Madibeng Centre for Research

Annual Report 2011

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1. Message from the Chairman of the Madibeng Centre for Research Board of Trustees

Dear Colleagues, Research Partners and Members of the Community

It is with pleasure that we are writing our very first annual report for the Madibeng Centre for Research (MCR). This institution is now 10 years old and has achieved much of what we had set about doing right at its inception.

In 2000 and 2001 there was much thinking and talking about how to ensure that South Africa obtains a comprehensive healthcare system, where preventative healthcare would play a key role at district level in ensuring the health of local communities. Prof Jannie Hugo and I had many insightful discussions around this topic and realised that this was an opportunity to establish a research institution right in the heart of a semi-rural community. This institution was to become the heart and source of information to the public and private health sector through the research it conducted. At that point most health research was conducted at academic institutions and remained the property of those institutions. Here was the opportunity for a bottom-up approach where communities would work together, taking ownership of the process of research and becoming the custodians of their development based on findings of research conducted at this centre. The MCR is ideally situated to make a difference in the Madibeng community by informing this community and the North West Province through the research it conducts.

The inception of the MCR came at a time when a community that was destined to be removed from its location, organised itself through the Oukasie Development Trust. The MCR formed a partnership with the trust to focus on the real need of the people. Through this collaboration other role players became involved in the process of research and development including the Brits Industrialist Association, the Transitional Local Council of Brits, and various universities and medical fraternities.

The MCR is situated in the heart of the Madibeng community and is independent of any academic institution. As such it is free to partner with any medical fraternity to conduct its research. It is not run by any government body or other institution, though it seeks to work with these role players in obtaining its objectives in health research. It aims to inform these institutions to ensure that key district and even national health decisions are based on accurate information obtained through quality research. Comprehensive healthcare should thus include, as a cornerstone of its practice, a collaboration with local research institutions to ensure that plans and policies are based on sound information. Such policies and plans should continuously be re-evaluated to facilitate a method of improving the quality of its overall health plan for the relevant districts. It is here where a community-based research centre, such as the MCR, can make a difference and secure better and adequate healthcare for its local community.

Over the past 10 years the MCR has sought to create, strengthen and maintain partnerships with many levels of society. It has created a good example of a social compact through its interaction with the entire community. The MCR is a people-centred organisation, liaising with the local community and its

leaders, the district and provincial health systems, medical fraternities, non-governmental organisations, non-profit organisations, business and other research partners. It is energised through these relationships and seeks to deliver its best in even the toughest of circumstances. The MCR is an organisation we, as the Board of Trustees, are proud of.

As such, we at the MCR, have the following mission:

A community-based centre that conducts high quality comprehensive health research for the local community and our business, scientific and administrative partners.

Our vision is to be: **A sustainable, community-based health research centre of international repute.**

We believe that we have certainly lived up to these statements. We intend to grow in our expertise as an organisation, benefiting our local and national community through the work we do and the knowledge we gain through research.

We invite you to read our annual report and enjoy it. We hope you will be as proud as we are of this fledgling organisation that has grown so much over these past 10 years.

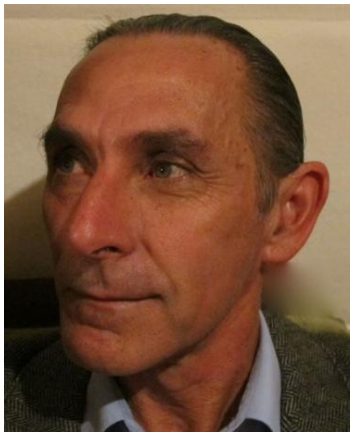
Yours sincerely,

Jacob Moatshe

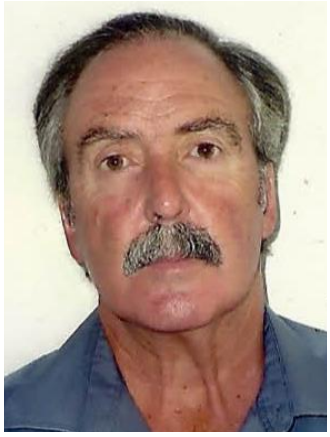
Chairman of the Board of Trustees

Board of Trustees

Prof Ian Couper



Prof Jannie Hugo



Bert Badenhorst

2. Background and Introduction

2.1 History

2011 saw the Madibeng Centre for Research celebrating its 10th anniversary. This was a momentous occasion as the MCR had some uncertain days at its inception with a future that was rather unclear. The history of how the MCR began has never been coherently recorded and now requires documentation for all to know how this organisation came to be and for the centre to consider its past and chart a course into the future.

