



# WHO WE ARE WHAT WE DO

**HIV PREVENTION** 



### **HIV Prevention**

Aurum's work spans the cascade of health care from innovation to implementation, as illustrated below:

Our Model: Bridging the worlds of research, policy and implementation for impact

# Clinical Research Testing the safety and efficacy of new medical products: TB / LTBI treatment, vaccines, diagnostics HIV vaccines, PrEP, treatment, diagnostics COVID vaccines TB / COVID vaccines TB / LTBI treatment, diagnostics Treatment, diagnosti

HIV prevention expertise at Aurum, and its affiliate the Centre for HIV-AIDS Prevention Studies (CHAPS), is centred on two core areas:

- HIV prevention research, including clinical trials of candidate biomedical interventions
- for HIV prevention, and implementation research of novel prevention practices
- 2. HIV prevention services and technical assistance, including work with key populations<sup>1</sup>

'Key populations are defined groups who, due to higher-risk behaviours, are at increased risk of HIV irrespective of local epidemic trends. They include male and female sex workers (SWs); men who have sex with men, including men in prisons and in other closed settings (MSM); people who use and/or inject drugs, (PWUD, PWID); and transgender people (TG)

#### **A. Our Technical Expertise**

#### 1. HIV Prevention Research

Aurum has participated in ten HIV vaccine trials since 2011 and five microbicide trials. It was recently awarded a seven-year grant in 2020 by the U.S. National Institutes of Health (NIH) for a Clinical Trials Unit (CTU) to drive the scientific agendas of two HIV/AIDS Clinical Trials Networks: the HIV Vaccine Trials Network (HVTN) and the AIDS Clinical Trials Group (ACTG). The CTU will implement multicentre studies to find new HIV prevention and treatment options as part of a comprehensive epidemic response.

CHAPS played a pivotal role in the clinical trials that established medical male circumcision as an effective HIV prevention intervention, and in driving national policy to roll out voluntary medical male circumcision (VMMC) as a basic standard of care. It has since undertaken 14 community-based research studies on the scale-up of VMMC in Southern Africa to further scientific understanding of VMMC reach and efficacy.

Aurum undertook several pilot studies on the use of the PrePex device for MMC and found it be both safe and acceptable when used in routine VMMC service delivery.

## 2. HIV Prevention Services and Technical Assistance

In partnership with CHAPS, Aurum has been implementing **comprehensive**, **combination HIV prevention** programmes across the Southern Africa region since 2011.

Our prevention package has evolved over the years as new scientific and social evidence has emerged. Currently it comprises the following biomedical interventions:

- Voluntary Medical Male Circumcision (VMMC) and Early Infant Male Circumcision (EIMC)
- Pre-Exposure Prophylaxis (PrEP)

These services are offered in conjunction with structural and behavioural interventions, including:

- Community education and mobilisation campaigns
- Provision of male and female condom and lubricant
- Health screening
- Risk reduction education and counselling

Our combination prevention programmes consider factors specific to each setting, such as levels of infrastructure, local culture and traditions, and populations most affected by HIV. For example, Key Population services comprise tailored messaging and community engagement through peer networks, preferred service modalities (outreach over fixed site) as well as peer-led interventions such as PrEP clubs.

#### 2.1. Community Education and Mobilisation

Aurum sub-contracts specialist service providers to develop and/or implement initiatives that are tailored to specific target populations using suitable messaging and media platforms to create community dialogue, shift social norms, promote protective behaviour, and reduce stigma.



Most recently, this role has been fulfilled by Community Media Trust (CMT) who have implemented the following campaigns and programmes with priority populations, which expand on the work started under the DREAMS<sup>2</sup> initiative for adolescent girls and young women (AGYW):

- Families Matter! parenting program, for parents and other primary caregivers of preadolescents
- Social asset building through the Girls Clubs Initiative, a model for empowering AGYW
- Stepping Stones, a workshop-based programme for young people, designed to shift social norms around gender, sexuality and HIV, and to decrease gender based violence (GBV)
- Man2Man programme (M2M), which draws on Stepping Stones methods and content but targets men to promote HTS, VMMC, and condom use; and shift gender norms to reduce GBV
- The AS'BANGENE community mobilisation campaign to promote HIV prevention behaviour among young people, and support those with HIV to ensure that they attend clinic appointments and take their

medication. WhatsApp Squads provide young people with information on HIV and STIs, help them to access health services, and raise awareness to end stigma.

