

# Abstracts of the Joint Australasian Sexual Health and HIV & AIDS Conferences

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## HIV – Social, political and cultural aspects of HIV and sexual and reproductive health in the Australasian region

### 1 HEARD BUT NOT SEEN: EXPERIENCES OF TELEHEALTH BY PEOPLE LIVING WITH HIV (PLHIV) IN COVID TIMES

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**Background:** COVID-19 has brought about – or hastened – innovations in clinical care such as ‘telehealth’ (i.e. consultations conducted via video-conferencing platforms or telephone) that are likely to persist beyond the pandemic. It is therefore important to consider the ways in which the clinical encounter is changed through these innovations.

**Methods:** As part of an ongoing cohort study, in-depth interviews were conducted with people living with HIV (PLHIV) diagnosed since 2016. This paper draws on the accounts of 23 participants (median age 32 years; 21 male and 2 female) about their experiences of HIV clinical service provision during COVID-19. Interviews were conducted between June 2020 and April 2021.

**Results:** Participants’ accounts included positive reflections on telehealth, primarily related to convenience and reducing risk of COVID-19. However, accounts also included concerns that telehealth consultations may lead to some health issues being overlooked because the participant’s body was not physically present (or even visible when conducted by telephone only). However, telehealth could also lead to different kinds of attentiveness or care. Some participants suggested that clinicians inquired into the lived experience of antiretroviral therapy (e.g. adverse effects) more frequently and/or in ways that differed from in-person visits; and some participants reported that they had raised issues previously undiscussed with clinicians. Participants’ accounts indicated a trend towards less frequent clinic visits (and less frequent monitoring) during the COVID-19 pandemic. However, more than half of participants changed antiretroviral regimens during this period – although not for reasons of virologic failure – indicating that greater attention may have been given to people’s actual experiences of taking medications.

**Conclusion:** Existing critiques of HIV surveillance and policy contend that physical bodies have become decentred as clinical markers increasingly stand in for PLHIV. Encouragingly, experiences of telehealth suggest that these clinical encounters may sometimes actually enable modes of engagement that prioritise the lived experience of HIV.

#### Disclosure of interest statement:

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## 2 CLINICAL GUIDELINES: THEIR INFLUENCE ON HIV-RELATED LEGAL PROCEEDINGS

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**Background:** Clinical guidelines form an increasingly central practice of clinical governance. As clinical guidelines have proliferated, researchers have examined their content and relationship to evidence, have tested methods of guideline development, have debated the practical and political aspects of guideline use, have measured compliance and have observed ‘work-arounds’ and improvisation surrounding their use. There is more limited research on the use of clinical guidelines in the legal context. This study examines the use of clinical guidelines in the context of legal proceedings relating to HIV and sexual health. In particular, it focuses on the ways that clinical guidelines are used as evidence in these proceedings.

**Methods:** A structured review of recent use of clinical guidelines in Australian legal proceedings relating to HIV and sexual health.

**Results:** The use of clinical guidelines is very common in legal proceedings relating to HIV and sexual health. Their use is diverse, driven largely by the specific legal questions that are in dispute. Rather than representing fixed clinical definitions, legal concepts such as ‘reasonable precautions’ or ‘harm’ take their meaning from clinical guidelines, which means that guidelines can influence the law itself.

**Conclusion:** Legal processes – often thought of as misaligned with HIV and sexual health-related clinical practice – adopt the values and standards of medical practice expressed by clinical guidelines.

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### 3 EXAMINING HIV ANXIETY IN GAY MEN AS AN EMBODIED RESPONSE TO THE AIDS CRISIS

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**Background:** Discussions of ‘HIV anxiety’ abound in recent behavioural studies examining gay men’s use of pre-exposure prophylaxis for HIV (PrEP). These studies provide evidence that PrEP can reduce or even eliminate this anxiety. PrEP scholarship usually frames HIV anxiety in broad terms as a response to ‘stigma’; however, little research has examined HIV anxiety as an embodied phenomenon, particularly for gay men who did not directly participate in gay sexual subcultures during the AIDS crisis. This paper will suggest that HIV anxiety can be understood as an embodied response with its origins in the cultural and historical legacy of the AIDS crisis.

