BOTSWANA
HARVARD AIDS INSTITUTE
PARTNERSHIP
FOR HIV RESEARCH AND EDUCATION

ANNUAL REPORT
YEAR 2022

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Botswana Harvard AIDS Institute Partnership

2022 ANNUAL REPORT

BOTSWANA
HARVARD AIDS INSTITUTE
PARTNERSHIP
FOR HIV RESEARCH AND EDUCATION

Botswana Harvard AIDS Institute Partnership
Private Bag BO320 Gaborone
Plot No. 1836, Northring Road, Princess Marina Hospital, Gaborone
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2022 - Annual Report
Complied and Produced by:
BHP Annual Report Task Team
Design by:
BHP Communications Team

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1. STRATEGIC FOUNDATIONS

VISION: To Be a World-Renowned Public Health Institute.

MISSION: To Fight HIV/AIDS and Emerging Public Health Challenges Through Innovative Research, Education and Capacity Building That Impacts Policy and Practice.

CORE VALUES

- EXCELLENCE

To achieve our vision of being a "world renowned public health institute" we at BHP commit to quality driven research and training programmes and processes. We will be second to none in our drive to attain quality in our research and training.

- INNOVATION

BHP staff is committed to finding solutions to the evolving HIV /AIDS pandemic and other public health challenges. We shall endeavor to be continuously innovative and resourceful in our quest to understand and address public health challenges.

- COLLABORATION

BHP recognizes that the fight against HIV /AIDS and other public health challenges will not be won by one individual or one institution. We commit and emphasize the importance of teamwork and collaborative research in our activities.

- BOTHO

An encompassing Setswana word that means amongst other, integrity, respect, honesty, and compassion. We are committed to adhering to moral and ethical principles treating all our customers, including research participants, with respect, dignity and compassion. All information about studies will be handled with utmost confidentiality.

- BENEFICENCE

All activities done at BHP shall be of relevance and benefit to those affected by HIV /AIDS and/or other public health challenges. The knowledge generated through our research shall be availed to advise public health policy and shall be shared with the general public and scientific community for the benefit of mankind. We shall be guided by the principle of "Do Not Harm" in our Research and related activities.

2. BHP AT A GLANCE

ESTABLISHMENT

Botswana Harvard AIDS Institute Partnership (BHP) is a Not-for-Profit, limited liability organization, established through a partnership between the Government of Botswana, represented by the Ministry of Health (MoH), and Harvard University (HU), represented by the Harvard T.H. Chan School of Public Health (HSPH). It was established in 1996 and registered as a limited liability company in 2009.

BUSINESS

Knowledge generation and dissemination, advocacy, health policy transformation and systems strengthening through research, education and capacity building.

CONTACT DETAILS

Registered Office: Botswana Harvard HIV Reference Laboratory
Plot 1836 (Princess Marina Hospital premises)
North Ring Road, Gaborone, Botswana

MAILING ADDRESS

Postal Address: Private Bag B0320, Gaborone, Botswana
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Company Auditors: Price Waterhouse Coopers
Company Secretaries: DPS Consulting
Company Attorneys: Armstrong's Attorneys, Notaries & Conveyancers
Main Bankers: Standard Chartered Bank & Stanbic Bank

3. GOVERNANCE

A. BOARD OF MEMBERS

Prof. Michelle Williams

Angelopoulos Professor in Public Health and International Development, Dean Harvard T.H. Chan School of Public Health.

Prof. Sarah Fortune

John LaPorte Given Professor of Immunology and Infectious Diseases at the Harvard TH Chan School of Public Health, Director of the TB Research Program at the Ragon Institute of MGH, Harvard and MIT and Chair of the Department of Immunology and Infectious Diseases.

Prof. Sheila Tlou

Co-Chair of the Global HIV Prevention, Former Minister of Health and Wellness Botswana.

Prof. Mark Elliott

Mark Schwartz Professor of Chinese and Inner Asian History, and Vice Provost for International Affairs, Harvard University.

Prof. Michael Hughes

Professor of Biostatistics, Director, Center for Biostatistics in AIDS Research Harvard TH Chan School of Public Health.

Mpaphi Blasis Mbulawa

Director Health Laboratory Services/Head National Health laboratory, Ministry of Health, Botswana

B. BOARD OF DIRECTORS

Chair: Prof. Roger Shapiro

Professor, Department of Immunology and Infectious Diseases, Harvard T.H. Chan School of Public Health.

Mr Modise Modise

Economist & Former Permanent Secretary of Development, Office of the President

Ms Katie Hope

Chief Financial & Administrative Officer, Harvard T.H. Chan School of Public Health.

Dr Shahin Lockman

Associate Professor in the Department of Immunology and Infectious Diseases at Harvard TH Chan School of Public Health.

Christopher Hughes

Head of Group Business Transformation for the Letshego Group of Companies and the Founding Director of LEAD Consultancy.

Dr Pamela Smith Lawrence

Director of Health Services, Ministry of Health (MOH), Botswana.

Dr. Joseph Makhema

Chief Executive Officer BHP.

Ms. Ria Madison

Chief Operations Officer BHP - Ex Officio Member, non-voting Director

C. EXECUTIVE MANAGEMENT

Joseph Moeketsi Makhema

MB. ChB, FRCP (UK)

Dr. Makhema is a Practicing Internal Medicine Physician and is the CEO of the Botswana Harvard AIDS Institute Partnership (BHP), He Provides strategic leadership, manages and supervises all initiatives of the BHP. He oversees grant funded research and training awards sponsored by NIH, Wellcome Trust, EDCTP, and various PI initiated research projects. He is the Co- PI of the BHP/HSPH Clinical Trials Unit, providing oversight and clinical mentorship for all CTU trials. He is Site PI for HPTN and the newly established COVID-19 Prevention Trials Network. He advises on the selection of the BHP clinical research portfolio. He has published and been involved in over 100 publications. He is interested in community HIV prevention initiatives, translational policy issues, and health systems strengthening.

Mompati Oganne Mmalane

MD, FRCS-Ed, MSc – Ortho

Dr Mmalane obtained his MD Degree from the University of Tuebingen then trained in surgery and became a Fellow of the Royal College of Surgeons of Edinburgh. He also holds an M.Sc. degree in Orthopaedics from the University College London. He has worked for 22 years in the public health sector before joining BHP as Co-Director in 2009. He is a co-investigator in several BHP studies. He has co-authored over 80 papers. Dr Mmalane's strength is in partnerships creation and management, community engagement, systems thinking, and strategic management and leads BHP's strategic planning activities. His main interest is in community- based research.

Ria Madison

Ms Ria Madison is Chief Operations Officer of BHP, providing overall oversight for Administration, Finance, Grants, Human Resources, IT and DMC. She is responsible for the oversight of all donor/grant funds, compliance of spending per donor requirements and meeting statutory and compliance audits. She also oversees the implementation and development of operating policies and strategic planning for Administration. Ms. Madison has been with BHP since its inception. She studied Accounts and Business Studies, Grants Management and Human Resource Management.

Cornelius Gaetsaloe

BCom, AHMP, AFP

Mr. Cornelius Gaetsaloe is Director of Finance and Grants. He is responsible for BHP's strategic financial management; grant administration and sustainability planning, the implementation of BHP policies and procedures through the administrative stewardship of BHP's portfolio of grants and research projects. Cornelius is also responsible for risk management and compliance and has more than 18 years' experience working in senior strategic positions in non-profit organizations.

Dineo Thebe

BAcc

Mrs. Dineo Tumagole is the Finance and Grants Manager at the BHP. Her role is to ensure effective management of BHP's funds through monitoring of Grant Budgets and compliance with sponsor regulations. She keeps tab of the internal control environment to ensure smooth Statutory and Yellow Book Audits. Dineo is a self-driven individual whose over 10 years of experience in the financial accounting and grants management environment has enabled her to build a robust Finance, Grants and Procurement Team and drive change. She has been working for the partnership since July 2012.

Beauty Mphonyana Malumbela

Dip.HRM, BSc, MBA

Beauty Mphonyana Malumbela is a Human Resources Specialist with demonstrated experience in the whole HR value chain, with emphasis in Cultural Transformation, Organizational Development and Performance Improvement. Ms. Malumbela holds a Bachelors of Science Degree, Diploma in Human Resource Management, and Master's in Business Administration. She has HR experience across multiple industries; Private, Governmental and NGOs. Ms Malumbela has broadened her knowledge in delivering powerful Human Capital Strategic Solutions for the Business, and understanding in the HR business partnering model.

D. SENIOR MANAGEMENT

Sikhulile Moyo - MSc, MPH, PhD

Dr. Moyo is BHP's Laboratory Director and a Research associate with HSPH. He is a former Harvard T.H Chan School of Public Health McGoldrick Fellow Biostatistics, and has completed2 Post-Doctoral Fellowships supported by NIH Fogarty International Center (Global Health Fellow, Harvard HBNU) and Wellcome Trust funded DELTAS SANTHE program (Post-Doc Scientific Fellowship, BHP). His interests include characterization of early HIV-1 Infection, estimating HIV incidence, evolutionary bioinformatics, phylogenetics and molecular epidemiology. He has made a number of significant recent advances in the analysis of HIV recency of infection by incorporating HIV diversity refine cross-sectional incidence estimation and over 140 peer reviewed publications. He has worked on various projects including: evaluation of point-of-care viral load and CD4 devices, early infant treatment, community-based prevention studies, Hepatitis, CMV and HPV genotyping, HIV-1 drug resistance. In 2016, Sikhulile was nominated co-vice Chair of the ACTG/IMPAACT Laboratory Technologist Committee. He participates in various international and local HIV technical working groups. Dr Moyo is a member of the Botswana's Presidential COVID-19 Task Force Team as a co-Chief Scientist. He and his team are the first to report the discovery of the omicron variant of SARS-CoV-2 to the world. He is an Investigator & Site-Principal Investigator for some NIH funded projects and is a supervisor/mentor for many fellows/researchers at BHP.

Gaerolwe R. Masheto - MD, PGDip FamMed

Dr. Gaerolwe Masheto started working at Botswana Harvard AIDS Institute (BHP) Clinical Trial Unit (CTU) in 2011 as a Study Physician and has worked with a team which has successfully conducted International Maternal, Paediatric, Adolescents AIDS Clinical Trials (IMPAACT), AIDS Clinical Trials Group (ACTG) and HIV Prevention Trials Network (HPTN) clinical trials. Currently Dr. Masheto is current CTU Coordinator, IMPAACT Network Project Leader/Principal Investigator (PI) and Molepolole Clinical Research Site Leader. Dr. Masheto is also a Co-Investigator for ACTG and HPTN studies. Dr Masheto graduated from Ross University School of Medicine in 2007 and from Stellenbosch University in 2012 with Post Graduate Diploma in Family Medicine. He is enrolled to Masters (MSc) in Clinical Epidemiology at the London University's London School of Hygiene and Tropical Medicine. Dr. Masheto's interests are in Public health, Infectious Disease Epidemiology and Management with a focus on design, modelling, implementation, monitoring and evaluation of HIV/AIDS and TB prevention, care/support, treatment programs, and PMTCT interventions. He is also interested in research for HIV Cure and he is a fellow for International AIDS Society (IAS) 2018 Academy-for-Cure Research

Ayotunde Omoz-Oarhe - MBBS, MPH

Dr Omoz-Oarhe is ACTG principal investigator and Gaborone clinical research site leader. He has worked with BHP Clinical Trials Unit (CTU) for 12 years now where he has served in various capacities and gained a wealth of research experience. He has been at the forefront in the conduct and oversight of numerous NIAID sponsored protocols covering a wide variety of public health issues including Tuberculosis and women's health. He has also served in various ACTG committees and is currently a serving member of the ACTG Performance Evaluation Committee (PEC).

Coulson Kgathi - BSc

Mr. Coulson Thabo Kgathi is a Software Engineering & Data Management Centre Manager at Botswana Harvard Partnership. His team builds data collection systems and laboratory systems for the research lab. He holds a BSc Computer Science and is currently doing his MSc in Computer Science. He has been part of the team that developed robust systems that collect data across the country in multiple communities with limited connectivity, with a system designed for functioning offline and capable of transmitting data when there is low bandwidth. This system enforces research protocols to ensure quality data, data security and easy data sharing.

Thuso Mokane - Bsc

Mr. Thuso Mokane is a Bachelor of Science in Computer Science graduate from the University of Botswana. He began his career in IT in 2012 as an Associate Software Engineer at DCDM Consulting and joined BHP in 2014 as a Systems Administrator, where he gained a lot of experience working on IT Systems based on open-source technologies. Throughout his career, he has gathered certifications in Linux System Administration, and is internationally recognised as an ISC2 System Security Certified Practitioner. Thuso Mokane is now the IT Infrastructure & Security Manager and utilises his skills in both systems administration and cyber security to ensure the availability of information systems and security of data

Terence Mohammed - BSc

Mr Terence Mohammed is the Laboratory Operations Manager at Botswana Harvard AIDS Institute Partnership (BHP). His primary role is to oversee technical operations of the clinical laboratory; including the clinical trials processing and testing labs, logistics of operations, maintenance of the laboratory accreditation and DAIDS GLCP status, implementation of the quality management plan, compliance to regulatory and sponsor requirements. Terence is a Biomedical Scientist by training and has been at BHP since Dec 2007, rising through the ranks and receiving multiple research/training fellowships.

Nyaladzi Comfort Maphorisa - BSc

Mr Nyaladzi Comfort Maphorisa is a medical laboratory scientific officer registered with the Botswana Health Professions Council. He is a product of Curtin University of Technology in Perth, Australia. He possesses twelve years' work experience in the medical laboratory field for which six years were in managerial position. He is currently the Clinical Laboratory Manager at Botswana Harvard HIV Reference Laboratory (BHHRL). The Clinical Laboratory Manager (CLM) is responsible for the technical and delegated administrative functions of the clinical laboratory day-to-day operations, including facilitating the conduct of BHP clinical research studies, maintenance of equipment, infrastructure and collaborative activities that involve laboratory operations. The CLM is required to ensure adherence to defined quality standards, regulatory and sponsor requirements, including timely, consistent, proficient and competent laboratory outputs

Tshepho Theodorah Frank - BPharm

Tshepho Theodorah Frank completed her pharmacy degree at the University of West Indies, Trinidad and Tobago. She completed an internship through the Botswana Government pharmacy internship program, which involves rotation in different pharmacy disciplines. She joined BHP in August 2010 as a Pharmacist of Record for Clinical Trials Unit. She was promoted to Pharmacy Coordinator and Pharmacist of Record for multiple protocols and multiple sites in April 2013.

Tumalano Sekoto - RN, MPH

Tumalano Sekoto is a Registered Nurse, Midwife and a Family Nurse Practitioner all obtained from the then National Institutes of Health between 1989 and 1996. She holds a BA (Psychological Counselling) and BA (Honors) Psychology from University of South Africa (UNISA), Postgraduate Diploma in Health Research Ethics from University of Stellenbosch and a Masters Degree in Public Health from UNISA. She joined BHP in 2000 as a Research Nurse based at the Mochudi Mashi Site. She was the first Study Coordinator for IMPAACT Network in 2007. She is currently the BHP Regulatory Coordinator responsible for all issues of Ethical Conduct of research and Human Subjects Protection. She is passionate about Research Ethics.

Tshenolo Ntalabgwe - BSc, MPH

Tshenolo Ntalabgwe is the Laboratory Quality Assurance Manager at BHP and her role is to implement the quality management systems, GCLP/GCP requirements and maintenance of laboratory accreditation. She has a BSc Biomedical Sciences degree from the University of KwaZulu Natal (UKZN), South Africa and completed Master's in Public Health at the University of Limpopo (UL), South Africa (Medunsa Campus). She is a National Quality Management Systems mentor, a Certified Auditor for the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) and a Trainer of Trainers for Strengthening Laboratory Management Towards Accreditation (SLMTA). Ntalabgwe started working for BHP in June 2005 as Laboratory Master Trainer. She has held various positions including Deputy Head, Viral Load Department and Section Head, DNA PCR section. She also worked as Quality Officer. She has also worked at the Ministry of Health and Wellness as Medical Laboratory Scientist.

E. PRINCIPAL INVESTIGATORS

Gbolahan Ajibola - MD, MPH

Dr Ajibola is a trained physician with a Master's in Public Health and over 10 years experience in clinical research at Botswana Harvard AIDS Institute Partnership (BHP). His research focus is on maternal-child health. Starting off as a study physician, routinely performing clinical evaluations on mothers and infants enrolled in both observational and interventional clinical trials. He was able to build logically on his prior works, and expertise, which earned him an early-stage investigator grant award by the EDCTP for his proposal to evaluate the risk of HIV acquisition among infants born preterm to women living with HIV and to quantify haematological toxicities of antiretroviral prophylaxis in preterm infants compared to infants born full-term, he has partcipated in several other clinicals trials in different capacities. He curently serves as Co-Principal investigator for the Point of Care HIV testing and Early Dolutegravir Use for infant study "MOSO", Co-Investigator and Study Coordinator/ Physician for the Early Infant Treatment Study (EIT) and the follow-up Tatelo study entitled "A Clinical Trial to Evaluate the Impact of Broadly Neutralizing Antibodies (bNAbs) VRC01LS and 10- 1074 on Maintenance of HIV Viral Suppression in a Cohort of Early-Treated Children in Botswana". He has authored and co-authored several publications.

Motswedi Anderson - BSc, PhD

Dr. Motswedi Anderson is a Wellcome International Training Fellow /BHP Research Associate. She has been with Botswana Harvard AIDS Institute Partnership since 2006. Her research interests are in viral hepatitis (B, C, D and E) and human immunodeficiency virus. She completed her PhD in Biological Sciences in 2018 and her project was 'Prevalence and molecular characterization of hepatitis B virus infection in Botswana'. She did Bsc in Biomedical Sciences with University of KwaZulu Natal, Durban, South Africa in 2005. She currently holds a Wellcome International Training Fellowship and an EDCTP-AREF training Fellowship. Her current project is 'Occult Hepatitis B Virus Infections in HIV-1- Infected Individuals in Botswana: Incidence, Kinetics and Mechanisms'. She aspires to be a renowned researcher and to play a key role in viral hepatitis elimination.

Ava Avalos - MD

Dr. Ava Avalos, a research associate with BHP, is an HIV/TB specialist physician who has been living and working in Botswana for the past 18 years. She has extensive clinical, research, policy, and programmatic experience, serving as a clinical advisor to the Department of HIV/AIDS Prevention and Care in the Botswana Ministry of Health and Wellness, since 2006. Her area of clinical research and technical expertise focus on ART treatment failure, HIV drug resistance, programmatic implementation and health economics. She is a member of the HIV & TB Clinical Care Guidelines Committee, the University of Botswana IRB, and serves as vice-chair on the board of the International Treatment Preparedness Coalition (ITPC).

Laura Bogart - PhD

Dr. Laura Bogart, PhD, Senior Behavioral Scientist at RAND Corporation, is a social psychologist with expertise in behavioral factors in HIV prevention and treatment. In collaboration with BHP, she previously conducted a study to examine individual and social network-level factors associated with viral suppression among people living with HIV and their treatment partners, and she is now conducting a study to develop and pilot test a clinic-based intervention to improve the effectiveness of treatment partners in Botswana. In Uganda, she is conducting a community-based PrEP intervention among fisher folk, as well as research to develop a program for people living with HIV to promote HIV prevention in their social networks. Her U.S. work includes interventions to reduce HIV-related health inequities.

Lisa Butler MA, MPH - PhD

Dr. Lisa Butler is a research associate with BHP. She is a behavioral scientist and epidemiologist with methodologic expertise in the development and evaluation of community-based interventions to improve health and mental health outcomes for vulnerable and low-literacy populations in sub-Saharan Africa (sSA), particularly in high HIV prevalence settings. Her interventional research often incorporates the use of media (e.g., video, photography, radio, comics) and mobile technology. In collaboration with BHP, she is the PI of Monona ke Isago (Youth are the Future) , a multi-component intervention designed to raise awareness and reduce stigma related to perinatal depression, and to identify and provide support to adolescents with symptoms of depression during pregnancy or in the early postpartum period.

Ellen Caniglia - ScD

Ellen (Ellie) Caniglia is a perinatal and HIV epidemiologist who works to improve health outcomes among pregnant people and their children, and among people with HIV. She completed her doctorate in Epidemiology from the Harvard Chan School of Public Health and is now an Assistant Professor at the University of Pennsylvania. She has been working with the Tsepamo Study in Botswana since 2016. Her current work is funded by a K01 award from the National Institutes of Health to estimate the effects of multiple micronutrient supplementation strategies during pregnancy on adverse birth outcomes, to identify barriers and facilitators to supplementation, and to pilot an intervention to provide supplementation at antenatal clinics in Botswana.

Adam R. Cassidy - PhD, LP, ABPP-CN

Adam R. Cassidy, PhD, LP, ABPP is a board-certified pediatric neuropsychologist, senior associate consultant, and assistant professor of psychology at the Mayo Clinic in Rochester, Minnesota, USA, where he has joint appointments in the Departments of Psychiatry & Psychology and Pediatric & Adolescent Medicine. He is also a member of the scientific staff at Boston Children's Hospital and Harvard Medical School. Dr. Cassidy's research focuses on understanding and optimizing neurodevelopmental and psychosocial outcomes in at-risk populations, primarily individuals with congenital heart disease and children exposed in utero to HIV. He has been involved in research in Botswana since 2015 and is currently co-PI (along with Dr. Shahin Lockman) of the NIH/NIMH-funded "Motheo Study" (Neurodevelopment In HEU Children Exposed In Utero To Dolutegravir Or Efavirenz and HIV-Unexposed Children). In addition to research, Dr. Cassidy has an active clinical practice, is Consulting Editor for the journals Child Neuropsychology and The Clinical Neuropsychologist, serves on the Board of Directors of the American Board of Clinical Neuropsychology, and is Co-Chair of the Cardiac Neurodevelopmental Outcome Collaborative (CNOC).

Bruce Chabner - MD

For the past 48 years Prof. Chabner has devoted himself to a career in cancer research and drug development. He directed the Drug Development Program and the clinical trials efforts of the National Cancer Institute, as Director of the Division of Cancer Treatment, for 14 years (1981-1995), and have designed, participated in, and reported clinical and laboratory studies of new agents, including maytansine, folate analogues, paclitaxel, fludarabine, and yondelis. He moved to Harvard Medical School and the Massachusetts General Hospital many years ago, where he was Chief of the Division of Hematology/Oncology from 1995-2006 and Clinical Director of the MGH Cancer Center from 1995-2010.

Scott Dryden-Peterson - MD, MSc (epi)

Dr. Dryden-Peterson's research centers on epidemiology and therapeutic approaches for cancers arising in the context of HIV. He directs one of the largest prospective cohorts of HIV-associated cancers at BHP. Ongoing projects include evaluation the impact of HIV and ART on the cancer burden in sub-Saharan Africa, development of new diagnostics and diagnostic approaches to cancer in LMICs, treatment outcomes of HIV-associated cancers in Botswana, and strategies to improve access to timely oncology care in resource constrained settings. He is co-founder of Botswana Oncology Global Outreach (BOTSOGO).

Jason A. Efstathiou - MD, DPhil

Dr Jason Efstathiou serves as Associate Professor of Radiation Oncology at Harvard Medical School and the Massachusetts General Hospital (MGH) and holds an Associate Researcher position with BHP. He is the Director of the Genitourinary Division in Radiation Oncology and Clinical Co-Director of The Claire and John Bertucci Center for Genitourinary Cancers Multidisciplinary Clinic at MGH. He holds a B.S. from Yale University, M.D. from HMS, Ph.D. from University of Oxford, and completed his residency training in the Harvard Radiation Oncology Program. Dr. Efstathiou's clinical practice focuses on treatment of patients with prostate, bladder, testicular and other urologic cancers, as well as proton beam and brachytherapy. He co-founded and co- directs BOTSOGO (Botswana Oncology Global Outreach).

Tendani Gaolathe - BS, MD

Dr. Tendani Gaolathe graduated from St Georges U. School of Medicine in Grenada in 1996 and residency in Internal Medicine from Seton Hall University. Dr Gaolathe as a clinician has managed public health programs and conducted observational and clinical trials related to the HIV/AIDS epidemic in Botswana since 2001. She joined BHP in 2005 as Director for the Master Trainer Program, BHP's flagship training program that has been instrumental in securing success of the Botswana's Antiretroviral program clinic rollout, task shifting, laboratory decentralization, and national Monitoring and Evaluation efforts. She was also the Project Director for BCPP. She is currently a lecturer at the University of Botswana within the Faculty of Medicine and she is the Assistant Program Director of the Department of Internal Medicine.

Simani Gaseitsiwe - BSc, PhD

Dr. Simani Gaseitsiwe is with Botswana Harvard AIDS Institute Partnership (BHP) as well as with the Harvard T. H. Chan School of Public Health. He is the Botswana Principal Investigator for the H3ABioNet and SANTHE grants. His research focuses on HIV-1 subtype C drug resistance, Hepatitis B Virus and TB molecular epidemiology in Botswana and more recently he is also involved in SARS-CoV-2 molecular epidemiology studies. Dr Gaseitsiwe is responsible for overall supervision of basic science research laboratory, and for guidance and mentorship of research fellows, scientists, and students. He has over 90 publications in peer-reviewed journals.

Jennifer Jao - MD, MPH

Dr. Jennifer Jao is an Associate Professor at the Northwestern University Feinberg School of Medicine in the Departments of Pediatric and Adult Infectious Diseases whose research focus is HIV maternal child health. She obtained her BA in French Literature at Tulane University and MD at the Medical College of Georgia. She went on to complete a combined Internal Medicine/Pediatrics residency at Rush University Medical Center in Chicago and her Infectious Disease Fellowship along with her MPH degree at the Icahn School of Medicine at Mount Sinai. Dr. Jao has led NIH-funded cohorts of pregnant women with HIV and their children both in the U.S. and Africa, and as a translational researcher, her research portfolio targets the long-term metabolic effects of in utero exposure to HIV and antiretroviral medications. She is a member of the U.S. Panel on the Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission Guidelines Panel, Co-Chair of the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) network P1115 protocol “Very Early Intensive Treatment of HIV-Infected Infants to Achieve HIV Remission” and Co-Chair of the Nutrition, Growth, and Metabolic Working Group in the Pediatric HIV/AIDS Cohort Study (PHACS).

Joseph Jarvis - MBBS, BSc, MSc, MRCP, PhD, DTMH

Prof. Joe Jarvis is a Research Associate at the Botswana Harvard AIDS Institute Partnership, and a Professor at the London School of Hygiene and Tropical Medicine, based full time in Gaborone, Botswana. His main research interests are advanced HIV disease, opportunistic infections, cryptococcal meningitis, and strategies to rapidly and safely initiate ART in individuals with low CD4 counts. In addition to being the Chief Investigator for the AMBITION-cm trial examining new treatments for HIV associated cryptococcal meningitis, he recently worked as Research Director for the CDC Implementation Protocol of the Botswana Combination Prevention Project (BCPP). He is also a member of the external review group for the WHO Guidelines for Managing Advanced HIV Disease and Rapid Initiation of Antiretroviral Therapy, and a guidelines development group member for WHO guidelines on preventing, diagnosing, and managing cryptococcal disease in HIV infected adults, adolescents and children.

Sara Schwanke Khilji - MD, MPH, FACP

Dr. Sara Schwanke Khilji is an Associate Professor of Medicine at Oregon Health & Science University (OHSU). She currently serves as the Internal Medicine Site Director for the Botswana Harvard Partnership's Clinical Capacity Building Program in Kweneng District. In this role, she supports clinical stewardship, health professional education, quality improvement, and related research initiatives at Scottish Livingstone Hospital and the surrounding district. Dr. Schwanke Khilji completed her MD and MPH at Mount Sinai School of Medicine, followed by residency in Internal Medicine and Primary Care at Massachusetts General Hospital and an Overseas Research Fellowship in Thailand with the London School of Hygiene & Tropical Medicine (LSHTM). She is actively involved in medical, inter-professional, and public health education in Botswana and at OHSU, while continuing to serve as a distance learning tutor for LSHTM. Her research interests include women's health, health policy, and non-communicable diseases (NCDs)

Catherine K. Koofhethile - BSc, MSc, PhD

Dr Koofhethile is a Motswana scientist currently based in the United States of America. In 2017 she joined Prof. Max Essex laboratory at the Harvard T.H. Chan School of Public Health (HSPH), in Boston, USA as a Postdoctoral Fogarty Fellow and is now under the mentorship of Prof. Roger Shapiro and Prof. Phyllis Kanki. She is also a visiting/collaborative Postdoctoral fellow at The Ragon Institute of MGH, MIT & Harvard under the mentorship of Prof. Mathias Lichterfeld. She holds a Research Associate position at the Botswana Harvard AIDS Institute Partnership (BHP), Botswana working closely with Dr. Joe Makhema and Dr. Sikhulile Moyo. She holds PhD in Immunology from University of KwaZulu-Natal, South Africa sponsored by Organization for Women in Science for the Developing World (OWSD), Master's Degree in Immunology from University of Birmingham, UK and a Bachelor of Science Degree with Honors in Medical Microbiology from the University of Surrey, Guildford, UK sponsored by the Government of Botswana.

