



ITHEMBA!



March 2007 Volume 2, Number 1



EDITOR'S NOTE

Welcome to our first *iThemba* issue for 2007. With a new year, comes a brand new look and the promise of another exciting year in the HPRU.

2007 had a disappointing start with the premature closing of the Cellulose Sulphate microbicide trials. This follows the termination of SAVVY trials in Nigeria and Ghana in 2006. This has certainly come as a blow to the microbicide field, but researchers are committed as ever to finding a safe and effective product to protect women against HIV.

Despite this set-back, 2007 promises to be a landmark year, with results of the Phase III vaginal diaphragm trial and completion of the first Phase III microbicide trial expected mid-year. You can be sure that the *iThemba* team will be there every step of the way.

In this issue, we feature the completion of the MIRA phase III diaphragm study, and bring you news and pictures from World AIDS Day activities and other recent events. In "A Day in the Life", Zakir walks in the shoes of a fieldworker tracking participants' homes in sometimes treacherous conditions. A huge "Congratulations" to Gita Ramjee and the MRC for being named a Clinical Trial Unit by the NIH.

We hope you enjoy the first issue of *iThemba* for 2007, and look forward to sharing future news and achievements with our readers.

- Melanie Mills and Zakir Gaffoor

In this Issue

Editors' Note
Pg 1

Features
MIRA Trial draws to a close – HPRU celebrate the completion of a Phase III trial of the vaginal diaphragm for HIV prevention
Pg 2

HPRU Research Day 2006
Pg 2

World AIDS Day – Stop AIDS: Keep the promise
Pg 6

A Day in the Life...
Coming face-to-face with the challenges of fieldwork in developing country sites
Pg 3

Upcoming Events
Pg 2

Recent Events
Pg 7

Staff Corner
Pg 7

ANNOUNCEMENT

MRC HPRU NAMED AS NIH CLINICAL TRIAL UNIT

The South African Medical Research Council (MRC) has been named as one of twelve institutions globally by the US based National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to be an HIV/AIDS Clinical Trial Unit (CTU) for the Microbicide Trials Network (MTN).

Other CTUs affiliated to MTN are located in Africa, India and the United States. The CTUs will engage in multi-centre studies spanning 17 locations in seven countries that seek to determine if topical microbicides can help prevent the sexual transmission of HIV in women. The MRC CTU, under the leadership of Prof Gita Ramjee, consists of three clinical research sites in Durban, KwaZulu-Natal.

"The MRC is proud to be part of this global network," said Ramjee, "and we are committed to continuing our work in partnership with communities, stakeholders, NGOs and other research organisations in finding HIV prevention options for women." The MRC CTU has been named "Sindawonye Clinical Trials Unit". Sindawonye is the isiZulu word which means "we are together" and embodies our commitment to working together in the fight against HIV and AIDS.

A complete listing of the newly funded CTUs and clinical research sites are available at <http://www3.niaid.nih.gov/about/organisation/d aids/Networks/d aidsnetworkunits.htm>
For more information on MTN, see www.mtnstophiv.org

- Melanie Mills

FEATURE

March 2007 Volume 2, Number 1



Above: Ntombifuthi Mnyandu, clinical trial nurse shares some of her experiences from site

HPRU RESEARCH DAY 2006

25 years into the HIV/AIDS epidemic, the field of HIV prevention clinical trials, and in particular, Phase III microbicide clinical trials, is still new territory. There are currently 5 microbicide products in Phase IIb/III trials globally. Majority of these trials are conducted in Africa, with 4 of the products being tested here in South Africa by the HPRU across 6 research sites. In addition to microbicide trials, the Unit has recently completed a Phase III trial of the vaginal diaphragm to prevent HIV infection amongst women, and is also conducting a treatment trial at acute HIV infection. The Unit has screened 1200 women and enrolled over 5000 women to date in Phase II/III trials.

Conducting Phase III clinical trials of vaginal microbicides and other prevention technologies in a developing country poses several important and complex challenges. Included in these challenges is the issue of high HIV prevalence, high incidence of pregnancy, problems relating to gel adherence, male involvement, co-enrolment in other trials, stigma and disclosure, standard of care, access to health care facilities and uptake of health care referrals. Many of these challenges pose potential barriers to meeting recruitment and retention targets, as well as primary and secondary study outcomes. Being confronted with a variety of challenges has mobilised clinical trialists to develop novel strategies to overcome these potential barriers, and in so doing, ensuring successful implementation of the study protocol.

