<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACABs</td>
<td>Adolescent Community Advisory Boards</td>
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<td>ALWH</td>
<td>Adolescents Living With HIV</td>
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<tr>
<td>ART</td>
<td>Antiretroviral treatment</td>
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<tr>
<td>ASLM</td>
<td>African Society for Laboratory Medicine</td>
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<tr>
<td>BILHIV</td>
<td>BILHARZIA and HIV study</td>
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<td>BCWs</td>
<td>BILHIV Community Workers</td>
</tr>
<tr>
<td>CABs</td>
<td>Community Advisory Boards</td>
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<td>CITAM+</td>
<td>Community Initiative for Tuberculosis, HIV/AIDS and Malaria plus related diseases</td>
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<tr>
<td>CE</td>
<td>Community Engagement</td>
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<tr>
<td>CD4</td>
<td>T cells expressing Cd4 antigen</td>
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<tr>
<td>CHiP</td>
<td>Community HIV-care Provider</td>
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<td>CPP</td>
<td>Community Partners' Platform</td>
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<tr>
<td>CRT</td>
<td>Cluster-Randomised Trial</td>
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<td>CSE</td>
<td>Comprehensive Sexual Education</td>
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<tr>
<td>DCE</td>
<td>Discrete Choice Experiment</td>
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<td>DFID</td>
<td>Department for International Development</td>
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<tr>
<td>EDC</td>
<td>Electronic Data Capture Device</td>
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<td>European &amp; Developing Countries Clinical Trials Partnership</td>
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<tr>
<td>EGPAF</td>
<td>Elizabeth Glaser Paediatric AIDS Foundation</td>
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<td>EPHSA</td>
<td>Evidence for HIV Prevention in Southern Africa</td>
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<tr>
<td>ETB</td>
<td>Eradicate TB Project</td>
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<tr>
<td>EWEC</td>
<td>United Nations Every Woman Every Child</td>
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<tr>
<td>HBHCT</td>
<td>Home Based HIV Counselling and Testing</td>
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<tr>
<td>HCT</td>
<td>HIV Counselling and Testing</td>
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<td>Health Economics Unit</td>
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<td>HIVST</td>
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<td>HPTN071</td>
<td>HIV Prevention Network</td>
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<tr>
<td>HTS</td>
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<tr>
<td>IEC</td>
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<td>National Health Research Authority</td>
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<td>NTLP</td>
<td>National TB and Leprosy Program</td>
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<td>OR</td>
<td>Operational Research</td>
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<tr>
<td>Acronym</td>
<td>Definition</td>
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<tr>
<td>P-ART-Y</td>
<td>PopART for Youth</td>
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<td>PLHIV</td>
<td>People Living With HIV</td>
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<tr>
<td>PMTCT</td>
<td>Prevention of Mother to Child Transmission</td>
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<tr>
<td>PopART</td>
<td>Population effect of universal testing and immediate ART to Reduce HIV</td>
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<tr>
<td>Transmission</td>
<td></td>
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<tr>
<td>PC</td>
<td>Population Cohort</td>
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<tr>
<td>PEPFAR</td>
<td>U.S. President’s Emergency Plan for AIDS Relief</td>
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<tr>
<td>RA</td>
<td>Research Assistant</td>
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<td>SA</td>
<td>South Africa</td>
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<td>Swedish International Development Agency</td>
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<td>SRH</td>
<td>Sexual and Reproductive Health</td>
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<td>Sexually Transmitted Infections</td>
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<td>SSA</td>
<td>Sub-Saharan Africa</td>
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<tr>
<td>STAR</td>
<td>HIV Self-Testing AfRica</td>
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<td>TASP</td>
<td>Treatment as Prevention</td>
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<td>TB018</td>
<td>TB Vaccine study</td>
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<tr>
<td>TREATS</td>
<td>Tuberculosis Reduction through Expanded Antiretroviral Treatment and</td>
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<td></td>
<td>Screening for active TB</td>
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<tr>
<td>UNZABREC</td>
<td>University of Zambia Biomedical Research Ethics Committee</td>
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<td>U.S. Agency for International Development</td>
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<td>Universal Test and Treat</td>
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<td>VMMC</td>
<td>Voluntary Medical Male Circumcision</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<td>ZCSPP</td>
<td>Zambart Civil Society Partnership Platform</td>
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<tr>
<td>ZDHS</td>
<td>Zambia Demographic Health Survey</td>
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<tr>
<td>ZNHRC</td>
<td>Zambia National Health Research Conference</td>
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Executive Director’s Report

On behalf of the management of Zambart, I am pleased to introduce Zambart’s Annual report for 2017–18.

The two years covered by this report provided several challenges and opportunities for growth and development for the Organization. Having evolved from a research collaboration established between the University of Zambia, School of Medicine and the London School of Hygiene and Tropical Medicine as far back as 1988, Zambart has grown into a fully-fledged Research Organization that is internationally recognized for the high quality research conducted, with public health impact. From its beginnings as primarily a TB/HIV research organization, that resulted in the coining of its names as the Zambian AIDS-Related Tuberculosis Project (hence the acronym ZAMBART), research activities have expanded over the ensuing years to other areas of public health concern, while retaining a focus on HIV and TB. In view of this development, Zambart changed its name from an acronym, to a name. However for many of our collaborators, and indeed even for some Zambart staff, the change from an acronym to a name has very slowly taken root.

In order to ensure that Zambart becomes an Organization that is ‘fit for purpose’ and able to play a significant role in contributing to the Sustainable Development Goals, and Zambia’s Vision 2030, Zambart embarked on a process of strategic planning in 2017. A retreat of senior and middle management staff in April 2017 resulted in the framing of Zambart’s 2025 Ambition which was ‘to be recognised as Zambia’s leading public health research and training organization’ and the development of six strategic priorities for the organization. A year-long leadership development program was conducted in 2018 by The Missing Piece that focused on 21 Senior and Middle management staff and was characterised by Breakthrough Development Days, and individual coaching and mentoring for key staff. A significant output from this process was the reorganization of the Organogram with expansion of the leadership of the Research Directorate to include two Deputy Research Directors, for Qualitative and Quantitative studies, in recognition of the critical role the Research Directorate plays in the Organization.

During the period covered by this report, Zambart successfully completed what is undoubtedly the single largest HIV prevention trial that has ever been conducted, the HPTN071 (PopART) trial. With the ending of the Intervention activities in November 2017, the Population Cohort in July 2018, and the new studies that began in 2018, Zambart’s staff numbers decreased from a peak of 742 in 2017 to just over 400 by the end of 2018. Whilst it was hard to bid farewell to many dedicated field staff, there was some comfort in knowing that these staff had gained various skills in research methods and public health that would be useful in their subsequent endeavours. In addition several new studies and extensions of the PopART enabled many of the former PopART CHiPs and research assistants to be taken on by the new studies.
The environment in which Zambart operated continued to evolve in 2017–18, providing a number of new challenges and opportunities for growth. Over the past 15 years since registration as a Company Limited by guarantee in 2004, Zambart has fostered and established many strategic and trusted partnerships across the health and public health sectors. In collaboration with these partners, the organisation has continued to develop and attract funding for studies required to inform national policy and health and public health priorities. Throughout the period, Zambart continued to work closely with the Ministry of Health (MoH) and other local partners. Our staff participated in various MoH Technical Working Groups (TWG) activities, thus contributing to the development of public health policy. With the reorganization of the School of Medicine into four schools in 2016 (School of Medicine, School of Public Health, School of Nursing, and School of Health Sciences), and due to the fact that Zambart primarily conducts research within communities, a Memorandum of Understanding between the School of Public Health and Zambart was signed in May 2018 to replace the original MoU signed with the School of Medicine in 2004. This MoU seeks to strengthen the links between both organizations in research and training.

The Zambia National Health Research Act (enacted into law in 2013), provides a framework for regulation of all health-related research in Zambia through the establishment of the National Health Research Authority and the National Health Research Ethics Board in 2016 and 2017 respectively. Zambart ensures that all research conducted is in line with the research priorities established by the NHRA. In addition, Zambart is registered with the National Science and Technology Council.

The achievements included in this report would not have been possible without the support of our funders and collaborators, that include; NIH/NIAID, FHI360, International Initiative for Impact Evaluation (3ie), Bill and Melinda Gates Foundation, PSI/UNITAID, International Initiative for Impact Evaluation (3ie), Bill and Melinda Gates Foundation, PSI/UNITAID, London School of Hygiene and Tropical Medicine, DFID/Mott McDonalds/EPHSA, AERAS/GSK, PATH/USAID, SHM Foundation, ICRW – MACAIDS Foundation, Trust, University of Toronto, and Avenir Health.

I would also like to acknowledge the staff and management team for their outstanding contribution, commitment, and expertise that have made Zambart’s achievements possible.

Dr Alwyn Mwinga
The last two years have been an extremely busy but productive time for Zambart as we head towards a celebration of our current organisation’s 15th anniversary since it was incorporated as a company limited by guarantee. Developed out of a collaboration between the University of Zambia School of Medicine and the London School of Hygiene and Tropical Medicine, which started in the late 1980s, Zambart became an official organization in 2004 and has grown to become a trusted partner conducting people-centred health research. Zambart continued to build on this reputation in 2017–18, conducting many different research studies and providing a powerful insight into the health and social issues that affect Zambians and people across the globe.

Zambart’s research studies during 2017-2018 included the ongoing HPTN 071 (PopART) study, the largest HIV prevention trial ever conducted. This study has many different parts apart from the main trial and in 2017/2018 we included work on HIV-related stigma, phylogenetics, adolescents (the PopART for Youth P-ART-Y study) a trial of HIV self-testing, and a trial of different methods of delivering ART to people in the community. In November 2017 we started the TREATS (Tuberculosis reduction through expanded access to ART and TB screening) study which was developed to test whether the PopART intervention has affected tuberculosis at population-level. This study, funded by the European and Developing Countries Trials Partnership (EDCTP) allows us to work with some new partners including KNCV and the Health Systems Trust in South Africa. We also recruited some of the participants from the PopART trial into a study on the effect of genital schistosomiasis on HIV in Livingstone. Other studies apart from PopART also looked at new diagnostics for HIV, the STAR consortium looking at HIV selftesting, as well as TB, a study on diagnosing TB meningitis in severely ill patients in UTH. Zambart is one site in a large multi-centre trial of a new TB vaccine manufactured by Glaxo Smith Kline (GSK) in collaboration with Aeras. Another new study that was awarded during this period was “Yathu Yathu, For us, by us” which will allow us to use all of the learning from the P-ART-Y study as well as qualitative work from MacAIDS. We started formative work on this study in July 2018. Finally we also learned that Zambart was awarded the contract to conduct the 2019 TB Drug Resistance Survey by the Ministry of Health.

From a qualitative perspective, the social science and community engagement teams have been very involved in PopART and the different sub-studies and are working on a social science component within TREATS. Social science led the stigma ancillary study nested within PopART. This had a strong focus on health workers and their role in HIV stigma. The unit has also conducted studies to improve understanding of experiences, develop and showcase interventions of adolescents and young adults living with HIV (with funding from MacAIDS, ESRC (UK) and CIHR (Canada)), to further establish the overlap between disability, social protection and HIV (SEPO II and disability and social welfare policy review funded respectively by CIHR and the Edith Strauss Foundation) and HIV self-testing (with funding from UNIT AID and BMGF). Engagement with other UTT trials, community engagement strategies and health related stigma in the region and beyond have continued to be key areas of interests.

The breadth of our research studies is a testament to the high quality research that Zambart conducts and enhances our role as a committed partner in conducting research to improve health for all.
Key achievements for Zambart in 2017–18 include:

» successful completion of the HPTN 071/PopART study
» successful completion of MacAIDS study
» successful completion of SEPO II
» successful completion of Insaka Project
» successful completion of the Phase 1 of the STAR study leading to commencement of the Phase 2
» first release of preliminary results of the P-ART-Y study results
» release of preliminary results of the TB AERAS study
» approval and commencement of work on TREATS
» approval and commencement of formative work on Yathu Yathu
» creation of the Zambart's Wellness Team, commitment to a safe and healthy workplace to promote staff wellness and culture in the organisation.
» successful retraining of 21 senior and middle managers in leadership skills over an 12 month period

What lies ahead?

As research is the core of Zambart, the leadership of the Research Directorate has recently been expanded with the appointment of two new deputy directors, Dr Kwame Shanaube - Quantitative and Dr Musonda Simwinga - Qualitative, and is working on finalizing the Zambart research directorate strategy 2019-2025. This strategy will be the blue-print of the organisation’s direction for the next seven years building on our mission to conduct quality interdisciplinary health research on issues of public health importance in Zambia and contribute to improving health policy and practice leading to better health for all.

The staff of our organisation are critical to our success and 2018–19 will see us reinforce the role our people play in developing and maintaining the organisation as an agile organisation. We are committed to remaining relevant in the public health research sector as part of the public health sector research agenda, ensuring that our research findings can be used to inform discussion, debate and public policy.

We will build on our existing study governance framework and capabilities by increasing oversight of our studies, reviewing internal governance-related policies, and identifying opportunities to fill gaps created by the changing research and data handling landscape. We will focus on closing gaps by ensuring that our research staff are trained to keep abreast with issues relating to ethics in research as they develop.

We will continue to implement our new research and development strategy and ensure our organisation infrastructure supports the needs of the research directorate. This will include retraining and employing new staff as the need arises.

Above all, we will strengthen our attention on being an organisation at the forefront of conducting high quality health research while adhering to our key values of Excellence, Quality and Compassion.

I would like to thank the Zambart Board and Zambart Executive Director, Dr Alwyn Mwinga, for their oversight and direction during the year, and extend my heartfelt thanks to Zambart staff, whose dedication, passion and expertise are the foundations on which the organisation is built.

Prof. Helen Ayles
Director of Research
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In brief

Our Vision
To contribute to global public policy and practice through the generation of an evidence base by conducting high quality health research in Zambia

Our Mission
To conduct quality inter disciplinary health research on issues of public health importance in Zambia and contribute to improving health policy and practice leading to better health for all

Our values
Zambart’s key values are Excellence, Quality and Compassion.

Key elements underpinning all of the strategic priorities of the research directorate are excellence, quality and compassion. Zambart aims to conduct all of its activities to the highest standards of research and ethics. The motivation for all that Zambart does is to improve the health of the people of Zambia and the rest of the world.