AS'BANGENE has weekly slots on four radio stations, and screens live talk shows on Facebook with dynamic hosts and expert guests from Aurum, partner organisations and the community. A different topic is tackled each week relating to PrEP, HIV, TB and other contemporary issues such as GBV, COVID-19 and blessers. The shows reach a wide audience and are interactive, giving young people an opportunity to have their specific questions answered, and establishing a connection for further engagement.

#### 2.2. Health Screening

Aurum provides health screening to underserved communities that have poor access to health care, using mobile service models to promote prevention and early detection of disease. Our services comprise:

 HIV Testing Services (HTS), including contact tracing, index testing, and HIV self-screening (HIVSS)

<sup>2</sup>DREAMS = Determined, Resilient, Empowered, AIDS-free, Mentored and Safe



- Symptom screening for TB and Sexually Transmitted Infections (STIs)
- Screening for chronic diseases such as hypertension and diabetes

**Counselling for Prevention:** While the focus of HTS is on case finding, counsellors are required to counsel clients, as appropriate, on risk reduction to mitigate the spread or acquisition of HIV.

Linkage to care: Clients diagnosed with a medical condition are promptly referred to local health services and followed up to ensure that they accessed treatment. If feasible, Aurum offers same-day ART initiation before referring the client.

# 2.3. Voluntary Medical Male Circumcision and Early Infant Male Circumcision

Aurum has implemented 3 large VMMC grants in the period 2011-2018, and together with CHAPS has performed **over 1,180,000 circumcisions** (430,000 and 750,000 respectively) in South Africa since 2010.

In eSwatini, CHAPS conducts campaigns among adolescent boys and young men aged 10-29 to promote VMMC as a mechanism for HIV prevention. They also sensitise teachers, parents/caregivers and students in schools, churches, and communities to encourage boys and men to be circumcised with parental consent.

In Namibia, CHAPS advises the Ministry of Health on VMMC programmes and on the feasibility and costing of integrating EIMC in health care services; and trains clinicians on suitable EIMC surgical techniques. Please refer to the addendum for more detail on VMMC programmes

#### 2.4. Pre-Exposure Prophylaxis (PrEP)

Aurum provides pre-exposure prophylaxis (PrEP) through its Key Populations programme. Aurum's innovative home delivery project ensured that these populations continued to receive this life-saving medication while staying at home and safe during the COVID-19 lockdown.

Please refer to the capability statement on Key Populations for more detail.

#### 2.5. HIV Prevention training

Aurum and CHAPS provide training and inservice mentoring to health care workers on HTS counselling, VMMC, EIMC, PrEP, and Prevention of mother-to-child transmission (PMTCT) to ensure integration into routine health services. The VMMC training programmes are accredited in SA, Namibia and eSwatini, and comprise theoretical and practical components augmented by modules on medical ethics, data management and quality assurance. Health care providers are equipped with the necessary technical skills and are given ongoing support to successfully, safely and efficiently implement VMMC services.

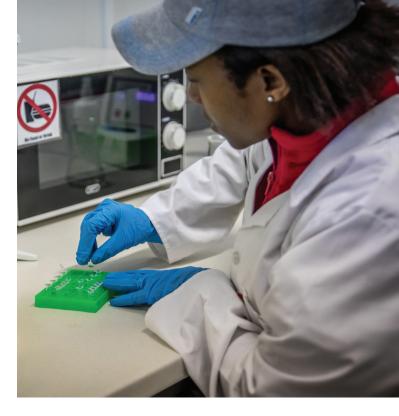
#### **HIV Prevention Research**

#### **HIV Vaccines Trials**

- HVTN 705/VAC89220HPX2008: A multicentre, randomized, double-blind, placebocontrolled phase 2b efficacy study of a heterologous prime/boost vaccine regimen of Ad26.Mos4.HIV and aluminium phosphateadjuvanted Clade C gp140 in preventing HIV-1 infection in women in sub-Saharan Africa
- HVTN 703/HPTN 081: A phase 2b study evaluating the safety and efficacy of VRX01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection in women in sub-Saharan Africa
- HVTN 702: A pivotal phase 2b/3 multisite, randomized, double-blind, placebocontrolled clinical trial to evaluate the safety and efficacy of ALVAC-HIV (vCP2438) and Bivalent Subtype C gp120/MF59 in preventing HIV-1 infection in adults in South Africa
- HVTN 107: A Phase 1/2a partially doubleblinded, randomized clinical trial to characterize the safety and immunogenicity of clade C ALVAC-HIV (vCP2438) and Bivalent Subtype C gp120 alone, with MF59® adjuvant, and with alum adjuvant in healthy, HIV-uninfected adult participants
- HVTN 108: A phase 1/2a clinical trial to evaluate the safety and immunogenicity of HIV clade C DNA, and of MF59®- or AS01Badjuvanted clade C Env protein, in various combinations, in healthy, HIV-uninfected adult participants