In 1999 MEDUNSA undertook to establish learning districts for the North West Department of Health. Community-based research was viewed as the vehicle to establish these learning districts. Learning districts were meant to be focal points where research related to local community health would be conducted to inform policy makers and guide public health decision making. At about the same time, the Diarrhoeal Pathogens Research Unit (DPRU) at MEDUNSA started researching the Rotavirus. Brits was identified as the ideal location away from the academic institution to study the virus at community level, but there was a shortage of capacity to do the work. Potential existed in the Madibeng community, but people lacked training and knowledge. It was decided to establish a research organisation in the Madibeng district in Brits, where people could be trained and equipped to conduct research. However, this research organisation was to be independent of MEDUNSA, as well as other academic, government and bureaucratic institutions. It was to be a research organisation by the people, for the people.

In August 2001 the search started for research cadets to work on this project. More than 300 applications were received and 25 candidates were selected. The Madibeng Centre for Research (MCR) was born in September 2001 and started work, but the organisation was not yet registered. Collaboration began with the Brits Industrial Association. A research trust was established and the MCR was registered as a non-profit organisation with the Oukasie Development Trust as its initial sponsor. The concept of this research unit was supported by the Madibeng municipality, but the MCR was not seen as part of the municipality.

The MCR was formed with the initial aim of developing young people from the Madibeng district in research activities. The 25 research cadets were trained in research principles and methods. The cadets had no prior work experience and had to be taught to work professionally. The MCR trained them so well that many are now researchers at other established research units. The cadets did small studies in teams. No salaries were initially paid as the MCR had no funds. Lunch was provided and transport costs were later paid.The challenge remained to find projects with sufficient funds to build the staff complement and offer job security.

The MCR had no home to call its own at its inception. Mr Jacob Moatshe, who served on the Brits Hospital Board, arranged temporary use of the old nurses' home at the Brits Hospital. In 2003 the hospital required the space because of a growing staff complement. A park home was purchased and set up at the back of the hospital. Three years later the hospital was broken down to construct a new facility. The MCR had to remove its park home from the hospital premises. The park home was taken to

Bertoni Clinic where it was used for a large Rotavirus vaccine study. A sponsor assisted with the purchase of a house in Pienaar Street in October 2006. The MCR is still based there and has since conducted various important clinical trials on the premises. In 2010 the park home was moved back to Brits, behind the property in Pienaar Street. It was used to conduct clinical trials into new TB treatment regimens.

The park home where the MCR was based between 2003 and 2006

The house in Pienaar Street where the MCR has been based since 2006

The MCR has collaborated with several universities during its first 10 years. The centre first worked with MEDUNSA's Department of Family Medicine. Prof Jannie Hugo, Prof Ian Couper and Dr John Tumbo

were involved. Prof Couper moved to the University of the Witwatersrand and involved the Wits Rural Health Department. Prof Hugo accepted a position at the University of Pretoria and the University's Department of Family Medicine began working with the MCR.

The MCR has also worked with mines in the area including Hernic Ferrochrome, Lonmin Plc and others. Several studies were done for the industrial sector in the town. Per request the MCR also conducted research for the North West Department of Health into healthcare services and HIV/AIDS care.

2.2 Staff

The MCR currently has 24 staff members — 13 lay people and 11 skilled personnel. The staff includes medical doctors, scientists, nurses, recruiters, counsellors and administrative personnel. The organisation has since March 2010 been run by a three-member management team: Dr Cheryl Louw, Principal Investigator, Sister Marthie de Villiers, Site Manager, and Lizeth Ferreira, Accountant. The MCR is also governed by a Board of Trustees — Jacob Moatshe (Chairman), Prof Jannie Hugo (Vice-chairman), Prof Ian Couper and Bert Badenhorst.