Our strategic goals
Over the next 5 years, we will apply and strengthen our capabilities to:
1. Strengthen existing areas and Expand beyond HIV & TB into other areas of health research
2. Develop strong strategic Partnership: Strengthening existing partnerships and developing new ones
3. Develop great Global Reputation: being visible and well known locally, regionally and globally
4. Have demonstrable Policy Impact & Influence: Locally and internationally
5. Ensure financial Sustainability
6. Develop a robust Training and Consultancy arm: a self-sustaining business providing services to others
7. Be a great place to work

Our organisation
The Companies Act of 2017 is our enabling legislation and establishes the Zambart Board which is the organisation’s governing body. Further information about how we operate and the role and composition of the Senior Management Team are specified in Chapter 4 Our organisation.

The board is responsible for setting the overall policy and strategic directions of the organisation. For planning purposes, Zambart prepares a corporate plan and budget estimates as required by the Act. The Executive Director manages the day-to-day affairs of the organisation with the assistance of the Director of Research and a Senior Management Team.

For reporting purposes, it prepares an annual report an annual performance statement, also as required by the Act. All of the work we undertake is subject to ethical clearance by the various local and international Ethics Committees.
Stakeholders

Our stakeholders are important to us as groups to which we are accountable, who fund us, and to whom we target our studies. They include:

» The people of Zambia
» The Zambia Government through the Ministry of Health and its departments and agencies
» Provincial and district health administrations and their departments with responsibilities for health and community services, education and justice
» Public health service providers, professionals and non-government organisations
» Consumers of public health assistance services
» The research community.

Zambart collaborates closely and has effective partnerships with many individual government entities, universities, research centres, non-government organisations and individual experts throughout the country. More details on our collaborative partners are provided in Chapter 4 Our organisation on page 57.

Over the last 2 years, Zambart has been receiving feedback from participants in our studies to gain insight into the perceptions of our stakeholders. Overall, the feedback provided positive results and evidence that Zambart is achieving its strategic objectives. Further details of the feedback are provided in Chapter 1 Our studies on page 4

International partnerships

Zambart developed out of a strong partnership between the London School of Hygiene and Tropical Medicine and the University of Zambia, School of Medicine. The strong partnership between Zambart and the two institutions has continued to grow. In May, 2018, Zambart signed a Memorandum of Understanding with the University of Zambia School of Public Health which aims to further strengthen our relationship in the areas of research capacity building through provision of opportunities to engage in research, and through attachments, internship, undergraduate, post-graduate and post doctoral training and research opportunities.

Zambart has also enjoyed strong partnerships with other institutions including Stellenbosch University, Imperial College, HPTN, International Centre for Research on Women and the Universities of Toronto and McMaster. Zambart is committed to developing new partnerships with organisations that share a similar goal of conducting high impact public health research to improve health for all.

Zambart would like to acknowledge the contribution and support of some of our funders and partners over the last two years:

Funders

International Initiative for Impact Evaluation (3IE)
European and Developing Countries Clinical Trials Project II
Medical Research Council- UK
National Institute of Health, USA
Bill & Melinda Gates Foundation
Implementing Partners

AERAS
Avenir Health
Beth Israel Deaconess Medical Centre
Delft Imaging Systems, Netherlands
Desmond Tutu TB Centre- Stellenbosch University
Family Health International 360 (FHI360)
Imperial College
Johns Hopkins University
KNCV
London School of Hygiene and Tropical Medicines (LSHTM)
Ministry of Health, Zambia
PATH Zambia
Population Council, Zambia
Qiagen
SHM Foundation
Sheffield University
The TB UNION
The University of Toronto and McMaster
The University of Zambia, School of Public Health
University of Cape Town
University Teaching Hospital, Lusaka

If we failed to mention your contribution to our organisation, please bear with us. We appreciate you.
Chapter 1 - Our Studies

TREATS

Started in November 2017 and officially launched in March 2018, the TREATS (Tuberculosis reduction through expanded access to ART and TB screening) study was developed to measure the impact of a combination TB and HIV intervention when delivered to the entire population of 14 urban, high-prevalence communities in South Africa and Zambia.

Background

TB and HIV are the leading infectious causes of death worldwide – in 2016 1.7 million people died of TB with sub-Saharan Africa being significantly affected. For people living with HIV, TB is the most significant co-infection, 40 percent of HIV deaths in 2016 were due to TB. The TREATS project [Tuberculosis Reduction through Expanded Anti-retroviral Treatment and Screening] was developed in response to this.

TREATS aims to inform new policies and approaches for tackling the TB / HIV epidemic. As the global health community works towards ambitious new goals to end TB, TREATS will provide invaluable new information for accelerating effective interventions.

TREATS is being conducted by a consortium of organisations, some of whom were part of the largest ever trial of a combination HIV prevention strategy, known as HPTN 071 (PopART). This trial is being conducted across 21 communities in Zambia and South Africa, covering around one million people in total. PopART involves universal testing and treatment for HIV through house-to-house visits on an annual basis over four years – from 2014 – 2018. As part of PopART, all community members are also screened for TB.

Building on PopART, TREATS will measure the impact of this combined TB / HIV intervention on tuberculosis – measuring prevalence of disease as well as incidence of infection. The project runs until 2021 and includes: a social science component to better understand stigma related to TB; mathematical and economic modelling to provide answers for how future large-scale interventions can be undertaken effectively; use of the newest tools available for diagnosing TB infection and operating effectively on a large scale.

In Zambia, the study communities are spread across 4 provinces and 6 districts namely Kitwe and Ndola on the Copperbelt Province, Kabwe in Central Province, Lusaka in Lusaka Province and Choma and Livingstone in Southern Province.

The study objectives are:

1. To investigate the effect of active case finding for TB and universal testing and treatment for HIV on:
   - Notified TB incidence
   - The clinical characteristics and treatment outcomes of notified TB cases
2. Investigate the association between the uptake of active case finding for TB and universal testing and treatment for HIV in the intervention communities, on notified TB incidence
3. Explore the characteristics of TB cases identified by and missed by the active case finding strategy in the intervention communities.
Research Components

Incidence of infection cohort

In Zambia, the incidence of infection cohort was activated in the last quarter of 2017 when the incidence cohort study manual was developed and preliminary work on the study procedure manual for Infection Cohort was conducted. In the first part of 2018, the team aimed to recruit the "Infection cohort". Three hundred adolescents and young adults (15-24 years of age) will be recruited in each community (total 4200) over a period of 4-6 months. This cohort will be followed up for a total period of 24 months each with phone contact every 6 months and 2 annual visits. The last follow up visit will be completed in 2020.

Recruitment progressed steadily and enrolment was completed on Dec 7, 2018.

TB Prevalence Survey

The "TB Prevalence survey" will start in 2019 with the aim of completing the survey within all 14 communities by the end of 2019.

Quantitative component

The overall aim of this study is to investigate the effect of the HPTN 071 intervention (active case finding for TB and universal testing and treatment for HIV) on TB epidemiology. Routine health centre data and HPTN 071 research data from the Zambian and South African HPTN 071 communities (14 intervention and 7 control communities) over the study period (2013-2018) will be used. Routine health centre data comprise TB treatment register data and presumptive TB register data. HPTN 071 research data comprise Population Cohort data (a research cohort of young adults aged 18-44 years, who were followed up annually over 36 months to address the primary objective of HPTN 071) and CHiPs intervention data.
This study started in January 2017 and is expected to run to December 2019. To date routine health centre TB data from all Zambian communities (which are in paper form) over the study period have been collected, with double data entry and validation in progress. Requests to access routine health centre data in South Africa (which is electronic) have been submitted.

**Qualitative component**

**Implementation science and qualitative research**

Recruitment of local social science research assistants was conducted. Qualitative data collected in Zambia during 2017 which observed CHIPs screening for TB and TB corners was reviewed and rapidly analysed to present some findings at the November meeting. Both qualitative and quantitative research tools were developed on TB prevalence and stigma as well as a TB data base. All activities started prior to TREATS.

TREATS consortium members include: London School of Hygiene & Tropical Medicine, Imperial College London, Zambart, KNCV Tuberculosis Foundation, Sheffield University, the International Union Against Tuberculosis and Lung Disease (The Union), Health Systems Trust, Delft Imaging Systems and QIAGEN.

The EUR 12.9 million project is part of the [European & Developing Countries Clinical Trials Partnership](https://edctp.europa.eu/) (EDCTP2 programme) supported by the European Union under Horizon 2020 – its Framework Programme for Research and Innovation.

**Community engagement**

is active in the TREATS study. For full details, kindly turn to page 30 under social science and community engagement.

**Funders**

[European & Developing Countries Clinical Trials Partnership](https://edctp.europa.eu/)

**Implementing Partners**

[London School of Hygiene & Tropical Medicine](https://www.lshtm.ac.uk/)
[Zambart](https://www.zambart.org/)
[KNCV Tuberculosis Foundation](https://www.kncv.org/)
[QIAGEN](https://www.qiagen.com/)
[Health Systems Trust](https://www.healthsystemstrust.org/)
[Imperial College London](https://www.imperial.ac.uk/)
[The University of Sheffield](https://www.sheffield.ac.uk/)
[International Union Against Tuberculosis and Lung Disease (The Union)](https://www.theunion.org/)
[Delft Imaging Systems](https://www.delftimaging.com/)
[Health Systems Trust](https://www.healthsystemstrust.org/)

In August 2017, Zambart commenced the second phase of HIV self-testing (HIVST) study, the HIV Self-testing Africa phase II (STAR II). STAR II is expected to continue until August, 2019. The aim of STAR II is to address low uptake of HIV testing by increasing the effective use of HIVST and to support access to HIV care, treatment and preventive services. In this study, Zambart has continued to work together with other partners to conduct STAR II activities. Among the partners include Society for Family Health (SFH) and Ministry of Health staff who are leading the implementation of HIVST kit distribution using different models, London School of Hygiene and Tropical Medicine (LSHTM), population services international (PSI), World Health Organization, and Liverpool School of tropical Medicine. STAR II is being conducted in 50 peri-urban and rural communities across Zambia.

In STAR II, Zambart has developed case studies of four promising models of HIVST distribution. The purpose of these case studies is to conduct an in-depth evaluation of the process of distributing HIVST through the four models. The case studies aim to understand user and provider experiences of HIVST distribution, contextual factors that affect HIVST distribution, to measure the cost of distribution, and determine who is reached if the distribution model is to deliver an HIVST to an index individual for distribution to their partner (termed secondary distribution of HIVST). The HIVST distribution models that are being evaluated included: 1) community-led distribution through community structures such as small shops, 2) the workplace model, 3) secondary distribution of HIVST through antenatal care (ANC) and 4) secondary distribution of HIVST through HIV positive individuals attending HIV testing and treatment services.
In the **two secondary distribution models** the study will also explore factors associated with successful secondary distribution of test kits. We will interview individuals who will accepted an offer of an HIVST kit for secondary distribution at two time points (after the clinical consultation and approximately 1-month after the initial interview). We also follow-up intended users of the HIVST kits approximately 3-months after distribution to measure linkage to confirmatory testing, HIV care or prevention services.

Qualitative data will provide understanding of contextual factors that mediated people’s choices and behaviour. The qualitative research will explore the following themes:

In October, 2018, the Zambart STAR team reoriented and trained the field research assistants. Data collection begun with implementation of participatory activities through community consultation processes and stakeholder discussion. We worked with SFH and MoH staff to successfully recruit two groups of individuals who were offered and HIVST for secondary distribution to their partners. The first group included individuals aged 16 years and older attending ANC at George clinic where as the second group included HIV positive individuals who were offered an HIVST kit for secondary distribution at George and Matero level 1 hospital. At the point of recruitment in the group, individuals responded to the baseline questionnaire that included questions related to history of HIV testing and reasons for accepting or not accepting an offer of HIVST for secondary distribution. During the period under review, we also collected data using individual in-depth and group interviews, mapping, and observation of HIVST distribution.

**Outlook for 2019**

In 2019, our primary focus will be to complete the recruitment of individuals into the two groups until we reach the targeted numbers of approximately 450 individuals per group. The study team will also follow-up individuals recruited in the two groups after 1 month of the initial interview to measure the use of HIVST kits distributed through secondary distribution. Approximately after 3 months of the first interview, we will also follow-up the interned users to measure linkage to confirmatory testing, HIV care or preventive services.

We expected to finish data collection in June, 2019 after which the study teams will start data analysis and report writing. The findings of this study will disseminated at site, national and international level.

This study was made possible with funding from:

![Unitaid](logo.png)

Implementing partners:

- PSI
- World Health Organization
- London School of Hygiene and Tropical Medicine
- LSTM
- UCL
USAID Eradicate Tuberculosis (ETB) Project

Zambart is one of the six (6) consortium members of the five-year (2017 -2022) USAID sponsored Eradicate TB (ETB) Project. The lead partner on this project is PATH-Zambia. Other partners include Afya Mzuri, CITAM++, African Society for Laboratory Medicine (ASLM), and Initiatives Inc.

ETB works in partnership with the Ministry of Health (MoH), through the National TB and Leprosy Program (NTLP), to strengthen the national response to control TB in Zambia. The project works in six provinces—Central, Copperbelt, Luapula, Muchinga, North-Western, and Northern. Zambart’s role on this project is to build the capacity of MoH provincial and district-level staff to conduct operational research (OR) on TB service delivery within their local context. Two Zambart staff are working on the ETB project. A summary of ETB-Zambarts 3 key achievements from 2017-18 is presented below.

1. **Training and mentoring District level staff to conduct OR studies**

In 2018, the ETB-Zambart team trained and supported 4 districts (Mpulungu, Chingola, Ndola and Kapiri Mposhi) to conduct OR studies which interrogated their TB service delivery systems. These high-TB burden districts were invited to a meeting to identify their local TB research priorities, in line with the national TB-related OR priority areas.

