ANNUAL REPORT

2023

BHP
BOTSWANA HARVARD HEALTH PARTNERSHIP

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Botswana Harvard Health Partnership

2023 ANNUAL REPORT

BHP

BOTSWANA HARVARD HEALTH PARTNERSHIP

Botswana Harvard Health Partnership
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2023 - Annual Report
Compiled 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
The Botswana Harvard Health 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 2007 initially as The Botswana Harvard AIDS Institute and Re-named The Botswana Harvard Health Partnership on the 2nd November 2022 in recognition of the expansion of mandate and portfolio of research and programmes beyond HIV/AIDS.

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)
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Fax: (+267) 3901284
Web: www.bhp.org.bw

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

Dean Jane J. Kim

Dean for Academic Affairs at the Harvard T.H. Chan School of Public Health and K.T. Li Professor of Health Economics in the Department of Health Policy and Management and the Center for Health Decision Science.

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. 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.

Prof. Sheila Tlou

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

Mphaphi Blasis Mbulawa

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

b. Board of Directors

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

Kate Calvin

Executive Dean for Administration at the Harvard T.H. Chan School of Public Health.

Dr. Shahin Lockman

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

Dr. Pamela Smith -Lawrence

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

Mr. Christopher Hughes

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

Dr. Joseph Makhema

Chief Executive Officer BHP

Mr. Cornelius Gaetsaloe

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

c. Executive Management

Joseph Moeketsi Makhema
MB. ChB, FRCP (UK)
Chief Executive Officer

Gaerolwe R. Masheto
MD, PGDip FamMed
Deputy Chief Executive Officer

Cornelius Gaetsaloe
BCom, AHMP, AFP
Chief Operations Officer

Dineo Thebe
BAcc
Director, Finance and Grants

Beauty Malumbela
Dip.HRM, BSc, MBA
Head of HR, Comms & Strategy

c. Senior Management

Sikhulile Moyo MSc, MPH, PhD

Laboratory Driector

Ayotunde Omoz -Oarhe, MBBS, MPH

Gaborone Clinical Research Site Leader

Ponego Ponatshego, MD, DTMH

Molepolole Clinical Research Site Leader

Coulson Kgathi BSc

Manager, Software Development and Data Management

Thuso Mokane BSc

Information Technology (IT) Manager

Terence Mohammed BSc

Laboratory Operations Manager

Nyaladzi Comfort Maphorisa, BSc

Laboratory Clinical Manager

Tshepho Theodorah Frank, BPharm

Pharmacy Coordinator

Tumalano Sekoto RN, MPH

Senior Regulatory Coordinator

Tshenolo Ntalabgwe BSc, MPH

Quality Assurance Manager

Kevin Opelokgale AAT, CERM

Grants Manager

Ronald Ruele AAT, ACCA

Finance Manager

c. Principal Investigators

Gbolahan Ajibola
MD, MPH

Motswedi Anderson
BSc, PhD

Ava Avalos,
MD

Laura Bogart,
PhD

Lisa Butler,
MA, MPH, PhD

Ellen Caniglia,
ScD

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

Bruce Chabner,
MD

Scott Dryden
-Peterson
MD, MSc (epi)

Jason A. Efstathiou
MD, DPhil

Tendani Gaolathe,
BS, MD

Simani Gaseitsiwe,
BSc, PhD

c. Principal Investigators

Jennifer Jao, MD, MPH

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

Sara Schwanke Khilji MD, MPH, FACP

Catherine K. Koofhethile, BSc, MSc, PhD

David Lawrence, MD

Shahin Lockman, MD, MPH

Rebecca Luckett, MD, MPH

Richard Marlink, MD

Chelsea Morroni MBChB, DFSRH, MPH, PhD

Mosepele Mosepele, MD, MSc

Lucy Mupfumi, PhD

Rosemary Musonda, PhD

c. Principal Investigators

Vladimir Novitsky, MD, PhD

Rebecca Zash, MD

Kathleen M. Powis, MD, MPH, MBA

Kaelo Seatla, MD, MPH, PhD

Roger L. Shapiro, MD, MPH

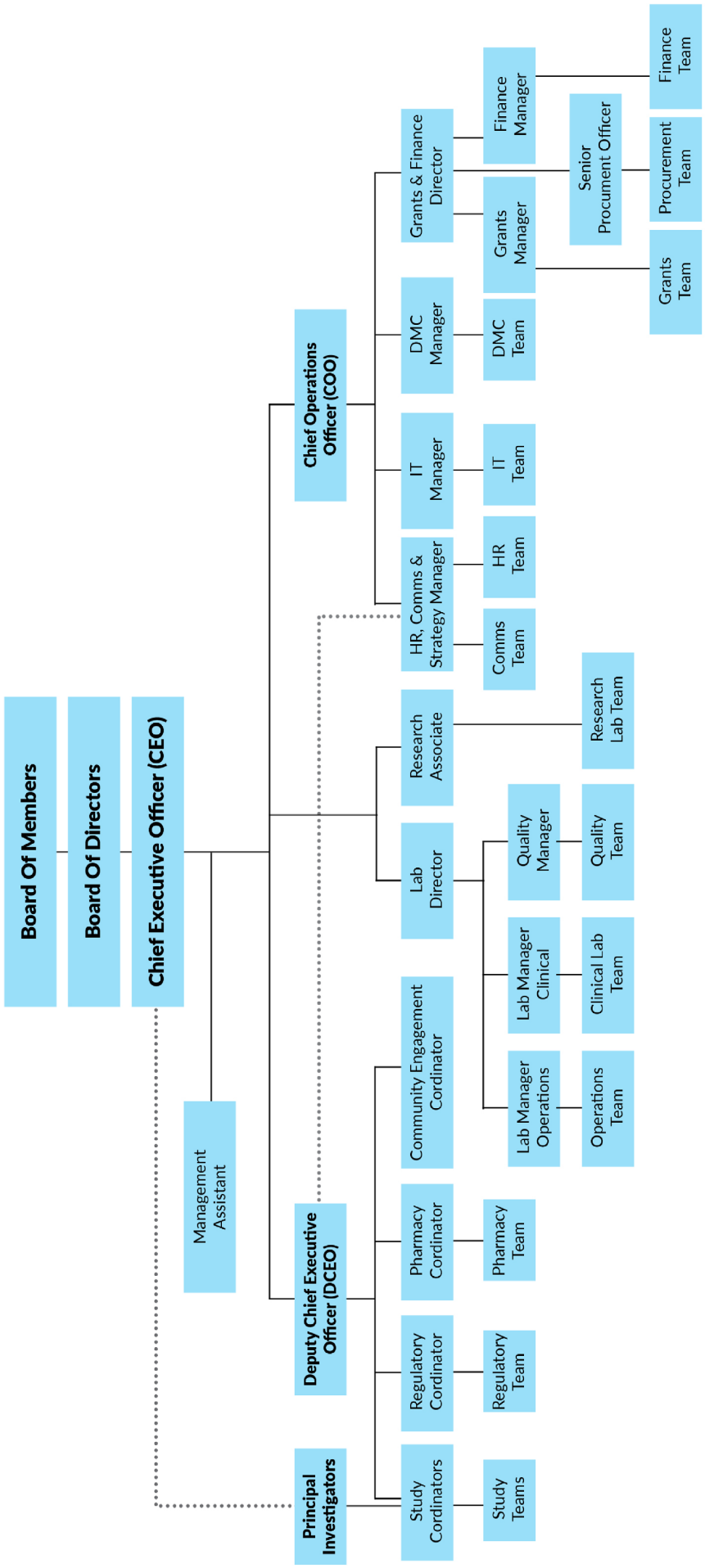
Emily Shava, MBChB, MSc

Nabila Youssouf, PhD

Neo M. Tapela, MD, MPH

Prof. Doreen Ramogola-Masire

BOTSWANA HARVARD HEALTH PATNERSHIP 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 Health 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 Organization
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
FOGARTY	-NIH global health programme dedicated to supporting and facilitating global health and training of next generation scientists.
GAGAS	-Generally accepted Government Auditing Standards
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
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-Governmental Organization
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 Organization
WLHIV	-Women living with HIV

6. FOREWORD BY BOARD CHAIRMAN

As Chairman of the BHP Board of Directors, I look back at the year under review (2022/23) with a sense of great pride in how we have addressed challenges while executing and expanding our mission. This report details achievements and milestones during another transformative year for the institution.

For many years, it has been clear that we have outgrown our original name. The work at BHP reflects so many critical research and health issues in Botswana, and our work in HIV is so often related to prevention and cure and maintaining healthy lives while living with HIV, that it was time to make a change. Consistent with our expanding mandate and portfolio of research, on the 2nd November 2022 the institution was renamed "Botswana Harvard Health Partnership." This new name more directly reflects our current work and our future aspirations to address the key public health challenges faced by Botswana.

During the past year, we also had a successful European Medicines Agency (EMA) Inspection for the HPTN O84 Study (A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral Truvada (TDF/FTC) for Pre-Exposure (PrEP) Prophylaxis in HIV-Uninfected Women), securing BHP's place among the highest rated clinical research institutes in the world. This was BHP's first EMA inspection, and I am very proud of the positive outcome. The success of this EMA inspection demonstrates the quality of our research infrastructure, and is testimony to the scientists, research staff, and all individuals affiliated with the institution whose invaluable contributions made it all possible. This is by no means a small feat, and the outcome of this rigorous inspection was never a guarantee. DAIDS leadership acknowledged our accomplishment during their congratulatory visit to BHP, led by DAIDS's Office of Clinical Site Oversight (OCSO) Director on the 15th to 16th August 2023.

The successful EMA inspection adds to the increasing global recognition of our laboratory following the discovery of the Omicron variant of SARS-CoV-2 by BHP's laboratory director, Prof. Sikhulile Moyo. During the past year, Dr. Moyo was awarded the Presidential Order of Honour by His Excellency President Dr Mokgweetsi Eric Keabetswe Masisi, and the BHP Molecular Virology Team was awarded the Presidential Order of Meritorious Service. The awards recognized the devotion shown to the country during successive waves of COVID-19 by Prof Moyo (who served on the Presidential Taskforce on COVID-19 as Co-Chief Scientist) and the BHP Molecular Virology team (who performed much of the SARS-CoV-2 testing and all of the sequencing during the country's COVID-19 response). Prof. Moyo won further awards at the Inaugural Botswana National Research Excellence Awards 2023 Ceremony, hosted by the Ministry of Communications, Knowledge and Technology (MCKT) on the 7th of March 2023 in Gaborone. He also received the COVID-19 Research Award, the Special Award for Omicron Discovery, and the Most Outstanding Researcher Award. At the same event, Kabo Baruti received the Early Career Researcher Award. During the 8th Botswana International HIV Conference held in Gaborone from 8-11 November 2022, Prof. Moyo received the Dr Festus Mogae Award which is presented to the most impactful researcher, and PhD candidates at BHP, Natasha Moraka and Bonolo Phinius, won Best Abstract and Best Emerging Researcher awards, respectively. These numerous awards are testament to the dedication, quality of research, training, and collaboration that BHP continues to offer. BHP is so proud of this well-deserved recognition for Prof. Moyo and the whole laboratory team.

Clinical trials and cohort studies continued to advance and thrive at BHP in 2022/2023. This work included guidelines-changing pediatric and adult trials of new HIV and TB treatment and prevention agents, led by the Clinical Trials Unit; completion of a novel HIV treatment and cure study using broadly neutralizing antibodies; studies with policy implications for the management of sexually transmitted infections; studies to better understand pediatric development and neurodevelopment following HIV exposure and incorporate brain imaging; and implementation science-focused to optimize cancer diagnosis and management in Botswana. In late 2023, BHP launched the first-ever clinical trial to offer pre-exposure prophylaxis with a highly-effective long-acting injectable agent (cabotegravir-LA) to breastfeeding women at high risk for HIV acquisition.

Looking ahead, I believe we will see continued success at BHP in the year ahead, expanding and strengthening our research impact, led by our outstanding team of Batswana and international researchers. To support this work, BHP will need to invest in infrastructure and build partnerships both in Botswana and globally. I commend our staff for their dedication and hard work, and thank our collaborators and partners for their continued support.

With sincere gratitude,

Prof. Roger Shapiro
BHP Board Chairman

7. FOREWORD BY CHIEF EXECUTIVE OFFICER

The year under review will go down as part of BHP's remarkable history with the change from Botswana Harvard AIDS Institute Partnership (BHP) to the Botswana Harvard Health Partnership (BHP). We are currently the depths of aligning the BHP strategy with the expansion of the institution's mandate as we recognize the evolving research portfolio beyond HIV/AIDS to encompass other emerging public health challenges in Botswana and across the globe. This expansion and includes other infectious diseases such as sexually transmitted diseases, hepatitis, HPV, Tuberculosis and other new public health challenges e.g. SARS-CoV-2 and associated pathogenomics and bioinformatics. The BHP's research portfolio has also grown to include HIV cure research, non-communicable diseases including malignancies as well as the impact of climate change on health.

We hope that this renewed identity will invoke a new sense of purpose, and vigor for BHP as we continue to break new grounds in our expanding research portfolio and success against the many public health threats and challengesconfronting us. The acronym BHP remains the same, withthe organization continuing being commonly referred to as BHP. The BHP logo has also been refreshed while still retaining the key elements.

During this reporting period, two members of the Executive, Dr Mompati Mmalane (Deputy Chief Executive Officer) and Ms Ria Madison (Chief Operations Officer) retired from the organization in December 2022 and May 2023 respectively. Dr Gaerolwe Masheto and Cornelius Gaetsaloe have been subsequently promoted as Deputy Chief Executive Officer and Chief Operations Officer respectively. I once again extend my sincere gratitude to Dr Mmalane and Mma Madison for the selfless service they have rendered to the BHP contributing towards the BHP being the center for research excellence it has become locally and globally. f. In the same vein, I congratulate their successors andwish them success in their work as they provide strategic and management leadership to effectively deliver the BHP mandate.

BHP research and scientific scholarship, and capacity building initiatives continues to be robust. We published 78 manuscripts, a slight reduction from last year's tally of 89 of which were in peer reviewed scientific journals, including those with impact factor of >10. Of published manuscripts had local first author. The number of abstracts presented at different local and international conferences increased to 31. Our Principal Investigator (PI) initiated research projects increased from 30 to 37 with 16 projects having a local PI while our Network Clinical Trials remained at 11.

The BHP's Annual Financial and Generally Acceptable Government Auditing Standards (GAGAS) audits have once again remained unqualified, thanks to effective financial management and compliance best practice systems deployed byfinance and grants management. Pursuant to BHP expansion of research grants and to enhance efficiencies, the grants and finance department has been uncoupled with stand alone Finance and Grants departments. Mr Ronald Ruele and Mr Kevin Opelokgale have been promoted to the positions of Finance Manager and Grants Manager respectively.

The Financial Year 2023 revenue increased by 6%, resulting in a total of $11.1m compared to $10.4m achieved in financial year 2022. Grant applications during the period declined from 44 to 35 applications, presenting a decline of 26%. Of the 35 grant applications, 23 were small value grants, 11 were medium value grants and one was a large grant in comparison to the previous year where 13 small value grants, 19 medium grants and 12 large grants were applied for. Eighteen 18 out of 35 (51%) applications were successfully awarded (15 small value grants and three 3 medium value grants). All the 12 large value grants applied for were unsuccessful leading to a decline in revenue from new applications from $2.7m in financial year 2022 to $0.586m in financial year 2023.

Despite being confronted with this drastic revenue decline, we take pride in our prudent financial management strategies, and I applaud our staff for being able to carefully prioritize our capital and operating expenditure to ensure that we remain solvent. I further encourage all studies to maintain an intensive focus on cash conservation to mitigate against the company's declining revenue streams.

I once again extend my profound gratitude to the BHP Board of Directors for their unrelenting support and wise guidance especially during challenging times. I also commend the BHP Principal Investigators, Research Associates, Scientists, Staff and Collaborators for their unwavering resolve to selflessly serve BHP.

Dr. Joseph Makhema
BHP Chief Executive Officer

8. EXECUTIVE SUMMARY

The Botswana Harvard Health Partnership (BHP) presents yet another successful 2022/23 annual report, of impactful research and capacity building. The performance results of the year under review are summarized below under the five BHP strategic themes; Research Excellence, Capacity Building and Training, Operational Excellence, Public Policy and Advocacy, as well as Sustainability.

Research Excellence

Consistent with its mission statement of addressing HIV/AIDS and emerging public health challenges, the organization continues to diversify, and grow its research portfolio and to expand beyond HIV/AIDS. For this reporting period, BHP had a total of 48 active research projects compared to 50 in the previous year. Of the 48 studies, 37 were Principal Investigator initiated projects, an indication of the capability and quality of BHP investigators to develop new study concepts, source funding mechanisms, initiate and execute various studies across different health topics. There were 11 active studies under BHP Clinical Trials Unit (CTU) across three Clinical TRIALS networks (IMPAACT, ACTG, HPTN). These studies are; REPREIVE, PHOENIx, A5375, IMPAACT 2019, P1093, IMPAACT 2017, IMPAACT 2026, HPTN 084, HVTN805/HPTN093, CoVPN5001, CoVPN3008. The studies covered different research categories that includes SARS-CoV-2, Mother and Child studies, Sexual Reproductive Health, Tuberculosis, HIV and Cardiovascular diseases, Malignancies, Human Papilomavirus, Pre-Exposure Prophylaxis and Dru-Drug interactions.

During this reporting period, 78 manuscripts were published with 31 abstracts presented at national and international conferences.

Capacity Building & Training

As a major component of BHP's mission, capacity building and training is a key strategic objective. Various grants have continued to contribute to the training of upcoming investigators. These include Trials of Excellence in Southern Africa (TESA), Sub Saharan African Network for TB/HIV Research Excellence (SANTHE), FOGARTY (NIH global health programme dedicated to supporting and facilitating global health and training of next generation scientists). In this reporting period, three fellows obtained PhD degrees whilst another two attained MSc Degrees. The fellows enroll with different partner academic institutions locally or regionally, but have their laboratory work conducted at the BHP. They are supervised by BHP scientists collaboratively with university academics. Currently there are 6 students pursuing their master's degrees and four PhD degrees in training of whom two have completed and defended their PhD thesis and are awaiting graduation. It is a source of great pride that BHP trained fellows awarded PhDs continue to flourish. Two such post graduate fellows Dr's Kaelo Seatla and Dr Motswedi Anderson are now pursuing post-doctoral training with Dr Seatla at the NIH having been awarded an APTI fellowship while Dr Anderson is at the African Health Research Institute in Kwa Zulu Natal , both independent committed to being fully fledged independent Principal Investigators on their own initiated studies.

The BHP also offers other capacity building initiatives in conjunction with its collaborators. These include the training of University of Botswana residents in Obstetrics & Gynaecology, Anaesthesia, Internal Medicine, and internship training at Scottish Livingstone Hospital (now moved to UB), through the BIDMC/OHSU program which also provides global health resident training of fellows from the Harvard affiliated Hospitals. A significant initiative is the mentoring of early career investigators towards a successful research pathway by senior principal investigators.

Operational Excellence

As at the end of the reporting period BHP had an active staff compliment of 270 (70% females) responsible for direct and indirect support of it's cutting edge scientific agenda, which has catapulted BHP to be among leading health research institutions globally.

The established grants and finance division has developed robust compliance systems which have resulted in sequential unqualified audited annual financial and Generally Acceptable Government Auditing Standards (GAGAS) audits buoyed by effective prudent resource management through effective monitoring of project budgets and timely reporting. The overall grant portfolio grew by 6% to a total of $11.1m in the Financial Year 2023. The Laboratory was accredited to the ISO 15189 laboratory standard by the Southern African Development Community Accreditation Services (SADCAS) in June 2019 and has maintained the accreditation ever since.

Public Policy & Advocacy

The BHP leverages research outcomes to inform public health policy, development of health strategies, guidelines and to inform programme implementation through engagement of decision-makers. BHP scientists are actively involved in national technical working teams and committees, giving expert advice on various health subjects to strengthen the public health system. The research results from the BHP studies are presented and disseminated at both general and scientific communities, nationally and globally. This is done through conference presentations and manuscript publications in peer-reviewed journals contributing to global evidence-based decisions.

Sustainability

To help sustain and grow its critical missions of research, training and capacity building, the BHP is implementing a strategic initiative to diversify its revenue streams in order to augment grant funding which has been on the decline over the years. This includes a local and international fund development drive, the latter resulting in the establishment of the "Friends of Botswana Harvard Partnership" fund through Myriad USA to facilitate the receipt of philanthropic giving by international donors, individuals, foundations and corporations.

9. INTRODUCTION

The BHP is a not-for-profit, health research and capacity building Institution which was established in 1996 as a partnership between the Government of Botswana represented by the Ministry of Health (MOH) and Harvard University represented by the Harvard T.H. Chan School of Public Health (HSPH). Its mission is to fight HIV/AIDS and other emerging public health challenges through research, education, and capacity building that impacts policy and practice.

The BHP continues to deliver on its mandate, delivering impactful research across a wide range of health research areas. The organization's research portfolio includes clinical trials, both network trials and BHP Principal Investigators initiated studies, implementation science studies, and laboratory-based research.

Apart from conducting cutting edge research, BHP also trains the next generation of scientists through its capacity building and training initiative. Through its collaborative initiatives, the BHP 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. It also collaborates with local and regional universities who confer degree qualifications for BHP-mentored and supervised MSc/MPhil and PhD candidates registered with those institutions.

The BHP plays a significant role in the 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.

