific to them, and help them to feel supported on a more personal level.” – Jesse Coleman, Programme Manager, mHealth
Chapter Two: Treatment Optimisation – Improving treatment options

Antiretroviral therapy and other related treatment guidelines are designed to provide the greatest number of patients possible with appropriate treatment. There are a number of considerations to take into account when prescribing treatment, including side effects, cost and availability, as well as patient factors such as co-morbidities and even age or gender. Closing the knowledge gaps around treatment options is a key part of Wits RHI’s work.

Antiretroviral therapy needs to be safe AND affordable: Is low-dose stavudine the key?

Stavudine (d4T) has been widely used in antiretroviral treatment programmes due to its low cost, but the well documented toxic side effects of d4T have resulted in the World Health Organization amending its HIV treatment guidelines to suggest that it no longer be used. The new recommendation is that national treatment programmes phase out d4T and replace it with tenofovir (TDF) or other antiretroviral treatment alternatives such as AZT. Given the higher costs of these alternatives, it is worth examining whether the dose of d4T can be reduced while maintaining the efficacy of the medication.

Wits RHI’s Professor Francois Venter is leading an ongoing study to determine whether a decreased dose of d4T is a viable alternative to TDF. Global experts have agreed that this study is a priority to ensure that developing countries with restricted budgets are able to place people on treatment that is both effective and safe. The "The reality is that affordability is a very real restriction when implementing an antiretroviral programme. This research has the potential to fill a very important gap, by giving us information on whether we can find an inexpensive and non-toxic option in low-dose d4T.” – Professor Francois Venter, Principal Investigator, d4T study
randomised, double-blind, Phase 3b trial is being implemented in three sites in South Africa, Uganda and India, and will compare patients on TDF with those on a dose of d4T which is half of the standard dose used currently. If the research indicates that this lowered dose is not inferior to TDF treatment, it could improve the lives of the people on antiretroviral therapy in countries who continue to use d4T due to economic constraints. It could also result in increased access to ARVs for those who are not yet on treatment. The study recruited participants until 2013, with excellent retention, and will finish in the last quarter of 2015. The results of the study will be available in 2016.

Optimising treatment for infants, children, adolescents and pregnant women

Shandukani means “asking for change” in the Venda language, and at Wits RHI’s ground-breaking new maternal and child health care and research facility, many studies are being conducted which may bring positive change to the treatment landscape for this vulnerable group. South Africa’s maternal and child mortality statistics highlight just how profoundly the twin HIV and TB epidemics have affected pregnant women and children, and HIV/AIDS remains a leading cause of death in this group. Many of the research projects conducted at Shandukani are focused on finding ways to make HIV and TB treatment safer, more accessible and more effective for mothers and children. In 2013 the staff complement in Wits RHI’s paediatric programme grew significantly, doubling in size. This is due to the fact that the unit has taken on a large number of new studies, as well as sister studies to those currently being conducted. 2014 saw increasing diversification of research studies with excellent recruitment and quality of care including data quality and retention in care. The results of
these studies will help to strengthen the current commitment from government to reduce the risk to child and maternal health, as outlined in the Women and Child Health Strategic Plan for Maternal, Newborn, Child and Women’s Health (MNCWH) and Nutrition in South Africa 2012 – 2016.

Additionally, 2014 saw RHI helping the districts it supports to improve all aspects of paediatric HIV and TB care, including access to testing, linkage to care, initiation of ART and retention in care through workshops, training, mentoring and support of the district teams. RHI enabled a number of NiMART nurses to become “paediatric ART initiation-ready” through training and the development of paper-based cases as a learning tool.

**IMPAAACT**

Wits RHI runs a research site for the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) at Shandukani. IMPAACT is a co-operative group of institutions, investigators, and other collaborators who work to decrease HIV and HIV-related infections and deaths among infants, children, adolescents and pregnant/postpartum women by evaluating potential therapies. At Shandukani, trials are underway in the areas of HIV treatment, prevention, complications and vaccines. Shandukani was recognised as an IMPAACT clinical research site (CRS) in 2013, and Dr Lee Fairlie, Technical Head of Paediatrics and Investigator of Record for the Shandukani CRS, was re-elected to the IMPAACT HIV Treatment Scientific Committee. As one of the largest paediatric enrolment sites in the IMPAACT network, Shandukani is often audited by bodies such as the US Food and Drug Administration (FDA), the Medicines Control Council (MCC), the European Medicines Agency (EMA) and sponsors. Audits in 2013 and 2014 were successful, reflecting RHI’s ongoing efforts to maintain well run, high-quality clinical trials.

Current studies conducted at Shandukani include:

**Paediatric ARV Dose-finding**

Adherence in children and adolescents is difficult to manage, especially considering the long-term toxicities of being on ARV treatment. This may result in drug resistance mutations, creating the need for new drugs to form second- and third-line paediatric regimens. Children have metabolic differences to adults, and thus the pharmacokinetics of new drug formulations must be studied to evaluate how they are absorbed and metabolised in the body, a critical step in determining safety and tolerability, as well as the lowest effective dose. To assist in closing this knowledge gap, RHI is running a number of Phase I and II trials.

In 2014 Shandukani was the largest recruiting site for third-line dosing, efficacy and safety studies through IMPAACT, giving many children the opportunity to access these life-saving drugs.

**Prevention of Mother-to-Child Transmission of HIV**

The majority of children living with HIV are infected via mother-to-child transmission (MTCT) during pregnancy, labour, delivery or breastfeeding. South Africa has made considerable progress in the prevention of mother-to-child transmission but, although it is estimated that the South African MTCT rate was below 4% in 2010, approximately 240,000 children globally were infected with HIV in 2013, and 91% of all children living with HIV reside in sub-Saharan Africa. As part of the IMPAACT network, the Promoting Maternal and Infant Survival Everywhere (PROMISE) study is investigating how to prevent MTCT during pregnancy, delivery and breastfeeding, as well as how to ensure the health of the mother.

Wits RHI is part of this multinational clinical trial, enrolling study participants from 2011 onwards. The results are expected in 2015. The results will help to find the most feasible and cost-effective antiretroviral drug regimens for preventing new paediatric HIV infections, and RHI’s participation aligns with the ongoing support RHI provides to the Department of Health in achieving the aim of the National Strategic Plan for HIV, STIs and TB 2012 to reduce MTCT to less than 2% over the next five years.

In 2014 RHI supported a successful change management process at Shandukani Antenatal Clinic and Postnatal Clinic to improve rates of early booking and first visits, with resultant decrease in HIV transmission risk in pregnant women.

**TB Prevention**

TB is particularly dangerous in children in developing countries, where approximately 40% are infected by the age of 15 years. Younger children have a higher risk of progressing to TB disease and TB mortality is highest in infants. Given the threat to children,
Wits RHI is participating in a TB vaccine study through the IMPAACT network. This research will indicate if the new vaccine is safe and effective in preventing or reducing TB infection. 2014 saw the successful close-out of the THINK study with over 10 publications planned from the team.

“Wits RHI is participating in a TB vaccine study through the IMPAACT network. This research will indicate if the new vaccine is safe and effective in preventing or reducing TB infection. 2014 saw the successful close-out of the THINK study with over 10 publications planned from the team.

At Wits RHI there is a culture of assisting trial participants and this does not end when the study is closed. We recognise that we are dealing with individuals, and provide them with ongoing care and treatment. One particular young man was diagnosed with lymphoma whilst on long-term follow-up for one of our studies. We referred him for chemotherapy and he is doing very well, and he remains virologically suppressed, so he is a treatment success story. We even assisted him in getting into a bridging course at UNISA by writing motivation letters, so that he can go on to further his education. He has made us all very proud.” – Dr Gurpreet Kindra, sub-Investigator, IMPAACT studies

IeDEA

The International Epidemiologic Databases to Evaluate AIDS (IeDEA) network is an international research consortium which is collecting a very large pool of HIV/AIDS data from seven regions internationally on an ongoing basis in order to answer high-priority research questions. By collecting valuable clinical data from the Harriet Shezi Children’s Clinic at Chris Hani Baragwanath Hospital, the largest paediatric HIV clinic in the country, Wits RHI contributes to the IeDEA data set on infants, children, adolescents and pregnant women.

RHI’s ongoing collaboration with IeDEA is generating data with the potential to address significant public health concerns such as the impact of the provision of ART and waiting times on paediatric patient survival, monitoring of treatment responses in children and pregnant women, and adverse events related to ART. IeDEA was established in 2005 by the National Institute of Allergy and Infectious Diseases.
Chapter Three: Reproductive Health – Improving reproductive health policy through research

All men and women have the right to high standards of reproductive health care and access to services such as family planning. In countries where resources are constrained and health systems are overburdened by diseases such as HIV and TB, it remains a challenge to develop strategies for reproductive health care that are able to reach populations in need. Evidence is needed from high-quality studies in order to design and implement these strategies – a gap which Wits RHI is addressing through its research.