Shahin Lockman - MD, MPH

Dr. Lockman is an infectious-disease trained clinician (Associate Professor at Harvard Medical School/Brigham and Women's Hospital and adjunct at HSPH). She has conducted epidemiologic and clinical trials investigation related to HIV-1 and tuberculosis with colleagues in Botswana since 1996, including randomized trials of antiretroviral treatment among pregnant and postpartum women with HIV; trials and observational studies aimed at optimizing the health and neurodevelopmental outcomes of HIV-exposed children, and community-based interventions to prevent HIV transmission (including the Botswana Combination Prevention Project). She helped establish and co-leads the BHP Clinical Trials Unit. Dr. Lockman mentors many early-stage investigators in both Botswana and the US on a range of clinical research projects and is supported by a K24 mentoring grant to do so.

Rebecca Luckett - MD, MPH

Rebecca Luckett is an Obstetrician Gynecologist at Beth Israel Deaconess Medical Center in Boston and at Princess Marina Hospital in Botswana. She is an Assistant Professor in Obstetrics and Gynecology at Harvard Medical School and the Assistant Programme Director of OBGYN at the University of Botswana. Dr. Luckett's research focuses on the intersection of cervical cancer and HIV, maternal perinatal outcomes and education in a global context. An active educator, Dr. Luckett facilitated the development the first OBGYN residency training program at the University of Botswana and participates in resident and undergraduate medical education.

Richard Marlink - MD

Richard Marlink, MD is a medical oncologist, the founding director of Rutgers Global Health Institute, and the inaugural Henry Rutgers Professor of Global Health at Rutgers University. He trained in hematology/oncology at Beth Israel Deaconess Medical Center, a teaching hospital of Harvard Medical School, and was a professor of public health at Harvard University, working in various countries. Marlink was one of the first members of the Botswana-Harvard AIDS Institute Partnership and a co-founder of the African Comprehensive HIV/AIDS Partnerships. Along with Tendani Gaolathe and others, he created Botswana's KITSO AIDS Training Program. Following the launch of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in 2003, he was Botswana's country director for the Botswana-Harvard joint PEPFAR effort. Concurrently, he was principal investigator of the Elizabeth Glaser Pediatric AIDS Foundation's Project HEART, a PEPFAR effort in five other African countries that provided HIV/AIDS care for over a million people. At Rutgers, he established the Botswana-Rutgers Partnership for Health, which is focused on building comprehensive cancer care and prevention programs while also contributing to pandemic preparedness and response in Botswana.

Chelsea Morroni - MBChB, DFSRH, MPH, PhD

Dr. Chelsea Morroni a research associate at the Botswana-Harvard AIDS Institutewhere she directs the Botswana Sexual and Reproductive Health Research Initiative (BSRHI). She is an epidemiologist and medical doctor with over 20 years of experience in Southern Africa. She has an undergraduate degree from Harvard, an MPH and medical degree fromtheUniversity of Cape Town, and a PhD from Columbia University. She has lived with her family in Botswana for 8years. Here, she conducts mixed-methods research and provides clinical care relating to women's and girl's sexual and reproductive health (SRH), particularly prevention of unintended pregnancy and HIV/STIs. Chelsea is a Chancellor's Fellow and a Reader in Global SRH at the University of Edinburgh Centre for Reproductive Health, an honorary Professor ofWomen's Health at University of Cape Town, and Co-Director of the UK Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit.

Mosepele Mosepele - MD, MSc

Professor Mosepele Mosepele is a Research Associate with BHP since 2014. As an Infectious Disease Consultant and Clinical Epidemiologist, his research focuses on HIV-associated complications such as cardiovascular disease and immune dysregulation. Professor Mosepele is the Botswana site Principal Investigator on several protocols funded by partners in Europe and the US, including the AMBITION-cm trial (High Dose AMBISOME on a Fluconazole and Flucytosine Backbone for Cryptococcal Meningitis Induction Therapy in sub-Saharan Africa: A Randomised Controlled Non-Inferiority Trial), the REPRIEVE trial (Randomized Controlled Trial of Prevention of Vascular Events in HIV) at BHP and also acts as Co- PI on a pilot study focusing on social network-level factors associated with viral suppression among HIV-infected patients at a Gaborone HIV Clinic, also at BHP. He was awarded a prestigious NIH implementation science grant in 2020, to integrate cardiovascular care cascade within existing HIV services in Botswana (InterCARE), a collaborative trial with stakeholders in the US, UK, Botswana and other countries in the SSA region. He is a committed educator with faculty position at the University of Botswana (UB) where he lectures medical students and mentors several early career researchers, both at UB and the BHP. Professor Mosepele has been working as the Deputy Coordinator for the Botswana Presidential COVID-19 Taskforce since March 2020.

Lucy Mupfumi PhD

Dr. Lucy Mupfumi is an infectious disease scientist with interests in the epidemiology of HIV and tuberculosis (TB) co-infection in HIV-prevalent settings in sub-Saharan Africa. Over the past 6 years, Lucy's work has revolved around HIV-associated TB and point of care diagnostics. She has over 18 publications describing the impact of Xpert MTB/RIF assay on patient outcomes, incident TB in ART programs, biomarkers for HIV and TB treatment response, and point of care diagnostics for HIV. Lucy is currently a Fogarty Global Health Fellow and is modelling the trajectory of the TB epidemic in Botswana with expanded ART.

Rosemary Musonda - PhD

Dr. Musonda is a BHP Research Associate and former Laboratory Director. She is also a Research Associate at the Harvard T.H. Chan School of Public Health. Her main interests are in understanding the molecular structure of HIV, its pathogenesis, and the nature of host immunity to the virus. She is involved with capacity building and training young investigators in Africa. Dr. Musonda holds several grants dedicated to postgraduate training of African scientists in southern Africa.

Vladimir Novitsky - MD, PhD

Dr. Vladimir Novitsky, MD, PhD, is a Principal Research Scientist in the Department of Immunology and Infectious Diseases at the Harvard T.H. Chan School of Public Health. Dr. Novitsky has made a number of significant contributions to the virological and immunological study of HIV-1 infection. The main focus of Dr. Novitsky's research is molecular analysis of the HIV-1 subtype C epidemic, genotypic and phenotypic characterization of the HIV-1 subtype C genome, and potential associations between virological and immunological parameters in early and acute HIV-1 subtype C infection. He contributed significantly to the design, planning, capacity building, and supervision of the Botswana Harvard AIDS Institute Laboratory in Botswana.

Ponego Ponatshego - MD, DTMH

Dr. Ponego Ponatshego is the Study Physician/Coordinator for IMPAACT studies in the Botswana Harvard AIDS Institute Partnerships's Clinical Trials Unit (CTUDr Ponatshego holds a medical degree from Rostov State University, Russia; Diploma in HIV Management from Colleges of Medicine of South Africa; a Professional Diploma in Tropical Medicine and Hygiene from the London School of Hygiene and Tropical Medicine and a postgraduate Diploma in Public Health from University of South Africa. He is also an AIDS Clinical Trials (ACTG) Fellow currently conducting clinical research termed Albuminuria and Frailty association in HIV Infection.

Kathleen M. Powis - MD, MPH, MBA

Dr. Kate Powis is board certified in both Internal Medicine and Pediatrics and has held a medical license to practice medicine in Botswana since 2008. In addition, Dr. Powis is an Associate Professor at Harvard Medical School. Her primary research is focused on HIV and maternal-child health, with a particular focus on understanding short- and longer-term health and developmental outcomes of children with exposure to HIV and antiretroviral drugs in utero who remain HIV- uninfected. She currently is the Principal Investigator of three NIH funded studies being conducted at BHP and provides mentoring to BHP clinicians who are early career researchers.

Kaelo Seatla MD - MPH, PhD

Dr Kaelo Seatla is a medical doctor and since 2011 has been caring for persons living with HIV (PWH) in clinics in Botswana, including patients with extensive HIV-1 drug resistance mutations (DRMs). He has been trained in clinical research at the Botswana Harvard AIDS Institute Partnership where he worked on ACTG, IMPAACT and HPTN network trials for over 5 years. Dr Seatla is currently an Africa Research Excellence Fund Postdoctoral Research Fellow training on advanced viral replicative capacity assays at Prof. Thumbi Ndung'u's lab at the Africa Health Research Institute (AHRI), Durban, South Africa. His primary research interests are in the development and implementation of low-cost HIV drug resistance (HIVDR) testing assays, monitoring for DRMs amongst PWH failing DTG ART, and evaluating viral replication capacities and subsequent in-vitro DTG susceptibilities to HIV-1C viruses laden with DRMs in Botswana. He has developed one of the largest cohorts of treatment-experienced individuals infected with HIV-1C with virological failure while on DTG-based regimens. Dr Seatla completed medical training at University of the West Indies, Trinidad and Tobago, East African Diploma in Tropical Medicine and Hygiene (DTM&H) from the London School of Hygiene & Tropical Medicine and has a PhD in Health Sciences from the University of Botswana where he also serves as a part-time Clinical Skills Tutor in the Faculty of Medicine.

Roger L. Shapiro - MD, MPH

Prof. Roger Shapiro is an Associate Professor of Immunology and Infectious Diseases at the Harvard TH Chan School of Public Health in Boston, and an Infectious Disease physician at the Beth Israel Deaconess Medical Center in Boston. He has been working with the Botswana-Harvard Partnership since 1999 on studies to prevent mother-to-child HIV transmission (PMTCT) and to improve pregnancy outcomes and childhood survival. In Botswana, he has led randomized clinical trials to evaluate optimal antiretroviral strategies for PMTCT at delivery and during breastfeeding; a randomized trial to study the efficacy of prophylactic cotrimoxazole among HIV exposed uninfected infants; nationwide surveillance studies to evaluate the mechanisms by which antiretrovirals impact adverse birth outcomes; an ongoing clinical trial of early antiretroviral treatment to improve clinical outcomes in HIV-infected infants; and an ongoing study of broadly neutralizing antibodies for HIV treatment in children.

Emily Shava - MBChB, MSc

Dr Emily Shava is a Clinician who is also a Research Associate at the Botswana Harvard AIDS Institute Partnership and at Harvard T. H. Chan School of Public Health. She holds an MBChB from the University of Zimbabwe College of Health Sciences and an MSc from London School of Hygiene and Tropical Medicine. She was previously a Co-Investigator and Study Physician for HIV Prevention Trials Network within the Clinical Trials Unit at BHP from 2009-2019. She is interested in HIV prevention amongst high risk populations and is currently conducting a study to pilot HIV self- testing in female sex workers in Gaborone (Ikitse Study).

Neo M. Tapela - MD, MPH

Dr. Tapela is an internal medicine physician, epidemiologist and healthcare innovator who is currently Chief Scientific Officer and VP (Outcomes Research) at the international non-profit, ICHOM. She has been a research associate at BHP since 2015. Her research specializes in understanding the determinants and patient-centered outcomes of chronic non-communicable diseases (NCDs), and designing innovative equity-driven interventions addressing these conditions in resource-limited settings. Dr Tapela has over a decade's experience leading research in the sub-Saharan African region, including co-leading the Potlako+ study: a cluster-randomized trial evaluating a multicomponent intervention for early diagnosis of cancer. Her research and consultancy work are informed by experience in health policy, NCD strategic planning and program evaluation (she is former Head of Botswana's National NCDs Program). Dr Tapela holds an MD and MPH from Harvard University; she is Associate Physician at Brigham and Women's Hospital (Division of Global Health Equity) and Visiting Fellow at the University of Oxford (Nuffield Department of Population Health)

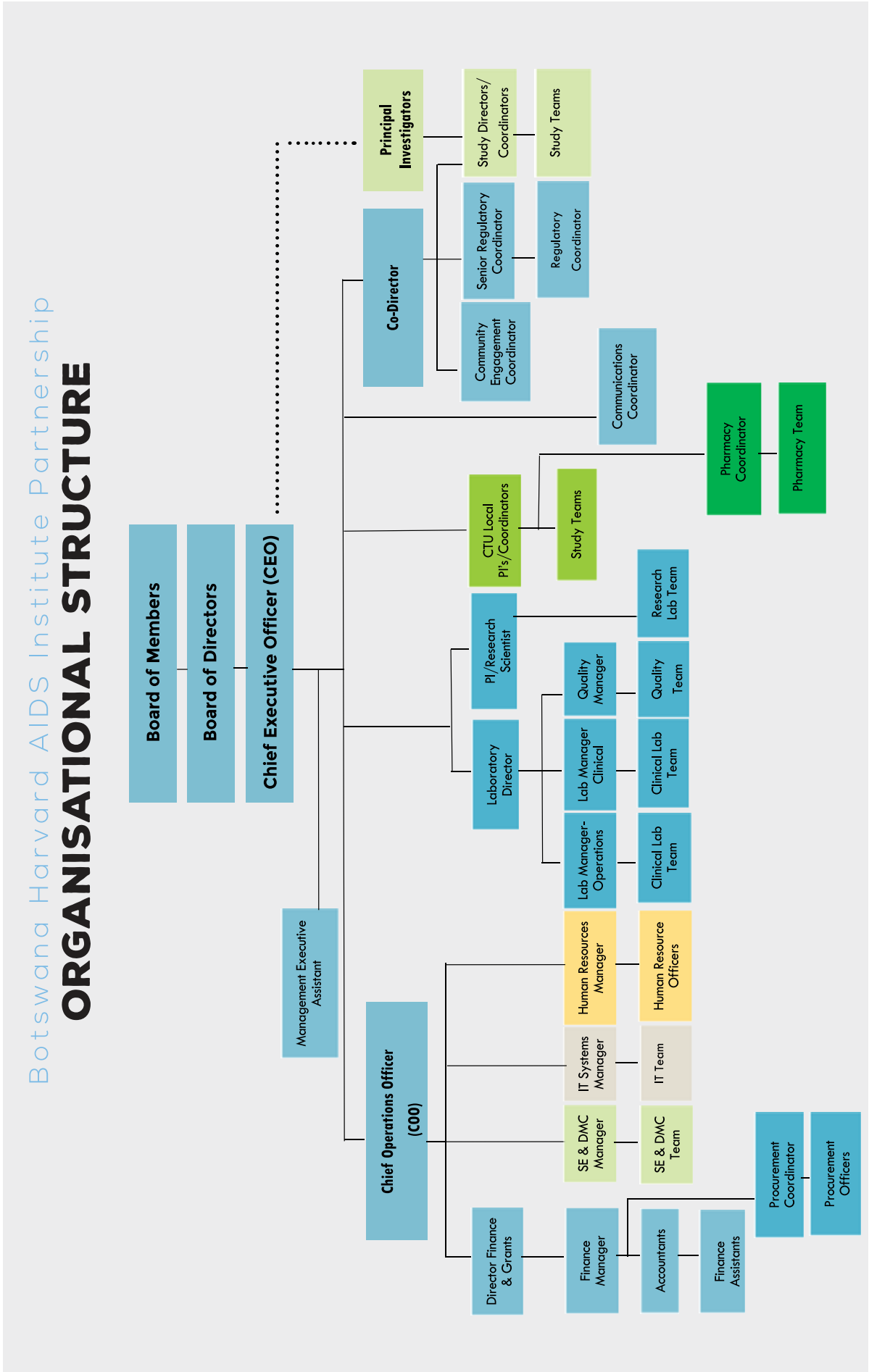
Nabila Youssouf - PhD

Dr Youssouf is an alumnus of Imperial College London (MSc Human Molecular Genetics 2008; PhD Statistical Genetics 2012), where she started her career in clinical research, overseeing breast cancer drug trials. She moved to the London School of Hygiene and Tropical Medicine in 2015 where she managed several trials including the CRASH trials (use of tranexamic acid in patients with TBI) and the AMBITION-cm trial which prompted her relocation to Botswana in 2017. Since the completion of the AMBITION-cm trial, Nabila joined Professor Mosepele's research group as its Research Program Manager where she holds a hybrid role, 1. Performing administrative, financial and regulatory duties, mainly on the InterCARE trial (integration of CVD care within existing HIV services) and the WHO Solidarity PLUS trial (RCT of additional treatments for COVID-19 in hospitalised patients who are all receiving the local SoC), and 2. Leading research projects as principal investigator and developing proposals. Her interests include public engagement; implementation science methodology and COVID-19 related impact on healthcare systems and clinical research. She was recently awarded an early-stage investigator grant through the NIH/NHLBI to investigate the effects of the pandemic on 6 implementation science research projects in sub-Saharan Africa. Nabila was elected to the United Kingdom Trial Managers Network (UKTMN) Executive Board in September 2021 to lead its professional development strategy and trial management competency groups. Nabila is an active educator with teaching positions on the distance learning Infectious Diseases program and the newly established course on Pandemic Preparedness Response & Research, both at the London School of Hygiene and Tropical Medicine.

Rebecca Zash - MD

As an assistant professor at Harvard medical school, Dr. Rebecca Zash is an infectious diseases physician and performs research focused on the impact of HIV and antiretroviral medications on pregnancy, and holds a research associate position with BHP. Dr. Zash went to medical school at the University of North Carolina, and completed internal medicine residency and infectious disease fellowship at Beth Israel Deaconess Medical Center in Boston, USA. She has been working with BHP since 2013 and currently serves as PI for one study to understand why HIV-infected women on ART have an increased risk of adverse birth outcomes and one study to evaluate cardiometabolic adverse effects of ART in post-partum women and their infants. She also helps to lead a large birth outcomes surveillance study, Tsepamo, which examines the comparative safety of antiretroviral treatments in pregnancy.

4. ORGANISATIONAL STRUCTURE



5. ACRONYMS

ACEI	- Angiotensin Converting Enzyme Inhibitors
ACHAP	- African Comprehensive HIV/AIDS Partnerships
ACTG	- AIDS Clinical Trials Group
AIDS	- Acquired Immuno-Deficiency Syndrome
ANC	- Antenatal Clinics
ART	- Antiretroviral Therapy
BCG	- Bacille Calmette-Guerin
BHHRL	- Botswana Harvard HIV Reference Laboratory
BHP	- Botswana Harvard AIDS Institute Partnership
BDIMC	- Beth Israel Deaconess Medical Center
BIUST	- Botswana International University of Science & Technology
bNAbs	- Broadly Neutralizing HIV-1 Antibodies
BOMAID	- Botswana Medical Aid Society
BOTSOGO	- Botswana Oncology Global Outreach
CAB	- Community Advisory Board
CAB-LA	- Cabotegravir Long Acting
CBO	- Community Based Organisations
CE	- Community Engagement
CODA	- Contraceptives & Dolutegravir-based ART
CoVPN	- COVID-19 Prevention Network
CROI	- Conference on Retroviruses and Opportunistic Infections
CTU	- Clinical Trials Unit
DHMT	- District Health Management Team
DLM	- Delamanid
DTG	- Dolutegravir
DMPA	- Depot Medroxyprogesterone Acetate
EDC	- Electronic Data Capture
EDCTP	- European and Developing Countries Clinical Trials Partnership
EFV	- Efavirenz
EIT	- Early Infant Treatment
EBI	- Evidence-Based Interventions
EQA	- External Quality Assurance
FLOURISH	- Following Longitudinal Outcomes to Understand, Report, Intervene and Sustain Health
GCP	- Good Clinical Practice
HHCs	- Household Contacts
HEU	- HIV Exposed uninfected
HIV	- Human Immunodeficiency Virus
HIV/AIDS	- Human Immunodeficiency Virus/ Acquired Immuno-Deficiency Syndrome
HPV	- Human Papilloma Virus
HSPH	- Harvard TH Chan School of Public Health
HPTN	- HIV Prevention Trials Networks
HU CFAR	- Harvard University Center for AIDS Research

HU	- Harvard University
HUU	- HIV Unexposed Uninfected
IMPAACT	- International Maternal, Pediatrics, and Adolescents AIDS Clinical Trials
IRB	- Institutional Review Board
KFBUS	- King Baudouin Foundation United States
LMICs	- Low- and Middle-Income Countries
LTBI	- Latent TB Infection
MBA	- Master of Business Administration
MBBS	- Bachelor of Medicine, Bachelor of Surgery
MD	- Doctor of Medicine
MOH	- Ministry of Health
MPH	- Master of Public Health
MPhil	- Master of Philosophy
MRCP	- Membership of the Royal Colleges of Physicians of the United Kingdom
MSc	- Master of Science
NCI	- National Cancer Institute
NHL	- National Health Laboratory
NIH	- National Institutes of Health
NGO	- Non-Organizational Organisations
NTDs	- Neural Tube Defects
OLE	- Open Label Extension
PBMCs	- Peripheral Blood Mononuclear Cells
POC	- Point-of-Care
PRC	- Polymerase Chain Reaction
PhD	- Doctor of Philosophy
PI	- Principal Investigator
PK	- Pharmacokinetic
PMTCT	- Prevention of Mother to Child Transmission
PrEP	- Pre-Exposure Prophylaxis
REPRIEVE	- Randomized Trial to Prevent Vascular Events
SADCAS	- Southern African Development Community Accreditation Service
SANTHE	- Sub-Saharan Network for TB/HIV Research Excellence
SES	- Socio-Economic Status
SIEM	- Security Information and Event Management system
SLH	- Scottish Livingstone Hospital
SOC	- Standard-of-care
TB	- Tuberculosis
TDF/FTC	- Tenofovir Disoproxil Fumarate/Emtricitabine
TESA	- Trials of Excellence in Southern Africa
UB	- University of Botswana
USA	- United States of America
USD	- United States Dollar
WHO	- World Health Organisation
WLHIV	- Women living with HIV

6. FOREWORD BY BOARD CHAIRMAN

On behalf of the Board of Directors, I am delighted to present to you the 2021/22 Annual Report. The report records BHP performance for the year ending June 2022. As in 2021, BHP operations were impacted by COVID-19, but this did not dampen our resolve to conduct cutting edge public health research, and a great deal of work has been accomplished.

In 2021/2022, BHP turned the tide in the fight against COVID-19, playing an important role in the global pandemic. Our major highlight for the year, which reflects success against all odds, is the discovery of the Omicron SARS-CoV-2 variant by our Laboratory Director, Dr. Sikhulile Moyo. This breakthrough catapulted BHP and Dr. Moyo to the front page of newspapers around the world, and placed BHP at the heart of the scientific response to the COVID-19 panademic. Since the discovery, Dr. Moyo has received global accolades that include being named one of the 100 most influential people in the world for the year 2022 by TIME Magazine, being named among the 100 Most Influential Africans in 2022 by New African Magazine, and winning the prestigious German Africa Award for 2022. Dr. Moyo has also been awarded the Jesse Jackson International Humanitarian Award at the 32nd Annual Rev. Dr Martin Luther King Jr Celebration, where he received a special commendation by Rev. Dr Jesse Jackson during his annual speech.

The discovery of the Omicron was a result of an unrivaled Pathogen Genomic Surveillance program at BHP, which to date has contributed over 5000 SARS-CoV-2 whole genome sequences to GISAID, a global science initiative that provides open access to genomic data of influenza viruses and the coronavirus responsible for the COVID-19 pandemic. BHP has been able to track lineages and SARS-CoV-2 variants of concern in circulation in Botswana, contributing to our understanding of the SARS-CoV-2 viral evolution. These data have also informed vaccine design by pharmaceutical companies, helping to adapt and strengthen vaccine development.

Other BHP scientists have risen to the challenge of the COVID-19 epidemic as well. BHP participated in and conducted several SARS-CoV-2/COVID-19 studies in 2021/2022. From July 2021 to June 2022, BHP conducted 10 studies related to SARS-CoV-2, including eight led by BHP principal investigators and two Network Studies (CoVPN 3008 and CoVPN 5001). Conducting these studies demonstrated our devotion to fight emerging public health challenges that generate high impact scientific data and inform policies and COVID-19 treatment guidelines. At the same time, we have never taken our eye off of our mission to fight HIV and related diseases, and BHP expanded its portfolio of studies in HIV during 2021/2022.

BHP prides itself in these scientific accomplishments, even as it has faced financial constraints and operational challenges related to COVID-19. I commend our scientists and staff for their tireless commitment, selflessness, and dedication during this crisis. They set high research standards and achieved their goals. The accomplishments in 2021/2022 are testimony to our vision to be a world-renowned public health institution, generating impactful scientific knowledge that influences health policy and practice for the entire world.

With sincere gratitude,

Roger L Shapiro

Prof. Roger Shapiro
BHP Board Chairman

7. CHIEF EXECUTIVE OFFICER'S REMARKS

The past year continued to pose inconceivable challenges and change but we at BHP together with our stakeholders remained focused on executing our mandate. BHP developed and introduced new strategies in response to the disruptions to normal business operations caused by COVID-19. The implementation of these strategies resulted in the continued realization of significant overall BHP strategic objectives.

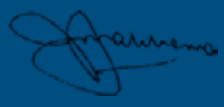
During the year we published 89 manuscripts in international peer-reviewd scientific journals, a slight reduction from last year's tally of 91. We increased the number of abstracts presented at the different local and international conferences from last year's 16 to 30. Even with the challenge of delivering under enormously adverse conditions, we conducted more research than in the previous period. Our Principal Investigator (PI) initiated research projects increased from 24 to 30 while our Network Clinical Trials remained at 11. COVID-19 studies at BHP saw a sharp increase from four studies to 10 this year.

Because of our effective financial resources management and compliance to best practices in finance and grants management, BHP's Annual Financial and Generally Acceptable Government Auditing Standards (GAGAS) audits have remained unqualified over the years. The Financial Year 2022 revenue increased by 9%, resulting in a total of USD 10.4 million compared to USD 9.6 million in financial year 2021. Grant applications during the period also saw a substantial rise from last year's 30 to 44 applications, (an increase of 47% from the previous year). Of the 44 grants, the number of funding applications for large , medium and small sized grants were 19, 12 and 13 respectively. Of these 44 grants applied for, 24 were successfully awarded. Overall, however, BHP revenue from new grants declined from USD3.4m to USD2.7m.

We take pride in our prudent financial management strategies where we intensively prioritise our capital and operating expenditure as a critical survival factor for the company. In order to increase our presence to our various publics, this year we launched our refurbished website (www.bhp.org.bw) which will go a long way in sharing our incredible success story of public health research. The website will also provide a means for fundraising through a donation button where donors can make online cash donations to help us fund our research.

BHP continues to strive towards sustainability by nurturing and maintaining a pipeline of early career investigators and trainees who can independently apply for research grants and are ever ready to take up various roles and positions in the organization. This year, one of our young scientists, Ms Bonolo Phinius won the innaugral Charles Boucher Award for Excellence in Science 2022, an immense accomplishment which is testament of the excellent Training and Capacity Building at BHP. Other emerging early investigators include Dr Ajibola's MOSO Study "Point-of-care HIV testing and Early Dolutegravir use in Children" Dr Seatla's "Evaluating Clinical and molecular responses amongs SARS-COV-2 coinfected individuals in Botswana" Dr Anderson's "In vitro functional analysis techniques to characterize occult hepatitis b infection associated mutations in Botswana"

I extend my profound gratitude to the BHP Board of Directors for their relentless support and wise counsel and commend BHP investigators, Research Associates, Scientists, Staff and Collaborators who continue to serve with great self application to ensure that we produce quality research outputs that save lives.



Dr. Joseph Makhema
BHP Chief Executive Officer

8. EXECUTIVE SUMMARY

The Botswana Harvard AIDS Institute Partnership (BHP) is proud to report on yet another successful year (July 2021 to June 30, 2022) of research and capacity building. The year 2021 was a year characterized by the worst impact of SARS-CoV-2 pandemic. The negative impact of the COVID-19, driven mainly by the Delta variant of SARS-CoV-2, was felt not only at individual level, but also at organization, and at country level. BHP was not spared, but despite the challenges resulting from the pandemic, the organization continued to perform exceptionally well in delivering on its mandate.

BHP's strategic direction is anchored on five strategic themes, namely; 1) Research Excellence, 2) Capacity Building & Training, 3) Operational Excellence, 4) Public Policy and Advocacy, 5) and Sustainability.

RESEARCH EXCELLENCE

BHP continues to diversify, and grow, its research portfolio in line with its mission statement of addressing HIV/AIDS and any emerging public health challenges. At the pinnacle was the discovery, and reporting to GISAID, of the SARS-Cov-2 variant eventually named omicron by our laboratory scientists. This discovery earned BHP scientists, together with their Ministry of Health partners, international recognition and many accolades.

