The Ikusas'elihle Clinic:
Health research with the Sweetwaters community

In April, the HSRC's Centre for Community-based Research launched a clinic facility in Sweetwaters near Pietermaritzburg in KwaZulu-Natal. This clinic will be home to several current and future clinical trials aimed at improving the health and wellness of this community. By living and working in the community, researchers gain a deeper understanding of its challenges.

By Antoinette Oosthuizen

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The HSRC has been conducting research in Sweetwaters (Mpumuza), a semi-rural community on the outskirts of Pietermaritzburg in the Umgungundlovu District of KwaZulu-Natal (KZN), since 2004. Many people who live there experience unemployment and extreme poverty. While conducting research in the community, the researchers have become particularly sensitised to the challenges posed by HIV and tuberculosis (TB).

On 20 April 2022, the HSRC's Centre for Community-based Research (CCBR) launched the Ikusas'elihle Clinic in Sweetwaters, which was built in partnership with the Bill and Melinda Gates Foundation and the University of Washington. Several clinical trials will be carried out at the facility focusing on health challenges in the region, for example, to evaluate the efficacy of pre-exposure prophylaxis (PrEP) treatments to prevent HIV infection, and to evaluate methods to improve TB detection.

Why PrEP?

The World Health Organization (WHO) recommends daily PrEP treatment with the antiretroviral drug tenofovir for HIV-negative individuals who are at substantial risk of contracting HIV due to their personal circumstances. When a person on PrEP is exposed to HIV – for example through sexual activity – the drug can stop the virus from entering the body's cells. One of the highest rates of new HIV infections in the world is among young African women. They are therefore a critical target population group for PrEP treatment, Dr Shannon Bosman, director of clinical projects at the CCBR, said at the official opening of the Ikusas'elihle Clinic.

"In recent HIV prevention trials, which provided the best available standard of prevention services – including condoms, services to treat and prevent sexually transmitted infections (STIs) and counselling – we still saw that women were becoming newly infected with HIV."

Truvada, a drug containing tenofovir, is available in South Africa, but the fact that it needs to be taken daily at least 90% of the time to be effective is a challenge, said Bosman. Other forms of PrEP include the intravaginal dapivirine ring, and cabotegravir, a long-acting injectable that women take every two months to protect them from HIV infection, but these are not yet available in South Africa.

Another option is the long-acting islatravir PrEP tablet, which is available locally, and is the focus of the ImPower Clinical Trial at the Ikusas'elihle Clinic. It is the third phase of a clinical study to evaluate the efficacy and safety of oral islatravir, which is a once-monthly PrEP treatment for women at high risk of HIV infection.

From left: Prof Khangelani Zuma, divisional executive of the HSRC Human and Social Capabilities division, HSRC Deputy CEO- Research (Acting) Prof Heidi van Rooyen and KwaMpumuza Traditional Council's Inkosi Ntsikayezwe W. Zondi oversaw the official opening of the Ikusas'elihle Clinic in Sweetwaters (Mpumuza), KwaZulu-Natal.
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"The study will evaluate how well islatravir works, how safe it is and how tolerable it is, compared with Truvada," explains Bosman. "Participants will be randomised, so they will get either islatravir or Truvada and then be followed up for three years to see what happens during the study." It will be a double-blind study, meaning neither the researchers nor the participants will know which of the two drugs participants receive, thereby ensuring that the results aren't biased. Approximately 4500 participants – 90% from Africa and 10% from the USA – will participate. At Sweetwaters, 200 to 250 young women will be enrolled.

The researchers will also work on the INSIGHT clinical trial, a study to evaluate daily oral PrEP uptake, adherence, persistence, and preferences among young women in several African countries.

"We know PrEP works well, but we need to understand who takes PrEP and who doesn't, how long women want to stay on it and their preferences for attributes of such long-acting PrEP products. Attributes of drug formulations would include dose and form (injectables or pills and the size of the pills), frequency of dosing (e.g., daily versus monthly or six-monthly) and the side effect profile."

Researchers will enrol 3000 sexually active, HIV-negative women aged 16 to 30 in eSwatini, Kenya, Malawi, South Africa, Uganda, Zambia, and Zimbabwe. At the Ikusas'elihle Clinic, 150 young women will be offered PrEP and followed up for six months.

"The results of these trials will guide future interventions and provide information on how the Department of Health's current PrEP rollout programme can be strengthened," said Bosman.

Finding TB faster

Undetected TB in Africa remains a major public concern with catastrophic health and financial consequences. "Current guidelines rely on active TB case finding – testing those with symptoms, and then diagnosing and treating them. However, we know there is a long period when people with TB can be asymptomatic," said Bosman. The delayed onset of treatment results in prolonged infection, increased disease transmission and a higher risk of suffering and death. "To diagnose these cases earlier, we need cost-effective screening tests that can guide us on who to test with the more expensive sputum sample TB test."

Community-based TB screening and triage testing as part of a health campaign could be a cost-effective and impactful diagnostic strategy. "A triage strategy is when you take inexpensive rapid tests that can be performed first to guide you on when to conduct the more expensive tests. This will reduce diagnostic costs and improve early access to diagnoses and outcomes."

Researchers at the Ikusas'elihle Clinic have completed enrolment and are working on the follow-up phase of a trial to evaluate the accuracy of two TB screening tests.

Computer-Aided Detection for TB (CAD4TB) is a software program using artificial intelligence to analyse a chest X-ray, producing a risk score that indicates the need for further TB screening. The other method is a C-reactive protein (CRP) assay measuring an inflammatory marker to determine the risk of having TB.

This phase of the research looks at the accuracy of the CAD4TB and CRP methods compared with the GeneXpert test, which is the most widely used rapid diagnostic test for TB and the standard of care. "We have enrolled 700 adults who were symptomatic of TB and offered them the chest X-ray, CRP, GeneXpert, and sputum testing. Another 700 were enrolled in Lesotho and a follow-up will be completed in the next three months. We will then use this study to guide the upcoming community phase of this study," said Bosman.

The purpose of the next phase is to investigate the effectiveness of a community-based TB testing algorithm consisting of the chest X-ray analysed by the CAD4TB system, point-of-care CRP triage testing and GeneXpert testing to evaluate the cost and the cost-effectiveness of the screening triage algorithm.

"We will enrol adults living in the community with or without symptoms of TB. They will be offered a chest X-ray. If it indicates they may have TB, they will be offered the CRP assay test and then sputum testing for TB. The aim is to see if this approach works to reduce the cost of diagnosing TB and increase the number of cases we find," said Bosman. The trial will enrol 20 000 adults 18 years and older, 5700 of them from the Msunduzi and Greater Edendale areas and the rest in Lesotho.

The value of a community centre

Prof Khangelani Zuma, divisional executive of the HSRC's Human and Social Capabilities research division, said the community plays an important role in the success of the HSRC's research in Sweetwaters. Living and working in the community helps to sensitise our researchers to local challenges and needs, while providing democratic spaces for knowledge co-creation. "This enables us to generate high-quality, evidence-based findings that are non-exploitative and community-owned," he said.

Note: The ImPower and INSIGHT trials are funded by the Bill and Melinda Gates Foundation through the University of Washington, Seattle in the USA. The TB trials are funded by the European and Developing Countries Clinical Trials Partnership through the Swiss Tropical and the Public Health Institute, Switzerland.

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