#### **Other HIV Prevention Trials**

 <u>ECHO study:</u> A multi-center, open-label, randomised trial comparing HIV incidence and contraceptive benefits in women using depot medroxyprogesterone acetate, levonorgestrel implant, and copper intrauterine devices (IUDs). Short Title:



Evidence for Contraceptive options and HIV Outcomes

- <u>FACTS 001B:</u> Observational cohort substudy of FACTS 001 participants postwithdrawal from placebo or tenofovir 1% vaginal gel use
- <u>FACTS 001:</u> A phase III, multi-centre, randomised controlled trial to assess the safety and effectiveness of the vaginal microbicide 1% tenofovir gel in the prevention of HIV Type 1 infection in young women, and to examine effects of the microbicide on the incidence of Herpes Simplex Virus type 2 infection

# Implementation Research in Health Facilities

- HASH study: A situational analysis to investigate the socio-behavioural risk factors for blood borne (HIV, hepatitis B and hepatitis C) infections in South African correctional facilities
- AZIKO study: Aurum institute is leading a study in the mining sector investigating the social risk factors for mineworkers to acquire HIV. The study is also including hidden populations in peri-mining communities around the selected mines to understand these risks.

#### **OUR EXPERTS**

**Dr Regina Osih,** TB/HIV Senior Technical Expert. Dr Regina Osih has 14 years' experience in infectious disease and public health. She brings to the team technical expertise in infectious diseases, specifically HIV and TB as well as epidemiology and operational research. She has previously worked on projects in several countries in Africa and has spent the last 6 years working in the public health realm in South Africa. Dr Osih was previously employed as the director for TB Access at the Clinton Health



Access Initiative where she oversaw the global TB programme for the organization. Prior to this, she was the clinical and health programmes director at the Wits Reproductive Health and HIV institute with oversight of HIV, TB and PMTCT programmes within the organisation. In addition, she has had several short periods as an independent consultant in South Africa and Switzerland, managing projects in the fields of clinical research, public health research, HIV prevention and health policy development. Dr Osih holds an MD from the University of Lausanne, Switzerland, an MPH from Johns Hopkins University and is board-certified in Internal medicine and infectious diseases through the University of Maryland.

Prof Keitshepile Geoffrey Setswe, Managing Director: Implementation Research Division. Prof Setswe's research interests are in the behavioural and social aspects of HIV/AIDS/STI and TB, health policy, epidemiology and global health issues where he has about 98 publications and more than 60 conference presentations in these fields. He previously worked for the Human Sciences Research Council (HSRC) for 11 years, growing through the ranks until his appointment as Executive Director of the HIV/AIDS/STI/TB (HAST) research programme. Prof Setswe was the founding Head of the School of Health Sciences at Monash South Africa where he also



served as Chair of the Senate (Board of Studies) between 2010 and 2013. He obtained his Master of Public Health from Temple University in Philadelphia, USA, under a Fulbright Scholarship, and has a Doctor of Public Health (DrPH) degree from the University of Limpopo. Prof Setswe was the founding Director of the AIDS Research Institute at the University of Witwatersrand where he coordinated AIDS research between 2003 and 2005. He was deputy chair of the AIDS Consortium from 2005-2011. He has previously worked at the Medical University of Southern Africa (MEDUNSA) as a lecturer, senior lecturer and professor of public health over an 11-year period where he was in the founding staff of the National School of Public Health (NSPH). In 2008-2012, he served as Co-Chair of the Research, Monitoring and Evaluation Technical Task Team of the SA National AIDS Council (SANAC) and has served on the Board of the Medical Research Council (MRC) as a non-executive director. He is a member of Council of the University of Venda and is Extraordinary Professor and Adjunct Professor at Universities of Stellenbosch and Venda respectively.