**Methods:** In order to examine how gay men understand their embodied experience of HIV anxiety, in-depth qualitative interviews were conducted with 15 gay and other same-sex attracted men born between 1981 and 1996. These interviews explored participants’ relationships to AIDS history, and the impact of PrEP use on participants’ HIV anxiety.

**Results:** Many participants understood their HIV anxiety to have its origins in their exposure to cultural and other messaging relating to the AIDS crisis during childhood and adolescence. Participants noted that prior to initiating PrEP, their embodied experiences of HIV anxiety persisted despite receiving HIV stigma-reduction education. For many, PrEP was able to reduce their embodied experience of HIV anxiety in ways that more discursive or ‘rational’ education about HIV stigma was not.

**Conclusion:** This study sheds new light on HIV anxiety as an embodied experience among gay and other same-sex attracted men. It relates this anxiety to childhood and adolescent experiences of the cultural and historical impact of the AIDS crisis. Further, by highlighting the embodied experiences of HIV anxiety, these results may also prompt a need to re-think approaches to HIV stigma-reduction education to engage directly with embodied experience.

**Disclosure of interest statement:**

The author has no interests to disclose.

## HIV – Clinical management and therapeutics: managing HIV and/or sexual health, related infections and co-morbidities

### 4 WEIGHT AND LIPID CHANGES IN PHASE 3 CABOTEGRAVIR AND RILPIVIRINE LONG-ACTING TRIALS

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**Background:** Long-acting (LA) cabotegravir (CAB), an integrase strand transfer inhibitor (INSTI), and rilpivirine (RPV), a non-nucleoside reverse transcriptase inhibitor, constitute a highly effective 2-drug regimen administered intramuscularly monthly or every 2 months for the maintenance of virologic suppression. Weight and lipid changes over 48 weeks in virologically suppressed adults receiving CAB+RPV LA in Phase 3/3b clinical trials are presented.

**Methods:** Data from CAB+RPV LA-naïve participants randomized to CAB+RPV LA every 4 weeks (Q4W), 8 weeks (Q8W), or oral comparator antiretroviral therapy (CAR) were pooled from ATLAS, FLAIR, and ATLAS-2M studies. Changes in weight, body mass index (BMI), and lipids from baseline to Week 48 were analyzed.

**Results:** Baseline demographic characteristics and weight were similar across treatment groups. Median weight change from baseline to Week 48 was 1.20, 1.25, and 1.00 kg in Q4W, Q8W, and CAR groups, respectively. Weight increase  $\geq 10\%$  occurred in 8%, 5%, and 7% of participants in Q4W, Q8W, and CAR groups, respectively. Median BMI change was 0.40, 0.42, and 0.35 kg/m<sup>2</sup> in Q4W, Q8W, and CAR groups, respectively. An upward shift from normal BMI category occurred in 13.4%, 14.6%, and 13.8% of participants in Q4W, Q8W, and CAR groups, respectively; 3.9% (Q4W), 4.1% (Q8W), and 4.7% (CAR) developed clinical obesity (BMI  $> 30$  kg/m<sup>2</sup>). No clinically significant changes in triglycerides; total, high-density lipoprotein (HDL), and low-density lipoprotein cholesterol; or total cholesterol/HDL ratios were found across treatment groups.

**Conclusion:** In this pooled analysis, changes in weight and lipid parameters over 48 weeks were modest and similar, respectively, in participants receiving CAB+RPV LA Q4W or Q8W compared to CAR. Since INSTI-associated weight changes recently emerged, weight data collection across the CAB development program was not standardized at sites and limited metabolic data were collected. Future and on-going studies will further characterize potential INSTI-associated weight gain and metabolic perturbations.