Next, district teams (including TB focal persons, Clinical Care Officers, and Biomedical Specialists) developed their research proposals during a 10-day workshop in January 2018. The four research proposals successfully passed through an extensive review process by various stakeholders that included PATH Headquarters in Seattle, USAID-Zambia, University of Zambia Biomedical Research Ethics Committee (UNZABREC) and the Ministry of Health, through the National Health Research Authority (NHRA). ETB staff supported the four districts to collect data and provided guidance to analyze their data and write a study report. The 10-day data analysis and report writing workshop took place in December 2018. All four districts completed their studies and the findings are ready for dissemination to stakeholders. See table XX for the titles of these studies.
<table>
<thead>
<tr>
<th>District</th>
<th>Operational Research Study Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chingola</td>
<td>Identification of Risk Factors for Unfavorable Tuberculosis Treatment Outcomes among Patients from January to June 2017 in Chingola District, Zambia</td>
</tr>
<tr>
<td>Kapiri Mposhi</td>
<td>Adult TB care reporting cascade in 4 TB diagnostic centers in Kapiri Mposhi, Zambia, July – December 2017</td>
</tr>
<tr>
<td>Mpulungu</td>
<td>Investigation of staff and non-staff-related factors contributing to low sputum sample referrals in Mpulungu District, Northern Province, Zambia</td>
</tr>
<tr>
<td>Ndola</td>
<td>Investigating leakages in the pediatric TB care cascade through examination of patient records from point of entry to the point of TB notification: a case study of Ndola District</td>
</tr>
</tbody>
</table>

2. **Support 8th Zambia National Health Research Conference (ZNHRC)**

More than 1,000 delegates from across the globe gathered in Lusaka for Zambia’s 8th Health Research Conference, organized by the National Health Research Authority (NHRA). The conference, whose theme was, “Breaking new ground in health research: Moving from results to implementation—without leaving anyone behind,” took place from October 15-17, 2018.

Prior to the conference, ETB-Zambart staff attended planning meetings and reviewed abstracts as members of the scientific subcommittee. ETB also funded 54 participants from the six project-supported provinces to attend the conference, including 13 trainees from the four districts implementing OR projects.

The project also supported a five-hour symposium on “Finding the Missing TB Cases,” which consisted of 14 oral presentations by key stakeholders spread out over three days. ETB’s Chief of Party Dr. Joseph Nikisi and Zambart CEO, Dr. Alwyn Mwinga made separate presentations on, “Mass screening for tuberculosis during special days” and “role of the community in TB control”, respectively. The ETB-Zambart team also presented a poster about the OR training program titled, “When locals lead—empowering districts to set their own TB operational research agenda: Success story from the USAID Eradicate TB project.”

In a thank-you letter to ETB’s Chief of Party, Dr. Godfrey Biemba, the NHRA Executive Director, said:

“...Because of your support, we were able to host a successful conference for three days. We had over 1,200 people attend the conference, which wouldn’t have been possible without your support.”

3. **Operational research advocacy meeting with the mining companies**

An additional mandate for Zambart on the ETB project is to lobby and advocate for funding and support of TB OR by the private sector. On 26th April 2018, the ETB-Zambart team held an advocacy meeting with representatives of mining companies in Copperbelt province. Twenty-seven participants representing three mining companies (Mopani, KCM, Luanshya) including medical superintendents for four mine hospitals (Konkola, Nchanga, Wusakile, and Luanshya) and their respective TB focal persons, attended this meeting. Also, in attendance were representatives of the National Health Research Authority (NHRA), Mine Workers Union of Zambia (MWUZ) and the national Occupational Health and Safety Institute. Each of the three mining companies identified their priority areas for TB-related OR.
HPTN 071 (PopART) Study

HPTN 071 - Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART) is a research study that examined the impact of a package of HIV prevention interventions on community level HIV incidence. The prevention interventions included universal voluntary HIV counseling and testing provided at household level, linkage of HIV infected individuals to care and early initiation of antiretroviral therapy (ART) for all those testing HIV-positive. The study was conducted in 21 communities in the Western Cape of South Africa, and in Zambia.

Who participated in the study?

21 urban and peri-urban communities in Zambia and South Africa, with a total population of around 1 million, participated in this study. To measure the impact of the intervention, a research cohort called the Population Cohort, consisting of a sample of approximately 2,300 adults aged 18–44 years, was recruited from the general population of each of the 21 communities (an overall total of 48,302 across all communities) and was followed up once a year for three years to measure HIV incidence and other outcomes.

Why did the HPTN conduct this study?

HIV incidence rates remain at very high levels in many parts of southern Africa. There is an urgent need for more effective HIV prevention strategies. Currently there are still nearly 2 million new HIV infections every year. More effective prevention strategies are needed to steeply reduce the number of new HIV infections and to ensure that care can be provided for all people living with HIV. Findings from HPTN 071 (PopART) will help inform the scale-up of future HIV programs and identify cost-effective interventions.

Three Arm Cluster Randomized Trial with 21 Communities (Original Study Design)

In total 21 communities participated in the HPTN071 (PopART) trial. In Zambia, 12 communities participated in the study. The 12 communities were divided into four matched “triplets” of three communities each. The triplets were composed of communities that had been matched so all three had similar estimated HIV prevalence, to minimize the variability in baseline HIV
incidence within the triplet. Then each community in the triplet was randomly assigned to one of three study arms: A, B or C. Arm A received the full PopART HIV combination prevention package including the offer of immediate ART, Arm B received the PopART package, but with ART only offered to those eligible according to national guidelines, and Arm C communities had no household intervention but could access HIV testing and treatment services according to the local standard of care.

### Study Communities in Zambia (PopART Triplets)

<table>
<thead>
<tr>
<th>Southern Province</th>
<th>Lusaka</th>
<th>Ndola</th>
<th>Kitwe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dambwa (A)</td>
<td>Chipata (A)</td>
<td>Chipulkusu (A)</td>
<td>Ndeke (A)</td>
</tr>
<tr>
<td>Maramba (B)</td>
<td>Kanyama (B)</td>
<td>Makululu (B)</td>
<td>Chimwemwe (B)</td>
</tr>
<tr>
<td>Shampande (C)</td>
<td>Chawama (C)</td>
<td>Chifubu (C)</td>
<td>Ngungu (C)</td>
</tr>
</tbody>
</table>

### PopART intervention in Arms A and B

The PopART HIV prevention combination package in Arms A and B was delivered throughout the study community by community HIV care providers (CHiPs) who were specially trained lay counsellors. The CHiPs worked in pairs, each pair responsible for delivering services to a zone consisting of around 500 households. CHiPs teams were tasked with visiting every household at least once a year for the duration of the trial, and provided the following services:

- Offering voluntary HIV counseling and testing annually through a house-to-house campaign
- Linking those with HIV to care at the local health center
- Follow-up visits to HIV-positive clients to ensure they had linked to care and to support retention and ART adherence
- Promoting voluntary medical male circumcision for men who tested HIV-negative
- Promoting services for the prevention of mother-to-child transmission (PMTCT) to HIV-infected pregnant women
- Referring for treatment of sexually transmitted infections
- Providing condoms in the community
- Screening and referral for tuberculosis (TB)

HIV care and ART were provided at the local government clinic serving that community. In Arm A, all HIV positive patients were offered ART irrespective of CD4 count or clinical stage. In Arm B, ART was initiated according to local guidelines. Initially this was at a CD4 count of 350, then later this changed to 500, and in 2016, following a change in WHO recommendations, ART was offered to all HIV-positive patients as in Arm A.

### Study objectives

The primary study outcome was HIV incidence between month 12 and month 36 amongst members of the Population Cohort who were HIV-negative at baseline, comparing HIV incidence across the three study arms (A vs C and B vs C). This allowed the effectiveness of the PopART intervention at population level to be measured.
Data to investigate secondary objectives were drawn from Population Cohort data as well as data from Community HIV-care Providers (CHiPs), health centers and social science research. These objectives assess the effect of the intervention on several additional variables, including:

- HIV incidence during each year of follow-up
- Community viral load
- HSV-2 incidence
- ART (drug use) and viral suppression
- HIV disease progression and death
- ART drug resistance
- ART toxicity
- Acceptance of HIV testing and re-testing
- Sexual risk behavior
- Uptake of medical male circumcision among HIV-uninfected men
- Case notification rate of tuberculosis
- ART screening and uptake
- HIV-related stigma
- Uptake of PMTCT services
- Retention in care

Three other trials were conducted in Southern Africa to investigate the impact of UTT on HIV incidence, at approximately the same time as HTPN 071 (PopART). These were: a) ANRS 1229/TasP (Treatment as Prevention), a 2 arm community-randomized trial undertaken in rural communities in KwaZulu Natal in South Africa b) The Sustainable East Africa Research in Community Health (SEARCH) study, was a 2 arm community randomized trial in rural communities in Uganda and Kenya and c) The Botswana Combination Prevention Project (BCPP) (also known as Ya Tsie) also a 2 arm community randomized trial undertaken in rural communities in Botswana.

HPTN071 (PopART) differed from the other trials in the following ways:

a) The PopART communities were large urban or peri-urban communities whereas the other trials were in smaller rural communities

b) HIV incidence was measured in a separately recruited population cohort in PopART and Ya Tsie whilst in TasP and SEARCH incidence was measured through the intervention.

c) In PopART and Ya Tsie, the control communities did not receive any additional intervention outside of current standard care whilst in SEARCH and TasP the control communities received enhanced community-wide HIV services, particularly for HIV testing and linkage to care, probably explaining the lack of observed difference between the intervention and control arms.

The study was conducted by the NIH-funded HIV Prevention Trials Network (HPTN). The study was led by investigators at the London School of Hygiene and Tropical Medicine (LSHTM) in collaboration with Imperial College London, the University of Oxford, Zambart and the Desmond Tutu TB Centre (DTTC) at Stellenbosch University, South Africa.
The study results will be announced at the Conference on Retroviruses and Opportunistic Infections (CROI). CROI 2019 will be held from March 4 to March 7, 2019, at the Washington State Convention Center in Seattle, Washington, and subsequently on the Zambart website http://www.zambart.org.zm.

Additional study analysis is underway examining other study outcome measures including herpes simplex virus -2 (HSV-2) incidence, tuberculosis (TB) reduction through ART and TB screening, and ART delivery among participants living with HIV, Phylogenetics, Stigma, Modelling, Health Economic and qualitative components of the study.

Funding

This study was sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) with funding from the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR). Additional funding was provided by the International Initiative for Impact Evaluation (3ie) with support from the Bill & Melinda Gates Foundation, as well as by NIAID, the National Institute on Drug Abuse (NIDA) and the National Institute of Mental Health (NIMH), all part of NIH.
PopART for Youth (P-ART-Y) also referred to as the Adolescents study was nested within the HPTN 071/PopART (Population Effects of Antiretroviral Treatment to Reduce HIV Transmission) trial. P-ART-Y aimed to evaluate the acceptability and uptake of a community level combination HIV prevention package that includes universal test and treat among young people aged 10 to 24 years in Zambia and South Africa with a primary focus on the 15 to 19 year olds. In all communities, adolescents and young people living with HIV were eligible to receive ART regardless of CD4 count.

The study was implemented for 26 months from November 2016 to December 2017.

In 2017 the P-ART-Y study’s main activity was conducting the Cross Sectional Survey from July to November. The purpose of the study was to compare knowledge of HIV status in standard of care study communities and other key process data with the intervention communities. The study optimized the SAG recommendations given at the start of the study by effecting school based activities which included offering HTC services for the first time in our study communities.

**Study Advisory Group recommendations**
- Community activities and mobilization
- School activities
- Employing youth counselors
- Providing support towards the youth friendly spaces at health facility and community level
- Developing targeted messages for parents, young people, Adolescent Community Advisory Boards (ACABs) and mainstream PopART Community Advisory Boards (CABs), as well as training of the intervention staff in adolescent friendly services

Other key activities included community mobilization activities aimed at promoting behavioral change among the adolescents and youths. The activities were delivered through schools, community sensitization and health facilities in study communities and through national events.

**Quantitative and Qualitative Research**

Quantitative research measured the uptake of the intervention and also compared the uptake of HIV testing in intervention and control communities. Qualitative research for P-ART-Y consisted of a pre-intervention phase that drew on observations of adolescent gathering places, social science community data and a stakeholder survey collected prior to the study to inform the intervention design; and an intervention phase observing youth-targeted interventions and following a small group of 23 young people who had made different decisions about HIV for a year.

**Key Findings**

**UPTAKE OF HIV TESTING**
- Door-to-door HIV testing services was well accepted by adolescents aged 10-19 years old with over 80% of those participating in the PopART intervention accepting HIV testing.
- No significant gender differences were seen in acceptance of HIV testing services. (Fig 2). It was challenging to find older adolescent males at home during the intervention compared
to females. This was largely due to male involvement in economic or income generation activities.

- More than 95% of adolescents are HIV negative (Fig 3)
- Qualitative data showed that HIV testing among adolescents below the age of consent was a prerogative of parents/guardians and thus led to a number of missed HIV testing opportunities due to refusing to allow adolescents to test. For example, one mother said of a 14 year old son, “The child does not know anything. The child does not know about HIV and he will test when he is old enough”.

**UPTAKE OF OTHER HIV PREVENTION OPTIONS**

- Young people found it uncomfortable to access condoms in the presence of adults at home due to cultural norms. Young people were aware of male and female condoms, but consistent use was a challenge due to issues of trust, pleasure and different types of relationship. For example, condoms were reported as used less used in ‘steady’ relationships.
- Awareness of treatment as prevention (TASP) continues to be low among young people living with HIV and HIV-negative young people.

**POLICY RECOMMENDATIONS**

1. Most Zambian adolescents are HIV negative (>95%) and we need to do more to keep them this way by strengthening access to HIV testing and preventative programs such as voluntary medical male circumcision (VMMC) as well as making condoms more available in places they feel safe to access them.
2. Adolescents living with HIV link to care at the same pace as older adults but services are lacking to assist retention.
3. More interventions are needed to ensure that young women living with HIV aged 15-19 years old are supported to link into care and subsequently improve the second 90.
4. Resource allocation to Comprehensive Sexual Education (CSE) should be increased as our data show that schools are the most popular sources of information.
5. Government should consider providing HIV testing and provision of sexual and reproductive health rights (SRHR) services within schools.
6. Government should consider reducing the legal age of consent for HIV testing services and other SRHR services from the current age of 16 years to 12 years as is the case for South Africa.
7. Provide youth friendly/safe spaces in the community and health centres for young people to collect condoms and other SRHR service

**Funding**

P-ART-Y was funded through the Evidence for HIV Prevention in Southern Africa (EPHSA), which supports an effective and efficient HIV prevention response in sub-Saharan Africa. EPHSA is funded by UK AID from the Department for International Development (DFID) and Sweden, through the Swedish International Development Agency (SIDA), mandated to represent the Norwegian Agency for Development Cooperation (NORAD). The programme was managed by Mott MacDonald.
The Phylogenetic Study, an ancillary study to the main HPTN 071 (PopART) trial was aimed at examining patterns of HIV transmission on a population level and identify factors associated with HIV transmission in all the 12 HPTN 071 study communities in Zambia. The study aimed to identify demographic, clinical and epidemiological factors that contribute to HIV transmission and evaluate the prevalence and spread of antiretroviral drug resistance in the study communities.