In total, 50 research projects (the majority 12 being research related to SARS-CoV-2 as the organization responded to the prevailing global health challenge) were conducted during this reporting period. These projects can be grouped into the following categories:

SARS-CoV-2/Covid-19 (12), Mother- Infant (9), Drug – Drug interaction and/or pharmacokinetics (6), Malignancies (5), HIV and Cardiovascular diseases (4), HIV Drug resistance (4), Tuberculosis (2), Sexually Transmitted Infections (1), HIV compartmentalization (1), Hepatitis (1), HPV (1), and PrEP (1).

During this reporting period 89 publications and 30 abstracts from work done at BHP were produced by BHP researchers and their collaborators.

CAPACITY BUILDING & TRAINING

Capacity building and training is one of the major components of BHP's mission with trainings, some leading to conferrement of academic degrees, and others being non-academic but resulting in upskilling staff being undertaken.

The institute, together with its collaborators, mobilizes funding used to train upcoming scientists within the region and further afield. Three students obtained PhD degrees whilst another two attained their MSc Degrees, in laboratory sciences. These individuals would have enrolled into a partner academic institution locally or regionally, but have their lab work conducted at BHP, and supervised by BHP scientists. Currently there are 8 students pursuing their masters degrees and five PhD degrees doing their research work at BHP. These are supported by grants applied for by BHP principal investigators.

Over the year, the institute offered major trainings attracting participants locally and internationally. These were:

1. Bioinformatics and Next Generation Sequencing Training
2. HIV-1 Drug-Resistance Genotyping Resistance Training
3. Corrective and Preventative Action
4. Quality Improvement
5. HIV Drug Resistance

Other capacity building initiatives offered by BHP and its collaborators include the training of University of Botswana residents in Obstetrics & Gynaecology, anaesthesia, Internal medicine, and internship training at SLH, through the BIDMC/OHSU program, on-the-job training and mentoring of upcoming researchers conducted largely by senior PIs, based locally and/or internationally. This latter training/mentoring has led to increase of grants applications, as well as increase of abstracts/manuscripts writing, by the trainees; a very critical factor in the growth and sustainability of the organization.

OPERATIONAL EXCELLENCE

BHP continues to be the leading health research organization in the country, and among the top in Africa. This is so because of the quality of human capital, both researchers and the non-scientist support staff. By the end of the reporting period BHP had a staff complement of 300 employees, majority being females. Ninety four percent of the employees were citizens.

Several trainings/activities aimed at improving the welfare of the employees were conducted, thereby improving the moral and motivation of the employees.

These included a training on financial literacy to help individuals manage their financials better and a wellness day where individuals could go for a free health screening offered by the BOMAID.

In order to remain competitive in attracting and retaining quality manpower, BHP has embarked on reviewing its salary structures. Job descriptions have been reviewed and updated, and draft pay scales have been developed. The final stage will be to compare the proposed scales with those of those organisations in the health industry, and to assess affordability by BHP.

Another area of excellence is in the grants and finance division, which continues to strengthen owing to sound internal control environment. Revenue flow during this period stood at USD10M, representing a 9% increase as compared to the previous period. Contributing to this is partly the increase in the number of awards successfully competed for (24 out of 44 applications), and partly due to some additional supplementary funds from the already existing grants.

PUBLIC POLICY & ADVOCACY

The discovery of the omicron variant of SARS-CoV-2 variant by the BHP scientists had major impact not only on health, but also on travel and economies across the whole world. Countries had to come with new interventions to mitigate the impact of the virus, including pharmaceuticals using the genotyping information from BHP to develop new COVID-19 vaccines.

BHP was instrumental in capacitating the public health laboratory in rolling out COVID-19 testing. BHP scientists have been actively involved in national technical working teams including the Presidential Covid-19 task force, TB technical working teams, HIV, and others.

SUSTAINABILITY

BHP has taken a strategic decision to diversify its revenue streams in order to reduce its over-reliance on grants funding. Over the past 3 years there has been yearly increase on the number of grants applied for, but the revenue generated is not large enough to propel growth and provide cushion funds against unexpected financial shocks.

One viable option identified as possible revenue generation is to seek philanthropy funding both locally and internationally. To this end a fundraising mechanism through the King Baudouin Foundation United States (KFBUS) has been established, and a bank account in which to receive the donations has been opened. Efforts to mobilise local philanthropists are on-going.

9. INTRODUCTION

BHP is a not-for-profit, health research and capacity building organization in existence since 1996. Its mission is to fight HIV/AIDS and other emerging public health challenges through research, education, capacity building that impacts policy and practice.

BHP has continued to deliver on its mandate as seen by the wide range of projects it works on. The organizations research portfolio includes clinical trials (both network trials and Principal Investigators initiated trials), implementation science studies, and laboratory-based studies.

In the sphere of education and capacity building, BHP, being a partnership between the Government of Botswana and Harvard University, and through its collaborative initiatives, has a wealth of scientists locally and internationally from Harvard affiliated institutions and other US and European institutions, who provide mentoring and training of upcoming scientists on research and publications. Furthermore, BHP collaborates with local and regional universities who confer degree qualifications for BHP-mentored and supervised MSc/MPhil and PhD candidates registering with those institutions.

BHP plays a significant role in Ministry of Health systems strengthening by having several BHP scientists solicited to participate in and providing technical expertise in various MoH committees and technical working groups.

10. RESEARCH EXCELLENCE

CLINICAL RESEARCH PROJECTS

PRINCIPAL INVESTIGATOR INITIATED RESEARCH PROJECTS

a) MOTHER AND CHILD STUDIES

1) Tsepamo: Birth Surveillance Outcomes

PI: Professor Roger L. Shapiro, MD, MPH

Tsepamo study has been conducting surveillance of birth outcomes in maternity wards throughout Botswana since 2014. The primary objectives of the study are to compare birth outcomes by HIV status and ART regimen, and to determine whether there are associations between ART regimens and congenital abnormalities. The methodology involves prospectively extracting data from obstetric records from 16 delivery sites across the country, representing about 70% of all deliveries in Botswana, and capturing anonymous photos of infants with congenital abnormalities.

To date, 234,000 out of the targeted 410,000 records have been captured into the data set. Fig 1 and 2 below shows data and ART exposure captured from July 2021- June 2022.

Figure 1. Birth and HIV data extracted from July 2021-June 2022

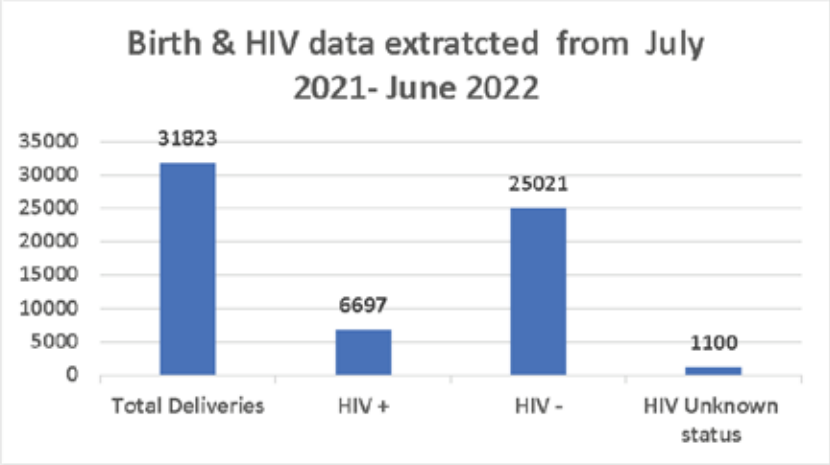


Figure 2. Maternal ART Exposure

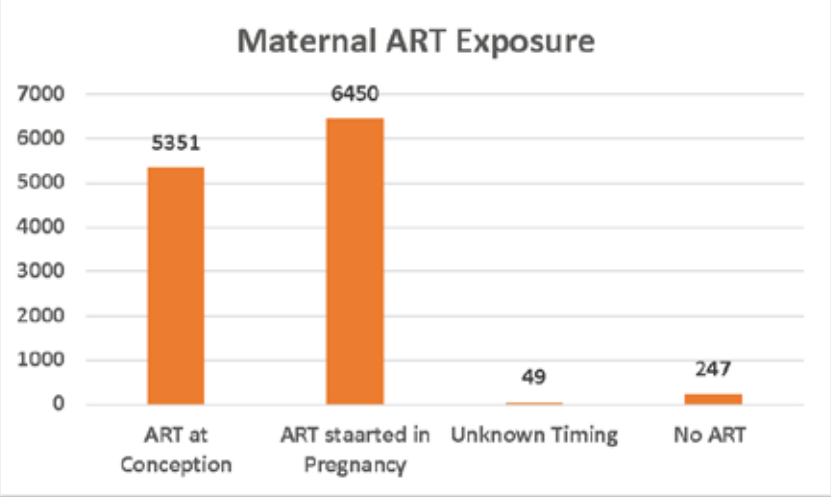


Figure3. Study Sites

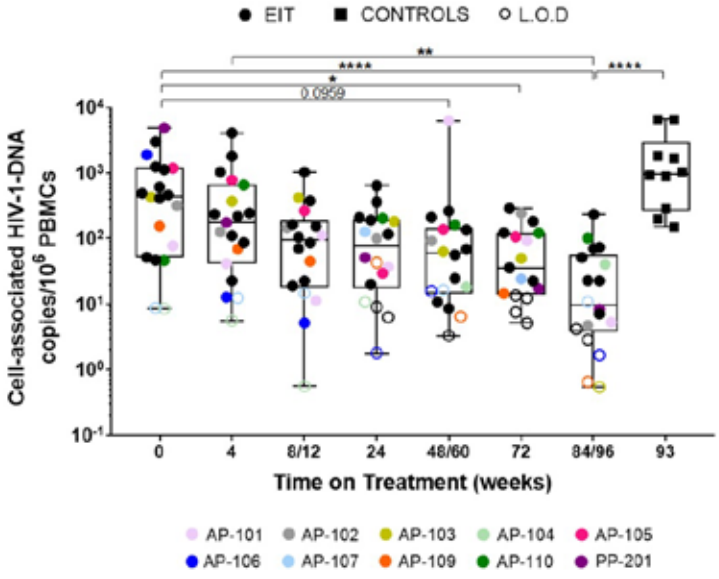
2) Early Infant Treatment Study: A Clinical Trial of HIV Positive Infants in Botswana

PI: Professor Roger L. Shapiro, MD, MPH

Early Infant Treatment Study (EIT) is a single arm non -randomized clinical trial of early Antiretroviral Therapy (ART) in antepartum and peripartum infected children. In the study, HIV- exposed infants are tested at birth and, if HIV positive are offered immediate ARVs. The study seeks to determine whether very early ART initiation in HIV infected infants limits the seeding of viral reservoirs and maintains immune response. Study Retention has been excellent (100%) over a period of 7 years. The study is closed to accrual and it is currently on extended follow up until 2024.

The study findings showed that a pediatric HIV treatment strategy starting NVP, ZDV AND 3TC in the first week of life and then transitioning to LPV-r, ZDV and 3TC resulted in lower viral reservoir (Fig 1). Negative serostatus and qualitative DNA were useful markers of sustained viral suppression from 24 – 84 weeks.

Figure 1: Comparison of the viral reseviors between EIT and control cohort



3) A Clinical Trial to Evaluate the Impact of Broadly Neutralizing Antibodies VRC01LS and 10-1074 on Maintenance of HIV Suppression in a Cohort of Early-Treated Children in Botswana (Dual bNAb Treatment in Children)/ Tatelo Study

PI: Professor Roger Shapiro, MD, MPH

The Tatelo Study is an interventional clinical trial of dual treatment with two broadly neutralizing monoclonal antibodies (bNAbs), VRC01LS and 10-1074, in HIV-1 infected virally suppressed children. The study is comprised of four steps: PK Step, Step 1, Step 2, and Step 3. In the PK Step, antiretroviral treatment (ART) is continued and 12 study participants will undergo safety and PK testing, 6 for each bNAb used in the study (10-1074 and VRC01LS). In Step 1, participants received ART and dual bNAb for a minimum of 8 weeks. In Step 2, ART is withdrawn and dual bNAb only treatment continued for a period of 24 weeks for participants who remained virally suppressed. In Step 3, dual bNAbs was discontinued and participants re-started on ART.

A total of 29 participants have been enrolled into the study and participants follow-up was completed in December 2021 with 100% retention throughout the study period of over two years. There were however challenges of adherence identified in participants who took longer to suppress, mainly socio-economic status and behavioural issues with mothers who have minimal support at home.

4) Karabo Study: Immune Correlates of Tuberculosis and non-Tuberculosis Infectious Morbidity in Southern African HIV- Exposed, Uninfected Infants

PI: Dr Kathleen Powis, MD, MPH

The Karabo study is evaluating TB and non-TB correlates of immunity in Bacille Calmette-Guerin (BCG)-vaccinated infants who are HIV-exposed and uninfected (HEU) and HIV-unexposed and uninfected (HUU). The study was designed to quantify differences in rates of latent tuberculosis infection (LTBI) through 18 months of life between the BCG-vaccinated. Karabo enrolled infants who are HEU and those who are HUU. Additionally, prevalence of the combined outcome of infectious morbidity and mortality will be calculated overall and by a child's HIV exposure status.

A total of 168 mothers provided informed consent for their participation and the participation of their 168 children for a total of 336 participants.

All participant study activities have been completed, a PhD candidate working as one of the Co-Investigators for the Karabo study, will present the Karabo infant TB infection data at IAS 2022 and at the 14th International HIV & Pediatrics Workshop in July 2022 in Montreal, Canada.

5) FLOURISH: Following Longitudinal Outcomes to Understand, Report, Intervene and Sustain Health for Infants, Children, Adolescents who are HIV Exposed Uninfected

PI: Kathleen M. Powis MD, MPH, MBA; Jennifer Jao, MD, MPH; Joseph Makhema, MB.ChB, FRCP

The FLOURISH study is a NIH funded prospective observational study designed to evaluate short- and long-term health and development outcomes of children and adolescents with fetal exposure to HIV who have remained HIV-uninfected. Outcomes will be compared to children and adolescents who are born to women without HIV. The study seeks to identify possible biological, social, and structural mechanisms for identified differences between children who are HIV-exposed uninfected (HEU) and those born HIV-unexposed uninfected (HUU). The FLOURTISH study will also explore differences in outcomes among children who are HEU by the antiretroviral drug to which the child was exposed.

The scientific aims for the FLOURISH Study include:

- Establish a cohort of 1,100 infants/children/adolescents who are HEU from birth through 17 years of age and a comparison cohort of 475 infants/children/adolescents who are HUU.
- Evaluate differences in rates of infectious morbidity and all-cause mortality between children who are HEU and HUU up to 5 years of age.
- Assess whether HIV/antiretroviral (ARV) fetal exposure is associated with differences in neurobehavioral functioning among school aged (6-10 years) children who are HEU compared to those who are HUU.
- Assess for associations between HIV/ARV fetal exposure and cardiometabolic risk factors (central obesity, dyslipidemia, elevated blood pressure, and insulin resistance or impaired fasting glucose) in adolescents ≥ age 10 using age, sex, and body mass index frequency matched individuals who are HUU as a comparator.

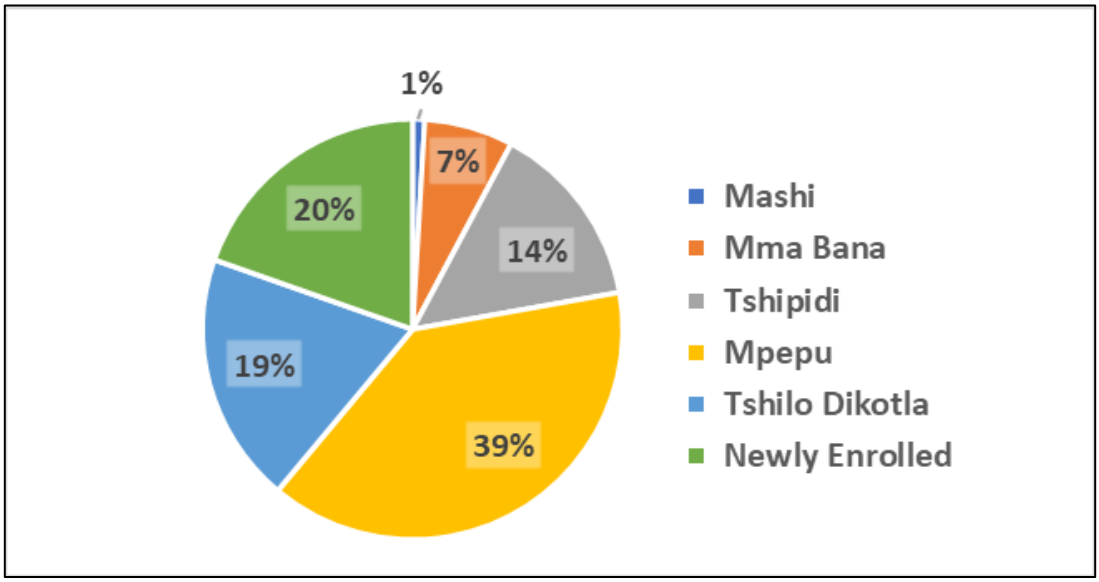
Study Funding

The FLOURISH study has a unique NIH funding mechanism whereas the first two years are allocated to meet recruitment targets. Given the successful achievement of the recruitment targets, an additional three years of funding was awarded to address Aims 2 through 4 (listed above). The funding mechanism for FLOURISH also offers the potential to apply for competitive renewal of funding every five years starting in 2025. Currently the FLOURISH study is in the third year of funding.

Study Recruitment and Retention

A total of 3899 potential participants were identified from previous BHP studies and were deemed eligible for recruitment into the FLOURISH study. The first Caregiver-child dyad was consented on 30 April 2021. As of June 2022, the FLOURISH study has consented 1,747 participants into the study, including 862 caregivers and 885 (accounting for siblings and twins). Figure 1 below represents consented participants according to source of recruitment. One hundred and sixty-nine were newly enrolled pregnant women from the local antenatal clinics (ANC). A total of 10 caregiver-child dyads have gone off study since study initiation presenting a 98.9% retention rate.

Figure 1: Consented participants from previous studies and newly enrolled



Upcoming Study Plans

In collaboration with Pediatric Radiologist Dr. Hansel Otero based at the University of Pennsylvania, the FLOURISH study added an infant brain ultrasound component for newborns to describe differences in brain development detectable by ultrasound between infants who are HEU and HUU. This additional aim is funded by University of Pennsylvania's Center for AIDS Research (CFAR). Dr. Otero will train FLOURISH study clinicians at BHP on how to perform infant brain ultrasounds. As an initiative to routine disseminate study updates and findings, as well as a commitment toward capacity building study staff capacity, FLOURISH study team members will present updates to all government ANC sites from which FLOURISH recruits bi-annually.

6) SAFE BIRTH STUDY

PI: Rebecca Luckett MD, MPH

Causes of maternal morbidity and mortality are multifactorial and identifying effective interventions to improve perinatal care in order to reduce avoidable maternal and neonatal morbidity and mortality is challenging. Measurement of the impact of such interventions is equally challenging.

Building on the Birth Outcomes Surveillance (Tsepamo), the Safe Birth Study is designed to better understand maternal morbidity and mortality in Botswana by collecting additional observational data around mode of delivery, delivery complications, perinatal medical complications, and extraordinary interventions. Baseline data and ongoing surveillance will enable the design and evaluation of quality improvement interventions aimed at reducing maternal near-miss and maternal mortality. The study was launched in November of 2021 at Princess Marina Hospital.

7) Iron and folic acid supplementation and adverse birth outcomes in Botswana

PIs: Ellen Caniglia, ScD

This career development award to study iron, folic acid, and multiple micronutrient supplementation and adverse birth outcomes in Botswana began in 2020. The primary objectives of the study are to (1) estimate the causal effect of supplementation strategies (iron alone, iron and folic acid, multiple micronutrient supplementation) during pregnancy on adverse pregnancy outcomes, (2) to assess barriers and facilitators to implementing an intervention to improve prenatal supplementation using qualitative interviews, and (3) to develop and test thefeasibility of an intervention to improve prenatal supplementation. The study leverages data from the ongoing Tsepamo study, as well as conducting new data.

In addition to data from Tsepamo Study, in-depth qualitative interviews were conducted among pregnant women, nurses/midwives, pharmacists, dietitians, and reproductive health officers. Analysis of the qualitative data is ongoing and preliminary findings have been presented to stakeholders in Botswana.

8) Point-of-Care HIV Testing and Early Dolutegravir Use for Infants “Moso study”

PIs: Roger Shapiro MD, MPH, Gbolahan Ajibola MD, MPH

Moso study will explore the feasibility of implementing targeted birth HIV testing of high-risk neonates using facility-based point-of-care (POC) HIV diagnostics. The study also aims to improve the ability to implement the best standard-of-care (SOC) treatment possible consisting of very early initiation of antiretroviral treatment (ART) within seven days of life with a switch to DTG-based treatment at four weeks of age.
The study will enroll 10-30 HIV positive neonates up to 96 post diagnosis and ART initiation and their mothers. The main study sites are Gaborone and Francistown.

9) Neurodevelopment In HEU Children Exposed in Utero to Dolutegravir or Efavirenz and HIV-Unexposed Children (Motheo Study)

PIs: Shahin Lockman MD, MPH & Adam Cassidy PhD, ABPP-CN

Motheo is a longitudinal observational cohort study that will, over a 1-2 year period, prospectively enroll three new cohorts of children (aged 2 years at enrollment and followed till they are 5 years old) and their mothers in Botswana and follow children's neurodevelopmental and social-emotional outcomes and mothers' mental health and sleep status in 560 mother-child pairs consisting of :

- 200 HEU children previously exposed in utero to EFV/TDF/XTC and their mothers (XTC indicates either 3TC or FTC);
- 200 HEU children previously exposed in utero to DTG/TDF/XTC and their mothers;
- 160 HUU children and their mothers.

Study Objectives

- To assess developmental outcomes (neurodevelopment, psychosocial) at 2 years of age in HEU children exposed in utero to DTG/TDF/XTC (N=200); EFV/TDF/XTC (N=200); and community controls without HIV or ARV exposure (N=160), and compare outcomes between groups.
- To assess and compare developmental outcomes in the same children at 5 years of age. Further deterioration of 2-year deficits would be expected at 5 years; and, evaluation of children during the early childhood period will allow us to more comprehensively examine a range of cognitive and self-regulatory capacities, including emerging core executive function skills (i.e., inhibitory control, working memory, and shifting/ flexibility) that are recognized as critical for future achievement, independence, and resilience.
- To assess the presence/severity of depressive symptoms, anxiety symptoms, and sleep problems in the mothers of participating children. Results of this aim are relevant to millions of women on ART globally, and are also important for analyses of child outcomes, as maternal mental health affects child development.

The study opened to accrual in March 2021 and by the end of June 2022 the study had enrolled 355 out of 560 two-year old children and their mothers in Gaborone and Molepolole. Enrollment is expected to be complete during the first half of 2023.

b) HIV/TB STUDIES

1) Improving TB Screening in Pregnant and Postpartum Women Living with HIV in Botswana

PIs: Melanie M. Dubois, MD, MPH; Joseph Makhema, MBChB, FRCP

The maternal tuberculosis (TB) study is a sub-study of the FLOURISH study. The sub-study aims to evaluate the extent to which TB screening is occurring during the antenatal and postpartum period among women living with HIV (WLHIV), perform TB screening in the postpartum period for WLHIV, and provide referral for participants screening positive for TB with subsequent assessment of barriers to care engagement and delivery.

Up to 100 pregnant or postpartum WLHIV will be enrolled into this sub-study. As of June, 2022, 35 participants have beenenrolled. Of these, 18 have completed the two-month postpartum visit. Three of these participants screened positive, reporting a cough that triggered referral to their local government health centers for evaluation of TB disease under Botswana National TB Program Guidelines. Individual semi-structured interviews with participants referred for evaluation of TB symptoms and medical staff will be conducted towards the end of the year.

2) Evaluating Opportunities to Improve TB and HIV Care for Adolescents in Botswana

PIs: Melanie M. Dubois, MD, MPH; Sikhulile Moyo, MSc, MPH, PhD

The adolescent tuberculosis (TB) study is a newly approved sub-study of the FLOURISH study. This sub-study is designed to quantify the prevalence of HIV and TB among 50 adolescents ages 10 to 17 enrolled in the FLOURISH study, including 25 who were HIV-exposed at birth but did not acquire HIV through vertical transmission and 25 who were born to women without HIV. In addition, this study will explore barriers to care engagement and delivery among adolescents referred by the study team for further evaluation at government health centers following positive HIV testing or TB testing and/or screening.

c) HIV WITH OR WITHOUT NON- COMMUNICABLE DISEASES

1) Albuminuria Among Virally Suppressed HIV-infected Patients in Botswana: Longitudinal Changes and Association with Inflammation and ACEI/ARB Use in a Clinical Setting- Albuminuria Study

PI: Professor Mosepele Mosepele, MD, MSc

This is an observational prospective study in a high HIV prevalence clinical setting with the following three main objectives;

- Describe the prevalence and longitudinal changes in albuminuria over a 12-month period among treated HIV-infected adults overall, and in relation to the use of ACEI/ARB
- Describe the association between albuminuria and inflammation among treated HIV-infected adults overall and in relation to the use of ACEI/ARB
- Create a human bio-repository and HIV-CVD outcomes clinical registry for the study of long-term clinical outcomes of albuminuria.

The EDCTP-sponsored study commenced enrolment in January 2020 and has to date enrolled 447 participants (target enrolment 1537) from Princess Marina Hospital IDCC and it is expanding enrolments to Gaborone DHMT Clinics.

2) Mopati: A Pilot HIV Treatment Partner Intervention in Botswana

PIs: Professor Mosepele Mosepele, MD, MSc & Laura Bogart PhD

Mopati Study is a multi-level intervention that guides healthcare providers and patients about treatment partner selection, and trains treatment partners on provision of effective support.

The first part of the study was to develop a multi-level treatment partner intervention with input from community and healthcare provider stakeholders in Botswana. This phase of the project included getting input from a variety of community stakeholders, and conducting focus groups with healthcare providers.

The study has enrolled 36 healthcare providers from seven healthcare facilities. The objective was to assess the feasibility and acceptability of implementing an intervention that uses treatment partners to support ART adherence. Recruitment has been completed and analysis is ongoing.

3) Innovative HIV Testing Strategy for Middle-to-Upper Income Men in a Resource-Limited Setting

PIs: Prof. Mosepele Mosepele MD, MSc, Laura Bogart PhD

In Botswana, men aged 40 show relatively high levels of HIV prevalence and risk behavior, and low levels of HIV testing. Moreover, higher income is associated with increased risk of being HIV-positive in sub-Saharan Africa. This study will use mixed methods to develop an intervention that de-stigmatizes and encourages HIV testing among men of middle-to-higher socio-economic status (SES) in Gaborone, Botswana. The study is focusing on increasing HIV testing among men of higher SES

Study Objectives

1. To initially conduct formative qualitative work to explore the role of stigma on low HIV testing uptake among 20 men via face-to-face interviews, and then to obtain feedback about potential interventions using asynchronous online focus group discussion among 40 men all with relatively high socio-economic status (SES) in Botswana.
2. To develop and conduct a small pilot test of a local, culturally appropriate HIV testing strategy targeting 100 men in the higher socio-economic status in Botswana.
3. To build capacity for HIV stigma and related behavioral research by conducting focused workshops in Botswana. To reach the remaining 10-10-10, it is essential to develop differentiated, tailored approaches for risk groups, such as men of relatively higher SES, that are untouched by existing prevention and testing frameworks in countries of high HIV prevalence.

A total of 32 participants completed all study procedures and focused interviews.

Study Results

The study established barriers and facilitators for HIV self-testing among men in the middle- and high-income category in Botswana. Men expressed frustrations with long clinic queues at public clinics and were concerned about confidentiality if they tested positive.
Furthermore, men raised concerns about the ability to accurately use the HIV self-testing kits. However, after using a provided HIV self-testing kit that involved swabbing inside the cheek, men found HIV self-testing acceptable, and wished for this service to be made more widely available.

While there was no statistically significant decline in internalized stigma associated with HIV testing, the study demonstrated a trend towards the decrease in HIV testing stigma when men were offered an opportunity to perform HIV self-testing at a time and venue convenient to them.

4) Integrating Hypertension and Cardiovascular Diseases Care into Existing HIV Services Package in Botswana (InterCARE Study)

PIs: Prof. Mosepele Mosepele MD, MSC, Tendani Gaolathe BS, MD, Kathleen Wirth Hurwitz

The InterCARE study proposes the adaptation and testing of strategies to effectively integrate evidence-based interventions (EBI) into HIV care to improve the hypertension cascade of care (awareness, diagnosis, treatment, control) and general cardiovascular disease (CVD) risk factor knowledge, diagnosis and treatment.

