

Folder eCC_00014424 is in stage Annual Report Due

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

London School of Hygiene and Tropical Medicine, LSHTM

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, STI

Report Year 05-2019 to 05-2020

Please briefly describe the progress made in the implementation of your agreed workplan as WHO
collaborating centre during the past 12 months (or the reporting period listed above). Please report on
how each workplan activity was implemented, if any outputs have been delivered, if any results have
been achieved and if any difficulties have been encountered during this time. If an activity has
previously been completed, has not started yet, or been placed on hold, please indicate this.

The WHO Collaborating Centre for Sexually Transmitted Infections at the London School of Hygiene & Tropical Medicine (LSHTM) is based in the Clinical Research Department. Staff of the Department who work with WHO on STIs include Professors Rosanna Peeling, David Mabey, Philippe Mayaud, Rashida Ferrand, Martin Holland and Deborah Watson-Jones; and Drs. Robert Butcher, Emma Harding-Esch, Kate Gallagher, Helen Kelly, Katharina Kranzer, Michael Marks, Jason Ong and Joe Tucker. Colleagues in other departments at LSHTM who also work with WHO on STIs include Professors Chris Bonell, Richard Hayes, Peter Weatherburn and Virginia Wiseman; Drs. Suzanna Francis, Fern Terris-Prestholt, Aoife Doyle, Matthew Chico, Ford Hickson, Axel Schmidt and Elizabeth Fearon; and Rebecca Meiksin and Charles Witzel.

Activity 1

Support the STI POCTs initiative (advise on research/validation, support normative work (guidelines), training on STI POCTs in LMICs.

Description:

- Update the performance of commercially available POC STI tests
- Finalize TPPs and core protocols for evaluation of STI POC tests
- Technical advice on the road map for the evaluation and implementation of new STI POC tests
- Evaluation network for STI POC tests
- Investment cases for POC STI tests

The ongoing evaluation of STI POCTs is a common priority shared by WHO RHR and the London School. Professors Peeling and Mabey have developed protocols for laboratory and clinic-based evaluation of POCTs for a variety of STIs in the past. In collaboration with Dr Igor Toskin, Prof Peeling has adapted those

6/23/2017 11:44:02 AM Page (1/16)



protocols into 9 core protocols that can be used for the independent clinic-based and clinic-utility validation of STIs POCTs in different populations and in different use case scenarios. Prof Peeling worked with Dr Toskin and other colleagues to finalise the site-specific protocols for independent clinic-based evaluation of dual HIV/syphilis POCT and POCT to detect NG/CT and TV in 10 countries and for the clinic-utility evaluation of dual HIV/syphilis tests in 4 countries, following feedback from the WHO ERC, and they have now been approved by the ERC. Prof Peeling worked with colleagues at WHO to provide research training for selected sites in the Global Evaluation Network, in particular, training in Good Clinical Practice and Good Clinical Laboratory Practice to ensure the evaluations are conducted with the highest ethical and quality standards. Prof Peeling also provided technical assistance through site visits and on-line, facilitating collaboration with the manufacturers involved in the evaluation and supporting capacity building for reference testing. She is now working with Dr. Toskin and the site PIs to submit the site protocols for publication. Prof Peeling is also a co-PI on the WANTAIM Trial in Papua New Guinea led by Dr. Andrew Vallely to determine if point-of-care testing and treatment of sexually transmitted infections can improve birth outcomes in high-burden, low-income settings using a cluster randomised crossover trial design. The study protocol for this trial has been published.

Prof. Peeling worked with Dr. Toskin and colleagues at WHO in organising three international meetings in 2019: A symposium on STI POCT at the 2019 IUSTI/ISSTDR Conference in Vancouver, July 2019; a symposium on STI POCT at the 2019 IUSTI/EURO Conference in Tallinn, September, 2019; and the 3rd WHO Technical Consultation on STI POCT in Verona, December 2019. They also collaborated in completing two surveys in 2019: one on the balance of etiology-based and syndromic-based approaches to STI case management in 8 countries, and one on the impact and use of WHO Target Product Profile among 17 manufacturers of POC diagnostic tests.

Dr Harding-Esch is a member of the Public Health Applications of *Chlamydia trachomatis* Serology (PHACTS) group, with WHO leadership from Igor Toskin, which aims to develop Target Product Profiles for new diagnostics. She was a collaborator on a YERUN grant (Young European Research University Network) Research Mobility Award (RMA) with Maastricht University and Brunel University London, to develop outputs from the Diagnostics and the Developing World conference, held at Brunel University London in January 2017 (www.ddwconference.com).

During 2019/20, Prof Mayaud has supported the Ministry of Health in Uganda STI unit within the NACP (Dr Simon Mwima) and participated in a WHO-led workshop to review the implementation of a large WHO study of the field evaluation of the Duo test Syphilis/HIV among female sex workers (overall led by Dr Toskin).