This was one of the first very large scale studies using state of the art molecular technologies to analyse the impact of interventions for HIV prevention on a population level and samples and data were collected from two overlapping sources from the HPTN 071 trial communities.

The study was activated in July 2016 and ended in July 2018. The study recruited 5,648 patients from health care facilities and 12,265 participants from the HPTN 071 Population Cohort participants. 2 year study; study activated July 2016; ended July 2018

Phylogenetic study in numbers

Phylo HCF

<table>
<thead>
<tr>
<th>Sex/Category</th>
<th>Yes consents</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>Male</td>
<td>2447</td>
<td>5692</td>
</tr>
<tr>
<td>Female</td>
<td>3245</td>
<td></td>
</tr>
<tr>
<td>Adolescents</td>
<td>00 (eligibility was 18 and above)</td>
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</table>

Phylo-PC

<table>
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<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
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<td>590</td>
<td>2317</td>
</tr>
<tr>
<td>Female</td>
<td>1727</td>
<td></td>
</tr>
<tr>
<td>Adolescents</td>
<td>00 (eligibility was 18 and above)</td>
<td></td>
</tr>
</tbody>
</table>

The information obtained from this study will be used to help guide future studies and public health prevention programs that build on the results of the HPTN071 (PopART) trial to optimize community-based approaches for HIV prevention.

The study had recruited one research assistant and Laboratory technician in each community and participation in the communities were overwhelming as there was a lot of community engagement and sensitization prior to the start and during the study. Researchers from Zambart and the London School of Hygiene and tropical Medicine and partners including Imperial College London and the University of Oxford worked closely on this trial with colleagues from the HIV Prevention trial Network (HPTN). This study was funded by the US National Institutes of Health, office of the United States Global AIDS Coordinator, and the Bill and Melinda Gates Foundation.
The Community ART study was an ancillary study to the main HPTN 071 (PopART) study that was comparing different models of ART delivery amongst stable HIV+ patients in two urban settings in Zambia. Although community models of ART delivery have shown promising outcomes in relation to care and adherence to treatment, additional data is required from innovative community based models of care to support long term retention in care as number of patients now on treatment has increased in the context of universal treatment. to try and reduce frequent clinic visits for drug pickups, thus reducing patient waiting time and congestion in the clinic and transport.

Community models of ART delivery are aimed toward stable patients’ costs to the clinic. However it is still not known whether these models of care are feasible in urban resource limited settings or whether care will be as good as the standard quality care provided by local health facilities and therefore conducting this study is innovative as it will be a first study in an urban setting to rigorously evaluate different models of ART delivery and information obtained will be critical for the continued scale up of differential service delivery models and also provide policy makers with evidence on operational feasibility, acceptability and cost-effectiveness of HIV delivery models.

The study was being conducted in 2 HPTN 071 urban communities and comparing 2 models of care (Home based ART delivery and Adherence clubs) to the standard of care. The primary objective of the study is to compare viral suppression at 12 months in HIV+ patients receiving care via community ART models with those receiving care in the clinic (standard of care). The secondary objectives is to compare the two models of care with the standard of care with respect to retention to treatment, feasibility, lost-to-follow-up, acceptability and cost effectiveness of the models of care.

The two models of care include Home delivery where patients are visited in their homes by community HIV providers (CHiPS) who offer adherence support, counselling and deliver pre-packed medications for 3 months. In the clubs a group of 20-30 patients meet at a selected venue in the community where CHiPs provide adherence counselling and deliver pre-packed drugs. In both models Patients only have to go to the clinic once every 6 months for their clinical review and laboratory tests.

*850 patients were enrolled in home visits and 840 in the adherence clubs.*

The study started recruitment in May 2017 and stopped recruiting in December 2017. We have recruited over 2500 patients across both communities and currently followed these patients in the respective models of care up to April 2019.
Every three months, the CHiPs delivered my medication to my house. This helped me to get permission in advance from my employer and was less stressful because I didn’t have to worry about missing work. They also offered me counselling and other services. This encouraged me to take my medication every day.

1 Participant, Chipata

This study changed my life. Belonging to the adherence club made me realize that I was not alone and that I could get support from the CHiPs and also from the other club members anytime. The support I received was very important in my journey to stay on course with taking my medication.

2 Participant, Kanyama

There was an overwhelming response from the community as these models of ART delivery allowed patients to receive their adherence support and pre-packed medications either in their homes or clubs as these models reduced patients’ costs and time travelling to the clinic.

The study will end in April 2019 and analysis will be done to determine the patient outcomes, feasibility and cost effectiveness of the different models of ART delivery.

PI: Dr Mohammed Limbada, Study Manager Community ART

This study has been innovative and exciting from the beginning as stable HIV+ patients on treatment showed a lot of enthusiasm taking part in the models of ART delivery. We had over 97% of patients who were eligible accepting to take part in this study and showing high preferences towards different models of ART delivery outside the health care facilities.
**BILHARZIA and HIV (BILHIV) study**

**Introduction**

The BILHIV Study was an ancillary study to the main HPTN 071 (PopART) study that was aimed at testing the performance of home-based self-sampling procedures for the detection of Schistosoma haematobium DNA and validate new molecular diagnostic assays to accurately diagnose female genital schistosomiasis (FGS) in Zambian women with high HIV co-infection.

FGS affects over 45 million women worldwide and mostly in sub-Saharan Africa and is caused by the waterborne parasite Schistosoma haematobium. FGS constitutes egg entrapment in the vagina, cervix, uterus, fallopian tubes and/or vulva. Disease of the genital tract is caused by inflammation from egg-deposition that leads to erosion of the mucous and granulomatous reaction. The genital sores (lesions) of FGS are distinctive and identifiable. Diagnosis is challenging, as it relies on expensive equipment that is rarely available in resource limited areas. Women who have been treated at least once in their lifetime for FGS have been found to have 50% less FGS later on in life and efficient treatment of schistosomiasis has been suggested to decrease the number of new HIV infections by 16-20%.

**Sites and duration**

BILHIV study was implemented in two Livingstone PopART communities. Study activities started on the 10th of January 2018. This was immediately after the training that encompassed 6 BILHIV Community Workers (BCWs), 1 Livingstone Zambart laboratory staff and 3 Livingstone Central Hospital cancer clinic staff. All trained BILHIV staff were equipped with knowledge and skill to perform their daily duties.

At inception, data collection was planned for six months from January to June 2018. However, this was later extended for two months (January to August 2018). Eligible age group was also revised, and ethical approval was obtained to change recruitment age from 18 – 24 to 18-31 years. The reason for adjusting both the study duration and the age of the participant was to enable the study to enrol as many women as possible.

**Participant Recruitment**

Recruitment was restricted to women already recruited in Population Cohort (PC) of the PopART study.

A total of 1,104 PC participants were eligible for BILHIV study and of these, 3.6% (40/1104) declined to be in the study at PC 36 visit (end of PC study), 189 were women that could not be recruited in one community despite being eligible because recruitment was stopped and 875 (79.3%) were screened for recruitment. Among those screened for recruitment, 272 were not recruited due various exclusion criteria which include but not limited to relocating out of the study site, aged 32 years and above at the time of recruitment, pregnancy, travelling out of town at the time of first recruitment, failure to locate certain households, declining to participate in the study.
Of the 603 women recruited, 87.4% (527/603) completed all procedures (both home and clinic visits). Total of 12.6% (76/603) did not attend clinic. Among those who did not attend clinic, 9 withdrew consent, 8 were pregnant at clinic follow up visit, 17 relocated, 3 were stopped by family members, 17 fails, 13 declined clinic appointment, 6 had work/school conflicting schedules and 3 did not give reasons for not attending clinic.

**BILHIV Specimen**

1. Urine specimens 603
   - Urinalysis and microscopic examination were performed on all urine specimen submitted.
   - Every 10th slide was packed and sent for quality assurance (both positive and negative slides).

2. Vaginal swabs 603

3. Cervical swabs 603

4. Vaginal lavage 527

5. High resolution images 527
   - All images were successfully uploaded.

**Study outcome**

The study outcome will be shared soon after processing all specimens and data analysis.
Post PopART Hubs

The post PopART intervention hubs were a scaled down version of the PopART intervention implemented through selected points within the community. Community HIV-care Providers (CHiPs) and their Supervisors were recruited from amongst those who had worked during the PopART intervention due to their past experience. Training was done for all staff in the health facility (? Is this correct?) to introduce the concept of the hubs and how to capture data.

The community and other stakeholders such as Ministry of Health and other government line ministries, Community Advisory Boards (CABs) and PopART implementation partners were engaged on how to provide services through the hubs. These consultative discussions were held during PopART intervention close out and dissemination meetings. The feedback gained from the community and stakeholders suggested that hubs should be located in easily accessible locations in the community. Where hubs received low uptake, they were re-located to try and improve usage. As such, the hubs were static entities but not permanent and responsiveness to community feedback was key in deciding the location of the hubs.

Services clients sought for at the hub

The majority of clients who visited community hubs came for HIV testing and collection of condoms. Oral HIV self-test kits (HIVST) was the preferred method for testing compared to the traditional rapid finger pricking method. From April to October, 2018 106,151 clients visited the hub with 95.70% (n=101,587) testing for HIV.

![Client reached with HIV prevention services](image)

Some clients came to the hubs on their own volition and others needed to be mobilized from the community via door to door visits for them to make a decision to come and access hub services. This effort witnessed an increase in the uptake of our services by men both adults and adolescents. Overall 63% of clients seen were males. Adolescents discussed issues more freely and openly at the hub than they did during the door-to-door visits by the CHiPs. Some people use the hubs services as entry point for other services at the health facility i.e. women going to the health facility for services like family planning accessed HIV testing services at the hubs before proceeding to health facility.

Stakeholder engagement was crucial for the hubs to offer the services to the community. In some sites stakeholders came to the hubs to start treatment for clients who tested positive for HIV. This increased the proportion of clients linked into care.
AERAS

TB-018 Study (TB Vaccine Trial)

Zambart was one of 11 sites for a Phase IIb trial of a new Tuberculosis (TB) vaccine being conducted by Aeras and GlaxoSmithKline Vaccines, S.A. (GSK) in Zambia, South Africa and Kenya which started in May 2016. The trial aimed to evaluate the efficacy, safety and immunogenicity of GSK’s proprietary vaccine candidate M72/AS01E also known as the TB018 against TB disease, in healthy adults aged 18 – 50 years, living in a TB endemic region. It was a double-blind randomized, placebo controlled study.

The TB018 was implemented in two large communities in the Zambian Capital of Lusaka by Zambart at Kanyama First Level Hospital and at Kalingalinga Clinic by our implementing partner Center for Infectious Disease Research (CIDRZ). The vaccine was administered to participants in a two dose regimen with interval of 4 weeks in between, and participants will be followed up for a period of 3 years until February 2019.

Primary Results

Primary results of the study were released in September 2018. Primary results – meaning we are looking at the data we have collected so far, but the study is still ongoing. All participants have now been followed for at least two years, allowing us to look at the data and see if the vaccine has helped prevent TB disease. The study will continue until all study participants have completed 3 years of follow up so we can collect all the data and publish the final results.

Efficacy – did the vaccine work?

- 32 participants met all the requirements for a diagnosis of active TB disease according to the study protocol – 22 of these participants had received the placebo
- 10 of these participants had received M72/AS01E
- The study showed that the participants who received M72 were 54% more protected from TB than those who received placebo

Safety – was the vaccine safe?

- M72/AS01E was found to have an acceptable safety profile and was well tolerated (as in previous studies)
- Participants who received M72/AS01E had stronger reactions to the injection than those receiving placebo – Some had sore, swollen, and red injection sites. Some participants also reported fever (these side effects are similar to other vaccines of this type)
- There were no other noticeable differences between M72/AS01E and placebo

The Zambart site recorded a 100% retention of all participants.

Next Steps

- Participants will continue with follow up visits until all have completed 3 years of follow up. At the end of the study we will look at the data from all 3 years (final analysis) and see if there is anything else we can learn about M72/AS01E.
- This is one of the biggest advances in TB vaccine research in 100 years and there are ongoing discussions on how to progress this candidate vaccine.
- Blood samples from those participants who consented to the blood storage as part of a parallel study sponsored by Aeras (now IAVI) will be stored for later testing – these samples will help us understand why some people got TB and what protected others. These samples are extremely useful and may provide information which will advance the understanding of TB and also help improve efficacy of TB vaccines.

Implementing Partners

[Images of implementing partners]
Zambart recognizes the importance of young people in the fight against the dual epidemics of TB and HIV/AIDS in Zambia. According to UNAIDS, young people between the ages of 15 – 24 accounted for a significant percentage in all new infections in TB and HIV/AIDS in sub Saharan Africa in 2018 and these figures can rise if measures are not put in place to mitigate the spread of the diseases.

**Insaka Platform**

The Insaka project was a collaboration between Zambart and the SHM Foundation which aimed to address the mental health and wellbeing of HIV positive pregnant and feeding mothers in Lusaka, Zambia. The project was based on the SHM Foundation’ s Zimbido Health model of peer to peer text message support groups that were implemented in South Africa, Mexico, Guatemala and the UK and was tailored to meet the needs of Zambian HIV positive and breastfeeding mothers.

The study specifically looked to break down the barriers to delivering psychological support to women living with HIV, in order to improve ART adherence and prevent onward transmission. The Insaka Project is the award winning project of ViiV Healthcare, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) and United Nations Every Woman Every Child (EWEC) Retention of Breastfeeding Mothers Challenge.

The information in this article is from interim findings and a more detailed account will be provided during the course of 2019. The initial analysis indicates that there is a potential to expand Insaka in Zambia and elsewhere as the level of engagement amongst the participants was high.

**Background to Pregnancy and HIV**

In Zambia and in most sub Saharan African countries, pregnancy is the point at which most young women find out their HIV status and is highly stigmatized. Experiencing stigma during pregnancy, compounded with the difficulties of managing a chronic condition like HIV alongside motherhood can have negative consequences. Women often deny their condition and don’t take their medications, or find it difficult to breastfeed their children. This increases the risk of transmitting HIV to their child.

**Implementation**

Insaka aimed to look at overcoming these barriers by establishing peer to peer support groups for women living with HIV, via mobile phones that were anonymous, immediate and accessible. The project commenced in January 2018, the support groups launched in July and ran for four months until November 2018. It enrolled 61 young women aged between 15 -24, living with HIV, attending antenatal clinics and receiving HIV treatment in the communities of Chipata and Kanyama. The women were divided into 6 mobile support groups, each facilitated by a trained peer mentor from their community.

