

Tsepamo Study results informs WHO Recommendations on DTG use



Dr Rebecca Zash presenting the Tsepamo study results at IAS 2019 (aidsmap)

The results from the Botswana Harvard AIDS Institute Partnership (BHP)'s Tsepamo Study have allayed fears of the safety of dolutegravir (DGT) use by pregnant women. Following the presentation of study results at the 10th International AIDS Society Conference (IAS 2019) in Mexico in July by Dr Rebecca Zash, the World Health Organisation (WHO) moved swiftly to recommend that DTG should be made accessible for women of childbearing age.

The preliminary results from this national birth outcomes surveillance study that started in 2014 suggested that DTG treatment at the time of conception was associated with a higher risk of neural tube defects in infants exposed to the drug, raising safety concerns of the DTG drug. WHO then issued treatment guidelines

over the introduction of dolutegravir-based treatment stating that HIV positive pregnant women should take effective contraception if they opt to take dolutegravir-based treatment.

The Tsepamo surveillance study initially looked at birth outcomes at eight government hospitals in Botswana between August 2014 and May 2018. The Tsepamo study team has subsequently expanded the surveillance from 8 hospitals to 18 in 2018 capturing data on the outcomes of 119,477 deliveries up to March 2019. The findings from the follow-up showed that the risk is lower than the preliminary results suggested.

WHO has since recommended Dolutegravir-based antiretroviral therapy (ART) as the preferred first-line regimen for all adults and adolescents with HIV.

Roger Shapiro Appointed BHP Board Chairperson



NEW ROLE: BHP'S new Board Chairperson, Professor Roger Shapiro

Professor Roger Shapiro, an Associate Professor of Immunology and Infectious Diseases at the Harvard T.H. Chan School of Public Health (HSPH) has assumed the role of chairperson of the Board of Directors of the Botswana Harvard AIDS Institute Partnership (BHP) following the retirement of the founding Chairperson, Prof. Max Essex last year after serving for 22 years.

Prof. Shapiro received his Medical Degree from New York University and a Master's Degree in Public Health from Harvard University. He

also holds a Bachelor's of Arts Degree from Yale University.

Shapiro who has been a board member of the BHP under the chairmanship of Professor Essex was one of the first clinical investigators of the institute and has participated in BHP's groundbreaking clinical trial, the Mashi Study in 2003 that looked at the prevention of mother-to-child HIV transmission (PMTCT). The results from the BHP's Mma Bana Study led by Prof. Shapiro informed the World Health Organization (WHO) guidelines for PMTCT in

2010 and 2013, accentuating the significant contribution of BHP to global health.

"I have some big shoes to fill," said Shapiro who admits that taking the reigns after Prof. Essex is an incredible challenge, as he believes that Prof. Essex is a giant scientist with an unmatched record of success who has tremendously contributed to science.

Nevertheless, Shapiro has his sleeves rolled up figuratively and literally as he routinely rolls up his shirtsleeves

as a dress style in real life. Prof. Shapiro is ready to provide the oversight necessary for the partnership to achieve its strategic objectives and lead it to the future.

“We want the institution to have more tools to work with in providing innovative solutions to health challenges. We will continue to look into how best we can still make a difference even with high HIV prevalence,” he said.

He envisions a high performing BHP that has its fingers right on the pulse of innovative research, making important advances in the provision of long-lasting solutions to a myriad of health challenges. Under his stewardship, Prof. Shapiro would want the BHP research portfolio spread to cover many other public health problems than it does now, expanding to even include the potential health impacts of climate change.

“BHP is the leader in clinical trials in this country and we have contributed greatly in the fight against HIV/AIDS. We have made significant contribution with studies such as the CTU and, cancer studies, we shall continue to make a difference with our new studies such as AMBITION and the bNAb’s,” said Dr. Shapiro.

The BHP Board Chair is content that BHP continues to make an impact globally as findings from the Tsepamo Study was recently used by WHO to update its recommendations on antiretroviral therapy and

Dolutegravir (DTG) use for pregnant women, declaring it safe for use as first line treatment.

“Botswana is the only place with enough exposure to DTG hence it is the only place with sufficient data to inform DTG treatment guidelines that can benefit the whole world,” he said.

With the fact that research funding is becoming more competitive and therefore tough to get, the new Board chair believes that BHP will be able to overcome its financial challenges with a great deal of ingenuity. Like the strongest oak of the forest “that is not protected from the storm and hidden from the sun”, BHP is compelled to stand in the open and “struggle for its existence against the winds, the rains and the scorching sun.”