The MCR staff between 2004 and 2005

The MCR staff in 2009

Several people have made a significant contribution to the achievements of the MCR. Wilhelm van Deventer was the first Manager of the centre. He was followed by Dr John Tumbo, Monica Tumbo, Sivaan Mari and Prof Ina Treadwell. Dr John Tumbo was the first Principal Investigator at the MCR and trained many recruiters. He also built the capacity of the centre to conduct clinical studies. Marije Versteeg, a Social Scientist, led many projects at the MCR between 2003 and 2007. Margaret Hugo, the previous Site Manager, improved the management of clinical trials significantly and managed the Rota-037 study. Prof Ina Treadwell was the centre's first Project Manager and managed the IPM studies. She brought more professionalism to the MCR and with Sr de Villiers co-developed many of the standard operating procedures now used at the MCR. The current team is building on the solid foundation laid by these individuals.

2.3 Capacity

Over the years, the MCR has built extensive expertise in a wide range of health-related research areas including:

- Community and District Health
- Clinical Trials
- Quality of Care
- Behavioural Research
- Epidemiology
- HIV/AIDS in the Workplace
- Monitoring and Evaluation

Exploratory, descriptive, explanatory, comparative, and intervention studies are done at the MCR. Data collection techniques include desk top research, observational research, focus group discussions,

interviews, questionnaires, physical examinations, and sample taking and testing as required per study protocols.

The MCR conducts clinical trials and social research. The clinical trials completed by the MCR to date have focused on paediatric vaccines, novel hypertension treatments, treatment comparisons for new TB treatment regimens, new HIV prevention methodologies, and oral candidiasis treatment. Social research includes studies on community and district health, quality of care, behavioural research, epidemiology, HIV/AIDS in the workplace, and evaluation of HIV/AIDS programmes.

The centre has 18 equipped rooms. It has a drug storage room with secure study medication cupboards where the temperature is controlled. Documents and participant files are stored in lockable cupboards in the data room. The centre has three equipped clinical examination rooms, including a multipurpose room. There is also a blood sampling room and two counselling rooms. The centre has a small laboratory where blood samples are processed for shipping to larger laboratories for analysis as well as facilities for short-term storage of samples at -40°C or in a refrigerator. The centre boasts adequate space for monitoring while trial activities are ongoing. Emergency facilities include two emergency boxes equipped with drip sets and emergency medication, two hospitals within 500m of the site, and ambulance services based across the road from the site. Study medication and other medication, e.g. STI treatment is dispensed by either the Pharmacist or the Principal Investigator, who has a dispensing licence. The MCR is well-equipped for clinical trials due to its infrastructure and experienced personnel. It is also ideally situated for taking care of emergencies and is easily accessible by participants.

Staff members at the MCR are experienced researchers and have conducted several clinical trials. Principal Investigator, Dr Louw, has eight years' experience as a clinical researcher. Since 2003 she has participated in 11 clinical trials: three Phase III trials, five Phase I/II trials, an epidemiological study, a new dosage formulation study, and a Phase III trial researching new TB treatment regimens. She served as Co-Investigator on five of these trials (two Phase II trials, two Phase III trials and an epidemiological study) and served as Principal Investigator on the remainder. Sr De Villiers, Site Manager, has 13 years' experience in clinical research.

Dr Keith Michael, a Co-Investigator, has 2.5 years' experience in clinical research. He was a Co-Investigator on two Phase I/II trials between 2009 and 2010, and Co-Investigator on a Phase III trial researching new TB treatment regimens.

Dr J.S. Mangwane is currently a Co-Investigator on a Phase III trial researching new TB treatment regimens. The trial started in November 2010. Hanlie Veldsman is a Pharmacist who has been working on three Phase I/II clinical trials since Jan 2010. She is currently a Pharmacist on a Phase III trial researching new TB treatment regimens.