HARP: HPV in Africa Research Partnership

Across the world, women have an enhanced vulnerability to infectious diseases. This is highlighted by the UNAIDS estimate that over 60% of people living with HIV in sub-Saharan Africa are women, and is further emphasised by emerging evidence regarding diseases such as cervical cancer. Cervical cancer, which is caused by Human Papilloma Virus (HPV) infection, is the one of the leading causes of cancer deaths in women of reproductive age. Black South African women have a far higher risk of developing the disease – 1 in 26 as opposed to the global average of 1 in 126 – a worrying statistic given that cervical cancer is preventable if those at risk are identified and treated early enough. If HPV is detected before a precancerous lesion develops, women can be treated and their risk of progressing to cervical cancer is greatly reduced. There is a complex
interplay between the factors that contribute to the high incidence of cervical cancer in South African women, including the contribution by the HIV epidemic which results in a weakened immune system, and the fact that many women are unable to access adequate preventative health care such as cancer screening.

Research in women living with HIV can inform future treatment and prevention strategies for cervical cancer. With this aim in mind, Wits RHI participated in HARP, a research partnership between RHI, the London School of Hygiene and Tropical Medicine, the University of Montpellier, the Université de Ouagadougou and the South African National Health Laboratory Service. The HARP study, funded by the European Commission, evaluated cervical cancer screening approaches in Burkina Faso and South Africa. The ultimate aim was to find ways to detect abnormal cervical lesions earlier and manage cancer progression in the high-risk populations found in these countries. The study compared three different methods of screening women for HPV: the high-risk HPV test, the visual inspection with acetic acid method and conventional cytology. Any positive tests were studied further. The results of this evaluation are critical to informing policy decisions regarding the most effective national cervical cancer screening programmes, given the resources available. The aim was to find the method which is the most cost-effective, without sacrificing the ability to accurately detect HPV infection.

“Screening and early detection of cervical cancer is critical if we want to improve female reproductive health. It is a disease that disproportionately affects South African women and if we are to find and treat these women, we need technologies that are appropriate for our setting. This is what HARP aims to do.” - Dr Sinead Delany-Moretlwe, Director: Research Programmes
By 2013 Wits RHI had enrolled over 600 women living with HIV in the HARP study. Of these, 125 had precancerous lesions. These women were referred for immediate care. After researchers noted the difficulty in convincing women to access health care services for cervical cancer screening, a spin-off study was developed to understand the factors that influence the uptake of these services. It was hypothesised that the information provided to women living with HIV is complex and does not prioritise cervical cancer, and this may lead to adjustments in the messaging directed at women in order to better promote more comprehensive care. During the year the team at Wits RHI also provided support and technical assistance to the Department of Health around HPV vaccine policy, sitting on various expert committees in order to advise on vaccine strategies. Related work done by RHI in assessing how the HPV vaccine could be used as a platform from which to deliver a package of adolescent care services was published in the journal BMC Public Health in 2013, underlining the role RHI’s research plays in informing national policy around public sector delivery of reproductive health services.

The HARP study was completed in March 2014. Results were disseminated at various national and international conferences and a number of abstracts presented. One article has been published and several manuscripts are in different phases of development.

HIM: HPV in Men

Much of the existing work done on HPV has focused on women and the detection of cervical cancer. However, HPV infection is very common in both men and women. In either gender, HIV infection...
can worsen disease caused by HPV and, for men in particular, HIV increases the risk of HPV-related anal cancer. Other strains of HPV can cause genital warts. There is also mixed evidence on the effect of ART on disease progression in HPV-infected men. For these reasons, there is a need to understand how men are affected by HPV infection in South Africa. Wits RHI worked with the National Institute of Communicable Diseases and the London School of Hygiene and Tropical Medicine to close this knowledge gap through the HIM study, which was funded through the European Developing Country Clinical Trial Partnership. Men living with HIV in Johannesburg were recruited to the study in order to learn more about the rates of HPV disease and about the contextual and behavioural factors that might influence rates of HPV infection. Another question asked was whether men would accept diagnostic and preventative services such as anal swabbing and vaccination. This information could inform reproductive health policy decisions around screening men for HPV infection and the feasibility of introducing a vaccination programme for men.

In 2013, enrolment of study participants was completed, and researchers noted that providing sexual and reproductive health services specifically for men helped to strengthen their engagement with health services.

This was an important observation in light of the fact that many men present for HIV counselling and testing later than women, and begin ARV therapy later as well. The interest expressed by men in their urogenital health could be a potential entry point to persuade men to access other health services.

The HIM study made use of mHealth data collection technology to facilitate speedier data entry and improve accuracy. Tablet devices were used to capture information and network connectivity ensured that results were sent to a central database in real time. This decreased errors and increased efficiency during data capture.
The HIM study was completed in October 2014. Whilst final data analysis and manuscript preparations are ongoing, preliminary data analysis indicates that there is a high prevalence of HPV infection and disease among HIV-positive men. Qualitative data suggests that anal swabbing and HPV vaccination are acceptable among men in South Africa.

Sinawe mama! We are with you, mother!

Violence against women and children is rife in the South African context. It is difficult to accurately estimate the real scope of the problem, given that many cases go unreported, but 56% of women have reported experiencing physical and sexual abuse within intimate relationships. A particularly distressing fact is that 25% - 35% of pregnant women in sub-Saharan Africa have experienced intimate partner violence in the 12 months leading up to pregnancy, which has been associated with many adverse health outcomes for the pregnant woman and her baby, including physical trauma, poor mental health, and the physiological effects of stress from current or past abuse on foetal growth and development. Although violence against women has historically been considered a social issue, it has severe public health implications, including a strong bidirectional link to HIV incidence and prevalence.

Wits RHI is pioneering one of the first sub-Saharan African research trials to reduce violence against pregnant women: the Safe and Sound intervention, delivered by nurses in four antenatal clinics in
Johannesburg. Antenatal clinics represent a window of opportunity to identify women experiencing violence as this is a key point of contact with the health care system. Safe and Sound gives women access to counselling, legal and shelter resources and helps women understand the cycle of violence and their legal rights in South Africa.

In 2013 the “Safe and Sound” name and logo were revealed, and a great deal of groundwork and formative research was undertaken in preparation for the planned recruitment of women to the study in 2014. Organisations working in the gender-based violence sector were brought together to strengthen the support networks to which nurses could refer women, including Lawyers Against Abuse (LvA), ChildLine, Teddy Bear Clinics, FAMSA, Hillbrow SAPS, Bethany House and Hotel Hope Ministries. Job aids were developed for nurse training, with a focus on empowering patients and improving their ability to take up referrals to protect themselves and their children. In partnership with the World Health Organization, this clinical trial has been designed to be sustainable, and it is hoped that the evidence will support roll-out of the intervention on a broad scale, thereby capacitating health care providers to respond to intimate partner violence in pregnancy and provide more comprehensive care and treatment to mothers and their infants.

“If you talk about keeping me and my baby safe, I will listen.” – Expectant mother
While preventing the transmission of HIV is essential to addressing the epidemic, HIV prevention is a vastly complex issue. Vulnerable populations such as women and girls need options that do not simply advise them to “Abstain, Be Faithful and Condomise”. To boost efforts to provide people with expanded options to protect themselves against HIV infection, Wits RHI collaborates with a number of partners to conduct large-scale research on a number of biomedical interventions which aim to reduce the physical risk of becoming infected, and structural interventions which are examining how best to address the contextual factors that drive the HIV epidemic.

FACTS: Helping women to take control of their health

In sub-Saharan Africa, the HIV epidemic has hit women particularly hard. 60% of all people living with HIV in this region are women, partly due to the fact that gender inequality and gender-based violence make it very difficult for women to insist on HIV prevention methods such as condoms. To expand the range of HIV prevention options available, microbicide options are being studied. Microbicides are substances such as gels, creams, films or rings which are inserted into the vagina with the aim of reducing the risk of HIV infection during sexual exposure. Wits RHI participated in ground-breaking research which may help make a microbicide to prevent HIV
infection a reality, by leading the FACTS collaboration.

