

Folder eCC_00021011 is in stage Annual_Report_Review

Name of the University, Hospital, Research Institute, Academy or Ministry

London School of Hygiene and Tropical Medicine

Name of the Division, Department, Unit, Section or Area

Department of Clinical Research

City London Reference Number UNK-274

Title WHO Collaborating Centre for Sexually Transmitted Infections

Report Year 05-2021 to 05-2022

1. Annual report on the agreed workplan

Describe progress made on the agreed workplan. For each activity, detail (1) the actions taken, (2) the outputs delivered, as well as (3) any difficulties that may have been encountered. Three responses are expected. [maximum 200 words per activity]. Indicate, if an activity has been completed previously, has not yet started or has been placed on hold.

Activity 1

Title: At WHO's request, support the development, implementation and evaluation of STI diagnostic strategies, including point-of-care tests (POCTs).

Description: WHO estimated around 370 million new cases of the four curable sexually transmitted infections (STIs) worldwide in 2012: syphilis,

chlamydial and gonococcal infections as well as trichomoniasis. Such a high burden of STIs is the reality that the world is facing in the 21st century despite the fact that the above infections are preventable and treatable. In most cases the current treatment for these STIs is based on a one-dose cure by antibiotics administrated per os, "traitement minute". The WHO Department of HIV,Viral Hepatitis, and STI (HHS) and Department of Sexual and Reproductive Health and Research (SRH) in collaboration with National STI Programmes and Technical Partners have been implementing the Global Health Sector Strategy Strategy for STI control and prevention, 2016-2021/2030. Such a process requires technical support from Specialized Institutions with strong and internationally recognized expertise in STIs mainly from a public health perspective. The Department of Clinical Research of the London School of Hygiene and Tropical Medicine is one the most well-known centres in this field.

The collaboration with this proposed institution will help to strengthen the WHO work on critical components of STI control and prevention, particularly STI testing, prevention and clinical management of STI cases in key and vulnerable populations through assistance in

conducting research, particularly implementation research, and developing STI policies, providing technical inputs that may inform guidelines and recommendations as well as technical support to the countries through WHO in translating these recommendations into practice.

Status: ongoing

- 1. Evaluate impact of testing strategies (inclusive of self-testing, self-collection) on STI/HIV.
- In partnership with FIND and WHO, Dr. Tucker was part of an HCV self-testing pilot study in China and a follow-up randomized controlled trial of HCV self-testing among men who have sex with men.
- Dr. Tucker co-led the first randomized controlled trial evaluating syphilis self-testing (Wang et al, PLoS Medicine, 2022).
- Dr. Kpokiri led the development of a social innovation research checklist and a WHO monitoring and evaluation framework for social innovation. This tool has been used to assess social innovations focused on

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increasing STI/HIV test uptake. Dr. Kpokiri has presented on this research as part of TDR training workshops and in partnership with BRAC in Dhaka, Bangladesh.

- In partnership with a local CDC in China, Dr. Wu co-led a social media-based secondary distribution of HIV/syphilis testing program among key population in China and is currently optimizing this strategy to enhance effectiveness (Wu at al, Clinical Infectious Diseases, 2021; Zhou et al, PloS Medicine, 2022).
- MeSH implemented an algorithm for testing for recent HIV infections in Kenya and Zimbabwe and have published guidance on how recency assays can be used to characterise risk.
- MeSH successfully implemented CLOVÉ ("Clinic vs Venue Testing: An Assessment of Expanded HIV Testing and Surveillance to Improve HIV Prevention in Blantyre") in the field. Data generation is ongoing, first analysis will compare the population size and characteristics of clinic-based populations vs the venue-based populations among people with acute, recent, or chronic HIV infection.
- Prof. Mayaud and Daniel McCartney with colleagues in Brazil are investigating the acceptability, feasibility and usefulness of multiple anatomical sites self-sampling for the diagnosis of Neisseria gonorrhoeae and Chlamydia trachomatis (NG/CT) among transgender women participating in the PAHO/Ministry of Health Brazil funded TransOdara study conducted in 5 State capital cities in Brazil. The impact of the use of point of care/near POC tests for the identification of asymptomatic infections (HIV, syphilis, NG/CT, HPV) and uptake of preventative (vaccines, HIV-PREP) and treatment (for STI and HIV) services will be analysed later this year.
- Prof. Bustinduy, Dr. Kelly and Prof. Mayaud are evaluating the performance and acceptability of home-based self-sampling using multiplex point-of-care tests for detection of female genital schistosomiasis, human papillomavirus (HPV) and Trichomonas vaginalis among women living with and without HIV in Kafue and Livingstone, Zambia (currently enrolled 700/2000 women).
- Dr. Ong and Prof. Peeling have completed a systematic review of the literature on pooled testing for STIs.
- Kevin Martin, supervised by Prof. Ferrand, has completed the protocol for the IPSAZ study "Investigation of a package of STI testing (Gonorrhoea, chlamydia, Trichomonas, syphilis) integrated with HIV and hepatitis testing in antenatal care settings in Zimbabwe". This will establish an EGASP system for GC antimicrobial resistance surveillance) and WGS of GC isolates. Evaluation of cost and process evaluation are embedded. The project is awaiting ethical approval.
- Chido Dziva Chikwari is leading STICH study ("STI in CHIEDZA") alongside Rashida Ferrand. The study aims to evaluate the effectiveness of community-based screening for STIs using newer diagnostic technologies among youth in Zimbabwe. The study is being conducted in partnership with Ministry of Health and Child Care in Zimbabwe. Non-lab professionals were trained in using GenXpert platforms for STI testing to be conducted outside laboratory settings. Toolkit for partner notification has been developed and implemented. The study protocol has been published and a manuscript on self-collected vaginal swabs for STI testing (showing high acceptability among young women) is in preparation. Manuscript on pilot study, risk prediction tool, feasibility of POC testing in community-based settings) published. The intervention and the population-based outcome survey have completed and trial unblinding is planned for 2022.
- Dr. Marks is leading the MAGUS study on the aetiology of genital ulcers and sequencing of T. pallidum. A multi-country study involving Zimbabwe, Ghana, Uganda and Argentina in collaboration with Wellcome Sanger Institute.
- Dr. Harding-Esch has evaluated the compliance on online STI self-sample and self-testing kits with UK national guidelines.