Publications on POC tests and testing

- Broad CE, Furegato M, Harrison MA, Pond MJ, Tan N, Okala S, Fuller SS, Harding-Esch EM, Sadiq ST.High prevalence of coinfection of azithromycin-resistant *Mycoplasma genitalium* with other STIs: a prospective observational study of London-based symptomatic and STI-contact clinic attendees. Sex Transm Infect. 2020 May 11:sextrans-2019-054356. doi: 10.1136/sextrans-2019-054356. Online ahead of print.PMID: 32393529
- 2. Francis SC, Parajuli A, Mardh O, Falconer J, Andreasen A, Harding-Esch E;. Technologies, strategies and approaches for testing populations at risk of sexually transmitted infections: a systematic review protocol to inform prevention and control in EU/EEA countries. NASSTI.Syst Rev 2020 Mar 25;9(1):64. doi: 10.1186/s13643-020-01303-y.PMID: 32213195

6/23/2017 11:44:02 AM Page (2/16)



- 3. Oakeshott P, Kerry-Barnard S, Fleming C, Phillips R, Drennan VM, Adams EJ, Majewska W, Harding-Esch EM, Cousins EC, Planche T, Green A, Bartholomew RI, Sadiq ST, Reid F 'Test n Treat' (TnT): a cluster randomized feasibility trial of on-site rapid Chlamydia trachomatis tests and treatment in ethnically diverse, sexually active teenagers attending technical colleges. Clin Microbiol Infect. 2019 Jul;25(7):865-871. doi: 10.1016/j.cmi.2018.10.019. Epub 2018 Nov 1.PMID: 30391581
- 4. Fuller, Sebastian S; Pacho, Agata; Broad, Claire E; Nori, Achyuta V; Harding-Esch, Emma M; Sadiq, Syed Tariq; (2019) "It's not a time spent issue, it's a 'what have you spent your time doing?' issue..." A qualitative study of UK patient opinions and expectations for implementation of Point of Care Tests for sexually transmitted infections and antimicrobial resistance. PLOS ONE, 14 (4).
- 5. Vallely AJ, Pomat WS, Homer C, Guy R, Luchters S, Mola GDL, Kariwiga G, Vallely LM, Wiseman V, Morgan C, Wand H, Rogerson SJ, Tabrizi SN, Whiley DM, Low N, Peeling R, Siba P, Riddell M, Laman M, Bolnga J, Robinson LJ, Morewaya J, Badman SG, Batura N, Kelly-Hanku A, Toliman PJ, Peter W, Babona D, Peach E, Garland SM, Kaldor JM. Point-of-care testing and treatment of sexually transmitted infections to improve birth outcomes in high-burden, low-income settings: Study protocol for a cluster randomized crossover trial (the WANTAIM Trial, Papua New Guinea). Wellcome Open Res. 2019 Mar 22;4:53. doi: 10.12688/wellcomeopenres.15173.2. eCollection 2019. PMID: 32030356
- 6. Peeling RWW, Mabey D. Point-of-care tests to reduce the burden of sexually transmitted infections. Lancet Infect Dis. 2019 Jun;19(6):570-571. doi: 10.1016/S1473-3099(18)30783-7. Epub 2019 Apr 26. PMID: 31036512
- 7. Mashamba-Thompson, Tivani P; Drain, Paul K; Kuupiel, Desmond; Sartorius, Benn; (2019) Impact of Implementing Antenatal Syphilis Point-of-Care Testing on Maternal Mortality in KwaZulu-Natal, South Africa: An Interrupted Time Series Analysis. Diagnostics (Basel, Switzerland), 9 (4). p. 218. ISSN 2075-4418 DOI: https://doi.org/10.3390/diagnostics9040218
- 8. Toskin, I., Govender, V., Blondeel, K., Murtagh, M., Unemo, M., Zemouri, C., Peeling, R. W., Kiarie, J. Call to action for health systems integration of point-of-care testing to mitigate the transmission and burden of sexually transmitted infections Sex. Transm. Infect. 2020;0: 1-6. sextrans-2019-054358v1-sextrans-2019-054358

Activity 2

Title: Assist WHO in activities that aim to improve STI control and prevention in key populations, mainly MSM, as well as to improve SRH services in adolescents.

Dr Emma Harding-Esch & Dr Suzanna Francis (co-directors of LSHTM's STI Research Interest Group (STIRIG), along with Sarah Harman), in collaboration with Public Health England, have conducted an ECDC-funded systematic literature review of novel testing technologies, strategies and approaches for testing high-risk populations for STIs in the EU/EEA.

Research into social entrepreneurship and crowdsourcing approaches to enhance the uptake of STI testing in MSM

Prof Peeling, Dr. Jason Ong, and Dr. Joe Tucker have worked on organizational characteristics of HIV/syphilis testing services for men who have sex with men in South China since 2010 using social entrepreneurship and demonstrating that it is an effective service model. This work resulted in a "Practical Guide on Crowdsourcing in Health and Health Research" that was launched at a special session of the International AIDS Society Conference in Amsterdam, the Netherlands, and was successfully presented at the World Health Assembly in

6/23/2017 11:44:02 AM



May 2019. In addition, a crowdsourced project called "pay-it-forward" was found to increase gonorrhoea/chlamydia test uptake among MSM in China. The recently published randomized controlled trial showed that this approach was effective and saved money. In 2020, the WHO Innovation Department selected pay-it-forward as one of the finalists in the Re-Boot Challenge. In addition, Dr. Tucker has a new grant using crowdsourcing to enhance STI testing from the US NIH (R34MH119963, 2019-2022).

Publications on social entrepreneurship and crowdsourcing:

Halpaap B, Peeling RW, Bonnici F. The role of multilateral organizations and governments in advancing social innovation in health care delivery. Infect Dis Poverty. 2019 Sep 13;8(1):81. doi: 10.1186/s40249-019-0592-y. PMID: 31514738

Srinivas ML, Yang EJ, Shrestha P, Wu D, Peeling RW, Tucker JD. Social innovation in diagnostics: three case studies. Infect Dis Poverty. 2020 Feb 19;9(1):20. doi: 10.1186/s40249-020-0633-6. PMID: 32070433

Research into STI epidemiology among users of pre-exposure prophylaxis (PrEP) for HIV

Drs. Ong, Tucker, Terris-Prestholt and Prof. Mayaud led a systematic review and meta-analysis of the prevalence and incidence of STIs among PrEP users, in collaboration with the WHO HIV Department and WHO Department of Reproductive Health and Research. This work was presented at the WHO Think Tank Meeting on PrEP in Montreux, Switzerland (March 2019), at the IAS in Mexico (July 2019) at a special WHO satellite workshop, at a STIRIG seminar (March 2020), and has been published in *JAMA* (see below) attracting much media attention, and a special announcement in WHO and STIRIG networks.