In 2010, after the CAPRISA 004 trial announced the breakthrough results that a topical microbicide gel containing a 1% formulation of the antiretroviral drug tenofovir was 39% effective in reducing the risk of HIV infection during sex, the Follow-on African Consortium for Tenofovir Studies (FACTS) was established. Led by Wits RHI, FACTS was an ongoing Phase III randomised controlled clinical trial aimed at evaluating the safety and effectiveness of 1% tenofovir gel in preventing sexually transmitted HIV-1 infection in women.

FACTS was the first South African-initiated and -led research consortium and was the largest medical research study funded by the South African Government, through the Department of Science and Technology. The study was conducted in nine sites across the country. In 2013, FACTS reached a significant milestone when, after a review of the data generated to date, it was given the go-ahead to continue. This is in contrast to other microbicide trials which have been ended early due to futility.

As the trial progressed, interesting information about the social context of HIV prevention tools came to light and the understanding of the way that microbicides are used by women has shifted. Initially thought to be a tool for women to use without the knowledge of a sexual partner, researchers have come to realise that it is also being used to facilitate trust and intimacy in regular relationships. However, many women are still unsure about using the gel at all, as evidenced by previous studies such as the VOICE study, which used blood tests to determine that only a quarter of women in the study were using the microbicide.

2013 saw an intensive effort from Wits RHI to make the microbicide a more appealing and acceptable option for women. Adherence was seen as the “Achilles heel” – in order to prove that the gel is effective, women have to use it regularly. Thus, RHI pioneered innovative and fun campaigns to encourage use of the gel by trial participants. This involved learning from other studies and creating opportunities for women to become more engaged and empowered. The gel was marketed to young women through campaigns designed to be relevant and fun. Text messages, posters depicting the gel as part of a normal lifestyle and even Christmas trees decorated with condoms were all part of this initiative. Other efforts to boost
adherence included work done at the individual sites to identify any challenges unique to that particular site, and address them, as well as motivating women by emphasising the value of their involvement to make them feel included and important. The women were also educated about the particular benefits of this microbicide, such as the fact that unlike other microbicides tested, it only needed to be applied up to 12 hours before and after sex, as opposed to obligatory daily use. This makes the product much more convenient and practical. This participant-centric approach is a hallmark of the way that Wits RHI approaches clinical trials.

The FACTS study was completed in October 2014 and results were due to be announced in February, 2015.

“
We know that other trials have struggled to show whether microbicides work or not, because women aren’t using them. We were committed to making women active and invested participants in this trial. We had to keep thinking about who will use the product and how it will fit into their lives.”

– Deborah Baron, Programme Manager, Clinical Research Consortium

Good participatory practice

Good participatory practice (GPP) refers to effective engagement with stakeholders such as trial participants, their families, people living with HIV and residents living in the area where a trial is being conducted. GPP guidelines, such as those published by UNAIDS and AVAC, provide direction on how to plan, conduct and evaluate community engagement in biomedical HIV prevention trials.

Wits RHI recognises how important GPP can be to enhance both the quality and outcomes of research. Thus, FACTS worked in partnership with Global Advocacy for HIV Prevention (AVAC), of which Wits RHI’s Executive
Director, Professor Helen Rees, is a board member. The collaboration with AVAC aimed to implement GPP guidelines throughout the FACTS trial. All FACTS study staff received comprehensive training on GPP guidelines and site teams were supported in all GPP activities. FACTS was a trailblazer with regards to GPP, as the first study to formally implement GPP, with the financial and technical support that AVAC provides.

"At Wits RHI we are positively impacting women’s lives beyond the scope of the clinical trial. Although we hope to find that the Dapivirine ring is effective in preventing HIV transmission, we also ensure that we empower women with knowledge so that they are able to better negotiate safer sex and safer, healthier relationships for the rest of their lives.” – Dr Thesla Palanee-Phillips, Director: Network Trials and international co-chair of the ASPIRE study

ASPIRE: Assessing whether vaginal rings can prevent HIV

Women in gender-imbalanced relationships may find it hard to negotiate male condom use with partners for HIV prevention. Vaginal rings are flexible discreet products that fit comfortably inside the vagina and provide sustained delivery of a drug over a period of time. They are already used in many countries to deliver hormonal contraception.

ASPIRE – A study to Prevent Infection with a Ring for Extended Use – is a Phase III clinical trial that seeks to determine whether a vaginal ring containing the antiretroviral drug Dapivirine is a safe and effective method for protecting against HIV infection during sex. Led by the Microbicide Trials Network, and co-chaired by Wits RHI’s Dr Thesla Palanee-Phillips, the trial was launched.
in 2012 and has enrolled more than 2000 women at 15 sites in Malawi, Uganda, Zimbabwe and South Africa. If the ring is proven to be effective and safe, it will give women an additional option that could help to address individual needs, such as not having to disclose using an HIV prevention method. RHI recognises the value of giving women choice, and that providing a selection of methods to cater for the differing needs of women in various life stages or relationship types could have a powerful effect on the dynamics of HIV transmission and shift the face of the epidemic locally and globally.

RHI also invested a lot of effort into working with trial participants to empower them and meet their additional sexual and reproductive health needs. Recognising that the inclusion of male partners in studies like this improves communication within participants’ relationships and can impact positively on adherence to the study intervention, partners were proactively engaged in many trial activities such as community advisory boards and one-on-one sessions. These sessions counselled women and their partners jointly on issues such as HIV testing, disclosure of HIV status, family planning and the prevention of sexually transmitted infections, and helped to ensure that partners’ concerns were addressed directly.

**EMBRACE**

Wits RHI is also involved in the MTN’s EMBRACE study – Evaluation of Maternal and Baby Outcome Registry After Chemoprophylactic Exposure – which follows up women who become pregnant during any microbicide trial. RHI has enrolled women who became pregnant on the VOICE and ASPIRE trials. The study will determine if microbicides are safe to use during pregnancy and if there are any harmful effects on the infant. The current lack of data makes this research an essential component of ongoing epidemiologic studies on the safety of microbicide products.
MTN015

Does prior exposure to a microbicide change the way that HIV disease progresses, should a trial participant become infected? This is the question asked in the MTN015 study. Given that many of the individuals who are enrolled in microbicide trials are at high risk of becoming infected with HIV, it is essential to determine whether microbicide exposure poses an additional risk should HIV infection occur. This includes the development of drug-resistant strains of HIV as well as differences in the immune response to the virus. At present there is no information regarding the risk or benefits of previous microbicide use in newly-infected individuals, making the knowledge gathered as the MTN015 study progresses extremely valuable. MTN015 is uniquely poised to capture extensive data on the clinical progression of HIV disease and the prevalence of drug resistance among study participants who become HIV-positive during a microbicide trial.

VOICE-C

The VOICE (Vaginal and Oral Interventions to Control the Epidemic) trial, of which Wits RHI was a part, was a large-scale clinical trial aimed at preventing HIV infection in women in sub-Saharan Africa, comparing daily tablets or a microbicide gel as protective options. However, the
trial encountered a stumbling block: whilst over 90% of women informed researchers that they used the product provided to them daily as recommended, blood tests revealed that this was the case in only 25% of women. This insight underscored how important it is to design an intervention that suits the preferences and lifestyles of the target population. One of the key messages that emerged during analysis of the results of the VOICE trial was that ensuring the convenience and acceptability of a proposed intervention is as important as determining its biological efficacy.

To examine specific factors and beliefs at the community and household level that could influence willingness or ability to use the products provided in the VOICE study, the VOICE-C sub-study was conducted at Wits RHI’s VOICE clinical research site. By conducting interviews and focus group discussions with women enrolled in VOICE, male partners, members of RHI’s Community Advisory Board (CAB) and community stakeholders, researchers were able to identify some of the social, cultural and contextual factors that influenced women during VOICE. It emerged that women were fearful of the social consequences of participating in the trial, such as being judged by other members of their household or experiencing violence from a partner as a consequence. The fact that many of the women had lengthy work hours, family obligations and domestic responsibilities also meant that they found it difficult to stick to the routine of using the products. Additionally, the long queues and extended waiting times during clinic visits placed further pressure on the already time-constrained participants and demotivated them.

It also emerged that individuals taking part in trials, especially those that involve antiretroviral-based products, have diverse – and not always positive – ideas about the research process. Women had questions about the legitimacy of the research and concerns about taking a product with an unknown efficacy, especially given that side effects were experienced. These issues influenced the level of trust women had in the trial, which in turn affected their overall use of the products provided.

The VOICE study provided a catalyst for the research community to re-evaluate methods for monitoring and enhancing product adherence in clinical trials. Several trials have already incorporated ways to better understand product adherence while the trial is underway so that researchers can address challenges as they occur.