Prof. Shapiro says he has confidence in the leadership of the partnership and is convinced that together they will continue to come up with creative ways of generating revenue to fund BHP research studies. BHP is currently implementing the business plan for Sesikalla Investments that is aimed at diversifying BHP income streams. Sesikalla Investments’ mandate is to generate alternative revenue streams for the partnership to ensure long-term sustainability of its research and capacity building initiatives.



Prof Roger Shapiro with Prof. Max Essex and Dr Madisa Mine at the BHHRL in January last year on the eve of Prof. Max Essex’s Farewell Dinner held at Masa Square Hotel.

BHP Laboratory gets SADCAS ISO15189 accreditation



A BROAD SMILE FOR THE ACCREDITATION: BHP Quality Assurance Manager, Thabani Ncube

The Botswana Harvard HIV Reference Laboratory (BHHRL) was successfully re-accredited by the Southern African Development Community Accreditation Services (SADCAS) following the annual audit on the 21st November 2019. The laboratory was granted the ISO 15189 accreditation after a rigorous assessment process that began in 2018 and the Certificate officially handed over on the 19th June 2019. The ISO 15189 standard is an international standard developed by the International Organization for Standardization (ISO) which specifies management system requirements for quality and competence for medical laboratories.

The approved scope of accreditation includes Chemistry, Haematology, Molecular Virology, and Serology. As an accredited organisation, the BHHRL is required to adhere to all the conditions of SADCAS accreditation as stipulated in the SADCAS Agreement and all the various applicable SADCAS requirement documents.

To achieve SADCAS accreditation, the facility first went through a systematic quality improvement programme that included personnel training; documentation and implementation of quality management system policies and procedures; and a continuous process of self evaluation and audit of implementation system effectiveness.

Quality Assurance Manager at the BHHRL, Mr. Thabani Ncube had been confident that the laboratory would be certified this year after addressing non-conformities identified during the assessment and has since met all the requirements.

“This accreditation elevates the BHHRL to be amongst the few accredited public health laboratories in Sub Saharan Africa. ISO15189 accreditation is an international mark of recognition of quality and competence in medical laboratory practice. It does not only strengthens

public trust and confidence in the quality of care in routine clinical laboratory practice, but it increases our competitive advantage to participate in high quality international clinical trials," said Ncube.

He further noted, "The BHHRL was established to support the National ARV Programme and to lead cutting edge, innovative clinical research that informs policy and practice in the fight against HIV/AIDS. Because the results of our research influences policy and practice in our health care systems, it is critical that all stakeholders have confidence in the quality of data that we are generating."

Ncube also stated "the accreditation process is beneficial to any healthcare organisation as it provides objective, independent assessment of the level of performance in relation to established standards and provides opportunities to continually improve". He further noted, "other benefits of accreditation include improved quality and safety of care; reduced costs; more effective organisational structures and efficient service delivery. It also boosts investor or funder confidence since sponsors would rather not invest in a health facility that that does not meet international standards".

Guided by clear quality management policies, rocedures and supportive systems, Ncube argues that the laboratory naturally becomes a more pleasant working environment for staff.

BHP Chief Executive Officer, Dr Joseph Makhema in his congratulatory message to the team pointed out that, "the successful audit towards the accreditation is a significant milestone in BHP's continued strengthening of it's systems and confirms the immense capabilities and competence of it's staff to meet the challenge of delivery of high quality laboratory services for both clinical trials and routine medical care for participants and patients.

Dr Makhema has implored the laboratory staff to ensure that the accreditation status is maintained, pointing out that despite budgetary challenges, accreditation is core business and therefore management is committed to support the laboratory as best as they could. He noted that there is need for continued capacity building for relevant staff on the technical needs and expectation for accreditation, including applicable trainings to ensure that accreditation is maintained.

Laboratory Manager from the Ministry of Health and Wellness, Julia Ngidi commended the laboratory team for the accreditation. She emphasized the need to maintain the accreditation. She stated that while



Ministry of Health & Wellness Laboratory Manager, Julia Ngidi

arriving at accreditation is tough work, the most difficult and most important part in accreditation is to sustain it. Ngindi said preserving the status and sustaining the accreditation calls for highest commitment from all the laboratory staff members to follow to the latter the processes that they have set for themselves.

The BHHRL has previously been accredited to the ISO 17025 South African National Accreditation Systems (SANAS) standard and has maintained DAIDS quality standards for the hosting of various NIH and network clinical trials. The decision to upgrade to SADCAS was premised on transitioning to a standard that is specific for medical laboratories.

SADCAS is an oversight multi-economy accreditation body established to meet the accreditation needs of SADC member states mainly those that do not have national accreditation bodies.