Publications

Clarke E, Horner PJ, Muir P, Turner KME, Harding-Esch EM. Assessment of online self-testing and self-sampling service providers for sexually transmitted infections against national standards in the UK in 2020. Sex Transm Infect. 2022 Apr 12:sextrans-2021-055318. doi: 10.1136/sextrans-2021-055318.

McCartney, D. J., et al. (2022). "Acceptability of self-sampling for etiological diagnosis of mucosal sexually transmitted infections (STIs) among transgender women in a longitudinal cohort study in Sao Paulo, Brazil." Braz J Infect Dis 26(3): 102356.https://www.ncbi.nlm.nih.gov/pubmed/3551305510.1016/j.bjid.2022.102356 Oladele, D., et al. (2021). "The 4 Youth By Youth mHealth Photo Verification App for HIV Self-testing in Nigeria: Qualitative Analysis of User Experiences." JMIR Form Res 5(11):

e25824.https://www.ncbi.nlm.nih.gov/pubmed/3478757910.2196/25824

Ong, J. J., et al. (2021). "Designing HIV Testing and Self-Testing Services for Young People in Nigeria: A Discrete Choice Experiment." Patient 14(6): 815-

826.https://www.ncbi.nlm.nih.gov/pubmed/3394224810.1007/s40271-021-00522-2



Sha, Y., et al. (2022). ""Just felt so convenient and warm by the non-profit help". Optimizing HIV self-test secondary distribution among men who have sex with men in China." AIDS Care: 1-6.https://www.ncbi.nlm.nih.gov/pubmed/3528750410.1080/09540121.2022.2050885

Uzoaru, F., et al. (2021). "Costs of implementing community-based intervention for HIV testing in sub-Saharan Africa: a systematic review." Implement Sci Commun 2(1):

73.https://www.ncbi.nlm.nih.gov/pubmed/3422582010.1186/s43058-021-00177-y

Wang, C., et al. (2022). "Expanding syphilis test uptake using rapid dual self-testing for syphilis and HIV among men who have sex with men in China: A multiarm randomized controlled trial." Plos Medicine 19(3).<Go to ISI>://WOS:00078420050000210.1371/journal.pmed.1003930

Zhang, J., et al. (2021). "Internet-Based HIV Self-Testing Among Men Who Have Sex With Men Through Preexposure Prophylaxis: 3-Month Prospective Cohort Analysis From China." Journal of Medical Internet Research 23(8).<Go to ISI>://WOS:00068973160000310.2196/23978

- 2. Provide technical inputs that may inform WHO in the development of guidelines for STI case management (e.g. syndromic management of genital ulcer disease (GUD), pelvic inflammatory disease (PID), anorectal syndrome).
- Dr. Ong, Prof. Mayaud and Dr. Falconer have conducted several systematic reviews and meta-analyses of various STI syndromes (genital ulcer disease [GUD], pelvic inflammatory disease [PID] and anorectal syndromes) for WHO. These were used in the review of the WHO guidelines for the management of STI (WHO 2021, https://www.who.int/publications/i/item/9789240024168), and prepared for publication (Loh AJW, Ting EL, Wi TE, et al. The Diagnostic Accuracy of Syndromic Management for Genital Ulcer Disease: A Systematic Review and Meta-Analysis. Frontiers in Medicine 2022;8 doi: 10.3389/fmed.2021.806605).
- 3. Support STI diagnostic test development (including Target Product Profiles (TPPs), evaluation and implementation, including for POCTs detecting Chlamydia trachomatis (CT)/Neisseria gonorrhoeae (NG), Trichomonas vaginalis (TV) and Mycoplasma genitalium (MG).
- Prof. Mayaud, Dr. Ruzagira, Dr. Mayanja and Sylvia Kusemererwa are conducting a study of CT/NG POC test development among young male and female at risk populations (ie, young sex workers and PREP users) in urban, peri-urban and rural sites in Uganda. Participant enrolment is on-going. The first phase lasting 2 years included 900 individuals, and further funding has been obtained for 2 years to collect samples from an additional 2000 individuals. The data currently obtained helps describe the prevalence of NG/CT in various high groups including people living with HIV (see Activity 2).
- Dr Matthew Chico is leading the ASPIRE study: an evaluation of antigen-based POC tests for Trichomonas vaginalis and bacterial vaginosis among pregnant women in Zambia with Dr Sumire Sorano, Dr Emma Harding-Esch, and Professor Daniel Chandramohan, in partnership with Dr Igor Toskin of the WHO Department of Sexual and Reproductive Health, and Dr Magnus Unemo of the Örebro University Hospital, as reference laboratory and WHO Collaborating Centre in WHO Collaborating Centre for Gonorrhoea and Other STIs. The protocol has approval from the ethics committee at the Tropical Disease Research Centre in Zambia and from HRP2 at WHO. It is presently under review by ethics committees at the WHO and LSHTM, as well as the Health Research Authority in Zambia. Study initiation is likely to occur in the second half of August or first half of September.
- Drs Tucker, Marks and Terris-Prestholt We completed a trial in China evaluating syphilis-Self testing uptake of testing amongst MSM compared with facility based testing. (https://journals.plos.org/plosmedicine/article/authors?id=10.1371/journal.pmed.1003930)
- Drs Tucker, Marks and Terris-Prestholt completed both formative work and a pilot RCT on syphilis self-testing in Zimbabwe (Formative work https://sti.bmj.com/content/98/3/197, Trial paper in review).
- Dr. Harding-Esch is leading the implementation work package of the GIFT study, with Dr. Chido Dziva Chikwari leading work at the Zimbabwe clinical site, with Katharina Kranzer. This is a multi-centre clinical study to evaluate the feasibility and performance of the Genital InFlammation Test (GIFT), a lateral flow point of care test, for identifying women with inflammatory STIs and bacterial vaginosis among women attending family planning services in Zimbabwe, Madagascar, and South Africa. The study will also evaluate how the GIFT device can be integrated into routine care (feasibility, acceptability, and cost effectiveness).
- Dr. Harding-Esch has conducted a systematic review of CT/NG rapid tests implemented in routine clinical practice.

Publications:



Fuller SS, Clarke E, Harding-Esch EM. Molecular chlamydia and gonorrhoea point of care tests implemented into routine practice: Systematic review and value proposition development. PLoS One. 2021 Nov 8;16(11):e0259593. doi: 10.1371/journal.pone.0259593.