VOICE-C was a very important study as it helped to make sense of the findings in VOICE and contribute to a broader understanding of what motivates or deters women from using HIV prevention technology. Researchers can use this information to develop products that women are more likely to use; it will also help to refine the way that future clinical trials are conducted.

STRIVE: Tackling the structural drivers of HIV

Structural drivers – legal, economic and social factors – shape the HIV risk of individuals and populations. Addressing the structural drivers of HIV is recognised as becoming increasingly important. Issues such as gender inequality and gender-based violence, poverty, alcohol use and stigma are some of the social, political and economic factors that international research consortium STRIVE focuses on. STRIVE is a collaboration between six partners: Wits RHI; the International Center for Research on Women (Asia Regional Office, India and Washington, DC, USA); the Karnataka Health Promotion Trust (Bangalore, India); Tanzania’s National Institute for Medical Research; and the Mwanza Intervention Trials Unit (Mwanza, Tanzania). The consortium is working to understand how the issues highlighted drive the epidemic and how to tackle them effectively. The ultimate
aim is to translate the research into policy for broad-scale HIV prevention interventions.

In 2013, STRIVE formed working groups that focus on different key pathways to HIV prevention. The Structural Factors and Biomedical Prevention working group is co-led by Wits RHI's Sinead Delany-Moretliwe and Deborah Baron. Wits RHI is conducting a number of studies linked to STRIVE. In 2014 Wits RHI hosted an international meeting of consortium members.

**Swa Koteka**

One disturbing feature of the sub-Saharan HIV epidemic is the fact that young women are disproportionately affected. Girls acquire HIV five to seven years earlier than boys and have up to eight times the risk of becoming infected when compared to boys in the same age group. It is speculated that poverty strongly influences HIV risk, which has led to studies which provide cash grants to youth in order to reduce HIV infection rates. These small studies have indicated that staying in school has a positive impact on HIV risk reduction, and also point to conditional cash grants as a possible effective way to decrease HIV transmission in school-going girls in rural areas. This has paved the way for a large-scale trial to determine whether providing cash transfers to young women and their households, conditional on school attendance, will decrease the rate of new HIV infections within this group.
Wits RHI, together with the University of North Carolina at Chapel Hill’s Gillings School of Public Health, is conducting a randomised controlled trial in a rural area in the Mpumalanga province of South Africa. Young women of school-going age are being assessed to see if being given monthly cash grants to stay in school decreases HIV infection, as well as decreasing Herpes Simplex Virus-2 (HSV-2) infection, unprotected sex and reported pregnancies. The study began in 2011 and will run for four years. In 2013, the study had finished enrolling participants, having enrolled 2900 young women from Grades 8 – 11, and was following them up over time. It is anticipated that the results will be released in 2015.

**CHANGE: Cash transfers for HIV prevention in adolescents in a generalised epidemic**

It is feared that in urban areas, interventions that provide an economic incentive to young people may have unintended consequences or an increase in negative behaviours, such as cash grants being used for drugs, alcohol or sex. Wits RHI partnered with Johns Hopkins Bloomberg School of Public Health on the USAID-funded CHANGE study, a novel study which examined what impact poverty has on sexually active youth living in a low-resource urban setting such as Hillbrow. The study was particularly focused on how these young people access sexual and reproductive health
(SRH) services, and whether cash incentives could result in reduced risk within this group. Three mechanisms of cash transfer were compared: an unconditional cash transfer, a cash transfer conditioned on 80% school attendance and a direct incentive to attend a SRH clinic visit.

Initiated in late 2011, the study was finalised in 2013 and the results indicate that all cash transfer strategies are equivalent in terms of their positive effect on sexual behaviour. Another very encouraging result was that no obvious unintended consequences of the cash transfers were detected, with little evidence for increases in alcohol consumption, tobacco or drug use. This indicates that cash transfers are feasible in the urban environment as well.

WAVE: Well-being of Adolescents in Vulnerable Environments

There are many social and contextual factors that put adolescents at risk. For this largest-growing demographic group in Africa, the social, physical and psychological transition into adulthood can make them increasingly vulnerable to infectious and non-communicable diseases. In South Africa, this demographic has the highest rate of new infections in the country. The WAVE study was designed to understand the factors that affect adolescent health. It was the first study of its kind to focus on very disadvantaged urban adolescents and their health in six cities across the world: Johannesburg, Baltimore, Ibadan, Delhi, Shanghai and Rio de Janeiro.

In the two-phase research study, Wits RHI conducted interviews, focus group discussions and a survey amongst adolescents to understand what prevents them from accessing health care. The data from the survey was gathered in 2013, and the results were published in 2014. They showed considerable variance in the prevalence of sexual experience and adolescent pregnancy across settings and by gender. Among youth living in very impoverished areas, there were varying levels of sexual and reproductive health needs, suggesting that prevention approaches need to take into consideration local communities and be carefully targeted to their specific requirements.
Chapter Five: Key Populations – Addressing the drivers of the epidemic and the challenges of the most vulnerable and marginalised in society

The vulnerability of certain populations results in their being disproportionately affected by HIV. For a truly effective response to the epidemic, the issues relating to these populations need to be carefully considered, such as the social barriers that prevent them from accessing care. Through a long history of community engagement, Wits RHI has a strong understanding of the context that places certain groups of individuals at risk. With a firm belief that equitable and high-quality health care services should be available to all those who need them, RHI has undertaken several projects to close this critical gap.

Sex worker and male client programme

Sex workers are among the most vulnerable populations affected by the HIV epidemic globally. They are often powerless to negotiate condom use and face stigma and negative perceptions of health care workers which can prevent them from accessing health services, placing them at high risk of contracting HIV and other sexually transmitted infections. Additionally, male clients of sex workers act as a link to the general population, further fuelling the transmission of HIV and STIs. It
is estimated that 19.8% of all new HIV infections are related to sex work. To address the need evident in this underserved population, Wits RHI has partnered with the City of Johannesburg and the National and Provincial Departments of Health to provide health services to sex workers and reduce the number of HIV infections amongst them and their clients. The National Strategic Plan on HIV, STIs and TB 2012-2016 highlights the critical importance of working with sex workers, and RHI has pioneered this concept in South Africa through the creation of a programme that is now used as a benchmark for similar sex worker projects implemented by the Department of Health and other NGOs. RHI supported the DoH during the development of the National Strategic Plan, assisting to position the sex work industry as a key driver of the epidemic and supporting the development of the strategy to address the issue.

The Wits RHI Sex Worker Programme has been in existence since 1996. A PEPFAR Innovations grant in 2012 significantly increased the capacity of the project and in 2013 additional funding was secured from the Global Fund, allowing RHI to build on this work. Services were expanded, from the Johannesburg inner city at Esselen Street Clinic in Hillbrow, to two new sites, one in Johannesburg’s East Rand and another in Pretoria, the latter opening its doors in 2014. These health care facilities give sex workers access to HIV counselling and testing (HCT); antiretroviral (ARV) therapy and linkage to care; condom demonstrations; TB screening; treatment for minor ailments; and sexual and reproductive health services such as STI diagnosis and treatment, provision of contraception and assistance with cervical cancer screening.

The programme also delivers services through a mobile clinic, taking into consideration the fact that sex workers’ lifestyles can hinder them from attending a clinic in a fixed location. The van offers clinical care to 22 brothels in Johannesburg’s inner city twice a week, with RHI-trained sex worker peer educators helping to promote and encourage uptake of clinic services and distribute condoms.

“We learn to respect each other, to know each other and to make friends.” – Sex workers, on the Creative Space workshops held in Hillbrow

Additionally, the clinics provide sex workers with health and wellness education and psychosocial support. The Creative Space workshops invite sex workers
to participate in activities such as art and drama therapy and facilitated sessions where they can share their stories to relieve stress and form support networks.

“I have four words for this place: Sorrow decrease, pressure release.” – Sex workers, on the creative space workshops held in Hillbrow

Part of what makes the Sex Worker Programme innovative is its focus not only on health services, but on creating a broader enabling environment in which sex workers can feel secure enough to access health care without fear of prejudice. This includes promoting a positive attitude amongst health care workers, and engaging with the South African Police Services to decrease the harassment of sex workers.

The programme is not exclusively female-centric, and acknowledges the vulnerability of men who have sex with men (MSM) and transgender individuals. MSM are at a far higher risk of acquiring HIV than heterosexual men of the same age and the transgender population is highly marginalised and open to abuse and stigma. Wits RHI collaborates with other NGOs that work with MSM and transgender people, such as the Anova Health Institute, to introduce the inclusion of sex workers into their current interventions.