Case studies from HPRU clinical trials were presented at their annual Research Day held in November 2005. The aim of the workshop was to share challenges both unique to particular studies, as well as generic challenges across protocols, with the aim of facilitating discussion and development of strategies to overcome these challenges.

- Melanie Mills

FEATURE

MIRA TRIAL DRAWS TO A CLOSE

HPRU staff celebrated as the last participant completed follow up in the Phase III vaginal diaphragm trial



Smiles and celebration marked the completion of the MIRA (Methods for Improving Reproductive Health in Africa) Phase III diaphragm trial. The trial, sponsored by the University of California, San Francisco and in collaboration with Ibis Reproductive Health, University of Zimbabwe, Perinatal HIV Research Unit at Chris Hani Baragwanath Hospital, Johannesburg, and Medical Research Council, aims to assess the effectiveness of a latex diaphragm in preventing HIV infection in women.



The MIRA trial began in 2003 at 2 HPRU sites: Umkomaas (south of Durban) and Botha's Hill (inland of Durban). Other sites included Zimbabwe and Johannesburg.

A total of 5045 women were enrolled in the trial, 1515 of who were enrolled at the 2 HPRU sites.

- Read more on Page 5

Left: The Ortho All-Flex latex diaphragm used in the MIRA trial



Above: The spectacular, scenic countryside of the Valley of a Thousand Hills – one of the rural areas in which research participants live

COMING FACE TO FACE WITH THE CHALLENGES OF FIELDWORK IN DEVELOPING COUNTRY SITES

Battling heat, humidity, and poor road conditions, Zakir Gaffoor becomes a Fieldworker for a day...

A day in the life of the fieldworkers at HPTN 035 microbicide trial site in Chatsworth (Durban south) begins much like anyone else's at the HPRU - the 30-minute drive to site, a quick morning cup of tea and maybe breakfast, some discussion about the days activities, and anticipation of the challenges that lie ahead. Challenges in far-flung locations, across the rolling green hills of our province, and accessed via very, very bad roads. If there is any doubt as to the need for 4 X 4 vehicles, a drive into the locations where participants are recruited from will quickly dispel any such doubts. When confronted with steep, rain-driven dirt roads with sheer cliffs on either side, one could be forgiven for thinking that the only way to get to the participants house is to parachute in!

Bad roads aside, it remains a challenge locating participants' homes, even with the use of GIS/GPS technology that is currently employed in mapping participant locator information. As part of the screening

stage of the study, fieldworkers are often requested to confirm that locator information given by the participant is correct. In the absence of formal street names and house numbers, the only way to verify locator information is to follow the directions given by participants themselves and verify its authenticity. Once located, the participant's home is mapped using GPS, enabling fieldworkers to navigate their way back to her house for home visits when needed. This was the task at hand on this 32 ° C, humid January day.

Our first stop is Botha's Hill, a rural area and the location of the HPRU MIRA trial. Accompanied by fieldworkers Saziso Dlamini, Thami Ngema, Ayanda Khwenkweza and driver Msawenkosi Nxumalo, we attempted to locate the home of a participant. The drive there passes scenic green countryside, part of the spectacular Valley of a Thousand Hills, where the participant's home was finally

located and confirmed. Our driver Msawenkosi seemed unperturbed by the narrow, pot-holed dirt roads and sudden, startling appearance of cattle nonchalantly standing in the way. With great skill, and even greater

“We are the frontline for the HPRU. The first thing people see or hear about the trials is from us the fieldworkers”.

A DAY IN THE LIFE

March 2007 Volume 2, Number 1



Local children collecting water in a rural area of Botha's Hill

humour, he successfully guided the vehicle through these obstacles and seemed to enjoy being part of the fieldwork process.

The next stop was Magabheni Township not far from Umgababa, approximately 90 km south of the HPTN site in Chatsworth, where another participant's locator information was confirmed. Following a refreshment stop in Amanzimtoti, we hit the road again in search of a participant who had missed a visit. Her locator information for a hostel in Lamontville Township was sketchy at best, and the fieldworkers had to stop frequently to ask directions from local people on the road. The hostel itself, once finally located, was known anecdotally as a crime-ridden, dangerous place, yet the fieldworkers are prepared to take the risk in order to complete the job at hand. The woman in question was not available, but fieldworkers managed to speak to her sister, whereupon they concluded that a second home visit may be necessary.