Research into STI epidemiology in sex workers

Prof Mayaud and Dr Ong have published on the epidemiology, clinical features and resistance of *Mycoplasma genitalium* among women living with HIV in South Africa. In new work in Uganda, Prof Mayaud has been working with a population of HIV-infected and non- infected sex workers in Kampala, and the Uganda Defence Force.

Publications on STIs in key populations

- Bahemuka U, Abaasa A, Seeley J, Byaruhanga M, Kamali A, Mayaud P, Kuteesa M. Feasibility of
 establishing an HIV vaccine preparedness cohort in a population of the Uganda Police Force: lessons
 learnt from a prospective study. *PLoS One* 2020 (in press).
- Namale G, Kamacooko O, Bagiire D, Mayanja Y, Abaasa A, Kilembe W, Price M, Ssemwanga D, Lunkuse S, Nanyonji M, Ssenyonga W, Mayaud P, Newton R, Kaleebu P, Seeley J. Sustained Virological Response and Drug Resistance among Female Sex Workers Living with HIV on Antiretroviral Therapy in Kampala, Uganda: a cross sectional study. Sex Transm Infect. 2019 Sep; 95(6): 405-411. doi: 10.1136/sextrans-2018-053854. Epub 2019 Jul 2.
- 3. Ong JJ, Mahlape Precious Magooa MP, Chikandiwa A, Kelly H, Didelot M-N, Muller EE, Maseko V, Segondy M, Delany-Moretlwe S, Kularatne R, Mayaud P, on behalf of the HARP Study Group. Prevalence and antimicrobial resistance of *Mycoplasma genitalium* infection among women living with HIV in South Africa: a prospective cohort study. *Clinical Infectious Diseases* 2019; Aug 16; 69(5): 873-876. doi: 10.1093/cid/ciz045.

6/23/2017 11:44:02 AM Page (4/16)



- Ong JJ, Magooa MP, Chikandiwa A, Kelly H, Didelot MN, Muller EE, Maseko V, Segondy M, Delany-Moretlwe S, Kularatne R, Mayaud P, on behalf of the HARP Study Group. Clinical characteristics of Mycoplasma genitalium infection among women living with HIV in South Africa. Sexually Transmitted Diseases 2019; Jul 25: 46(12): 801-804. doi: 10.1097/OLQ.00000000001054.
- 5. Ong JJ, Baggaley RC, Wi TE, Tucker JD, Fu HT, Smith K, Rafael S, Anglade V, Falconer J, Ofori-Asenso R, Terris-Prestholt F, Hodges-Mameletzis I, Mayaud P, Epidemiology of sexually transmitted infections in HIV pre-exposure prophylaxis users: A systematic review and meta-analysis. *JAMA Network Open* 2019; 2(12): e1917134. doi:10.1001/jamanetworkopen.2019.17134.
- 6. Wayal, S; Reid, D; Weatherburn, P; Blomquist, P; Fabiane, S; Hughes, G; Mercer, CH; (2019) Association between knowledge, risk behaviours, and testing for sexually transmitted infections among men who have sex with men: findings from a large online survey in the United Kingdom. HIV medicine. 2019 May 24
- 7. M Kumi, Smith; Stein, Gabriella; Cheng, Weibin; Miller, William C; Tucker, Joseph D; (2019) Identifying high risk subgroups of MSM: a latent class analysis using two samples. BMC infectious diseases, 19 (1). p. 213.
- 8. King, Carina; Llewellyn, Carrie; Shahmanesh, Maryam; Abraham, Charles; Bailey, Julia; Burns, Fiona; Clark, Laura; Copas, Andrew; Howarth, Alison; Hughes, Gwenda; +7 more... (2019) Sexual risk reduction interventions for patients attending sexual health clinics: a mixed-methods feasibility study. Health technology assessment, 23 (12). pp. 1-122.
- 9. Kohli, Manik; Hickson, Ford; Free, Caroline; Reid, David; Weatherburn, Peter; (2019) Cross-sectional analysis of chemsex drug use and gonorrhoea diagnosis among men who have sex with men in the UK. Sexual Health. DOI: https://doi.org/10.1071/SH18159
- 10. Kuteesa, Monica O; Quaife, Mathew; Biraro, Sam; Katumba, Kenneth R; Seeley, Janet; Kamali, Anatoli; Nakanjako, Damalie; (2019) Acceptability and predictors of uptake of anti-retroviral Pre-Exposure Prophylaxis (PrEP) among fishing communities in Uganda: a cross-sectional discrete choice experiment survey. AIDS and behavior. AIDS Behav. 2019 Feb 8.
- 11. Todesco, Eve; Day, Nesrine; Amiel, Corinne; Elaerts, Stéphane; Schneider, Véronique; Roudiere, Laurent; Hue, Stéphane; Liotier, Jean-Yves; Bottero, Julie; L'yavanc, Thomas; +11 more... (2019) High Clustering of Acute HCV Infections and High Rate of Associated STIs Among Parisian HIV-Positive Male Patients. International journal of antimicrobial agents. 2019 May;53(5):678-681
- Schmidt, Axel Jeremias; Altpeter, Ekkehardt; (2019) The Denominator problem: estimating the size of local populations of men-who-have-sex-with-men and rates of HIV and other STIs in Switzerland. Sexually transmitted infections. ISSN 1368-4973 DOI: https://doi.org/10.1136/sextrans-2017-0533
- 13. Gu, Xin; Gao, Ying; Yan, Yan; Marks, Michael; Zhu, Lin; Lu, Haikong; Guan, Zhifang; Shi, Mei; Ni, Liyan; Peng, Ruirui et al (2020) *The importance of proper and prompt treatment of ocular syphilis: A lesson from permanent vision loss in 52 eyes*. Journal of the European Academy of Dermatology and Venereology. ISSN 0926-9959 DOI: https://doi.org/10.1111/jdv.16347 Item availability may be restricted.
- 14. Blomquist, Paula Bianca; Mohammed, Hamish; Mikhail, Amy; Weatherburn, Peter; Reid, David; Wayal, Sonali; Hughes, Gwenda; Mercer, Catherine H; (2020) *Characteristics and sexual health service use of MSM engaging in chemsex: results from a large online survey in England.* Sexually transmitted infections. ISSN 1368-4973 DOI: https://doi.org/10.1136/sextrans-2019-054345
- 15. Kasamba, Ivan; Nash, Stephen; Shahmanesh, Maryam; Baisley, Kathy; Todd, Jim; Kamacooko, Onesmus; Mayanja, Yunia; Seeley, Janet; Weiss, Helen A; (2019) *Missed Study Visits and Subsequent*