In 2013 Wits RHI hosted a two-day international Sex Work Consultation Meeting, which brought together representatives from UNAIDS, the WHO, India, Kenya, the UK and the US. The meeting was an opportunity for sex workers to give their input to academics in the field, giving them a more accurate perception of the challenges faced in bringing HIV treatment and prevention interventions to sex workers. The meeting was embraced by the sex workers, who greatly appreciated the opportunity to become involved.

In 2014 RHI, along with the Sex Worker Education & Advocacy Taskforce (SWEAT), participated in a sex worker dialogue organised by the Gauteng legislature, which attracted more than 400 sex workers. In addition, to commemorate World AIDS Day 2014, RHI, in conjunction with the City of Johannesburg, organised a dialogue that brought sex workers and the South African Police Services together in direct engagement.

This illustrates RHI’s inclusive and hands-on approach to working with underserved populations to give them the health care that they most need. And the introduction of human rights defenders to the peer education component of the Sex Worker Programme in 2014 demonstrates RHI’s commitment to a rights-based approach to health care.

The Sex Worker and Trucker Programme

Long-distance truck drivers are a challenging group to treat for HIV and STIs. They can spend up to 26 days a month on the road and are thus unable to access health services. They also seek out the services of sex workers whilst away from their homes and families, often participating in high-risk behaviour. An inventive approach is the implementation of roadside wellness centres. In 2013, in partnership with North Star Alliance, which specialises in bringing health care to hard-to-reach populations, Wits RHI established five out of eight planned centres. The centres, run out of converted shipping containers, provide basic primary health care services such as STI, malaria and TB screening, HCT, and treatment of chronic conditions such as hypertension and diabetes. By 2014, all eight centres were up and running. RHI also entered into a public/private partnership with Sappi, which is supporting the clinics to ensure long-term sustainability of the project. Other key partnerships developed in 2013 included an invitation to join the National Transport Sector Committee and ongoing co-operation with the Gauteng Department of Roads and Transport.

Sexually transmitted infection surveillance

Despite being identified as a high-risk population, little is known about the HIV and STI epidemics among sex workers in South Africa. Understanding the prevalence, resistance pattern and clinical presentation of STIs will facilitate the design of an intervention that can be implemented into
existing sex worker programmes in South Africa. Supported by AIDS Fonds, CDC and PEPFAR, RHI is conducting surveillance of STIs among female sex workers attending services within the inner city of Johannesburg. Recruitment for this study was from March to December 2014, when 268 female sex workers agreed to participate. The objectives of the study are to determine the prevalence of HIV and STIs among symptomatic and asymptomatic sex workers, to determine the proportion of local genital tract infections that are asymptomatic STIs, and to detect susceptibility of N. gonorrhoeae to antimicrobial agents. The prevalence of STI pathogens identified will be used to validate existing syndromic management treatment guidelines and validate the Standard Diagnostics’ Duo HIV and Syphilis test.

Child & adolescent health

2013 was the start-up year for Wits RHI’s adolescent project. The lack of focus on caring for and treating this particularly vulnerable population represents a gap in current HIV management programmes. Historically, HIV and sexual and reproductive health programmes have been categorised as either paediatric- or adult-targeted. However, as RHI acknowledges, the adolescent period between 10 and 19 years of age is a difficult and challenging one. Children are transitioning physically, emotionally and psychologically, and for those living with HIV the care and treatment of their HIV places an additional burden on them. Adolescents are beginning to become responsible...
for their own health and are developing sexual identities in an often risky environment. RHI’s adolescent programme works to identify and diagnose adolescents living with HIV, to improve the quality of care that they receive and to retain them within treatment programmes. The programme is tailored for the specific needs of this age group and is constantly striving to make services more adolescent-friendly.

“...We are working hard to help sex workers take responsibility for their own health, by creating an environment where there is no judgement, where they can feel safe and respected.” – Maria Sibanyoni, Programme Manager: Sex Worker and Male Client Programme

**Strengthening health systems**

Through its Adolescent Programme Wits RHI aims to develop a model of strategic interventions specifically targeting adolescents which can be adopted and replicated throughout South Africa’s public health system. The programme works across a number of facilities in two of the regions that Wits RHI supports – Region F in Gauteng and the Matlosana sub-district in the Northwest Province. Throughout the period the team worked to achieve buy-in from the provincial Departments of Health and the health management teams, to ensure that the work done at the facilities was supported and sustained. A Wits RHI mobilisation team was also active, attending youth events to conduct outreach, promote HIV counselling and testing (HCT) and distribute condoms.

**Specialist adolescent clinics**

Wits RHI supports two specialist adolescent clinics, one in Johannesburg’s Region F and the Tsepong Expert Adolescent Clinic in the North West. These clinics provide a package of comprehensive sexual and reproductive health services to all
adolescents, as well as HIV-related services, at the primary health care level. This is integrated with services to treat minor illnesses. The clinics employ doctors, nurses and social workers, so that adolescents can access medical care and psychosocial support from one central facility. Tsepong provides additional support in the form of specialists in family medicine, internal medicine, and infectious diseases. The clinics are also working to pilot up- and down-referral networks.

Each clinic has been specifically designed to create an environment conducive for young people. The staff are trained to be attuned to the needs of adolescents and medication is dispensed in examination rooms, creating a sense of privacy and confidentiality. There is even entertainment, a chill room with TV sets and computers for them to use to do homework, so that they can feel relaxed and at ease while they wait to see a health care provider. The establishment of adolescent and youth-friendly services (AYFS) at the clinic in Region F was a major achievement, as no other clinic offers accredited AYFS. Before, the clinic struggled to attract young people under 20 years of age; it now attracts hundreds of adolescents a year.

Technical assistance to Primary Health Care clinics

In addition to the specialist clinics, Wits RHI is making primary health care (PHC) more accessible and more approachable for adolescents through mentorship and training of PHC nurses. This assists the nurses in providing integrated clinical services to adolescents, including sexual and reproductive health care, family planning services and HCT. Offered to all adolescents, this is a way of identifying adolescents living with HIV, who can then be placed on ARV treatment if necessary, with additional adherence support. Training on support group formation and facilitation was provided for PHC nurses by RHI.

“These children and young adults are in a period of transition, one which we all find difficult to navigate. Through the Adolescent Programme, we hope to give them the support and encouragement that they need to shoulder the additional burdens of living with HIV, being orphaned due to HIV and living in high-risk environments. We want to see them become responsible adults who are in control of their lives and their health.”

– Memory Muturiki, Technical Head: Adolescent Programme
Chapter Six: Teaching & Training – Closing the knowledge gap among health care workers

The knowledge gathered by staff members at Wits RHI over 20 years of working in the field of sexual and reproductive health is extensive, from clinical experience to research skills. Embedded in the organisation’s vision and mission is the responsibility to pass on this knowledge and experience, not only to new staff members but also to other colleagues working to combat the numerous health challenges faced in the African region. Thus, RHI has invested in internal and external training structures that develop the capabilities of health care workers in Africa.

Internal training and capacity-building

In 2013, Wits RHI built on existing processes to further address training needs internally. The focus was on establishing standardised programmes for different cadres of staff and ensuring all staff learning needs were identified via a rigorous learning needs analysis and met with appropriate interventions to enable them to perform at the highest level. This internal training was applied across the board covering technical, supportive and behavioural skills. In addition to the actual learning interventions such as clinical updates, quality improvement training, business writing courses and management development programmes, strategies to support the transfer of learning were applied. These ranged from clinical mentoring at Johannesburg specialist sites for the Health Systems Strengthening (HSS) district-based teams to mentoring in report-writing and business coaching for management programme alumni.

The critical role of the HSS team in making an impact on the ground within health care facilities was recognised, leading to intensive skills-building exercises, particularly from a clinical perspective. The HSS team is instrumental in improving patient outcomes and quality within facilities (read more about the HSS programme in Chapter 1). The HSS team was also boosted through the development of a data traineeship. The combination of theoretical and experiential learning was designed to develop critical data skills to support the HSS programme and strengthen the pool of skilled data staff in hard-to-recruit areas.

2013/14 was a busy period regarding strengthening our organisation. We take the development and mentoring of our staff seriously. Investing in RHI employees empowers them, and is also critical for the delivery of our organisational commitments.” – AJ Edge, Technical Head: Training and Teaching
External training

The continuous professional development of health care workers is central to evidence-based and high-quality patient care. RHI offers a number of training courses and programmes designed for different cadres of health care professionals and their delivery requirements. In 2013 an in-house team of professional instructional designers was integrated into the training team for increased emphasis on the quality improvement of curricula and learning materials. These are designed with rigour, with practical learning outcomes at the core. The provision of training to Department of Health staff was bolstered in 2014 with the arrival of clinical trainers within each South African district supported by RHI. The Training and Teaching Department works closely with this group, meeting monthly not only to provide professional development but also collectively to analyse training data from standard training evaluations and assessments to further improve the programmes, identify additional learning needs and solve problems.