The InterCARE study is in 2 stages:

Stage 1: A pilot that will test study protocols and procedures in two clinics to check whether proposed interventions (interviews, survey, training with patients, treatments partners and stakeholders) are feasible and if they improve cardiovascular outcomes for participants. This pilot started last March 2020 and is due to end in December 2022.

Stage 2: A larger randomized trial that will be rolled out to 10 clinics around Botswana from January 2023.

BHP is working in collaboration with University of Botswana, African Comprehensive HIV/AIDS Partnerships (ACHAP), Northwestern University Feinberg School of Medicine and New York University in this project. A total of 288 participants and their treatment partners have been enrolled between September and November 2021. In addition, 100 surveys and 10 interviews were completed, to gather an understanding of the perceived barriers and facilitators of integrating HIV and cardiovascular care systems.

The InterCARE team is currently working on the roll-out of the second phase of the study, which entails a randomized, controlled cluster trial recruiting participants and their treatment partners in 10 infectious diseases care clinics around Botswana.

d) DRUG-DRUG INTERACTIONS

1) Contraceptives and Dolutegravir- based ART (CODA) Study

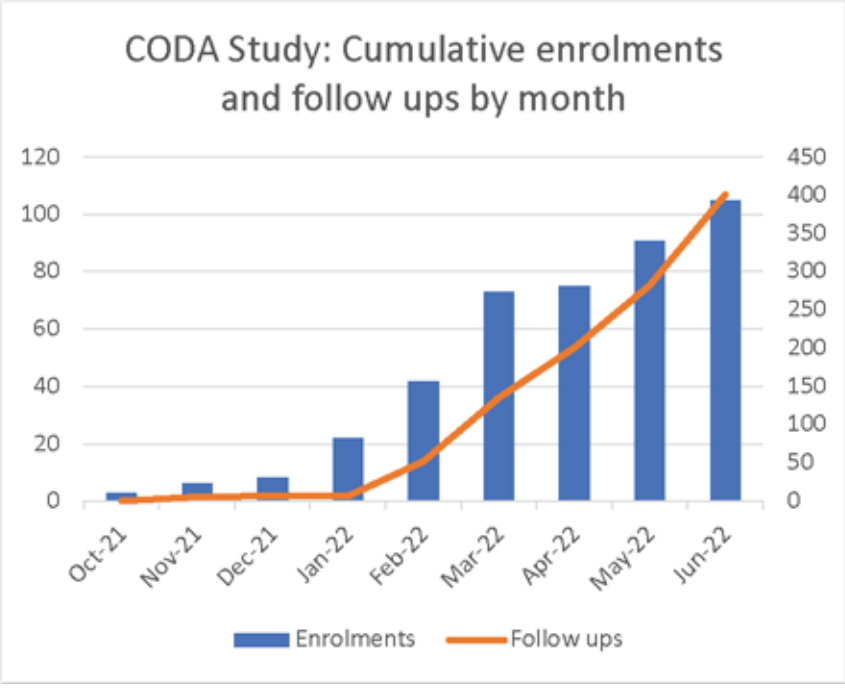
PIs: Dr Chelsea Moroni, MD, MPH, PhD

The Contraceptives and Dolutegravir -based ART (CODA) Study is a Phase IV, open label, non-randomized, parallel-arm, pharmacokinetic study, investigating whether drug-drug interactions occur when the subdermal contraceptive implant (levonorgestrel) or the depot medroxyprogesterone acetate

(DMPA) injectable are concurrently used with dolutegravir (DTG)-based ART. Provision of contraception is complicated in high HIV prevalence settings due to proven drug-drug interactions between some anti-retroviral therapy (ART) agents and hormonal methods. Dolutegravir (DTG) is highly effective in managing HIV and is a WHO recommended first-line agent. However, thus far, there is little data on the effect of DTG on hormonal contraception. Rigorous and complete evidence on the risk of drug-drug interactions between hormonal contraceptives and DTG is urgently needed to inform local and international guidance. The CODA Study is funded by ViiV Healthcare.

Recruitment for the study began in October 2021. To date, 105 (75%) of 140 participants have been recruited. 32 (23%) participants have completed the study. Recruitment is projected to end in October 2022 and follow-up visits are expected to end in April 2023.

Dr Rebecca Ryan, Dr Samuel Ensor and Dr Imogen Mechie (Study Doctors) and Bame Bame (Nurse Coordinator) conducting an introductory presentation on the CODA Study for clinic staff at Mafitlhakgosi Clinic



e) SEXUAL REPRODUCTIVE HEALTH

The diagnosis and treatment of Chlamydia Trachomatis and Neisseria Gonorrhea in Woman to prevent adverse neonatal consequences (Maduo/STI Study).

PI: Dr Chelsea Moroni, MD, MPH, PhD

The Maduo ("Results" in Setswana) Study is an NIH-funded cohort study aiming to determine the burden of gonorrhoea and chlamydia among asymptomatic pregnant women in Botswana and to investigate the impact of gonorrhoea and chlamydia testing during pregnancy on vertical transmission and associated adverse neonatal health outcomes. Through this study, we hope to inform stakeholders and policymakers as they work to improve management of STIs during pregnancy.

Between March 2021 and April 2022, 500 participants were recruited from four clinics across Gaborone. Enrolment on the study is complete and 61% of participants have completed follow-up. All follow-up visits are expected to be complete by December 2022.

Maduo Study team reviewing results on the Gene Xpert Platform

f) MALIGNANCIES STUDIES

1) HIV and Malignancy in Botswana: An Observational Study of Medicine Toxicity of Concurrent Treatment and Clinical Outcomes (Thabatshe Study)

PI: Dr Scott Dryden-Petersen, MD, MSc

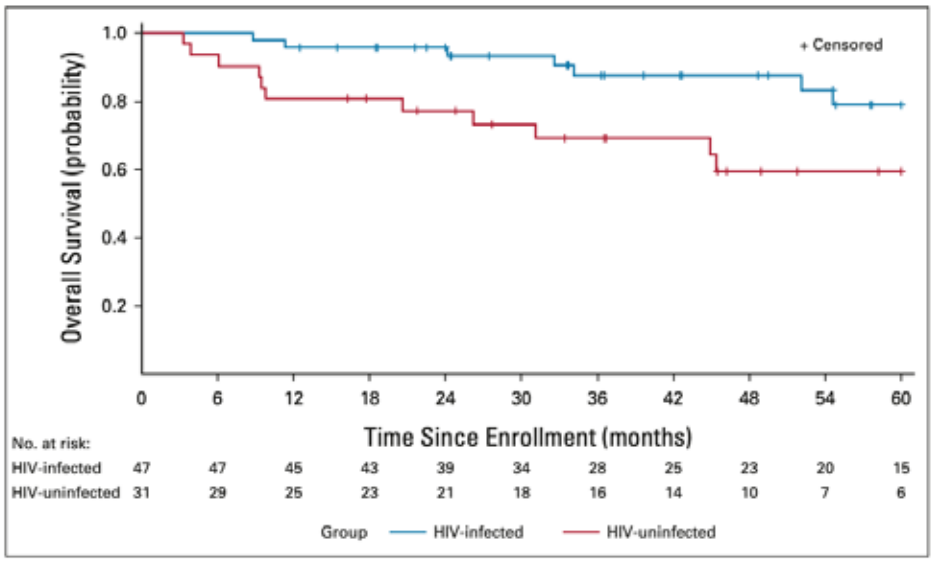
Since 2010 the Thabatse team at BHP has worked to understand and reduce the burden of cancer in Botswana and the region. Successful HIV treatment programs in southern Africa have led to dramatic reductions in mortality from tuberculosis, cryptococcosis, and other non-cancer AIDS deaths. However, except for Kaposi sarcoma and aggressive lymphomas, the incidence of infection and non-infection-related cancer deaths have not decreased. In Botswana cancer is the leading cause of death for persons with HIV and one of the most common causes of death for Motswana without HIV.

Thabatse Study is one of the largest prospective cancer cohorts in Africa (n = 5734), Thabatse enrolls all consenting patients entering cancer care from the principal treatment facilities in Botswana. Patients are followed quarterly for 5 years (>98% retention) to inform on leading factors associated with development of cancer, delayed cancer treatment, and outcomes of cancer treatment. Findings from the Thabatse cancer cohort have been integrated in cancer control planning of the Botswana Ministry of Health, WHO guidance, international NCCN treatment guidance, and was highlighted in 2022 as a leading global source epidemiologic and outcome data for cancer in context of HIV infection at National Cancer Institute (NCI) and International Agency for Research on Cancer (IARC, WHO) meeting. The Thabatse Cancer Cohort has formed the basis for four University of Botswana student theses.

Recent Findings

- Quantified that 20% of cervical cancer cases in southern Africa are due to HIV infection. These data inform prevention programs in settings with high burden of HPV and HIV infection. Ibrahim Khalil A. et al. IJC 2022.
- Identified that survival with Hodgkin lymphoma is similar in patients with and without HIV infection, but overall survival in Botswana is below international norms. Analysis led by Motswana medicine resident. Moahi K. et al. JCO Global Oncology 2022.

Survival with Hodgkin Lymphoma by HIV Infection Status



- Limitations in pathologic capacity, principally molecular techniques to determine subtypes, led to frequent misdiagnosis and decreased survival among lymphoma patients in Botswana. Work led by Zimbabwean radiation oncology resident. Chipidza F.E. et al. JCO Global Oncology 2021

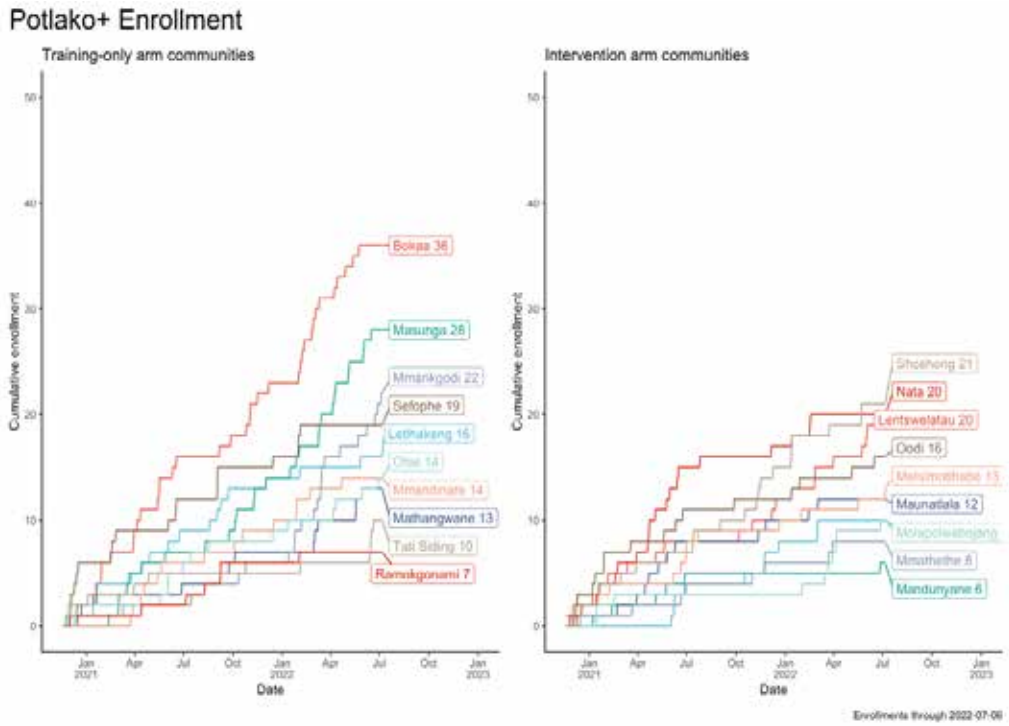
- Community-based, breast screening campaigns (Journey of Hope) in previously unscreened populations was an efficient method to diagnose breast cancer, particularly in women 50 and older (one cancer per 196 screened women). Dykstra et al. JCO Global Oncology 2021.

2) Potlako+ : A Multilevel Intervention to Improve Timely Cancer Detection and Treatment Initiation in Botswana

PI: Dr Scott Dryden-Petersen, MD, MSc & Dr Neo M. Tapela, MD, MPH

Building on prior Potlako pilot, the Potlako+ trial is a community- randomized (20 geographically dispersed communities, 1:1), pragmatic, and a hybrid effectiveness-implementation trial to assess a complex, intervention to promote earlier clinic presentation with symptoms suggestive of cancer, enable efficient diagnosis, and facilitate prompt initiation of oncologic treatment. Interventions target breast cancer and squamous cell carcinomas of the head and neck and anogenital tract (cervix, penis, vulva, vagina, anus)— that together account for nearly 70% of cancer deaths in PLWH and 50% in HIV-uninfected individuals.

Following extensive initial health provider training, onsite support, and longitudinal support to over 450 patients with suspected cancer have been enrolled and 30 cancers diagnosed. Two more years of enrollment planned in the 5-year project.



Potlako+ Trial Enrollment

Recent Findings

- Strong interest among health clinic staff in rural communities to improve diagnosis and linkage-to-care for patients with cancer. Gaps in knowledge were identified but following training staff were able to efficiently identify patients with symptoms suggestive of moderate or high risk of cancer.
- COVID contributed to considerable decrease in access to timely cancer diagnosis and a large burden of untreated cancer in Botswana.
- Longitudinal partnership with clinics essential to maintain timely cancer diagnoses.

3) Characterization of Anthracycline Induced Cardiotoxicity Using Cardiac Magnetic Resonance in Botswana (Pelo Study)

PI: Dr Scott Dryden-Petersen, MD, MSc

The cardiotoxicity in HIV breast cancer study (Pelo) is pilot study which aims to evaluate patients with and without HIV who need high-dose anthracyclines for treatment of their cancer. Patients are evaluated by cardiac MRI to sensitively examine possible differences in cardiac changes following treatment by HIV status. This study has a total of 25 Enrolments all recruited from Gaborone site (Gaborone Private Hospital and Princess Marina Hospital) (13 HIV positive and 12 HIV negatives). The study is still enrolling and due to close within a year.

4) Tumor Immunology of HIV Malignancies

PI: Dr Scott Dryden-Petersen, MD, MSc

People with HIV are more likely to develop cancer and, for many cancers, are more likely to die from that cancer. This project examines the hypothesis that differences in the tumor microenvironment, particularly the expression of immune inhibitory molecules, lead to increased risk of invasive cancer and oncologic relapses following treatment. Utilizing residual tissue Thabatse team is examining expression of tumor neoantigens and immune inhibitors.

5) Cervical cancer screening in women with HIV using HPV testing

PI: Dr Rebecca Luckett, MD, MPH

This study aims to improve cervical cancer screening in women with HIV using Human Papillomavirus (HPV) based screening. It evaluates standard-of-care or novel triage strategies and screening intervals in an HPV-based screening programme.

Data from this study will provide critical effectiveness and implementation data to guide HPV-based screening programmes in the region. A total of 2870 women have been enrolled to date, and recruitment is anticipated to be complete by July 2022.

The HPV research team at Bamalete Lutheran Hospital: Simon Boikhutso, Queen Nonyane Ramarumo, Lorato Mochoba, Sibongile Phiri & Janet Gaborone

g) SARS-CoV-2 / COVID-19 STUDIES

1) COVID-19: An observational cohort of cases treated in Gaborone, Botswana

PI: Professor Mosepele Mosepele, MD, MSc

The COVID-19 Study is an observational cohort study to describe the presentation, clinical course and outcome of individuals who are diagnosed and treated for COVID-19 in Gaborone, Botswana. The study recruited consecutive eligible participants for a three months period and then conducting an interim analysis and review thereafter. The BHP is collaborating with the University of Botswana and the Sir Ketumile Masire Teaching Hospital for study conduct. Enrolment is ongoing.

The study's objectives are:

1. To describe the presentation, severity, outcome and persistence of each case of COVID-19 managed in Gaborone.
2. To compare the difference between cases in HIV-infected and HIV-uninfected individuals
3. To determine if individuals with HIV infection remain infectious for longer than those without HIV infection
4. To determine the impact of COVID-19 on HIV infection
5. To establish a bio-repository to conduct future studies on host genetics and COVID-19.

The study team is working on a Manuscript.

2) Acceptability and Feasibility of COVID-19 Screening and Testing Among Workers and Businesses in Gaborone, Botswana

PIs: Dr Nabila Youssouf PhD; Laura Bogart PhD and Mosepele Mosepele, MD, MSc

This study seeks to explore the acceptability and feasibility of COVID-19 testing among workers and businesses in Gaborone, Botswana and to acquire feedback about potential interventions to further respond to COVID-19 in the workplace. The study aims to conduct qualitative work to explore the knowledge, experiences and attitudes on COVID-19 testing.

Hundred (100) workers from various industries around Gaborone were asked questions on their understanding of the virus, their knowledge on transmission and prevention methods, their opinions on the government measures and responses to the virus and the impact of such measures on their industries. The study also explored their thoughts on what can be done to improve the screening and testing approaches that are currently in place.

The study started in September 2020 and conducted 30 face-to-face interviews with workers and two focus group interviews of 8 workers and 7 workers respectively. Data collection has been completed and data analysis is ongoing.

3) Exploring the Acceptability and Feasibility of COVID-19 Testing among Truck Drivers in Botswana

PIs: Nabila Youssouf PhD; Laura Bogart PhD and Mosepele Mosepele MD, MSc

Truck drivers have been regarded as the major vector for COVID-19 transmission as border testing in most countries has shown a high number of cases among this population. Truck drivers in Botswana show relatively high levels of COVID-19 prevalence and grievances on COVID-19 testing. The study was conducted in partnership with health officials at the borders to understand the acceptability of COVID-19 testing among truck drivers in Botswana. The study used a qualitative data collection strategy, using survey and interviews to explore COVID-19 testing knowledge, perceptions and attitudes among truck drivers entering Botswana. Findings from the study could help inform the response to the COVID-19 testing approach and be scaled up across other sectors of the population.

The study started in September 2020 and has conducted 30 face-to-face interviews with truck drivers and one focus group interview consisting of 8 truck drivers. Data collection has been completed and data analysis is ongoing.

4) Evaluation of antibody responses to SARS-CoV-2 in Botswana

PIs: Mosepele Mosepele MD, MSC, Sikhulile Moyo and Modisa Motswaledi PhD

Serology tests play an important role in assessing the immune response to a previous SARS-CoV-2 infection, the virus that causes COVID-19. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody response studies have proved to be a valuable tool in the assessment of the COVID-19 pandemic dynamics and ability of vaccines to elicit a durable immune response. It is important to understand the dynamics and breadth of Antibody (Ab) responses in the context of correlates of protection from hospitalisation or severe diseases.

This study will evaluate SARS-CoV-2-specific antibody responses after complete vaccination using various vaccines in Botswana. It will also compare the responses of individuals with confirmed prior infection to those of individuals without prior evidence of infection.

5) A mixed methods study of COVID-19 vaccine hesitancy in Botswana

PIs: Mosepele Mosepele MD, MSc, Laura Bogart PhD, Sara Schwanke-Khilji MD, MPH, FACP, Nabila Youssouf PhD, Rebecca Zash MD

The availability of COVID-19 vaccines is an important tool to mitigate the impact of the virus on populations and healthcare systems, particularly by lowering rates of severe COVID-19 disease and related mortality. Botswana received its first batches of COVID-19 vaccines in March 2021 and to date, approximately 70% of the population is fully vaccinated. While this low uptake may be affected by several factors, it is thought that vaccine hesitancy may be playing a major role as observed in other countries worldwide.

The degree of vaccine hesitancy in Botswana is generally unknown but anecdotal evidence shows that vaccine hesitancy among health care workers is common, despite this being one of the groups most affected by the virus. To date, there is very limited published literature on this topic, particularly on the continent. This project aims to measure the degree of vaccine hesitancy among healthcare workers and other key stakeholders in Botswana and explore the knowledge, attitudes, and experiences towards COVID-19 vaccination.

A survey circulated online has been completed by 400 participants. A primary analysis recently took place and the team is submitting abstracts to upcoming conferences. The next stage will be to conduct focus-groups discussions as well as interviews to gain a deeper understanding of the reasons behind vaccine hesitancy.

6) A phase III international randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care – Solidarity PLUS trial

PIs: Mosepele Mosepele MD, MSC, Joseph Makhema MB.ChB, FRCP

The WHO Solidarity trial involves collaboration between the World Health Organization (WHO) and hundreds of hospitals in dozens of countries. Botswana is participating in this multi-country clinical trial to evaluate drugs and therapeutic agents with potential to impact outcomes of COVID-19 among hospitalized patients. The trial began enrolment of participants in December 2021 and is ongoing at the Sir Ketumile Masire Teaching Hospital (SKMTH) in Gaborone. To date 24 participants have been enrolled. The study is continuing.

7) AZD 1222 Study: Open-Label, Single-Arm, Phase 3b Study of the incidence of severe COVID-19 and adverse events following AZD1222 COVID-19 vaccination in Botswana against SARS-CoV-2.

PI: Dr Joseph Makhema, MB. ChB, FRCP

The AZD 1222 study was activated in Botswana in September 2021. The objectives of the study are to assess the occurrence of severe COVID-19 disease among individuals vaccinated with AstraZeneca (AZD1222) by number of vaccine doses as well as to assess adverse events among individuals vaccinated with at least one dose of AstraZeneca vaccine. The study aims to recruit 50 000 participants and as of June 2022, 9138 participants have been enrolled into the study and have received their first vaccine dose. Of these participants 6825 (69%) have received their second vaccine doses. The study is ongoing.

Figure 1: AZD 1222 study sites

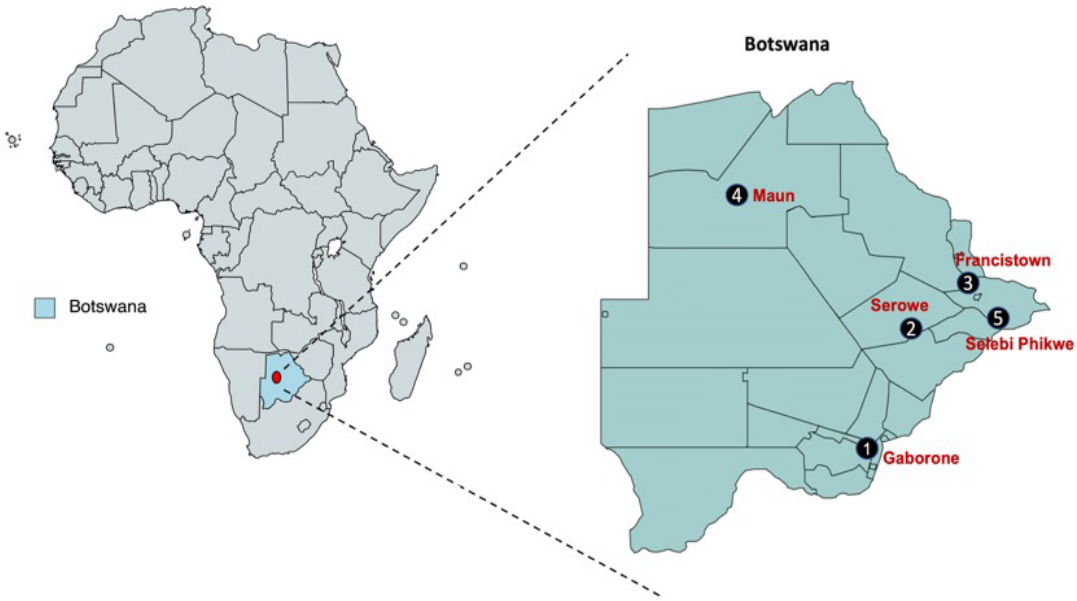
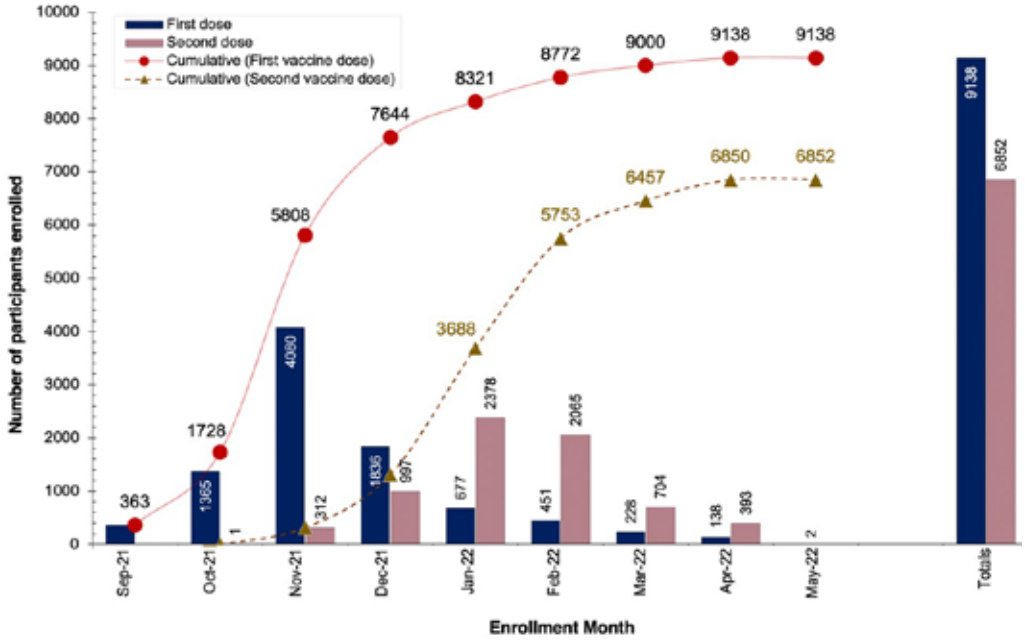


Figure 2. Participants vaccinated from all the AZ1222 study sites



8) Post-Acute Sequelae of SARS-CoV-2 Infection (PASC) / 'Long COVID': Observational Cohort (Motlhala Study)

PIs: Shahin Lockman MD, MPH, Gaerolwe Masheto MD, PGDip FamMed, Kaelo Seatla MD, MPH, PhD

Motlhala Study is a newly approved observational cohort study which seeks to describe the prevalence and clinical manifestations of post-acute sequelae of SARS-CoV-2 (PASC) also known as long COVID, in persons with confirmed SARS-CoV-2; in adults living with HIV versus those without HIV and in children regardless of HIV status. The study will also establish a biobank to allow future evaluation of possible mechanisms and biomarkers of PASC.

This study will enroll a cohort of approximately 700 adults with confirmed SARS-CoV-2 and an additional 200 persons with SARS-CoV-2 negative test. Approximately 100 children with confirmed SARS-CoV-2 and 100 with SARS-CoV-2 negative test will also be enrolled.

CLINICAL RESEARCH PROJECTS

NETWORK CLINICAL TRIALS

CTU PI: Dr Shahin Lockman MD, MPH ; Dr Joseph Makhema, MB. ChB, FRCP

The BHP Clinical Trials Unit (CTU) comprises of the AIDS Clinical Trials Group (ACTG), International Maternal, Paediatric, Adolescents AIDS Clinical Trials (IMPAACT) and HIV Prevention Trials Network (HPTN)/ COVID-19 Prevention Network (CoVPN) and inclusive of two clinical research sites (CRS); Gaborone and Molepolole.

There were 11 active studies under CTU during the period under review. These studies are; REPREIVE, PHOENIx, A5375, IMPAACT 2019, P1093, IMPAACT 2017, IMPAACT 2026, HPTN 084, HVTN805/HPTN093, CoVPN5001, CoVPN3008.

ACTG STUDIES

The mission of the ACTG is to cure HIV infection and reduce the burden of disease and its complications, including tuberculosis and viral hepatitis. The ACTG supports thelargest Network of expert clinical and translational investigators and therapeutic clinical trials units in the world, including sites in resource-limited countries. These investigators and units serve as the major resource for HIV/AIDS research, treatment, care, and training/education in their communities.

1) REPRIEVE (A5332): A randomized trial to prevent vascular events (such as stroke and heart attack) in people living with HIV.

REPRIEVE study seeks to investigate if the use of a cholesterol lowering medicine (Pitavastatin) may reduce the risk of heart attack or stroke in HIV infected individuals. The study has been on going in Botswana since 2017 and it has enrolled 7560 participants globally, 281 of which was enrolled in Botswana. The study retention stands at 94% and participant follow up is expected to close in March 2023.

2) PHOENIx (A5300B): Protecting Households on Exposure to Newly Diagnosed Index Multidrug Resistant TB patients.

This study seeks to assess the efficacy and safety of Delamanid (a novel anti-TB drug) compared with Isoniazid (standard of care) for protection of high-risk Household Contacts (HHCs) against acquiring TB. The study has a global enrolment target of 5160 participants over 3 years (MDR-TB index cases and their household contacts). Botswana has enrolled 28 participants out of its target of 300 since the study opened in 2019. The study has enrolled lower than expected because of difficulty in finding participants due to apparent low burden of MDR cases in Botswana. The study is anticipated to reach full accrual in March 2024.