From the dusty streets of Lamontville Township, it was back to the low-income housing area of Wellbedacht near Chatsworth, where we again faced the challenges of locating participants' homes. Saziso and Thami spoke often about the "behind-the-scenes" role they play in making the HPRU trials a success. Said Thami, "We are the frontline for the HPRU. The first thing people see or hear about the trials is from us the fieldworkers". Saziso and Ayanda agreed with their colleagues, and I got a first hand look at just that, when they passed a group of young women on the road. Msawenkosi stopped the vehicle, and the guys got out to speak to the women about recruitment into the HPTN trial. Although the attempt was unsuccessful (most of the women were under the age of eighteen and still in high school), it demonstrated the vital role fieldworkers play in informing communities about the trials, and recruiting potential participants. At some point, after meetings with leaders, community groups, chiefs and other stakeholders, it remains the task of fieldworkers to actually go out and speak to the people at grass roots level.

It is heartening to see their work being done in such a friendly, professional manner, attributed in part to the extensive and on-going training that they undergo through the HPRU. Despite the challenges of weather, bad roads, crime and often inadequate locator information, it is clear that our fieldworkers are prepared to go the extra mile in bringing the study to the people. Finally, after a long day spent driving between participant's homes, the fieldworkers returned to site with the satisfaction of knowing that, despite many challenges, they will return tomorrow, and the day after that, and the day after that, until they have successfully recruited and followed up every woman.

- Zakir Gaffoor



Above: Fieldworkers Sasizo, Thami and Ayanda try to locate a participant's home in a rural area near Botha's Hill



Above: Fieldworkers Sasizo, Thami and Ayanda conducting a home visit in Magabeni Township

FEATURE

March 2007 Volume 2, Number 1

MIRA TRIAL DRAWS TO A CLOSE

- Continued from Page 2

Benefits of Covering the Cervix

Several existing studies suggest that the cervix is a “hot spot” for numerous STIs, many of which likely facilitate HIV transmission. Most importantly, new evidence points to the cervix as the site for most HIV infections as well. Therefore, the cervix may benefit from the type of protection a diaphragm could offer. In addition, diaphragms are woman-controlled and can be used clandestinely when women are unable to negotiate male condom use. They are also inexpensive, simple, reusable, accessible, acceptable, and stable under any environmental conditions, imposing no disposal problems and little difficulty with cleaning and storage.

The study is currently in the data cleaning stage, with the first set of results expected in June 2007.

Speaking on behalf of Ibis Reproductive Health, Naomi Lince said “Implementing a phase III HIV prevention trial requires the enthusiasm and dedication of not only researchers, clinic and support staff, but also thousands of trial participants. As the MIRA trial comes to a close, the Monitoring Team from Ibis Reproductive Health would like to express its gratitude to all who contributed.”

A Celebration

Successfully recruiting and following up 1515 women over 3 years with a retention rate of over 90% is a huge achievement. In recognition of the hard work and dedication of the MIRA team, a celebration was held at the HPRU. The research teams from Umkomaas and Botha’s Hill sites attended, along with HPRU Unit staff, Naomi Lince and Tanusha Mudlay from Ibis Reproductive Health. Gita Ramjee (study Principle Investigator) presented the Project Leaders and Co-ordinators with commemorative trophies, and the entire study team each received a framed, engraved team photograph.



THE HPRU MIRA TEAM

With Naomi Lince and Tanusha Mudlay from Ibis Reproductive Health front right seated and 2nd row far right respectively)

In a heartfelt speech, Gita Ramjee dedicated the trial to the memory of dear friend and founder of Ibis reproductive Health, Charlotte Ellertson who died of cancer in 2004. “Charlotte dedicated her life to improving the reproductive health of African women, and seeing this trial to fruition is a shining example of her commitment to the lives of women,” said Ramjee. “Regardless of the outcome, Charlotte would have been proud of the contribution this trial has made to improve the reproductive health and education of women in Africa,” continued Ramjee.