6/23/2017 11:44:02 AM Page (5/16)



- HIV Incidence Among Women in a Predominantly Sex Worker Cohort Attending a Dedicated Clinic Service in Kampala, Uganda. JAIDS-Journal of Acquired Immune Deficiency Syndromes, 82 (4). pp. 343-354. ISSN 1525-4135 DOI: https://doi.org/10.1097/QAI.000000000002143
- 16. Ong, Jason J; Li, Chang Chang; Fu, HongYun; Nie, Juan; Tang, Weiming; Chang, WeiBin; Smith, M Kumi; Marks, Michael; Yang, Bin; Wang, Cheng et al (2019) Risk attitudes, risky sexual behaviours and willingness to test negative for syphilis using lottery-based financial incentives among Chinese men who have sex with men. Sexually Transmitted Infections. ISSN 1368-4973 DOI: https://doi.org/10.1136/sextrans-2019-054072
- 17. Witzel, TC; Bourne, A; Burns, FM; Rodger, AJ; McCabe, L; Gabriel, MM; Gafos, M; Ward, D; Collaco-Moraes, Y; Dunn, DT et al (2019) HIV self-testing intervention experiences and kit usability: results from a qualitative study among men who have sex with men in the SELPHI (Self-Testing Public Health Intervention) randomized controlled trial in England and Wales. HIV MEDICINE, 21 (3). pp. 189-197. ISSN 1464-2662 DOI: https://doi.org/10.1111/hiv.12818
- 18. Wu, Dan; Huang, Wenting; Zhao, Peipei; Li, Chunyan; Cao, Bolin; Wang, Yifan; Stoneking, Shelby; Tang, Weiming; Luo, Zhenzhou; Wei, Chongyi et al (2019) A Crowdsourced Physician Finder Prototype Platform for Men Who Have Sex with Men in China: Qualitative Study of Acceptability and Feasibility. JMIR public health and surveillance, 5 (4). e13027-. ISSN 2369-2960 DOI: https://doi.org/10.2196/13027
- 19. Zhang, Tiange P; Yang, Fan; Tang, Weiming; Alexander, Marcus; Forastiere, Laura; Kumar, Navin; Li, Katherine; Zou, Fei; Yang, Ligang; Mi, Guodong, et al (2019) Pay-it-forward gonorrhea and chlamydia testing among men who have sex with men in China: a study protocol for a three-arm cluster randomized controlled trial. Infectious diseases of poverty, 8 (1). 76-. ISSN 2095-5162 DOI: https://doi.org/10.1186/s40249-019-0581-1
- Berg, Rigmor C; Weatherburn, Peter; Marcus, Ulrich; Schmidt, Axel J; (2019) Links between transactional sex and HIV/STI-risk and substance use among a large sample of European men who have sex with men. BMC infectious diseases, 19 (1). 686-. ISSN 1471-2334 DOI: https://doi.org/10.1186/s12879-019-4326-3
- Beale, Mathew A; Marks, Michael; Sahi, Sharon K; Tantalo, Lauren C; Nori, Achyuta V; French,
 Patrick; Lukehart, Sheila A; Marra, Christina M; Thomson, Nicholas R; (2019) Genomic epidemiology of
 syphilis reveals independent emergence of macrolide resistance across multiple circulating
 lineages. Nature communications, 10 (1). 3255-. ISSN 2041-1723
 DOI: https://doi.org/10.1038/s41467-019-11216-7
- 22. Wang, Cheng; Cheng, Weibin; Li, Changchang; Tang, Weiming; Ong, Jason J; Smith, M Kumi; Fu, Hongyun; Marks, Michael; Nie, Juan; Zheng, Heping et al (2019) *Syphilis Self-testing: A Nationwide Pragmatic Study Among Men Who Have Sex With Men in China*. Clinical infectious diseases, 70 (10). pp. 2178-2186. ISSN 1058-4838 DOI: https://doi.org/10.1093/cid/ciz603 Item availability may be restricted.
- 23. Chemaitelly, Hiam; Weiss, Helen A; Smolak, Alex; Majed, Elzahraa; Abu-Raddad, Laith J; (2019) Epidemiology of Treponema pallidum, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, and herpes simplex virus type 2 among female sex workers in the Middle East and North Africa: systematic review and meta-analytics. Journal of Global Health, 9 (2). 020408-. ISSN 2047-2978 DOI: https://doi.org/10.7189/jogh.09.020408

Epidemiological studies on HPV and related diseases in LMIC, including HIV-positive and HIV-negative women and men

6/23/2017 11:44:02 AM Page (6/16)



Profs. Mayaud and Watson-Jones and Dr Kelly and Gallagher have continued to publish studies on the epidemiology and prevention of HPV infection in Tanzania, Ghana, Burkina Faso and South Africa, in support of the ongoing WHO work on HPV testing and cervical cancer management guidelines and the Global Strategy for elimination of cervical cancer. The studied populations have included general populations of young women, HIV-negative and HIV-positive women and men. Prof Mayaud and Drs Kelly and Francis have published on the role of the vaginal microbiome in enabling the persistence of high-risk HPV which paves the way to progression towards higher grade cervical lesions.