Hensen B, Phiri M, Schaap A, et al. Uptake of HIV Testing Services Through Novel Community-Based Sexual and Reproductive Health Services: An Analysis of the Pilot Implementation Phase of the Yathu Yathu Intervention for Adolescents and Young People Aged15-24 in Lusaka, Zambia. AIDS Behav 2022;26(1):172-82. doi: 10.1007/s10461-021-03368-9 [published Online First: 2021/07/25]

- 4. Carry out capacity building to develop implementation and evaluation of STI diagnostic methodologies and strategies as well as to support its implementation through training of experts from the WHO list of priority LMICs. To lead and coordinate the specified research and normative work.
- MeSH supported the development of the forthcoming 2022 WHO Consolidated HIV Strategic Information Guidelines, and the 2022 WHO/UNAIDS HIV recent infection technical guidelines entitled "When and How to Use Recency Assays for HIV Surveillance".
- MeSH held the co-chair of the incidence chapter for the forthcoming 2022 WHO Consolidated HIV Strategic Information Guidelines.
- Prof Mabey has taught on STI diagnostics to the LSHTM DTM&H and MSc TMIH students and to the students on the Diploma in Tropical Nursing course.
- Dr. Tucker presented at a WHO-WPR Regional Office Innovation Forum and served as a judge and technical advisor for the inaugural 2022 WHO Western Pacific Innovation Challenge. In partnership with TDR and PAHO, Dr. Tucker organized a social innovation special issue in partnership with BMJ Innovations and other BMJ journals.

Activity 2

Title: At WHO's request, support WHO in activities that aim to improve STI prevention and control and sexual and reproductive health (SRH) services in key and vulnerable populations for STIs including HIV. Description: WHO estimated around 370 million new cases of the four curable sexually transmitted infections (STIs) worldwide in 2012: syphilis,

chlamydial and gonococcal infections as well as trichomoniasis. Such a high burden of STIs is the reality that the world is facing in the 21st century despite the fact that the above infections are preventable and treatable. In most cases the current treatment for these STIs is based on a one-dose cure by antibiotics administrated per os, "traitement Minute. The WHO Department of HIV, Viral Hepatitis, and STI (HHS) and Department of Sexual and Reproductive Health and Research (SRH) in collaboration with National STI Programmes and Technical Partners have been implementing the Global Health Sector Strategy for STI control and prevention, 2016-2021/2030. Such a process

requires technical support from Specialized Institutions with strong and internationally recognized expertise in STIs mainly from a public health perspective. The Department of Clinical Research of the London School of Hygiene and Tropical Medicine is one the most well-known centres in this field. The collaboration with this proposed institution will help to strengthen the WHO work on critical components of STI control and prevention, particularly STI testing, prevention and clinical management of STI cases in key and vulnerable populations through assistance in conducting research, particularly implementation research, and developing STI policies, providing technical inputs that may inform guidelines and recommendations as well as technical support to the countries through WHO in translating these recommendations into practice.

Status: ongoing

- 1. Provide technical support to WHO in assessing the burden of STIs in key populations.
- Prevalence of five curable sexually transmitted infections in The Gambia: Dr Robert Butcher, Dr Emma Harding-Esch, Prof Martin Holland and Dr Ed Clarke have led a study which has tested archived urine and serum from women in The Gambia for five curable sexually transmitted infections. In May 2021, MRC Gambia staff were trained how to run the qPCR diagnostic assay on urine samples and on how to use Syphilis DPP tests on serum. Laboratory analyses were conducted in the second and third quarters of 2021. Prevalence analyses were completed in the fourth quarter of 2021. Final analysis of association with other metadata variables and preparation of a manuscript for publication was ongoing in May 2022.
- Philippe Mayaud, Richard Hayes, Ian McCormick and Allen Foster at LSHTM collaborated to produce estimates on global burden of HIV attributable to HSV-2, and on global burden of HSV-1, with colleagues at

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Imperial College London and Bristol University, UK (Silhol, JAIDS 2021; McCormick, Ophthalmic Epidemiology 2021). Further manuscripts are being developed on the impact of HSV-2 on HIV epidemic in South Africa, and on the burden of neurological HSV.

- Philippe Mayaud and collaborators have reported on the epidemiological burden of NG/CT and other STIs among students attending higher learning institutions in Tanzania (Mcharo, PLoS One 2022), among young atrisk populations in Uganda (Mayanja, IUSTI 2022 abstract) and among transgender women in Brazil (McCartney, IUSTI 2022 abstract).
- Dr Chico has led several systematic reviews and meta-analyses to quantify the burden of STIs in key populations. One has been published; seven will be presented at meetings of IUSTI in Victoria Falls (September 2022), Zimbabwe or ASTMH in Seattle, USA (November 2020) and published in the coming year.
- Dr Yunia Mayanja has worked with 14-24-year-old HIV negative adolescent girls and young women at risk of HIV infection; 92.8% reported engaging in paid sex (IPAD cohort). This was a cohort study that assessed uptake of oral PrEP but also involved testing for STIs and completed follow up in December 2020. https://doi.org/10.1002/jia2.25909.
- Dr Yunia Mayanja was Principal Investigator for a cohort study among 14-17-year-old male and female adolescents from urban slums of Kampala (FERDAR study). The study completed participant follow up in March 2021 had a number of outcomes including STIs and showed a high prevalence of STIs.
- Dr Harding-Esch supervised a LSHTM MSc student's project on "Epidemiology of Neisseria gonorrhoeae in Europe: A systematic review, meta-analysis, and meta-regression", in collaboration with Weill Cornell Medicine Qatar (WCM-Q). The project is currently being written up for publication.