All staff is regularly trained on the International Convention on Harmonisation of Good Clinical Practice (ICH-GCP) and has learnt to work according to ethics guidelines as described in ICH-GCP on all their trials. The MCR staff also adheres to ethics guidelines, regulations and laws as described by the Declaration of Helsinki, the South African Good Clinical Practice guidelines, the South African Health Act and the Food and Drug Administration (FDA) requirements. Staff ensures that their studies are

conducted ethically and in a manner that safeguards patient confidentiality, safety, and the integrity of data. Staff members have built their capacity in various areas pertaining to the effective conduct of clinical trials including data management, electronic data capturing, internal quality control (QC) of lab procedures, rapid tests, and external QC procedures.

3. Research Studies

The MCR has conducted a wide variety of research studies in the last 10 years. These include clinical trials, social research and epidemiological studies.

3.1 Epidemiological studies

The MCR has conducted two epidemiological studies. Between 2002 and 2008 the MCR, together with the Diarrhoeal Pathogens Research Unit (DPRU) at MEDUNSA, completed a burden of disease study in Brits. The aim of the study was to determine the prevalence of the Rotavirus that causes diarrhoea in infants under the age of two, mostly in winter in South Africa's Highveld region. Stool samples were collected at the Brits Hospital and the Oukasie Clinic. The study confirmed that there is Rotavirus in the area and that the peak Rotavirus season lasts from March to July.

The MCR conducted the IPM 100 study between April 2007 and July 2008. The aim of the study was to determine the prevalence and incidence rate of HIV/AIDS in five areas in the Madibeng sub-district. The study found that the prevalence rate of HIV in women aged between 18 and 35 years in these communities was 24.6% and the incidence rate was 6%. Several risk factors were identified including low education levels, anal sex, young sexual debut and having multiple partners.

3.2 Social studies

The MCR has conducted several social studies since 2001. Social research includes studies on community and district health, quality of care at clinics, HIV behavioural research, HIV/AIDS in the workplace, and evaluation of HIV/AIDS programmes of mines.

Some examples are:

HIV/AIDS in the workplace (2004-2006)

Various studies were conducted on HIV/AIDS in the workplace, including an assessment of the construction industry's response to HIV/AIDS, which was done in collaboration with Wits Business School, as well as a health-related absenteeism study in a local manufacturing company in Brits.

Wits medical student research training and operational programme (2004-2008)

The aim of this project was to familiarize students from Wits Medical School with health research methods and ethics and to apply this through small-scale HIV/AIDS knowledge, attitudes and practices surveys in various communities of Madibeng. This project took place in close collaboration with the then Rural Health Unit at the University of the Witwatersrand.

Client satisfaction at Brits District Hospital (2005)

This study assessed client satisfaction at the Brits District Hospital by looking at various indicators including tangibles, reliability, accessibility and empathy. It was commissioned by the hospital.

Evaluation of the North West Department of Health HIV/AIDS programmes (2005)

The aim of this study was to evaluate the implementation of the HIV/AIDS programmes (ART, VCT, PMTCT, NPEP, STC, STI, HBC) in the North West Province according to the Provincial Strategic Plan. Assessment took place at provincial government, four regional hospitals, eight district hospitals, eight health centres, eight clinics, clinic clients, as well as 400 household members to determine levels of implementation, barriers and opportunities, and user experiences. The study was commissioned by the North West Department of Health.

Impact of diarrhoea on quality of life of low-income households (2006)

This study, done in collaboration with the University of Pretoria, assessed the impact of diarrhoea in infants on the quality of life of low-income households in a rural township and informal settlement.

Health status of communities around Lonmin PLC: Baseline surveys (2006/2007)

In 2006 and 2007 two research studies were commissioned by Lonmin PLC which aimed to provide insight into the main health problems and needs in the health of communities surrounding Lonmin Plc in the Bojanala (North West) and Lebowakgomo regions (Limpopo). The studies provided baseline information for Lonmin PLC to apply in its corporate responsibility programme and were collaborative efforts between the MCR, NOVA Institute and the University of Pretoria.

Based upon the findings and recommendations of this study in Bojanala the Lonmin mine helped build a clinic in Wonderkop, made improvements at Segwaelane, Marikana and Majakaneng clinics, and initiated a school nutrition programme in the local area as well as a peer education programme to educate people about HIV/AIDS.