Publications on HPV epidemiology and risk factors

- 1. Chikandiwa A, Pisa PT, Muller EE, Tamalet C, Mayaud P, Chersich MF, Delany-Moretlwe S. Incidence, persistence, clearance, and correlates of genital human papillomavirus infection and anogenital warts in a cohort of men living with Human Immunodeficiency Virus in South Africa. *Sex Transm Dis.* 2019; 46(5): 347-353.
- Chikandiwa A, Pisa PT, Tamalet C, Muller EE, Michelow P, Chersich MF, Mayaud P, Delany-Moretlwe S. Prevalent, persistent anal HPV infection and squamous intraepithelial lesions: Findings from a cohort of men living with HIV in South Africa. *PLoS One*. 2019 Dec 5; 14(12):e0225571. doi: 10.1371/journal.pone.0225571.
- 3. Chikandiwa A, Faust H, Chersich MF, Mayaud P, Dillner J, Delany-Moretlwe S. Human papillomavirus seroprevalence and seroconversion among men living with HIV: Cohort study in South Africa. *JAIDS*. 2020; 20 Feb 14. doi: 10.1097/QAI.000000000002328.
- 4. Stuart A, Obiri-Yeboah D Adu-Sarkodie Y, Hayfron-Benjamin A, Akorsu AD, Mayaud P. Knowledge and experience of human papillomavirus (HPV) and cervical cancer screening in a cohort of HIV-positive and HIV-negative Ghanaian women. *BMC Women's Health* 2019 Oct 23; 19(1):123. doi: 10.1186/s12905-019-0818-y.
- Van de Wijgert JHHM, Gill C, Chikandiwa A, Verwijs M, Kelly HA, Omar T, Delany-Moretlwe S, Segondy M, Francis S, Darby A, Mayaud P. Human papillomavirus infection and cervical dysplasia in HIVpositive women: potential role of the microbiota. *AIDS* 2020 Jan 1; 34(1): 115-125. doi: 10.1097/QAD.000000000002381.
- 6. Van de Wijgert JHHM, Verwijs MC, Gill AC, Borgdorff H, van der Veer C, and Mayaud P on behalf of the Rwanda VMB, HARP, and HELIUS VMB study groups. Pathobionts in the Vaginal Microbiota: Individual Participant Data Meta-analysis of Three Sequencing Studies. *Frontiers in Cellular & Infect Microbiol.* 2020 Apr 15; 10: 129. Doi: 10.3389/fcimb.2020.00.129.
- 7. Baisley K, Andreasen A, Irani J, Nnko S, Changalucha J, Crucitti T, Francis SC, Holm Hansen C, Hayes RJ, Buvé A, Watson-Jones D. HPV prevalence around the time of sexual debut in adolescent girls in Tanzania. *Sexually Transmitted Infections*, 2019 Jun 20. [Epub ahead of print]

6/23/2017 11:44:02 AM Page (7/16)



Studies on HPV vaccination and the prevention of cervical cancer

Prof Mayaud and Dr Kelly have pursued their work with colleagues at WHO Cancer Collaborating Centre Institut Catala d'Oncologia (ICO) Barcelona on the role of ART and HIV-related factors on the natural history of cervical cancer, anal cancer and response to lesional treatment, showing the importance of good HIV control in decreasing the frequency of negative outcomes and published their work in high impact journals. Collectively, these papers and previous publications from the HARP study in Burkina Faso and South Africa among women living with HIV have led Prof Mayaud and Dr Kelly to be invited to participate in the development of the future WHO Global Guidelines for the screening and management of cervical cancer, and an IARC Handbook. Another systematic review with colleagues from ICO and Queen Mary University London (QMUL) has shown the potential of methylation markers in detecting cervical neoplasia which could be combined with a primary triage test and would be particularly useful for screening in settings where the expected prevalence of HPV is high, where a single HPV based screening would be less effective.

Emma Harding-Esch, Martin Holland and Robert Butcher have been awarded an ISSF pump priming grant to study STI infection and AMR prevalence in The Gambia, using residual samples collected as part of HPV vaccine HANDS Trial (https://clinicaltrials.gov/ct2/show/NCT03832049).