Publications:

de Wit MM, Rice B, Risher K, et al. Experiences and lessons learned from the real-world implementation of an HIV recent infection testing algorithm in three routine service-delivery settings in Kenya and Zimbabwe. BMC Health Services Research 2021;21(1):596. doi: 10.1186/s12913-021-06619-6

Silhol R, Coupland H, Baggaley RF, et al. What Is the Burden of Heterosexually Acquired HIV Due to HSV2? Global and Regional Model-Based Estimates of the Proportion and Number of HIV Infections Attributable to HSV-2 Infection. J Acquir Immune Defic Syndr 2021;88(1):19-30. doi: 10.1097/QAI.0000000000002743 [published Online First: 2021/06/13]

Tsuboi M, Evans J, Davies EP, et al. Prevalence of syphilis among men who have sex with men: a global systematic review and meta-analysis from 2000-20. Lancet Global Health 2021;9(8):E1110-E18. doi: 10.1016/s2214-109x(21)00221-7

- 2. Support WHO's work on understanding sexual behaviour to improve sexual and reproductive health and STI prevention and control.
- MeSH, in collaboration with the University of Georgetown, became the custodians of a database on evidence behind risk factors for HIV acquisition. We have analysed these data in the context of FSW and will soon submit a paper entitled "Understanding HIV prevention data needs for key populations in sub-Saharan Africa: an evidence synthesis". In collaboration with the UNAIDS Reference Group on Estimates, Modelling and Projections we have submitted an abstract to IAS 2022 entitled "Estimating key population size, HIV prevalence, and ART coverage for sub-Saharan Africa at the national level".
- Chris Bonell, Clare Tanton, Wendy Macdowall and Laura Oakley are involved in the fourth round of National Survey of Sexual Attitudes and lifestyles (Natsal-4). Ethical approval has been obtained and qualitative exploratory research, piloting and dress rehearsal all completed. Main survey research will occur next.
- Chris Bonell is leading an RCT of Positive Choices sex education intervention in English secondary schools (with Ruth Ponsford, Rebecca Meiksin, Nerissa Tilouche, Neisha Sundaram). The project has been set up. Schools are recruited and baseline surveys completed. The schools have been randomised and intervention and process evaluation are beginning. Ethical approval has been obtained and protocols registered (IRCTN 40365).
- In Panama, Amanda Gabster, Philippe Mayaud and Joe Tucker have studied the impact of COVID-19 pandemic on sexual behaviours of young populations (Gabster, Sex Transm Infect. 2021).
- Philippe Mayaud and colleagues have identified SRH education gaps among higher-learning institutions in Tanzania (Mcharo, BMC Public Health. 2021) and among indigenous adolescents in Panama (Gabster, Sex Education 2021).
- Drs. Kpokiri, Wu, and Tucker led the development of a sexual health survey instrument in partnership with the WHO/HRP. This project included a crowdsourcing open call, a participatory designation in Kenya, and a

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multi-step adapted Delphi process to finalize a consensus survey instrument.

- Joe Tucker serves as a coordinator of the I-SHARE network, a 30-country open science collaborative research study focused on understanding the impact of COVID-19 on sexual and reproductive health (more details here). Drs. Wu, Kpokiri, and Mayaud are also members of the I-SHARE network and have contributed to country or regional analyses. As part of the I-SHARE study, Dr. Tucker presented at the annual meeting for the ANSER network at the University of Ghent, a WHO/HRP Collaborating Center.
- Dr. Kpokiri is leading a WHO/HRP project examining the impact of COVID-19 on sexual and reproductive health services. This project includes a systematic review on SRH disruptions and adaptations as well as a global crowdsourcing open call. The open call identified 80 submissions from 42 countries.

Publications:

Booton RD, Ong JJ, Lee A, et al. Modelling the impact of an HIV testing intervention on HIV transmission among men who have sex with men in China. HIV Med 2021;22(6):467-77. doi: 10.1111/hiv.13063 [published Online First: 2021/01/30]

Erausquin JT, Tan RKJ, Uhlich M, et al. The International Sexual Health And Reproductive Health Survey (I-SHARE-1): A Multi-Country Analysis of Adults from 30 Countries Prior to and During the Initial COVID-19 Wave. Clin Infect Dis 2022 doi: 10.1093/cid/ciac102 [published Online First: 2022/02/10]

Gabster A, Erausquin JT, Michielsen K, et al. How did COVID-19 measures impact sexual behaviour and access to HIV/STI services in Panama? Results from a national cross-sectional online survey. Sex Transm Infect 2021 doi: 10.1136/sextrans-2021-054985 [published Online First: 2021/08/18]

Gabster A, Cislaghi B, Pascale JM, et al. Sexual and reproductive health education and learning among Indigenous youth of the Comarca Ngabe-Bugle, Panama. Sex Education-Sexuality Society and Learning doi: 10.1080/14681811.2021.1915757

Gonsalves L, Hunter EC, Brizuela V, et al. Cognitive testing of a survey instrument to assess sexual practices, behaviours, and health outcomes: a multi-country study protocol. Reprod Health 2021;18(1):249. doi: 10.1186/s12978-021-01301-w [published Online First: 2021/12/21]

Hlatshwako TG, Shah SJ, Kosana P, et al. Online health survey research during COVID-19. Lancet Digit Health 2021;3(2):e76-e77. doi: 10.1016/S2589-7500(21)00002-9 [published Online First: 2021/01/30] King R, Muhanguzi E, Nakitto M, et al. Mobility study of young women who exchange sex for money or commodities using Google Maps and qualitative methods in Kampala, Uganda. Bmj Open 2021;11(5) doi: 10.1136/bmjopen-2020-043078

Kpokiri EE, Chen E, Li J, et al. Social Innovation For Health Research: Development of the SIFHR Checklist. PLoS Med 2021;18(9):e1003788. doi: 10.1371/journal.pmed.1003788 [published Online First: 2021/09/14] Kpokiri EE, Wu D, Srinivas ML, et al. Development of an international sexual and reproductive health survey instrument: results from a pilot WHO/HRP consultative Delphi process. Sex Transm Infect 2022;98(1):38-43. doi: 10.1136/sextrans-2020-054822 [published Online First: 2021/04/14]

McHaro RD, Kisinda A, Njovu L, et al. Prevalence of and risk factors associated with HIV, Herpes Simplex Virus-type 2, Chlamydia trachomatis and Neisseria gonorrhoeae infections among 18–24 year old students attending Higher Learning Institutions in Mbeya-Tanzania. PLOS ONE 2022;17(5):e0266596. doi: 10.1371/journal.pone.0266596

McHaro RD, Mayaud P, Msuya SE. Where and how do young people like to get their sexual and reproductive health (SRH) information? Experiences from students in higher learning institutions in Mbeya, Tanzania: a cross-sectional study. Bmc Public Health 2021;21(1) doi: 10.1186/s12889-021-11728-2