Botswana Harvard HIV Reference Lab

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

The Tsepamo study team has been conducting surveillance of adverse birth outcomes and congenital abnormalities throughout Botswana since 2014. The study compares birth outcomes by HIV status and ART regimen and also seeks to determine whether there are associations between ART regimens and congenital abnormalities. The study prospectively extracts data from obstetric records from 16 delivery sites across the country, which represent about 70% of all deliveries in Botswana, capturing anonymous photos of infants with congenital abnormalities.

To date, 260,000 records have been captured into the dataset. Figures 1 and 2 below show birth and HIV and birth abnormalities captured from July 2022- June 2023.

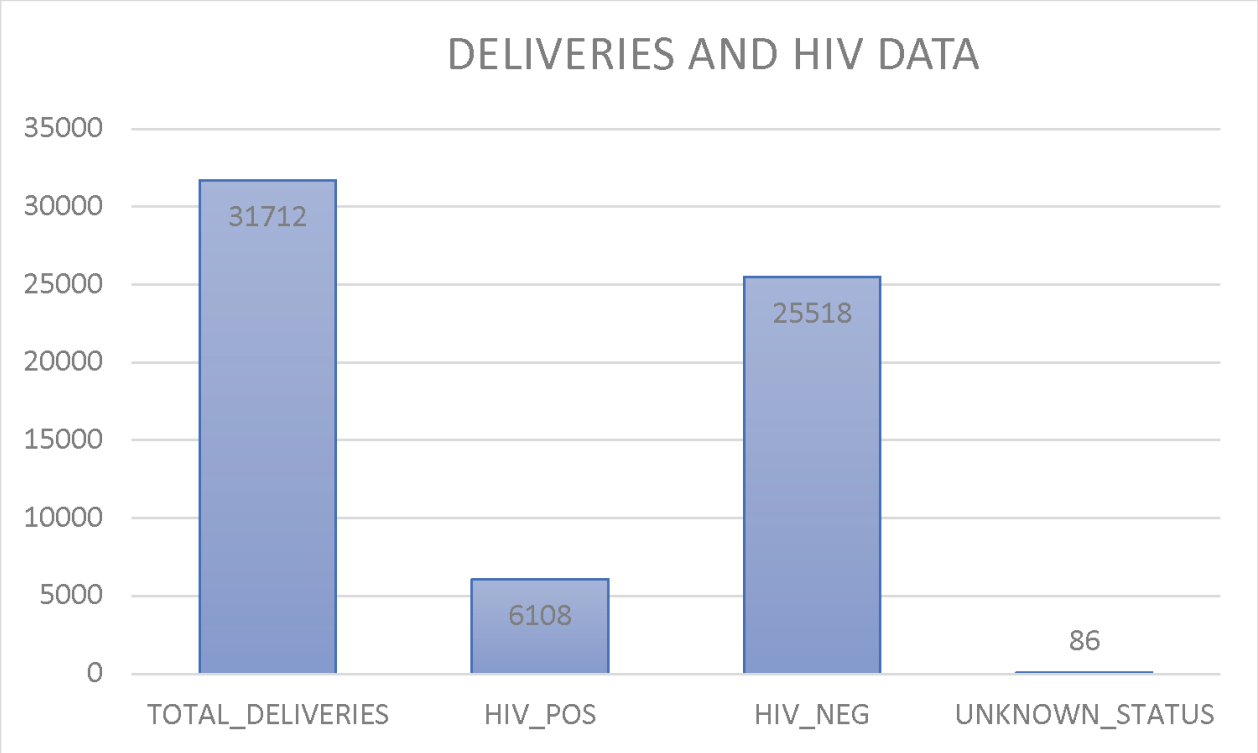


Figure 1. Birth and HIV data extracted from July 2022-June2023

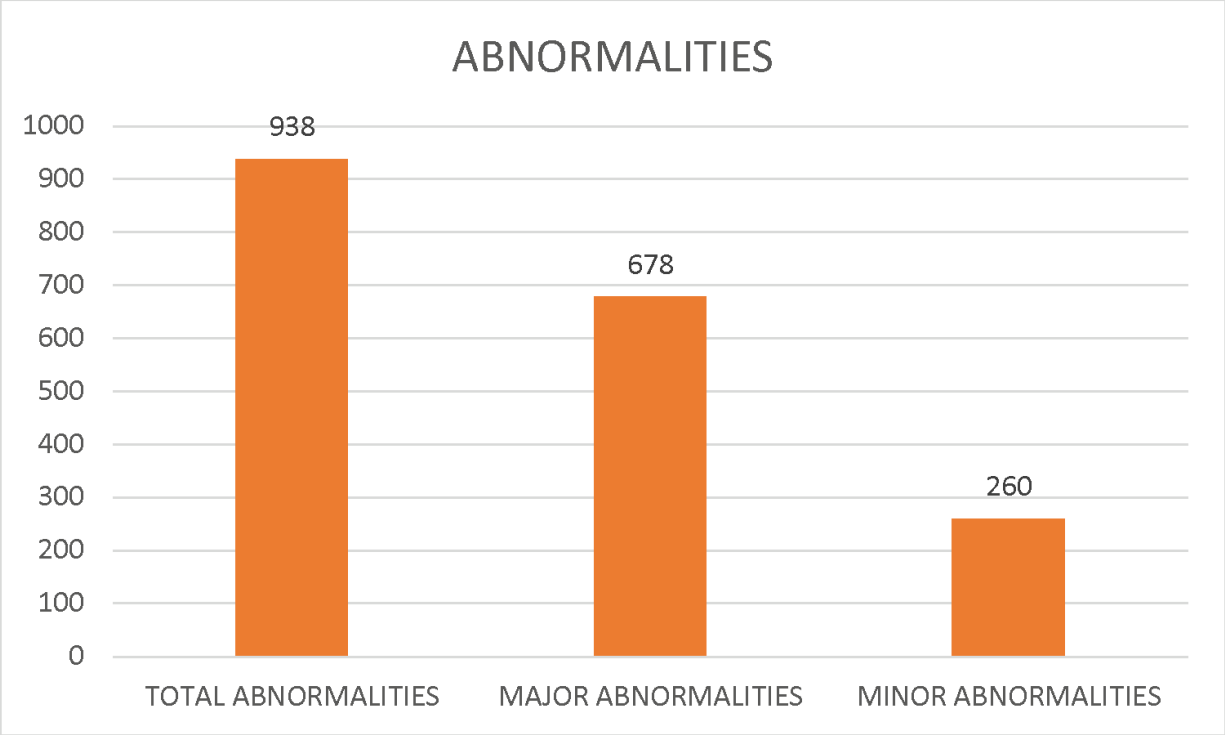


Figure 2. Birth Abnormalities

Achievements

• This year, the study has organized a small group of clinicians from Southern Africa (Botswana, South Africa, Kenya and Malawi) who will be mentored by Dr. Lew Holmes on the identification and categorization of congenital abnormalities. This group will review photos with Dr. Holmes on a quarterly basis.
• The study team continues to present the study findings at Sub-Saharan Congenital Abnormalities Network (sSCAN) on Quarterly basis.
• A stakeholder meeting to present key results is scheduled for August 2023.

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

PI: Professor Roger L. Shapiro, MD, MPH

The Early Infant Treatment Study (EIT) is a single arm non-randomized clinical trial of early Antiretroviral Therapy (ART) in antepartum and peripartum infected children. The study sought to determine whether very early ART initiation in HIV infected infants limits the seeding of viral reservoirs and maintains immune response. HIV- exposed infants were tested at birth and if HIV positive, immediately offered ARVs.

The study has achieved 100% retention and is closed to accrual. It is currently on extended follow up with ongoing evaluation of viral reservoir.

Follow-up results have been published, providing a comprehensive assessment of long-term treatment outcomes and viral reservoirs following early ART initiation. Figure 1 below shows preservation of CD4 cell count over time in the cohort compared with the reference CD4 range by week of age.

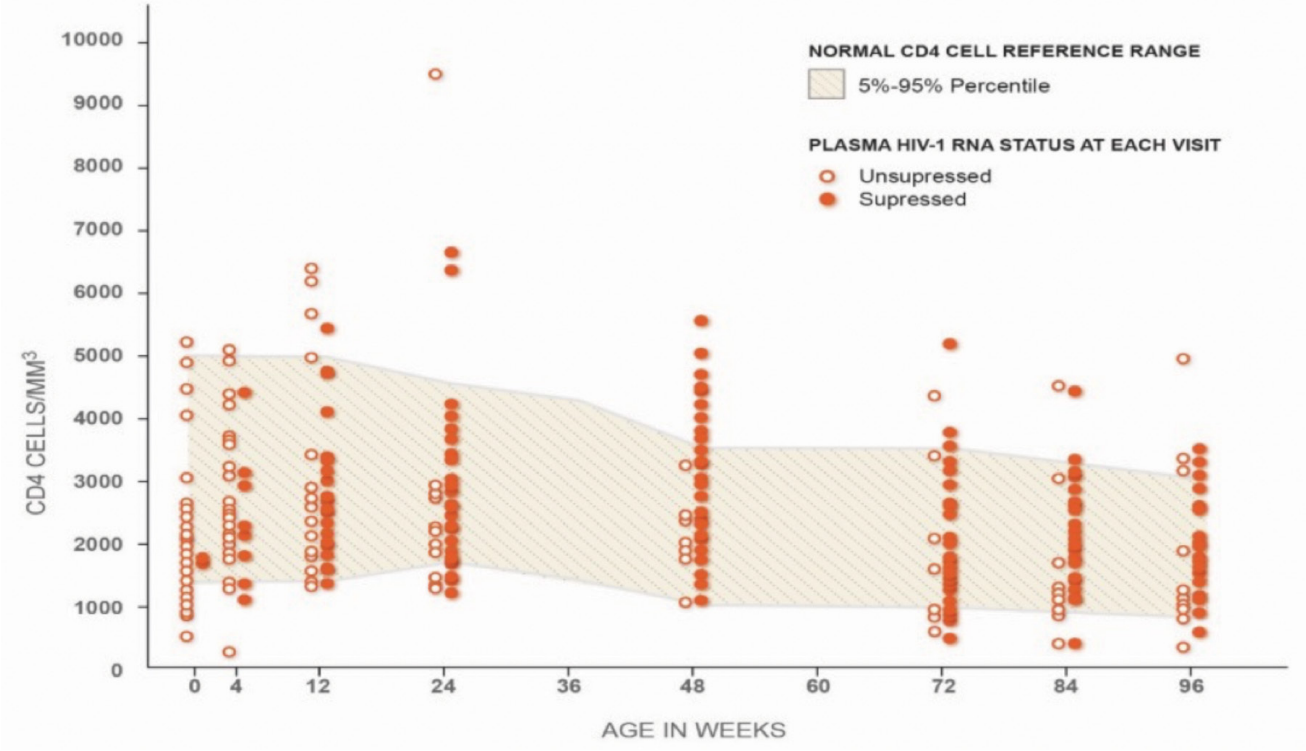


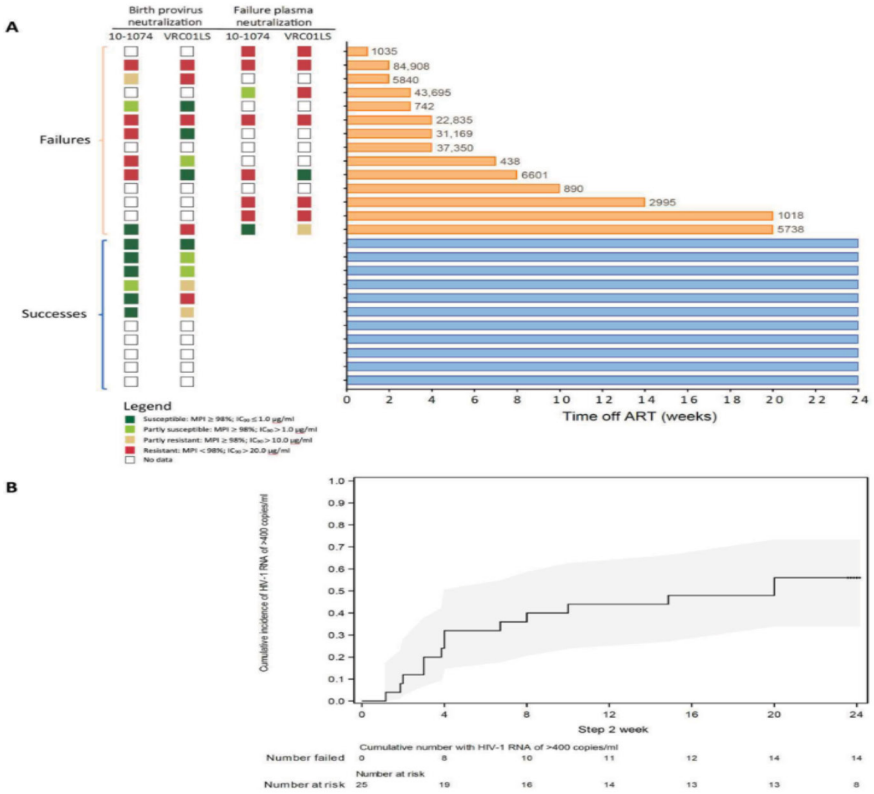
Figure 1. Absolute CD4 cell count distribution per study visit for early-treated HIV+ children

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 has had 100% retention and is now closed.

Despite the challenges of adherence identified in participants who took longer to re-suppress after viral failure, they all successfully re-suppressed by 20 weeks. The study findings were presented in the Science Translational Medicine and provided proof-of-concept that combination bNAbs can maintain viral suppression in early treated children and helped to identify factors that predicted success on bNAbs (Figure 1).



Treatment outcomes in the Tatelo study. (**A**) Shown on the left are available participant antibody neutralization assay results for *env* amplicons of full-length intact provirus near birth and plasma at failure. Proviral samples from PBMCs at baseline were available for all participants, but amplification succeeded in only 14 of 25. Baseline amplicons were from birth (85%), 4 to 24 weeks (13%), or 84 weeks (2%). Plasma samples were available for 14 failures but amplified in only 8. We defined full susceptibility to each bNAb as 90% inhibitory concentration (IC_{90}) of ≤1.0 μg/ml and maximum percent inhibition (MPI) of ≥98%. The plot on the right shows bNAb-only step HIV-1 RNA outcomes, grouped by failures (top, orange) and successes (bottom, blue). Participant HIV-1 RNA outcomes are shown by bNAb-only week; the bars extend through week of completion of this study step. Values at ends of bars indicate HIV-1 RNA copies/ml at first virologic failure. Each row in (A) indicates the same participant. (**B**) Shown is the cumulative proportion of participants with HIV-1 RNA-detectable viremia of ≥400 copies/ml over time during the bNAb-only phase. The shaded area shows the 95% CI.

Figure 1. Treatment success in Tatetlo

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 tuberculosis (TB) and non-TB correlates of immunity in BCG-vaccinated infants who are HIV-exposed and uninfected (HEU) and HIV-unexposed and uninfected (HUU). The study enrolled mother-infant pairs in Gaborone, Botswana and Cape Town, South Africa. The primary aim of the study was to compare the prevalence of TB infection by child HIV exposure status

The study findings showed that the overall prevalence of TB infection was 3.3% but did not differ by infant HIV exposure status. There was also no difference in prevalence of TB infection between infants enrolled at the Botswana site and those enrolled at the South African sites.

The findings were presented at the 24th International AIDS Conference and the 14th International HIV & Pediatrics Workshop in July 2022 in Montreal, Canada and a manuscript, entitled Prevalence of Mycobacterium tuberculosis infection in Southern African children with and without in utero HIV, has been accepted for publication by Clinical Infectious Diseases.

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 is a 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. The 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 FLOURISH study will also explore differences in outcomes among children who are HEU by the antiretroviral drug to which the child was exposed.

Study Recruitment and Retention

A total of 3899 potential participants were identified from previous BHP studies and were eligible to participate in the FLOURISH study. The first Caregiver-child pair was consented on 30 April 2021. As of June 2023, the study has consented 2,309 participants into the study, including 1.134 caregivers and 1,175 children (accounting for siblings and twins). Figure 1 below represents consented participants from previous BHP studies. Of the participants enrolled, 273 mother-child pairs represent women newly enrolled in pregnancy and their infants. Retention rate of previous BHP participants within the FLOURISH study is 98.9%, while newly enrolled pregnant women present a 97.7% retention rate.

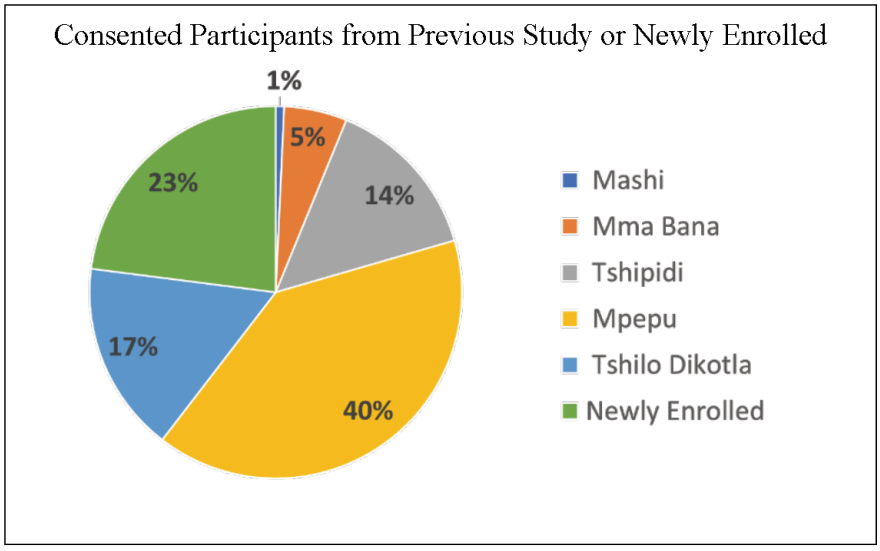


Figure 1. Consented Participants from Previous Study or Newly Enrolled

Interim Findings

1). Academic Acheivement

Using caregiver reporting of child's school grades, academic performance in Mathematics, Science, English, Setswana and overall was compared by HIV exposure status among children attending standard 3-6 primary grades. In unadjusted analyses, children HEU are more likely to have lower overall academic performance compared to children HUU (Odds Ratio 77 [OR]: 2.05 [95% Confidence Interval (CI): 1.23, 3.44]) (Table 1), and lower performance in Mathematics, Science, and English.

Table 1. Logistic Regression Model of Factors Associated with Lower Overall Academic Performance

	Unadjusted Models		Adjusted Model	
Covariates of Interest	Odds Ratio (95% CI)	p-value	Odds Ratio (95% CI)	p-value
HEU versus HUU	2.05 (1.23, 3.44)	<0.01	1.96 (0.85, 4.51)	0.11
Low Maternal Education[1]	2.46 (1.06, 5.74)	0.04	2.13 (0.89, 5.09)	0.09
Caregiver Depression/Anxiety at Enrollment[2]	1.10 (0.50, 2.38)	0.82		
Absence of Household Electricity	1.52 (0.72, 3.22)	0.27		
Household Food Insecurity in the Last Year[3]	0.86 (0.52, 1.40)	0.54		
Male Child	1.66 (1.04, 2.64)	0.03	1.81 (1.12, 2.94)	0.02
Preterm Birth[4]	1.46 (0.69, 3.11)	0.32		
Low Birthweight (<2500 grams)	1.81 (0.89, 3.69)	0.10	1.71 (0.83, 3.56)	0.15
Never Breastfed	1.48 (0.93, 2.37)	0.10	0.88 (0.41, 1.88)	0.75

[1]Low maternal education defined as no or primary education only
[2]Maternal Depression was evaluated using the PHQ9 screening tool and anxiety via the GAD7 screening tool.
[3]Household food insecurity was defined as being present if a caregiver reported that in the last 12 months that the household ever had to cut the size of meals or skip meals because there was not enough food in the household.
[4]Preterm birth was defined as a gestational age < 37.0 week completed gestational age.
Abbreviations: HEU: HIV-exposed uninfected; HUU: HIV-unexposed uninfected; P=Pula
NB: Covariates in unadjusted analyses with a p-value ≤ 0.20 were included in the adjusted model.

2). Lead Levels

During follow-up visits being conducted with FLOURISH caregiver-child pairs, one aspect of the follow-up visit includes testing the child's blood lead levels. Lead levels are not routinely assessed in Botswana. As of 22 May 2023, 156 FLOURISH children had been tested for blood lead levels, with 28% of the children having lead levels greater than 3.5 mcg/mL, a threshold recognized by the Centers of Disease control as having the potential for adverse health consequences, including impacting cognitive performance. Of the 44 children who exceeded lead levels of 3.5mcg/mL, there was no significant difference by a child's HIV exposure status. The study team is partnering with the Ministry of Health to identify and mitigate sources of lead exposure.

Collaborations and Sub-studies

Two FLOURISH sub-studies are poised to open for accrual in August and September, respectively. One, entitled Experiences of Infant Feeding Decision-Making among Mothers Living with and without HIV in Botswana, will explore how mothers living with and without HIV are making their infant feeding choice during pregnancy and, for those who elect to breastfeed, the barriers and facilitators to sustained exclusive breastfeeding. The second study, entitled The FACET Study: Family Dynamics and Child Neurodevelopment in Botswana will explore family dynamic structures in FLOURISH participants' households, including male and family involvement in parenting, and how structures are associated with infant neurodevelopment.