Publications on HPV screening and vaccination

- 1. Atemnkeng N, Aji AD, de Sanjose S, Mayaud P, Kelly H. Antiretroviral therapy and recurrence of cervical intraepithelial neoplasia (CIN) following management among women living with HIV: systematic review and meta-analysis. *Clin Infect Dis.* 2020; Mar 11. pii: ciaa238. doi: 10.1093/cid/ciaa238.
- 2. Kelly H, Chikandiwa A, Alemany Vilches L, Palefsky JM, de Sanjose S, Mayaud P. Effective antiretroviral therapy, anal high-risk human papillomavirus, anal intraepithelial neoplasia and anal cancer: a systematic review and meta-analysis. *Lancet HIV.* 2020; Feb 25. pii: S2352-3018(19)30434-5. doi: 10.1016/S2352-3018(19)30434-5.
- 3. Kelly H, Benavente Moreno Y, Pavon MA, de Sanjose S, Mayaud P, Lorincz A. Performance of DNA methylation assays for detection of high-grade cervical intraepithelial neoplasia (CIN): a systematic review and meta-analysis. *Br J Cancer* 2019; Oct 16. doi.org/10.1038/s41416-019-0593-4.
- 4. Abbas KM, van Zandvoort K, Brisson M, Jit M. Effects of updated demography, disability weights, and cervical cancer burden on estimates of human papillomavirus vaccination impact at the global, regional, and national levels: a PRIME modelling study. Lancet Glob Health. 2020;8: e536–e544. doi:10.1016/S2214-109X(20)30022-X
- Baisley, Kathy; Andreasen, Aura; Irani, Julia; Nnko, Soori; Changalucha, John; Crucitti, Tanya; Francis, Suzanna Carter; Hansen, Christian; Hayes, Richard; Buve, Anne; +1 more... (2019) HPV prevalence around the time of sexual debut in adolescent girls in Tanzania. Sexually Transmitted Infections. (In Press)
- Bains, Irenjeet; Choi, Yoon Hong; Soldan, Kate; Jit, Mark; (2019) Clinical impact and cost-effectiveness of primary cytology versus human papillomavirus testing for cervical cancer screening in England. International journal of gynecological cancer. ISSN 1048-891X DOI: https://doi.org/10.1136/ijgc-2018-000161
- 7. Karafillakis, Emilie; Simas, Clarissa; Jarrett, Caitlin; Verger, Pierre; Peretti-Watel, Patrick; Dib, Fadia; De Angelis, Stefania; Takacs, Judit; Ali, Karam Adel; Pastore Celentano, Lucia; +1 more... (2019) HPV

6/23/2017 11:44:02 AM Page (8/16)



- vaccination in a context of public mistrust and uncertainty: a systematic literature review of determinants of HPV vaccine hesitancy in Europe. Human Vaccines & Immunotherapeutics. pp. 1-13. ISSN 2164-5515 DOI: https://doi.org/10.1080/21645515.2018.1564436
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6/23/2017 11:44:02 AM Page (9/16)



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Studies on sexual and reproductive health in adolescents

In 2020 Professor Ferrand and colleagues were awarded a grant of £998,169 by DFID/MRC/NIHR to study the impact of STI screening and comprehensive case management among youth in a cluster randomised trial in Zimbabwe. Prof. Ferrand is also leading a cluster randomised trial in Zimbabwe (the CHIEDZA trial) evaluating the impact of a multicomponent package of SRH and HIV services offered to 16-24 year olds in a community-based setting on population level HIV and SRH outcomes. The CHIEDZA package will be offered to all clients aged 16-24 year olds living in the intervention clusters (a geographically defined area that includes a community venue and a primary care clinic). An additional study will investigate the uptake, acceptability, prevalence and yield of STI screening using the CT/NG Genexpert assay is embedded within the CHIEDZA trial. STI screening will be offered to all clients attending the CHIEDZA service, including those who present with STI symptoms. The outcomes will be:

- 1. Uptake of STI screening
- 2. Prevalence of chlamydia, gonorrhoea and *Trichomonas vaginalis* infection
- 3. % of symptomatic clients who are NG and/or CT or TV positive
- 4. % of partners that attend for screening and treatment

She will also conduct a qualitative assessment of KAP and acceptability of STI screening. and a cost-evaluation of providing community-based testing of for STI to youth.

Prof Mayaud is working with two PhD students in Panama (Amanda Gabster) and Tanzania (Ruby Mcharo) on adolescent STI epidemiology, and developing STI testing programmes with adolescent accessing PREP in Uganda. In Panama, among indigenous populations, rates of chlamydia and syphilis were found to be very high (syphilis particularly in boys) and STIs were related to forced and transactional sex.

Dr Aoife Doyle and Prof. Helen Weiss are collaborators on the following WHO-led project: "Reaching adolescents with health services: a multi-country study of adolescent health check-ups in low- and middle-income countries Phase 1 (Intervention Development)". This multi-country WHO led project aims to develop an adolescent check-up visit intervention with development work ongoing in Tanzania, Ghana and Zimbabwe. The intervention, currently at the formative stages of development, may include STI screening. They attend monthly meetings, provide technical input into protocols and research tools, and were due to travel to an investigators' workshop in Zimbabwe in May funded by the project.

Dr. Meenakshi Gautham was awarded a grant of £149,980 by the MRC Public Health Intervention Development Scheme for the development of an intervention for improved management of self-reported abnormal vaginal discharge by women in rural north India.

Publications on SRH in adolescents

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6/23/2017 11:44:02 AM Page (10/16)



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- 4. Sturt A, Webb EL, Francis SC, Hayes R, Bustinduy AL. Beyond the barrier: Female Genital Schistosomiasis as a potential risk factor for HIV-1 acquisition and transmission. Acta Tropica, in press
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6/23/2017 11:44:02 AM Page (11/16)



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Activity 3

Title: Assist WHO in activities that aim to improve women's and children's health particularly in the area of dual elimination of mother to child transmission of HIV and Syphilis (eMTCT) and prevention of cervical cancer.