Mendez-Lopez A, Hickson F, Jansen K, et al. What is the empirical basis for converting banded ordinal data on numbers of sex partners among MSM into a continuous scale level variable? A secondary analysis of 13 surveys across 17 countries. BMC Medical Research Methodology 2022;22(1):59. doi: 10.1186/s12874-021-01483-8

Michielsen K, Larrson EC, Kagesten A, et al. International Sexual Health And REproductive health (I-SHARE) survey during COVID-19: study protocol for online national surveys and global comparative analyses. Sexually Transmitted Infections 2021;97(2):88-92. doi: 10.1136/sextrans-2020-054664

Tan RKJ, Michielsen K, Campbell L, et al. Sexual and reproductive health during COVID-19 - the I-SHARE multi-country survey. Nat Rev Urol 2022;19(6):325-26. doi: 10.1038/s41585-022-00603-3 [published Online First: 2022/05/11]

3. Provide support in developing interventions to improve the sexual and reproductive health of vulnerable

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populations, including adolescents and (pregnant) women.

- Helen Weiss is leading the MENISCUS trial, a school-based cluster-randomised trial to evaluate the effect of a menstrual health intervention girls' education, health & wellbeing outcomes including RTI (Joint Global Health Trials, Weiss). Since May 2021 we have: Received ethics approval, Undertaken a rapid assessment to select 60 schools for the trial; Done the parental consent for all eligible participants (around 4000 girls); Done the student assent & baseline survey in around half of these; Presented at a webinars.
- Philippe Mayaud and colleagues from Burkina Faso and University of Montpellier, France, have summarised a multi-year research programme of targeted behavioural and STI interventions conducted among young FSWs in Burkina Faso (Taofiki, RESP, submitted).
- The Yathu Yathu trial (PI Helen Ayles) of comprehensive, community-based and peer-led sexual and reproductive health services on knowledge of HIV status among adolescents and young people in Lusaka, Zambia was completed in March 2022.
- Aoife Doyle has been leading the Y-Check project, an innovative strategy for health check-up visits during adolescence in LMICs. In the reporting period, the protocol has been written and ethical approval obtained, a crowdsourcing competition was held, staff were recruited and trained, and intervention co-design workshops were held.
- Aoife Doyle has led the Zvatinoda! Study:(What we want!): Increasing demand and uptake of sexual and reproductive health services by young people in Zimbabwe. Intervention implementation took place Jul 21-Oct 21; Paper writing in May 21- May 22; Data analysis in May 21- Dec 21; Dissemination workshop in March 22; Public engagement video recorded March 22; Spoken word recording in May 22. Publications:
- B H, M G, M P, et al. Access to menstrual hygiene products through incentivised, community-based, peer-led sexual and reproductive health services before and during the COVID-19 pandemic: findings from the Yathu Yathu trial. BMC Public Health 2022;22(1):554. doi: 10.1186/s12889-022-12915-5
- Hensen B, Phiri M, Schaap A, et al. Yathu Yathu ("For us, by us"): Design of a cluster-randomised trial of the impact of community-based, peer-led comprehensive sexual and reproductive health services for adolescents and young people aged 15 to 24 in Lusaka, Zambia. Contemporary Clinical Trials 2021;110 doi: 10.1016/j.cct.2021.106568

Devine A, Xiong XQ, Gottlieb SL, et al. Health-related quality of life in individuals with genital herpes: a systematic review. Health and Quality of Life Outcomes 2022;20(1) doi: 10.1186/s12955-022-01934-w lwelunmor J, Ezechi O, Obiezu-Umeh C, et al. Enhancing HIV Self-Testing Among Nigerian Youth: Feasibility and Preliminary Efficacy of the 4 Youth by Youth Study Using Crowdsourced Youth-Led Strategies. AIDS Patient Care STDS 2022;36(2):64-72. doi: 10.1089/apc.2021.0202 [published Online First: 2022/02/12] lwelunmor J, Tucker JD, Obiezu-Umeh C, et al. The 4 Youth by Youth (4YBY) pragmatic trial to enhance HIV self-testing uptake and sustainability: Study protocol in Nigeria. Contemp Clin Trials 2022;114:106628. doi: 10.1016/j.cct.2021.106628 [published Online First: 2021/11/21]

Ong JJ, Fu HY, Baggaley RC, et al. Missed opportunities for sexual transmitted infections testing for HIV preexposure prophylaxis users: a systematic review. Journal of the International Aids Society 2021;24(2) doi: 10.1002/jia2.25673

Phiri MM, Hensen B, Schaap A, et al. Adapting community-based sexual and reproductive health services for adolescents and young people aged 15-24 years in response to COVID-19 in Lusaka, Zambia: the implications on the uptake of HIV testing services. Bmc Health Services Research 2022;22(1) doi: 10.1186/s12913-022-07878-7

Simuyaba M, Hensen B, Phiri M, et al. Engaging young people in the design of a sexual reproductive health intervention: Lessons learnt from the Yathu Yathu ("For us, by us") formative study in Zambia. Bmc Health Services Research 2021;21(1) doi: 10.1186/s12913-021-06696-7

Tahlil KM, Obiezu-Umeh C, Gbajabiamila T, et al. A designathon to co-create community-driven HIV self-testing services for Nigerian youth: findings from a participatory event. Bmc Infectious Diseases 2021;21(1) doi: 10.1186/s12879-021-06212-6

- 4. Provide support in developing interventions to improve the sexual and reproductive health of key populations, including female sex workers (FSW) and men who have sex with men (MSM).
- Drs. Tucker, Wu, and Peeling are all part of the PIONEER study, a randomized controlled trial to assess the effectiveness and cost of a pay-it-forward intervention to increase gonorrhoea and chlamydia testing among MSM in China. A related pay-it-forward RCT to increase gonorrhoea/chlamydia testing among female sex workers was recently completed in China. The pay-it-forward team was recognized in August 2021 as part of a

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WHO World Youth Day event organized by the WHO Innovation Team.