The model enabled participants to receive and share psychological support and information with one another and to interact with professionals who joined the group discussions as ‘guest speakers’ in the field. A schedule of topics and issues to discuss was developed before the beginning of the program in consultation with the local health professionals, community health care workers, potential user and mentors. Participants interacted with one other anonymously - using nicknames. A general practitioner with Obstetrics and Gynecology experience, a Pediatrician and a nutritionist participated in the program where they were invited on a specific day and time to a group to run a session. The sessions gave participants the opportunity to ask specific questions and generated a lot of interest.

**Demographic data of participants**

- 61 pregnant women living with HIV were recruited to the program: 25 from Chipata and 36 from Kanyama. 43 actively participated. Reasons for participants not returning to the groups after
recruitment included tensions with their partners, technological issues and poor literacy levels

- 60 participants were between the ages of 18 – 24, only one was 16-17; the main age of the participants was 22 years.
- 74% of women were married; 23% had never been married; and 3% were divorced, separated or widowed
- Only 5% were employed
- 75% of participants had been pregnant before, 48% of participants had one other child, 26% had two children and only one participant had three other children.

Challenges

The main challenge in setting up the model was in establishing a relationship with the telecommunications company in Zambia and ensuring that the right contract was in place to provide the program with the requirements it needed which took longer than anticipated.

Technology

The program utilized the digital open source communications platform Rocket.Chat to facilitate the support groups. Rocket.Chat proved a reliable, feasible and low cost technology solution compared to others which are outdated and expensive.

The service was easy to use, providing easy admin controls which made it easier to organize the groups and users. The platform also made it easy to collect data securely and to automatically monitor the data in ‘real time’. This meant that should a participant be in need of immediate assistance, their message was immediately flagged and circulated to the monitoring team.

The program worked well in Lusaka where the minimum viable connection is 3G. Each participant was given a basic smart phone – ITEL 1503 model running the Android Kit Kat operating system. The devices had Rocket.Chat application installed before distribution to the participants. The phones were set up in such a way that they could only be used on Rocket.Chat and not any other application as well as prevent the use of mobile data for non-support group purposes.

Experience of participants

Some of the participants stated that they “never knew how to handle a touch screen, but through Insaka I have learnt how to use one”; “I learnt how to write a message in English words, especially because of the spell-check and speech-to-text button”.

Participants enjoyed the anonymity of the platform. They reported that they had no trouble expressing themselves in the group because they had no profile photos, no phone numbers or real names.

Participants were allowed to keep the phones after the intervention ended, but expressed displeasure that they were unable to continue chatting on Rocket.Chat as the app was removed. The app had to be removed as there were financial implications in continuing to use the platform. They were however reminded that there were other platforms that they could use such as WhatsApp.

Funders

Please visit our website www.zambart.org.zm for the full interim findings report
Overview

In 2017-2018, Zambart social science unit’s work was either nested within community randomised trials on HIV prevention with adults and adolescents, Tuberculosis, stigma and HIV Self-Testing, or carried out as stand-alone qualitative studies on disability policy and interventions for young people living with HIV. The unit is led by Virginia Bond (LSHTM overseas staff) and Musonda Simwinga and their areas of interest include community engagement in research, ethnography of HIV and TB, innovative qualitative methods, health related stigma, the influence of urban community systems on epidemic response and intervention uptake and HIV self-testing. The unit has a broad mix of social science disciplines and is committed to capacity building and interdisciplinary research.

Social Science and the HPTN071/PopART Study

In 2017, the social science team working on the PopART study continued to document the story of the trial. This included observations of: the CHiPs delivering the intervention; HIV service delivery and utilization in the clinics; community mobilization activities; and CAB and stakeholder meetings. Additional observations of the CHiPs doing TB screening and community ART delivery were carried out. Observations of optimizations of the PopART intervention for young people linked to PopART for Youth (P-ART-Y), an adolescent sub-study also continued. In June 2018, documenting the story of the trial ended with observations of the delivery of the post-PopART interventions delivered through community hubs. The activities carried out during this fieldwork included observations of: CHiPs in the field following up clients to offer them the intervention package or link them to care as well as delivering HIV services in communal hubs; HIV and TB service delivery and utilization in the clinic post the PopART intervention and community observations.

One of the highlights of the year and linked to the annual retreat of all Zambian PopART staff, was a reflection activity with all PopART staff exploring challenges, successes, lessons learnt and memorable experiences during the three years of the PopART intervention. Together we built a tree that clustered all of these together in a wonderful visual.

Apart from the story of the trial, other social science fieldwork activities in this period were a qualitative cohort of families and individuals living in the study communities and their response to HIV and particular components of the study. A total of 62 participants (39 adults and 23 adolescents) were enrolled in four purposively sampled PopART study communities,
representing different genders and ages and different HIV decisions and status. Data were collected in four field rounds from February 2017 – March 2018. Implementing this data collection was especially challenging for staff in terms of cohort retention (24 adults and 18 adolescents were retained until completion), and discussing topics that participants and researchers experienced as sensitive.

Data analysis for these different components of the PopART social science research has been ongoing since 2017 and sometimes carried out alongside data collection. In 2018, the majority of the social science team’s efforts were the data processing and initial analyses toward a group of manuscript outputs directly linked to the protocol social science objectives. These manuscripts are at various stages of development and will be submitted in a staggered way between September 2018 and June 2019. The scope, focus, and timing of these manuscripts have been carefully planned with study leadership and Prof. Janet Seeley to maximise their relevance to and synergy with the primary outcome and other secondary outcome manuscripts. Most of the audio recordings have since been transcribed as the first part of the analysis process. A Complete dataset in Atlas.ti, a qualitative data analysis software has been set up for the planned manuscripts and the remainder are on track for completion per planned timelines. To support data analysis and development of manuscripts Dr Virginia Bond, with support from Prof. Janet Seeley of MRC/ UVRI & LSHTM Uganda Research Unit, Entebbe, Uganda and Dr Lindsey Reynolds, Social Science Unit, DTTC Stellenbosch University South Africa and in collaboration with Prof. Christopher Colvin and Dr Alison Swartz (University of Cape Town) secured funding from the British Academy to host a two-part writing workshop for promising Southern African social scientists. These workshops were implemented in June and October 2018 outside Cape Town with four participants from the department in attendance.

Stigma Ancillary study

STIGMA

The aim of the study is to measure the impact of the two intervention packages on HIV-related stigma and to use qualitative research to document the effect of the interventions on stigma. This is centred on 3 main hypothesis:

1. PopART intervention may change levels of HIV stigma
2. HIV stigma may undermine the effectiveness of the PopART intervention
3. PopART intervention may change the forms of HIV stigma

The quantitative component of the Stigma Ancillary Study consist of a self-administered questionnaire conducted on a Personal Digital Assistant (PDA) device which takes about 30-60 minutes. While the qualitative component consisted of in-depth interviews, observations and mapping exercises.

2017 and 2018

- 2017 was mainly focused on completion of round 3 quantitative data collection, which was happening in all 12 PopART Sites.
- Quantitative Data collection was completed mid-2018 and we had 1827 HCW who participated.
- The study disseminated at both national and community level. National level disseminations were incorporated into the main trials dissemination while at community level results were disseminated to all health workers at all 12 participating clinics.
2018 -2019

- The main focus of 2018-2019 is data analysis and writing of manuscripts.
- Dissemination of results to community members in all 12 sites will occur in the first quarter of 2019 after the release of the HPTN071/PopART study.

P-ART-Y study

Social science was a key component of the P-ART-Y sub-study. Alongside observations of the ‘story of the trial’ the social science team also observed the implementation of the P-ART-Y optimization activities. Observations and documentation of the P-ART-Y study interventions continued throughout 2017 up to the end of the study intervention. Similarly to the PopART qualitative cohort, a sub-sample of young people are part of the qualitative cohort. In February 2017, a qualitative cohort of 23 young people was recruited and followed throughout 2017 and January 2018. The 23 were recruited into either one of the three categories, young people living with HIV (YPLHIV), young people not living with HIV, and adolescents who did not know their HIV status (or had never tested for HIV) at the time of recruitment. The participants were a mix of young men and young women aged 15-24 years old, in-school and out-of-school. Each participant was involved in three research activities which included participant observations, individual in-depth interviews, and a participatory workshop. The activities were carried out at a three months interval throughout the year and site based research assistants made drop in visits every 4 weeks to maintain contact with the participant to take note of any necessary changes with the participant and their household.

STAR Phase II: Case studies to investigate the process of delivering HIV self-testing services through five models of distribution in Zambia

The implementation of STAR II was started in June 2018. The intervention of distributing HIV self-testing kits through various models is been implemented by Society Family Health. The HIVST distribution models that are being used by SFH include VMMC clinics, public health facilities, community-led distribution through community structures such as small shops, and secondary distribution of HIVST through antenatal care (ANC) and HIV testing and treatment services.

The role of Zambart is to conduct an in-depth evaluation of the process of distributing HIVST through these five models of HIVST distribution. The study aims to understand user and provider experiences of HIVST distribution, contextual factors that affect HIVST distribution, to measure the cost of distribution, and determine who is reached if the distribution model is to deliver an HIVST to an index individual for distribution to their partner (termed secondary distribution of HIVST). This evaluation is using a mixed method and the social science team has been observing the distribution process at ANC, ART, community distribution points and workplaces, and conducted focus group discussions and in-depth interviews with community members. In-depth interviews are being conducted with ANC and ART cohort participants and respective health care workers; community point distributors and users; and members of staff during workplace HIVST distribution. A number of participants who refused to collect test kits have also been interviewed. Social harm meetings have also been conducted to identify and report incidents to study staff.
Community-based Distribution of Oral HIV Self-testing Kits:

The HPTN071 (PopART) trial provided HIV testing services (HTS) to a large proportion of individuals residing in PopART intervention communities. Despite reaching the UNAIDS first 90 target overall, gaps remained, particularly among men. Zambart conducted a cluster randomised trial in 4 intervention communities to evaluated the impact of the door-to-door offer of oral HIV self-testing (HIVST) as an option for HIV testing, in addition to the offer of home-based rapid HIV testing through community HIV providers (CHiPs), on knowledge of HIV status among the general adult and adolescent population in four communities in Zambia (refer to page *).

The social science team was part of this study and nested within it a qualitative study that aimed to assess the acceptability of door to door delivered HIV self-testing kits. The team also wanted to know how household management the test kits in their homes and this including the handling, storage, interpretation of results and disposal of used test kits. In additions, the team was interested in determining whether there were any harms associated with the use of HIVST and impact of HIVST on the role of CHW (community health workers).

To find answers to these questions, Qualitative data were collected between February and May 2017 during implementation of the HIVST intervention. In each community, at the beginning of the intervention observations of the CHiPs going door to door delivering HIVST and making follow up on test-kits left for couple distribution were carried out. Additional observations of social and physical differences between zones, mobilization activities, and at points at the health facility where self-testers were supposed to drop off used test kits were also conducted. Towards the end of the intervention, in-depth interviews (IDIs) with 40 purposively selected individuals who had either chosen or not chosen to self-test focus group discussions with men and CHiPs were also conducted.

Mac-AIDS study

In the wake of an earlier study with adolescent girls living with HIV looking at healthy transitions to adulthood, with the International Centre for Research on Women, we conducted a feasibility and acceptability study of a support group intervention for adolescent girls living with HIV in two Lusaka communities. A total of 24 young women aged 15-19 participated in a six session support group intervention that we evaluated. We produced a curriculum and a brief from this study that was disseminated to the communities involved. (see chapter 3)
SEPO III

Promising Practices that Improve the Functioning, Disability and Health of Children and Young People Living with HIV as a Chronic Illness in Zambia (Sepo III)

Sepo III builds on a previous study, Sepo II that was conducted to understand the experiences of men and women living their lives with HIV as a chronic illness in Zambia. Results of the Sepo II Study revealed stories of hope and optimism among people living long-term with HIV and challenges. The Sepo II findings pointed out shortcomings in the model of HIV care focused primarily on initiating and adhering to ART. These health services are necessary but not enough to meet the ‘new needs of people living their lives on ART’. During policy dialogue on the Sepo II results in December 2015 in Lusaka, the Zambian Minister of Health declared, “It’s not enough to dish out tablets; you need to go into the life of the person”, and called for further research to identify and mobilize solutions. In the light of this, the Sepo III project aimed to identify and showcase existing ‘promising practices’ (e.g. policies, programs, services, community initiatives, or other innovations) designed to meet the new needs of young people (0-24 years of age) living with HIV as a chronic illness in Zambia.

A total of 7 promising practices were identified from Lusaka (3), Southern (2) and Western (1) provinces of Zambia. Organisations included the Ministry of Education, a youth led organization, a university based organization, a mission hospital in a rural community and an organisation providing support for young men who have sex with men living with HIV (YMSMLHIV). Data was collected by members of the project team including a social scientist, 2 research assistants, and 2 Zambian based professors serving as co-PIs on the project. Seven case study reports have been developed for each site. Following the conclusion of data collection a two day workshop was held in May 2019. Three representatives (including at least one young man or woman) were invited from each organisation. The purpose of the workshop was to validate data collected and give the participating organisations an opportunity to showcase their promising practice.
INTRODUCTION

The 2017-18 period under review was an exciting transition period for the Community Engagement (CE) department in that several studies were completed and new ones were started. The CE team prepared exit plans for completing studies and community preparedness plans for the new studies. Community and social mobilization activities namely school based sensitization activities, door to door campaigns, community announcements and meetings with key community based stakeholders were conducted for ongoing studies. Other activities included men’s forums, drama performances, sporting events, choir competitions and church based sensitization.

CONCLUDING AND EXITING THE POPART STUDY

2017 was the last year of delivering the PopART intervention and the intervention team focused on making sure that participants who tested positive were linked to care. To support this, the CE team delivered messages which encouraged members of the community to link and remain in care. This was done during clinic talks, community meetings, and other community mobilization events. Other focus areas included sensitization for the absent men while mass sensitization for VMMC was specifically done during school holidays.

In the adolescents study, also known as PopART for Youth (P-ART-Y) study, appropriate (CE) activities for adolescents and young people (AYP) were conducted. These included sporting events, quiz shows, and community meetings inviting young people to join the study and to test for HIV.