Description:

- Update dashboard for eMTCT of HIV and Syphilis
- Update toolkit development for eMTCT of HIV and Syphilis
- Conduct epidemiological studies of HPV and related disease in various population groups
- Evaluate the efficacy of HPV vaccination for the prevention of cervical cancer
- Produce systematic reviews, clinical validation studies and health economic evaluations for HPV

6/23/2017 11:44:02 AM Page (12/16)



Prof Peeling is a member of the WHO/UNAIDS Global Validation Advisory Committee (GVAC) for the dual elimination of the Mother to Child Transmission of HIV and Syphilis. She participated in the review of dossiers submitted to GVAC from countries claiming to have achieved elimination of HIV and Syphilis. She also contributed to the revision of the dual elimination handbook. In particular, she developed diagnostic quality standards that countries need to meet when they submit data to prove that they have achieved elimination. The International Diagnostics centre has created a dashboard to help countries track their progress with dual elimination. Prof Peeling worked with WHO RHR on a systematic review of the accuracy of dual rapid HIV-syphilis syphilis test.

Prof Peeling worked with WHO and UNICEF to organize workshops for 25 countries in Africa, and 8 countries in the Western Pacific Region on the use of the rapid HIV-Syphilis duo test in the context of the dual elimination of Mother-to-Child Transmission (eMTCT) of HIV and Syphilis and to promote implementation of policies for the use of diagnostics for the eMTCT of HIV/Syphilis 5.13. During these workshops, countries report on the testing gap between prenatal HIV and syphilis screening rates, identify reasons for the difference and opportunities for increasing syphilis screening and treatment in pregnancy. Each country developed national roadmaps for the adoption of new testing algorithms including the dual HIV/syphilis POCT, procurement of tests, quality assurance, training and increasing community awareness of syphilis stillbirth prevention. As a result, many countries, with donor and partner support, have identified reliable and predictable sources of additional funding to supplement existing HIV PMTCT programmes to include dual HIV/syphilis testing and ensure a reliable supply of benzathine penicillin for treatment of syphilis. A number of countries, including Uganda, Kenya and Nigeria have updated their testing algorithm to include the dual HIV/syphilis POCT as the first test for pregnant women attending ANC.

Prof Mayaud has completed a new 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. The study is being analysed.

Publications on improving women's and children's health

Storey A, Seghers F, Pyne-Mercier L, Peeling RW, Owiredu MN, Taylor MM. Syphilis diagnosis and treatment during antenatal care: the potential catalytic impact of the dual HIV and syphilis rapid diagnostic test. Lancet Glob Health. 2019 Aug;7(8):e1006-e1008. doi: 10.1016/S2214-109X(19)30248-7. PMID: 31303285.

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2. Please briefly describe your collaboration with WHO with regards to the activities of the WHO collaborating centre during the past 12 months (e.g. means of communication, frequency of contact, visits to or from WHO). Please feel free to mention any difficulties encountered (if any) and to provide suggestions for increased or improved communication (if applicable).

LSHTM's STI Research Interest Group (STIRIG) held a two-day international conference at LSHTM, 9-10th January 2020: "From global to local: addressing the threat of AMR to STI control". It was co-hosted with

6/23/2017 11:44:02 AM Page (13/16)



LSHTM's AMR Centre, Bristol Health Partners' Sexual Health Improvement Programme Health Integration Team (SHIP), Public Health England (PHE) and the World Health Organization (WHO). Dr Teodora Wi (Medical Officer, Human Reproduction) gave the keynote talk "Progress and Challenges in Addressing AMR in *Neisseria gonorrhoeae*". Eight session covered topics such as surveillance, treatment guidelines, new diagnostic and treatment initiatives, antibiotic stewardship, and vaccines. A report of the conference is being prepared for publication by WHO. Details of the conference are at:

https://www.lshtm.ac.uk/newsevents/events/global-local-addressing-threat-amr-sti-control

STIRIG co-hosted a half-day "STI Vaccine Workshop: Innovations for impact" with LSHTM's Vaccine Centre: https://www.lshtm.ac.uk/newsevents/events/sti-vaccine-workshop-innovations-impact. The workshop included an opening talk by Dr Sami Gottlieb from WHO (Medical Officer, Dept of Reproductive Health and Research), who presented the WHO roadmap for STI vaccine development, followed by talks by leading researchers on vaccines for chlamydia, gonorrhoea and Herpes simplex virus. A manuscript for publication in the peer-reviewed literature is being prepared as an outcome from the workshop.

Profs Peeling and Mayaud have made frequent visits to WHO in the past year to discuss our collaboration in the field of STI/SRH. Prof Mabey was a member of the committee which reviewed target product profiles for POC tests for the diagnosis of gonococcal infections and for identifying antimicrobial susceptibility of *Neisseria gonorrhoeae*. Prof Peeling is a member of the WHO/UNAIDS Global Validation Advisory Committee (GVAC) for the dual elimination of the Mother to Child.

Prof. Peeling and Dr. Tucker have visited the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases several times in the past year to discuss the Social Innovation in Health Initiative (SIHI), a programme that supports several STD-related projects. Both Prof. Peeling and Dr. Tucker are members of the TDR SIHI and TDR Global Working Group. In addition, Dr. Tucker has organized three open challenge contests in partnership with the TDR related to infectious diseases and one global open call on sexual health research in partnership with HRP. Drs. Peeling and Tucker joined the virtual SIHI Hub meeting 25-27 May 2020.

Prof Mayaud is a member of the committee reviewing the burden of STI, of the committee reviewing the management of STIs and syndromic management guidelines, and part of the committee reviewing the global cervical cancer screening guidelines. In 2019, Prof Mayaud has been appointed as an STI expert to the International Health Regulations (IHR) Roster of Experts. During the COVID-19 crisis, Prof Mayaud has been in touch with WHO/RHR to set up studies of the impact of SARS-COV-2 on pregnant women and their babies and to investigate the potential for mother-to-child transmission of the new virus.