- Jason Ong, Prof. Mayaud, Prof. Terris-Prestholt, A/Prof Tucker and Dr. Falconer conducted a systematic review and meta-analysis to identify the gaps for STI testing for HIV PrEP users.
- Jason Ong conducted a systematic review to identify the quality of life tools used for people living with genital herpes.
- James Hargreaves, Joanna Busza and S Ali are involved in the AMETHIST trial (2020-2024) using RDS surveys conducted in Zimbabwe, South Africa and Malawi among female sex workers to test effectiveness of a risk-differentiated programme to reduce HIV acquisition and transmission. Testing for syphilis, Chlamydia and Gonorrhoea and biomarkers will also be used to verify condom-use reporting. The process evaluation and endline RDS survey completed in Zimbabwe and RDS surveys have started in South Africa and Malawi. A nested study on sex workers' life history of sex work and engagement with care, complemented by coital diary completed in Zimbabwe and started in Malawi and South Africa. The trial protocol has been published. A qualitative analysis training and writing workshop for the Zimbabwe process evaluation field team was held in January 2022 (led by J Busza). A data interpretation and paper drafting workshop for Zimbabwean research team was held in May 2002 (led by J Busza).
- The same team completed the AMETHIST intervention (2020-2021) using risk-differentiated services using microplanning and self-help groups to reduce female sex workers' vulnerability and increase their engagement with care, implemented in 11 out of 22 study sites in Zimbabwe. Zimbabwe's nationally-scaled sex worker HIV programme provides syndromic management as a routine part of clinical services. The trial intervention ended November 2021 but programmatic funds allow continuation and scale-up of AMETHIST service delivery model.
- Dr Axel Schmidt, as part of the Sigma Research group (https://web.archive.org/web/20220401104145/https://sigmaresearch.org.uk/local/item/unaids) added on the UNAIDS key populations Atlas (https://kpatlas.unaids.org/dashboard#/home) several STI-relevant 68-country maps among MSM, including: Comprehensive STI Screen; STI testing; Disclosure in health care; Syphilis and symptomatic syphilis; Gonorrhoea and symptomatic gonorrhoea; Chlamydia infection and symptomatic chlamydia infection: Partner notification syphilis; Partner notification gonorrhoea.

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Matambanadzo P, Busza J, Mafaune H, et al. "It went through the roof": an observation study exploring the rise in PrEP uptake among Zimbabwean female sex workers in response to adaptations during Covid-19. Journal of the International Aids Society 2021;24 doi: 10.1002/jia2.25813

Sha Y, Xiong Y, Ong JJ, et al. Comparing the effectiveness of secondary distribution of HIV/syphilis dual self-testing to testing card referral in promoting HIV testing among gay, bisexual, and other men who have sex with men in Guangzhou, China: a quasi-experimental study. Sex Health 2022 doi: 10.1071/SH21176 [published Online First: 2022/05/26]

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- 5. Carry out training activities to improve STI prevention and control and sexual and reproductive health (SRH) services in populations at-risk for STIs, including HIV. To lead and coordinate the specified research and normative work.
- We have provided input and advice in the development of the new, Buffet-foundation funded, online/hybrid MSc Sexual & Reproductive Health Policy & Practice (SRHPP) to be launched in 2022 and organised jointly between LSHTM and University of Ghana School of Public Health; it will target African students, aiming to provide 50 one-year fellowships to African scholars over 3 years.
- MeSH held a series of national HIV data and epidemiology focused convenings in South Africa which have been attended by an extensive number of national and provisional stakeholders, with each stimulating good discussion. Presenting on the HIV epidemiology in the Western Cape, on pregnant women, and on advanced disease, our convenings have filled an HIV epidemiological gap in South Africa and have led to robust discussions on, for example, gaps in the delivery of HIV care, the need for improved access to ART, the importance of CD4 monitoring, and patterns of engagement in care. Following our three convenings, we held a MeSH consolidation meeting with provincial stakeholders. Stakeholders acknowledged that the sessions provided an excellent space for reflection, and requested that we continue the sessions.

Activity 3

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Title: At WHO's request and under its leadership, support WHO in activities related to PMTCT, hepatitis and STIs/sequelae elimination, including cervical cancer, and provide technical inputs that may inform the development of the WHO guidelines.

Description: WHO estimated around 370 million new cases of the four curable sexually transmitted infections (STIs) worldwide in 2012: syphilis,

chlamydial and gonococcal infections as well as trichomoniasis. Such a high burden of STIs is the reality that the world is facing in the 21st century despite the fact that the above infections are preventable and treatable. In most cases the current treatment for these STIs is based on a one-dose cure by antibiotics administrated per os, "traitement Minute. The WHO Department of HIV, Viral Hepatitis, and STI (HHS) and Department of Sexual and Reproductive Health and Research (SRH) in collaboration with National STI Programmes and Technical Partners have been implementing the Global Health Sector

Strategy for STI control and prevention, 2016-2021/2030. Such a process requires technical support from Specialized Institutions with strong and internationally recognized expertise in STIs mainly from a public health perspective. The Department of Clinical Research of the London School of Hygiene and Tropical Medicine is one the most well-known centres in this field. The collaboration with this proposed institution will help to strengthen the WHO work on critical components of STI control and prevention, particularly STI testing, prevention and clinical management of STI cases in key and vulnerable populations through assistance in conducting research, particularly implementation research, and developing STI policies, providing technical inputs that may inform guidelines and recommendations as well as technical support to the countries through WHO in translating these recommendations into practice.

Status: ongoing

1. Evaluate of the efficacy and impact of human papillomavirus (HPV) vaccination and screening strategies for cervical cancer elimination.

Our work has on cervical cancer screening in women living with HIV (WLHIV) has been very influential globally.