Sharika Gappoo, Project Leader at the Umkomaas site, has been involved in the trial since it began in 2003. “Working on MIRA trial for the last three years has been a wonderful experience”, she said. “A great deal has been accomplished in the trial and in working with the two different communities. The teams at each site have changed over the years however their hard work and dedication throughout has paid off in ensuring a very successful clinical trial”.

For more information, visit www.wghi.org/research/mira.htm

- Melanie Mills



Gita Ramjee and Botha’s Hill site Project Leader, Sarita Naidoo



Gita Ramjee and Umkomaas site Project Leader, Sharika Gappoo



Gita Ramjee and Umkomaas site Co-ordinator, Kureshnee Reddy



Gita Ramjee and Botha’s Hill site Co-ordinator, Nonqubela Bantubani



Gita Ramjee and Botha’s Hill site Co-ordinator, Nonhle Mtungwa



Above: A candle in the shape of an AIDS ribbon burns brightly as a symbol of hope in finding an end to the HIV and AIDS epidemic

WORLD AIDS DAY

Highlights from World AIDS Day activities in the HPRU

2006 marked the 18th anniversary of World AIDS Day, first commemorated in 1988. Dedicated to raising awareness of the epidemic, this year's theme was Stop AIDS: Keep the Promise – Accountability, reminding us that we are accountable for our own actions.

For the HPRU, World AIDS Day is part of our everyday lives. Each day, our teams are out in the field spreading HIV and AIDS awareness messages in the community, and encouraging people to volunteer for HIV testing. But 1 December, World AIDS Day, is special. We dedicate this time to remember colleagues, friends and families who have succumbed to this disease. We focus our thoughts on the hundreds and thousands of men, women and children who are dying of AIDS on a daily basis.

In commemoration of World AIDS Day 2006, the HPRU held a candle-lighting ceremony in memory of colleagues, friends and loved-ones who have been lost to AIDS. The ceremony, held simultaneously at our offices in Westville and our research sites throughout KwaZulu-Natal, reminded us all of the importance of knowing your HIV status and seeking treatment.

Gita Ramjee addressed staff via video message from Italy, offering words of encouragement and motivation for the important work of the Unit in curbing the epidemic.

Members of the HPRU Wellness Team spoke to staff about the facilities available within the Unit for VCT, counselling and treatment, as well as sharing their personal stories of stigma, disclosure, empowerment and living positively with HIV. Interspersed by songs and poetry, the programme culminated in a ceremonial candle-lighting in memory of loved ones and colleagues lost, and in hope of finding a prevention method to protect all South Africans from HIV infection.

Members of research teams then went out into the community educating people on HIV prevention and dispensing information leaflets and condoms. Various staff members gave talks at community World AIDS Day meetings on the importance of knowing your HIV status, the use of condoms and living with HIV.

- Melanie Mills



Above: HPRU Wellness Team member, Thabo Cele addresses staff at Westville



Above: Thandi Sithole and Thembeke Nkala (Peer Educator) lighting the AIDS candle



Above: HPRU staff spreading HIV and AIDS awareness messages in Klaarwater community

UPCOMING EVENTS

March 2007 Volume 2, Number 1



3rd South African AIDS Conference
 5-8 June 2007, Durban, South Africa.
 The 2007 AIDS conference aims to serve as a platform for deliberations on the key contentious issues relating to prevention, treatment and care.
www.sa-aidsconference.com



The 4th IAS Conference on HIV Pathogenesis, Treatment and Prevention
 22-25 July 2007, Sydney, Australia
www.IAS2007.org

RECENT EVENTS

HPRU MASKED BALL held at Durban Exhibition Centre



STAFF CORNER



Congratulations to Rashika Maharaj and Zakir Gaffoor who achieved academic milestones in 2006. Rashika (*pictured left*) completed her Bachelor of Technology *cum laude*. Her majors were Molecular Biology, Integrated Pathophysiology, Laboratory management and Research Methodology.



Zakir Gaffoor (*pictured right*) obtained his Masters in Medical Science from the University of KwaZulu-Natal, South Africa.



Remember – we welcome your comments and suggestions.

For further information or questions regarding the stories in this publication, please contact the editing team Melanie Mills and Zakir Gaffoor at ithemba@mrc.ac.za