Dr Ntombifikile Mtshali, Managing Director: Health Systems Division. Dr Mtshali's background is in medicine and public health implementation programmes and management, both with the Department of Health and the private sector. She most recently led the turnaround of Bertha Gxowa Hospital from a struggling district hospital to a facility used as the benchmark in what government care and excellence should be. Dr Mtshali has over 10 years' experience in the health sector as a clinician in both private and public sector, hospital build environment, health financing/medical advisory, clinical and



hospital management and leadership, giving her a holistic view of health care delivery. Dr Mtshali has been involved in health advocacy for over 15 years, from student representation and the right to equal education and funding, to community outreach projects such as the Happy Valley Clinic project. As a champion for the right to accessible and cost effective quality health, Dr Mtshali strongly believes in value based healthcare for all. She is also a passionate advocate for women and reproductive health rights, she led the first hospital to provide CTOP in Ekurhuleni for first trimester pregnancies, and also established youth friendly services for young people and outreach programme to neighbouring schools for sex and health education. In the private sector, she has worked in corporate and as a successful family physician with a focus on HIV and TB. Dr Mtshali is a keen student of leadership philosophy and is passionate about African solutions for African challenges and dedicates some of her time to community development programmes.

Jacqueline Pienaar, Technical Director and CEO of the Centre for HIV-AIDS Prevention Studies (CHAPS), is a public health specialist with extensive experience in conceptualizing and implementing large public health interventions and programmes. She has a background in research, specifically managing large consortium HIV, TB and Microbicide clinical trials (SAPIT, START, AACTG, IPM, HVTN), sexual and reproductive health research, and in biomedical HIV prevention, bio-ethics and research statistics. Currently, her roles include leading the multiple Aurum and CHAPS VMMC programmes funded by CDC-SA and the South African Department of Health, and leading the



CDC-funded Aurum Key Populations programme across 5 districts in South Africa. Ms Pienaar's public health experience includes serving the US Government in the capacity of both CDC VMMC Lead and USAID Biomedical Prevention Specialist, managing the implementation and policy directives of USG public health programmes. She served as the Key Populations Lead at CDC-SA in 2013, where she implemented several key population strategies, and was subsequently appointed as Chief of Party of Jhpiego's VMMC programme.

**Dr Tonderai Mabuto**, Director HIV/AIDS Research: Implementation Research Division, has interdisciplinary interests and expertise in epidemiology, behavioural economics, and implementation science. Over the past 11 years, he has participated in the development and evaluation of public health interventions to promote engagement of clients in HIV/TB medical care. His work, funded through USAID, CDC and NIH, has contributed towards a better understanding of the important role that health communication and patient-centred care play in promoting initial and sustained engagement in HIV care. Landmark publications in this area include a simplified framework for implementers



to improve linkage-to-care, the role of case management in HIV programs, and the quality of health communication in routine HIV programmes. With a passion in bridging the research-to-practice gap, his work in implementation science has promoted systematic uptake of research findings and evidence-informed practices into routine programmes.

In his role as Director for HIV Implementation Research, he is at the interface between researchers and the health programme staff and provides guidance on the use of routine programme data and mixed method approaches to monitor programme implementation outcomes. Further, over the past three years, Dr Mabuto has led two national bio-behavioural surveys among HIV key populations, notably female sex workers and men who have sex with men. These two surveys are of strategic importance to the global HIV response for populations that are at high risk of HIV infection. Dr Mabuto serves on the South Africa HIV Research Think Tank and is a steering committee member of the African HIV in Prisons Partnership Network. Dr Mabuto holds a Master in Epidemiology and Biostatistics, and a Doctorate in Public Health from the University of Witwatersrand, South Africa.

#### C. OUR PROJECT EXPERIENCE

The projects listed below include only the most recent ones that illustrate this capability.

#### **HIV Prevention Services and Technical Assistance**

Project name	Programmatic Implementation and Technical Assistance for HIV/AIDS & TB Prevention, Care & Treatment Services throughout the Health System in South Africa under PEPFAR		
Funder	PEPFAR-CDC	Funder ref. no.	NU2GGH001981
Funding period	Oct 2016 – Sep 2021	Funding amount	\$ 227,363,170 (at Sep 2020)

Overall Project Goal: To contribute directly to HIV and TB/HIV epidemic control by providing technical assistance (TA) on HIV prevention, care and treatment; and in select programs, direct service delivery (DSD) for targeted, priority, and key populations at facility and community levels.