6) Safe Birth Study

PI: Rebecca Luckett MD, MPH

Launched in November 2021 in Princess Marina Hospital (PMH), the Safe Birth Study seeks to better understand maternal morbidity and mortality in Botswana by collecting additional data on maternal outcomes, building on data of the ongoing Birth Outcomes Surveillance (Tsepamo Study). The study has created a database of maternal outcomes at Princess Marina Hospital and has provided an opportunity for several University of Botswana and Harvard-affiliated investigators and trainees to embark on independent research projects aimed at understanding maternal morbidity and mortality at Princess Marina Hospital.

7) Point-of-Care HIV Testing and Early Dolutegravir Use for Infants "Moso study"

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

The Moso study explores 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. This study will demonstrate the feasibility and clinical benefits of implementing facility-based POC and an improved DTG-based early infant treatment approach.

The study opened to accrual in July 2022 and screened a total of 1274 high-risk infants in Gaborone and Francistown. As of 30 June 2023, 698 out of 1098 (63.6%) children eligible for six weeks testing were tested at local facilities, and 400 (36.4%) have pending results or are yet to test. The longitudinal study has enrolled 10 study participants across both sites in the DTG cohort. One death occurred in the Gaborone site, at 2 weeks of age, due to events unrelated to study participation. There has been 100% retention of all 9 study participants at both sites (Figure 1).

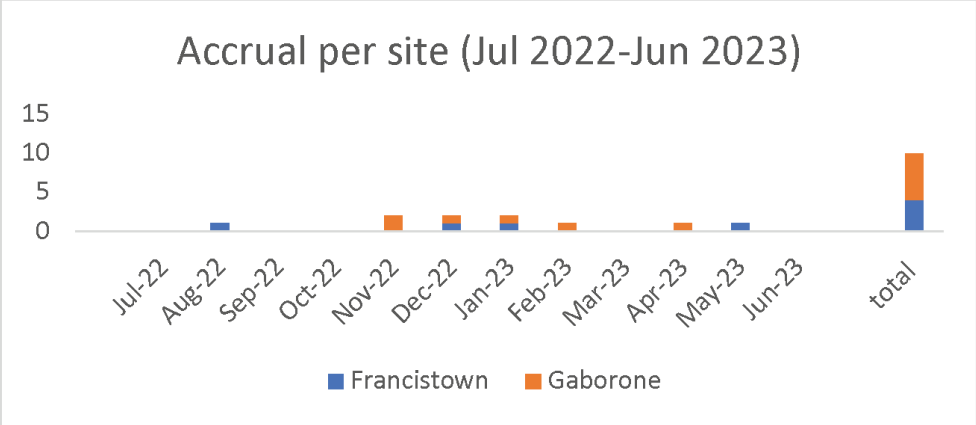


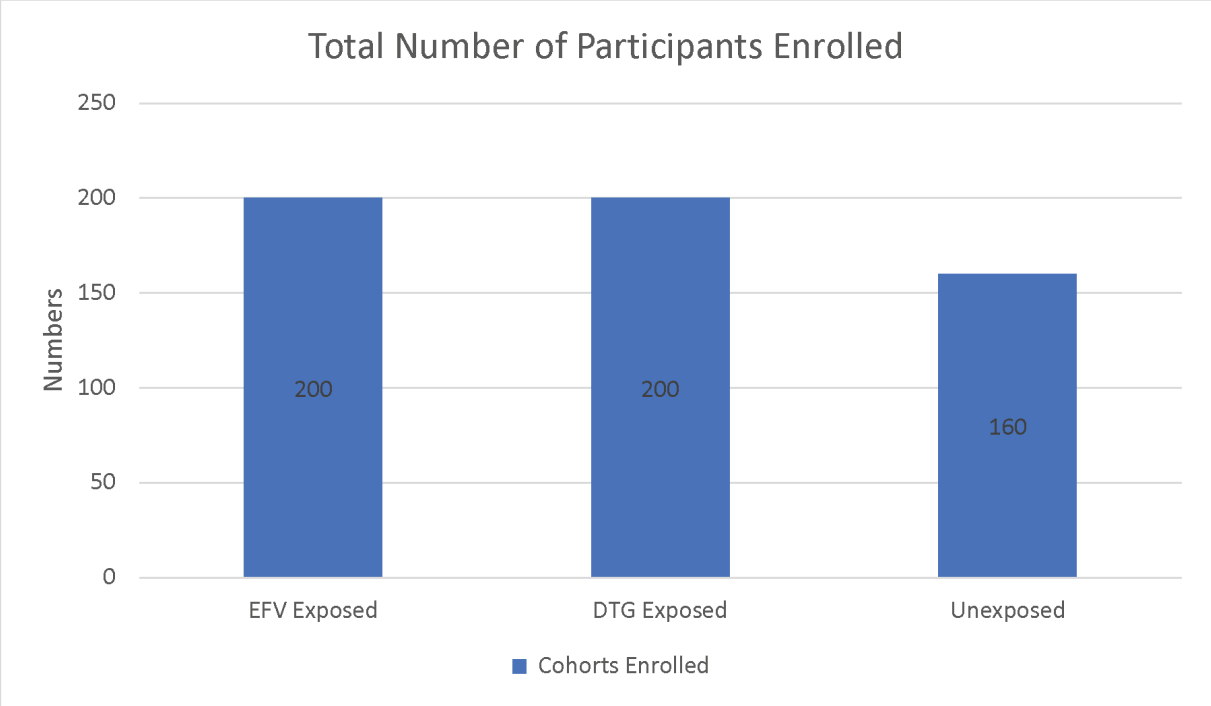
Figure 1: Accrual per site

8) Motheo Study: Neurodevelopment in Children Exposed in Utero to Dolutegravir of Efavirenzeoint-of-Care HIV Testing and Early Dolutegravir Use for Infants

PIs: Dr Shahin Lockman MD MSc, Dr Adam Cassidy PhD, LP, ABPP

Opened to enrollment in March 2021, the Motheo Study seeks to compare neurodevelopment, neurological conditions, and psychosocial outcomes at two years of age in HIV-negative children born to women with HIV (HEU children) who were previously exposed in utero to DTG/TDF/FTC or EFV/TDF/FTC, and in children born to women without HIV.

The study will also compare these outcomes in the same children at five years of age and evaluate for symptoms of depression or anxiety, sleep problems, and weight in the mothers of the participating children. The study has reached its enrollment target of 560 child-mother pairs. Data cleaning and analysis are ongoing.



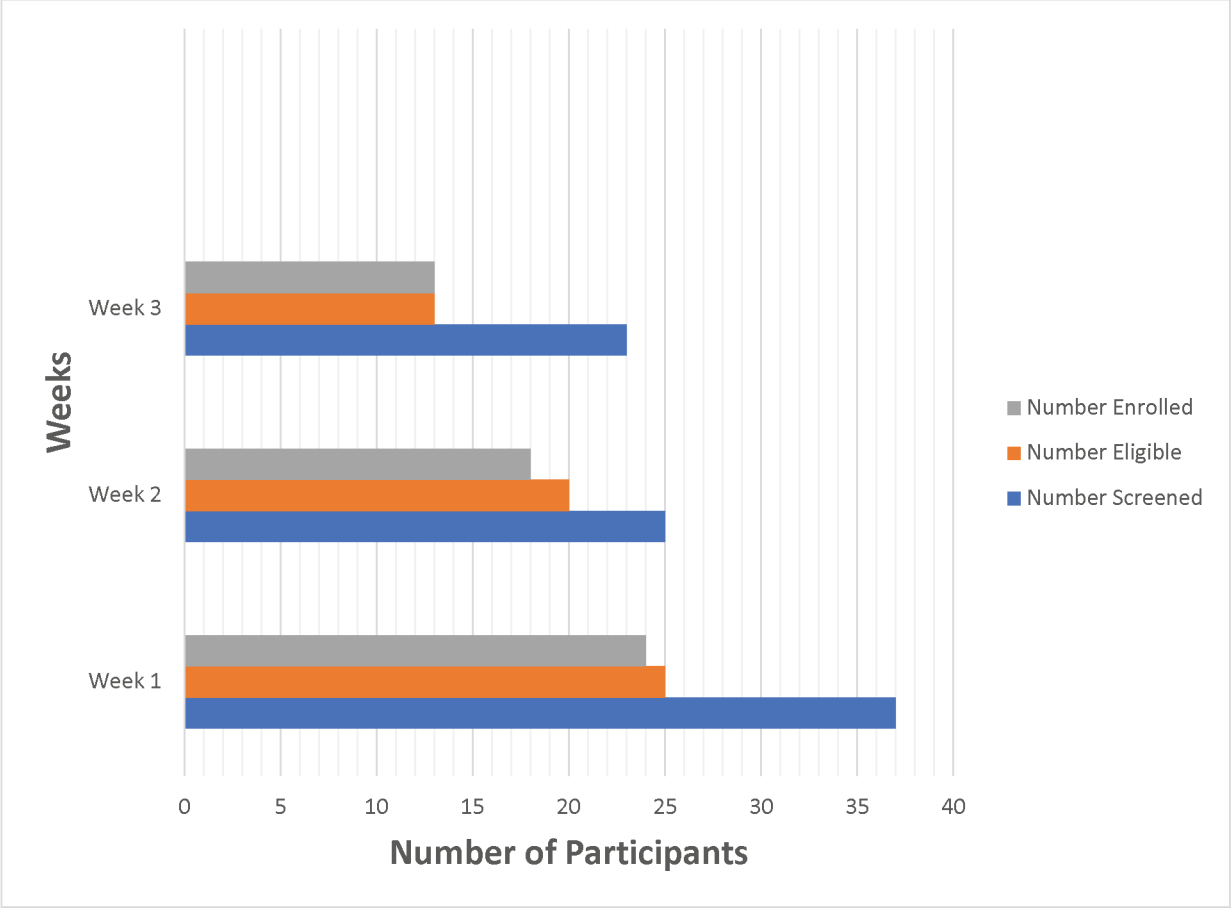
9) The Doris Duke Study: Adverse cardiometabolic impact of antiretroviral treatment regimens among pregnant and postpartum women and their infants

PI: Dr Rebecca Zash, MD

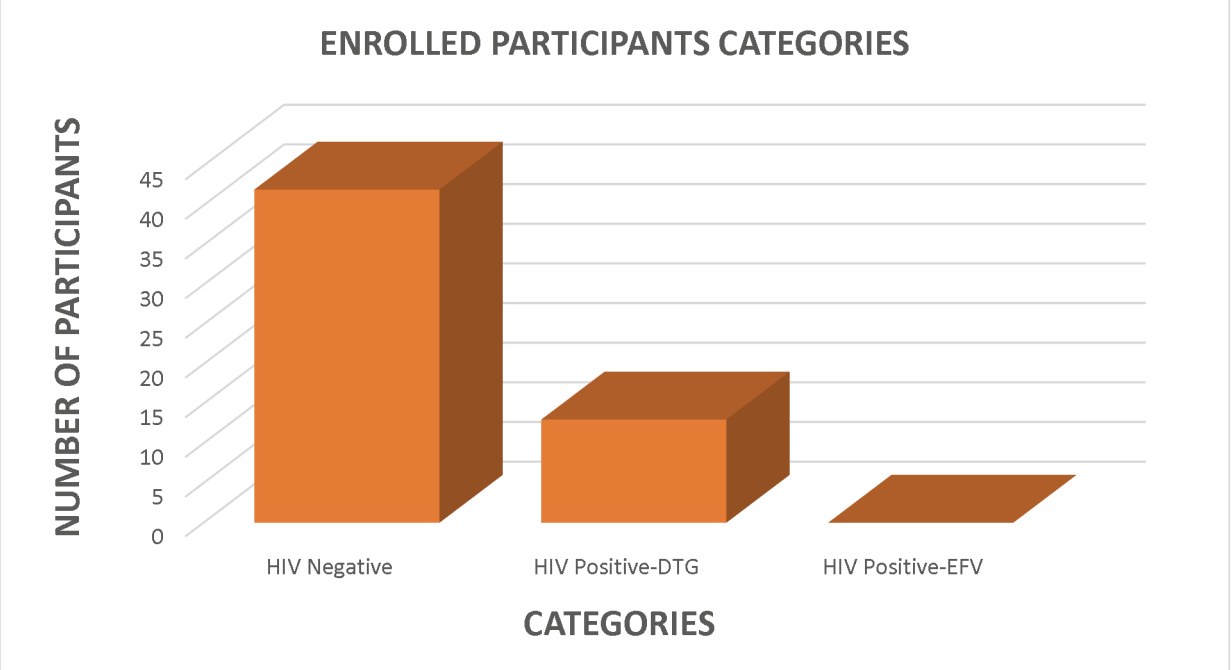
The Doris Duke study is a prospective cohort study that aims to assess the cardiometabolic impact of Antiretroviral treatment in pregnant and postpartum women. The study aims to enroll and prospectively follow 900 mother-infant pairs immediately after delivery to 18 months post-partum. The 900 women and their newborn infants will be divided into three arms: approximately 300 women on DTG, 300 on EFV and 300 without HIV. The number of infants enrolled may be higher than 900 due to multiple births (twins/triplets).

Recruitment will take place in Princess Marina Hospital (PMH) in Gaborone, Scottish Livingstone Hospital (SLH) in Molepolole and Deborah Retief Memorial Hospital (DRM) in Mochudi. The study duration will be thirty-six (36) months.

The study has so far enrolled 46 participants at SLH in Molepolole. Out of the forty-five (49) eligible women approached, forty-six (46) consented to participate in the study. Making the participation consent rate 93.8% so far.



Forty-six (55) mother-infant pairs have been enrolled.



Challenges

Challenges so far have been finding participants on Efavirenz (EFV) based ARV regimen. Since the introduction of DTG-based ARV regimen as the first-line option in 2016. Many patients who were on EFV regimens have been subsequently switched in the past seven years.

10) Tshireletso Study: Linking HIV Prevention and Postpartum Care: Safety, Efficacy and Feasibility of Cabotegravir-LA PrEP in a High-Risk Breastfeeding Population in Botswana

PI: Dr Rebecca Zash, MD

The Tshireletso study is a hybrid implementation and safety study of long-acting cabotegravir (CAB-LA) as pre-exposure prophylaxis (PrEP) to prevent HIV infection in a post-partum cohort in Botswana where breastfeeding is common. The study aims to enroll 500 women at high risk for HIV immediately after delivery. Recruitment will take place in up to four government healthcare facilities in Gaborone and Molepolole. The mothers will be followed up for 24 months.

Primary Objectives

• To evaluate the uptake, adherence, implementation metrics, acceptability and effectiveness of a CAB-LA PrEP program for women at high risk of HIV enrolled immediately post-partum, with follow-up co-located with routine postpartum/paediatric care whenever feasible.
• To evaluate the safety of CAB-LA PrEP in postpartum women and their breastfed infants.
• To evaluate the pharmacokinetics of CAB-LA PrEP in postpartum women and their breastfed infants.

The study has not opened yet pending receipt of the study product (CAB-LA) from the manufacturer ViiV Pharmaceuticals. The study product is estimated to arrive in the third quarter of 2023.

Challenges

The major challenge has been the delay in the implementation of the study due to delayed registration processes of the study product with BoMRA (which occurred in May 2023).

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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

This is a sub-study of the FLOURISH study that aims to evaluate the extent to which TB screening is occurring during the antenatal and postpartum period among women living with HIV (WLHIV). It also performs TB screening in the postpartum period and provides referral to care for participants screening positive for TB.

The study enrolled 95 WLHIV and is now closed to accrual. Participants are being followed up through two months postpartum and screened for TB symptoms. If no symptoms are reported, they are placed off study. As of June 27, 2023, 77 (81%) WLHIV have completed the two-month postpartum visit. To date, 69 participants have screened negative for TB and completed the study. Eight (10%) of the participants screened positive for TB at their two-month postpartum study visit, all of whom were referred for further diagnostic evaluation to their local government health facility.

Semi-structured interviews have been conducted with these eight participants and have been referred for evaluation of TB symptoms. Semi-structured interviews are also being conducted with medical staff at the government health facilities, with four out of up to ten interviews complete. Qualitative analysis for these interviews is ongoing.

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

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

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

To date, thirty-nine participants, 25 adolescents HEU and 14 adolescents HUU, are enrolled in the study. Qualitative analysis for adolescents' interviews is ongoing. The study plans to conduct interviews with up to five medical staff providers at the government health clinics starting in August 2023.

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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. The study aims to 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 Angiotensin-Converting Enzyme Inhibitors/Angiotensin Receptor Blockers (ACEI/ARB). It also describes the association between albuminuria and inflammation among treated HIV-infected adults overall and in relation to the use of ACEI/ARB.

The Albuminuria study also aims to 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 enrolled 1537 participants from Princess Marina Hospital IDCC and other IDCCs in the Gaborone area. The study was completed in 2022 and the manuscript summarising the main results is in preparation.

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

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

The 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 study aim 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 in the Gaborone area. Data analysis is ongoing.

3) 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 trial 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 two phases, the pilot and the main trial. The pilot phase was successful with early analyses showing an increase in achieving normal blood pressure readings at six and 12-months follow-up visits. The second phase is a cluster randomized clinical trial recruiting adult participants with a dual diagnosis of HIV and hypertension in 14 clinics (7 control; 7 intervention) around Botswana. Intervention clinics receive a tailored package including CVD training for healthcare professionals, treatment partner support and an enhanced electronic health record (PIMS) with integrated flags relating to CVD risk-factors (smoking; alcohol; high blood pressure readings etc).

The randomized component of the trial started in January 2023 and is due to complete recruitment of 4652 participants by end of August 2023. As of June 2023, the study has enrolled 3400 participants and will be followed up to 24 months.

This study is a collaboration between BHP; the University of Botswana, ACHAP, the Botswana Ministry of Health, Northwestern University Feinberg School of Medicine and the New York University.

4) IMPRINT NIHR Global Health Research Group

PIs: Prof Joe Jarvis MBBS, BSc, MSc, MRCP, PhD, DTMH, Prof. Mosepele Mosepele MD, MSc

The group aims to improve the diagnosis and treatment of the major HIV-associated fungal infections of public health importance and to ensure that these improvements are made widely available to populations most commonly affected in Africa (Botswana, Democratic Republic of Congo, Mozambique, Guinea, Malawi, South Africa), and South East Asia (Vietnam). The group brings together leading academic researchers, clinical and public health leaders, non-governmental organizations including Médecins Sans Frontières and the Drugs for Neglected Diseases initiative, and community and patient representatives.

Focused on people living with advanced HIV disease (or AIDS), the group's objectives are:

1. Treatment: To implement new, short-course treatments for cryptococcal meningitis in routine care in African and South East Asian countries, building on the results of two landmark trials, ACTA and AMBITION-cm. And to support early work in talaromycosis using a single high-dose liposomal amphotericin B treatment approach used for cryptococcal meningitis in the AMBITION-cm trial, and to lay the foundations for future studies in histoplasmosis.

2. Prevention: To improve the screen-and-treat strategy to identify and treat early cryptococcal disease, before it becomes clinically apparent, in Africa and South East Asia. New tests will be evaluated for cryptococcal antigen screening, and we will assess a slow-release formulation of the oral antifungal medicine flucytosine within the ongoing EFFECT trial. Screening will be evaluated to prevent talaromycosis and histoplasmosis in South East Asia and histoplasmosis and emergomycosis in Africa.

3. Health economics: To generate essential economic data to support the different screening and treatment approaches being investigated for cryptococcosis, histoplasmosis and talaromycosis. These individual and, if appropriate, combined analyses will be crucial evidence in the group's efforts to effect the policy changes needed to reduce deaths from HIV-associated fungal infections.

4. Diagnostics: The group will initiate a programme of laboratory-based work on Pneumocystis Carinii Pneumonia (PCP) to develop and test new diagnostic tests for PCP.

5. Training: The group's goal is to train and mentor clinicians and researchers in clinical epidemiology, health economics and/or public health, and laboratory research who will help drive and develop this partnership beyond the 4-year grant period. Training will be enabled by a recent strategic UK-African partnership and will build on extensive experience of training and capacity strengthening within existing multinational projects.

6. Community engagement: To ensure that the voices of people living with advanced HIV disease and community representatives are meaningfully included and heard across the entire scope of work, the group will develop strategies and tools to increase patient health literacy around HIV-associated fungal infections, collect qualitative data to learn from the experience of patients with HIV-associated fungal infections and facilitate meaningful engagement through a community advisory board.

5) Single, high-dose AmBisome to reduce excess mortality from cryptococcal meningitis (SHARE-CM)

PIs: Prof Joe Jarvis MBBS, BSc, MSc, MRCP, PhD, DTMH, Prof. Mosepele Mosepele MD, MSC and David Lawrence

This is a 5-year (2021-2026) non-research grant funded by the CDC to facilitate implementation of the short course regimen for the treatment of HIV-associated cryptococcal meningitis. Following successful completion of the AMBITION-cm phase III study, the purpose of this project is to to leverage individual and institutional experience in delivering the ACTA and AMBITION-cm short-course regimens to facilitate widespread implementation across Botswana with the aim of reducing mortality from CM in real-world settings.

The objectives of the project are to:

1. Perform a comprehensive baseline situational analysis to ascertain the status of cryptococcal meningitis management guidelines, national policy, and resource access in Botswana.
2. Engage stakeholders to integrate short-course regimens into national treatment guidelines and facilitate access to essential antifungals.
3. Train healthcare workers to deliver high quality care for HIV-associated cryptococcal meningitis including screening, diagnosis, and treatment using the short-course regimens and other nationally recommended CM treatment regimens.
4. Increase patient and community awareness of HIV-associated cryptococcal meningitis and encourage health-seeking behaviours.
5. Monitor and evaluate the progress and impact of implementing short-course regimens to support routine HIV programming goals.