3) A5372: Drug-Drug Interactions Between Rifapentine and Dolutegravir in HIV/LTBI Co-Infected Individuals

A5372 study is investigating the potential interactions between DTG and RPT when RPT is given with isoniazid (INH) daily for 4 weeks as part of treatment for latent TB infection (LTBI) in HIV-1 and LTBI co-infected individuals. The study opened in February 2021 and enrolled 37 participants globally and 3 in Botswana. The interim findings released in February 2022, showed that DTG 50mg twice daily dosing during INH treatment achieved higher minimum concentrations than with standard dose of DTG once daily alone (i.e., without INH co-administration). Combination of DTG and INH was well tolerated.

IMPAACT STUDIES

The IMPAACT Network is a global collaboration of investigators, institutions, community representatives and other partners organized for the purpose of evaluating interventions to treat and prevent HIV infection and its consequences in infants, children, adolescents and pregnant/ postpartum women through the conduct of high-quality clinical trials.

1) IMPAACT 2019 – This is a Phase I/II Study of the Pharmacokinetics, Safety, and Tolerability of Abacavir/ Dolutegravir/ Lamivudine Dispersible and Immediate Release Tablets in HIV-1-Infected Children Less than 12 Years of Age

The study is comparing the pharmacokinetic exposure of dolutegravir, as contained in the paediatric formulation Abacavir/Dolutegravir/Lamivudine to exposures shown to be efficacious in adults. It also evaluates the safety and tolerability of this paediatric formulation over 48 weeks of treatment. The study aimed to enrol up to 75 participants to achieve at least five dose-evaluable participants in each of five weight bands (Figure 1). A total of 57 participants were enrolled at participating study sites, 13 in Botswana. The study completed follow-up on 31 May 2022 and the Botswana sites had maintained an excellent retention rate of 100% until the last participant was taken off-study.

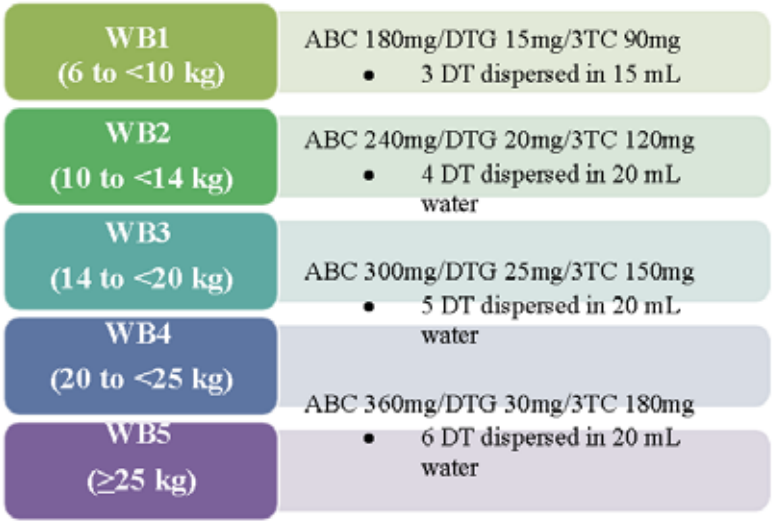


Figure 1. IMPAACT 2019 Weight Bands

Study Results

Preliminary safety and PK data for children weighing 6 to <14 kg were presented at Conference on Retroviruses and Opportunistic Infections (CROI 2022) and the results are as follows;

- PK targets were met for dispersible release ABC/DTG/3TC in children 6 to <14 kg.
- ABC/DTG/3TC formulation was well tolerated, and results provide reassurance for dosing of this Fixed Doze Combination (FDC) formulation.
- Longer-term safety, tolerability, and efficacy data through 48 weeks in all weight bands is still being analyzed.
- Findings expected to support global efforts to expand the availability of pediatric-friendly DTG-containing FDCs in alignment with WHO weight band dosing.

2) P1093 - Phase I/II, Multi-Centre, Open-Label Pharmacokinetic, Safety, Tolerability and Antiviral Activity of Dolutegravir, a Novel Integrase Inhibitor, in Combination Regimens in HIV-1 Infected Infants, Children and Adolescents.

The study enrolled 181 participants across nine IMPAACT clinical research sites between April 2011 and February 2020. The study is in follow up stage with one out of the five participants enrolled in Botswana.
The results indicate that once daily dosing of dolutegravir dispersible tablets provided drug exposures similar to those for adults, and was safe and well tolerated. These data support the use of dolutegravir dispersible tablets as first-line or second-line treatment for infants and children aged less than 6 years living with HIV-1.

3) IMPAACT 2017 - Phase I/II Study of the Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents.

The study's primary objective is to confirm the dose and evaluate the safety, tolerability, acceptability, and PK of oral CAB, long-acting injectable CAB (CAB LA), and long-acting injectable RPV (RPV LA) among virologically suppressed HIV-1 infected children and adolescents aged 12 to <18 years. The study targets to enrol 155 participants and is expected to run for approximately 7 years. A total of 150 participants have been enrolled as of June 2022. In Botswana has reached its target of 25 participants and is currently on follow-up stage.

4) IMPAACT 2026 - Pharmacokinetic Properties of Antiretroviral and Anti-Tuberculosis Drugs during Pregnancy and Postpartum.

The study's primary objective is to describe the pharmacokinetic (PK) properties of antiretroviral (ARV) and anti-tuberculosis (TB) drugs administered during pregnancy and postpartum. The study will enroll up to 325 women and their infants globally. In Botswana 10 women and their infants will be enrolled. The study was opened in April 2022 and no participant has been enrolled yet.

HPTN/HVTN STUDIES

The HIV Prevention Trials Network /HIV Vaccine Trials Network (HPTN/HVTN) is a worldwide collaborative clinical trials network that develops and tests the safety and efficacy of interventions designed to prevent the transmission of HIV.

1) 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.

This is a Pre-Exposure Prophylaxis (PrEP) study being conducted in HIV-uninfected women at 20 sites in 8 countries across Sub-Saharan Africa to evaluate the safety and efficacy of injectable cabotegravir against Oral Truvada. Although both products for HIV prevention were generally safe, well tolerated, and effective, cabotegravir was superior to TDF-FTC (Oral Truvada) in preventing HIV infection in women.

Forty (40) incident infections were observed, four in the cabotegravir group and 36 in the TDF-FTC group (Delany-Moretlwe et al). In Botswana 91 participants were enrolled. The protocol has now transitioned to an open label extension (OLE) where women who were enrolled have an option to a PrEP method of their choice i.e either oral Truvada or Injectable Cabotegravir (Fig 2). During the blinded part of the study 46 participants were taking CAB-LA and 45 were taking oral TDF-FTC (Truvada). Participants switching from TDF/FTC to CAB LA can now choose between taking oral CAB for 4 weeks (oral lead-in/OLI) before beginning injections or can immediately start CAB LA injections.

Based on the review of DTG and neural tube defect safety data, participants in the OLE will not be required to use any form of contraception. The Tsepamo study collected information on 153,899 deliveries. An updated analysis reported 7 neural tube defects among 3,591women exposed to dolutegravir at conception. In comparison, neural tube defects occurred in 21/19361 women on any non-Dolutegravir regimen at conception. The prevalence of neural tube defects did not differ significantly between dolutegravir and any non-dolutegravir antiretrovirals from conception (0.09% difference). After a period of decline since the original safety signal in May 2018, the prevalence of neural tube defects in infants born to women on dolutegravir around the time of conception appears to have stabilized at 2 per 1000 (Zash R, Holmes L, Diseko M, et al. Update on neural tube defects with antiretroviral exposure in the Tsepamo study, Botswana. AIDS 2020. Virtual.)

Fig 1: Number of participants randomized per study arm in Botswana

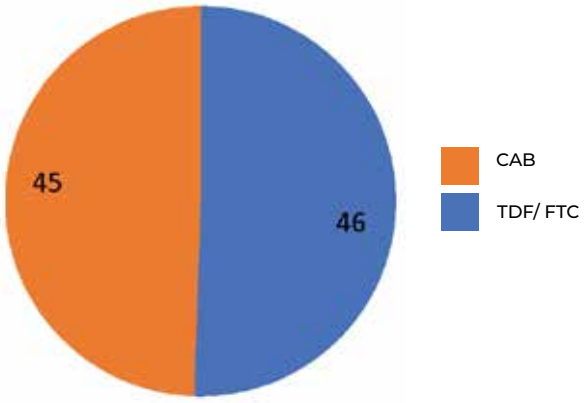
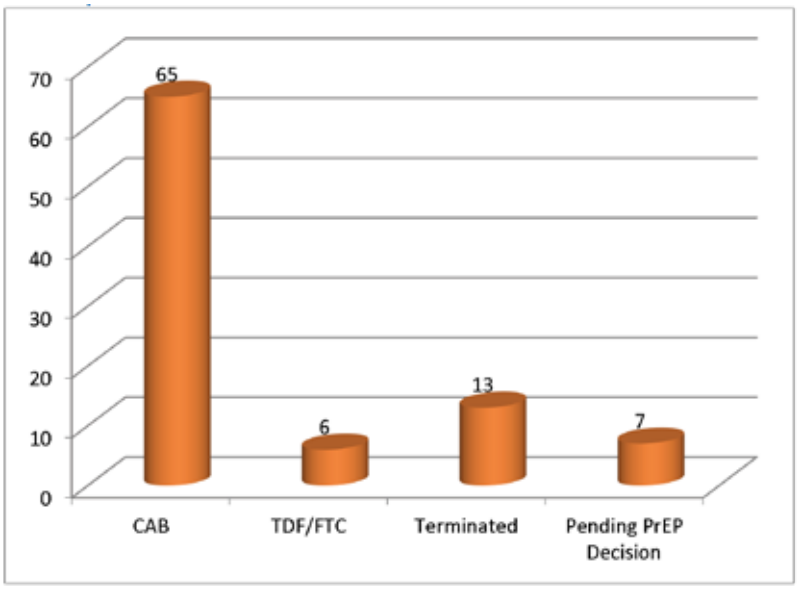


Fig 2: How participants in Botswana subsequently made a choice on the PrEP method during OLE (Open Label Extension)



2) HVTN805/HPTN093: Antiretroviral analytical treatment interruption (ATI) to assess immunologic and virologic responses in participants who initiated ART in early HIV infection after having received VRC01 or placebo in HVTN 703/HPTN 081

This is an exploratory study of participants living with HIV undergoing an analytical treatment interruption after early initiation of antiretroviral therapy (ART) following HIV acquisition in HVTN 703/HPTN 081, where they received VRC01 or placebo infusions. Gaborone CRS had recorded 7 HIV positive cases in the AMP study (HVTN703/HPTN081) and has enrolled thus far 1 participant on this high impact study on 09 Jun 2021 with majority of the seroconversion participants not eligible to enrol in the study due to timing of HIV diagnosis and the last infusion received whilst in the study. A total of 11 participants of the 61 expected are enrolled globally. Follow-up visits are ongoing.

CoVPN STUDIES

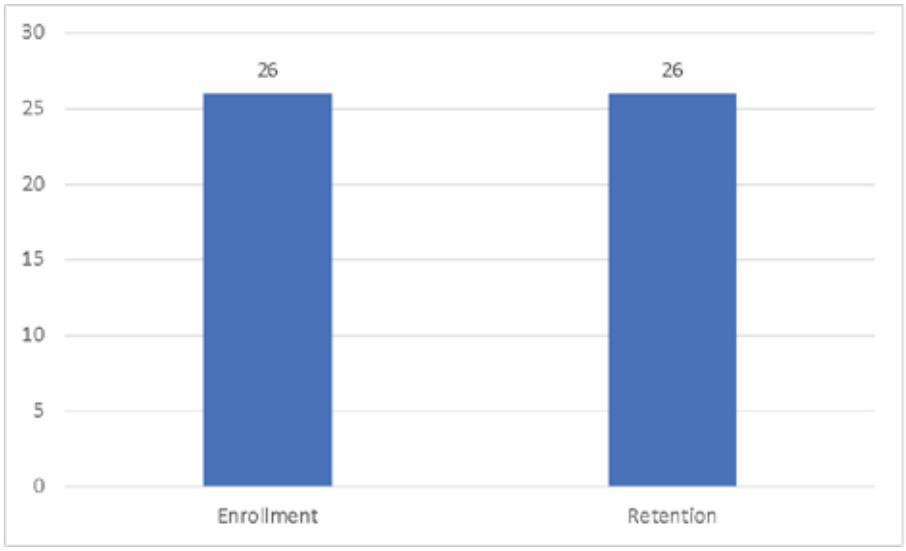
PI: Dr Joseph Moeketsi Makhema- MB.ChB, FRCP

1) CoVPN 5001: A prospective study of acute immune responses to SARS-CoV-2 infection

This is a prospective study of acute immune responses to SARS-CoV-2 infection that seeks to generate standardized datasets characterizing the quality, magnitude, and kinetics of humoral immune responses to SARS-CoV-2 infection in asymptomatic participants and symptomatic participants (both hospitalized and non-hospitalized) experiencing a range of clinical outcomes in order to prepare for similar assessments during trials of immune-based preventive strategies.

It also included characterizing the innate and cellular immune responses to SARS-CoV-2 infection during infection with SARS-CoV-2 in asymptomatic and acutely symptomatic participants (both hospitalized and non-hospitalized). Study enrolment had come to an end by 06 Aug 2021 but resumed in December 2021 following the discovery of the Omicron Variant. Gaborone site enrolled a total of 26 participants of the 953 enrolled globally from 54 sites across different continents. The site achieved 100% retention of participants and currently awaiting final study results.

Fig 1: Gaborone CRS participant enrolment and retention



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2) CoVPN 3008: Multi-Centre, Randomized, Efficacy Study of an Early vs Deferred mRNA COVID-19 mRNA Vaccine in Regions with SARS-CoV-2 Variants.

CoVPN 3008 Study also known as UBUNTU study seeks to determine if the Moderna Vaccine can prevent severe COVID-19 illness caused by the strains of the virus that are circulating in Eastern and Southern Africa. The study is also investigating how many doses of vaccine are needed for protection against COVID-19 for adults living with HIV and adults with existing health conditions. The Study is conducted in Botswana, eSwatini, Kenya, Malawi, South Africa, Uganda, Zambia and Zimbabwe.

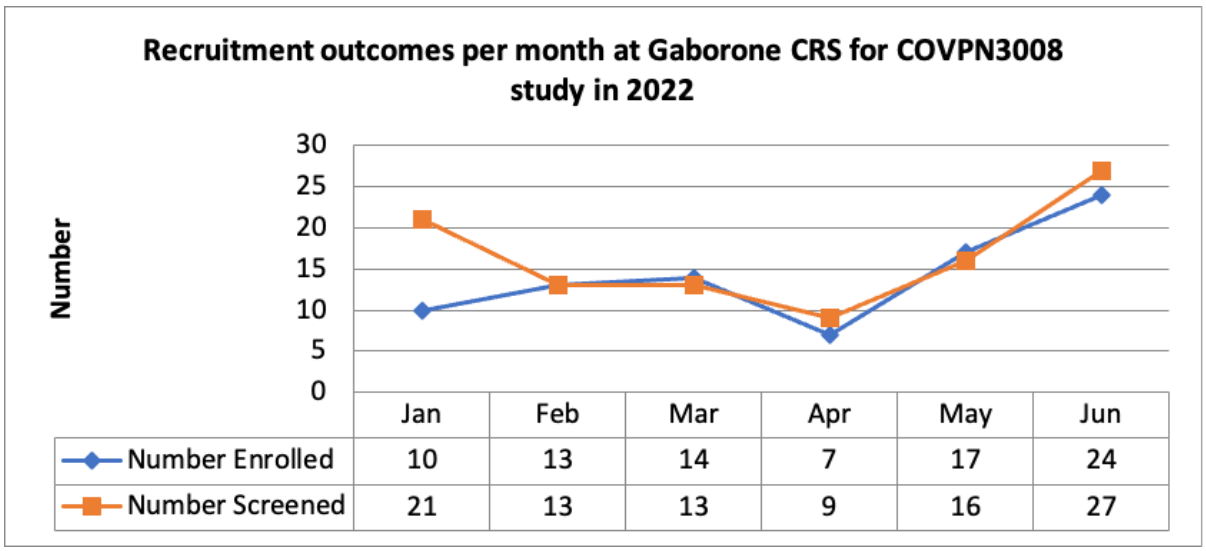
Participants are enrolled in to 4 study groups according to their HIV status and SARS-CoV-2 antibody status. The Gaborone CRS was initially allocated 250 but due to the high uptake of vaccines in the country, the target was revised to 125 participants. The first enrolled participants at Gaborone CRS were on 28 January 2022 and as at June 2022 there were 85 participants enrolled.

Table 1: CoVPN3008 enrolments per group at Gaborone CRS as at 30 June 2022

Group	HIV-1 sero-status	SARS-CoV-2 sero-status	M0 Vaccine	M1 Vaccine	M6 Vaccine	Number enrolled at Gaborone
1.	Positive	Negative	mRNA-1273	mRNA-1273	mRNA-1273	29
2.	Positive	Positive	mRNA-1273		mRNA-1273	22
3.	Negative	Negative	mRNA-1273	mRNA-1273	mRNA-1273	16
4.	Negative	Positive	mRNA-1273		mRNA-1273	18

The study team engaged with numerous stakeholders and members of the community in their recruitment efforts to educate generally on benefits of COVID-19 vaccination and to address concerns on vaccine hesitancy. The study has engaged communities in the Kgatleng, Kweneng and Greater Gaborone regions. The team also took part in a Health Expo at Tlokweng organised by Kalafhi Medical Centre where the local and government leadership showed support.

Fig 1: Number of participants screened and enrolled per month at Gaborone CRS



RESEARCH SUPPORT

1) Clinical Laboratory

The Botswana Harvard HIV Reference Laboratory (BHHRL) supports the clinical trials and various studies conducted by the Botswana Harvard AIDS Institute Partnership (BHP) and collaborating institutions, as well as contributing to various aspects of the national public health response. During the 2021-2022 period, BHHRL continued to provide the needed coverage for all the clinical trials at BHP providing requisite data, from receiving and processing labs, cell separations and cryopreservation, diagnostic, safety, and monitoring, as well as specialized research assays, providing high-quality testing for the key assays for enrollment and management of study participants.

BHHRL continued to maintain its approved status in conducting clinical trials supported by the US National Institutes of Health (NIH), especially through the Division of AIDS (DAIDS) and through networks; ACTG, IMPAACT and HPTN. BHHRL also continued to provide laboratory support to clinical trials participating in the Covid-19 Prevention Network (CoVPN). In the past year, the laboratory maintained its accreditation to ISO 15189 through the Southern African Development Community Accreditation Service (SADCAS). This represents international recognition of quality and competency in all aspects of our medical laboratory services.

BHHRL received international accreditation for SARS-CoV-2 PCR testing and certification from the African Society for Laboratory Medicine. BHHRL has continued to collaborate with the National Health Laboratory through the Ministry of Health (MOH) to add capacity to the national SARS-CoV-2/COVID-19 testing. To date, approximately one million samples have been processed and tested at BHHRL since the start of the pandemic and this represents about a third of the national testing total.

SADCAS

CERTIFICATE OF ACCREDITATION

BOTSWANA HARVARD HIV REFERENCE LABORATORY

Facility Accreditation Number: MED 031

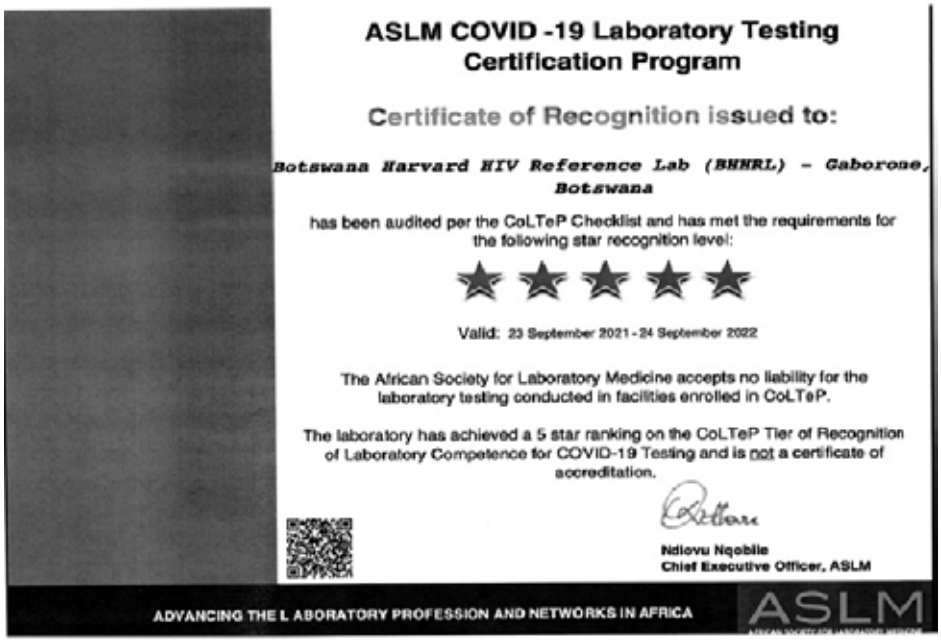
MEDICAL TESTING LABORATORY
CLINICAL CHEMISTRY, HAEMATOLOGY, MOLECULAR BIOLOGY AND SEROLOGY

ISO 15189:2012

SADCAS Chief Executive Officer

Botswana Harvard HIV Reference Laboratory Certificate of Accreditation for ISO15189:2012 standard issued by SADCAS

BHP Certificate of Recognition for ASLM COVID-19 Laboratory Testing Program



ASLM COVID -19 Laboratory Testing Certification Program

Certificate of Recognition issued to:

Botswana Harvard HIV Reference Lab (BHHRL) - Gaborone, Botswana

has been audited per the CoLTeP Checklist and has met the requirements for the following star recognition level:

Valid: 23 September 2021 - 24 September 2022

The African Society for Laboratory Medicine accepts no liability for the laboratory testing conducted in facilities enrolled in CoLTeP.

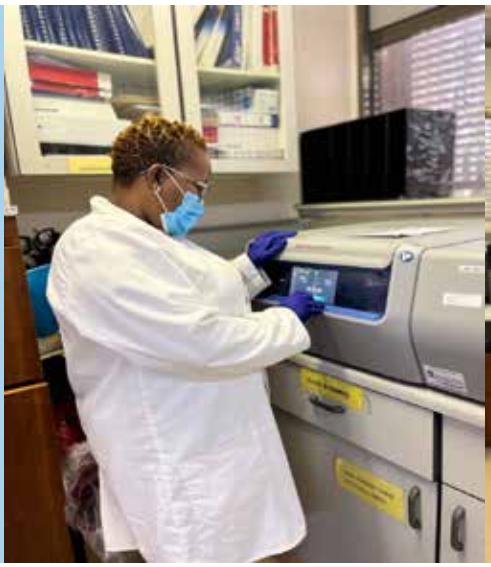
The laboratory has achieved a 5 star ranking on the CoLTeP Tier of Recognition of Laboratory Competence for COVID-19 Testing and is not a certificate of accreditation.

Ndiovu Ngobile
Chief Executive Officer, ASLM

ADVANCING THE L ABORATORY PROFESSION AND NETWORKS IN AFRICA ASLM

Activities of the Clinical Laboratory

- Processing and Accessioning,
- Inventory and Archiving (Biorepository management)
- Safety labs: Clinical Chemistry, Hematology,
- Monitoring Labs: CD4, Viral load,
- Molecular assays: Diagnostic DNA PCR, HPV PCR, Chlamydia and Gonorrhea, HIV Drug Resistance, SARS-CoV-2 RT-PCR testing, Cepheid Gene Xpert assays (Point of Care HIV-1 Viral load, HIV-1 Qualitative, MTB/RIF, HPV and SARS-CoV-2)
- Serological Assays: Fourth generation HIV ELISA, Hepatitis B profiles, Hepatitis C Antibody, Syphilis RPR and TPHA, HIV-1 confirmatory assays (Geenius), Incidence Assays [Limiting Antigen, Avidity, Bio-Rad Avidity and BED capture enzyme immunoassay], QuantiFERON TB Gold Plus assay and several in-house research assays.
- Referral Testing: TB (AFB, Molecular, culture and Drug Sensitivity), Cytology/Histology, and inflammatory cytokines).
- The laboratory has registered all assays in External Quality Assurance (EQA) programs and the EQA performance has been satisfactory in all tests during the past year. Specimen volumes received in the laboratory were stable over the year however, the nature and type of visits were increasing in processing intensity and complexity, for instance, pharmacokinetics sampling and PBMC isolation.



The laboratory is maintaining a specimen biorepository with over 80 ultra low temperature freezers and 6 liquid nitrogen storage facilities housing approximately 1.5 million samples. However, there are physical space, building infrastructure and equipment challenges encountered and are being attended to.

The laboratory added a number of new assays to its test menu. The Hepatitis B and Hepatitis C assays were validated and added to the serological automated system (Abbott Architect i1000SR). The laboratory also developed the capacity to do SARS-CoV-2 genotyping. Through this genotyping, in November 2021 the Omicron variant for SARS-CoV-2 was first identified here at BHHRL and subsequently contributed to the understanding the evolution of SARS-CoV-2

2) Regulatory Office

In order to ensure continued research integrity and ethical compliance for all BHP studies, the Regulatory office continues to provide support and maintains valid study permits for all studies from the overseeing Institutional Review Boards (IRBs). In the reporting period, there were 96 studies of which, 23(24%) were closed out with the IRBs after meeting requirements for closure. Fifty (52%) of the studies, were ongoing and 23 (24%) were new studies. (Figure 1).

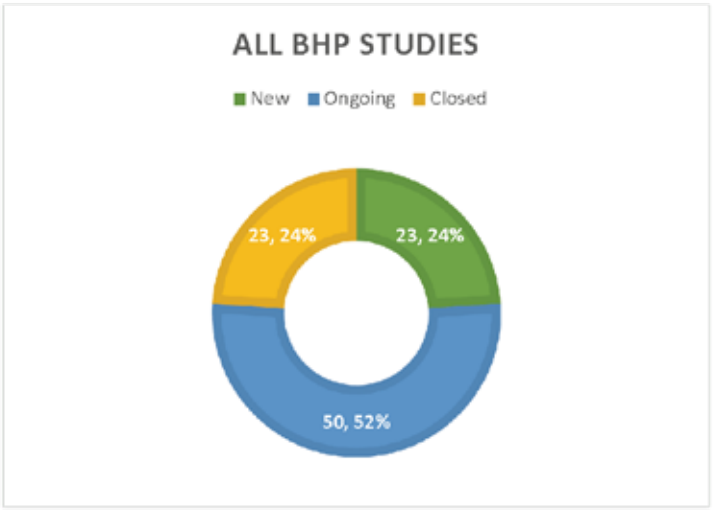


Figure 1. All BHP Studies

Of the 23 new studies, 10(44%) were COVID-19 related studies/protocols, 9(39%) were both network and non-network trials and 4(17%) were coming from research lab (Masters and PhD students) (Figure 2).