#### Disclosure of interest statement:

P. Patel, R. D'Amico, E. Elliot, J. W. Polli, J. van Wyk, M. Bosse, V. Vannappagari, and L. Gray are employees of ViiV Healthcare and may own stock in GlaxoSmithKline. S. Thiagarajah, S. Wu, and O. Upadhyay are employees of and may own stock in GlaxoSmithKline. R. Van Solingen-Ristea is an employee of Janssen Research and Development and may own stock in Johnson & Johnson. C. Orkin has received lecture fees, fees for advisory boards, travel bursaries, and research grants to her institution from ViiV Healthcare, Gilead, Merck, and Janssen. E. T. Overton has received research support to his institution and has served as a consultant for Gilead, Merck, Theratechnologies, and ViiV Healthcare. S. Swindells has received grants from ViiV Healthcare.

## 5 COMPARISON OF VIRAL REPLICATION FOR THE 2-DRUG REGIMEN (2DR) OF DOLUTEGRAVIR/LAMIVUDINE (DTG/3TC) VERSUS A 3/4-DRUG TENOFOVIR ALAFENAMIDE-BASED REGIMEN (TBR) IN THE TANGO STUDY THROUGH WEEK 96

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**Background:** TANGO demonstrated non-inferior virologic efficacy (HIV-1 RNA  $\geq 50$  c/mL by Snapshot) of switching to dolutegravir/lamivudine (DTG/3TC) vs continuing a tenofovir alafenamide (TAF)-based regimen (TBR) in HIV-1-infected, virologically suppressed adults at 96 weeks. Abbott RealTime HIV-1 assay measures viral load (VL) from 40 to 10,000,000 c/mL, and provides qualitative target detected (TD) or target not detected (TND) outcomes for VL  $< 40$  c/mL. Clinical significance of low-level VL  $< 50$  c/mL remains unclear. We assessed proportion of participants with TD/TND and elevated VL through Week 96 (Wk96).

**Methods:** Proportions of participants with VL  $< 40$  c/mL and TND were analysed by visit (Snapshot) through Wk96. Participants' TD/TND status over time, overall and by Baseline VL classifications, was assessed. Frequency of elevated VL categories including 'blips' was determined.

**Results:** At Wk96, similar proportions of participants had TND with DTG/3TC and TBR (73% [271/369] vs 69% [255/372], respectively; adjusted difference, 4.9%; 95% CI, -1.7, 11.4; Snapshot). Across Baseline VL categories, proportions with TND at all visits through Wk96 were higher at 37% (137/369) with DTG/3TC vs 31% (114/372) with TBR. Occurrence of elevated VL was low and similar across arms through Wk96 (6% [23/369] with DTG/3TC; 10% [36/372] with TBR). Most frequently observed VL rebounds across arms were 'blips' (5% [18/369] and 8% [28/372] with DTG/3TC and TBR, respectively). Zero and 3 confirmed virologic withdrawals were observed with DTG/3TC and TBR, respectively.

**Conclusion:** Similar proportions of participants had TND at all visits through Wk96 in both treatment arms. Regardless of Baseline VL, incidence of intermittent viremia was low and similar between arms. These 'deep dive' virology findings further support the potency and durability of DTG/3TC vs TBR in maintaining viral suppression.

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R. Wang, M. Ait-Khaled, P. Leone, B. Wynne, J. van Wyk, M. Underwood and A. Maccarrone are employees of ViiV Healthcare and may own stock in GlaxoSmithKline. J. Wright and N. George are employees of and may own stock in GlaxoSmithKline. T. Lutz has received grants from Gilead, Merck Sharp and Dohme, GlaxoSmithKline, Heidelberg ImmunoTherapeutix, Deutsche Leberhilfe e.V., and dagnä e.V. O. Osiyemi has nothing to disclose. M. Gorgolas has received clinical trial fees from ViiV Healthcare and personal fees from ViiV Healthcare, Gilead, and Janssen. This study was funded by ViiV Healthcare.

## 6 LIFETIME COST OF HIV MANAGEMENT IN AUSTRALIA: A MODELLING STUDY

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**Background:** Antiretroviral therapy (ART) for Human Immunodeficiency Virus (HIV) has significantly reduced morbidity and mortality but drugs can be expensive. Providing an accurate estimate of cost is beneficial for evaluating HIV prevention strategies and healthcare budgeting. This study aims to estimate the lifetime cost of HIV management in Australia, from the healthcare provider perspective.