"ISO15189 accreditation is an international mark of recognition of quality and competence in medical laboratory practice"

Thabani Ncube

HPTN 084 Protocol Chairperson visits BHP



HPTN 084 Principal Investigator, Dr Joseph Makhema and HPTN 084 Protocol Chairperson, Dr Sinaed Delany-Moretlwe

The Chairperson for the HIV Prevention Trials Network Protocol 084 (HPTN 084), Dr Sinead Delany-Moretlwe on July 8th visited the Botswana Harvard AIDS Institute Partnership (BHP) for a site support visit to appreciate the implementation of the HPTN 084 Study by the Gaborone Clinical Research Site (CRS). She was accompanied by two members of the management team of the HPTN Laboratory Centre.

The HPTN 084 "A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women" is a pre-exposure (PrEP) antiretroviral study to evaluate the safety and efficacy of the injectable cabotegravir (CAB LA) compared to daily oral tenofovir disoproxil fumarate/ emtricitabine (TDF/FTC) for PrEP.

The visit began with a briefing and presentation of the HPTN 084 recruitment and retention updates for the Protocol team to appreciate progress and the challenges faced by the Gaborone CRS in the implementation of

the study. After the briefing, the team was taken for a laboratory tour to further appreciate the laboratory processes as it concerns the HPTN 084 study. Following the tour, HPTN Laboratory Centre Deputy Director, Estelle Piwowar-Manning and HPTN Laboratory Centre OC/QA Coordinator, Yaw Agyei joined the BHP Laboratory management to discuss and review laboratory procedures while Delany-Moretlwe visited the Research Clinic.

The laboratory team discussed and reviewed laboratory procedures for HPTN studies. They looked at inventory management and HIV algorithm, reviewed site monitoring report and the Division of AIDS (DAIDS) action plan as well as validation for the Laboratory Data Management system to ensure that all processes are followed for the successful implementation and completion of the study.

At the HPTN Research Clinic, Delany-Moretlwe toured the clinic and had interactive discussions with the clinic staff, assessed site performance metrics, discussed

recruitment and retention updates and other study queries. She made a presentation on the global HPTN 084 implementation progress and suggested some of the interventions to help the site with recruitment and retention of study participants.

“Participants trust information from the Ministry of Health more, the clinic should thus ensure they have access to the ministry’s materials on PrEP and have them distributed to participants as this could help with recruitment,” she said.

She also pointed out the need to come up with recruitment techniques that are more appealing to young people. “ Involvement of young people in the Community Advisory Board as PrEP ambassadors could also help as they will be able to positively influence their

peers,” she said.

She noted that the provision of testing services and STI infection treatment for women at the site could also provide an opportunity to interact with young people and increase the chances of recruitment and enrolment into the study. Another suggestion by Delany-Moretlwe was that the site should consider extending recruitment to Family Planning Clinics where customers already understand the use of contraceptives.

BHP HPTN site had also arranged for Delany-Moretlwe to visit Mogoditshane Clinic for her appreciation of the recruitment site, recruitment process and the interaction of BHP staff with the clinic personnel. Mogoditshane Clinic is one of the sites where some of the enrolled study participants have been recruited from.



HPTN Laboratory Centre QC/QA Coordinator, Yaw Agyei, HPTN Laboratory Centre Deputy Director, Estelle Piwowar-Manning and HPTN 084 Protocol Chairperson, Dr Sinaed Delany-Moretlwe during the Laboratory Tour.