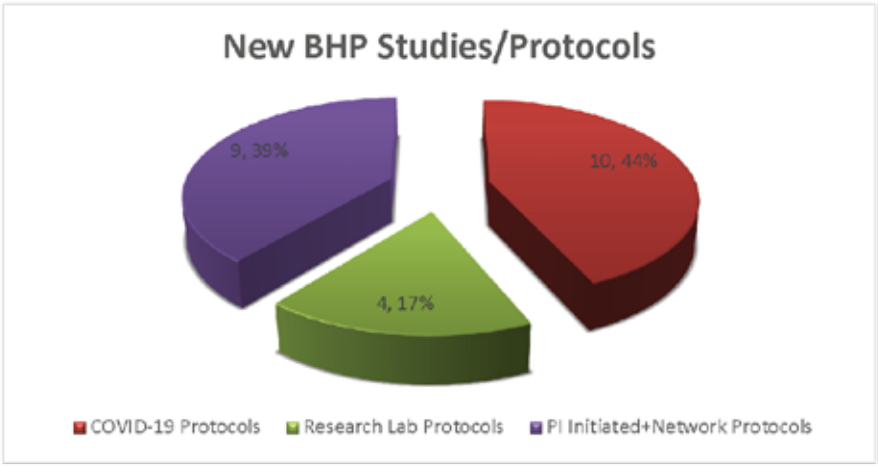


Figure 2. New BHP Studies/protocols

Capacity Building

Over the years, the Regulatory Office has been facilitating employee and stakeholder training on Responsible Conduct of Research (RCR). During the reporting period, one virtual training was facilitated in collaboration with the Harvard T.H. Chan School of Public Health (HSPH) Office of Regulatory Affairs and Research Compliance in which 27 BHP members were trained. (Figure 3)

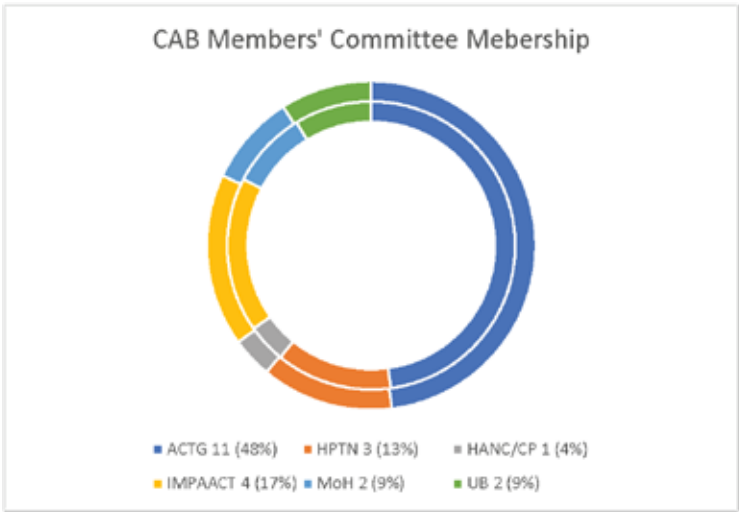
Figure 3. RCR Training since 2012

3) Community Engagement

Community Stakeholder Engagement is a process of working collaboratively with stakeholders to address their health needs through research. The engagement and involvement of community Stakeholders, ensures transparency, respect and builds trust between researchers, communities and other stakeholders. Community stakeholder engagement and involvement ensures that studies being conducted address the needs of the community and this ensures ownership and participation.

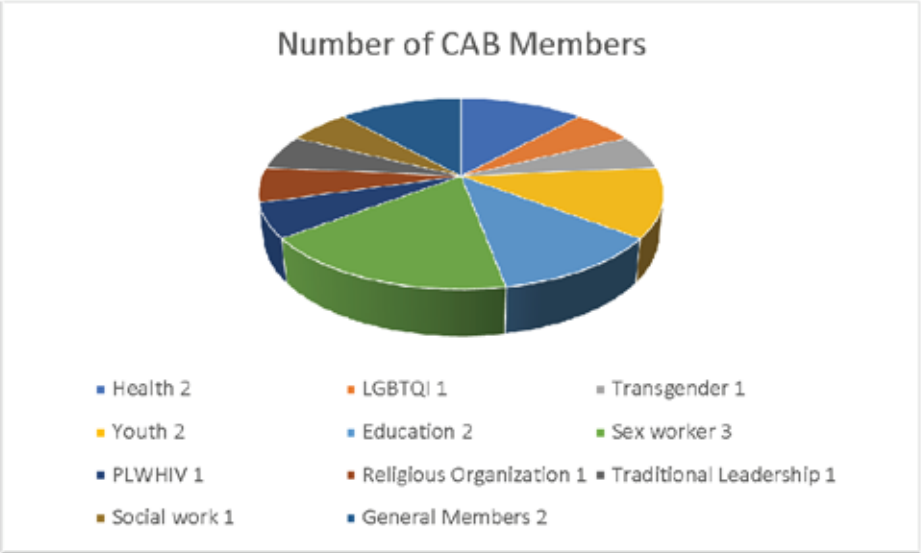
Though COVID-19 pandemic brought with it challenges, it also brought along important lessons of how to stay engaged and how to ensure that our communities access services during challenging times such as the COVID-19 pandemic. Despite these challenges, Community Advisory Board (CAB) successfully managed to conduct 8 in-house meetings, and 22 outreach activities. The CAB mainly through a number of structures that included, Community Based Organisations (CBO), Non-Organizational Organisations (NGO) and social media helped to identify challenges of access to services. This emphasizes the important role played by CAB members and other stakeholders in community Engagement and involvement.

The importance of CAB members is further demonstrated by their active participation in various committees, sub-committees and working groups of various networks and organizations locally and internationally.



The number of committee membership per organization

Number of committee membership per organization/community



Recruiting CAB members from various organizations and communities and having CAB members in various local and international networks and having outreach activities helps to ensure that BHP's accomplishments in the area of health/clinical research is known. It ensures that BHP stays in contact with its stakeholders.

CAB members are drawn from various organizations, communities and individuals to ensure that the membership is as inclusive as possible. This helps with the facilitation of communication with different communities when the need arises. The current membership is as follows:

The number of in person Community Stakeholder Engagement activities during the reporting period

Town / Village/ Institution	Number of Meetings	Project
Mochudi	1	BHP
Tlokweng	1	CoVP3008
IDM	3	AZD1222
Gaborone Technical College	3	AZD1222
Ebony	2	AZD1222
BOKOMO	2	AZD1222
Health Facilities	8	CoVP3008
DHMT (Kgatleng & Kweneng)	2	CoVP3008
CAB Meetings	8	Various Projects

Manuscripts in Development - HPTN084 Community Engagement in the Midst of COVI-19 Pandemic

4) Pharmacy

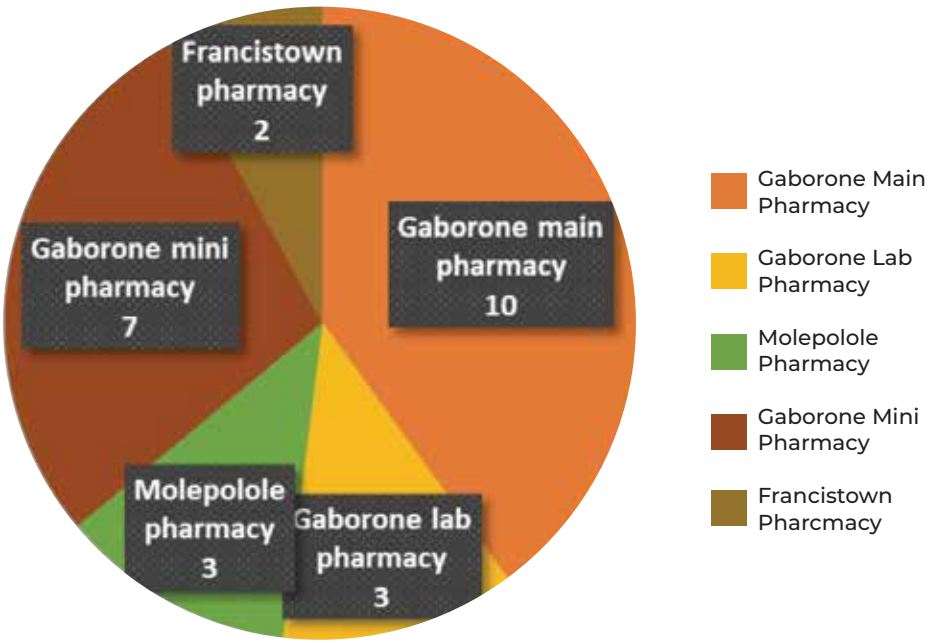
BHP pharmacy department has five study pharmacies in three different locations manned by four pharmacists and five pharmacy technicians. The department collaborates with some government hospital pharmacies to facilitate non-study drug acquisitions for some studies. The pharmacies are all adequately equipped to ensure that medication efficacy and integrity is preserved and maintained.

Pharmacy equipment include Biosafety cabinets, pharmaceutical refrigerators, -20 freezers, temperature regulating air conditioners, temperature monitoring thermometers, temperature data loggers and temperature alert systems, security doors and alarms, fire extinguishers and smoke sensors.

The pharmacies are connected to back-up power generators and Uninterrupted power supply (UPS) batteries for all equipment including computers, printer and lights to enable continuity of work and for all medications to always be under the recommended storage temperatures.

The pharmacies serve all studies both Network studies and Principal Investigator initiated studies (Non-Network Studies). There were 8 active Network studies and 5 Non-Network studies during the reporting period.

Studies across the BHP Pharmaies



Distribution of CTU Studies across pharmacies.

As part of sponsor requirement to ensure compliance, the Pharmacy department participated in 36 site monitoring visits. Additionally, the department participated in six Botswana Medicines Regulatory Authority (BoMRA) Good Clinical Practice (GCP) inspections.

5) Department of Software Engineering and Data Management

The Software Engineering and Data Management Center (SE & DMC) at BHP serves multiple clinical and research studies. By combining the efforts of well-trained software engineers and data management staff and a comprehensive scalable data management software system, the SE & DMC does its best to ensure a complete, accurate, compliant, auditable, confidential, secure and available research protocol data record. The Department has been able to achieve the following:

Laboratory Information System (LIS) Upgrades: This is an ongoing process that improves the performance on the LIS as well as adding some features that help with functionalities that are required for lab processes such as storage, integration with other data collection systems.

Sample Inventory clean up: We are currently half way through a sample storage data clean-up process that will allow BHP to have a full knowledge of what samples exists in storage and be able to strategically destroy samples that
are of less use, creating more space in freezers for new samples to be stored. This project paves a way for Data Warehouse project that is also currently ongoing.

AZD Study Electronic Data Capture: Developed and rolled out AstraZeneca Study systems for data collection of study data and lab data. This is a study that collects data across 5 sites. This system requires data to be pushed to the central server daily over a very poor network.

FLOURISH Study Data Capture: The DMC has developed a system for data collection for this study and it is still in development though a version of the system is live. This is one of the most complicated study systems that the BHP has designed due to its study design and the protocol. Though this is a one site study, it enrolled participants from multiple previous studies that were done at BHP and new enrollees with different criteria of enrollment into many different cohorts.

Data Warehouse: We are introducing a data warehouse that will hold all BHP sample data building a data repository that will also serve as a bio-repository. This will allow all PIs to be able to know what samples are available to formulate new research based on samples available. The same applies for use of other previous study data for further publications. The project is introducing the use of cloud technologies and developing skills for understanding and gaining experience in cyber-security for cloud computing.

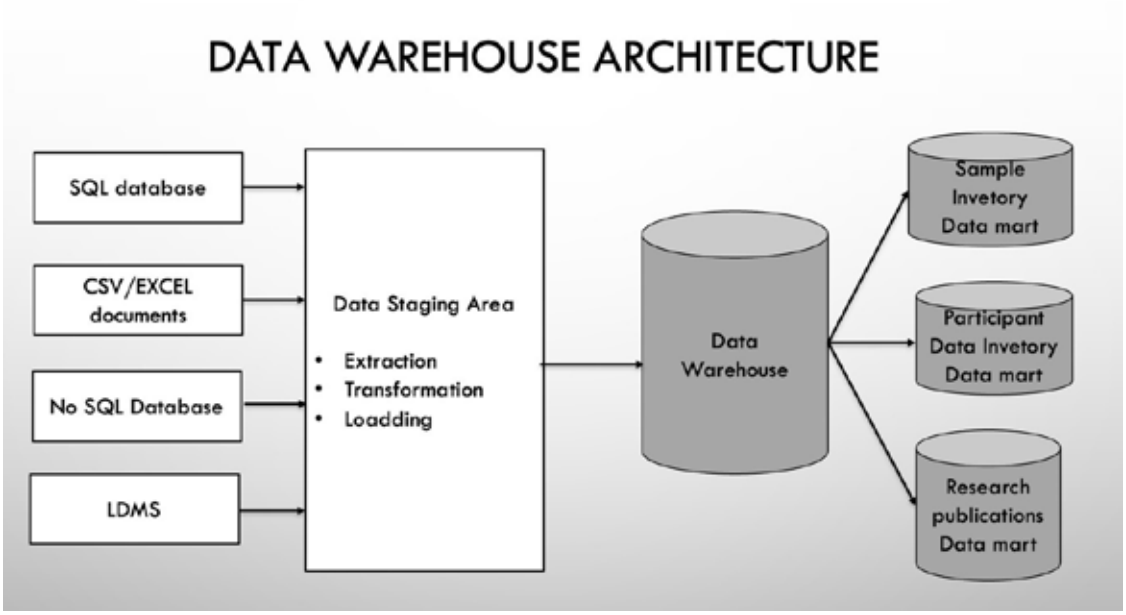


Figure 1.0: System architecture

Department Staff

The department has 7 Software engineers (1 Head of department, 1 Senior Systems Analyst/Developer, 1 Systems Analyst/Developer I, 2 Systems analyst/Developer II, 1 Data Manager and an Assistant Systems Analyst/Developer II) focusing primarily on system development, post-entry quality assurance, monitoring and reporting as well as data management. The department plans to convert some of the developers to also work as data analysts as well as doing some statistical work.

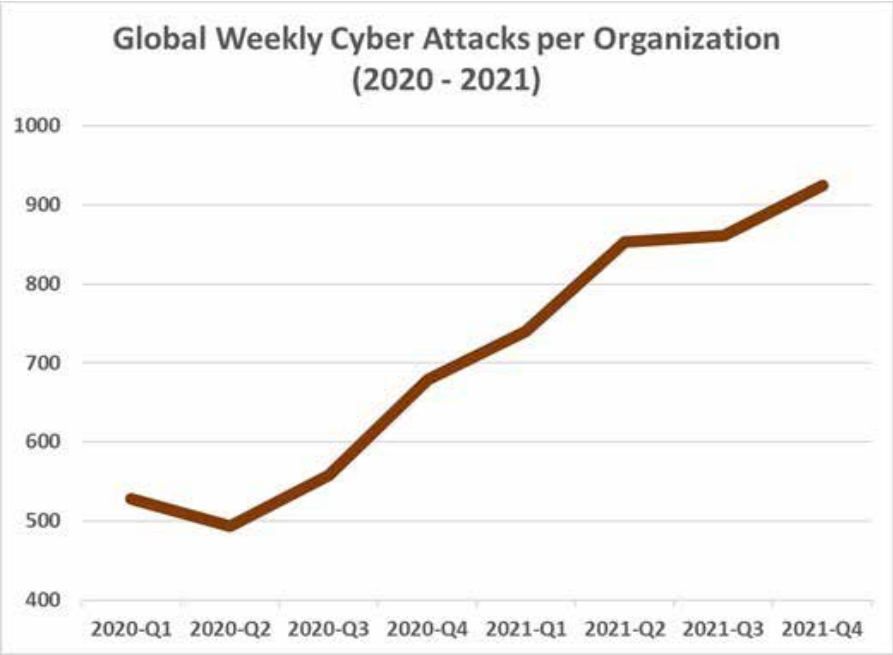
The department's intention is to attract and retain staff with diverse specialist skills in the area of software engineering. Furthermore, there is a wish to t set up a graduate trainee program that can help develop specialized staff for the department at the same time mentoring graduates to help them gain experience. Unfortunately, this has not been achieved partly due inadequate financial resources to support these objectives.

6) Information Technology

During the reporting period, the BHP Information Technology (IT) Department focused on two main activities being Cybersecurity and introduction of a Hybrid-Cloud Environment.

Cybersecurity

With a majority of the global workforce working away from the secure confines of a corporate network, 2021 was one of the most active years for cyberattacks. According to Check Point Research *(https://blog.checkpoint.com/2022/01/10/check-point-research-cyber-attacks-increased-50-year-over-year/)*, cyberattacks increased 50% year-over-year, with each organization facing 925 cyberattacks per week globally.



To improve security, the department reviewed and updated policies around data security and disaster recovery. The IT Department has also deployed an open-source Security Information and Event Management system (SIEM) to secure BHP's IT infrastructure. With this system, the department has been able to monitor all servers and curb potential threats to research systems.

Introduction of Hybrid-Cloud Environment

As the cost of high-performance IT infrastructure goes up, the IT department has turned to a hybrid-cloud setup, where some services are housed on-premises and some online. Failover of critical network services has been setup on the cloud to improve recovery of services as part of an improved Business Continuity and Recovery Plan.

The department continues to look at emerging technologies to improve its portfolio of services and obtain BHP ISO 27001 certification. The importance of the certification is to demonstrate to different stakeholders that BHP is committed to the improvement, development and protection of information assets, by implementing appropriate policies, risk assessments and IT controls.

11. CAPACITY BUILDING

1) Research Laboratory

The BHP research laboratory comprises of a vibrant group of research fellows at various stages of training and working on projects that are of public health importance in Botswana, the region and globally. The group works under the supervision of Dr Simani Gaseitsiwe, Dr Sikhukile Moyo and Dr Rosemary Musonda. Dr Motswedi Anderson who recently received a number of grants from Wellcome Trust and Africa Research Excellence Fund (AREF) as Principal Investigator takes a central role in spearheading the viral hepatitis research agenda at BHP. The group also boasts of international collaborators who assist in the supervision of fellows working on areas where there is limited capacity at BHP. The fellows are registered with various academic institutions including University of Botswana (UB), Botswana International University of Science and Technology (BIUST), Stellenbosch University (SU), University of Cape Town (UCT), University of Witwatersrand (WITS) and University of KwaZulu-Natal (UKZN).

The main areas of research focus include: HIV drug resistance, HIV incidence and tools to determine HIV incidence, Viral hepatitis, TB incidence and molecular epidemiology, Noroviruses and Sapoviruses, and HPV molecular epidemiology. The fellows are supported by various grants including SANTHE2.0, FogartyD43, H3ABioNet and TESA II.

Active Capacity Building Grants

- TESA III
- SANTHE
- H3ABioNet
- Wellcome Trust
- Fogarty D43
- Fogarty K43
- AREF
- Fogarty HBNU

TESA III

The overall aim of Trials of Excellence in Southern Africa consortium (TESA) is to develop, strengthen and expand clinical research capacities in the Southern African region through the consolidation of the TESA nodes of excellence for conducting clinical trials. The consortium focuses on conducting high quality research on infectious diseases with the most severe morbidity and mortality in the region. TESAII identified a framework of core capacity development activities that will take place within the larger context of the clinical trials in TB, HIV, and malaria to be managed by the network. TESAII established three referral laboratories (TB, HIV, and Malaria) to serve as training platforms for the less experienced members of the network.

BHP is recognized as the consortium's reference laboratory for HIV and offers training in HIV drug resistance and other related techniques. With TESA III, 15 institutions from 9 African and 3 European countries come together to strengthen and enhance the capacities for clinical research in Southern Africa and to strengthen the collaboration of North-South and South-South networking activities among its members.

To achieve this, TESA III focuses on transferring technology, strengthening the capacities among partner sites in Southern Africa, promoting professional development and scientific leadership and fostering collaborations to maximize impact. TESA develops specific activities aiming to increase researchers critical mass devoted to health, develop first-class institutions engaging clinical trials to prevent poverty-related diseases and promote dialogue between researchers, communities, and policymakers

TESA III Trainees

1. Bonolo Phinius, PhD candidate, (University of Botswana)
2. Nametso Kelentse, PhD candidate, (University of Botswana)
3. Doreen Ditshwanelo, MSc candidate, (Botswana International University of Science and Technology)
4. Ontlametse Bareng, MPhil candidate (University of Botswana)

Trainings Supported Through TESA III

1. Corrective and Preventative Action

BHP conducted training on Corrective and Preventive Action on the 01st to 02nd December 2021. The purpose of the training was to close non-conformities that were identified by the Southern African Development Community Accreditation Services (SADCAS) during the HIV Reference Laboratory audit in November 2021. The main objective of the training was to equip laboratory personnel with the necessary skills to investigate problems within the laboratory Quality management system and to prevent them from re-occurring. A total of 30 laboratory personnel was trained.

2. Quality Improvement Course

BHP collaborated with Biomedical Research Institute-Zimbabwe (BRTI) to facilitate the Quality Improvement course on the 4th to the 6th April 2022. The course was conducted virtually via the Zoom platform and involved quite a large number of participants from within the network. 40 participants from 3 countries namely; Botswana, Zimbabwe, and eSwatini benefited from this training. The main objective of the course was to provide participants with practical approaches to non-conformity identification, root cause analysis and monitoring effectiveness of corrective and preventive actions. The training is closely aligned with the requirements of ISO 15189:2012 standard and used hands-on activity and field-tested job aids.

3. HIV Drug Resistance Genotyping

BHP also hosted a training on HIV drug resistance genotyping from 30th May 2022 to 3rd June 2022. The main objective of the training was to train individuals on how to perform HIV drug resistance testing including setting up the experiment, carrying out the experiment from RNA isolation, the performance of polymerase chain reaction (PCR), amplification confirmation, amplicon purification, cycle sequencing, sequencing cleaning-up and determining HIV drug resistance mutations using ABI 3031xl genetic analyzer as well as editing raw sequences, sequence alignment, and identification of HIV drug resistance mutations using appropriate tools.

TAGENDI Fellowship Program

The TESA consortium was awarded more funds to offer further training to female candidates in Southern African region through the TESA Addressing Gender and Diversity Regional Gaps in Clinical Research Capacity (TAGENDI) PhD fellowship program. The purpose of this program is to contribute to the reduction of the gender and diversity gaps by training female PhD candidates from participating TESA member African countries or institutions which include South Africa, Angola, Mozambique, Namibia, Botswana, Eswatini, Malawi, Zambia, and Zimbabwe in collaboration with European country partner institutions from the Netherlands, Portugal, Spain, and France. BHP's Tuelo Mogashoa is a TAGENDI trainee reading towards her PhD with Stellenbosch University.

SANTHE 2.0

SUB-SAHARAN AFRICAN NETWORK FOR TB/HIV RESEARCH EXCELLENCE (SANTHE), is a multinational network of multidisciplinary experts, working together to empower African scientists, and to combat HIV, Tuberculosis and HIV/TB co-infection through pioneering basic, clinical and translational research. SANTHE aims to shape and drive locally relevant basic, clinical and translational research in Africa.

Its programme strategy targets 4 main areas:

- A cutting edge HIV and TB research programme.

- An innovative training and capacity building programme.
- The facilitation of a strong institutional network for research excellence as a pathway to intellectual and financial independence for African researchers and their institutions.
- Community engagement to ensure meaningful translational research and public health and community impact.

The Network aims to strengthen South-South partnerships, create enabling environments for excellence in research in Africa and train the next-generation leaders of African science. This consortium is specifically focused on HIV and TB as this 'syndemic' is a public health crisis in Africa that requires the full weight of basic science, translational/clinical research, and political and social mobilisation.

SANTHE 2.0 Fellows

- Natasha Onalenna Moraka, PhD Candidate
- Wonderful Tatenda Choga, PhD Candidate

Highlights of Projects

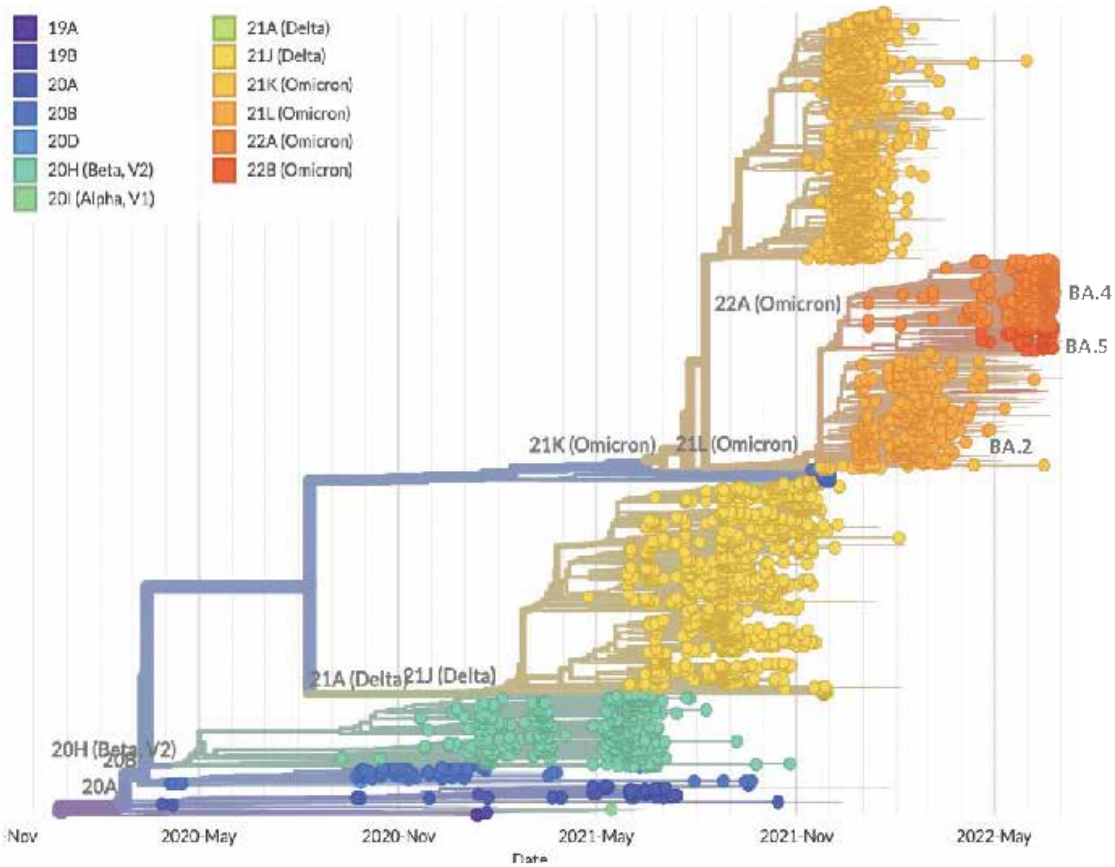
- Genomic Surveillance of SARS-COV-2
- Immune Responses to SARS-CoV-2 following vaccination
- Deep Sequencing of HIV for analysis of diversity and drug resistance
- Analysis of Drug Resistance in Low-level viremia
- Compartmentalization of HIV
- Pediatric Drug Resistance
- Prevalence of Hepatitis B virus the population-based household surveys
- Drug Resistance among Highly Treatment experienced individuals HPV genotyping and diversity

Pathogen Genomics and Surveillance of SARS-COV-2 variants

The Botswana Harvard HIV Reference Laboratory (BHHRL) played an important role in Botswana's COVID-19 response and the genomic surveillance of SARS-CoV-2 in Botswana. BHP initiated genomic surveillance of SARS-CoV-2 in support of the Ministry of Health and Botswana COVID-19 Taskforce efforts. To date, BHP has contributed 4700 SARS-CoV-2 whole genome sequences to the Global initiative on sharing all influenza data (GISAID).

BHP was able to track the lineages and variants of concern in circulation in the country, contributing to the global understanding of viral evolution and informing vaccine design. BHP scientists became first in the world to sequence and share the first genomes of the Omicron variant publicly (on the same day as our South African colleagues).

The fact that scientists in Botswana detected the Omicron variant before anyone on the European continent (where it was already circulating at the time) is remarkable – the sequencing at BHP was done with a small fraction of the resources, building on the capacity developed over years in various pathogen genomic projects. This work has resulted in several publications in high impact journals and several local and international recognitions.



[1]Former Ambassador to Botswana Michelle Gavin :

https://www.thinkglobalhealth.org/article/inside-lab-identified-omicron, 13 April 2022.

[2]Sikhulile Moyo named one of TIME magazine's 100 most influential for 2022.

https://www.hsph.harvard.edu/news/hsph-in-the-news/sikhulile-moyo-named-one-of-time-magazines-100-most-influential-for-2022/, 24 May 2022.

Training conducted or attended and Abstracts presented

1. Bioinformatics and Next Generation Sequencing

BHP through H3ABioNet grant hosted a course on Next Generation Sequencing Bioinformatics Training Course in collaboration with the University of Cape Town & H3ABioNet consortium. Next generation sequencing (NGS) has become an essential tool in genetic and genomic analysis. It is increasingly important for experimental scientists to gain the bioinformatics skills required to analyze the large volumes of data produced by next generation sequencers. This course intended to equip participants with the essential informatics skills required to begin analyzing NGS data and apply some of the most commonly used tools and resources for sequence data analysis. The course covered the prominent sequencing technologies, algorithmic theory, and principles of bioinformatics, with a strong focus on practical computational sessions using sequence analysis techniques and tools applicable to any species or genome size.

A variety of applications covered included post-sequencing analysis – QC, alignment, assembly, variant calling, RNA-Seq and ChIP-Seq.

2. HIV-1 Drug-Resistance Genotyping Resistance Training

BHP also hosted various participants for the HIV-1 Drug-Resistance Genotyping Resistance Training Workshop, which was held from 30th May – 3rd June 2022 in Gaborone, Botswana.