HIV Prevention work: Aurum conducts the following prevention activities in support of this goal:

- · Community mobilisation campaigns such as AS'BANGENE and priority population programmes that build on the DREAMS initiative to shift social norms and promote HIV prevention behaviour.
- · Provision of condoms and prevention counselling through community HIV testing services
- · Key Populations programme, including provision of PrEP
- · VMMC (only until Sep 2018)

Project name	National Treasury VMMC service contract		
Funder	South African National Treasury	Funder ref. no.	RT35-2019
Funding period	Sep 2020 – Aug 2023	Funding amount	

Provision of VMMC in 2 districts not supported by PEPFAR funding

Project name	National Treasury VMMC service contract		
Funder	South African National Treasury	Funder ref. no.	RT35-2016
Funding period	Nov 2016 – Feb 2020	Funding amount	

Provision of VMMC in 13 districts not supported by PEPFAR funding

Project name	Increasing access to Integrated TB and HIV Services at the Primary Health Care and Community Levels*		
Funder	Global Fund through NDOH	Funder ref. no.	SAF-H-NDOH
Funding period	Oct 2017 – Mar 2019	Funding amount	

Provision of a comprehensive prevention package to Informal Settlements of Ekurhuleni, including HTS, TB and STI screening, ART / TB / STI treatment

Project name	Comprehensive HIV & TB Prevention, Care and Treatment Services and Systems Strengthening in Facilities of South Africa's Department of Correctional Services (DCS) under PEPFAR*		
Funder	PEPFAR-CDC	Funder ref. no.	U2GGH001175
Funding period	Apr 2014 – Mar 2018	Funding amount	

Provision of VMMC and other HIV prevention services at correctional facilities in the Gauteng and Limpopo-Mpumalanga-North West management regions of the DCS, reaching 51000 inmate with prevention interventions.

Project name	Supporting Health Worker Staffing in the Republic of South Africa under PEPFAR (VMMC expansion component)*		
Funder	PEPFAR-CDC	Funder ref. no.	U2GGH000162
Funding period	Oct 2011 – Sep 2017	Funding amount	

Provision of VMMC in 2 PEPFAR districts

"To seek, to find, to share, to care,"

<sup>\*430,000</sup> circumcisions were performed during the course of the last 3 listed projects.

#### **Annexure 1: VMMC Programme Delivery**

Aurum has an exemplary performance in conducting quality VMMC in high volume settings, and in navigating rural and low demand areas such as Ngaka Modiri Molema and Dr. Kenneth Kaunda districts of the North West Province. In addition, Aurum has led the development of multiple innovations towards improving the VMMC programme, such as the Exclusive Men's Club, Food Voucher Reimbursement Models and the Prepex Pilot studies. Aurum achieved the highest results in South Africa for the CDC-SA COP17 programme, reaching 108% of its target by performing 132,164 MMCs.

Aurum is accredited through the South African Medical Association as a VMMC training institution, and has the demonstrated capacity to implement the entire continuum of VMMC activities, as shown in the model below.



Aurum has a long-standing footprint of VMMC service delivery in most provinces of South Africa. It employs local operational managers to ensure understanding of local culture and sensitivities, and to promote acceptance of the programme and collaboration from the community.

Aurum mostly sub-contracts local service providers, but also has established mobile units and roving clinical teams for rapid initiation of services. It has a dedicated VMMC Quality Assurance team of credentialed clinicians to monitor operational quality, and provide in-service training and mentoring for improved service delivery. The team includes a Data Quality Assurance Monitor whose sole responsibility it is to validate and verify MMC

"To seek, to find, to share, to care,"

data and coach teams on record-keeping and reporting. The DQA Monitor also conducts audits to prevent fraudulent expense claims, and ensures that MMCs are not reported multiple times to different funders.

Aurum has entrenched experience with Traditional Male Initiation (TMI) across South Africa. We have several TMI "approved" clinicians who practice MMC within TMI settings upon invitation from Traditional Leaders. Our TMI practitioners are part of traditional structures and serve as preferred clinicians during initiation seasons. Our favourable relationship with various Traditional Leadership authorities has resulted in an advantageous integration between TMI and MMC, reducing death and adverse events from circumcision in these communities.

# Contact us Business Development Office

Dr Dino Rech, Group Strategy and Business Development Officer Email: DRech@auruminstitute.org

#### **Clinical Trials in HIV Prevention**

Tanya Nielson, Managing Director: Clinical Research Division Email: TNielson@auruminstitute.org

#### **Implementation Research in HIV Prevention**

Prof Geoffrey Setswe, Managing Director: Implementation Research Division Email: GSetswe@auruminstitute.org

#### Service delivery and technical assistance for HIV Prevention programmes

Dr Ntombifikile Mtshali, Managing Director: Health Systems Division Email: N.Mtshali@auruminstitute.org

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