Third health survey (2011)

The MCR has recently partnered with Lonmin Plc and Nova Institute for a third health survey of the communities of the area surrounding the Lonmin mine in Marikana. The study is currently under data analysis. This was a follow-up study of the previous study conducted by the MCR in 2005 and 2006. That study had found that the mine's activities did not adversely affect the local community's health and identified various key points where the mine could be involved in contributing to the local community's overall health. As such Lonmin Plc built a clinic in Wonderkop and helped start a clinic-based ARV treatment centre. The mine also started feeding programmes and intensified its efforts in HIV prevention messaging to the local community and its own employees.

3.3 Clinical trials

The clinical trials completed by the MCR focused on paediatric vaccines, novel hypertension treatment, treatment comparisons for new TB treatment regimens, new HIV prevention methodologies, and oral candidiasis treatment.

Between 2001 and 2003 the MCR conducted the Rota 014 study to test the safety of the Rotarix® vaccine, then coded as "RIX4414" on HIV-negative babies in the Madibeng district. Partners in Pretoria and from MEDUNSA collaborated on this effort. Between 2003 and 2004 the centre conducted the Rota 013 study to test the safety and varying dosages of Rotarix® on HIV-negative babies in the same areas. The MCR completed the Rota 022 study between 2005 and 2008 in the Madibeng district to investigate whether the Rotarix® vaccine was safe to use for HIV-positive babies. Again various partners from MEDUNSA and the University of Pretoria collaborated in the effort. Between 2005 and 2008 the MCR completed the Rota 037 study to determine whether the Rotarix® vaccine could prevent infants from being infected with the Rotavirus. Different dosages were used and the study was conducted in Johannesburg, Pretoria, the Madibeng district and in Malawi with the assistance of the MCR's collaborating partners. All of these studies were funded by the Programme for Applied Technologies in Health (PATH) and the vaccine and monitoring services were supplied by GlaxoSmithKline. Together all these studies led to a substantial body of knowledge being created that was able to assist the then Minister of Health in making the momentous decision of including the Rotavirus vaccine, Rotarix®, into South Africa's expanded programme on immunisation (EPI) vaccine schedule. Now all babies in South Africa receive the benefit of this vaccine free of charge at public clinics.

Between 2009 and 2010 the MCR conducted the IPM 014A and the IPM 014B studies to determine the safety of a vaginal microbicide, Dapivirine gel, when it is used daily for a period of six weeks. The microbicide was tested on HIV-negative sexually active women between the ages of 18 and 40 years in KwaZulu-Natal, the Western Cape, Kenya, Rwanda, Tanzania, Malawi and the Madibeng district. The studies also investigated whether Daily Monitored Adherence (a system based on the Daily Observed Therapy used in monitoring TB treatment) could test or validate if women were using the gel as instructed on the study. The study required a lot of manpower as women had to be visited on a daily basis to collect the gels to establish whether they used it. The data is still being analysed, but it has been determined that the gel is safe to use for a period of six weeks.

In 2010 the MCR conducted the IPM 015 study which was designed to assess and compare the safety of a Dapivirine vaginal ring against a placebo vaginal ring when inserted once every 28 days over a 12-week period among sexually active, HIV-negative women between the ages of 18 and 40 years old. 280 women from Tanzania, Kenya, Malawi, KwaZulu-Natal, the Western Cape and the Madibeng district participated in the study. The Dapivirine vaginal ring is a slow release product consisting of silicone mixed with Dapivirine and was developed by the International Partnership for Microbicides (IPM). It seems the vaginal ring is safe to use for a period of three months. It is possible that some women did not keep the ring inserted for the entire time. The vaginal ring and blood samples were tested and in some cases women had very little of the medication in their bloodstream and the vaginal ring contained more medication. The vaginal ring can be used for a month at a time. Each woman on the study was given three rings. The study formed the basis for a safety and efficacy study that will be conducted in 2012 to determine whether the vaginal ring is safe to use for a longer period (up to 2 years) and whether it could prevent HIV.