Activities

- Establishment of community advisory board.
- Training of Health Care Workers on the use of short course regimens for CM.
- Ongoing Monitoring use of short-course regiments and evaluating outcomes.

d) DRUG-DRUG INTERACTIONS

Mr. Bame Bame, BSRHI Study Nurse coordinator attending to a participant

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 which investigates 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, there is little data on the effect of DTG on hormonal contraception and 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.
Recruitment for the study began in October 2021. Enrolment and follow-up were completed in February 2023 and Pharmacokinetic (PK) analysis is ongoing.

e) SEXUAL REPRODUCTIVE HEALTH

Botswana Sexual and Reproductive Health Initiative (BSRHI) team.

1) 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

Maduo ("Results" in Setswana) study aims to determine the burden of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) among asymptomatic pregnant women. It also investigates the impact of chlamydia and gonorrhoea testing on post-delivery CT/NG prevalence and vertical CT/NG transmission to infants. The study also seeks to assess acceptability, feasibility and cost-effectiveness of chlamydia and gonorrhoea testing and treatment during antenatal care as well as partner notification preferences and experiences.
Five hundred (500) participants were recruited from four clinics in the greater Gaborone area. Enrollment and follow up of all participants have been completed.

Key results to date:

• Chlamydia and gonorrhoea prevalence among 251 asymptomatic pregnant women screened at the first antenatal care (ANC) visit was 23% and 1%, respectively.
• The highest prevalence of chlamydia was in the 15-24 age group (31%) [Figure 1].
• Chlamydia and gonorrhoea screening were highly acceptable; 96% of eligible women accepted testing.
• Chlamydia and gonorrhoea screening and treatment was feasible; 100% of participants enrolled were successfully screened and notified of results and 98% of participants were treated.
• At test-of-cure which took place approximately four weeks post-treatment, all participants were cured.

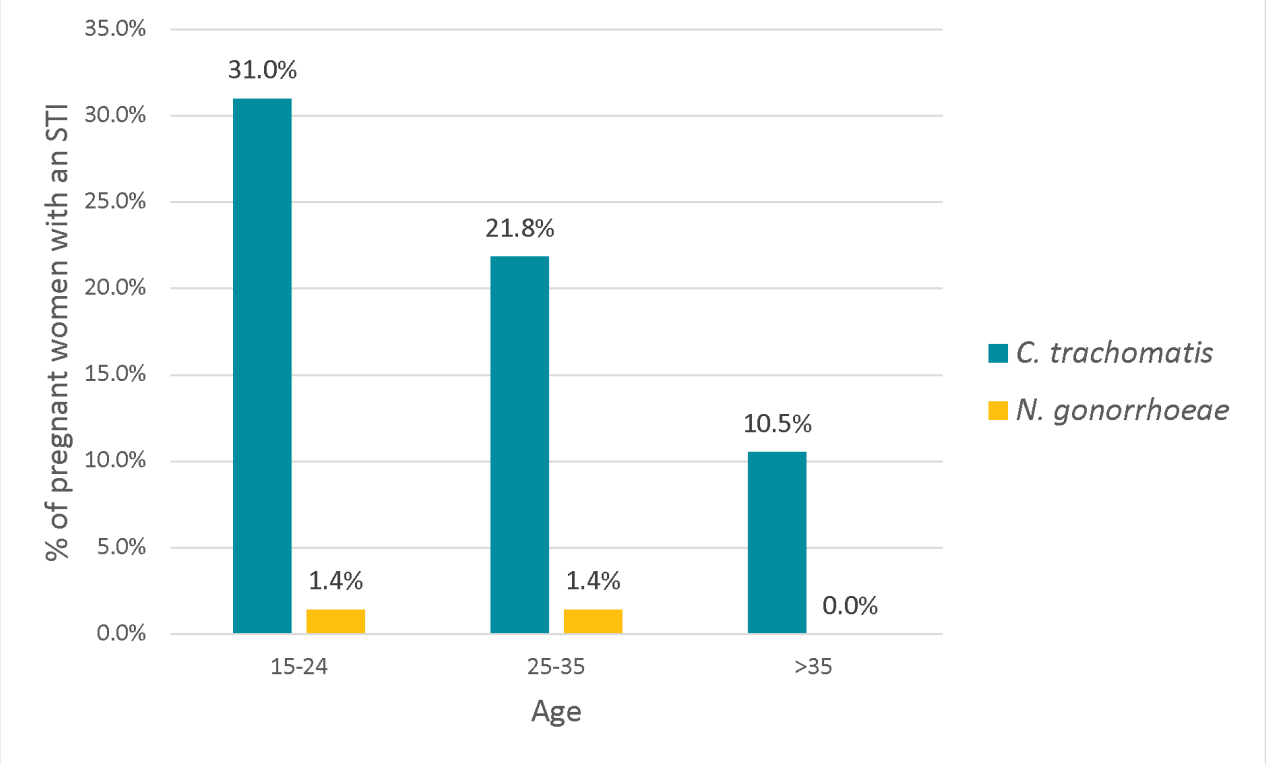


Figure 1. STI prevalence by age in pregnant women screened at first antenatal care visit in the Maduo Study, Botswana (2021-2022). STIs included Chlamydia trachomatis (C. trachomatis) and Neisseria gonorrhoeae (N. gonorrhoeae).

2) Maduo Syphilis Study: Dual HIV/syphilis point-of-care testing to improve identification and treatment of syphilis among pregnant women in Gaborone, Botswana

PI: Dr Chelsea Moroni, MD, MPH, PhD

Maduo Syphilis aims to assess the acceptability and feasibility of implementing point-of-care syphilis testing and treatment among pregnant women by providing: 1) dual HIV and syphilis point-of-care testing for pregnant women who are HIV uninfected/undiagnosed and 2) point-of-care syphilis testing for pregnant women with a known HIV infection with same-day treatment.

Botswana has the third-highest HIV prevalence in the world and has successfully scaled up rapid antenatal HIV testing coverage. However, antenatal syphilis testing and treatment lags behind and women living with HIV continue to face high rates of adverse pregnancy and neonatal outcomes. One strategy for improving syphilis testing and treatment coverage and reaching the World Health Organization's dual elimination goals is to integrate dual point-of-care HIV and syphilis testing. This strategy could increase syphilis testing by leveraging the success of the HIV testing program.

The study began in October 2022 and enrolled 400 participants from two clinics in Gaborone. Enrolment is complete and follow-up is expected to be completed in August 2023.

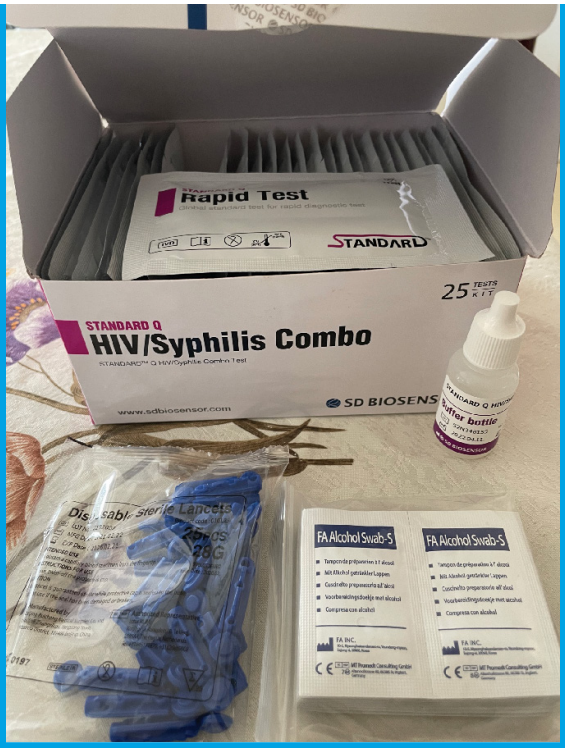


Figure 1. The dual HIV and syphilis test kit used for testing pregnant women in the Maduo syphilis study

3) Partner Notification Study: Use of expedited partner therapy in the treatment of sex partners of pregnant women with STIs.

PI: Dr Chelsea Moroni, MD, MPH, PhD

The Partner Notification Study is a sub-study of the Maduo Study and aims to explore the treatment of sex partners of pregnant women to prevent adverse pregnancy outcomes in a high HIV prevalence setting. The study is focused on the experiences and attitudes of index patients, sex partners, and local stakeholders with regards to expedited partner therapy, in which the index patient delivers treatment directly to the partner as a partner treatment strategy. The study aims to deepen understanding of social and structural factors in partner treatment and equip local health services with insight to better serve this population.

The study involves conducting qualitative in-depth semi-structured interviews with index paticipants and their partners as well as stakeholders (clinicians, programme managers and policy makers). The study started in October 2022 and is ongoing.

4) MAGUS Study: Multi-Country Aetiology of Genital Ulcer Study (MAGUS)

PI: Dr Chelsea Moroni, MD, MPH, PhD

The Multi-Country Aetiology of Genital Ulcer Study (MAGUS) seeks to understand the causes of genital ulcer disease. The study is being conducted in collaboration with the London School of Hygiene and Tropical Medicine and the Wellcome Sanger Institute.

Globally syphilis remains an important cause of morbidity and mortality and marked increases in incidence have been observed in many populations. Most low and middle-income countries, including Botswana, rely solely on syndromic management of STIs. As a result, there is limited diagnostic surveillance data to inform updates to national, regional or international guidelines. The MAGUS study will help inform treatment guidelines and deepen understanding of the genomic epidemiology of organisms identified in cases of genital ulcer disease. The study started in October 2022 and has to date enrolled 97 out of a target of 200 participants and it is ongoing.

The study has also received approval for the Nagoya Protocol and Access and Benefit Sharing. The Nagoya Protocol is a global, legal framework that helps to regulate the access to and subsequent utilization of genetic resources for research (and development) purposes.

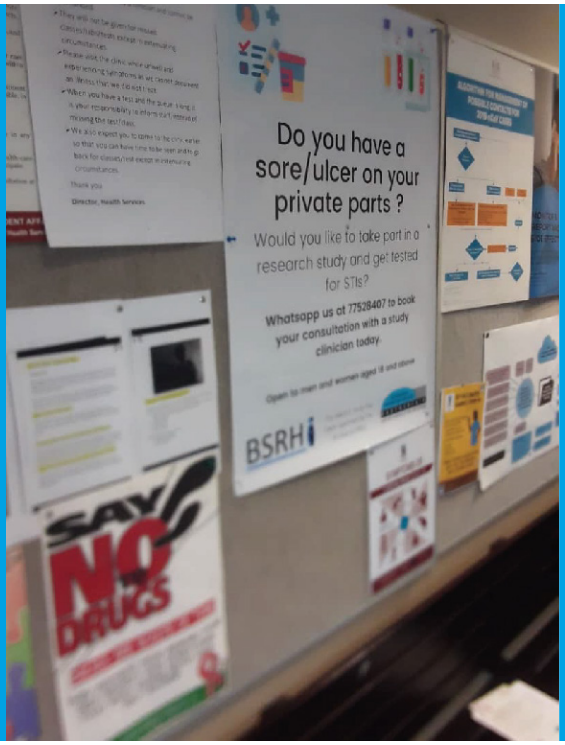


Figure 1. MAGUS Study recruitment poster at a local clinic in Gaborone.

5) PREPARE Study: PRomoting Equity for Pregnant Adolescents in REsearch (PREPARE)

PI: Dr Chelsea Moroni, MD, MPH, PhD

The PRomoting Equity for Pregnant Adolescents in REsearch (PREPARE) is a multi-country study seeking to address questions and confusions around the ethical permissibility of including pregnant adolescents in HIV/co-infections research. The study is being conducted in collaboration with the University of Northern California at Chapel Hill and Botswana-Baylor Children's Clinical Centre of Excellence.

Adolescents who are pregnant are often excluded from HIV prevention and treatment research, with some notable exceptions, which has resulted in significant gaps in the evidence base used to inform policy and care decisions. The study will interview adolescents who have been pregnant, living with or at risk of HIV, to understand their views and experiences about participating in research. The study will also conduct interviews with a broad range of HIV research stakeholders around the inclusion of pregnant and lactating adolescents in the HIV and co-infections research agenda and participation in clinical trials.

The study started enrolment in April 2023 and 21 of 40 adolescents have been enrolled and 14 stakeholders interviewed. The study has also formed a youth advisory board to ensure the work is relevant to and reflective of the needs of the population most directly affected – pregnant adolescents living with HIV.

Figure 1. Youth participation and engagement expert, Magda Conway, conducting a training with the PREPARE Study team in March 2023.

6) PrEP DCE Study: Evaluation of pregnant and breastfeeding women's preferences and attitudes towards long-acting pre-exposure prophylaxis: A discrete choice experiment (DCE)

PI: Dr Chelsea Moroni, MD, MPH, PhD

The PrEP DCE Study aims to evaluate pregnant and breastfeeding women's preferences and attitudes towards long-acting pre-exposure prophylaxis through a discrete choice experiment. Research on efficacy and safety of PrEP agents is pertinent. However, evidence shows that uptake of and adherence to new products by target populations is even more important to effective HIV prevention. This study seeks to understand the values, needs, practices and preferences of the target population, to inform customized health recommendations, future research, implementation, and sustainability of HIV prevention.

The study will have three stages; in-depth interviews, focus group discussions and a discrete choice experiment. Findings from this study will help inform future clinical trials and post-trial marketing to this population ensuring the sustainable roll out of long-acting PrEP modalities in these communities.
The study started in May 2023 and the in-depth interviews and focus group discussions have been completed. The findings from the in-depth interviews are currently being used to develop the discrete choice experiment which will be piloted in August 2023.

7) CoTSIS Study: Cognitive Testing of a survey instrument to assess sexual practices, behaviours, and health-related outcomes

PI: Dr Chelsea Moroni, MD, MPH, PhD

The Cognitive Testing of a Survey Instrument to assess Sexual practices, behaviours, and health-related outcomes (CoTSIS) Study aims to use cognitive interviewing to refine a standard sexual and reproductive health (SRH) instrument through testing in a variety of demographic cross-sections of the general population.

There are few examples of rigorous surveys on sexual practices and behaviours which have been conducted at sub-national or national levels. Robust population-level data on sexual health is needed in order to ensure adequate SRH services are available for all persons across the life course. The 'global applicability' of this instrument will be determined through this research by conducting cognitive interviews with participants across a variety of geographic and cultural environments. The study is being led by the World Health Organization (WHO) Human Reproduction Programme and is being conducted in 20 countries, including Botswana.

To date, 14 of 24 participants have been enrolled in Botswana. The study is expected to be completed in December 2023.

8) BACkUP Study: Botswana Assistance to Curb Unintended Pregnancies (BACkUP)

PI: Dr Chelsea Moroni, MD, MPH, PhD

The Botswana Assistance to Curb Unintended Pregnancies (BACkUP) Study is a quality improvement intervention study aiming to evaluate post-pregnancy contraceptive use in Botswana and to train health professionals in the provision of post-pregnancy long-acting reversible contraception. The BACkUP Study is supported by the Government of Canada. Despite concerted efforts by the Botswana Ministry of Health and non-governmental organisations, rates of unintended pregnancies in Botswana remain high, contributing to maternal and perinatal mortality as well as psychological and social harm. The most impactful way to reduce pregnancy-related adverse outcomes is to enable women to avoid unintended pregnancy. Provision of long-acting reversible contraception (LARC) after birth and pregnancy loss, particularly the copper intrauterine device (IUD), requires specific healthcare worker training. Innovative techniques in post-pregnancy IUD insertion are not yet widely utilised in Botswana. The BACkUP Study seeks to enhance access to postpartum LARCs through training and integrated service provision. Fifty-three staff members from the Obstetrics and Gynaecology Department at Princess Marina Hospital were trained on contraceptive counselling and several clinicians were trained on post-pregnancy IUD insertion.

Figure 6. Professor Justus Hofmeyr conducting a training on post-pregnancy IUD insertion with Princess Marina Hospital staff as part of the BACkUP Study

f) MALIGNANCIES STUDIES

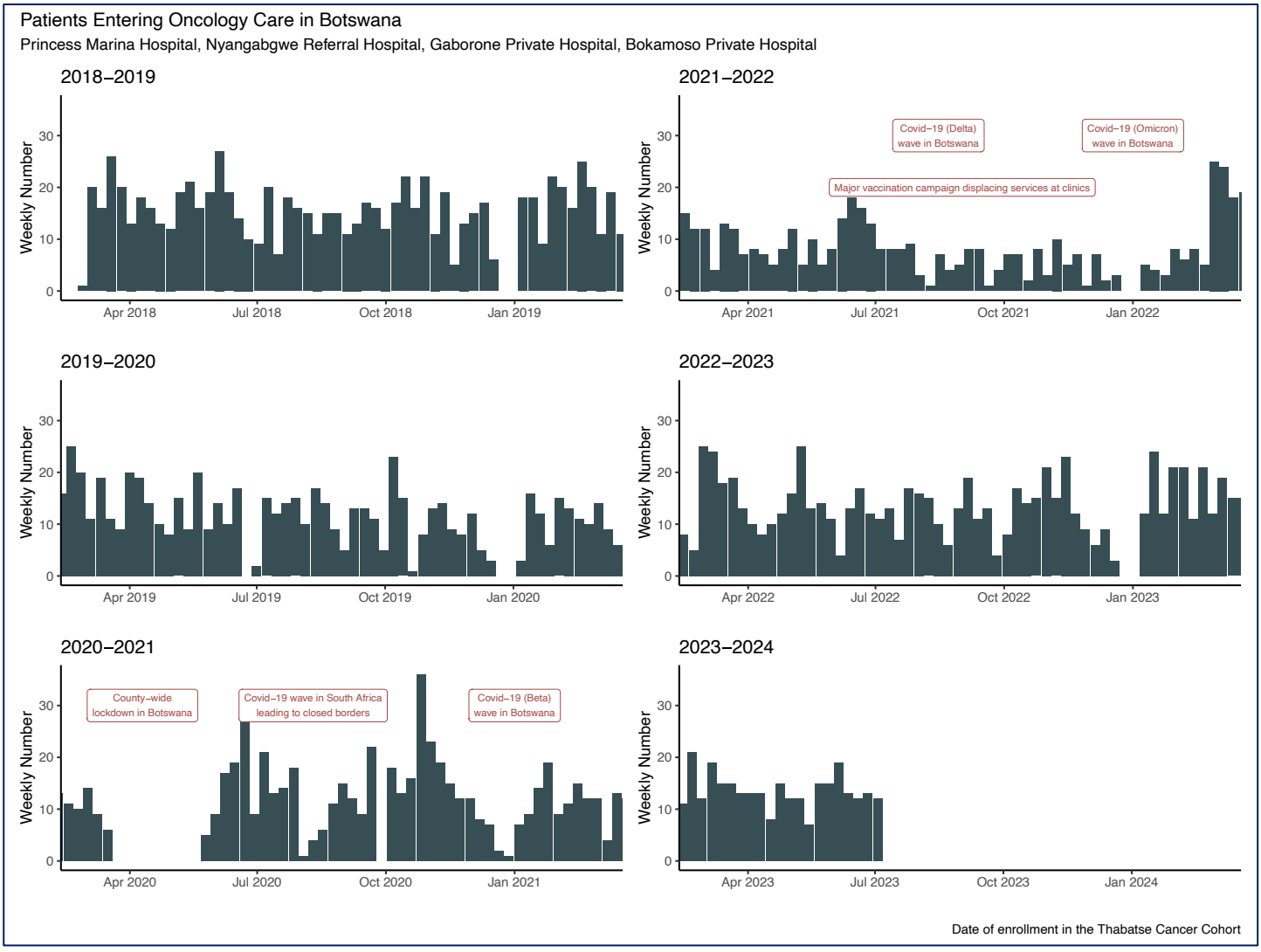
Cancer Team (file photo)

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

The Thabatse team has since 2010 worked to understand and reduce the burden of cancer in Botswana and the region. Successful HIV treatment programs in Southern Africa have led to drastic 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 the of the most common causes of death for people without HIV.

Thabatshe which is one of the largest cancer cohorts in Africa (n = 6277), enrolls consenting patients entering cancer care from the principal treatment facilities in Botswana. Patients are followed quarterly for five years (>98% retention) to inform leading factors associated with development of cancer, delayed treatment and outcomes of cancer treatment. Findings from the Thabatse Cancer Cohort (TCC) 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.