Conferences and Workshops Attended

During the current reporting period some of the research fellows attended the following workshops and conferences:

1. Workshop: Exploratory Data Analysis and Modelling in R with Microbiome Applications: 22nd to 26th August 2022
2. Keystone Symposia on Progress in Vaccine Development for Infectious Diseases - T8: 5th July – 13th October 2022
3. Conference on Retroviruses and Opportunistic Infection 2022 (Virtual): 12-24 February 2022
4. INTEREST 2022: 9-12 May, Kampala, Uganda

Graduations and Thesis Defense

During the current reporting period 4 of our research fellows;

- Dr Kaelo Seatla, Dr Leabaneng Tawe and Dr Prisca Thami successfully defended their PhD theses and graduated from the University of Botswana with Doctor of Philosophy (Medical Sciences) for Kaelo and Leabaneng and Doctor of Philosophy (Medical Sciences) from UCT for Prisca.
- Natasha Moraka successfully defended her MSc thesis and graduated from Stellenbosch University.
- Wonderful Tatenda Choga successfully completed his MSc from the University of Cape Town

2) The BHP Clinical Capacity Building Initiative at Scottish Livingstone Hospital

The BHP Clinical Capacity Building Initiative is a collaboration between the Botswana Harvard AIDS Institute Partnership (BHP), Beth Israel Deaconess Medical Center (BIDMC), Boston, and Oregon Health & Science University (OHSU), Portland. The initiative was launched in 2021 to support healthcare capacity building through clinical stewardship, medical education, quality improvement, and research in Botswana.

The program provides clinical training to University of Botswana medical students, interns, and residents as well as Ministry of Health medical officers, nurses, and other healthcare staff in collaboration with local partners. The program promotes systems/process improvement through quality improvement and research. In addition, the program regularly provides opportunities for rotating U.S. residents and fellows to participate in clinical, educational, quality improvement, and research efforts.

The initiative began at Scottish Livingstone Hospital (SLH) and Kweneng

East district, where the Internal Medicine program continues to focus. The Obstetrics & Gynaecology and Anaesthesia & Critical Care programs have since transitioned to the University of Botswana to support residency training.

Obstetrics & Gynaecology (OBGYN)

Now in the third year of supporting the new OBGYN residency training programme at the University of Botswana (UB), the OBGYN program has focused this past year on supporting subspecialty training for UB OBGYN resident trainees. In collaboration with the University of Botswana, BHP hosted a High-Risk Obstetrics Fellow for two months, contributing essential education and skills in advanced ultrasound and high-risk obstetrics topics to trainees. BHP also welcomed back a long-time friend and colleague for a Urogynaecology surgical camp to provide essential clinical care and education to trainees and faculty.

The programme welcomed a new OBGYN Site Director in June 2022, Dr. Sally Hanson, who will play a key role in upscaling laparoscopic gynecologic surgery and simulation training. Dr. Rebecca Luckett will continue to support the UB OBGYN residency training programme as Programme Director, while working to transition to a UB colleague by the time of completion of the first cohort of residents in December 2023.

Anaesthesia & Critical Care

During the past year, the Anaesthesia and Critical Care Program has focused primarily on the development and support of the anaesthesia residency program that has now entered its third year. Given the continued risk of COVID-19, the programme was lucky to have four anaesthesia residents and a paediatric anaethesia fellow visit from abroad over the course of this past year to assist in this effort.

The program has also continued to support the clinical capacity building that is ongoing at the University of Botswana's Sir Ketumile Masire Teaching Hospital (SKMTH). The ICU at the hospital continues to be used as a COVID-19 treatment centre and has proven to be a useful facility for critical care training as well.

At Scottish Livingstone Hospital, the programme continues to provide support in a number of ways, caring for paediatric patients undergoing ophthalmological surgery and continuing to train throughout the hospital in Basic Life Support, among other projects. Support of quality improvement projects is ongoing at each of these sites.

Internal Medicine

The Internal Medicine program continued to support education for Medical Officer Interns through the Medical Internship Training Programme at Scottish Livingstone Hospital, welcoming the largest intern cohort at SLH to date. In conjunction with the program in Anaesthesia & Critical Care, the program obtained funding and academic support from partner institutions to develop and implement an intensive Point-of-Care Ultrasound (POCUS) course for SLH Medical Officers to facilitate expedited diagnosis and

management of frequently encountered medical problems. The program welcomed the return of US resident trainees to SLH in February 2022, hosting seven Internal Medicine Residents and a BIDMC Global Health Fellow since that time as they supported clinical education and quality improvement activities at SLH.

In addition, the program contributed to design and implementation of a number of quality improvement initiatives and related research projects in Kweneng District, with particular focus on management of non-communicable diseases.

RESEARCH STUDIES (MEDICINE):

i.) Perceptions of Prevalence, Impact, and Management of Post-Acute Sequelae of SARS-CoV-2 Infection among Healthcare Workers in Kweneng District, Botswana.

PIs: Dr. Sara Schwanke Khilji, Mrs. Ditebogo J Mokone.

Botswana recorded its first case of SARS-CoV-2 infection in March 2020, but the prevalence of post-acute sequellae of SARS-CoV-2 infection (PASC) and its impact on the health system in Botswana remains unclear. Further, given the novelty of the PASC syndrome, providers have to date received little systematic training regarding evaluation and management of long-COVID symptoms. This is a mixed methods study combining cross-sectional survey of healthcare workers and key informant interviews to determine participants' perceptions of PASC burden, impact, and current management at the district level in Kweneng District, Botswana.

ii) Evaluation of Prevalence of Pericardial Effusion and Associated Risk Factors in Patients with Pulmonary Tuberculosis in the Kweneng District, Botswana.

PIs: Dr. Mahmoud Abu Hazeem, Dr. Sara Schwanke Khilji.

Although tuberculosis (TB) is a leading cause of morbidity and mortality in Botswana, there is a paucity of data on extra-pulmonary manifestations of TB, with anecdotal evidence of underreporting of TB pericardial effusion, in particular. Point-of-care ultrasound (POCUS) shows promise for rapidly identifying TB pericarditis, with potential benefit for patient treatment and outcomes. This cross-sectional study seeks to evaluate the prevalence of and identify risk factors for pericardial effusion in patients with pulmonary TB in Kweneng District, Botswana.

iii) Acute Heart Failure Presentation and Outcomes in Rural Botswana.

PIs: Dr. Abdelghani El Rafei, Dr. Sara Schwanke Khilji

Heart failure (HF) in Africa affects patients at relatively young ages, leading to poor quality of life, frequent hospitalizations, loss of economic productivity, and premature mortality. These outcomes vary significantly based on geographic location within the region. Most of the data on HF outcomes regionally come from large tertiary centers, possibly underestimating mortality in rural areas. This retrospective cohort study of patients admitted with a diagnosis of HF to a district-level hospital in rural Botswana aims to determine mortality rates associated with inpatient

mortality, and numbers of referrals to urban tertiary care settings.

iv) Supporting Continued Education on Non-communicable Disease Management for Outpatient Healthcare Providers in Kweneng District, Botswana during COVID-19.

PI: Dr. Sara Schwanke Khilji

Non-communicable diseases (NCDs) are the primary cause of death and disease globally, with 85% of premature deaths due to NCDs occurring in low- and middle-income countries. In Botswana, management of NCDs is challenging due to underlying high rates of HIV/AIDS compounded by a growing burden of other chronic diseases, such as high blood pressure and diabetes. A program of continuing professional development (CPD) supporting NCD training for primary care health workers in Kweneng District, Botswana was implemented in 2019 through a series of workshops and mentoring sessions. Planned refresher workshops and outcomes evaluation could not be completed due to COVID-19 related restrictions on meetings. This pilot study aims to assess the impact of a mobile-phone based education program on provider knowledge, adherence to NCH management guidelines, and achievement of treatment targets while also assessing the acceptability and feasibility of a mobile-phone based program for NCD content delivery and evaluation. This work is supported by a grant from the Tartar Trust. Status: Curriculum in development.

3) Botswana Global Oncology Outreach (BOTSOGO)

Botswana Oncology Global Outreach (BOTSOGO) is a capacity-building initiative that has joined the public and private oncology communities in Botswana with the Harvard oncology community to improve quality cancer care. With suspension of regular exchanges due to COVID disruptions, BOTSOGO has maintained monthly tumour board to promote clinician and nurse education on cancer management. This is a continued medical education for healthcare providers at public and private hospitals, and academic institutions. In 2022, BOTSOGO celebrated its 10th anniversary during a special Tumor Board honoring pioneer medical radiation physicist Remigio Makufa.

Mrs. Makufa was presented with a bouquet of flowers and a plague in honour of her husband Remigio Makufa

12. PUBLIC POLICY & ADVOCACY

Engaging the public on the impact of the research that we do remains an important factor as espoused by one of our key values, "Beneficence". The Beneficence value ensures that all activities done at BHP are of relevance and benefit those affected. BHP ensures that the knowledge generated through its research is made available to advise public health policy and is shared with the public and the scientific communality for the benefit of mankind.

BHP has continued to raise awareness of public health challenges and the research it conducts through fora such as the Journal Club, Tumor Board, Kgotla Meetings, Community Advisory Board meetings, Community Stakeholder Engagement meetings, Health Exhibitions and STEM Expo. Research findings from various studies have been presented with the Ministry of Health as well as presented at different international conferences.

New studies have also been introduced to MOH and other key stakeholders for implementation guidance and buy in. Key research findings and other milestone achievements have been shared with the public through media briefings and press releases as well as media interviews. The high-quality research that BHP conducts is published in different reputable peer-reviewed scientific journals to share the research results with a wide range of scientific audience. In this reporting period, BHP published 89 manuscripts in different peer-reviewed journals, and 30 abstracts have been presented at different international conferences.

BHP is committed to collaborative research and it emphasizes on the importance of teamwork by collaborating with international based investigators and partners as well as being active members of both international and several MOH technical committees where they give expert advice on different health topics. BHP staff together with CAB Members serves in 22 Committees and Teams.

During the advent of COVID-19 pandemic, BHP collaborated with Government through the National Health Laboratory (NHL) to conduct SARS-CoV-2 testing and virus surveillance through pathogen genomics. The surveillance by the BHP Lab resulted in the discovery of the Omicron variant of SARS-CoV-2, and together with a lab from South Africa, alerted the world of the threat. BHP has also facilitated training and conducted COVID-19/SARS-CoV-2 related studies. In this reporting period, BHP has conducted twelve COVID-19/SARS-CoV-2 studies.

BHP's CoVPN 3008 study team engaging with members of the public at a Health Expo held at Tlokweng

13. OPERATIONAL EXCELLENCE

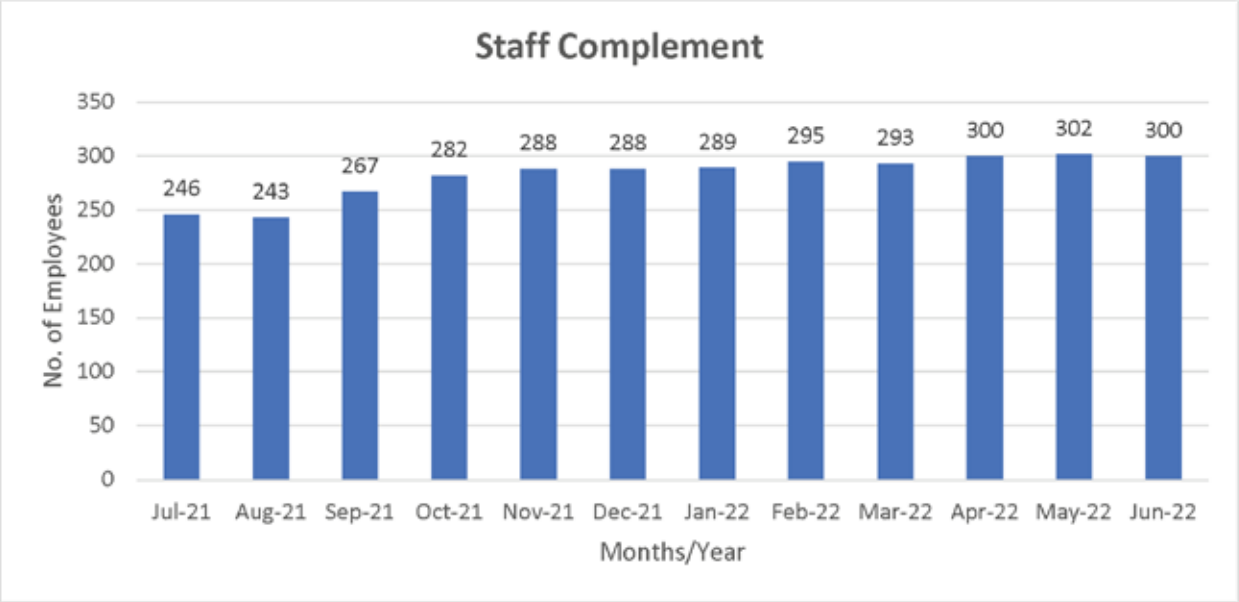
1) Human Resources

The Human Recourses (HR) Department ensures that BHP has appropriate talent to sustainably deliver its mandate as well as to promote a harmonious and sustainable work environment and relationships between management and the employees in general. This is achieved through the delivery of excellent supportive professional HR services designed to positively impact the organization's results. This includes bringing HR's knowledge of human capital trends to support Strategy and to provide access to the skills required. This report provides human resources-related statistics, insights, and metrics for the period 1st July 2021 to 30 June 2022.

Diversity and Manpower Strength

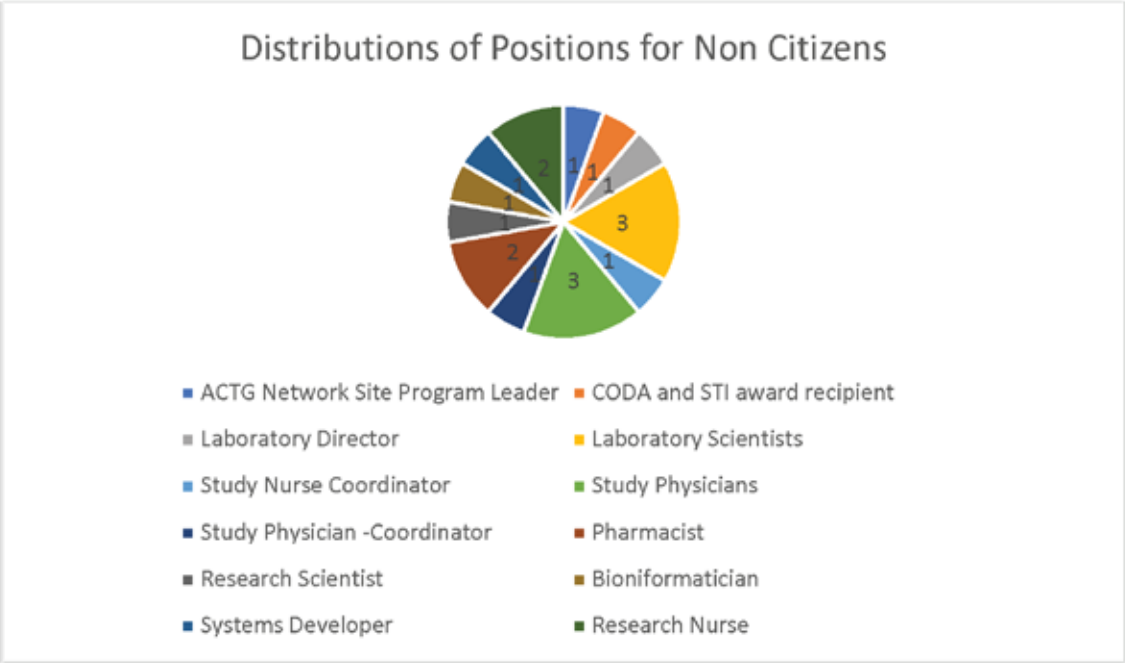
BHP is committed to an inclusive culture that respects and embraces the diversity of employees. The organization aims to attract, develop and retain the most capable employees from all cultures, and ethnicities.

As at June 2022 (Year-End), the staff complement was 300. A significant increase as compared to 240 for the previous year. This is as a result of the new studies that commenced during the course of the year.



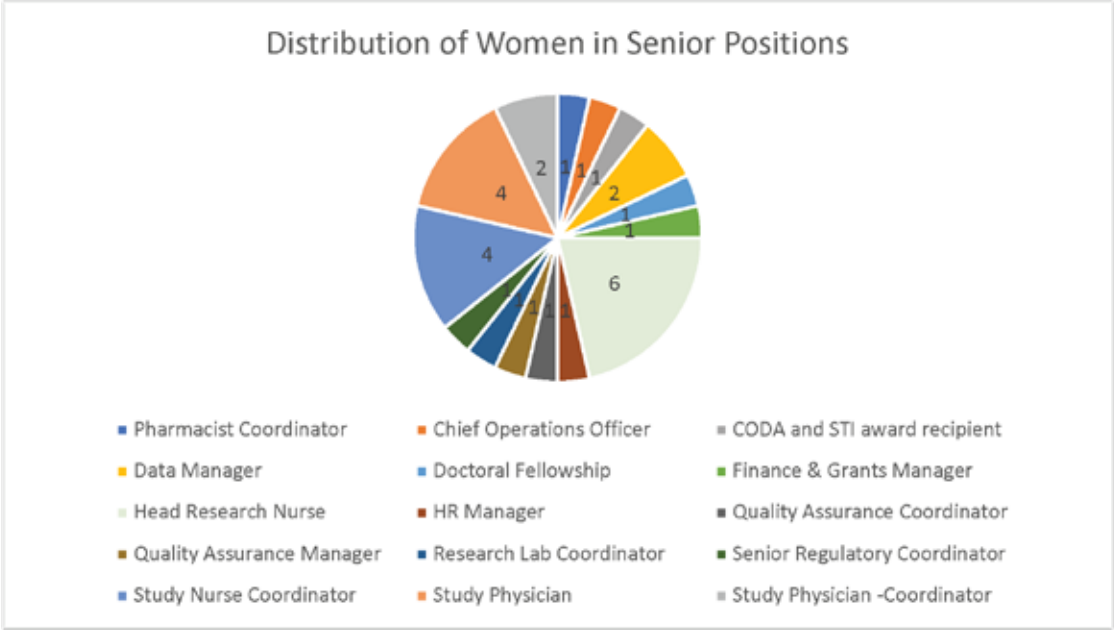
Nationality and Gender Distribution

Botswana citizens constitutes of the highest number of employees, with a total of 282 (94%) Batswana and 18 (6%) expatriates. Below is the distribution position of Non-Citizens within BHP.



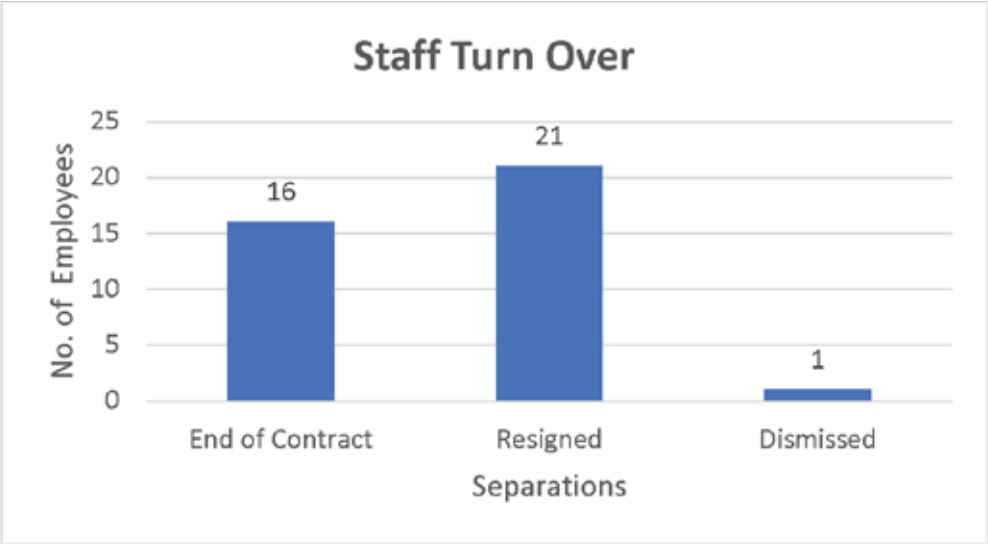
Gender Distribution

BHP aims to achieve gender diversity throughout all cadres with a keen interest of promoting women in Science.BHP staff compliment currently constitutes 66% women.



Staff Turnover

The previous reporting period (2021), BHP recorded a total of 41 separations, which were mostly due to end of contract non-renewals. For the period under review, BHP has seen a slight decrease of (from 41 to 38) terminated employees. The chart below indicates separations for the period under review.



Wellness

In an effort to curb the spread of COVID-19, BHP has implemented guidelines to facilitate effective management of the pandemic. BHP provides employees with disposable masks and personal protective equipment (PPE). Temperature screening points have been provided and automatic sanitizer dispensers installed in all buildings.

With the increased COVID-19 infections, BHP Management in collaboration with Botswana Government worked to ensure vaccination of front-line workers. Table 1 below indicates the COVID-19 vaccination statistics for BHP employees.

Table 1: COVID-19 Statistics Vaccinations at BHP

Fully Vaccinated	93%
Partially Vaccinated	1.50%
Not Vaccinated	5.50%
Boostered	77%

Human Resources Key Strategic Initiatives

i) Job Evaluation and Grading

Compensation plays an integral role in the successful delivery of strategic objectives. Attracting and retaining the most capable employees in the market is central to compensation strategy, hence the review of BHP remuneration structure.

The project commenced with organizing the remuneration and benefits committee. The first exercise was grading of jobs and determining BHP's intended pay philosophy and placement on the Botswana market. The current available benchmark pay markets data were used and moderated with a recent relevant targeted pay survey to determine the most appropriate representation of the Botswana market pay.

BHP's salary scales were developed, along the Botswana pay market and the given remuneration targeted placement. The implementation of the proposed salary scales will to some extent assist BHP to be competitive and attract the right talent for the business. However, a bespoke health industry remuneration survey will be facilitated to complete the project, in order to determine the final BHP pay scales.

Training and Development

Training and Capacity Building remains a key strategic mandate of the institution. Significant resources are invested in training and developing employees' capacity to deliver and meet its strategic objectives for clinical and laboratory research while also strengthening clinical research capacity in Botswana.

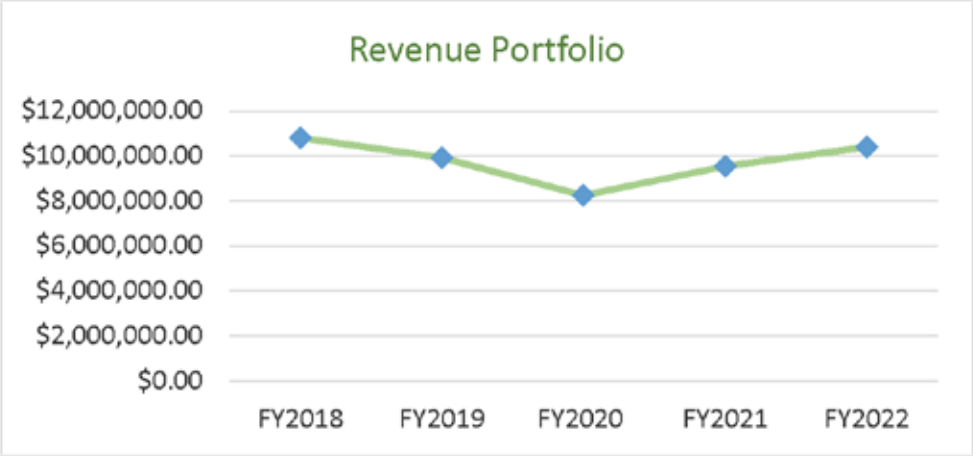
The Training is in two broad categories: a) Protocol Specific Training, b) Professional Academic and Self-development. The latter includes 14 candidates undertaking studies at MSc, MPhil, PhD and Post-Doctorate levels, for the period under review.

For the period under review, the below mandatory/ compliance trainings, Protocol specific meetings and conferences were attended by various employees locally, regionally and internationally to increase productivity and effectiveness.

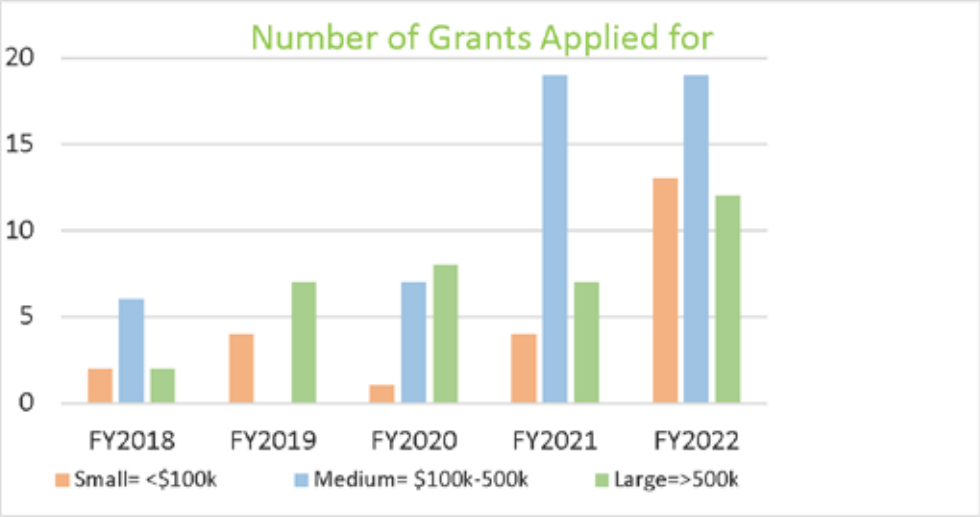
2) Finance & Grants

The Institution's financial and grants management functions continue to strengthen owing to a sound internal control environment and the existence of a well-structured segregation of duties.

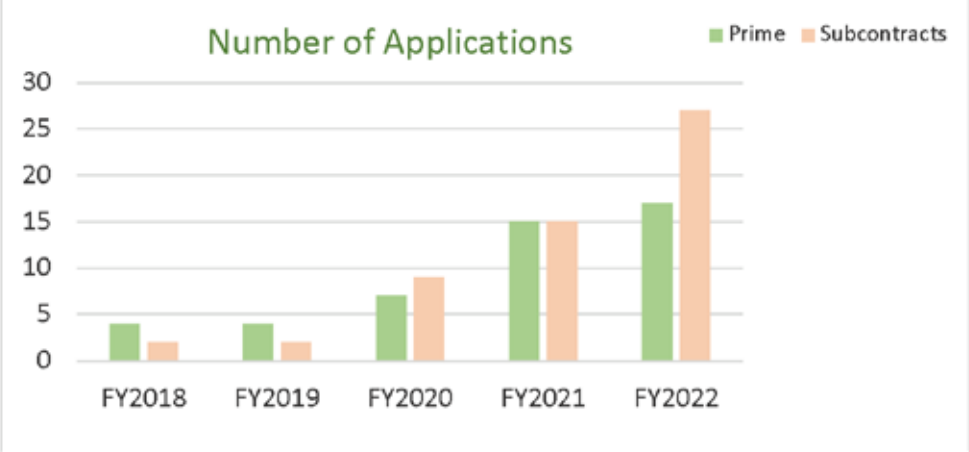
Financial Year 2022 (FY2022) revenue increased by 9%, resulting in a total of USD 10.4 million compared to USD 9.6 million in FY2021. The revenue trajectory is reflected in the linear graph below;



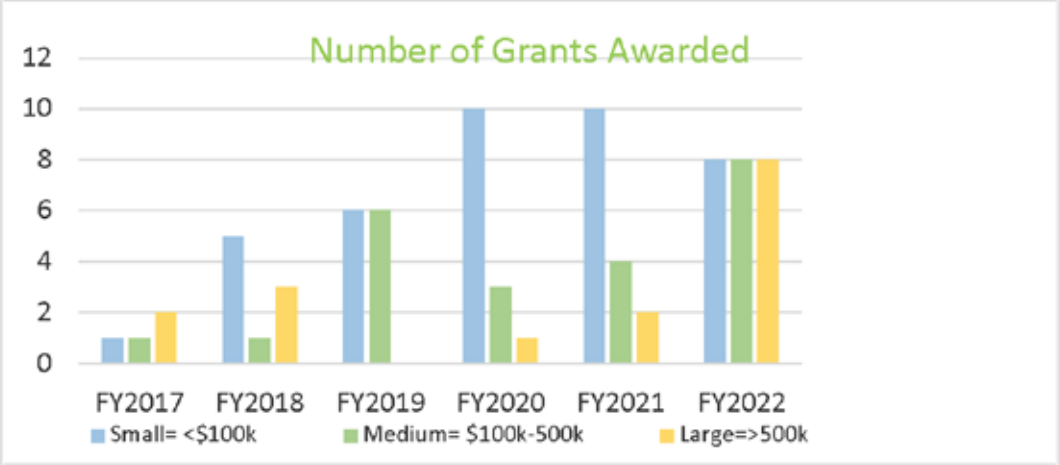
Forty-four (44) grants were applied for during the period under review. This is an increase of 47% from FY2021. Thirteen (13) small value grants, nineteen (19) medium grants and twelve (12) large grants were applied for.