From wetlands, extreme heat and rocky places: The BCPP Experience



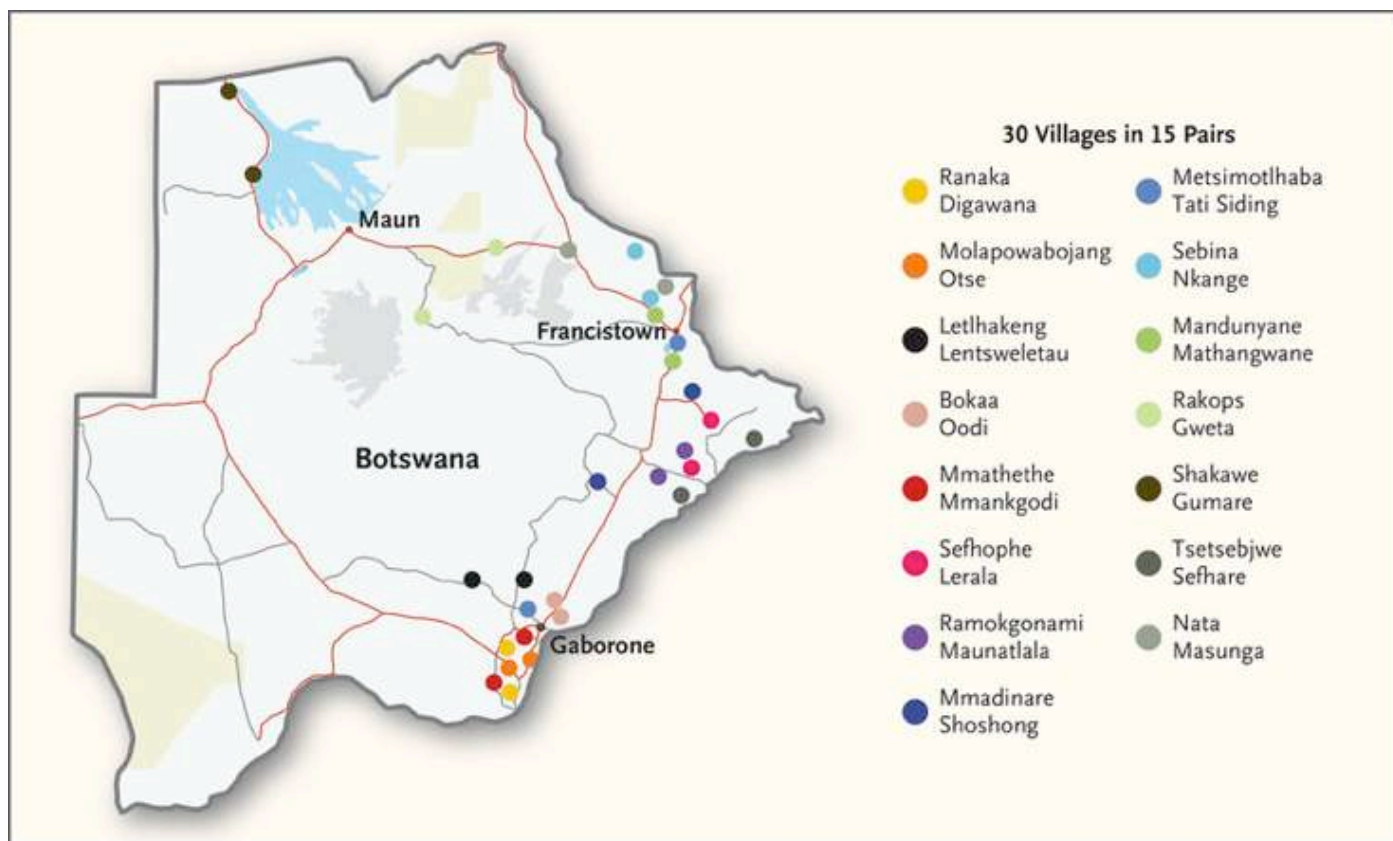
Former BCPP Assistant Project Coordinator, Kutlo Manyake

The Botswana Combination Prevention Project (BCPP) dubbed “Ya Tsie” is a study in which the Botswana Harvard AIDS Institute Partnership (BHIP) sought to find out if a combination of proven HIV prevention methods can reduce HIV incidence in a community. The study has since come to an end and here, two staff members who were engaged with the study from beginning to end share their experiences.

Kutlo Manyake who held the position of Community Based Supervisor (CBS) and later Assistant Project Coordinator in the BCPP study and a Driver, Ndaba Mdojwa share their warmhearted memories working on the BHIP’s largest clinical trial that covered 30 villages in Botswana. The two consider themselves privileged to have been part of the team that was involved to the end.

Manyake explains that BCPP was distinctive in that it was a very mobile study which enrolled a lot of participants of different cultures, educational level, wide age range, had unique randomization and involved many stakeholders. The study enrolled a total of 12610 participants from across the 30 villages.

The study had a staff compliment of about 117 people (1 Project Coordinator, 1 Assistant Project Coordinator, 1 HR Officer, 2 Administration Assistants, 2 Administration Drivers and 18 field drivers, 6 IT assistants, 6 Community Based Supervisors, 6 Clinic Research Nurses, 10 Laboratory Assistants, 4 Laboratory Scientists and 59 Research Assistants). According to Manyake, BCPP had good management structures that made supervision of this big team easier.



Map of the 15 Matched Community Pairs in Botswana.

“At field level, there was a senior RA, a lead driver and a CBS, and this helped to cascade management without a general feeling of being overwhelmed by senior staff”. At central level, there were coordinators for laboratory, clinic, IT, to help in ensuring department-specific plans and management. The coordinators and field supervisors worked closely together, with weekly meetings at coordinator level, and fortnight coordinator field Skype calls,” Manyake recalls.