Exiting the PopART study was particularly challenging because of the number of stakeholders that the CE team had to inform and consult about this process. Meetings were held across all the sites with Community Advisory Boards (CABs) and Adolescent Community Advisory Boards (ACABs) and other key community stakeholders. The CE team developed key message themes for use by CE staff and other key staff as part of the study exit and dissemination process. The key messages were reviewed by the National CAB (NCAB). The meetings served a duo role; to inform community stakeholders about the end of the PopART study intervention, and to disseminate the first study results to do with the intervention. The meetings were also an opportunity to appreciate the role of the stakeholders in the study. CAB members were given ‘farewell’ bags containing letters of appreciation, certificates of service and T-shirts. A separate meeting was held with the civil society representatives called the community partners’ platform (CPP)

CONCLUDING AND EXITING THE TB VACCINE STUDY (TB018)

The TB Vaccine study (TB018) was the first ever Tuberculosis vaccine study to be conducted in Zambia. Consequently, there was not enough material to refer to and therefore developing IEC material for creating awareness and educating the target population continued throughout the study. The extensive involvement of community stakeholders made the process of Information Education Communication (IEC) development, community preparedness, participant recruitment, participant retention and primary results dissemination much easier. This helped to address misconceptions about the study. For instance, some people thought that the study vaccine would
make participants impotent or develop tuberculosis disease later in life. Stakeholder meetings
and community sensitization were conducted to address the misconception. Just like for the
PopART study, an exit plan and communication strategy that guided the dissemination of the
study findings was developed. Final results were disseminated at community level meetings
attended by former participants who expressed happiness at the good results and also at being
part of this unique study.

Starting new studies - Tuberculosis Reduction through Expanded Antiretroviral Treatment
and TB Screening (TREATS)

The Tuberculosis Reduction through Expanded Antiretroviral Treatment and TB Screening
(TREATS) study will measure the effect of the PopART study on TB incidence (new cases of TB)
and prevalence (number of people with TB). Many people were screened for TB and had their
sputum collected and tested for TB during the PopART study. This is expected to have had an
effect on the incidence and prevalence of TB in the PopART communities. The TREATS study
therefore has two components; the Incidence of TB Infection Cohort and the TB Prevalence
Survey. Starting CE for this equally big study was a challenge. However, we decided to use
community structures created under PopART as far as possible. We maintained and trained both
the adolescent and adult community advisory boards to help them understand the study and
some basic information about TB.

Incidence of TB Infection Cohort

The Incidence of TB Infection Cohort was conducted first and involved recruiting 300 young
people, aged 15 – 24 in each community. We faced challenges recruiting young people because
most of them were not found at home and some were in boarding schools. Study material with
information for young people were left at home and sensitization schedules were adjusted to
times when the young people were likely to be home, such as on weekends.

TB Prevalence Survey

The TB Prevalence Survey will target people aged 15 years and above who are residents
and have been in the community for at least a period of 9 months and above. The survey
will involve setting up mobile field sites (MFS) in different zones of the community
and inviting people to come to the MFSs to access TB services provided using a
mobile van equipped with chest X-ray and a laboratory. In preparation for study
implementation which begins in 2019, the CE team conducted community preparation
activities in two Lusaka communities where the survey is scheduled to be implemented first.
This involved introducing the prevalence survey to different community stakeholders such as
CABs and Neighborhood Health Committees (NHC) and obtaining feedback. Mapping of the
two communities was then conducted. This involved dividing the communities into sections
to facilitate a systematic way of choosing areas of the community where the survey will be
conducted or not conducted.
Adolescent and Young People (AYP) participation

Participation in design and implementation of studies

Interesting conversations and consultations were conducted with young people. For instance, meetings were held to discuss whether parental consent would influence the manner in which young people answered questions in the adolescent study cross sectional survey for the PopART/P-ART-Y study. Adolescent CAB members overwhelmingly recommended waiver of parental consent to promote privacy and confidentiality when answering the survey questions. They were concerned parents would interfere in many ways including wanting to listen to the interviews. The young people also reviewed and provided feedback on the survey tool. They also took time to familiarize themselves with the electronic data capturing device that was to be used in the survey. The young people also recommended appropriate mobilization activities, emphasizing that the door to door visitations and community meetings with household heads were better suited for informing people about the survey.

Young people also participated in the recently funded Yathu Yathu (For us by us) study. This is a study that will assess whether providing sexual and reproductive health services at community centres, called the Yathu Yathu hubs, will increase the number of young people testing for HIV and accessing new methods of contraception, Prep, HIV self-testing and many more sexual and reproductive health services. An interesting condition by the funder, the Medical Research Council (MAC) of the UK, was that young people are consulted in the design of the study. We consulted existing adolescent CABs, and working with the social science team, we conducted formative research involving a series of consultation activities during which we asked young people what sexual and reproductive health services they want, where they should be provided from and who should provide them.

Information Education Communication (IEC) review

ACAB members from Lusaka communities participated in an IEC review meeting for the Community ART and the TREATS studies. The ACAB members suggested ways to make messages and the language used simple. They particularly wanted posters to have pictures of both adults and young people.

Special training

ACAB members were trained in Sexual and Reproductive Health (SRH) to improve sexual health knowledge amongst the members. The education sessions were facilitated by youth counselors and the CHiPs supervisors during routine monthly ACAB meetings. Certificates of attendance were awarded to ACAB members who completed a certain number of sessions.

Visiting the Zambart laboratories

ACAB members visited the Zambart labs. The aim of the visit was for the CAB members to familiarize themselves with the operations of the Lab and to help in providing answers to questions regarding blood draws, use and disposal. The members were impressed with the machinery used in the lab and the amount of samples processed in a day. They also stated that
the visits helped them understand what happens with blood samples and addressed the misconceptions related to blood.

**Adult CAB and other forms of participation**

The adult CAB and adults in the community participated in different ways. Men's forums called Insaka, where men met to discuss health and non-health issues were initiated to help improve male participation. Men were also followed at places of work and entertainment as well churches.

An important way adult CAB members were involved in the study was through the resolution of social harms. CAB chairperson were often asked to accompany study staff to investigate reported potential social harms. National CAB meetings attended by representatives from all the 12 CABs were organized aimed at promoting cross-learning amongst the CABs. The meetings also provided a platform for updating CAB members. During the last national CAB meeting, the members discussed exit plans for studies that were concluding, discussed welfare of CHiPs (PopART study) and recommended training for them, and also reviewed IEC material for new studies.

Quarterly meetings with representatives of organizations working with people living with HIV were held during the period under review. The aim of the meetings was to share study updates and provide a platform for the organizations to share their views about studies being implemented by Zambart. The CPP members conducted field monitoring visits. The team also held a capacity building workshop to discuss how to translate study result into policy and advocate for policy change. These activities were aimed at promoting effective representation of communities of PLWH and TB on the Zambart led studies.

A special training in Understanding the Clinical Research Process and Principles of Clinical Research was conducted for adult CAB members. This training was intended to provide information adult CAB members on clinical research, the clinical research process, principles of clinical research and the roles of CABs in the research process amongst other topics. The information shared during the training helped CAB members contribute to the research process more meaningfully.

**National and International Commemoration Days**

The CE team participated in national and international commemoration days such as the World TB Day, the National HIV Testing, Counselling and Treatment Day and the National Child Health Week. The team participated in community based activities leading to the events.

**Other collaboration - Africa Health Research Institute (AHRI) visit**

Two social scientists from the Africa Health Research Institute (AHRI) based in Durban, South Africa visited Zambart from December 10th to 14th 2018. The aim of the visit was to share and learn about ACABs and other youth engagement strategies Zambart has used.
Publications

Kindly see all publications on page 63

Awards

HIV Prevention Trials Network (HPTN) Best Community Engagement – ZAMBART CRS in Lusaka, Zambia and Desmond Tutu TB Centre CRS in Cape Town, South Africa for HPTN 071

National Science and Technology Council (NSTC) 2017 Individual Science and Technology Merit Award- Musonda Simwinga
The Health Economics Unit (HEU) aims to contribute positively to the performance of health systems in Zambia and surrounding regions through informing health policy and enhancing technical and managerial capacity. Its foundation is grounded on the need for research excellence in health economics and related health system issues in developing world. HEU has been conducting a number of economic analysis alongside other public health studies at Zambart. Zambart has been conducting health economics related research since late 1990.

The HEU endeavours to develop a reputation for high quality research in health economics, health policy and systems research. Currently, we conduct research in the following areas:

- Economic evaluation of key public health priorities including HIV prevention and treatment and TB programmes.
- Health care financing.
- Scaling-up access to priority interventions.
- Application of behaviour economics in healthcare evaluation.

This report outlines key research activities which were undertaken by the unit in the years 2017 and 2018.

### Research highlights for HEUZ in the period 2017-2018

#### Economic evaluation of HPTN071 - PopART

Economic evaluation of PopART has been underway for the past 4 years. The aim of the economic evaluation of PopART is to estimate the cost-effectiveness of PopART intervention by comparing the cost and benefit of the intervention delivered in the trial communities. The benefits being the positive marginal impact on individuals’ health both in HIV positive persons that are treated early and HIV negative persons for which infections are prevented. This study is conducted in Zambia and South Africa as a sub-study of HPTN071-PopART trial. In the period under review we have been conducting cost analyses of PopART interventions.
The cost analysis of PopART has two components; Health facility survey (HFS) which aims to estimate the cost of implementing PopART interventions at government clinics, and cost analysis of PopART implementation which aims to investigate the cost of implementing community health providers (door-to-door) component of PopART intervention. The team continued with the data analysis for both components of the costing. Working with the lead economists from Imperial college London, local economist are in the process of finalising the intervention costing, to calculate the cost effectiveness, model parameters were developed and currently under review. Data collection for health facility costing has been completed awaiting data analysis. We had an opportunity to present some preliminary findings from intervention costing at the HPTN071 PopART Dissemination meeting held in March, 2018. Unlike the findings presented previously at the annual meeting, the presentation included the costs of the 1st and 2nd round of the intervention. The total economic costs for Zambia were calculated at $3.34 million and the average cost per person tested was approximately $7.6 per annual round of interventions. The findings also showed some economics of scope and scale in that the costs were sensitive to community specific factors related to service delivery or population characteristics and this led to variations in costs across the various intervention communities.

**Economic analysis of Oral HIV self-testing strategies**

In the period under review, the team conducted economic analysis of Oraquick HIV-self testing (HIVST) strategies under two projects; a cluster-randomised trial (CRT) of community-based distribution of HIVST nested within four PopART communities in Zambia and a cluster-randomised trial of community-based HIVST distribution - a part of the HIV Self-Testing AFRica (STAR) project. The project is implemented in Zambia, Malawi and Zimbabwe. The economics team worked with economics from London School of Hygiene and Tropical medicine and economics from the other two countries under the leadership of Prof Fern Terris-Prestholt. The economics team were tasked to establish users' preference for oral HIVST using discrete choice experiment (DCE) and to estimate the cost of HIV testing through the routine finger prick and oral HIVST testing modalities. The DCE results suggest that community-based distribution and linkage are critical aspects of HIVST delivery. The team estimated the cost of HIV testing at US$4.24, US$16.42, US$15.81 and US$13.01 for facility-based routine finger prick and, Community HIVST distribution, facility-based HIVST distribution and VMMC clinic based HIVST distribution, respectively.
Highlights of Upcoming research activities

In the coming year, the economic team plans to continue with the data analysis as well as any publications of economic evaluation of PopART study, focusing on health facility costing.

The team is also excited to commence new studies which include:

1. Economic evaluation of the Tuberculosis Reduction through Expanded Antiretroviral Treatment and Screening for active TB (TREATS) study to calculate the cost-effectiveness of active case-finding for TB in the context of Universal Test and Treat (UTT).

2. Economic evaluation of new oral HIVST modalities in the STAR Phase II project.

3. Economic analysis of sexual and reproductive health service delivery for adolescents and young people in Zambia under Yathu Yathu project.

Check this space in the next Zambart report for progress and findings from these studies.
The Zambart Data Unit remains very central in all the research activities conducted by the organization. The unit is responsible for generating high quality, reliable and statistically sound data from all clinical trials and studies that Zambart undertakes and collaborates on. The data team members are involved in all the studies from inception to completion, thereby ensuring that our team members understand the workings of a study from the onset. This is translated in a team with key process knowledge and that consistently generates high quality data of an international standard which we share with our partners and collaborators. Zambart uses data generated by the data unit to maximize knowledge and understanding of the impact of our research and potential effect on national and global health policy.

In 2017, the data unit increased its staff from 16 in 2016 to 24 at the end of December 2018. During this period, an additional 4 members of staff were recruited to the data team on a part time basis as data entry assistants. This was necessitated by an increase in data flow from the PopART study transitioning from year three to year four, and the beginning of new studies.

**Staff Profile**

The Data, Statistics and ICT team is a multifaceted unit comprising of bio-statisticians, GIS specialists, data managers and technicians, network maintenance and security managers.

**What’s ahead in 2019?**

Zambart has undergone some changes over the last 2 years with the introduction of a new organogram (organisation structure). Departments have become more consolidated and streamlined. What this means for the Data, Statistics and ICT team is that come 2019, some of the studies’ data managers will be relocated from the data building and will be placed with

**Embracing Technology – Data Collection**

Zambart has embraced technology by moving from *Paper Based* to *Online Research Data Capturing*. This has been a gradual progression as summarised below.

1. **Paper Based (early 2000s)**

On inception data collection was all paper based. Questionnaires were printed and given to field workers to fill them in and then sent to head office for data entry. Data verification would then follow by printing the data and physically comparing it with the source documents (Questionnaires). Secondary outcome cohorts (SOCs) was one of the projects where paper based data collection was used.

2.1. During the ZAMSTAR study we migrated from the use of paper being sent for data entry to the use of cameras to capture images of the source documents (TB Registers).

These images from the cameras would then be printed at head office and then captured into the system. Verification process would follow as in paper based.


During the TBReach study, instead of using the camera to capture images, laptops were then used to capture data electronically from the sites (from TB cards). This data would then be saved on flash disks and then taken to head office for subsequent download into the system. Printouts would then be made and sent to sites for verification.
2.3. **In the field electronic data capturing (include timelines)**

When the Better Health Outcome through mentoring and Assessment (BHOMA) project was being undertaken, Personal Digital Assistant (PDA) were introduced to help with the collection of data directly in the field. The PDAs would then be taken to headoffice, the data would then be downloaded into the system.