**Methods:** A Markov cohort model was built to simulate disease progression and accrued costs over the lifetime of persons living with HIV (PLHIV). The model consisted of 21 health states based on their CD4 counts and line of ART. The model was parameterized using data from the Australian HIV Observational Database, Australian refined diagnosis-related groups, Medicare Benefits Schedule, Pharmaceutical Benefits Scheme, and other published sources of literature. We reported costs using 2019 Australian dollars (A\$) and used a discount rate of 3.5% per annum. One-way analysis was conducted to explore the impact of input costs, transition probabilities, discount rates and proportion of PLHIV on ART on lifetime cost estimates as well as changes in ART drug cost. Probabilistic sensitivity analysis determined the credible interval (CrI).

**Results:** The average discounted lifetime cost of HIV management was A\$282,093 [95% CrI: \$194,206–421,345]. The largest proportion (92%) of the estimate was due to the costs of ART drugs, and the lifetime cost was most sensitive to changes to third- and second-line ART drug costs. A 20% and 50% reduction in price of patented ART drugs would reduce lifetime cost to \$243,638 and \$161,400, respectively. Replacing patented ART drugs with currently available generic equivalents reduced the lifetime cost to A\$141,345.

**Conclusion:** The relatively high lifetime costs for managing HIV in Australia supports the urgent need to invest in HIV prevention strategies to avert new infections. Strategies to reduce the price of ART will have the greatest impact on lifetime costs.

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## HIV – Prevention, epidemiology and health promotion on HIV and/or sexual health in the Australasian region

### 7 INTENTIONS FOR FUTURE USE OF PREP FOLLOWING COVID-19 RESTRICTIONS: RESULTS FROM THE FLUX STUDY OF GAY AND BISEXUAL MEN IN AUSTRALIA

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**Background:** Some gay and bisexual men (GBM) recommenced sexual activity after stopping or reducing sex during initial COVID-19 physical distancing measures. Their intentions about when and how they will use PrEP will shape whether this period increases or diminishes HIV transmission risk. We investigate whether and how Australian GBM intended to use PrEP in the near future.

**Methods:** Between week 12 (19–26 July 2020) and week 44 (28 February–7 March 2021), 683 HIV-negative GBM were asked every four weeks about intentions for PrEP use in coming weeks and modes of use. Responses each week ranged from 319 to 498.

**Results:** Mean partner number increased from 0.88 in week 12 to 1.44 in week 44; PrEP use was 32.2% in week 12 and 37.0% in week 44. Intention for future use of PrEP was 38.3% in week 12, rising to 45.2% in week 44; this included 30.0% and 33.2% respectively who intended to use PrEP every day. Small proportions intended to use PrEP non-daily but at least 4 days a week, which remained stable (<3%) over time; 2.0% were unsure of how they would use PrEP in week 12, as were 0.5% in week 44. Intention to use the 2-1-1 on-demand method for PrEP increased from 3.9% in week 12 to 10.1% in week 44.

**Conclusion:** As levels of sexual activity have increased following the easing of COVID restrictions, intention to use PrEP has also gradually increased. Most men intending to use PrEP were already doing so. Although men mostly intended to use PrEP on a daily basis, there has been a substantial increase in the proportion of men intending to use PrEP on an on-demand basis. Information about preparing for, and modes of use of PrEP should be available prior to men recommencing sexual activity.

#### **Disclosure of interest statement:**

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## 8 ASSOCIATIONS BETWEEN SOCIAL CAPITAL AND HIV RISK-TAKING BEHAVIOURS AMONG MEN WHO HAVE SEX WITH MEN IN JAPAN

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**Introduction:** Social capital is increasingly recognized as playing an important role in HIV risk reduction strategies. However, there is limited research examining whether social capital networks accessed through MSM rather than through heterosexuals are associated with differing HIV risk-taking and testing behaviours among MSM.