Recent Findings

- Utilizing instrumental variable methods and seasonal fluctuations on access to cancer treatment, estimated that stage progression of cervical cancer (ie, IIIA to IIIB) occurs in approximately eight (8) weeks. Typical delay in treatment in Botswana currently averages 10 weeks. Ntloedibe and Dryden-Peterson, NCI symposium 2023.
- Identified that survival with Hodgkin lymphoma is similar in patients with and without HIV infection, but overall survival in Botswana below international norms. Moahi K. et al. JCO Global Oncology 2022.
- Estimated that 22% of cancer cases that would have been treated were likely died from cancer without oncologic treatment due to pandemic. Ntloedibe and Dryden-Peterson, NCI symposium 2023

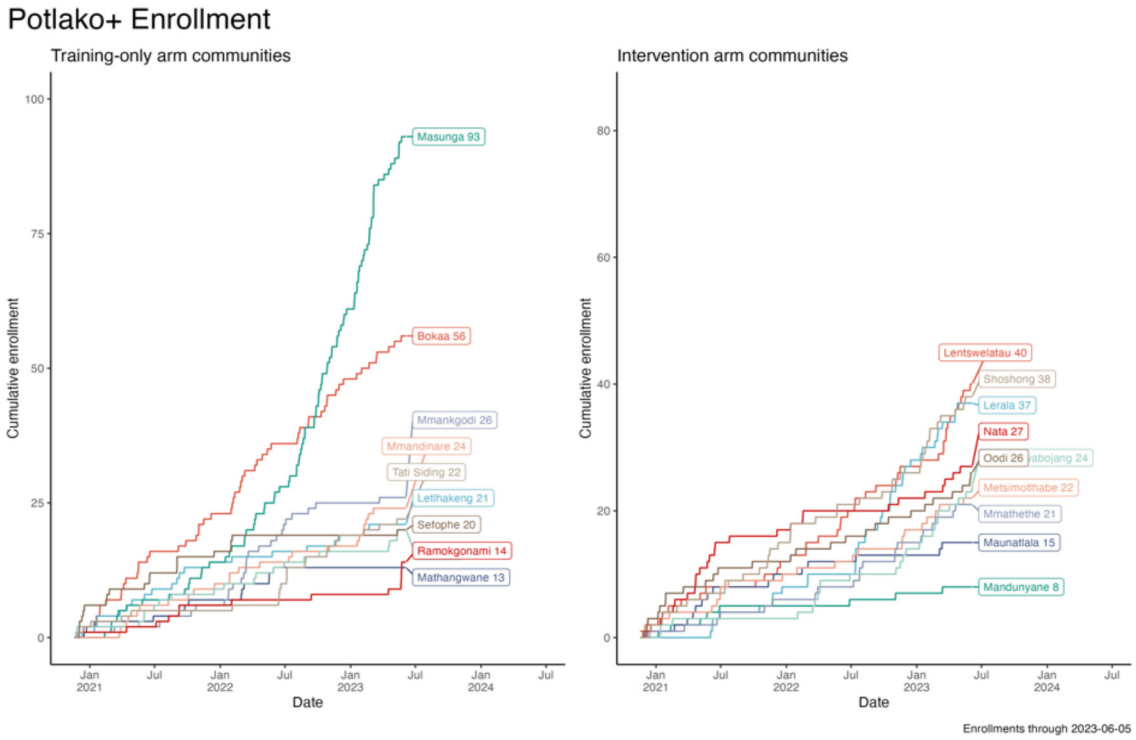
2) Potlako+: A Multilevel Intervention to Improve Timely Cancer Detection and Treatment Initiation in Botswana

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

Building on prior Potlako pilot, Potlako+ trial is a community-randomized, 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.

Recent Findings

- There was a substantial increase in clinic recognition of cancer symptoms and engagement with diagnosis since pandemic restrictions were lifted.
- Wider community and health service recognition that cancer has become a large threat to public health.
- Continued disruptions in clinic function due to vaccination campaigns (polio, measles) and severe staffing shortages



Potlako+ Study team during a community cancer screening event

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 a pilot study which aims to evaluate patients with and without HIV who need high-dose anthracyclines for treatment of cancer. Patients are evaluated by cardiac MRI to sensitively examine possible differences in cardiac changes following treatment by HIV status. This study has enrolled a total of 25 participants, all recruited from Gaborone site (Gaborone Private Hospital and Princess Marina Hospital).

4) Tumor Immunology of HIV Malignancies

PI: Dr Scott Dryden-Petersen, MD, MSc

People living with HIV are more likely to develop cancer and 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, the study is examining the expression of tumor neoantigens and immune inhibitors.

5) Evaluation of triage strategies and screening intervals in an HPV-based cervical cancer screening program in Botswana

PI: Dr Rebecca Luckett, MD, MPH

This is a longitudinal cohort study aimed at improving cervical screening by evaluating cancer screening using primary Human Papillomavirus (HPV) screening as well as standard-of-care and novel triage strategies in women in Botswana. The study has enrolled 3000 women in Southeast District and recruitment has been completed. Data analysis is underway. Follow-up of women living with HIV in the cohort (~1300 women) began in March 2023, and will continue at one, two, and three-year intervals depending on the results of baseline screening.

The HPV research team: Sibongile Phiri, Janet Gaborone, Lorato Mochoba, Lesedi Mokgopo & Dr Luckett

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

Scientist handling Covid-19 samples

1) 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 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 eight and seven workers respectively. Data collection has been completed and data analysis is ongoing.

2) 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 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 eight truck drivers. Data collection has been completed and data analysis is ongoing.

3) 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 hospitalization or severe diseases.

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

The study aims to collect a total of 7500 samples across a variety of populations and are continuing with recruitment. The team performed an initial analysis of the first 1000 samples with preliminary results published earlier this year:
https://medwinpublishers.com/VIJ/rhesus-blood-group-c-rh2-is-associated-with-protection-against-sars-cov-2-infections.pdf

4) 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 being 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 was circulated online has been completed by 400 participants. A primary analysis recently took place and the team is working on sharing the results. In addition, 12 interviews with key informants were completed to gain a deeper understanding of the reasons behind vaccine hesitancy.

5) 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

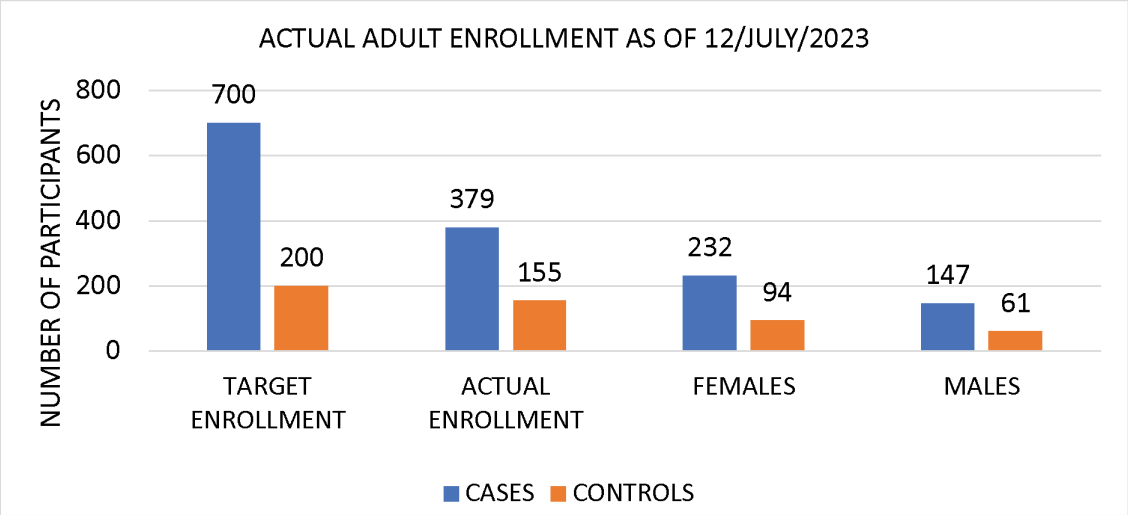
The WHO Solidarity trial involves collaboration between the World Health Organization (WHO) and hundreds of hospitals in dozens of countries. Botswana is participating in this multi-country clinical trial to evaluate drugs and therapeutic agents with potential to impact outcomes of COVID-19 among hospitalized patients. The trial began enrolment of participants in December 2021 at Sir Ketumile Masire Teaching Hospital (SKMTH) in Gaborone and enrolled 24 participants before it was stopped by the DSMB in February 2023. Data analysis is ongoing.

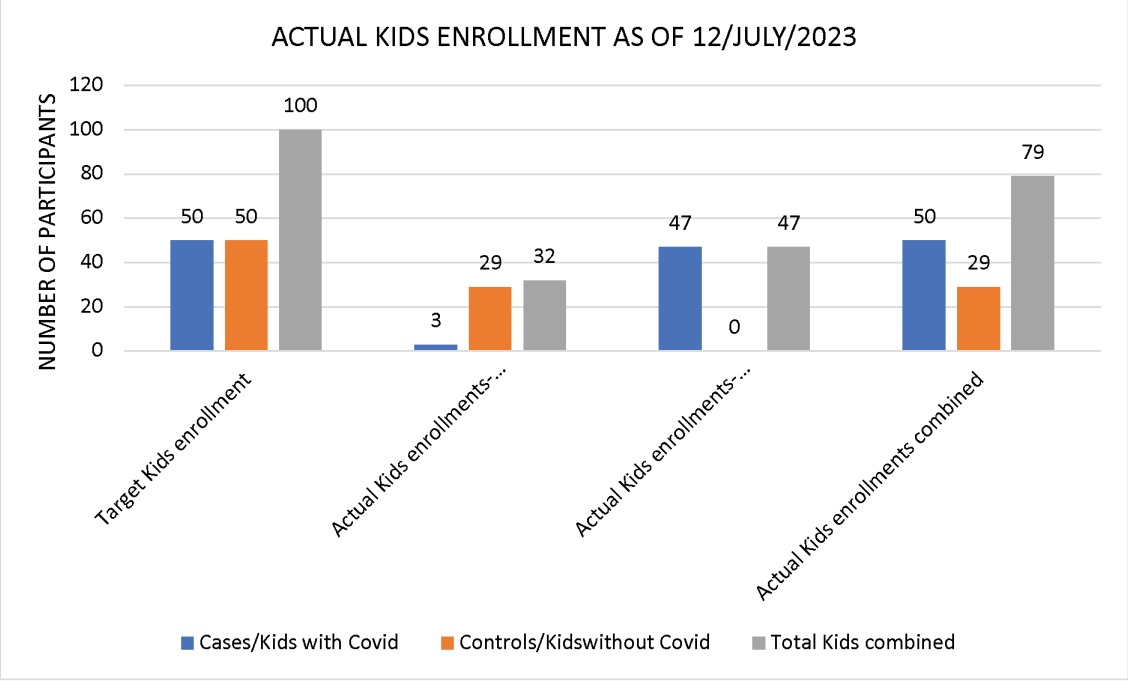
6) Motlhala Study: Post-Acute Sequelae of SARS-CoV-2 Infection (PASC) / 'Long COVID': Observational Cohort (Motlhala Study)

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

The Motlhala study is an 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 long COVID.

Figures 1 and 2 below show the number of participants enrolled into the study to date.





h) NETWORK CLINICAL TRIALS

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

Clinical Trials Unit (CTU) team

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 (with only IMPAACT network currently active in 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 ACTG is a global clinical trials network that conducts research to improve the management of HIV and its comorbidities; develop a cure for HIV; and innovate treatments for tuberculosis, hepatitis B, and emerging infectious diseases. The following studies are being conducted under the ACTG Network in Botswana:

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

Site PI: Prof Mosepele Mosepele, MD, MSc

REPRIEVE study seeks to investigate if the use of a cholesterol lowering medicine (Pitavastatin) may reduce the risk of cardiovascular events in HIV infected individuals. A total of 7560 participants were enrolled into this multisite study; 281 in Botswana. The study closed to follow up based on the observed efficacy of the study treatment. Study treatment has been shown to reduce the major adverse cardiovascular events (MACE) by 35% compared to the placebo. There was also a 21% reduction in MACE and death combined.

There were no unexpected safety signals. There was also no significant effect of Pitavastatin to increase liver enzymes and no effect to induce rhabdomyolysis. However, similar to other statin studies, a modest increased incidence of diabetes mellitus and the anticipated increase in myopathy rates were noted in the Pitavastatin arm relative to the placebo arm. Publication of the full study results is expected before the end of the third quarter. All study-related activities will come to an end in November 2023.

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

Site PI: Ayotunde Omoz-Oarhe, MBBS

This study assesses 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 aims to enrol 5160 MDR-TB index cases and their household contacts. Botswana has enrolled 36 participants out of its target of 300 since the study opened in 2019. Accrual into the study has been slower than anticipated because of difficulty in finding participants due to challenges with local testing as a result of shortages in GeneXpert cartridges and apparent low burden of MDR-TB cases in Botswana. The study is anticipated to reach full accrual in March 2024.

3)A5379: B-Enhancement of HBV vaccination in Persons Living with HIV (BEe-HIVe): Evaluation of HEPLISAV-B

Site PI: Ayotunde Omoz-Oarhe, MBBS

Vaccination is the cornerstone of prevention strategies against hepatitis B virus (HBV). However, the response to current standard hepatitis B vaccination is suboptimal in people living with HIV. A5379 study involves adults living with HIV with a history of nonresponse to hepatitis B vaccination (HBV vaccine-experienced) and adults living with HIV with no known prior history of HBV vaccination (HBV vaccine-naïve). The study will evaluate a two and three-dose regimen of HEPLISAV-B, each compared to a standard three-dose regimen of ENGERIX-B in HBV vaccine-experienced participants. It will also evaluate the efficacy of a three-dose regimen of HEPLISAV-B vaccine compared to historical response rates in the HBV vaccine-naïve participants. The study opened in 2022 and has enrolled 633 participants globally, 29 in Botswana.

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

Site PI: Ayotunde Omoz-Oarhe, MBBS

A5372 study is investigating the potential interactions between Dolutegravir (DTG) and Rifapentine (RPT) when RPT is given with isoniazid (INH) daily for four weeks as part of treatment for latent TB infection (LTBI) in HIV-1 and LTBI co-infected individuals. The study opens with Arm 1 where participants receive twice daily DTG co-administered with RPT and INH. Opening of Arm 2 will depend on analysis of DTG pharmacokinetics data from participants in Arm 1. Thirty-seven (37) participants have been enrolled globally since the study opened in February 2021, with three enrolled in Botswana.

The study team met with the District Health Management Team (DHMT) TB focal persons from the clinics in the greater Gaborone region to present the PHOENIX (A5300B) study. The team also had productive discussions on the prevailing challenges being experienced in relation to TB testing such as GeneXpert machine maintenance and stocks of cartridges which impact study recruitment.

IMPAACT STUDIES

The International Maternal, Paediatric, Adolescents AIDS Clinical Trials (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. The IMPAACT studies in Botswana are conducted at both Gaborone and Molepolole Clinical Research Sites.

1) 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.

Site PI: Gaerolwe R. Masheto, MD

The study's primary objective is to confirm the dose and evaluate the safety, tolerability, acceptability, and pharmacokinetics (PK) of oral Cabotegravir (CAB), long-acting injectable CAB (CAB LA), and long-acting injectable Rilpivirine (RPV LA) among virologically suppressed HIV-1 infected children and adolescents aged 12 to <18 years. The study reached the global accrual target of 155 participants as of 29 August 2022. Botswana enrolled its target of 25 participants and follow-up is ongoing with retention rate of 100%.

Study Results

Findings based on interim data collected through Week 16, from 23 participants enrolled in the U.S. to Cohort 1 who received either oral CAB or oral RPV followed by three injections of either CAB-LA or RPV-LA show that;

1. CAB-LA and RPV-LA, when given individually and with a background ART regimen, are well tolerated and achieve targeted pharmacokinetic concentrations.

2. No new or unanticipated safety concerns were identified. Of the injection site reactions which occurred, all were Grade 1 or 2, and none led to treatment discontinuation.

These interim results and future results are expected to support expanded options of treatment formulations for children and adolescents living with HIV-1 to improve adherence and treatment satisfaction.

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

Site PI: Gaerolwe R. Masheto, MD

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. A total of 325 women and their infants will be enrolled globally with 10 to be enrolled in Botswana. The study opened in April 2022 and no participant has been enrolled yet due to difficulties in finding potential participants.

3)IMPAACT 2005 - Phase I/II Open-label, Single-Arm Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Delamanid in Combination with Optimized Multidrug Background Regimen (OBR) for Multidrug-Resistant Tuberculosis (MDR-TB) in Children with MDR-TB with and without HIV

Site PI: Gaerolwe R. Masheto, MD

The study is evaluating the Pharmacokinetics of Delamanid, when added to optimized background regimen (OBR) in children with and without HIV at doses determined most likely to achieve exposures similar to those achieved in adults with 100mg twice daily. It will also evaluate the safety of Delamanid when added to OBR over 24 weeks of treatment. The study was re-opened in April 2022 after a pause of 14 months due to adverse events noted in Phoenix Study (which uses the same Investigational Product – Delamanid). Global accrual target for the study is 48 and currently 16 participants have been enrolled. No participants have been enrolled in Botswana.

4)IMPAACT 2016 - Evaluating a Group-Based Intervention to Improve Mental Health and ART Adherence Among Youth Living with HIV in Low Resource Settings.

Site PI: Gaerolwe R. Masheto, MD

The primary objective of this study is to evaluate whether a Trauma Informed-Cognitive Behavioural Therapy (TI-CBT) Intervention is associated with improved depression, anxiety, and/or traumatic stress symptoms for youth living with HIV compared to a Discussion Control at six months post intervention. Up to 256 participants to be enrolled globally and 56 in Botswana.

Participants for IMPAACT 2016 Expert Trainer Training held 27 February 2023 – 10 March 2023; included are Expert Trainers, Indigenous Youth Leaders, & Study Staff.

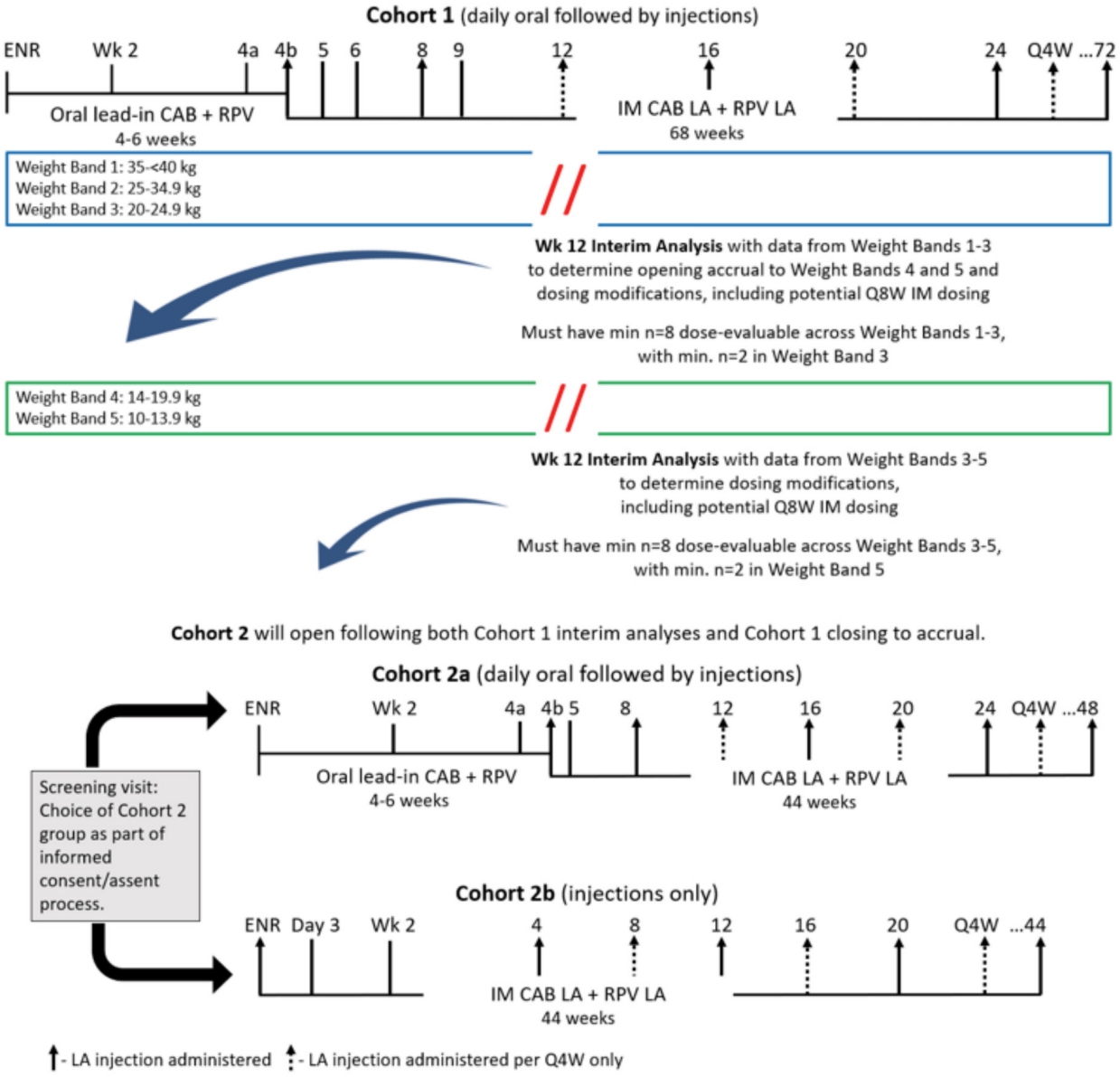
5)IMPAACT 2036 - Phase I/II Study of the Safety, Tolerability, Acceptability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Rilpivirine in Virologically Suppressed Children Living with HIV-1, Two to Less Than 12 Years of Age

Site PI: Gaerolwe R. Masheto, MD

The primary objective of this study is to describe the repeat-dose pharmacokinetics of CAB + RPV (oral and injectable) through week 24 and to assess the safety of the oral lead-in of CAB + RPV, and the safety of CAB + RPV (oral and injectable) through week 24. The study will enroll 90 participants and their parents/caregivers (20 in Botswana).

Study team representatives attended a regional start-up training in March 2023. The study is planned to start in the second quarter of 2023.