- Philippe Mayaud and Helen Kelly have published findings of an 18-month prospective study evaluating various cervical cancer screening strategies for cervical precancer detection in women living with HIV (HPV in Africa Research Partnership, HARP) (Kelly, PLoS Medicine 2021; Devine, PLoS One 2021; Maringa, Int J Gynaecol Obstet. 2020). As part of the WHO guideline development for screening and treatment of cervical cancer lesions between 2020-2021, these data were shared with WHO for the purposes of an individual patient-level data analysis on understanding age-related risk of cervical precancer and cancer to inform on age to initiate cervical cancer screening and frequency of screening for women living with HIV (Kelly, eClinicalMedicine, under review).
- Helen Kelly is Co-I on a multi-country research study, led by the National Cancer Institute, USA which aims to evaluate a novel screening strategy (screening with restricted HPV genotype approach with triage of genotype specific HPV positive women using automated visual evaluation methods) for the detection of cervical precancer in women with and without HIV in LMICs in Africa, Asia and Latin America (Desai, Int J Cancer 2022).
- Helen Kelly is leading on a review to identify national official recommendations and coverage data for cervical cancer screening of women living with HIV in the sub-Saharan Africa region working in collaboration with colleagues at the Catalan Institute of Oncology (ICO), Spain. This includes identification of countries or settings with integration of cervical cancer screening in HIV care. These data aim to inform on control and prevention measures for cervical cancer in settings where HIV is prevalent among women.
- Research outputs related to the HPV vaccine includes the publication of the DORIS trial main results, led by Deborah Watson-Jones (PI) with Kathy Baisley, Richard Hayes and Philippe Mayaud as other LSTHM co-ls. The DORIS trial taking place in Mwanza, Tanzania, is a randomised evaluation of dose reduction of both Gardasil and Cervarix to 2-doses and 1-dose regimens targeting girls in age of vaccination (9-14 yo) on immunological correlates of efficacy. The trial results have proven hugely influential both globally (WHO, IAVI) and nationally in the UK and Tanzania inter alia, with trial findings, bridging with other international studies studying efficacy, being considered to guide adoption of HPV vaccine 1-dose regimens for girls (Watson-Jones, Lancet Global Health, under review).
- Philippe Mayaud with colleagues at the University of Sao Paulo have investigated the effectiveness of HPV vaccination among solid-organ transplant patients in Sao Paulo (Miyaki, PLoS One 2022); and with colleagues



at Imperial College and Bristol University, UK, conducted a systematic review of the effects of vaccinations among WLHIV (Staadegaard, Lancet HIV, under review). Other research outputs of these collaborations are in preparation.

- Dr. Wu led a BMGF research study using pay-it-forward to promote HPV vaccination among young girls in China. Pay-it-forward has an individual receive a free service (eg, HPV vaccine) from someone in the local community and then ask if they would like to contribute money or messages to spur subsequent vaccination efforts. The pilot found that a pay-it-forward approach significantly increased HPV vaccination.
- Dr Yunia Mayanja and Dr Gertrude Namale together with Prof Janet Seeley have completed a study on which they investigated the usefulness of visual inspection with acetic acid (VIA) in detecting pre-cancerous and cancerous lesions among FSWs enrolled at the Good Health for Women Project (GHWP) in Kampala. Participants were enrolled in June 2014 July 2015. https://doi.org/10.1186/s13027-021-00373-4.

Publications

Watson-Jones D, Changalucha J, Whitworth H, Pinto L, Mutani P, Indangasi J, Kemp T, Hashim R, Kamala B, Wiggins R, Songoro T, Connor N, Mbwanji G, Pavon M, Lowe B, Mmbando D, Kapiga S, Mayaud P, deSanJosé S, Dillner J, Hayes R, Lacey CJ, Baisley K. Immunogenicity and safety results comparing single dose HPV vaccine with two or three doses in Tanzanian girls - the DoRIS randomised trial. The Lancet Global Health. 2022. (preprint April 22: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4055429.)
Miyaji KT, Infante V, Picone CM, Levi JE, Oliveira ACS, Lara AN, Tacla M, Dillner J, Kann H, Eklund C, Castanheira CP, Mayaud P, Sartori AMC; Study group on HPV vaccine in immunosuppressed persons. Human Papillomavirus (HPV) seroprevalence, cervical HPV prevalence, genotype distribution and cytological lesions in solid organ transplant recipients and immunocompetent women in Sao Paulo, Brazil. PLoS One. 2022 Jan 20; 17(1): e0262724. doi: 10.1371/journal.pone.0262724. eCollection 2022.PMID: 35051227. Desai KT, Befano B, Xue Z, et al. The development of "automated visual evaluation" for cervical cancer screening: The promise and challenges in adapting deep-learning for clinical testing: Interdisciplinary principles of automated visual evaluation in cervical screening. Int J Cancer 2022;150(5):741-52. doi: 10.1002/ijc.33879 [published Online First: 2021/11/21]

Devine A, Vahanian A, Sawadogo B, et al. Costs and cost-effectiveness of cervical cancer screening strategies in women living with HIV in Burkina Faso: The HPV in Africa Research Partnership (HARP) study. Plos One 2021;16(3) doi: 10.1371/journal.pone.0248832

Kelly HA, Chikandiwa A, Sawadogo B, et al. Diagnostic accuracy of cervical cancer screening and screening-triage strategies among women living with HIV-1 in Burkina Faso and South Africa: A cohort study. Plos Medicine 2021;18(3) doi: 10.1371/journal.pmed.1003528

Maringa VD, Chikandiwa A, Gilham C, et al. Performance of the Swede score to predict cervical intraepithelial neoplasia in women with HIV-1 in Johannesburg, South Africa. Int J Gynaecol Obstet 2021;152(2):188-95. doi: 10.1002/iigo.13392 [published Online First: 2020/09/26]

- 2. Develop technical synthesis and guidelines for HPV vaccine and cervical cancer screening, for cervical cancer elimination.
- Between 2020-2021, Dr Kelly participated in the WHO guideline development for screening and treatment of cervical cancer lesions for cervical cancer prevention. As part of the guideline development, Dr Kelly undertook a review of the evidence on the diagnostic accuracy and effectiveness of cervical cancer screening strategies for prevention of cervical precancer and cancer among women living with HIV which was presented to the Guideline Development Group at WHO to inform on these recommendations. These recommendations were published in July 2021.
- Dr Kelly is currently participating in a WHO Technical Working Group as part of the comorbidities/associated infections chapter of the WHO Consolidated Guidelines on Person-Centered HIV Strategic Information, with a focus on establishing a minimum set of monitoring and evaluation indicators for cervical cancer screening and treatment programmes for women living with HIV. It is anticipated that these guidelines will be published end 2022.
- Between 2020 to 2022, Dr Kelly contributed to the writing, review and editing of the International Agency for Research on Cancer (IARC) Handbook for Cervical Cancer Screening, published in 2022.

Publications:

• WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.



- Cervical Cancer Screening. IARC Handbooks of Cancer Prevention Volume 18. IARC/WHO, Lyon: 2022. ISBN-13 (PDF): 78-92-832-3024-3.
- 3. Studies to support the elimination of hepatitis.