“The number of the team members was high and the standard of living was essentially backpacking in nature, which was different from localized studies restricted to a particular area. BCPP had no 08:00-05:00 kind of work, it was based more on participant schedule and it differed from one community to another,” she says, explaining that this saw the team sometimes working from noon until around 10pm.

She points out that the level of teamwork needed to achieve set goals while keeping staff motivated was high and it needed creative, dedicated and flexible leadership. Mdojwa adds that because they had become research nomads, migrating from one place to another, being flexible to adapt to changing environments was a much-needed character from all members of the team.

The cultural diversities called for a lot of adjustments that were critical for good recruitment, retention

and co-existence. The terrain was also very different, from wetlands, extreme heat, and rocky places, daily operations were to be adjusted drastically almost every 3 weeks, Manyake recalls.

“The greatest strain was on the field team’s social life. The timelines were tight and the teams had to work extra hard to meet goals. At the end of a 40-hour week, the team would need to travel back home to their families, some with young children. This put a lot of emotional strain especially as we got further and further from the south where most families resided.”

The financial strain was also felt more the further the teams moved from the south and Manyake notes that it was never easy maintaining two households, a mobile and stationary one, and the cost of travel that increased with distance.

The further the teams moved from the South of the country to the Northern side, the more effort was needed for more flexibility, accommodation and boosting of team’s morale. The teams learnt survival skills and one was, for their sanity sake, inclined to be a team player than a loner.

Continues on page 10

The BCPP team learnt to create and build relations in the communities they lived in and it was not an unusual sight for them to be seen attending local functions. Manyake says this good spirit worked to their advantage, because in return, the communities were more hospitable, providing a sense of belonging and security. The teams even planned group travels to nearby attractions as a form of relaxation for the mind to take a shift away from the science.

Mdojwa is grateful for the amazing reception that they received from the various communities during home visits and even at their rented homes. Mdojwa and Manyake together concur that the landlords mostly treated them as their “children” and in some instances, would even call the supervisor when the “child” was unwell. The supervisor wore the “parent” hat and Manyake says the experience has made her grow in leaps and bounds in a very short period of time. She says the teams usually joked saying “BCPP is not for the faint-hearted”, and in many ways, she agrees, the statement was true.

As the supervisor she was even answerable to village leadership for anything concerning the team and was expected to attend clinic briefings to monitor and enhance partnership status and to ensure the team maintains cordial relations that would see them welcomed again on follow-up visits.

They both agree that being part of the study has individually contributed to their personal growth and development. Manyake’s biggest gain in the study was the opportunity to write her first abstract.

“How the investigators ensured that we, the junior researchers got exposed to abstract and manuscript writing was amazing. This is every researcher’s dream, to work tirelessly for a project, and to see its results published, for the betterment of both personal growth and informing health policies,” says Kutlo.

For Mdojwa, the BCPP experience did not only send him to different places around Botswana, it also opened his eyes to the different cultures and way of life of different people in the country. Being part of the study has also awakened him to the realities of HIV/AIDS and has generated a lot interest in knowing more about the scourge.

He noted that before BCPP, he did not have much interest in learning about HIV but the study has since exposed him to a lot of knowledge about the virus in general.

“I have grown in terms of my understanding of HIV/AIDS and my appreciation of the sad realities of the disease. Being part of the BCPP has broadened my scope of understanding of the health challenges posed by HIV/AIDS and it has changed my thinking around health in general,” said Mdojwa.

For both officers, the experience of the diverse cultures and different environments across the 30 villages, the professional experience gained, the data collected that has changed the milestone of HIV/AIDS research in Botswana, the amazing team spirit that prevailed from all the departments and the thrill of not knowing how each community, season and day could unfold, sums up their beautiful experience working in the Ya Tsie study.



Former BCPP Driver, Ndaba Mdojwa

“Being part of the BCPP has broadened my scope of understanding of the health challenges posed by HIV/AIDS and it has changed my thinking around health in general”

Ndaba Mdojwa

Dr Ajibola represents BHP at EDCTP Workshop

The Principal Investigator for the EDCTP funded “Effects of preterm birth on HIV acquisition risk and antiretroviral prophylaxis safety in HIV-exposed infants in Botswana” The PERHAPS Study, Dr Gbolahan Ajibola represented the Botswana Harvard AIDS Institute (BHP) at the European and Developing Countries Clinical Trials Partnership (EDCTP) workshop titled “Enhancing networking among European and African scientists to close regional and gender disparities experienced in EDCTP1 and EDCTP2 funded health research capacity activities in sub-Saharan Africa”. The workshop co-hosted by the Africa CDC was held from 19-20 November 2019 in Addis Ababa, Ethiopia.