**Methods:** Using cross-sectional data on 1,564 MSM collected using online dating apps in Greater Tokyo, we investigated whether social capital is associated with consistent condom use with regular and casual male partners, and lifetime HIV-testing, adjusting for individual and community level covariates. We measured social capital using eighteen questions assessing respondents' ability to access both physical and social-support resources embedded in their social networks. Respondents were grouped into high, medium and low levels of MSM and heterosexual social capital.

**Results:** Participants with high heterosexual social capital reported more consistent condom use with casual partners than participants reporting low heterosexual social capital (AOR = 1.97, 95%CI = 1.11–3.49). Participants with high MSM social capital were more likely to have undertaken HIV testing in their lifetimes (AOR = 2.44, 95%CI = 1.58–3.75), but half as likely as those with low MSM social capital to report consistent condom use (AOR = 0.57, 95%CI = 0.39–0.84). Participants who associated with MSM who influenced them to practice unsafe sex were less likely to use condoms consistently, but more likely to have undertaken lifetime HIV testing than participants who did not know MSM who influenced them to practice unsafe sex.

**Conclusion:** This study reveals important differences in HIV testing and condom use associated with MSM and heterosexual social capital. Associations between MSM social capital and HIV testing indicate the potential for integrating social capital enhancement programs such as social or peer support into current HIV interventions, and the important role that marginalization from heterosexual social networks can play in increasing HIV risk.

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## 9 HIV TESTING, TREATMENT AND VIRAL SUPPRESSION AMONG MEN WHO HAVE SEX WITH MEN (MSM) IN FIVE COUNTRIES: RESULTS OF THE ASIA PACIFIC MSM INTERNET SURVEY

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**Background:** Men who have sex with men (MSM) bear a disproportionately high burden of HIV in South-East Asia. However, there are few studies examining viral suppression and the HIV care cascade including HIV testing among this population, nor of factors associated with these outcomes.

**Methods:** We conducted an online cross-sectional survey among 15,938 MSM across Thailand, Malaysia, Indonesia, Japan and Vietnam from May 2020 to January 2021. Multiple logistic regressions were performed to obtain adjusted odds ratios (AOR) of factors associated with HIV testing within the past 12 months among HIV-negative/untested MSM; engagement with ART and viral suppression among those HIV-positive.

**Results:** Of the 10,953 HIV-negative/untested MSM who reported  $\geq 1$  male partners in the previous year, 39.0% (Thailand = 56.2%; Malaysia = 53.4%; Indonesia = 43.7%; Vietnam = 42.0%; Japan = 32.1%) reported that they had tested for HIV in the past year, which was associated with high income, group sex (AOR = 1.17, 95%CI = 1.01–1.36),  $>20$  male partners in the past year (AOR = 1.68, 95%CI = 1.31–2.14). Recent HIV testing was negatively associated with concerns relating to MSM stigma in healthcare settings, identifying as bisexual compared to gay, and compared to Thailand, residing in Japan or Indonesia. Three-quarters (75.5%;  $n = 815$ ) of 1,080 HIV-positive MSM reported current use of ART (Indonesia = 93.2%; Malaysia = 90.5%; Thailand = 78.5%; Vietnam = 76.2%; Japan = 70.7%), of whom 71.9% (Japan = 88.8%; Malaysia = 60.7%; Vietnam = 51.0%; Indonesia = 50.0%; Thailand = 46.0%) reported having an undetectable viral load (UVL). Identifying as bisexual compared to gay, and past-year transactional sex were associated with lower odds of ART adherence. UVL was associated with older age, high income and compared to Thailand, residing in Japan or Malaysia. Participants engaging in past-year transactional sex were less likely to report viral suppression.

**Conclusion:** Twelve-month HIV testing was low among sexually active MSM. ART uptake was reasonable although viral suppression among those HIV-positive remains much lower than international targets, except for Japan. Sustained and consistent investment in HIV testing promotion is required, hand-in-hand with stigma-reduction strategies within healthcare settings.

### Disclosure of interest statement:

The Australian Research Centre in Sex, Health and Society at La Trobe University as well as the Kirby Institute and Centre for Social Research in Health at UNSW Sydney Receive funding from the Commonwealth Department of Health.