Prof Peeling has interacted with WHO regional offices in Europe, Africa, Western Pacific, South East Asia and South America to discuss the evaluation and implementation of improved diagnostic tests for syphilis and other STIs, including Zika virus. Dr Natalie Broutet (WHO RHR) convened two meeting of experts in Geneva to discuss the sexual transmission of zika virus, and to develop research protocols that would lead to a better understanding of this phenomenon; Prof Mayaud was invited to present at those meetings his work with colleagues from EU funded Horizon 2020 ZIKAlliance.

Please briefly describe any interactions or collaborations with other WHO collaborating centres in the context of the implementation of the above activities (if any). If you are part of a network of WHO collaborating centres, please also mention the name of the network, and describe any involvement in the network during the last 12 months.

6/23/2017 11:44:02 AM



Prof Mayaud has collaborated with colleagues from Europe, Brazil and other Latin American countries in the large ZIKAlliance Consortium. The main aims of the Consortium are to quantify the incidence, transmission and impact of Zikavirus among humans (maternal and sexual transmission). In Brazil, they were able to demonstrate a moderate impact of Zikavirus on fertility among infected males. The Consortium has also submitted its research study design and a review of maternal diagnosis of TORCH infections including Zika showing the disparity of quality of diagnosis of these infections which for many have not been standardised or improved for decades leading to a general neglect or poor testing practices in resource constrained environments.

Isolde Birdthistle and Aoife Doyle co-organise a short-course on adolescent health in LMICs in collaboration with WHO (Valentina Baltag, previously David Ross) on which 3-4 WHO staff come and teach each year. https://www.lshtm.ac.uk/study/courses/short-courses/adolescent-health

Dr. Tucker is working on the ANSER (University of Ghent) WHO collaborating centre on reproductive health research to develop a multi-country population-based sexual and reproductive study. The purpose of this project is to better understand sexual and reproductive health needs in the COVID-19 era, with a focus on low and middle-income countries.

Publications on maternal and sexual transmission of Zika virus

- 1. Avelino-Silva VI, Mayaud **P,** Tami A, [...] Jaenisch T and the ZIKAlliance Clinical Study Group. Study protocol for the multicentre cohorts of Zika virus infection in pregnant women, infants, and acute clinical cases in Latin America and the Caribbean: the ZIKAlliance consortium. *BMC Infect Dis.* 2019; **19:** 1081. https://doi.org/10.1186/s12879-019-4685-9.
- Voordouw B, Rockx B, Jaenisch T, Fraaij P, Mayaud P, Vossen A, Koopmans M. Performance of Zika Assays in the Context of Toxoplasma gondii, Parvovirus B19, Rubella Virus, and Cytomegalovirus (TORCH) Diagnostic Assays. *Clinical Microbiology Reviews* 2019 Dec 18; 33(1). doi: 10.1128/CMR.00130-18. Print 2019 Dec 11;33(1). pii: e00130-18. doi: 10.1128/CMR.00130-18.

Please briefly describe any type of technical, programmatic, advisory or other support received from WHO during the past 12 months for the implementation of the agreed activities listed above (if any).

In the previous reporting period, Prof Mayaud reported having receiving grants for the following projects from WHO/STI:

- Measuring the global burden of non-genital HSV-1 (PI: K Looker, Univ Bristol; WHO/STI contact: Dr Sami Gottlieb). Findings have been discussed, 2 manuscripts are in preparation.
- Modelling the interactions between HSV-2 and HIV to estimate the burden of HSV2 associated HIV infections to predict the impact of HSV2 vaccines (PI: MC Boily, Imperial College London; WHO/STI contact: Dr Sami Gottlieb). Main manuscript ready for submission. Second manuscript on role of ART on HSV-2 disease draft stage.
- Systematic review of STI prevalence and incidence among HIV PREP users and models of STI care
 within PREP services (with Dr Ong). The work was presented at the PREP STI Think Tank group in
 March 2019 in Montreux; the IAS WHO Satellite meeting at IAS, Mexico, July 2019) at a special WHO

6/23/2017 11:44:02 AM Page (15/16)



satellite workshop, at a STIRIG seminar (March 2020), and has been published in *JAMA* (see below) attracting much media attention, and a special announcement in WHO and STIRIG networks.

In late 2019, Dr Ong and Prof Mayaud received a grant from WHO/STI (contact: Teo Wi) to conduct systematic reviews of three key STI syndromes (genital ulcer disease; low abdominal pain/PID; anorectal syndrome) ahead of the WHO STI Global Development Guidelines meeting in June 2020.

Prof Mayaud and Dr Ong are in discussion with Dr Sami Gottlieb to undertake a systematic review of quality of life of patients with HSV-2 in developing countries and reviews of the best methods to study this.

Prof Mayaud participated in the review with a BactiVacc grant (awarded to Dr Sami Gottlieb, WHO/STI) to develop the WHO preferred product characteristics (PPCs) for a gonorrhoea vaccine. The outcome of the first expert consultation meeting was recently published (see below). Prof Mayaud participated in a further WHO consultation organised by Dr Sami Gottlieb on May 13 and 14 (online during COVID19 crisis).

 Gottlieb SL, Ndowa F, Hook EW III, Deal C, Bachmann L, Abu-Raddad L, Chen X-S, Jerse A, Low N, MacLennan CA, Petousis-Harris H, Seib KL, Unemo M, Vincent L, Giersing BK, Gonococcal Vaccine PPC Expert Advisory Group (incl. P Mayaud). Gonococcal vaccines: Public health value and preferred product characteristics; report of a WHO global stakeholder consultation, January 2019. Vaccine 2020; (in press)

6/23/2017 11:44:02 AM Page (16/16)