EDCTP continues to provide significant research funding for clinical trials and capacity building initiatives for important Sub Saharan African diseases including Tuberculosis, HIV, Malaria and other challenging public health communicable and non communicable diseases. This has had a major impact on the development of clinical research capacity in both human capital, infrastructure and intervention strategies for the morbidities. While the number of EDCTP Fellows and grant holders taking up leadership positions in African science and the number of institutions across sub-Saharan Africa that now have improved facilities capable of carrying out clinical trials of international standards is growing, EDCTP is concerned with geographical and gender disparities in success rates of grant applications.

In a letter communicating Dr Ajibola’s selection as a delegate for this regional workshop, EDCTP indicates that analyses of successful applications have revealed geographical and gender disparities in success rates of applications for EDCTP1 and EDCTP2 programme funding, with the least number of applications received and funded being from Central and West Africa.

The communication states that there are countries in Eastern and Southern Africa with minimal participation or no participation yet, especially within the EDCTP fellowship schemes that aim to facilitate career growth and development for African-based scientists.

In an effort to address these disparities, EDCTP in partnership with Africa CDC, hosted this workshop to facilitate collaborations between African and European scientists geared towards closing regional and gender

imbalances in EDCTP1 and EDCTP2 funded projects. The collaboration is expected to facilitate the ease of conducting clinical research in affected countries.

Dr Ajibola joined about 150 scientists, researchers, policy makers, and strategic partners active in Africa and Europe to brainstorm on practical solutions to address the regional, sub-regional and gender research and research capacity imbalances; prioritise and discuss potential strategies and plans to address the gaps as well as to identify potential synergies that will compliment the efforts and plans of EDCTP strategic partners in addressing these disparities.



Dr Gbolahan Ajibola

Building AIDS Research Capacity in Botswana: Q and A with Dr Simani Gaseitsiwe



BHP Laboratory Director, Dr Simani Gaseitsiwe

Dr. Simani Gaseitsiwe began his research career nearly 20 years ago at the height of Botswana's AIDS epidemic. He took a job as a lab assistant for the Botswana Harvard Partnership (BHP), a research and training collaboration between the government and Harvard University, led by pioneering Harvard AIDS researcher and longtime NIH and Fogarty grantee, Dr. Myron "Max" Essex. Today, Gaseitsiwe directs BHP's laboratory in Botswana, trains young scientists and is among the accomplished researchers contributing to the NIH-funded Human Heredity and Health in Africa (H3Africa) project.

Dr. Simani Gaseitsiwe began his research career nearly 20 years ago at the height of Botswana's AIDS epidemic. He took a job as a lab assistant for the Botswana Harvard Partnership (BHP), a research and training collaboration between the government and Harvard University, led by pioneering Harvard AIDS researcher and longtime NIH and Fogarty grantee, Dr. Myron "Max" Essex. Today, Gaseitsiwe directs BHP's laboratory in Botswana, trains young scientists and is among the accomplished researchers contributing to the NIH-funded Human Heredity and Health in Africa (H3Africa) project.

What Fogarty training did you receive?

Professor Max Essex has been my mentor throughout my career. When he started the lab in Botswana in 2000, I was recruited, having just completed my undergraduate degree. In the beginning, the lab was focused on very basic HIV clinical laboratory work, doing CD4 counts to check disease progression, viral loads and patient monitoring. At the time, the epidemic was really bad because that was before the advent of antiretroviral therapy in places like Botswana.

After a year, I had the opportunity with Fogarty support to go to Max's lab in Boston to do more advanced molecular biology training, to do genotyping or sequencing the HIV strains that are circulating in Botswana. It was more hands-on training, which was very important at the time because we didn't have the capacity to do that kind of work here. It was a very cosmopolitan environment in Boston, with scientists from all over working together. Coming from my country, where there was basically no one doing HIV research, to train in such a prestigious institution like Harvard was very inspirational and motivated me to pursue further studies including a Ph.D.

How has your career progressed?

An HIV research lab in Botswana has expanded to offer advanced training to regional and international students with support from Fogarty. I have gone from being one of three lab assistants in a new operation capable of only doing basic HIV clinical lab work, to now being the director of 50 staff and a sophisticated, three-story facility with an expanded clinical laboratory, a million-sample repository, a research lab, sequencing facility and training space. Today, we have a number of students who are training at master's, Ph.D. and postdoctoral levels, and we attract students not only from the region but also internationally. From the humble beginnings to now, it's been really great to watch the lab develop over the past 18 years.