In addition to the clinical, psychosocial and quality improvement training provided to Department of Health staff, 2014 saw Wits RHI develop capacity in a new area for its major stakeholder. Khulani, RHI’s Leadership and People Management Programme, was tailored for Department of Health managers covering the employee life cycle from recruitment to staff development with cross-cutting communication and leadership modules. The eight-week, four-module programme allows time between modules for practice and assignment completion. Mentoring is provided in between modules to participants who must submit a complete and satisfactory portfolio. To further support leadership and people management practice, coaching is offered to alumni after the final module.

“I now know how to run effective meetings.”

– Khulani graduate

Two of RHI’s courses are regional and provide opportunities for clinicians and researchers from across the continent to engage with one another and the team of expert facilitators. These include the Research Methods Course in Sexual Reproductive Health, HIV and Gender-based Violence and the Advanced Clinical HIV Management Course.

**Research Methods Course in Sexual Reproductive Health, HIV and Gender-Based Violence**

Developed by Wits RHI, the Medical Research Council and the Population Council, this course has been held annually since 1997 with an alumna of over 400 students representing 21 countries across the continent. It provides African researchers with strong fundamental grounding in the specialist areas of sexual and reproductive health, HIV and gender-based violence, in order to conduct high-quality qualitative and quantitative research. Participants undergo an intensive 10-day programme which develops knowledge and skills to initiate and analyse research within the African region. The vision is to increase locally generated evidence to improve policy and programmatic efforts and help to address the sexual and reproductive health and HIV issues facing African populations. It also creates a network of alumni, promoting researcher collaboration. It not only builds research skills amongst individual participants, but results in a cascade of knowledge and mentorship provided by course graduates to their colleagues and students. In 2013 and 2014 a further 33 researchers engaged in the programme.

**The Advanced Clinical HIV Management Course**

The Advanced Clinical HIV Management course has been run successfully by Wits RHI since 2001. The aim is to build on existing regional HIV treatment knowledge and expertise, by developing clinicians’ abilities to effectively manage HIV complications and provide leadership in HIV prevention, treatment and care. The full-time, two-week course is facilitated by HIV specialists from Wits RHI, as well as external experts. The revised programme in 2013/14 introduced more creative methodologies that support adult learning and included a full day assessing participant competency in complex HIV management, in addition to a pre-course assessment on basic guideline implementation. Applicants who did not achieve the required level in the pre-course assessment were provided with feedback and advice. In 2013 the course produced 43 graduates and 68 in 2014, with a 92% competency rate. 2014 also saw
the introduction of clinical associate graduates to the programme with all five Malawian colleagues achieving competence. The Advanced Clinical HIV Management Course is endorsed by the College of Medicine of Southern Africa and provides a useful foundation for the College’s HIV Diploma. An analysis of the assessment cascade from applications and pre-course assessment to the rigorous oral and written assessment process at the end of the course to determine participant competency was profiled at the 2013 SA AIDS conference.

“One of the major successes of the HIV Management course is its transition from being PEPFAR-funded to being not only self-sustaining, but generating surplus whilst still offering bursaries to clinicians in the South African districts supported by RHI. The course is a model for sustainability, which can be replicated in appropriate, existing donor-funded programmes and new courses.” — AJ Edge, Technical Head: Training and Teaching

Fit for Life, Fit for Work

“I am a go-getter. Now I know what to do, what I need and what to decide” - Fit for Life, Fit for Work course graduate

South Africa’s youth unemployment rates are extremely high. Stats SA has estimated that out of nine million people between the ages of 15 and 34, almost a third (3.2 million) are unemployed. Young people in South Africa are exposed to a number of challenges such as poverty and the risk of HIV and sexually transmitted infections (STIs), which are exacerbated by poor knowledge of what constitutes safe sexual and reproductive health practices.

Fit for Life, Fit for Work is a youth empowerment programme which aims to build resilience and confidence in young people, while providing them with the information they need in order to prepare for the workplace and to make responsible decisions about their health. Aimed at young adults between 18 and 24 years of age, the four-week course is held six times a year, with 30 participants per course. Topics covered include entrepreneurial skills, how to search for a job and handle a job interview, and how to behave in a workplace environment. Other components of the course deal with HIV and STIs, understanding the dangers of risky sexual behaviour and how to make positive choices.

Wits RHI houses the National Desk for Fit for Life, Fit for Work. This allows for improved synergy amongst the five Fit For Life sites across the country and in 2014 progress was made in curriculum development, branding, and monitoring and evaluation framework development and application.

University and college teaching

Wits RHI is involved with the teaching and training of student health care workers, from undergraduate through to registrar level. RHI works closely with the University of the Witwatersrand and has had a strong relationship with the Wits Centre for Health Education for over 15 years. RHI lectures to students in the Graduate Entry Medical Programme (GEMP) and clinical associates to strengthen their knowledge of HIV and TB in adults, adolescents and children. In addition to teaching, RHI advises on appropriate curricula in these areas and in 2014 implemented a stronger HIV/TB thread throughout the three-year clinical associate programme. The Institute also supports the Wits Department of Internal Medicine.
and engages with internal medicine and microbiology registrars and trainee sub-specialists in infectious diseases, arranging for experienced senior clinicians to train on infectious disease and TB issues, both in a didactic and bedside manner. RHI also works with a number of nursing colleges providing trainers and clinical tutors with HIV and TB guideline updates to strengthen the pre-service programme offered to nursing students.

This investment in students from an early stage in their careers equips them for work in the South African context, highlighting RHI’s commitment to positively influence individual patient outcomes and public health at all levels.

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### Technical training assistance to SA Department of Health

The Training and Teaching Department works with the South African government at a number of levels. In 2013, it coordinated the development of the national curriculum and training materials on behalf of the National Department of Health to support implementation of the revised policy for contraception and fertility planning, bringing together technical experts in sexual and reproductive health. RHI’s training department also engaged with the NDoH and expert task team with regards to the training of trainers and quality assurance within the programme. In 2014, the Training and Teaching Department provided advice to the NDoH regarding the assessment process for Primary Care (PC) 101 training roll-out and developed many of the assessment tools to support the process. Details of the RHI NiMART mentoring programme have also been shared and discussed at that level. The team provides technical programmatic advice to the regional training centres (RTCs) in Gauteng and the North West Province regarding critical programmes, PMTCT, NiMART and mentoring programmes particularly. Technical assistance to the North West Province RTC included input to the strategic framework and generation of training-related policies to support their SAQA accreditation.
Chapter Seven: Governance, Operations & Research Support – A strong foundation for all our activities

Governance

Wits RHI has a strong and involved leadership structure that works to guide the organisation in a considered and strategic manner. The Executive Committee (ExCo), comprising Executive Director Professor Helen Rees and Deputy Executive Directors Professor Francois Venter and Dr Eugene Sickle, leads RHI in consultation with the Senior Management Forum, a group of senior RHI staff members representative of the various programme areas within RHI. This group ensures that the organisation is well governed, that the correct policies and procedures are in place and are followed, and that activity within RHI is aligned to its strategic goals and long-term objectives.

A Strategy & Development Department incorporating Grants and Development, Communications and Operations supports the needs of RHI with regards to finance, health and safety, asset management and IT. The Grants and Development portfolio includes managing all donor-related activity and ensuring compliance with donor regulations as well as budgeting and sustainability. Communications is responsible for internal communications activity as well as media and stakeholder relations.

RHI’s Executive Committee, Dr Eugene Sickle, Professor Helen Rees and Professor Francois Venter
Professor Helen Rees, Executive Director

Professor Helen Rees OBE is the Executive Director of Wits RHI. She is also Personal Professor in the Department of Obstetrics and Gynaecology at the University of the Witwatersrand and an Honorary Professor in the Department of Clinical Research at the London School of Hygiene and Tropical Medicine, where she also serves on their Visiting Committee. She is an alumna of Cambridge University and Harvard Business School.