![Electronic data collection using PDAs](image)


On PopART study, both the Population Cohort (PC) and Intervention electronic devices were deployed to capture data directly from the field using electronic questionnaires installed on either Winpads or Getac tablets. The captured data would immediately be transmitted to the cloud (PC using Winpads / Getacs) or to head office (Intervention using Getacs). This resulted in quick data collection, transmission and analysis. With the intervention, data is printed and the feedback given to the field workers monthly thereby knowing their weaknesses and improving on them.

In studies where clients were required to sign consent forms, these were collected and kept in paper based form and filed. Some of the consent forms are scanned as images and stored in electronic format so that in case hard copies are lost they could be accessed as electronic copies anytime.

![Win pad Configuration](image)
The current projects are also using the same fully electronic data collection tools.

4. **Back office**

   Our back office is powered with moderate state of the art infrastructure. We have two Dell PowerEdge R420 servers running Windows Server 2012 and MS SQL Server 2012 and MySQL as data servers. These data servers store transmitted data captured from the field via a Virtual Private Network (VPN) configured on a Cisco Firewall – ASA 5520 for maximum security.
Zambart Laboratories

2017 and 2018 were busy and challenging years for the Zambart Laboratories. With funding from PopART, our staff numbers swelled to a record high of 28 scientists, technologists and microscopists. Through great dedication, effort and teamwork, we achieved our goals for PopART and a number of other studies mentioned below.

### PopART Population Cohort (PC)

During PC24 in 2017 and PC36 in 2018, the Central and Regional Laboratories processed, stored and tested nearly 23,000 plasma specimens each year collected from participants in 12 communities. The frozen specimens were transported to the Central Laboratory where they were tested using the Abbott Architect HIV Combo assay. The results were used to determine the study’s primary endpoint, the incidence of HIV infection during the four-year study.

During PC36, from September 2017 to July 2018, the Central Laboratory tested 5915 plasma samples collected from participants in the 12 study communities for HSV-2 using the Kalon Herpes Simplex Virus Type 2 IgG ELISA.

### PopART Phylogenetics Sub-Study

During 2017-2018, blood was collected from 5629 individuals undergoing ART initiation at Ministry of Health clinics in 10 communities. The frozen specimens were transported to the Central Laboratory, then shipped to the University of Oxford for testing using a state-of-the-art HIV viral load and genotyping assay. The results of this testing will help us better understand the patterns of HIV transmission within the study communities and to develop improved strategies to control the spread of HIV and other STIs.

### SHINE TB Study

During 2017-2018, the Zambart TB Laboratory served as the Zambia testing site for the international, multi-site SHINE TB study investigating shortened treatment regimens for children treated for TB infection at University Teaching Hospital. In 2017, our TB laboratory performed MGIT culture and other tests on a total of 427 specimens (317 gastric aspirates, 93 induced sputum, 1 fine-needle aspirate, 1 CSF, and 1 gastric wash). In 2018, our TB laboratory performed MGIT culture and other tests on a total of 385 specimens (238 gastric aspirates, 142 induced sputum, and 5 fine-needle aspirate).

### Tuberculosis Meningitis Study (TBM)

Ending in 2017, the Zambart TB Laboratory served as the testing site for the TB Meningitis Study conducted at University Teaching Hospital. The study investigated the efficacy of CSF MGIT culture, CSF Xpert, and urine and CSF TB LAM for the diagnosis of TB meningitis. CD4 testing was performed, as well. In 2017, the TB Laboratory performed some or all of these tests on 173 patients.
**HIV Self-Testing Africa (STAR)**

Completed in June 2017, STAR assessed the acceptability and accuracy of HIV self-testing using the OraQuick HIV oral fluid rapid test by 2510 participants. Blood obtained from the same participants was tested at the Central Laboratory using the 4th-generation Abbott Architect HIV Combo assay. Of the 2510 participants, 253 recorded lab-based HIV test results that were discordant with the oral fluid self-test or blood-based rapid tests performed in the field. These samples were re-tested using the Biorad HIV Combo assay and 252 (99.6%) were in agreement with the Architect result (1 sample was considered to be false-positive on the Architect assay due to a low S/CO).

**TREATS Infection Cohort Year 1**

From July to December 2018, blood for Quantiferon TB testing was collected from a total of 2655 participants in 8 communities. The blood was incubated in the Central Laboratory and the 5 Regional Laboratories and the plasma was frozen and transported monthly to the Central Laboratory for testing using the Qiagen Quantiferon-TB Gold Plus assay.

**Other studies:**

SUVA Early Infant Diagnosis (EID) Study – In January 2017, the Central Laboratory tested the final 150 of 1350 dried blood spot (DBS) samples using the Biocentric HIV DNA PCR assay. Additional HIV antibody testing was performed on 114 DBS samples using the Abbott Architect HIV Combo assay and on 58 samples using both the Abbott assay and the Biorad HIV Combo ELISA with 100% concordance.

Population Council - Adolescent Girls Empowerment Programme (AGEP) – From July to December 2017, the Central Laboratory tested 2500 serum samples for HSV-2 using the Kalon Herpes Simplex Virus Type 2 IgG ELISA.

We gratefully acknowledge the outstanding efforts of the following staff who worked in the Zambart Laboratories during 2017-2018.

**Zambart Laboratories’ Staff Profile**

The Zambart Central Laboratory has 8 members of staff, Kanyama has one while the five regional laboratories in Livingstone, Choma, Kitwe, Kabwe and Ndola have two members of staff each all working on different studies.
RESEARCH GOVERNANCE UNIT

Major activities for the Research Governance department for 2017-2018 was routine monitoring and auditing of the studies being conducted by the teams. Majority of the monitoring and auditing was conducted on the HPTN 071/PopART P-ART-Y and STAR studies. The purpose of the monitoring and auditing was to ensure that the conduct of the study was compliant with the approved protocol or amendment(s), with ICH-GCP and the applicable national and international regulatory requirements.

**Routine monitoring**

In 2017, all HPTN071 sites and teams were monitored once. STAR study 1 site for the Clinical Performance Survey and 3 sites for Cluster Randomised Trial. In 2018, 8/12 HPTN 071 study sites were flagged audits.

**Flagged Audits**

In 2017, 20 out of 210 teams from 5 out of 12 teams of the HPTN071 study and 1 team out of 4, from 1 out 4 sites from the P-ART-Y study were audited.

Monitoring activities included verification of data recorded, number HIV test conducted; number of condoms distributed, verification of household visit &

**Verification of QC procedures**

Auditing activities involved verification of data collected from selected team flagged teams i.e. Verification of Household visited, verification of number participants seen & Verification of study procedures conducted.

All findings were presented to study teams and were necessary corrective action was conducted.

The Governance department also trained 4 new study news in ICH-GCP, Informed consenting procedures; Incident identification and reporting procedures source documentation, foundations of research ethics and research integrity.

Depending on the size and stage of a study, completed sourced received 10%-100% Quality Control checks to ensure completeness and accuracy of data collected.
Chapter 2 - Our people

Our people are our greatest strength and we are committed to ensuring that Zambart’s workplace continues to attract, develop and retain the right people with the right skills.

Workforce management

We aim to attract and retain talented staff by offering challenging and fulfilling work, competitive salaries, flexible working conditions, excellent learning and development opportunities, and a friendly and inclusive work environment.

Managing performance and behaviour

Our Appraisal Policy recognises that regular constructive feedback encourages good performance, enhances continuing development and helps employees and managers communicate with each other informally and regularly about performance matters. The policy also affirms that performance management is a core activity at Zambart that is embedded in all management functions.

Annual Individual Performance Appraisals are designed to align individual performance to our strategic priorities, with the overall aim of improving individual and organisational performance. They also focus on individual learning and development needs and broader career development. Zambart policy requires a current AP to be in place for existing staff, including contractors, by July–August each financial year and, for new employees, within 3 to 6 months of their commencement.

Recognising diversity

We continue to support and recognise the diversity of our staff. Our staff leave policy provides flexible working and leave arrangements to support employees’ caring responsibilities, religious commitments and attendance at events of cultural significance, including organisation-organised activities that commemorate country histories, cultures and achievements.

Women comprised more than two-thirds of our total active staff (68%). Among our active staff, 50% of middle management staff were women, and women continued to represent 65% of our study field staff. We maintain a staff policy aimed at ensuring that we:

- recognise, foster and make best use of the diversity of our employees within the workplace
- help employees to balance their work, family and other caring responsibilities
- comply with all relevant anti-discrimination laws.

Engaging with staff

We recognise the importance of engaging with staff in decisions that affect them. This leads to better service delivery, use of resources, overall performance and staff experiences. Our staff consultative arrangements include several formal committees, quarterly staff meetings, monthly/fortnightly departmental meetings and weekly briefings at field staff level.

Zambart Senior Leadership Team (Consultative Committee)

This committee is the principal forum through which formal consultation and discussions on workplace relations matters take place between management and employees. Consultative Committee processes support the change management and consultation obligations outlined in the organisations Staff Policy. The committee discusses workplace relations matters in a spirit of cooperation and trust. The committee met 8 times during 2017–18. A key focus was discussion of proposed changes to a number of human resources policies, accommodation to support the increase in staff numbers and increased storage facilities.
Health and Safety (Wellness Program)

The program facilitates cooperation between management and employees in initiating, developing and carrying out measures designed to ensure the health and safety of our people at work. Program team members met 4 times during the year and, among other matters, reviewed the mental health strategy, action items required following an audit of Zambart’s work health and safety management system which included but was not limited to testing and tagging of electrical and fire safety equipment, purchase of new chairs and revamping and outfitting of the staff kitchen to meet the increased number of staff employed at Zambart Headquarters during 2018.

Fitness

Within the Wellness program, Zambart has an active social activities calendar to help foster a positive and collaborative workplace environment. Membership of the Wellness program committee comprises a senior staff member who acts as a sponsor and staff at middle management level. Members take the lead in organising the annual staff Christmas party and other events held throughout the year. Zambart staff enthusiastically participate in a variety of activities promoting health and fitness, including the Madala’s soccer matches and lunchtime table tennis, yoga and aerobics classes.

Professional Development Committee

This committee provides strategic direction for, and enables stakeholder input to, the planning and delivery of Zambart’s learning and development program across the organisation. The committee comprises representatives from each department at Zambart. The committee met 3 times in 2017 and 4 times in 2018 and focussed on realigning the learning and development strategy to that of the organisation’s 2019 – 2025 strategy.

Corporate social responsibility

Zambart continues to foster stakeholder partnerships and engage collaboratively with selected community organisations by providing assistance in kind and making presentations at conferences and seminars.

Zambart staff recognise the importance of giving back to the community by holding a range of events throughout the year to raise funds or comfort packs for charities. In 2017 – 2018, Zambart staff donated clothes and stationery to the Heal Project in Ngombe Compound in Lusaka and recycled white bond paper to Apters International based at the University Teaching Hospital (UTH) Lusaka.

Recognising and building expertise

We recognise and make good use of the high levels of education and skills of our staff, both of which are critical to performing effectively in the complex work of the organisation.

Staff qualifications

Zambart values the professional capability of its staff. Most of our staff (79%) work directly on field research and data collection-related work. As at 31 December 2018, a significant percentage (over 24%) were tertiary qualified; we had staff with post-secondary qualifications (1 professorship, 6 doctorates, 17 masters degrees, 23 under-graduate degrees and over 70 diploma holders). These figures include staff on long-term leave.

External study

A study assistance scheme is available to fully or partially support employees for approved courses of study for a recognised qualification relevant to their work at Zambart. Twenty one staff received assistance for formal study during 2017–18. Areas of study included public health, health statistics, social science, economics and clinical trials research ethics.
Corporate learning and development program

We continue to invest in the learning and development of all our staff, including formal induction programs for all new employees. Our program of in-house training sessions complements on-the-job training and helps ensure that staff develop and maintain specialised knowledge and skills. We provided 25 in-house courses in 2017–18 as part of the Zambart’s corporate learning and development program. These courses were attended by over 300 staff. These programs continued to focus on activities and courses that relate to Zambart’s work and included Good Clinical Practice (GCP), technical training, written communication, report writing, statistical and data analysis and leadership.

Leadership Training and Mentorship

In addition, Zambart has embarked on the development of its middle-level managers, with the development of a highly interactive 12-month, modular Executive Leadership Program; 23 staff are currently participating in the program. Staff were also provided with regular opportunities throughout 2017–18 to attend other training courses and seminars relevant to their roles.

This program is designed to raise capabilities in both strategic and people/performance management. Other programs on harnessing feedback, leading and managing small teams and working effectively at level were also provided to staff, to assist in raising and maintaining capabilities to achieve Zambart goals.

External Awards

Zambart and its staff have been recognised for exceptional individual and team contributions to public health research in Zambia and internationally.

National Science and Technology Council Individual Awards 2017

Dr Musonda Simwinga

Dr Kwame Shanaube
Community Engagement Awards

HPTN Award: The PopART Community Engagement team was presented with an award for successfully mobilising for the biggest HIV study. This was at the HPTN annual meeting in Washington in April 2017

Internal Awards

In 2018, new criteria for assessing nominations were introduced to recognise excellence in supporting our new strategic goals, and excellence in delivering and/or supporting Zambart and its studies. Staff across board were invited to nominate an employee or team for the awards, with the final decision on successful candidates made by the Executive Director.

Zambart Awards were given out to 14 staff in 2017–18

Long Service Awards

At the end of 2018, 15 members of staff were awarded for their various contributions to Zambart.

Other Accomplishments

Pre-Exit Financial Management, Job Search Skills and Entrepreneurship skills Training

With various projects coming to an end during 2018, Zambart realised the anxieties associated with leaving employment and through the Human Resources Department successfully conducted pre-exit trainings of about 650 employees in 2017 which significantly improved the job satisfaction levels of employees in 2018. The training focussed on Financial Management, Job Search Skills and Entrepreneurship skills..

PopART Staff Retraining Workshop, Siavonga

Capacity building is a cornerstone of the Zambart philosophy of conducting quality research. Staff at all levels of the organization undergo at least three forms of training annually and in August 2017, all 721 staff working on the PopART study travelled to Siavonga for a 3-day workshop. The objective of bringing such a large number of staff together was to please complete
Zambart staff involved in various extracurricular activities
Chapter 3 - Our Communications

Outlines Zambart’s public affairs and publishing activities, including how messages from Zambart studies are presented to policy makers and the public.

This chapter focuses on how we communicate with our audience and stakeholders.