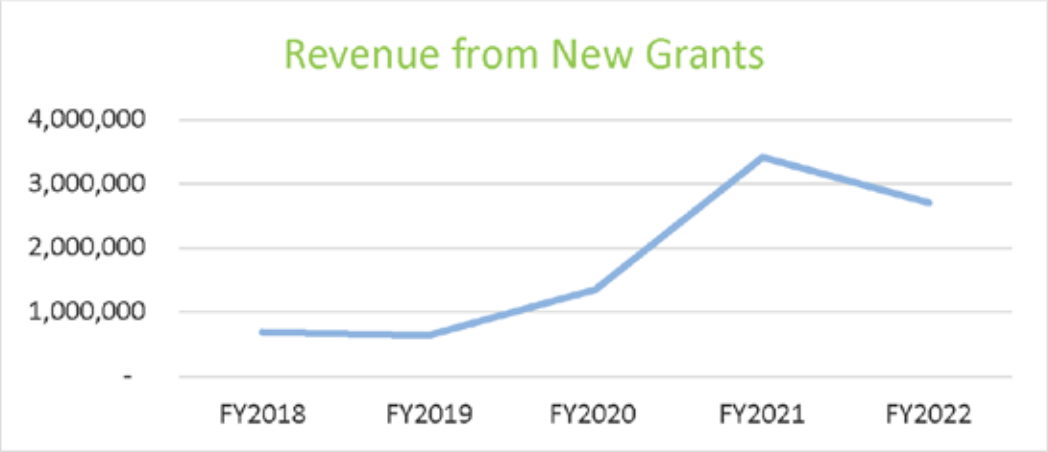
The table below classifies the number of applications submitted to sponsors during the reporting period, being 17 prime awards and 27 subcontracts.



Twenty-four (24) out of forty-four grants (44) were successfully awarded.



Revenue from new grants declined to USD2.7m from USD3.4m

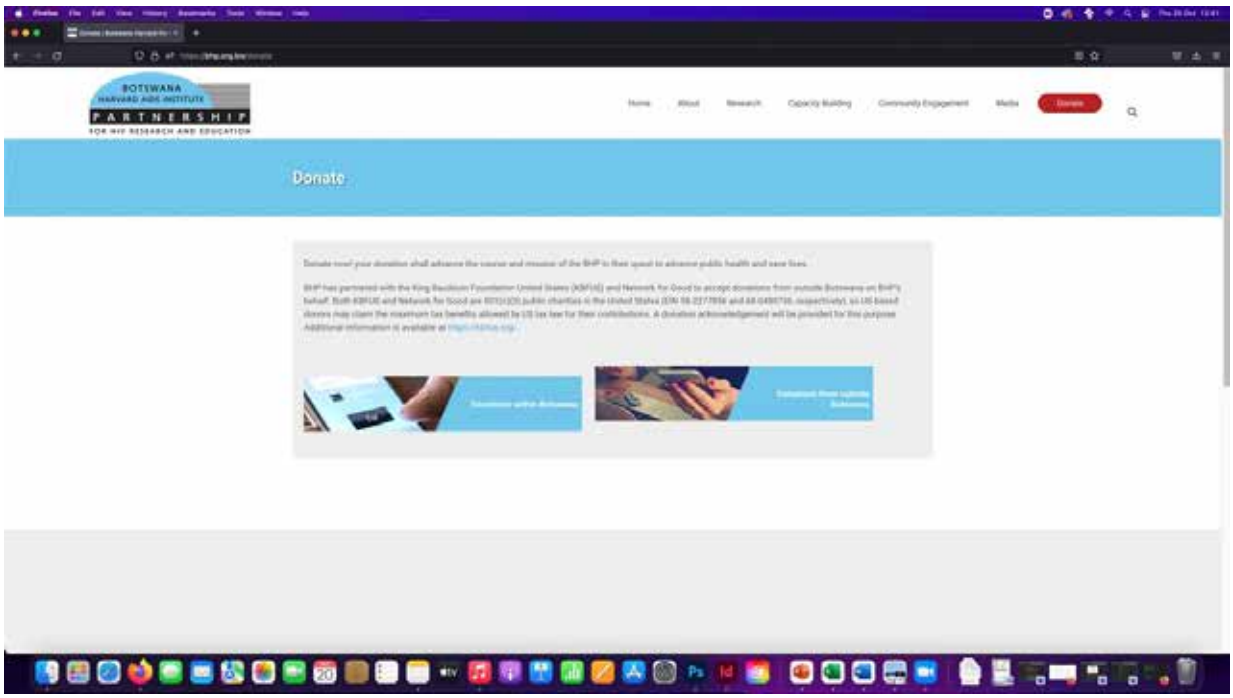


Forty-four (44) grants were applied for during the period under review. This is an increase of 47% from FY2021. Thirteen (13) small value grants, nineteen (19) medium grants and twelve (12) large grants were applied for.

14. SUSTAINABILITY

BHP is actively pursuing diversified revenue sources to help sustain and grow its critical missions of training, capacity building and research. BHP and affiliated supporters have embarked upon initiatives to raise additional funds, including targeted philanthropic activities. In support of international fundraising efforts, BHP has established a King Baudouin Foundation United States (KFBUS) Friends of Botswana Harvard Account to facilitate the receipt of philanthropic gifting by international donors, whether individuals, foundations or corporations.

Donations through KFBUS from US based donors are tax deductible. BHP continues to invest in supporting and developing early career investigators from Africa, including building grant writing capabilities, and over the current strategic planning period has mentored and developed local early career investigators.



Screenshot of the Donate Page on the BHP website.

ANNEXURE A: PUBLICATIONS AND ABSTRACTS

a) PUBLICATIONS

1. Human Herpesvirus-6 Detection in Cerebrospinal Fluid on the BioFire FilmArray Meningitis/Encephalitis Panel in a High Human Immunodeficiency Virus-Prevalence African Setting. Milburn J, Lechiile K, Siamisang K, Williams CG, Owen L, Gwakuba E, Machiya T, Leeme T, Barton HE, Doyle R, Tenforde MW, Mine M, Goldfarb DM, Mokomane M, Jarvis JN. Open Forum Infect Dis. 2022 May 17;9(7):ofac229. doi: 10.1093/ofid/ofac229. eCollection 2022 Jul. PMID: 35854999

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2. HIV-1 drug resistance mutations in proviruses of early treated infants in Botswana. N.O. Moraka, P. Garcia-Broncano, Z. Hu, G. Ajibola, M. Pretorius Holme, K. Maswabi, C. Maphorisa, T. Mohammed, G.U. VanZy, S. Gaseitsiwe, D.R. Kuritzkes, M. Lichterfeld,S. Moyo, R.L. Shapiro. International AIDS Society (IAS 2021) Berlin, 18-21 July 2021.

3. Prevalence of depression among postpartum women on Isoniazid-Preventive Therapy and Efavirenz-based treatment for HIV—an exploratory objective of the IMPAACT P1078 randomized trial. K. Baltrusaitis, L. Stranix-Chibanda, G. Montepiedra, L. Aaron, J. Mathad, C. Onyango-Makumbi, P. Mandima, M. Nyati, J. Ngocho, G. Chareka, P. Ponatshego, G. Masheto, K. McCarthy, P. Jean-Phillippe, A. Gupta, IMPAACT P1078 study team. International AIDS Society (IAS 2021) Berlin, 18-21 July 2021.

4. Single high-dose liposomal amphotericin-based regimen for treatment of HIV-associated Cryptococcal Meningitis: results of the phase-3 Ambition-cm Randomised Trial. D.S Lawrence, D.B Meya, E. Kagimu, J. Kasibante, E. Mpoza, M. Rutakingirwa, K. Ssebambulidde, L. Tugume, J. Rhein,D.R Boulware, H. Mwandumba, M. Alufandika, H. Mzinganjira, C. Kanyama, M.C Hosseinipour, C. Chawinga, G. Meintjes, C. Schutz,K. Comins, A. Singh, C. Muzoora, S. Jjunju3, E. Nuwagira, M. Mosepele, T. Leeme, K. Siamisang, C.E Ndhlovu, A. Hlupeni10, C. Mutata, E. van Widenfelt, W. Hope, O. Lortholary, D.G Lalloo, A. Loyse,T. Chen, S.F Molloy, T. Boyer-Chammard, D. Wang, N. Youssouf,S. Jaffar, T.S Harrison, J.N Jarvis, & The Ambition Study Group. International AIDS Society (IAS 2021) Berlin, 18-21 July 2021.

5. Update on neural tube defects with antiretoviral exposure in the Tsepamo study, Botswana R. Zash, L.B. Holmes, M. Diseko, D.L. Jacobson, G. Mayondi, J. Mabuta, M. Jackson-Gibson, M. Mmalane, T. Gaolathe, S. Lockman, J. Makhema, R.L. Shapiro. International AIDS Society (IAS 2021) Berlin, 18-21 July 2021.

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17. The impact of COVID-19 on adverse birth outcomes in Botswana by HIV status (ID 1297), Maya Jackson-Gibson, Modiegi Diseko, Ellen Caniglia, Gloria Mayondi, Judith Mabuta, Rebecca Luckett, Sikhulile N. Moyo, Paula Smith-Lawrence, Mogomotsi S. Matshaba, Mosepele Mosepele, Mompati Mmalane, Shahin Lockman, Joseph Makhema, Rebecca Zash, Roger L. Shapiro. Conference on Retroviruses and Opportunistic Infections (CROI). CROI 2022, Boston, USA. February 12-16, 2022.

18. growth of infants with perinatal exposure to maternal DTG vs EFV and TDF vs TAF (ID 683), Lynda Stranix-Chibanda, Lauren Ziemba, Sean Brummel, Benjamin Johnston, Tapiwa G. Mbengeranwa, Haseena Cassim5, Gerhard Theron, Sherika Hanley, Maxensia Owor, Katie McCarthy, Nahida Chakhtoura, Patrick Jean-Philippe, Lameck Chinula, Shahin Lockman. Conference on Retroviruses and Opportunistic Infections (CROI). CROI 2022, Boston, USA. Februay 12-16, 2022.

19. treatment with Broadly Neutralizing antibodies in children with HIV in Botswana Roger L. Shapiro, Kenneth Maswabi, Gbolahan Ajibola, Michael Hughes, Molly Pretorius Holme, Kathleen M. Powis, Sikhulile Moyo, Bryan S. Nelson, Marina Caskey, Lucio Gama, Patrick Jean-Philippe, Dwight E. Yin, Edmund Capparelli, Daniel Kuritzkes, Mathias Lichterfeld. Conference on Retroviruses and Opportunistic Infections (CROI). CROI 2022, Boston, USA. February 12-16, 2022.

20. The acceptability of the AMBITION treatment regimen for HIV associated cryptococcal meningitis: Findings from a qualitative study of patients and providers in Botswana and Uganda. D.S.Lawrence, A. Ssali, N. Moshashane, G. Nabaggala, L. Maphane, T.S. Harrison, D. Meya, J.N.Jarvis, J. Seeley. AIDS 2022, 29 July -2 August 2022, Montreal, Canada.

21. High prevalence of asymptomatic Omicron carriage and correlationwith CD4+T cell count among adults with HIVenrolling in COVPN 3008 Ubuntu clinical trial in sub-Saharan Africa. A. Tapley, J.Andriesen, L.Fisher, Y. Huang, N.Ketter, M.Villaran, P. Gilbert,J.Hural2, M. Yacovone, L.-G. Bekker, L.Corey, G.Gray, J.Makhema, H. Nuwagaba-Biribonwoha, T.Samandari, P. Elyanu, R. Chilengi, Z.Chirenje, S. Dadabhai, N. Mgodi, P.Kotze14, N. Garrett1, CoVPN 3008 Ubuntu study team. AIDS 2022, 29 July -2 August 2022, Montreal, Canada.

22. Long acting cabotegravir: update defficacy and safety results from HPTN 084S. Delany-Moretlwe, J.P. Hughes, P.Bock, S.Dadabhai, D.Gadama, P. Hunidzarira, S. Innes, D. Kalonji, J.Makhema, P.Mandima, C.Mathew, J.Mpendo, P. Mukwekwerere, N.Mgodi, P.Nahirya Ntege, C. Nakabiito,H.Nuwagaba-Biribonwoha, R.Panchia, F.Angira, N.Singh, B.Siziba, E. Spooner, J. Farrior, S.Rose, R.Berhanu1,Y.Agyei, S.H. Eshleman, M.A.Marzinke, E. Piwowar-Manning, S.Beigel-Orme, S.Hosek18, A. Adeyeye19, J.R. Rooney, A.Rinehart, B.Hanscom, M. Cohen, M. Hosseinipour, on behalf of the HPTN 084 study team. AIDS 2022, 29 July -2 August 2022, Montreal, Canada.

23. Update on neural tube defects with antiretroviral exposure in the Tsepamo Study, Botswana. R. Zash, L.B.Holmes, M.Diseko, D.Jacobson, G. Mayondi, J.Mabuta, M. Mmalane, T. Gaolathe, S.Lockman, J.Makhema, R. Shapiro. AIDS 2022, 29 July -2 August 2022, Montreal, Canada.

24. Analytical treatment interruption (ATI) among African women with early ART initiation with or without VRC01 circulating at HIV acquisition: study design and early observations of viral rebound and control. S.Karuna, K.Bar, A.DeCamp, E. Rudnicki,P.-C.Yu3, P.Andrew, C. Orrell, A. Takalani, S.Takuva, L. Gama, T.-W. Chun,N. Mgodi, S. Dadabhai, C.-A.Mathew, J.Makhema, P.Hunidzarira, F.Laher, M. Hosseinipour, R. Tressler,L.Soto-Torres, M. Cohen, J. Currier, J.Eron, L.Corey, for the HVTN 805/HPTN 093/A5390 Study Team. AIDS 2022, 29 July -2 August 2022, Montreal, Canada.

25. Cryptococcus qPCR assays: the future for routine mycology labs and clinical trials dealing with HIV-associated cryptococcosis. T.Mbangiwa, A. Sturny-Leclere, K. Lechiile, C.Kajanga, T.B.Chammard, D.Lawrence, J.C.Hoving, O. Lortholary, F.Dromer, M. Mosepele, H. Mwandumba,T.Harrison, J.N.Jarvis, A.Alanio. AIDS 2022, 29 July -2 August 2022, Montreal, Canada.

26. Doravirine Associated Resistance Mutations in Antiretroviral Therapy Naïve and Experienced Adults with HIV-1 subtype C Infection in Botswana. Sekgabo Seselamarumo, OntlametseT. Bareng, Kaelo K Seatla, Wonderful T. Choga, Blessing Bakae, Dorcas Maruapula, Nametso Kelentse, Natasha O. Moraka, Baitshepi Mokaleng, Tendani Gaolathe, Roger Shapiro, Joseph Makhema, Shahin Lockman, Max Essex, Vlad Novitsky, Sununguko Mpoloka, Sikhulile Moyo, Simani Gaseitsiwe. AIDS 2022, 29 July -2 August 2022, Montreal, Canada.

27. Hepatitis B Virus Sub-genotype A1 Evolutionary Dynamics in Botswana. Doreen Ditshwanelo, Wonderful T. Choga, Motswedi Anderson, Bonolo Phinius, Lynnette Bhebhe, Ontlametse T. Bareng, Rosemary Musonda1,6, Sikhulile Moyo, Kebaneliwe Lebani, Simani Gaseitsiwe. International Conference on HIV Treatment, Pathogenesis, and Prevention Research in Resource-Limited Settings, INTEREST 2022, May 9-13

28. Ellen C. Caniglia, Lerato E. Magosi, Rebecca Zash, Modiegi Diseko, Gloria Mayondi, Judith Mabuta, Kathleen Powis, Scott Dryden-Peterson, Mosepele Mosepele, Rebecca Luckett, Joseph Makhema, Mompati Mmalane, Shahin Lockman, Roger Shapiro.-COVID-19 Lockdown and Adverse Birth Outcomes in Botswana.

29. Ellen C. Caniglia, Rebecca Zash, Christina Fennell, Modiegi Diseko, Gloria Mayondi, Jonathan Heintz, Mompati Mmalane, Joseph Makhema, Shahin Lockman, Sunni L. Mumford, Eleanor J. Murray, Sonia Hernández-Díaz, Roger Shapiro. Emulating a sequence of target trials to avoid immortal time bias in pregnancy studies- an application to antibiotic initiation and preterm delivery. Society for Epidemiologic Research Annual Meeting. Chicago, IL. June 15-17, 2022.

30. Ellen C. Caniglia, Rebecca Zash, Christina Fennell, Modiegi Diseko, Gloria Mayondi, Jonathan Heintz, Mompati Mmalane, Joseph Makhema, Shahin Lockman, Sunni L. Mumford, Eleanor J. Murray, Sonia Hernández-Díaz, Roger Shapiro. Emulating a sequence of target trials to avoid immortal time bias in pregnancy studies- an application to antibiotic initiation and preterm delivery. Society for Perinatal and Pediatric Epidemiologic Research Annual Meeting. Chicago, IL. June 15-17, 2022.

ANNEXURE B: TRAINING AND CONFERENCES APPENDIX

CONFERENCES/ WORKSHOPS

Full Name	Title Of Conference/ Workshop	Date	Purpose	Funding Body
Natasha Onalenna Moraka	IAS 2021	18 -21 July 2021	Conference	IAS
Ontlametse Bareng	IAS 2021	18 -21 July 2021	Conference	IAS
Natasha Onalenna Moraka	SANTHE annual meeting 2021	25 -27 August 2021	Meeting	SANTHE
Lynnette Bhebhe	H3BioNet NGS Bioinformatic Training 2021	20 April -10 June 2021	Training	BHP
Lynnette Bhebhe	Research Proposal writing	5 -26 August 2021	Workshop	Global Health Network
Lynnette Bhebhe	COVEME 2021	30 August - 3 September 2021	Workshop	Rockfeller Fountain
Lynnette Bhebhe	COLDA 2021: Virtual conference	9 - 11 September 2021	Conference	COLDA
Lynnette Bhebhe	ICASA	6 - 11 December 2021	Conference	ICASA
Nametso Kelentse	INTEREST 2021	12 - 14 October 2021	Virtual	INTEREST
Nametso Kelentse	Responsible Conduct of Research	6 - 8 December 2021	Training	BHP
Bonolo Phinius	COLDA 2021: Virtual conference	9 - 11 September 2021	Conference	COLDA
Bonolo Phinius	INTEREST 2021	12 - 14 October 2021	Conference	INTEREST
Bonolo Phinius	IVHEM	3 - 4 December 2021	Conference	IVHEM
Doreen Ditshwanelo	INTEREST 2021	12 - 14 October 2021	Conference	INTEREST

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Doreen Ditshwanelo	Biodiversity Genomics 2021 Virtual Event	27th Sep - 1st Oct 2021	Conference	Biodiversity Gen
Doreen Ditshwanelo	CPHIA (Conference on public Health in Africa)	14 - 16 Dec 2021	Training	Africa Union
Olorato Morerinyane	Inter-disciplinary approaches to understanding the global burden of HIV and Youth	13 May - 17 June 2021	Conference	SANTHE
Wonderful Tatenda Choga	H3BioNet NGS Bioinformatic Training 2021	25 - 27 August 2021	Conference	SANTHE
Wonderful Tatenda Choga	Research Proposal writing	20 April -10 June 2021	Training	H3A Annual Training
Motswedi Anderson	Scientific Writing and Publishing	20 May 2021 - 15 July 2021	Workshop	JIAS
Motswedi Anderson	Research Proposal writing	5 - 26 August 2021	Conference	The Global Health
Motswedi Anderson	COLDA 2021: Virtual conference	9 - 11 September 2021	Conference	COLDA
Motswedi Anderson	INTEREST 2021	12 -14 October 2021	Training	INTEREST
Motswedi Anderson	Grant Writing	13 October - 13 October 2021	Workshop	INTEREST
Motswedi Anderson	Leadership Training	22 -26 November 2021	Conference	L'Oreal UNESCO
Motswedi Anderson	IVHEM 2021	3 - 4 December 2021	Workshop	IVHEM
Tuelo Mogashoa	WHO catalogue of mutations in Mtb and associated mutations	30 November 2021	Training	WHO
Boitumelo Zuze	H3ABioNet NGS Bioinformatics Training 2021	20 April -10 June 2021	Training	BHP

Name	Title Of Conference/ Workshop	Date	Purpose	Funding Body
Lucy Mupfumi	WHO SARS CoV-2 Antigen Rapid Diagnostic Test Online Training	31-Mar-21	Workshop	Free Registration
Lucy Mupfumi	McGill Summer Institute: Advanced TB Diagnostics and Quality of TB care	31 May - 11 June 2021	Workshop	Glocal
Lucy Mupfumi	Introduction to Infectious Disease Modelling	14 - 25 June 2021	Training	Glocal
Lucy Mupfumi	UW 13th Summer Institute in Statistics and Modelling of Infectious Diseases	7 - 23 July 2021	Training	Glocal
Lucy Mupfumi	VIIIth conference of the South African Immunology Society	30 August - 1 Septmeber 2021	Conference	Self Sponsored
Lucy Mupfumi	INTEREST 2021	12 - 14 October 2021	Conference	INTEREST
Lucy Mupfumi	UNION Systematic Screening for TB disease: adapting and implementing global recommendation	09-Nov-21	Workshop	Free Registration
Lucy Mupfumi	ASLM 5th internal Conference	15 - 18 November 2021	Conference	ASLM Scholarship
Lucy Mupfumi	UNION WHO Catalog of mutations in Mtb and associated mutations	30 Novemeber 2021	Workshop	Free Registration
Lucy Mupfumi	Africa CDC 1st International Conference of Public Health in Africa	14 - 16 December 2021	Conference	Free Registration
Natasha Onalenna Moraka	FIC HIV Research Training D43 Trainees and K Grantees Network Meeting	4 - 5 October, 2021	Meeting	NIH Fogarty
Ontlametse Bareng	FIC HIV Research Training D43 Trainees and K Grantees Network Meeting	4 - 5 October, 2021	Meeting	NIH Fogarty
Ontlametse Bareng	Responsible Conduct of Research	6 - 8 December 2021	Training	BHP
Natasha Onalenna Moraka	TESA GCLP Training Course hosted by LT Clinical Research	23rd - 24th February 2022	Training	TESA

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Ontlametse Bareng	TESA GCLP Training Course hosted by LT Clinical Research	23rd - 24th February 2022	Training	TESA
Nametso Kelentse	TESA GCLP Training Course hosted by LT Clinical Research	23rd - 24th February 2022	Training	TESA
Nametso Kelentse	TESA GCLP Training Course hosted by LT Clinical Research	23rd - 24th February 2022	Training	TESA
Nametso Kelentse	SANTHE Biostatistics Course	15th Feb to 5th March 2022	Training	SANTHE
Natasha Onalenna Moraka	TESA and BRTI Continous Quality Improvement Process	4th -6th April 2022	Training	TESA
Natasha Onalenna Moraka	H3ABioNet Introduction to Bioinformatics Training 2022	5th July - 13th October 2022	Training	H3Bionet
Natasha Onalenna Moraka	Keystone Symposia on Viral Immunity	30th June - 3rd July 2022	Training	Keystone Symposia
Natasha Onalenna Moraka	Keystone Symposia on Viral Immunity	29th June - 2nd July 2022	Training	Keystone Symposia
Natasha Onalenna Moraka	HIV-1 Drug-Resistance genotyping Resistance Training	30th May - 3rd June 2022	Training	TESA II
Natasha Onalenna Moraka	TESA and BRTI Continous Quality Improvement Process	4th - 6th April 2022	Training	TESA II

SPECIFIC DEVELOPMENTAL TRAINING

Course/ Training	Department	No. of Employees Attending/ Study	Venue	Date	Duration Days
Nurses Prescribing and Dispensing	Moso Study	1	Cresta Hotel Gaborone	27 - 28 Jan 2022	2
GCP, Clinic, Lab Pharmacy, Regulatory SOP's	Moso Study	14	BHP Conference Room	03 - 06 May 2022	3
RDT use, safety and Implementation considerations	AG-RTD Study	7	On-site	17 June 2022	1
ABBOT PanBio Covid-19 Ag-Nasal	AG-RTD Study	7	On-site	16 June 2022	1

GOOD CLINICAL PRACTICE (GCP) AND SOP TRAININGS (PERFORMANCE ASSESSMENT OF COVID-19

Employee Name	Course/ Training	Date	Venue
1. Isaac Nkele	GCP Training	13 June 2022	BHP Conference Room
2. Ngozana Seonyatseng	GCP Training	13 June 2022	BHP Conference Room
3. Nicholas Morebudi	GCP Training	13 June 2022	BHP Conference Room
4. Pearl Kgoreletso	GCP Training	13 June 2022	BHP Conference Room
5. Obonetse Phiri	GCP Training	13 June 2022	BHP Conference Room
6. Kabuba Kanwi	GCP Training	13 June 2022	BHP Conference Room
7. Salang Moutswi	GCP Training	13 June 2022	BHP Conference Room

CTU CRS REFRESHER TRAINING TOPIC; A5300B BLOOD SPECIMEN COLLECTION REFRESHER TRAINING

Employee Name	Date	Venue	Duration
1. Dr Ayotunde Omoz-Oarhe	11 March 2022	Virtual	Two Days
2. Dr Gaerolwe R. Masheto	11 March 2022	Virtual	Two Days
3. Dr Unoda A. Chakalisa	11 March 2022	Virtual	Two Days
4. Mpho S. Raesi	11 March 2022	Virtual	Two Days
5. Isaac Nkele	11 March 2022	Virtual	Two Days
6. Boitshep J Seme	11 March 2022	Virtual	Two Days
7. Georginah O Modise	11 March 2022	Virtual	Two Days
8. Tshepho Pharithi	11 March 2022	Virtual	Two Days
9. Shamillah F. Tshuma	11 March 2022	Virtual	Two Days

ACADEMIC TRAINING

Name	Programme of Training	Sponsor	Project Title	Institution
Nokuthula S. Ndlovu	MSc	Self-Supported	Evaluating the prevalence of multi-class antiretroviral drug resistant variants among PWH in Botswana	BIUST
Doreen Ditshwanelo	MSc	H3ABioNet /TESA III (Partial)	Evolutionary analysis of Hepatitis B virus genotypes A and D in Botswana	BIUST
Kwana Lechiile	MPhil	Self-Supported	Evaluation of saline gargle collection method for detection of SARS-CoV-2 in Botswana	UB/FHS
Kesego Motsumi	MPhil	Self-Supported	Comparison of metabolite signatures in breast tumour cells of HIV infected and HIV uninfected women in Botswana	UB/FHS
Monkgomotsi Maseng	MPhil	SANTHE	Association of CYP2B6 Genetic Variation with Efavirenz and Nevirapine Drug Resistance and Toxicity in HIV-1 Patients on Antiretroviral Therapy in Botswana	UB/FHS
Ontlametse T. Bareng	MPhil	Fogarty/ TESA	HIV Low-level viremia, drug-resistant mutations and virologic failure in Botswana	UB/FHS
Patrick Mokgethi	MPhil	Fogarty	Virologic and molecular characterization of HIV-1 in non-citizens in Botswana	UB/FHS
Baitshepi Mokaleng	MPhil	Self-Supported	HIV-1C adaptation to the population: Characterization of HIV-1 C Recently Infected Individuals In Botswana From The Earlier And The Later Parts Of The Epidemic	UB/FHS
Kesaobaka Molebatsi	PhD	SANTHE	Efficient estimation of Human Immunodeficiency Virus (HIV) incidence rate using a cross-sectional cohort study design	UB/FSS (Statistics Departm-ent)
Dorcas Maruapula	PhD	SANTHE/ Fogarty	Prevalence and impact of HIV low-frequency drug resistance mutations in antiretroviral naive individuals in Botswana	UB/FS

Name	Programme of Training	Sponsor	Project Title	Institution
Nametso Kelentse	PhD	TESA III/ Fogarty	HIV-1 Compartmentalisation in the Cerebrospinal Fluid and Plasma of Individuals with HIV-associated Cryptococcal Meningitis.	UB/FS
Kabo Baruti	PhD	Self-Sponsored	Prevalence and molecular characterization of hepatitis delta virus among people living with HIV in Botswana	UB/FS
Bonolo B. Phinius	PhD	Wellcome/ H3ABionet/ TESA	Hepatitis B virus burden and diversity among HIV infected individuals in rural and peri-urban communities in Botswana	UB
Motswedi Anderson	PostDoc	Wellcome/ AREF	Occult Hepatitis B Virus Infections in HIV-1 subtype C Infected Individuals in Botswana: Incidence, Kinetics and Mechanisms	University of the Witwate-rsrand

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