Professor Rees is internationally renowned as an expert in HIV prevention, reproductive health, vaccines and drug regulation; and she previously served as the chair of the South African Medicines Control Council. Professor Rees serves on numerous national and international committees and boards. She is the former chair of the World Health Organization’s Strategic Advisory Group of Experts on Immunisation (SAGE) and served as the SAGE focal point for HPV, rubella and HIV vaccines. She serves on WHO’s Global Advisory Committee on Vaccine Safety. Professor Rees is the Chairperson of the WHO’s African Regional Advisory Committee on Immunisation. She is a board member of the International AIDS Vaccine Initiative (IAVI) and serves on the board of the Global Alliance for Vaccines and Immunization (GAVI) and on the GAVI Policy and Programme Committee, and is a board member of the Medicines Control Council. She serves on the board of the University of KwaZulu Natal’s HIV Economics and HIV/AIDS Research Division (HEARD) and on the board of the Higher Education HIV/AIDS Programme (HEAIDS). She was the protocol chair of the first South African microbicide network trial (FACTS 001), a licensure Phase III trial of 1% tenofovir gel.

Professor Rees is the recipient of a number of prestigious awards including in 2001 being made an Officer of the British Empire by Queen Elizabeth II for her contribution to global health. In 2002 she was given a Lifetime Achievement Award by Amanitare, a pan-African NGO for African women and children’s rights. She was the first South African to be awarded the Department of Science and Technology’s award for the South African Distinguished Scientist recognised for outstanding contribution to improving the quality of life of women. She is a member of the Academy of Science of South Africa (ASSAf), and was awarded the 2011 Academy of Science of South Africa’s Gold Award for Excellence in Science and Contribution to Society. She was the LSHTM’s 2011 International Heath Clark Lecturer. In 2012 she was awarded both the South African Medical Association’s Lifetime Achievement Award and the University of the Witwatersrand’s Vice-Chancellor’s 2012 Research Award.

In 2011 The Lancet journal published her biography and in 2012 Cambridge University published her profile as a role model for Cambridge students.
Professor Francois Venter, Deputy Executive Director

Professor Francois Venter is Wits RHI’s Deputy Executive Director and lecturer in the Department of Medicine, University of the Witwatersrand. He is the Head of Infectious Diseases at the Charlotte Maxeke Johannesburg Academic Hospital. Professor Venter was previous President of the Southern African HIV Clinicians Society, and remains an active member of the board.

Professor Venter has expertise in programmatic HIV implementation, especially provision of antiretroviral and opportunistic infection therapy, prophylaxis, human resource allocation, data systems and service integration. He has extensive training experience in these areas and an interest in monitoring and evaluation of clinical interventions, as well as a human rights interest in access to quality care. He has published several operational research studies, and is currently responsible for a large dose-reduction antiretroviral clinical trial, as well as a programmatic intervention addressing the health needs of truckers and sex workers across South Africa. He has been part of and continues to participate in several important South African and regional policy-making fora.

Professor Venter was the Chairperson of the 5th SA AIDS Conference in 2011, and was Chair of the second SA HIV Clinicians Conference in 2014.

Dr Eugene Sickle, Deputy Executive Director: Strategy & Development

Dr. Eugene Sickle has a doctoral degree in Synthetic Organic Chemistry from the University of Cape Town and considerable post-doctoral experience in the area of Medicinal Chemistry. After several years in academia he moved to Wits RHI to lead the Institute’s USAID-PEPFAR programme and to head the Strategy and Development Department. Dr Sickle is an expert in strategic financial and programme management.
Staff Composition and Employment Equity Statistics

Employment Equity as at 31/12/14

- African Male: 60%
- African Female: 6.5%
- Coloured Male: 2.5%
- Coloured Female: 0.75%
- Indian Male: 3.25%
- Indian Female: 0.75%
- White Male: 0.75%
- White Female: 3.25%

Staff Composition

Number of Staff

- Full Time: 353
- Volunteer: 1
- Fixed Term: 106
- Permanent Part Time: 7
- Sessional: 45
- Consultant: 7
- Employees turning 65 years old: 1
- Disability: 2

Total: 522
Hillbrow Health Precinct

The Wits RHI’s head office is located in the Hugh Solomon Building, a historic building that was renovated as part of the Hillbrow Health Precinct (HHP). The HHP is a visionary undertaking which underscores the RHI’s commitment not only to address health-related issues, but also to engage and uplift communities holistically and sustainably.

The Hillbrow Health Precinct is a result of common vision between Wits RHI, the City of Johannesburg and the Gauteng Department of Health. The project aims to restore and convert obsolete buildings in Johannesburg to regenerate urban spaces in Hillbrow and create centres that provide a wide spectrum of medical-related services. It is unique in that it is the only urban regeneration-based health precinct in the world. The HHP provides the community with a secure space that delivers integrated primary health care services, improving health service delivery and practice. The HHP has been planned and developed so that the physical location of all the different components is established in a cohesive manner that supports the current local government and provincial and national primary health guidelines and policies. As the infrastructure of the HHP expands, so do the programmes that bring health care services to residents of the inner city. Additionally, the HHP is the ideal location to consolidate the research base and operational connections among stakeholders; and create world-class education and training facilities.

The HHP not only has an immediate positive effect on the community surrounding it, but has a far broader impact on health outcomes through research and training.

The HHP also closes the gap between Wits RHI colleagues and partners, by functioning as a conduit, not only in terms of access to a greater number of facilities, but also with regards to bringing people together and building relationships, which leads to improved organisational decision-making and integration.

“...The HHP allows people to meet and to mix, a fantastic way of breaking..."
down inter-organisational silos and creating better informal relationships with staff and partners on the ground. This is illustrated by the fact that something as simple as a re-opened walkway between Shandukani and Ward 21 has resulted in better research and health systems strengthening support.

” – Yael Horowitz, Programme Manager: Hillbrow Health Precinct

The scope of the HHP: The core area is bounded by Esselen, Smit, Hospital and Klein Streets. The entire Precinct including the NHLS, Forensic Mortuary etc. reaches in the west to Joubert Street and to the North to Kotze Street and thus represents the node between Braamfontein and Hillbrow. The HHP contains the RHI research and training centre; Esselen Street Clinic; Ward 21; RHI’s head office; the Shandukani Centre for maternal and child health; the Hillbrow Community Health Centre; and a medico-legal facility.

The Hillbrow Health Precinct in 2013 and 2014

The HHP is constantly being expanded, with selected buildings being upgraded to house new health care facilities that have been identified as addressing a critical need in the community. In 2013 an infrastructure upgrade to Ward 21 was completed with the refurbishment of the 1st and 2nd floors. Part of the Hillbrow Community Health Centre, Ward 21 is the largest non-hospital-based antiretroviral therapy initiation site in sub-Saharan Africa, and sees over 4000 patients a month. Ward 21 now contains a specialised adolescent clinic, a much needed addition to help adolescents manage issues related not only to HIV, but to gain support for psychosocial issues as well. The upgrade also included more research and consulting rooms, space for administrative support for monitoring and evaluation teams, a home for the mHealth project and an expanded pharmacy. RHI is part of the Hillbrow Health Precinct committee, along with high-level representatives of the Gauteng Department of Health, the City of Johannesburg and the University of Witwatersrand. Committee meetings are held monthly, and are a fundamentally important way to plan progress, share information and identify and remove bottlenecks.

In 2014 RHI secured a lease agreement for the empty plot adjacent to the Esselen Street Clinic in order to establish a stand-alone container facility for the continuation of the Sex Worker Programme during the refurbishment of the clinic by the City of Johannesburg. Working in partnership with Wits University, the vehicular and pedestrian routes in Esselen Street were reconfigured to improve access
and flow; and together with the City of Johannesburg and eKhaya Neighbourhood initiative RHI ended illegal occupancy of neighbouring buildings which posed a threat to the safety of the area.

A model for investment and sustainability

The Shandukani clinic in the HHP is a maternal and child health facility that was initiated as a flagship public-private partnership. Private sponsors Vodacom, Altron and Altech saw the value in contributing to the Shandukani clinic through CSI investments, but this process has evolved into ongoing business-to-business relationships between sponsors and Wits RHI. Additionally, the CSI-funded model that Shandukani utilised has been recognised as best practice by other organisations wishing to replicate the successes of the HHP. Relationships with these important partners continued to grow and flourish throughout 2013 and 2014.

“Recently I was contacted by a student from England who had chosen to research Shandukani as a model for human rights in health. This made me proud of what we have achieved as Wits RHI.”

Yael Horowitz, Programme Manager, HHP

The youth are the key to bridging the gap between what is happening now and what should happen for everyone to have fair and equitable access to fundamental rights like health care. If we can reach across the ocean and get 16-year-olds interested in what we are doing here in the HHP, then we are doing something right.”