Study Design



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

Site PI: Dr Joseph Moeketsi Makhema, MB. Ch.B., FRCP

This is a Pre-Exposure Prophylaxis (PrEP) study being conducted in women at 20 sites in seven countries across Sub-Saharan Africa. In November 2022, the HPTN 084 trial showed that CAB-LA administered through injection every eight weeks was effective and superior to daily oral TDF/FTC in preventing HIV infection in women. All participants were subsequently offered and transitioned to CAB-LA. Participants who were willing to continue taking CAB-LA PrEP are being followed up in the study in anticipation of receiving approvals for use of CAB-LA as PrEP in the country.

The study was inspected by the European Medicines Agency (EMA) in March 2023. The aim of the EMA inspection was to assess good clinical practice, efficacy and safety data to support EMA application of licensure of CAB-LA. The Gaborone CRS was one of two sites selected for this inspection. The inspectors concluded that the study had been conducted consistent with acceptable international standards for clinical trials. This is a major achievement and endorsement of the quality and conduct of clinical trials within the BHP.

CoVPN STUDIES

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

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

The CoVPN3008 study, also known as UBUNTU study, is a multi-site study conducted in 47 sites across seven countries. The study seeks to investigate if Moderna Vaccine can prevent severe COVID-19 illnesses caused by strains circulating in Eastern and Southern Africa. It also investigates how many vaccine doses would be needed for protection against COVID-19 for adults living with HIV and adults with existing health conditions.

The study enrolled adults randomly administered either a 3-dose or 2-dose Moderna (mRNA-1273) vaccine regimen depending on the enrolment SARS-CoV-2 antibody results. A total of 14,237 participants were enrolled globally in the study and Gaborone CRS enrolled 119 participants. In September 2022 the study introduced a bivalent Moderna vaccine (mRNA-1273.222), targeting the SARS-CoV-2 ancestral viral strain and the Omicron (BA.4/5 strains) with participants randomized to mRNA-1273.222 versus Moderna vaccine (mRNA-1273) at month six.

Study Findings

An interim analysis of the pre-month six study data has shown that the vaccine regimen was safe and well tolerated by all participant groups. Participants with hybrid immunity (i.e., had evidence of prior SARS-CoV-2 infection at enrolment and received one vaccination) experienced a reduced incidence of symptomatic COVID-19 compared to participants with immunity derived from vaccines alone. Importantly, serious COVID-19 was very uncommon in the study population: only nine cases in the entire study, seven in people living with HIV (PLWH) and two in people who were HIV uninfected. Therefore, vaccination with mRNA seemed to be effective in reducing the medical complications of COVID-19 in PLWH.

The findings also indicate that subclinical acquisition of COVID-19 was more common than previously appreciated, with 86% of cases of COVID-19 pre-month six being subclinical. In addition, the data showed that there were a significant number of likely persistent infections, especially among the participants without evidence of previous COVID-19, participants with active tuberculosis, and PLWH who had low CD4 T cell counts and/or detectable HIV viral load. The participants follow-up is ongoing.

RESEARCH SUPPORT

Labaoratory Scientist Doreen Ditshwanelo

1) Clinical Laboratory

The Botswana Harvard HIV Reference Laboratory (BHHRL) supports various clinical trials conducted by the Botswana Harvard AIDS Institute (BHP) and collaborating institutions. BHHRL also works with the National Health Laboratory (NHL) contributing to various aspects of the national public health including providing laboratory testing support for the National ARV program.

The laboratory continues 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.

The BHHRL sustained its approved status in conducting clinical trials supported by the US National Institutes of Health (NIH) and Division of AIDS (DAIDS) through the various clinical trials networks; ACTG, IMPAACT, HPTN and CoVPN. The laboratory again upheld 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 the medical laboratory services it offers.

Laboratory Scientists Basetsana Phakedi and Girlie Tlhabano busy at work

Activities of the Clinical Laboratory include the following:

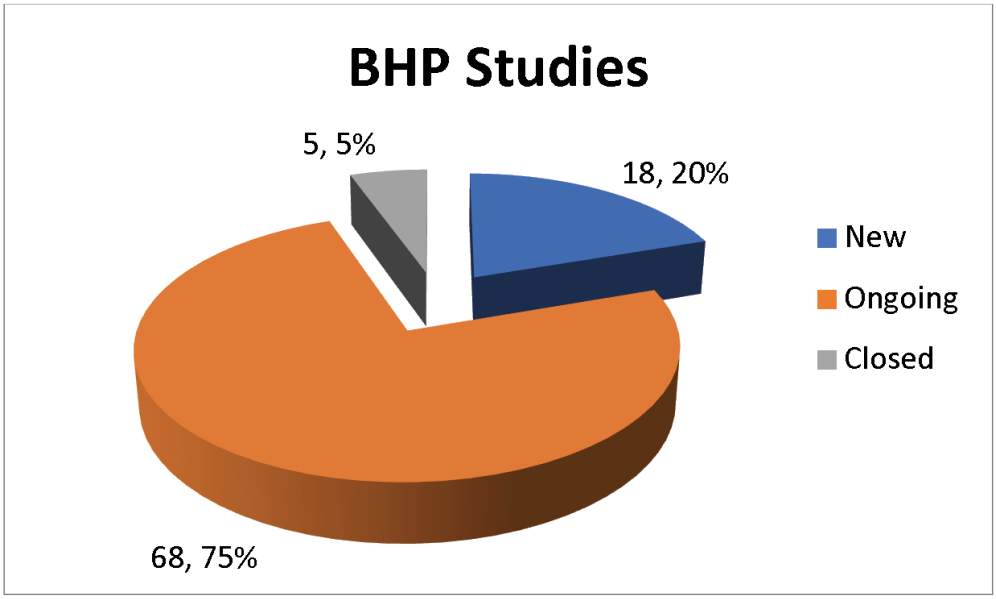
• Processing and Accessioning,
• Inventory and Archiving (Biorepository management)
• Safety labs: Clinical Chemistry, Hematology,
• Monitoring Labs: CD4, Viral load,
• Molecular assays: Diagnostic DNA PCR, HPV PCR, Chlamydia and Gonorrhea, HIV Drug Resistance, SARS-CoV-2 RT-PCR testing, Cepheid Gene 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 in-house
• 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 maintains a specimen biorepository with over 80 ultra-low temperature freezers and six liquid nitrogen storage facilities housing approximately 1.5 million samples. BHHRL is also part of several technical working groups such as; Biosafety & Biosecurity and Molecular testing for various pathogens.

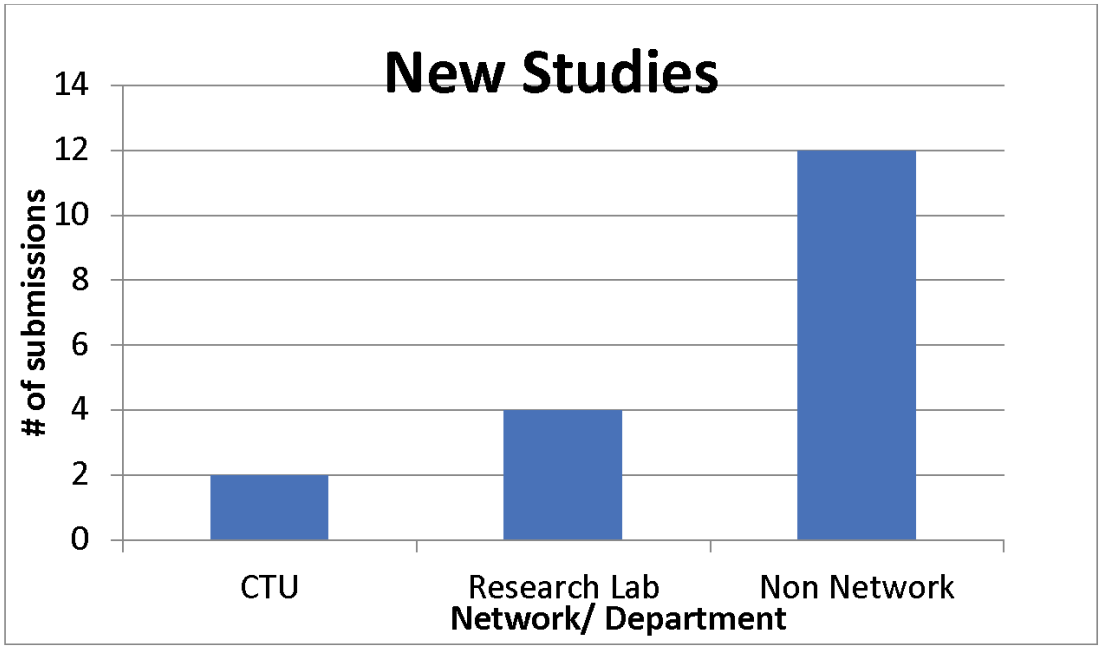
2) Regulatory Office

The Regulatory office continues to support BHP research projects to uphold research integrity and ethical compliance.

In the past one year, there were approximately 91 studies carried out at BHP. Sixty-eight studies (75%) were ongoing; 18 (20%) were new while 5(5%) were closed out with the IRBs.



Out of the 18 new studies, 12 were Principal Investigator initiated (Non-Network), four were carried out by Master's Degree and PhD students and two were network studies.



3) Community & Stakeholder Engagement

Community and stakeholder engagement in clinical trials is the active involvement, consultation and collaboration of various individuals, groups and organizations who either have an interest in contributing to the advancement of science and improvement of health care or those in whose environment clinicals a trial is conducted. This engagement is important for ensuring that research is conducted ethically, effectively, with consideration of diverse perspectives including in a culturally sensitive manner.

Patrick Mokgethi, Bonolo Phinius & Ernest Moseki interacting with students

1. Community Engagement: This involves the participation of the local community or the population that the clinical trial aims to benefit. It includes efforts to involve potential trial participants, patient advocacy groups, community leaders, and local organizations. Community engagement ensures that the trial design is culturally sensitive, addresses the needs and concerns of the community, and considers their perspectives on the research being conducted and post trial benefits.

2. Stakeholder Engagement: Stakeholders in clinical trials are individuals or groups with a vested interest in the outcome of the research. This can include researchers, healthcare providers, regulatory bodies, pharmaceutical companies, advocacy groups, government agencies, and the broader public. Engaging with stakeholders ensures that diverse viewpoints and expertise are considered in the planning, execution, and interpretation of clinical trial results. Effective and consistent engagement creates a collaborative environment and ensures open communication, mutual respect and bi-directional sharing of information. This can lead to relevant successful and impactful clinical trials that better serve the needs of the community and stakeholders while ensuring recruitment & retention of clinical trial participants.

Community and Stakeholder engagement in clinical trials is centred around the following objectives:
• Ethical Consideration: Ensuring the rights, interests, and well-being (safety) of trial participants are upheld.
• Enhancing Trial Design: Incorporating insights from stakeholders to improve the design, implementation, and dissemination of clinical trials.
• Increasing Trial Participation and Retention: Building trust and transparency within the community to encourage participation and maintain engagement throughout the trial.
• Education and Awareness: Providing information about the trial and its potential impact on the community, fostering understanding, and addressing concerns.

Community Advisory Board Meeting

Community Advisory Board Meeting

The BHP has a Community Advisory Board (CAB) which helps to ensure that the institution stays in tune with various communities and NGOs and that the communication channels stay open. The CAB members also represent BHP in committees of various clinical trials networks (e.g., ACTG, HPTN and IMPAACT) and in local Botswana committees such as the STI & PrEP Technical Working Groups, Ethics Review Committee of the University of Botswana and the Biological and Behavioural Surveillance Survey (BBSSIII) of the Ministry of Health. The BHP Cab is made up of the following:

1. Representatives from Civil Society/NGOs
    a. Rainbow Identity Association (RIA) for Transgender and Intersex individuals
    b. Nkaikela Youth Group for Female Sex Workers
    c. Lesbians Gays and Bisexuals of Botswana (LEGABIBO)
    d. Centre for Youth of Hope (CEYOHO) for young PLWH
    e. Botswana Network of People Living with HIV and AIDS (BONEPWA)
2. Former Study participant
3. Health workers
4. Teachers
5. Youth.

Activities:

1. There was a total of 7 CAB meetings held during the reporting period. These were mainly in person due to resource challenges including access to internet services.
2. There were 12 HPTN Community Working Group (CWG) meetings and 12 HPTN Community Steering Committee meetings, 24 ACTG and 24 IMPAACT virtual meetings.
3. Ms Mosidi Thari was recognised by the ACTG's Bridget Mutgah Award for her role in the CAB.
4. The BHP CAB was part of the team that drafted the Community Led Monitoring (CLM) Strategic Framework of the MOH.
5. One CAB member is a member of the STI Technical Working Group.

Challenges

Community engagement has a number of challenges;
1. The first of these is lack of funding to continue engaging community and stakeholders independent of a particular study. Availability of funds to do this would enable us to continue engaging, advocating and educating as the need arise. Efforts to address availability of resources to support the community engagement shall continue to be fostered by management
2. Scheduling of CAB meetings is a challenge due to member availability some of who reside outside Gaborone.
3. Meeting during the week has proved to be difficult since CAB members are volunteers some of who are employed. The walk-about has been holding these meeting/trainings on a Saturday. This has made it easy for majority of CAB member to attend and has allowed us to have a broader agenda and address more issues than on a week day.
4. Some CAB members represent BHP in network committees that have meetings after normal working hours. This means that they have to attend calls late at night and at their residences where there might not have internet and/or smart phones/laptops. Making these available to CAB members might make it easy for effective participation

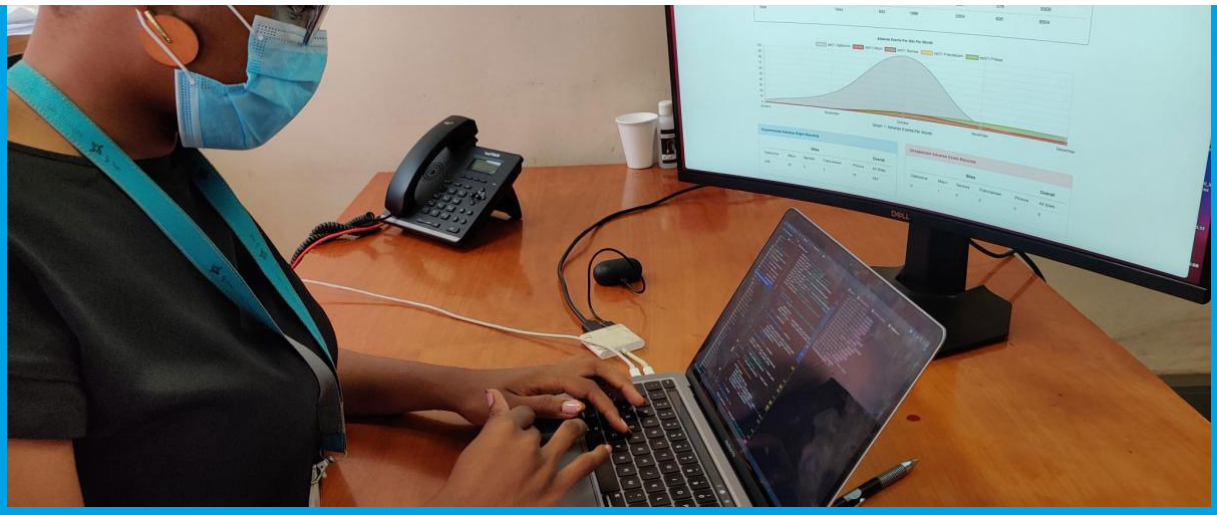
4) Pharmacy

The BHP Pharmacy is a support department for all BHP study drug related clinical trials and studies. It is recognized internationally by Division of AIDS (DAIDS) Pharmaceutical Affairs Branch (PB) and locally by the Botswana Medicines Regulatory Authority (BoMRA) and Botswana Ministry of Health (MOH) for high regulatory and pharmacy practice standards. It supports multiple clinical trial clinics with various study drug protocols for over 400 participants.

During the reporting period, the pharmacy department experienced an increase in participation on clinical trials with parenteral preparations using aseptic technique and Biosafety cabinets including preparation of COVID-19 vaccines The Gaborone pharmacy participated in the European Medicines Agency (EMA) audit under HPTN 084 study. The EMA audit provided great lessons that improved the capacity of the pharmacy on clinical trials. The pharmacy has not had a critical event or protocol deviation during the reporting period.

Pharmacist Relebohile Sekoboto dispensing pills at the CTU Pharmacy

5) Department of Software Engineering and Data Management



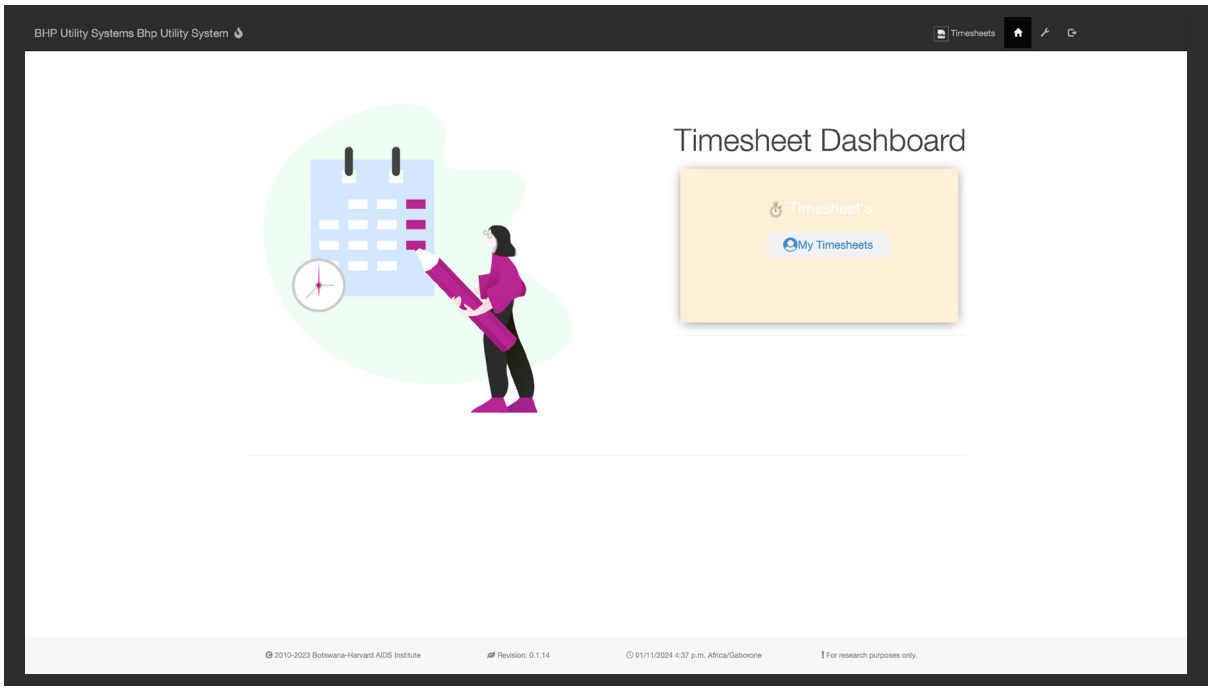
Data Analyst analyzing study data

The Software Engineering and Data Management Center (SE & DMC) serves all 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 ensures a complete, accurate, compliant, auditable, confidential, secure and available research protocol data record.

Current DMC Projects

Utility Systems

The DMC is building an intranet of office automation services for the different departments. These include timesheet system, contract management systems and grant systems.

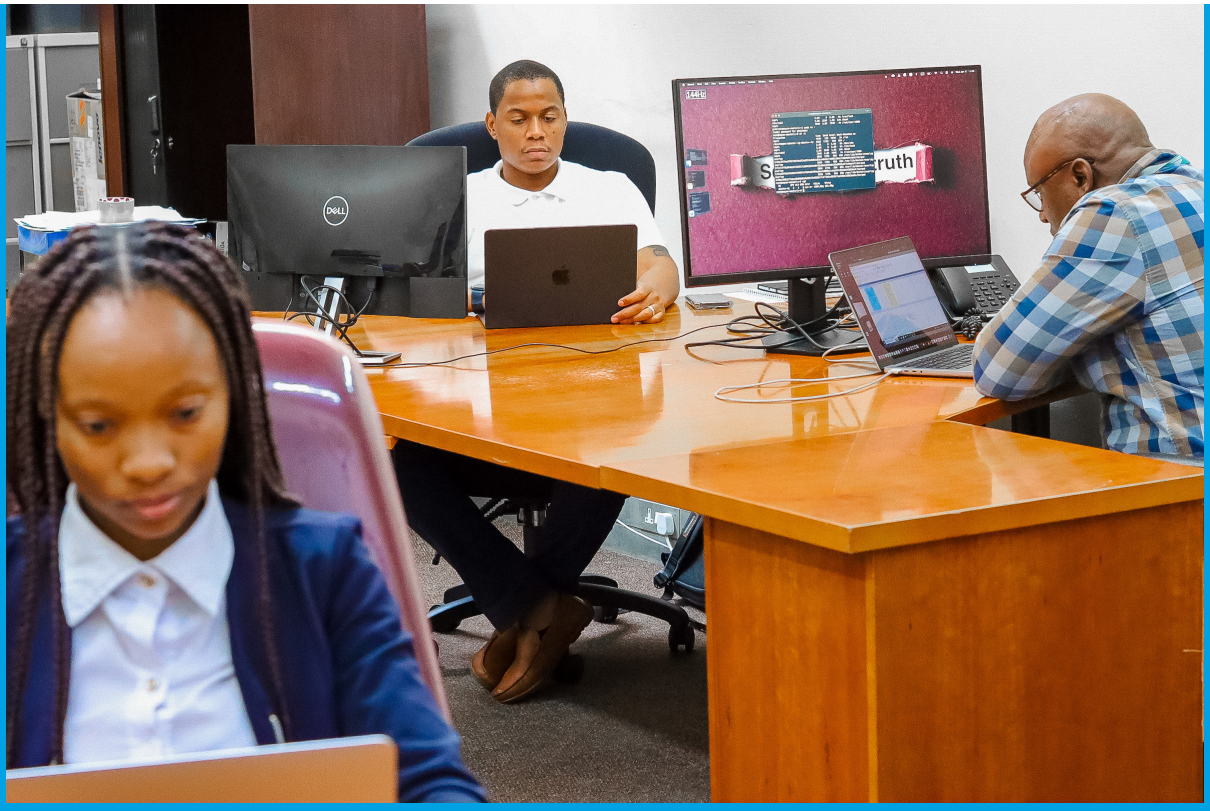


Screenshot of the BHP Utility System

Data Warehouse

The DMC is working on a data warehouse that will hold all BHP sample data. This will allow all Principal Investigators to be able to know what samples are available to formulate new research based on samples available. This project will introduce the use of cloud technologies and developing skills for understanding and gaining experience in cyber-security for cloud computing.