The MCR is participating, together with several other organisations, in a trial to investigate new TB treatment regimens. The MCR began participating in the REMox TB trial in July 2010 and is expected to

complete its part of the work in 2013. The study is being conducted at 50 sites around the world and 53 patients from the Madibeng district are participating in the study. The trial is testing two new types of treatment combinations and comparing it to the standard treatment for TB.

The MCR has also completed other vaccine studies including two Meningococ vaccine studies. The safety study was done between 2004 and 2005 and the booster study was completed in 2006. The MCR has also evaluated a single-day treatment in recurring genital herpes in immuno-competent patients as well as investigated medication administered alone and in combination in patients with essential hypertension.

4. Community Involvement

The MCR is extremely involved in the community of the Madibeng district. Approximately 95% of the staff members at the centre live in the area. The original 25 research cadets, also from the community, received training and many now work at other research institutions. The research participants also live in the Madibeng area and receive more comprehensive healthcare than they would otherwise be able to access. They also receive health education and benefit from receiving information about HIV/AIDS.

The MCR liaises and works with the Department of Health, district officials, chiefs, and community leaders in the area to get permission to recruit participants for studies from the area. The centre also organises and participates in awareness events such as World TB Day, World AIDS Day and Youth Day. Through such events the centre aims to create awareness among people about their right to access healthcare and provide relevant information regarding protection against HIV infection. In doing so the centre plays a strong advocacy role in the community.

The MCR also holds group sessions in the community where people are educated and informed about HIV/AIDS, women's rights and the value of research. People participating in these sessions include participants in the MCR's research studies. However, the vast majority of people that attend are ordinary citizens with no formal ties to the MCR. Residents make use of this opportunity to ask questions that they cannot always ask at a local clinic.

The centre also has a community advisory group comprising of officials from the Department of Health, staff members from non-governmental organisations, and HIV counsellors from local clinics. The group advises the centre on good participatory practices. They advise the MCR to ensure that the right message about a specific research study is communicated to the community, and that the centre uses a suitable approach when entering the community. The group also provides advice on language use, consent forms, and what challenges could arise during a study.

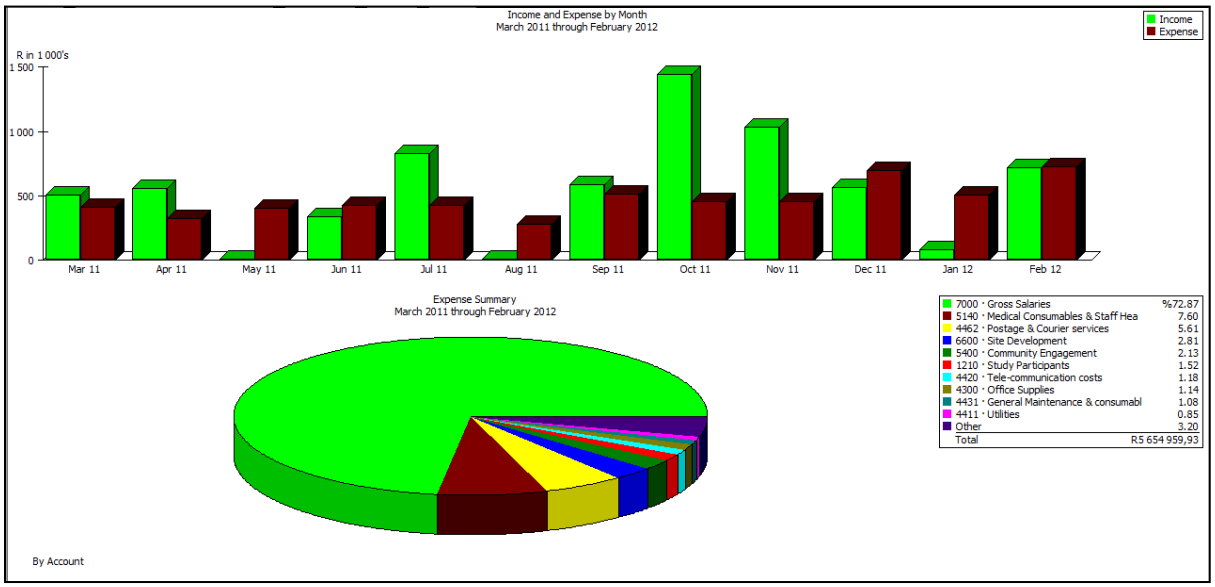
A children's choir performs at the 2011 World TB Day event in Damonsville