What research topics are you studying?

I've spent a lot of time trying to diversify the research agenda of BHP because most of the focus had been on HIV, but the situation is not as bad as it used to be. I've diversified the research portfolio to include viral hepatitis, which is under-researched in Botswana although it is highly prevalent here and in other sub-Saharan Africa countries. We've had a few projects looking at the TB incidence in patients who are on antiretroviral therapy because TB co-infection in HIV-infected individuals is the main type of TB in Botswana. Almost 60-70% of the TB patients are also HIV-infected, so I think there is a need to study the two infections together. The research that's happening here is a byproduct of my Fogarty training. So, you can multiply that by a factor of 10 or 20 because that's how many of us have had the opportunity for substantial training.

Why is local research capacity important?

It's something I've always had a passion for, especially learning from what Max has done in Botswana. There is

a dire need for individuals who are trained to the Ph.D. level to conduct research in places like this. By the time we really began to appreciate the magnitude of the HIV epidemic in my country, it had already reached levels where it was difficult to manage. I think we learned that there was a need to respond to outbreaks in a more timely manner.

We need to develop human capacity first of all, because those are the people who will drive the programs to control the epidemics. It's not only HIV, we are also seeing Ebola and other diseases spreading in nearby countries. I think Fogarty in its nature was, and continues to be, very instrumental in supporting the training of people from a resource-limited setting to go to more developed countries to train, and then come back home and be able to be the drivers of the research, ultimately trying to control the epidemics there.

What is your approach to mentoring?

My approach is to get young people to come into the lab and, to a great extent, allow them some freedom. I learn from all these graduate students that I have, because they are younger, they tend to look at things in a different way and question concepts that we take for granted. I also have come to appreciate diversity. So, whenever possible I always try to attract people from different backgrounds into the lab. You don't want a homogenous group because your approach, your solutions will be similar. But if you take a group from different backgrounds, then the approach and the solution will be more holistic.

What is your role with H3Africa?

The H3ABionet is an H3Africa-funded project that solely focuses on developing capacity in Africa for bioinformatics. I am the PI for that in Botswana. Through that we have been able to train a number of young scientists in bioinformatics, basically analyzing genetic data, not only human genetic data but pathogen genetic data. While Africans are quite genetically diverse compared to people from other areas, there is less human genetics information coming from Africa. So, I think it is an exciting initiative, which ultimately will build capacity across the continent.

SOURCE:

<https://www.fic.nih.gov/News/GlobalHealthMatters/september-october-2019/Pages/simani-gaseitsiwe-aids-research-in-botswana.aspx>

BHP presents PHOENix study to Kgatleng DHMT



ACTG Study Coordinator, Dr Unoda Chakalisa

The Clinical Trials Unit (CTU) at the Botswana Harvard AIDS Institute (BHP) is currently engaged in a community mobilization exercise, introducing to various stakeholders a new study called "Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Patients (PHOENix MDR-TB)". The study was launched last year and is currently enrolling.

Presenting the study recently in Mochudi at the Kgatleng District Health Management Team (DHMT) Workshop, the Study Coordinator responsible for the AIDS Clinical Trials Group (ACTG) Studies at BHP, Dr Unoda Chakalisa explained that PHOENix is a clinical trial investigating drugs for preventing high-risk household contacts (HHCs) of multidrug-resistant tuberculosis (MDR-TB) patients from developing the disease.

She explained that PHOENix is a phase III, open-label, multi-centre trial with a cluster-randomized superiority

design to compare the efficacy and safety of delamanid against isoniazid for preventing confirmed or probable active TB among high-risk household contacts (HHCs) of multidrug-resistant tuberculosis patients.

Dr Chakalisa emphasized the importance of conducting this study, noting that no randomized controlled trials have been conducted to guide the management of adults or children exposed to MDR-TB, and as such there is inconsistency in the available guidelines for the management of MDR-TB contacts.

Globally, an estimated 558 000 new cases of rifampicin-resistant TB were reported in 2017, of which, approximately 82% had TB resistant to at least isoniazid and rifampicin. There is therefore an urgent need for TB preventative therapy trials to inform international evidence-based TB prevention recommendations.

She revealed high-risk HHCs are those with HIV or non-HIV immunosuppression, latent TB infection, and young children below the age of 5 years. She pointed out that HIV-infected HHCs are likely to be at much higher risk of TB disease progression, based on their known susceptibility to TB infection, reinfection, and reactivation.