Strategy and development
Wits RHI’s Strategy and Development Department comprises Grants and Development, Communications and Operations, all of which are shared services supporting RHI’s projects and programmes. Communications manages intra-organisational information-sharing as well as media and external stakeholder relations, and maintains RHI’s website, intranet, social media and event coordination. Grants and Development manages RHI’s donor portfolio and ensures compliance with donor regulations and is responsible for budgeting to maintain and grow programmatic activities and ensure organisational sustainability. Operations includes finance, facilities, health and safety, IT, travel, and fleet and asset management. Each of these functions is carefully managed and monitored with the correct controls and standard operating procedures in place to keep Wits RHI functioning efficiently and effectively on a day-to-day basis.

Research support

Regulatory support

The expanding research portfolio of Wits RHI requires careful oversight to ensure that all research programmes and interactions with trial participants comply with local and international regulatory frameworks in order to minimise institutional risk. Drug regulatory authorities and institutional review boards have very strict requirements for conduct of research in adults, adolescents, children and other vulnerable populations. The use of Investigational New Drug (IND) entities in human research is managed under strict national control and requires extensive approvals with ongoing safety reviews and progress updates provided at specified times. Observational and community-based research is also strictly governed in terms of permitted participant interaction and informed consent processes. As Wits RHI continues to expand its involvement in research, there is increasing investment in streamlined processes of regulatory compliance. Investment in a transparent environment with greater accountability and better research practices provides research staff with a solid platform on which to conduct high-quality research. The Wits RHI Regulatory Oversight Group is mandated to create, establish and maintain regulatory systems for Wits RHI studies according to the Medicines Control Council, Wits Human Research Ethics Committee, sponsor and Department of Health/City of Johannesburg requirements. In addition, the Regulatory Oversight Group ensures that studies have all essential regulatory documentation in place prior to study start-up, and actively participates in the submission of research protocols for initial and ongoing approval.

Pharmacy support

The Wits RHI Pharmacy Committee (WRPC) provides guidance and support in terms of the pharmacy regulatory requirements of Wits RHI Pharmacies. It works closely with the Wits Number Four (WNF) Compliance Committee, Wits RHI management and internal and external auditors. The WRPC helps develop, establish and maintain pharmacy regulatory systems for Wits RHI pharmacies and ensures compliance with all regulatory and government requirements. WRPC also provides support to relevant staff for the completion of South African Pharmacy Council (SAPC), DoH and other regulatory authority applications. Members collaborate around the ordering and collection of concomitant medications from DoH and address any issues that arise. The WPRC provides guidance to Wits RHI management on pharmacy regulatory requirements and addresses queries from the SAPC and other regulatory authorities as well as from internal and external auditors. The Committee guides the development and review of regulatory aspects within Pharmacy Quality Management Plans (PQMPs) and assists with the development of relevant...
Standard Operating Procedures (SOPs). It assists in the conduct of preparatory audit assessments prior to major pharmacy audits and reviews pharmacy performance for monitoring and audit reports.

The Wits RHI Laboratory Oversight Group (LOG)

Wits RHI’s laboratory and pharmacy facilities are supported by a laboratory oversight group (LOG) which was formed in late 2013. The LOG provides technical advice on set-up of laboratory testing in keeping with required study protocol regulations and regulatory/sponsor requirements. It provides guidance to site management on lab operations, staff allocation, back-up plans and recruitment, and monitors outsourced service providers. The LOG guides the development and review of Laboratory Quality Manuals and Lab Standard Operating procedures and helps sites prepare for audits or monitoring visits. LOG team members assist with study-specific lab training and technical advice as required by study PIs, project or programme managers.

Research capacity-building

Research is a core function of Wits RHI, from the investigation of interventions to protect and care for patients to an understanding of the factors that put people at risk of contracting HIV and related infections. RHI strives to increase its research output and significantly contribute to the body of knowledge around these issues, and as an institute has an obligation to the University of the Witwatersrand to be highly productive with regards to generating research publications and encouraging staff to pursue postgraduate studies. In addition, RHI’s research portfolio is extremely extensive, requiring formal plans and policies regarding how best to manage the growth in the number of research projects whilst maintaining efficiency and upskilling research staff.

Thus, in the second half of 2013 a five-pronged capacity-building strategy for supporting RHI researchers was articulated and implemented, after an extensive process which analysed the existing systems and identified areas for improvement. The strategy’s main focus in 2013 was to increase the number of academic publications, particularly articles in academic journals. Activities included support for staff enrolled in PhD programmes, such as a PhD handbook, which was produced as a supplementary resource for RHI staff pursuing advanced degrees, and the establishment of regular journal clubs to encourage the review of relevant articles in academic literature. Several workshops on manuscript writing were held, giving staff the opportunity to strengthen their scholarly writing skills. Staff were encouraged to present their work at local and international conference proceedings. In 2013 21 RHI colleagues were pursuing postgraduate degrees, with two graduates in that period, and in 2014 there were 27 postgraduate students among the staff with two more graduations. The success of this renewed investment in developing accomplished and productive researchers was recognised at the end of 2013 by scientific advisory board assessment and in 2014 by a successful faculty quinquennial review, and the research capacity-building programme will continue to cultivate these scarce and necessary skills within RHI.

“...The research capacity-building initiative is an incredibly important set of activities. It signals our maturation as an institute, as we increasingly recognise the need to tell the story of the work that RHI does in the academic environment. And we are doing this by growing our research output and publishing our work.”

– Dr Sinead Delany-Moretlwe, Director: Research Programmes
Wits RHI Research Outputs for 2013/14

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<tr>
<th>Year</th>
<th>Oral Presentations</th>
<th>Publications</th>
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<td>2014</td>
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The pharmacy within RHI’s research centre
Community engagement in research

One theme that consistently emerges during clinical trials and other research studies is the need to work closely with the community throughout the duration of the study. The willingness of trial participants to commit to several years of ongoing involvement can strongly influence the quality of the data obtained during the study.

Wits RHI works at several levels to engage community members, with the aim of creating a lasting benefit for them that extends beyond the duration of the trial.

One mechanism for linking researchers and the community are community advisory boards (CABs), which are representative groups of stakeholders who meet to discuss issues around current research studies. Any proposed research must be presented to the CAB, which not only creates a group of people who are very knowledgeable about clinical trials, but also provides information which can be passed on to the broader community to alleviate any concerns.

Typically, approximately 15 people will sit on a CAB, which will meet once a month to discuss issues such as community feedback regarding the trials, recruitment, retention
challenges and strategies and the dissemination of information or results. The members of a CAB will be drawn from the community as well as special interest groups and trial participants who wish to sustain their involvement. The system allows for robust criticism of the research process and provides vital feedback that informs the planning and implementation of future studies. Currently, Wits RHI works with four CABs: a prevention CAB, a treatment CAB, a youth and adolescent CAB and a sex worker CAB.

“CABs are important, not only in the practical sense but also as a symbol of the fact that clinical trials are not about inaccessible teams of doctors and scientists but rather, about the people in the community.” – Dr Jonathan Stadler

Another way of engaging with community members is through community radio shows. Until 2014, Wits RHI hosted its own radio show, Tshireleloso Health Talk. This innovative method of connecting with individuals interested in health issues, as well as those affected by clinical trials, was pioneered by RHI, which is the only South African research institute to use this method of communication. The once-weekly radio show discussed new and ongoing clinical trials and encouraged people to enrol, providing information on the trials and creating a sense of legitimacy around each study. People could phone in and ask questions, which is a powerful platform for stimulating debate and addressing concerns. The show reached approximately 55 000 – 70 000 listeners in the Johannesburg inner city.

Lastly, the trials themselves create a conduit for researchers to work with participants to address broader health concerns and assist with psychosocial issues that affect the men and women who enrol in RHI studies. RHI staff facilitate counselling sessions with participants and their partners on issues such as family planning and intimate partner violence, and create networks between participants, linking them up over mobile phone-based social networks for mutual support or even social interactions like baby showers. Although the initial impetus in doing so was to retain participants in the trials by addressing issues that could lead to non-adherence or loss to follow-up, the sense of trust and connection created between RHI staff and community members has led to a culture of continuous engagement. It highlights the powerful commitment from RHI to address all health challenges encountered and the role played by the institute in bettering the lives of South Africans.

“ It’s not a nine-to-five job. Our phones are always on and people know that they can contact us at any time with questions and concerns. It is hard work but it is incredibly motivating and rewarding to know that we play such a large role in improving people’s lives above and beyond the scope of their participation in the trial.” – Dr Thesla Palanee-Phillips, Director: Clinical Trials
List of active donors in 2013/2014

Wits RHI is privileged to work with so many generous and prestigious donors. We gratefully acknowledge the support of the following beneficiaries:

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