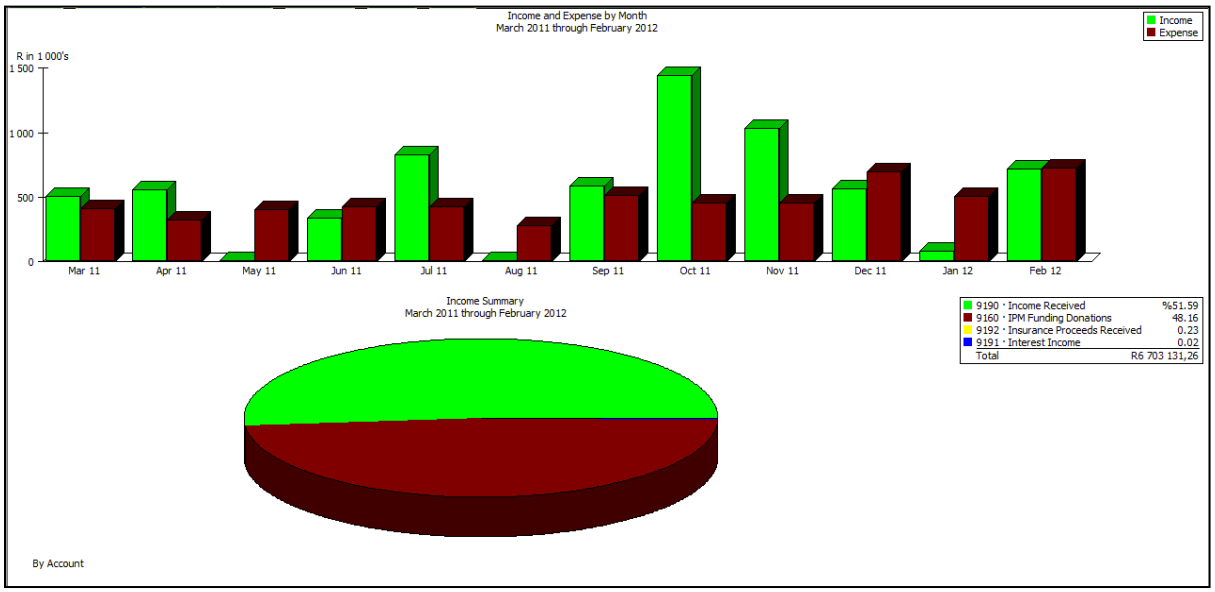
A drama about HIV and TB is performed during the 2011 World TB Day event in Damonsville

A youth choir at the 2011 Youth Day event at Oukasie

5. Funding

The MCR is a non-profit organisation. Prior to 2007 the centre did not have a steady source of income. In 2007 IPM signed the MCR on as a research organisation to which it would contract its research work for as long as the MCR would be able to contribute to IPM's required research objectives. Since 2007 IPM projects have been the main source of income as the centre is paid for work done on these projects. Currently the second source of income is the REMoxTB trial as the MCR also receives payments for work done on this study.





6. Future Plans for the MCR

The MCR is constantly seeking to position itself in such a manner that it can be involved in clinical trials that contribute to broader community health issues such as HIV/AIDS, TB and women's health. General health matters related to hypertension, paediatric health, and sexual and reproductive health are also areas of interest. Across the spectrum of the MCR staff the expertise to work in these areas exists.

The MCR is also seeking to maintain staff with capacity and skills in the area of social research as it is an essential part of research that helps inform the public and private health sector. As such it will also partner with institutions with expertise in this area to ensure the best possible quality research is conducted.

The Board of Trustees remains involved in oversight at the MCR and assists with guiding the MCR through periodic strategic planning. The MCR's Principal Investigator, Dr Louw, also maintains contact with contract research organisations, the pharmaceutical industry and non-profit organisations involved in key public health research to partner with them in future research at the MCR.