6) Information Technology



Information Technology Team

The IT Department is responsible for maintaining the hardware and software systems within BHP. Its functions include monitoring system performance, data storage and backups, cybersecurity, application management, troubleshooting and offering of IT support to staff across the whole organization.

During the reporting period, the organization transitioned to Microsoft 365 services, a cloud-based platform with robust email security features. The migration process involved assessing the existing email system, securely backing up data and implementing Microsoft 365. The migration was meant to enhance protection against email and data security threats.

11. CAPACITY BUILDING

1) Research Laboratory

The BHP research laboratory is a vibrant group of research fellows at various stages of training 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 Sikhulile Moyo and Dr Rosemary Musonda. Dr Motswedi Anderson who has 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 consists of international collaborators who assist with 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 include HIV drug resistance, HIV incidence, Viral hepatitis, TB incidence and molecular epidemiology, Noroviruses and Sapoviruses, and HPV molecular epidemiology. The fellows are supported by various capacity building grants.

Active Capacity Building Grants

· TESA III
· SANTHE 2.0
· 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. The consortium focuses on conducting high quality research on infectious diseases with the most severe morbidity and mortality in the region. TESA brings together 15 institutions from nine African and three European countries 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.

The BHP is recognized as the consortium's reference laboratory for HIV and offers training in HIV drug resistance and other related techniques. BHP is committed to organizing impactful training programs to contribute to the professional growth and development of its collaborators specifically in the field of HIV drug resistance testing. The laboratory has hosted scientists from Biomedical Research and Training Institute (BRTI) in Zimbabwe on the 5th to 7th of September 2022 for on-the-job training on HIV drug resistance.

The main objective was to train the team on how to perform HIV drug resistance testing, from 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 analyser, additionally, editing raw sequences, sequence alignment and identification of HIV drug resistance mutations using appropriate tools. BHP also assisted the team with drafting of relevant Standard Operating Procedures (SOPs) in preparation for the accreditation of BRTI's HIV drug resistance laboratory.

The BHP through the TESA III grant, took an initiative to support students in attending data analysis and manuscript writing bootcamp (organized by UTH, Zambia), recognizing the importance of equipping them with essential skills for their academic and professional development.

The BHP graduate students, Doreen Ditshwanelo and Bonolo Phinius had the opportunity to attend international conferences to share their project results. The data from their projects were shared at Conference in Retroviruses and Opportunistic Infections (CROI) 2023 in February 2023, Conference on Liver Disease in Africa (COLDA) in September 2022 and 8th Botswana International AIDS conference.

Ms. Nametso Kelentse successfully defended her PhD thesis on 25th November 2022 and will graduate with a PhD at the next graduation in October 2023. Ms Doreen Ditshwanelo also successfully defended her MSc thesis and will graduate at the university's next graduation ceremony.

TAGENDI Fellowship Program

The TESA consortium offers 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. Tuelo Mogashoa is the TAGENDI Botswana trainee. She is a PhD candidate at Stellenbosch University, South Africa.

SANTHE 2.0

The 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.

SANTHE's programme strategy targets four main areas which are;

- 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 mobilization.

BHP Research Fellows

No.	Name	Programme of Training	Sponsor
1	Dr Motswedi Anderson	Research Scientist	Wellcome Trust/AREF
2	Dr Kaelo Seatla	Post-Doc	Fogarty, AREF
3	Dr Dorcas Maruapula	Post-Doc	Fogarty, SANTHE 2.0
4	Dr Nametso Kelentse	Post-Doc	TESA II, Fogarty
5	Nokuthula S. Ndlovu	MSc (BIUST)	Self supported
6	Doreen Ditshwanelo	MSc (BIUST)	H3ABioNet/TESA III (Partial
7	Kwana Lechiile	MPhil (UB/FHS)	Self supported
8	Kesego Motsumi	MPhil (UB/FHS)	Self supported
9	Patrick Mokgethi	MPhil (UB/FHS)	Fogarty
10	Baitshepi Mokaleng	MPhil (UB/FHS)	Self supported
11	Bonolo Phinius	PhD (UB/FHS)	Wellcome, H3ABionet, TESA III
12	Kabo Baruti	PhD (UB/FHS)	
13	Ontlametse T. Bareng	PhD (UB/FHS)	Fogarty, TESA III
14	Tuelo Mogashoa	PhD (Stellenbsch University)	TESA III
15	Wonderful Choga	PhD (UB/FHS)	SANTHE 2.0
16	Natasha O. Moraka	PhD (UB/FHS)	SANTHE, Fogarty

Highlights of Projects in the reporting Period

- 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. The lab initiated genomic surveillance of SARS-CoV-2 in support of the Ministry of Health and Botswana COVID-19 Taskforce efforts. To date, BHP laboratory contributed 4700 SARS-CoV-2 whole genome sequences to the Global initiative on sharing all influenza data (GISAID).

The 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. Its 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.

Bioinformatics and Next Generation Sequencing Training

The 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 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.

HIV-1 Drug-Resistance Genotyping Resistance Training

The 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. Data analysis using R and manuscript writing, 25 June – 04 July 2023.
2. Global Hepatitis Summit 2023, 25th – 28th April 2023
3. TB Bioinformatics workshop, 14 -16 March 2023
4. Introduction to Biostatistics, 21 February – 8 March 2023
5. Introduction to R, 11, 14, 18, 21 April 2023
6. The 30th conference on Retroviruses and Opportunistic infections (CROI) 2023, 19 -22 February 2023
7. The 8th Botswana International HIV Conference, 8th – 11th November 2022
8. Conference on Liver Disease in Africa, 29 September – 1st October 2022
9. Workshop: Exploratory Data Analysis and Modelling in R with Microbiome Applications: 22nd to 26th August 2022
10. Keystone Symposia on Progress in Vaccine Development for Infectious Diseases - T8: 5th July – 13th October 2022

Graduations and Thesis Defense

During the reporting period five BHP research fellows successfully defended their MPhil and PhD theisis.

1. Dr Dorcas Maruapula successfully defended her PhD thesis and graduated from the University of Botswana.
2. Dr Kesaobaka Molebatsi successfully defended his PhD thesis and graduated from the University of Botswana.
3. Dr Nametso Kelentse successfully defended her PhD thesis at the University of Botswana
4. Monkgomotsi Maseng successfully defended her MPhil thesis and graduated from the University of Botswana
5. Doreen Ditshwanelo successfully defended her MSc thesis at the Botswana International University of Science and Technology.

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

The BHP Clinical Capacity Building Initiative is a collaboration between BHP, Beth Israel Deaconess Medical Center (BIDMC), Boston, and Oregon Health & Science University (OHSU), Portland. The initiative was launched in 2011 to support healthcare capacity building through clinical education, quality improvement, and research in Botswana. The program provides clinical training to University of Botswana (UB) medical students and residents as well as Ministry of Health (MOH) medical officer interns, 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. However, the Obstetrics & Gynaecology (OBGYN) and Anaesthesia & Critical Care programs have since transitioned to be based primarily at University Botswana and Princess Marina Hospital (PMH) to support residency training.

Obstetrics & Gynaecology

Thanks to the support of BHP, the new OBGYN residency training programme at UB is thriving. Now in the fourth year since its inception, the residency programme increased the intake cohort of residents by 50% in January 2023. Currently there are 18 in-country OBGYN trainees. The programme will celebrate the accomplishment of the first resident class to complete training at the end of 2023. In collaboration with UB, BHP hosted seven visiting OBGYN Residents, a Maternal-Fetal Medicine high-risk Obstetric Global Health Fellow, and multiple surgical subspecialists, including urogynecology and reproductive endocrinology, over the past year. These visitors helped support clinical education and quality improvement activities, training both residents and faculty. New interdisciplinary collaborations have helped to develop and implement training in critical care, ultrasound, and neonatal resuscitation.

The current OBGYN Site Director, Dr. S. J. Hanson, has been in her role for a year. In this time, she has spearheaded educational programs for both the UB MMED residency training programme and the OBGYN Department at PMH. These efforts have included coordination of subspecialists, technical training in minimally invasive gynecologic surgery and ultrasound, emergency simulation, and the introduction of a department Wellness program. Dr. Rebecca Luckett has continued to support the UB OBGYN residency training programme as Programme Director (APD) in collaboration with Dr. Hanson and they are working toward the transition of the APD role to a UB colleague in the coming year.

The BHP OBGYN, in collaboration with UB, is contributing to outreach through the MOH Airborne Lifeline program. These outreach visits focus on capacity-building for maternal-child healthcare in rural villages, including Tsabong, Ghanzi, and Hukuntsi. In addition, BHP OBGYN resumed capacity-building programming at SLH, including surgical outreach and training of SLH medical officers in specialty-specific technical skills.

Anaesthesia & Critical Care

During the past year, the Anaesthesia and Critical Care Program has focused primarily on the development and support of the UB Anaesthesia residency programme, which has now entered its fourth year. This year was the first in which nine of the residents transitioned to South Africa to complete their training, with their graduation expected in 2024. The residency programme welcomed three new residents, who began their training January 2023, as well as four visiting international Anaesthesia residents and a team of Paediatric Anaesthesiologists, who helped to build clinical experiences on the ground and supported the recent arrival of a Paediatric Surgeon in Botswana. The residency programme continues to build ties with international universities to improve Paediatric clinical experiences and training in the public sector.

The Anaesthesia and Critical Care Program continues to support ongoing clinical capacity building activities at UB's Sir Ketumile Masire Teaching Hospital (SKMTH). At Scottish Livingstone Hospital, the program continues to provide support in a number of ways, caring for Paediatric patients undergoing ophthalmological surgery and training staff throughout the hospital in Basic and Advanced Life Support, among other projects. Support of quality improvement projects is ongoing at each of these sites. The program will be undergoing a transition of leadership in the coming year as we welcome Dr. Catriona Stewart to the team. Dr. Ed Clune will be transitioning back to the USA but will continue to play a role in the clinical capacity building initiative in Botswana.

Internal Medicine

The Internal Medicine program, based at SLH, supports clinical education for multiple groups of learners. The program welcomed the addition of UB Family Medicine residents to the SLH medical wards as well as the return of UB fifth-year medical students for their core Medicine rotations. Education of Medical Officer Interns assigned to SLH under the Botswana Medical Internship Training Programme remains a core focus of teaching, from bedside rounds to formal didactics, with newly introduced intern teaching sessions on Point-of-Care Ultrasound (POCUS) and simulation. During the reporting period, the program hosted 19 visiting US Internal Medicine and Family Medicine Residents as well as a BIDMC Global Health Fellow, who contributed to the programmatic pillars of clinical education and quality improvement. The Medicine program is actively working toward building more equitable, bidirectional collaborative educational activities, and successfully piloted an obervership program at OHSU for SLH trainees interested in pursuing Internal Medicine training.

Plans are underway to expand this opportunity to more SLH trainees in the coming year. In addition, the program provides mentorship for career progression and research engagement to a broad group of trainees, ranging from interns to junior staff at SLH; a number of these mentees have successfully obtained placement in graduate training programs, international fellowships, and employment advancements in the past year. The program continues to contribute to design and implementation of quality improvement initiatives at SLH, as well as multiple research projects at SLH and across Kweneng District with emphasis on clinical problems prevalent in the district and medical education.

While focusing inpatient clinical education increasingly on POCUS, simulation, and resuscitation trainings, the Internal Medicine is simultaneously expanding collaborative educational activities in primary care. The program supports regular outreach visits to primary care facilities in Kweneng, and engages visiting residents in supporting quality improvement projects in partnership with DHMT staff. Work is currently underway to expand and formalize an outpatient teaching curriculum to complement the existing inpatient Medicine curriculum. This shift toward increased emphasis on promoting primary care and population health across Kweneng District aligns with a planned leadership transition during the upcoming year, as the program prepares to welcome Dr. Kesegofetse Chabaesele as the incoming Site Director for Medicine. Dr. Sara Schwanke Khilji will continue to support the program in a part-time capacity, with focus on bidirectional training opportunities and ongoing research programs.

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 remain 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. Status: Quantitative data collection complete, with publication pending; qualitative data collection and clinical algorithm development in progress.

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 specifically. 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. Status: Data collection ongoing.

iii) 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, including hypertension and diabetes. A continuing professional development (CPD) program supporting NCD training for primary care health workers in Kweneng District was implemented in 2019 through a series of workshops and mentoring sessions. This pilot study aims to assess the impact of a follow-up, mobile-phone based education program on provider knowledge, adherence to NCD management guidelines, and achievement of treatment targets while 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: Initial intervention and data collection complete, with Phase 2 in development.

iv) Assessing Educational Experiences Across Specialties Among Medical Officer Interns in Botswana

PIs: Dr. Thato Moshomo, Dr. Sara Schwanke Khilji

The Medical Internship Training Programme (MIT) was launched by the Botswana MOH, the Botswana Health Professions Council (BHPC), and the UB Faculty of Medicine to provide a framework for standardizing and improving internship training nationally. The MIT aims to prepare Medical Officer Interns to practice independently in Botswana's public health system as generalists, particularly in remote and rural areas. To promote consistency of learning outcome achievement across MIT training sites, assessment instruments are needed to understand interns' self-perceived readiness for independent practice and to objectively measure clinical knowledge. This project aims to test the feasibility, utility, and performance of two novel evaluation tools designed to assess medical knowledge across all four core specialties and perceived preparedness for independent clinical practice upon completion of internship, while identifying opportunities to strengthen current MIT training. Status: Medical knowledge assessment in development.

3) Botswana Oncology Global Outreach (BOTSOGO)

BOTSOGO
BOTSWANA ONCOLOGY
GLOBAL OUTREACH

The 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. BOTSOGO maintained monthly tumor board to promote clinician and nurse education on cancer management until 2022. The tumor board has been put on hold following oncology staffing challenges and irregular participation of some key partners. The tumor board will return in September 2023.

A picture taken at BOTSOGO's 10th Anniversary at the University of Botswana

12. PUBLIC POLICY AND ADVOCACY

The 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. Community and stakeholder Engagement are a key component of the BHP research agenda. As espoused by one of its key values, "Beneficence," BHP actively and continuously engages the public on the importance and impact of the research that it conducts. The Beneficence value ensures that all activities done at BHP are of relevance and benefit those affected and that the kn owledge generated through this research must be availed and shared with the public and scientific community to advise public health policies.

BHP continues 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. The research findings from various studies have been presented to the Ministry of Health as well as 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 also been shared with the public through presentations to MoH and conferences, media briefings and press releases as well as media interviews. The high-quality research that the BHP conducts is published in different reputable peer-reviewed scientific journals to share the research results with a wide range of scientific audience. The BHP published 78 manuscripts in the reporting period in different peer-reviewed journals, and 30 abstracts have been presented at different international conferences.

The BHP staff participate in several Technical Committees and Working Groups of both the Ministry of Health and different International Research Networks where they offer expert advice and insights on different health topics. BHP also collaborates with various international based investigators on various collaborative research, and this is testament to BHP's value for teamwork. The BHP staff together with CAB Members serve in over 22 Committees and Teams.

Chair of the BHP Board of Directors Prof. Roger Shapiro paid a courtesy to the office of the President on the 27th January 2023

13. OPERATIONAL EXCELLENCE

Human Resources Officer Tebogo Akanyang

1) Human Resources

This report encapsulates the department's achievements, challenges, and initiatives undertaken to support the strategic goals and objectives of the organization. Throughout the year, the Human Resources team has strived to foster a culture of excellence, inclusion, and talent development while effectively managing the diverse needs of our workforce. This report provides a comprehensive overview of our accomplishments and highlights the key areas where we have made significant contributions to the organization's overall success.

Diversity and Manpower Strength

Botswana Harvard Health Partnership is committed to an inclusive culture that respects and embraces employee diversity. As of June 2023, the staff complement was 270 inclusive of 19 non-Batswana. The graph below indicates the number of staff per month for the period under review. A significant reduction in the staff complement was a result of winding down COVID-19 studies.

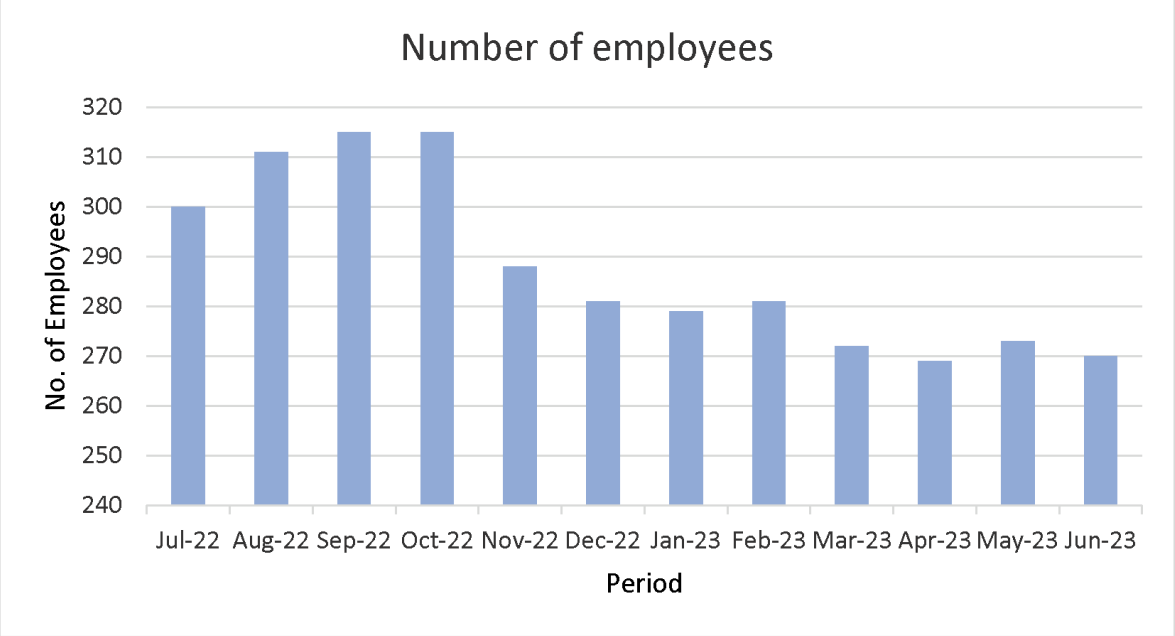


Figure 1: Staff Compliment trend per month

Gender Distribution

BHP aims to achieve gender diversity throughout all cadres with a keen interest of promoting women in Science and the Medical field. Figure 2 below indicates gender distribution in BHP.

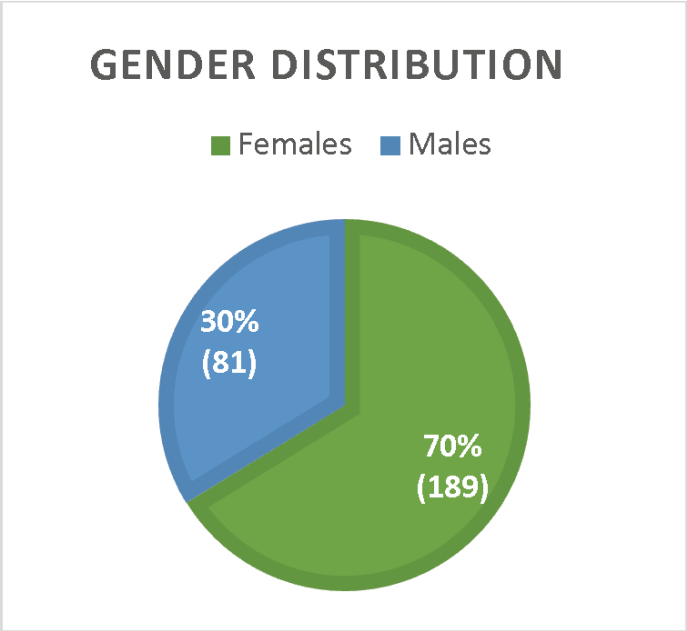


Figure 2: Gender Distribution

Wellness

i. Gym

To support employee wellness, BHP has partnered with various gyms to facilitate staff membership at discounted prices.

ii. Medical Aid

BHP cover all employees at 100% Medical Aid Cost. HR Department continues to host Member Educations with employees to enlighten employees on their benefits and to make sure they fully utilise the benefits since.