Drs. Wu, Kpokiri, and Tucker organized a global crowdsourcing open call to solicit stories related to hepatitis B and C advocacy. Supported by the Hepatitis Fund, the open call identified 119 submissions from 27 different countries across five continents. This led to a national-level domestic workshop in March in Bangladesh in partnership with the World Hepatitis Alliance and a side event to the World Hepatitis Summit on 8 June 2022. Dr. Tucker was part of a pragmatic randomized controlled trial using crowdsourcing to develop messages promoting viral hepatitis testing among primary care patients in China.

Dr. Tucker organized two hepatitis C virus diagnostic systematic reviews to inform the WHO hepatitis C guidelines. One focused on the accuracy of point-of-care HCV viral load diagnostic testing. The second systematic review examined the use of reflex HCV viral load testing. These were both accepted as posters at EASL and will be presented at the World Hepatitis Summit in Geneva in June.

Dr Yunia Mayanja has written a proposal to improve Hepatitis B vaccination completion among FSWs. This was after low vaccination completion rates in a simulated HIV vaccine efficacy trial (SIVET) that used Hepatitis B vaccine as a proxy for and HIV vaccine. In the SIVET study, 52.7% of FSWs completed the 3-dose vaccination schedule as prescribed. https://doi.org/10.1186/s12879-019-4328-1.

- 4. Studies to support the elimination of mother to-child-transmission (MTCT) of STIs, including HIV, syphilis and hepatitis.
- Philippe Mayaud and colleagues at MRC Unit in Uganda are conducting the analyses of a completed evaluation of the programmatic implementation of new POCT for HIV and syphilis to support the elimination of MTCT of syphilis and HIV in South-Western Ugandan districts (Bahemuka, IUSTI 2022 Abstract). Manuscripts are being developed.
- Prof Mayaud, working together with Dr Ubaldo Bahemuka completed a study at MRC/UVRI & LSHTM Uganda Research Unit on charting the progress towards eMTCT of syphilis and HIV with an evaluation of the implementation of the new Ugandan guidelines of dual testing using HIV and Syphilis Duo test to determine if there is any improvement in testing (and treatment) rates for both infections and the overall cure rates (the WHO 95-95-90 criteria) comparing the period of 9 months before and 9 months after implementation. Analysis is on-going and an abstract from this work was submitted to the 2022 IUSTI conference.
- Prof Peeling is a member of the WHO/UNAIDS Global Validation Advisory Committee for the triple elimination of MCTC of HIV, syphilis and HBV.
- Profs Wiseman and Yeung are leading the Menjaga study "An implementation trial of continuous quality improvement for antenatal syphilis and HIV detection and treatment in Indonesia", which started in April 2022. Prof Peeling is a study adviser.
- Profs Peeling and Wiseman from LSHTM, together with Andrew Vallely at University of New South Wales, are leading the project "Point-of-care Testing and Treatment of STIs to improve pregnancy outcomes in resource-limited, high burden settings", raking place in Papus New Guinea. Patient recruitment has just finished.
- 5. Carry out capacity building to elimination of STIs and their sequelae, including cervical cancer, and mother-to-child-transmission of STIs including HIV, hepatitis and syphilis. To lead and coordinate the specified research and normative work.
- The Control of STIs module taught at LSHTM includes lectures on elimination of STIs and syphilis and lectures on HPV/cervical cancer (including screening, vaccination and elimination).
- Prof. Mabey has taught on STIs to the DTM&H and MSc TMIH students and to the students on the Diploma in Tropical Nursing course, covering the epidemiology, clinical features, diagnosis, management, control and prevention of STIs. He has also taught on the MSc module on Control of STIs on the topic of STI elimination.
- Helen Kelly has participated in the Scientific organising committee of the IPV conference 2021 (virtually delivered by ICO Barcelona) and reviewer for IPV 2022 (Toronto). She will participate at the HPV Prevention and Control Board meeting technical meeting on control and prevention of HPV related cancers in people living with HIV in Antwerp (2-3 June 2022).



2. Annual report on other activities requested

Should WHO have requested activities in addition to the agreed workplan, please describe related actions taken by your institution [maximum 200 words]. Please do not include in this report any activity done by your institution thatwas not requested by and agreed with WHO.

3. Resources

Indicate staff time spent on the implementation of activities agreed with WHO (i.e. those mentioned in questions no. 1 and no. 2 above). Do not include any data related to other activities done by your institution without the agreement of WHO. Please indicate staff time using the number of "full-day equivalents" – a day of work comprising 8 hours (e.g. 4 hours work per day for 7 days should be recorded as 3.5 full-day equivalents).

Number of staff involved (either partially or fully)

Senior staff	Mid-career staff	Junior staff, PhD students
23	5	4

Number of full-day equivalents, total for all staff involved

Senior staff	Mid-career staff	Junior staff, PhD students
0	0	0

Implementation of the agreed workplan activities (i.e. those mentioned in questions no. 1 and no. 2 above) normally require resources beyond staff-time, such as the use of laboratory facilities, purchasing of materials, travel, etc. Please estimate the costs of these other resources as a percentage of the total costs incurred (e.g. if you incurred costs of USD 100 and the value of your staff time was USD 50 which makes the total of USD 150, please report 33.3% and 66.7%).

	Percentage of costs associated with other resources	Total
90.00	10.00	100.00

4. Networking

Describe any interactions or collaboration with other WHO Collaborating Centres in the context of the implementation of the agreed activities If you are part of a network of WHO Collaborating Centres, please also mention the name of the network and describe your involvement in that network [maximum 200 words].



No formally designated networking activities with other WHO Collaborating Centres.

The ASPIRE study (Dr Matthew Chico) partners with Dr Magnus Unemo of the Örebro University Hospital, as reference laboratory and WHO Collaborating Centre in WHO Collaborating Centre for Gonorrhoea and Other STIs.

We have reciprocal teaching arrangements between IMT, Antwerp (WHO Collaborating Centre for HIV/AIDS Diagnostics and Laboratory Support) and LSHTM.

Philippe Mayaud is current chair of the Track Clinical Sciences and Implementation of IUSTI World Congress 2022, Zimbabwe, whilst Daniel McCartney and Jason Ong are committee members.

Emma Harding-Esch is Implementation Science track chair for the 2023 STI and HIV World Congress in Chicago, IL, focused on the theme Local Engagement/Global Impact, 24-27 July, 2023. Joe Tucker, Jason Ong and Chido Chico are track committee members.