In 2017–18, there were many developments in Zambart’s approach to communicating its work and capabilities. During 2018, the Research Directorate launched its Strategic Plan 2019–2025, and we anticipate seeing many changes, both in our outputs and the ways in which we communicate them to the outside world. We plan to relaunch our website, as well as increase our media presence by leveraging the use of social media to broaden the reach of our messages. The website allows our audiences easier access to our research information, including increased data visualization and greater use of quick, ‘at a glance’ facts.

While better meeting the needs of our stakeholders through our studies is one important component of our communications approach, there has also been significant commitment to strengthening relationships with stakeholders through complementary release activities. We have done this in part through increased engagement with the government, health and civil society sectors through pre- and post-release activities with a wider network of stakeholders. One particularly notable example of this was during the dissemination of results for the PopART for Youth (P-ART-Y) Study in May 2018. A detailed stakeholder engagement plan was developed to engage expert groups before the study’s release.

Presentation at national, regional, and international conferences are other ways in which Zambart communicates results of studies.

Reaching our audiences

Zambart is committed to making its work widely accessible and easy to understand. Our information is downloadable free of charge on the Zambart website in PDF format. www.zambart.org.zm/publication
**Facebook**

In 2017-2018, we used Facebook (ZambartResearch) as a means of communicating with our stakeholders. Zambart had around 1,300 @ ZambartResearch followers as at 31 December 2018. We will continue in 2019 to increase communication with our Facebook followers through targeted Facebook campaigns.

**Spotlight on our studies**

In 2017–18, we published over 60 print-ready publications and 4 policy briefs. The publications most frequently downloaded from the Zambart website in 2017–18 are of the HPTN071 (PopART) study. By this measure, the Community Engagement page was our most popular page on the website during the year.

**Zambart website**

The Zambart website (www.zambart.org.zm) is the main conduit for all Zambart information; principally our PDF and HTML (web) reports and a range of other study-related outputs including press releases and policy briefs. Going forward, we plan to use ‘sessions’ as a measure of our web traffic - obtained through Google Analytics. A session is a discrete period of time in which a single visitor is actively engaged with the website. There were 9,304 sessions on our website in 2018, a low number that we aim to increase in 2019.

**Media coverage**

Zambart issued five media releases in 2017–18, two more than in 2016–17. Media coverage remained steady over this period due to the issue of several high-profile media releases during the year (for example, HIV Self Testing, PopART for Youth (P-ART-Y) and increased local-level reporting.

Below is a list of the policy briefs released in 2017 - 2018. All are available for download on our website (www.zambart.org.zm)

a) ICRW policy brief  
b) ICRW Tikabisane Curriculum  
c) HIV SELF TESTING policy brief  
d) SEPO 11 key findings and recommendations  
e) Insaka Project key findings  
f) PopART for Youth (P-ART-Y) policy recommendations
Chapter 4: Our Organisation

Legislation

Zambart was established as a limited company by guarantee in 2004 under the Companies Act (CAP 388 of the Laws of Zambia). The composition of the organisation and its functions in the conducting of, reporting, and dissemination of its health related information are set out in its enabling legislation.

Accountability

Zambart’s research activities are designed to respond to the public health needs of the country and therefore in accordance with national research priorities, with prior approval of the Ministry of Health, and in line with the governing principles of research in Zambia. We ensure that the Minister of Health and other relevant ministries and government departments have early embargoed access to our research study results.

Research governance

Zambart has an established Research Governance Unit that monitors and audits the conduct of studies and ensures compliance with the approved protocols/ or amendment(s), with ICH-GCP and the applicable national and international regulatory requirements.

Our research staff are vigorously trained in research ethics and data protection.

Data security

In keeping with various levels of data management and governance in place, Zambart ensures that all electronic data is comprehensively encrypted.
We have a range of mechanisms to ensure transparency and accountability in our operations.

**Zambart Strategic Plan** - is the foundation for establishing, recording, refining and assigning priorities to our activities.

**Audited Budget Statements** - Zambart conducts annual audits specific to the statutory and donor specific requirements, informing our funders of the proposed allocation of resources to study outcomes and programs. (see Chapter 5 Our Finance on page 59)

**Annual report** - informs our partners and other stakeholders of the previous year’s activities and summary future plans. This report is also used as an advocacy tool.

**Senior Leadership Team**

1. Executive Director Dr Alwyn Mwinga
2. Director of Research Prof. Helen Ayles
3. Head: Social Science Unit/ Professional Development Dr Ginny Bond
4. Deputy Director of Research- Quantitative Dr Kwame Shanaube
5. Deputy Director of Research- Qualitative Dr Musonda Simwinga
6. Head: ICT/Data and Statistics Albertus (Ab) Schaap
7. Finance Manager Frank Mbozi
8. Human Resources Manager Gilbert Jikubi
9. Internal Audit Consultant Girish Nair
10. Head: Zambart Laboratories Barry Kosloff
Chapter 5: Financial overview

Income

Zambart has enjoyed a strong grant income growth overall the past five years moving from Kw43.24 million in 2014 to Kw90.64 million in 2016 before slowing down to Kw87.63 in 2017 and Kw86.07 million in 2018.

The PopART grants reached the pick in 2016 and started to slow down in 2017 and 2018. However, the overall income in 2018 remained resilient at the back of a new four year study, the Tuberculosis Reduction through Expanded Anti-retroviral Treatment and Screening for active TB (TREATS) study funded by EDCTP.

We expect to see a downward trend in the coming year as the popart grant come to a close in 2019.

The graph below shows the five year grant income growth.

Expenditure

We saw expenditure growing from Kw45.04 million in 2014 to a high of Kw104.46 million in 2017 before slowing down to Kw72.13 million in 2018.

The figure below is a three year spending split by personnel cost and operating costs.
Organisational Development and financial assurance

The above financial picture indicate that Zambart has grown in both depth and breadth of its work. The budget and expenditure have doubled over the past five years and so has the number of active studies and the workforce.

This growth prompted the need to further strengthen internal operating processes, improve financial assurance and decision support.

To this end, the two years under review saw the establishment of a management accounting function to support financial planning and control. Additionally, we started the creation of an internal audit function to oversee compliance to internal and external policies and procedures and provide assurance as to the implementation of organisational policies.

Zambart continued to undergo the yellow book audit and the statutory audit over the period under review and received a positive bill of health in both audits for the two years.
### Condensed financial statements for 2017 and 2018

#### Zambart Condensed Financial Statements for the years ended 31 December 2017 and 31 December 2018

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2017</th>
<th>2016</th>
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<tbody>
<tr>
<td><strong>REVENUES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The money that we received</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donors Grants</td>
<td>86 074 357.00</td>
<td>87 626 907</td>
<td>87 655 244</td>
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<tr>
<td>Interest Income and other</td>
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<td>676 972</td>
<td>2 984 929</td>
</tr>
<tr>
<td><strong>EXPENSES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How we spent the money</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Personnel Costs</td>
<td>51 372 474</td>
<td>72 008 084</td>
<td>56 718 597</td>
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<tr>
<td>Operational Costs</td>
<td>20 740 688</td>
<td>32 440 086</td>
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<tr>
<td>Less Financing Cost</td>
<td>19 689</td>
<td>9 745</td>
<td>-</td>
</tr>
<tr>
<td><strong>Revenues over Expense</strong></td>
<td>18 628 845</td>
<td>-</td>
<td>-16 154 036</td>
</tr>
<tr>
<td>Equity and Reserves , at 1 January</td>
<td>12 196 399</td>
<td>27 797 689</td>
<td>22 050 608</td>
</tr>
<tr>
<td>Change in Net Assets</td>
<td>612 399</td>
<td>552 746</td>
<td>(110 200)</td>
</tr>
<tr>
<td>Equity and Reserves, at 31 December</td>
<td>31 437 643</td>
<td>12 196 399</td>
<td>27 797 689</td>
</tr>
</tbody>
</table>

**THANK YOU**

GSK
Bill & Melinda Gates Foundation (BMGF)
Department for International Development (DFiD)
European and Developing Countries Clinical Trials (EDCTP) Project II
International Initiative for Impact Evaluation (3IE)
International Centre for Research on Women (ICRW)
Medical Research Council- UK (MRC)
Mott MacDonald Limited
National Institute of Health, USA (NIH)
Population Services International/ UNITAID
SHM Foundation
The University of Toronto
### Active studies during 2017/2018 operational years

<table>
<thead>
<tr>
<th>STUDY</th>
<th>FUNDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Popart: Cluster randomised trial of the impact of the combination</td>
<td>National Institute of Health, USA (NIH)</td>
</tr>
<tr>
<td>prevention package on population-level HIV incidence in Zambia and</td>
<td>BMG Foundation via 3ie (BMGF)</td>
</tr>
<tr>
<td>South Africa (P_A_R_T_Y)</td>
<td></td>
</tr>
<tr>
<td>Impact of HIV combination prevention interventions on HIV prevalence</td>
<td>DfID via Mott MacDonald Limited</td>
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<td>among young people in Zambia and South Africa: (P_A_R_T_Y)</td>
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<td>HPTN 071 Sub study: HIV-related stigma and discrimination among</td>
<td>NIH</td>
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<td>health workers in sub-Saharan Africa in the context of universal</td>
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<td>combination HIV prevention and treatment:</td>
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<td>HPTN 071 Sub study: Phylogenetics in PopART</td>
<td>NIH</td>
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<td>Eradicate TB study</td>
<td>USAID</td>
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<td>Aeras TB Vaccine trials: A Phase IIb, double blind, randomised,</td>
<td>AERAS/GSK</td>
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<td>placebo-controlled study</td>
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<td>TB in the Mines</td>
<td>Ministry of Health, Zambia</td>
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<td>Community based Distribution of Oral HIV Self testing kits: A</td>
<td>International Initiative for Impact Evaluation (3IE)</td>
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<td>pilot intervention and rapid Impact evaluation TW2.2.18</td>
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<td>Telisinghe study: Can community-wide active case finding for</td>
<td>MRC</td>
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<td>tuberculosis and universal testing and treatment for HIV control the</td>
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<td>African tuberculosis epidemic?</td>
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<td>SHM Foundation - Positive Action Challenges Prize for Project</td>
<td>SHM Foundation</td>
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<td>Insaka</td>
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<td>PANGEA - Phylogenetics Networks to Address Transmission of HIV</td>
<td>BMGF</td>
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<td>BILHIV - Validation of home-based sampling and vaginal self-</td>
<td>The Wellcome Trust</td>
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<td>sampling for the diagnosis of female genital schistosomiasis (FGS)</td>
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<td>in Zambian women with and without HIV seroconversion</td>
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<td>Avenir Health-</td>
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<td>SEPO III - Advancing Chronic Disease Models of Care for People</td>
<td>University of Toronto</td>
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<td>Living with HIV in Resource-Poor Settings</td>
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<td>Tuberculosis Reduction through Expanded Anti-retroviral Treatment</td>
<td>EDCTP II</td>
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<td>and Screening for active TB (TREATS) study</td>
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<td>Sustainable Evaluation through the Analysis of Routinely Collected</td>
<td>BMG Foundation via LSHTM</td>
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<td>HIV data (SEARCH)</td>
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<td>Healthy Transitions: Understanding the needs and stigma-related</td>
<td>MAC AIDS Foundation via International Centre for Research on Women, USA</td>
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<td>concerns of adolescent girls living with HIV in Zambia</td>
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<td>HIV Self-Testing Africa Region (STAR II)</td>
<td>Population Services International via LSHTM//UNITAID</td>
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<tr>
<td>Yathu Yathu - A Cluster Randomised Trial of community-based SRH and</td>
<td>MRC via LSHTM/</td>
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<td>HIV services for adolescents and young people in Zambia</td>
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</table>

Thank You
Publications, conference and workshop presentations

Publications
The following manuscripts have been published:


41. Simwinga, M.; Porter, J; Bond, V. Who is answerable to whom? Exploring the complex relationship between researchers, community and Community Advisory Board (CAB) members in two research studies in Zambia Critical Public Health (2018) ; DOI: 10.1080/09581596.2018.1440072 ; Published Manuscript.

42. Belemu, S., Simwinga, M., Simuyaba M., Ng’ombe T., Makola N., White, R., Ayles, H., and Bond, V. on behalf of the HPTN 071 (PopART) Study team. From Principles to Action: Stakeholder Engagement in a community-based cluster randomized trial, the HPTN 071 PopART trial (accepted as oral presentation at National Health Research Authority- Zambia’ 8th Health Research Conference).

43. Simwinga, M., Bwalya, C., Ngulube, C., Gwanu, L., Mulubwa, C, Hensen, B., Phiri, M., Hayes, M., Fidler, F., Ayles, A., and Bond, V. on behalf of the HPTN 071 (PopART) Study team. Challenges of identifying and following up social harms related to HIV self-testing in the context of pre-existing poverty and gender inequalities in urban Zambia: Experience from the HPTN 071 (PopART) Study (accepted as oral presentation at National Health Research Authority- Zambia’ 8th Health Research Conference).

44. Simwinga, M., Mwate, J., Ng’ombe, T., Belemu, S., Makola, N., Mubekapi-Musadaidzwa, C., Hoddinott, G., White, W., Shanaube, K., Bond, V. for the HPTN 071 (PopART) Study Team. Adolescent and young people’s participation and representation in clinical trials: lessons from a community-wide HIV testing and treatment study, the HPTN 071 (PopART) study (accepted as oral poster presentation at AIDS 2018)


52. D’Elbee, M; Indravudh, P; Sibanda, E; Mwenge, L; Kumwenda, M; Choko, A; Maringwa, G; Johnson, C; Hatzold, K; Corbett, L; Terris-Prestholt, F.2018. Informing targeted HIV self-testing: a protocol for discrete choice experiments in Malawi, Zambia and Zimbabwe. Technical Report. London School of Hygiene and Tropical Medicine, UK, London, UK. DOI: https://doi.org/10.17037/PUBS.04648463


60. Seeley, J., Bond, V., Yang, B., Floyd, S., MacLeod, D., Viljoen, L., Phiri, M., Simuyaba, M., Hoddinott, G., Shanaube, K. Bwalya, C. and on behalf of the HPTN 071 (PopART) study team, 2018. Understanding the Time Needed to Link to Care and Start ART in Seven HPTN 071 (PopART) Study Communities in Zambia and South Africa. AIDS and Behavior, 1-18.

61. Simwinda, M.; Porter, J.; Bond, V. Who is answerable to whom? Exploring the complex relationship between researchers, community and Community Advisory Board (CAB) members in two research studies in Zambia Critical Public Health (2018) ; DOI: 10.1080/09581596.2018.1440072 ; Accepted Manuscript 2017


Other grey publications