Human Resources Strategy

The Botswana Harvard Health Partnership Strategy has five Objectives with the Organizational Capacity Objective as the main focus for Human Resources Department, as outlined below.

STRATEGIC PERSPECTIVE	STRATEGIC OBJECTIVES
Customer/ Stakeholder Perspective	-Increase publications in peer reviewed journals -Increase number of early career researchers -Deliver quality research outcomes and quality services
Financial Perspective	-Prudent resource management -Grow and diversify revenue
Internal Processes Perspective	-Promote awareness of BHP's products and services -Promote in-country stakeholder relations -Increase grants applications
Organizational Capacity Perspective	-Improve Human Capital -Enhance infrastructural capacity and intellectual capital -Improve grants application and manuscript writing skills

Human Resources	**STAFF ENGAGEMENT** -Training & Development, -Wellness -BHP News Letter **PRODUCTIVE WORKFORCE** -Robust performance management system

From the above diagram, the HR strategic mandate is to Improve Human Capital by enhancing the productivity of the workforce and fostering a well engaged staff.

Training and Development

BHP staff attending training

Capacity building at BHP focuses on research methodology, laboratory skills training and academic mentoring of students and early career investigators performing mentored research. Senior laboratory and clinical investigators serve as mentors to the research fellows, often in collaborative mentorship teams with one another and with other international investigators. Fellows pursuing MSc and PhD degrees are registered with various academic institutions including University of Botswana (UB), Botswana International University of Science and Technology (BIUST), Stellenbosch University, University of Cape Town, University of Witwatersrand, University of Kwazulu Natal, London School of Hygiene and Tropical Medicine.

Currently BHP has six staff pursuing their MSc/MPhil and another pursuing their PhDs with various Institutions. One of our Nurse Coordinators under the BSRHI Study has been fully sponsored to pursue Bachelor's Degree in Public Health. Two research fellows have defended their PhD Thesis at the University of Botswana, and they are awaiting graduation. (Dr Dorcas Maruapula and Dr Nametso Kelentse). They two are now doing their pos-doctoratal fellowship.

Dr. Ponatshego Ponatshego completed his MSc in Global Health from Liverpool School of Tropical Medicine in December 2022 while Dr. Unoda Chakalisa completed her MSc in Clinical Epidemiology from Stellenbosch University in March 2023.

Within this reporting period Dr Kelo Seatla was supported by AREF Fellowship, hosted at the Africa Health Research Institute (Durban, South Africa) in Prof Thumbi Ndung'u's Lab where he received additional mentorship and training on new laboratory techniques to successfully carry-out this work. He will transfer knowledge and skills learnt back to Botswana for patient care and further scientific research on HIV, SARS-CoV-2 and other emerging infectious disease pathogens. Dr Anderson was also supported by an AREF Fellowship to support acquisition of invitro functional skills at University of Witwatersrand under Professor Anna Kramvis.

Dr Kaelo Seatla, has recently been awarded a four-year Postdoctoral Training Fellowship supported by the U.S. National Institutes of Health (NIH), African Academy of Sciences (AAS) and Bill & Melinda Gates Foundation (BMGF) called the African Postdoctoral Training Initiative (APTI). The APTI programme entails placement and training at various laboratories of the NIH Institutes and centres.

Organisational Culture and Employee Engagement Initiatives

The employee culture and Engagement reflects the company's commitment to fostering a positive work environment, promoting teamwork, supporting good cause, and enhancing communication and engagement. These initiatives have contributed to a more cohesive and motivated workforce, ultimately benefiting the overall success of the organization.

a) Breast Cancer Awareness Months

Supporting important causes like cancer awareness is an integral part of employee engagement. During the reporting period, the company actively participated in cancer awareness months, including awareness campaigns to educate employees on early cancer detection methods and the importance of regular screenings.

b) Leteisi Day

To celebrate independence in style, BHP employees wore Leteisi in recognition and celebration of Botswana Day. This was also meant to promote a fun and positive enjoyable work environment essential for employee satisfaction and engagement.

c) End of Year Event

BHP hosted an end of year event to recognize the efforts of all the staff for their dedication and teamwork demonstrated over the year and mapping a foundation for the year ahead.

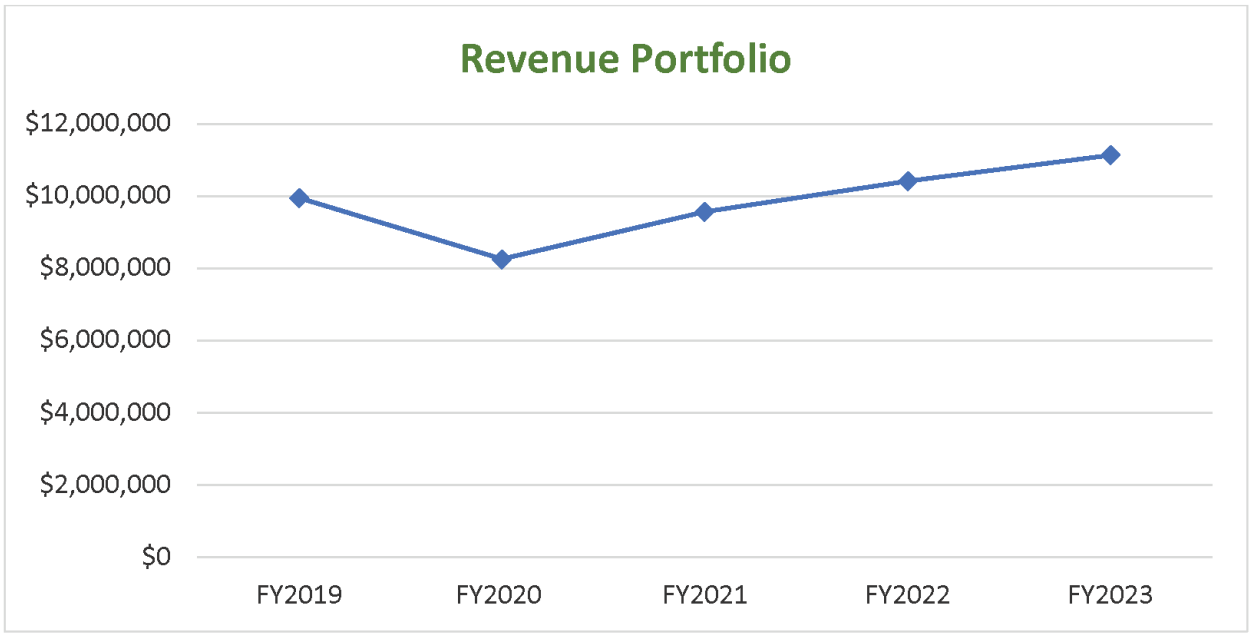
2) Finance and Grants

Grants Team

The institution remains committed to upholding prudency in resource management through effective monitoring of project budgets and timely reporting. The overall grant portfolio grew by 6% to a total of $11.1m in the Financial Year 2023 (FY2023). Below is the graphical and tabular analysis of the financial activities for the period under review. To enable an appreciation of historical events, a 5-year timeline is reflected in each presentation.

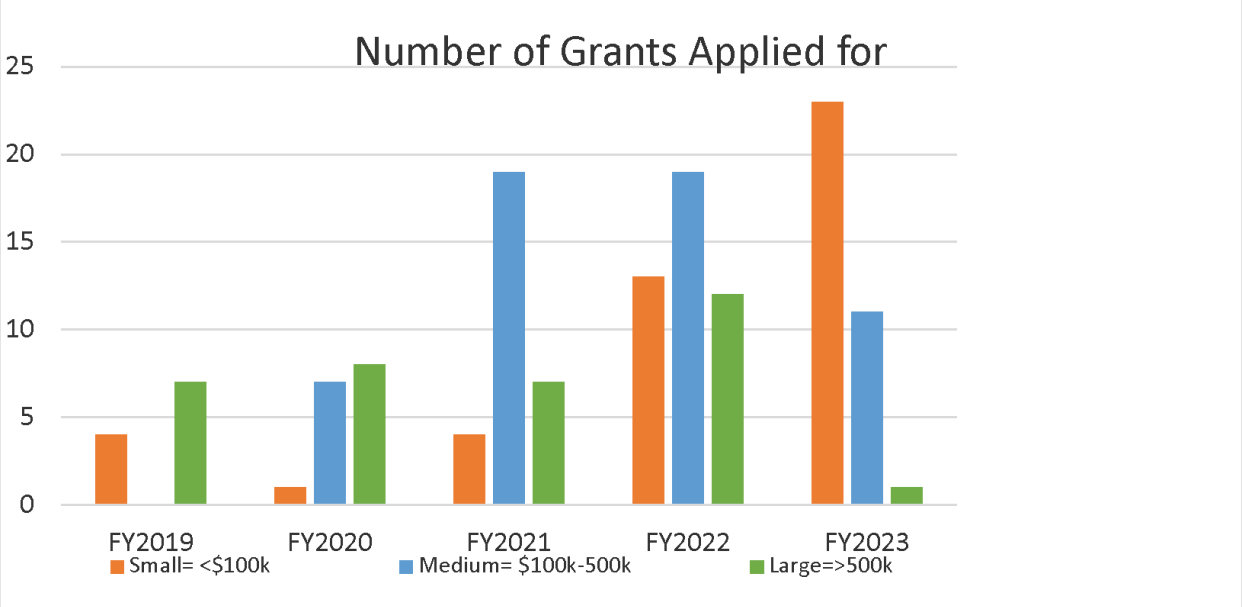
1. Funding Portfolio

FY2023 revenue increased by 6%, resulting in a total of $11.1m versus $10.4m in FY2022.



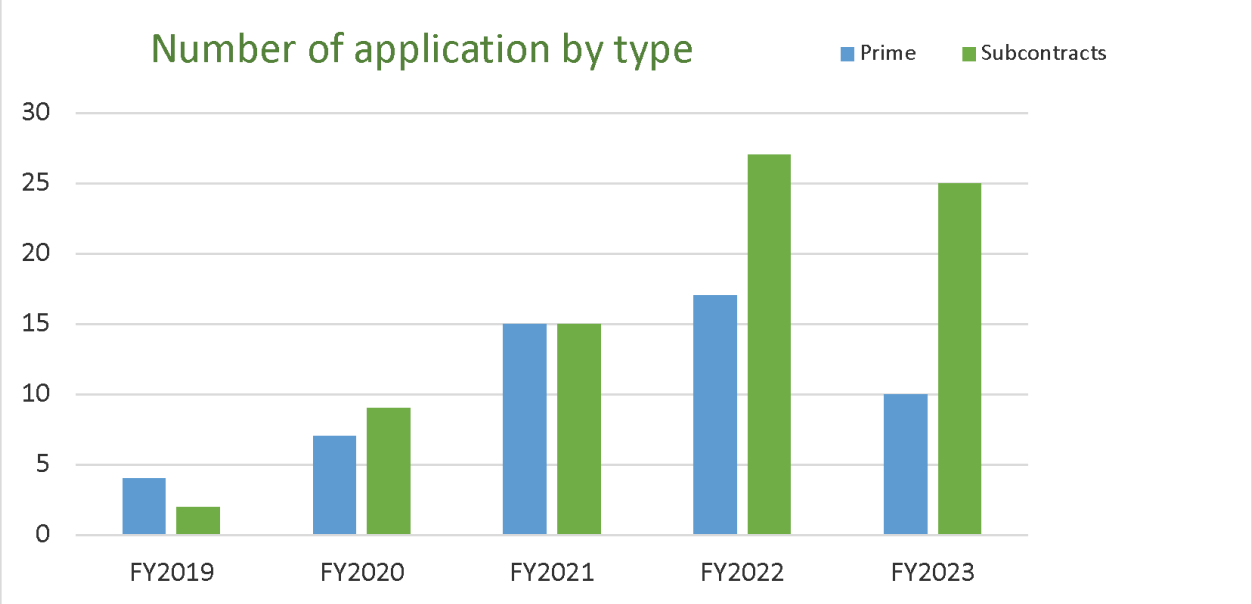
2. Number of Grants Applied For

Thirty-five (35) applications were submitted during the review period. This reflects a decline of 26% from FY2022. Of the 35 applications, 23 were small value grants, 11 medium value grants and one (1) large value grant were applied for in comparison to the previous year applications of 13 small value grants, 19 medium value grants and 12 large value grants.



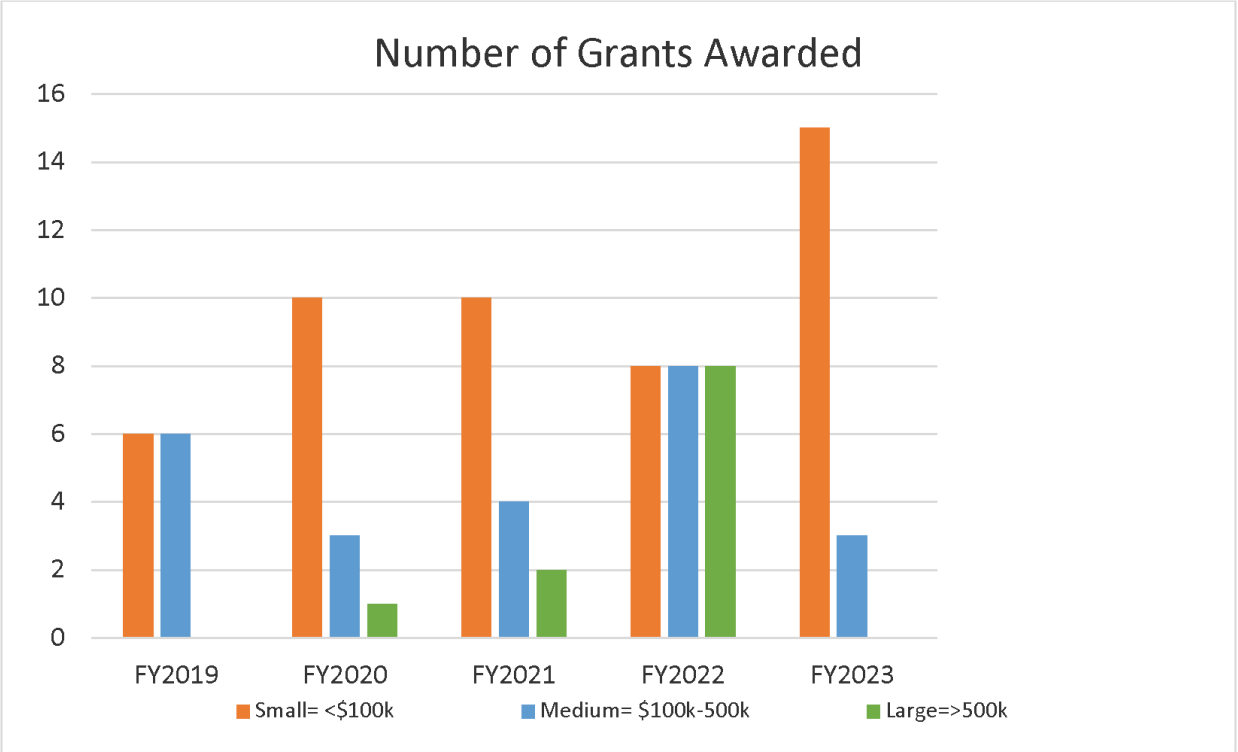
3. Number of applications by award type

The table below presents the number of applications submitted to the sponsors during the reporting period being 10 prime awards and 25 subcontracts. This is a decline from 17 prime awards and 27 subcontracts in FY2022.



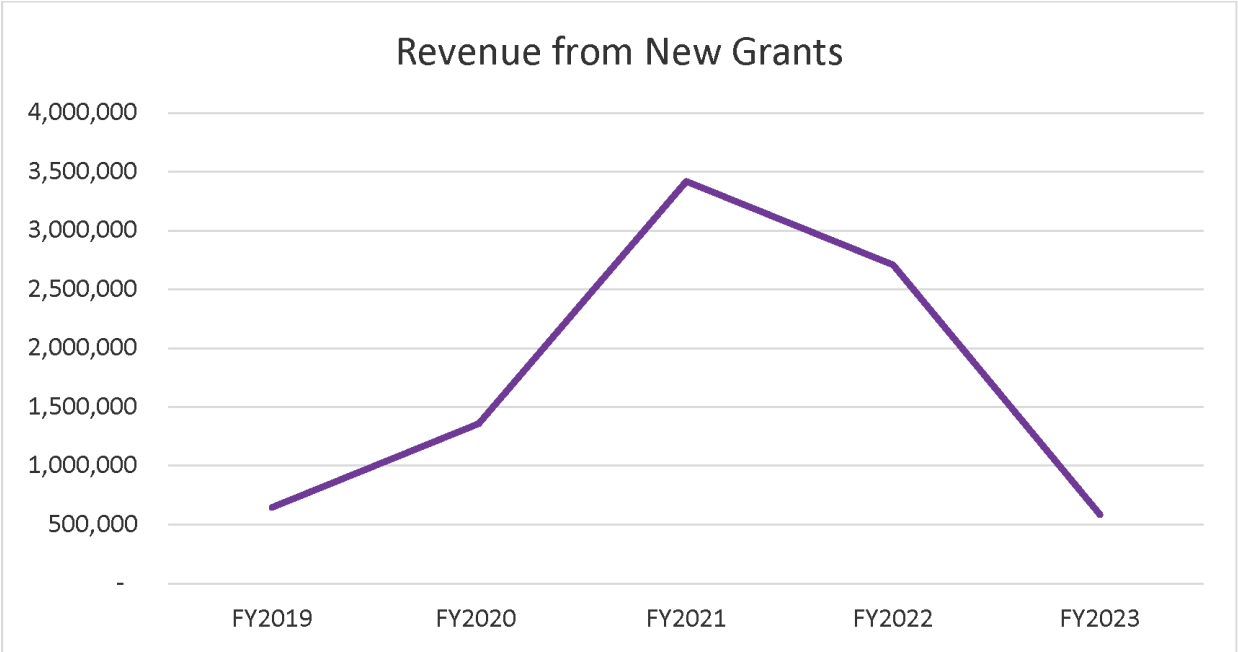
4. Number of Applications Awarded

Eighteen (18) out of 35 applications were successfully awarded in FY2023, of which 15 were small sized and three (3) were medium sized grants.



5. Revenue from New Grants

During the review period, revenue from new applications declined to $0.586m from $2.7m in FY2022.



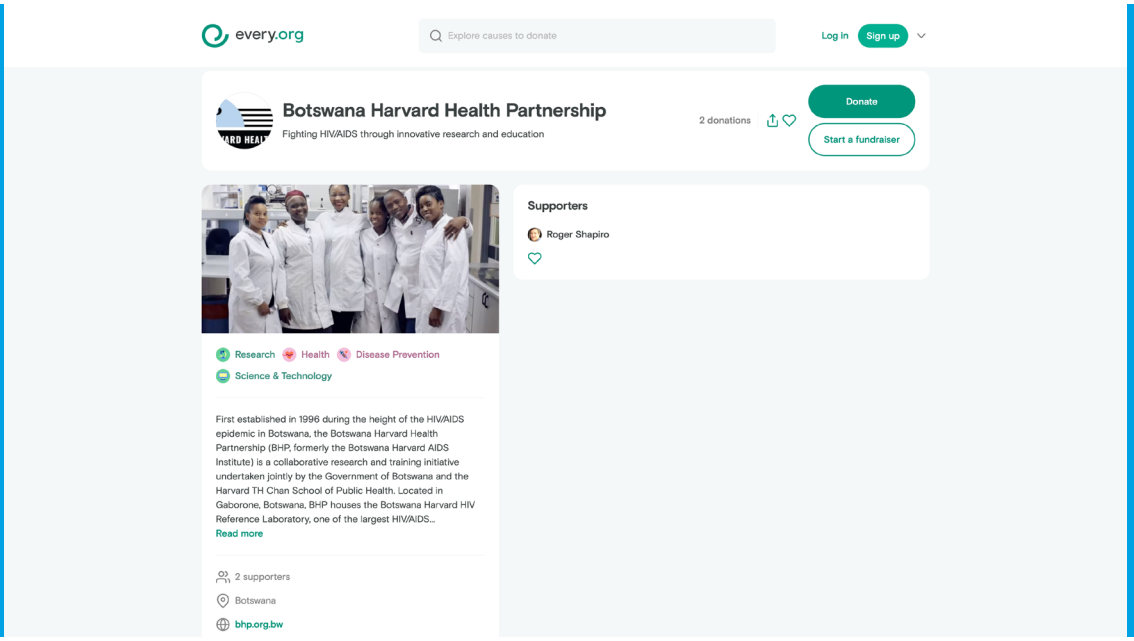
13. SUSTAINABILITY

SUSTAINABILITY

The 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 partnered with Myriad USA and their partner Every.org to accept donations from outside Botswana on BHP's behalf.

This partnership has established a Friends of Botswana Harvard Account to facilitate the receipt of philanthropic gifting by international donors, whether individuals, foundations or corporations.

Donations through Myriad USA from US based donors are tax deductible. The 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.



13. ANNEXURE

a) PUBLICATIONS

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Korutaro V, Cassim H, Fairlie L, Masheto G, Boyce C, Frenkel LM, Amico KR, Purdue L, Shapiro R, Mmbaga BT, Patel F, van Wyk J, Rooney JF, Currier JS, Lockman S; IMPAACT 2010/VESTED Study Team and Investigators. Lancet HIV. 2023 Jun;10(6):e363-e374. doi: 10.1016/S2352-3018(23)00061-9. Epub 2023 May 8. PMID: 37167996 Clinical Trial.

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