“Among household contacts in high-burden settings, the vast majority of MDR-T cases in children arise from transmission within the household, whereas adolescent and adult TB cases are equally likely to be from infections acquired within the household or in the community,” said Dr Chakalisa.

She added that previous systematic reviews of observational studies of HHCs of MDR TB patients indicated that 4–8% of the HHCs developed incident TB while 44–72% of the incident TB among HHCs was drug-resistant. Furthermore, TB incidence is greatest in first 2 years of exposure. The study will enroll index cases of MDR-TB and their high-risk HHCs. Index cases are

defined as an adult of 18 years or older with confirmed pulmonary MDR-TB who has started appropriate treatment within the past three months, while a HHC is a person who lives in the same dwelling unit and shares the same housekeeping arrangements as the index case and who reports exposure within three months prior to the index case starting MDR TB treatment.

The multi-centre study will take place in several countries, (Botswana, Brazil, Haiti, India, Kenya, Peru, the Philippines, South Africa, Tanzania, Thailand, Uganda and Zimbabwe) and will enroll approximately 5,178 participants (1726 Index MDR-TB cases, 3452 high-risk HHCs cases). The Botswana site intends to enroll a total of 300 participants (75 index cases and 225 HHCs).

Participating household members would be randomly allocated to receive either oral delamanid or oral isoniazid daily for 26 weeks. All HHCs in the same household will receive the same drug regimen. Enrolled HHCs will be followed up on study for 96 weeks.



Workshop participants listening to Dr Chakalisa's Presentation



“ Congratulations to BHP Research Fellows, Tshepiso Mbangiwa and Patricia Rantshabeng who recently graduated with MPhil in Medical Sciences at the University of Botswana.”

THESIS:

Tshepiso Mbangiwa: Hepatitis B Virus infection in pregnant women and 18 months old infants in Botswana: Impact of maternal HBV infection on pregnancy and infant health outcomes.

Patricia Rantshabeng: High-risk Human Papillomavirus genotypes distribution in patients diagnosed with anogenital malignancies in Botswana: Implications for vaccination strategy.



BHP Strategic Themes

Research Excellence

BHP aims to provide Botswana and the rest of the international community with knowledge to combat HIV/AIDS and emerging public health challenges through provision of quality research. Research is core to the BHP mission and is the primary source of its funding and outcome contributions. The ability and capacity of BHP to deliver relevant and quality research will continue to be a key success factor for the institution.

Capacity Building and Training

Capacity development is a key priority for the Government of Botswana, and as an extension, for the Ministry of Health and Wellness. The Ministry is continuously seeking to increase the capacity of Ministry employees and other players in the public health sector to strengthen the country's ability to respond to local public health issues and contribute more meaningfully to regional and global public health concerns.

BHP develops capacity of the health sector in various ways. Through its research, BHP develops the capacity of health professionals and other health resources involved in the delivery of this research. BHP also conducts training and capacity building events for various participants in the public health sector and community as a whole.

Operational Excellence

Continued focus on operational excellence will be essential during this strategic period. BHP continued relevance and retention of principal stakeholder interest will be dependent upon the institution's cost effectiveness against an increasingly pressured budget. In addition, quality of support services directly influences the quality of the research as well as the quality of the training services delivered by BHP. To achieve the vision of a 'world-renowned' institute, BHP

must continually improve its operational capabilities from processes to systems.

Public Policy and Advocacy

Ultimately, BHP aims to drive meaningful change in the lives of people impacted by HIV/AIDS and other public health challenges. This change is largely effected through public policy based on globally recognized research findings. BHP must continually maintain focus on this desired result through strategic decision-making and allocation of resources in the spirit of this theme. BHP's ability to advocate and realise improvements in policy and protocols will determine, in part, the institutions success.

Sustainability

BHP has come to accept that its long-term sustainability requires diversified revenue streams that reduce dependency on grants with strict funding utilization requirements. BHP is in the process of developing a business plan that will guide a key part of the financial sustainability strategy of the organization.

While Operational Excellence drives system improvements that support efficient and effective value chain delivery, Sustainability focuses on the financial model of BHP to diversify revenue streams and ensure BHP continues to be a viable going concern. The strategic aims will be achieved through;

- broadening BHP areas of focus beyond the traditional HIV/AIDS into areas of emerging public health challenges, resulting in access to new grants and funding areas;
- implementing a new business model that includes fee-for-service activities leveraging developed capabilities; and,
- identifying collaborations with key partners and other institutions when applying for grants to strengthen the value proposition and access larger, regional grants.

BHP Associated Research, and Associated Investigators Publications (July to September 2019)

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