## HIV – Discovery and translational science, biology, resistance and pathogenesis

### 10 LAYER-BY-LAYER PARTICLES DELIVER EPIGENETIC SILENCING SIRNA TO HIV-1 LATENT RESERVOIR CELL TYPES

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**Background:** Nanomaterials have been employed to facilitate intracellular delivery of small interfering (si)RNA to induce gene silencing via mRNA degradation using the post-transcriptional gene silencing (PTGS) RNA interference pathway. Besides PTGS, siRNAs are also capable of transcriptional gene silencing (TSG) or epigenetic silencing, which targets the gene promoter in the nucleus and prevents transcription via epigenetic modifications, however silencing efficiency is hampered by poor intracellular and nuclear delivery. Here, we describe the use of polyarginine-terminated multilayered particles for delivery of TGS siRNA. The HIV latent reservoir has potential to reactivate and is the major barrier to a HIV cure. It is hypothesized that particles can mediate delivery of TGS-inducing siRNA to the nucleus to induce a block in virus transcription and lock the virus in a ‘super latent’ state.

**Methods:** Fluorescently labelled siRNA (promoter-targeted siPromA or control siScrambled) were complexed with multilayered particles formed by the layer-by-layer assembly of poly(styrene sulfonate) and poly(arginine) incubated with HIV-infected cell types (HeLa T4+, HUT78, primary activated/resting CD4+ T cells and monocyte-derived macrophages (MDMs)). Nuclear delivery of siRNA was assessed at 48h using deconvolution microscopy to measure i) co-localisation of siRNA with NucBlue stained nuclei, ii) arbitrary line profile, and iii) 3D cell profile. Functional HIV-1 gene silencing by particle delivered siRNA was determined using Reverse Transcriptase assay and RT-qPCR of cell associated gag vRNA.

**Results:** Image analysis reported successful delivery of siPromA into the nucleus of all infected cell types assessed. Significantly decreased levels of Reverse Transcriptase and gag vRNA levels demonstrated functional silencing of particle delivered siPromA in HeLa T4+ and HUT78 cell lines, and in primary activated CD4+ T cells and MDMs (from three donors), compared to controls (Mock, NP alone, Buffer and siScrambled).

**Conclusion:** This work extends conventional nanotechnology-enabled PTGS siRNA delivery to the TGS pathway and paves the way for future studies on particle-delivered siRNA for efficient TGS of various diseases and infections.

#### Disclosure of interest statement:

This work was funded by NHMRC Program Grant 1149990. No pharmaceutical grants were received in the development of this work.

## 11 SUSTAINED HIGHER LEVELS OF INTRACELLULAR HIV-1 RNA TRANSCRIPT ACTIVITY IN VIRAL BLIP PATIENTS

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**Background:** Virally suppressed HIV patients on antiretroviral therapy (ART) occasionally experience viral blips, or low-level elevations of HIV-1 plasma viral load. The clinical significance of blips is unclear. It has been suggested that blips may be related to HIV-1 reservoir activity. We used a new highly sensitive assay to investigate HIV-1 RNA transcriptional activity of PBMCs in patients with and without blips, and further explored production of infectious virus from the viral reservoir.

**Methods:** RNA and DNA was extracted from cells in 6ml of peripheral blood, from HIV-1 patients on ART, virally suppressed, with no blips ( $n = 52$ ) or with one or two blips ( $n = 55$ ) in the previous 2 years. Follow-up samples of the patients were also studied. HIV-1 RNA transcripts and proviral DNA was measured using our assay, which targets the highly conserved 'R' region of the LTR, termed as Double-R assay. Transcriptional activity and measure of replication competent virus was also analysed in activated purified CD4+ T cells.

**Results:** Blip patients had significantly higher levels of HIV-1 RNA transcripts vs without blips (median 192 vs 49 copies/106 white blood cells;  $P = 0.0007$ , range 1.3 to 5,415). The follow-up sample analysis revealed that increased levels of HIV-1 transcription were maintained in follow up samples of blip patients. This correlated well with higher levels of inducible transcripts after activation *in vitro*, and production of replication competent HIV-1. Three distinct patients, including an elite controller, had very low levels of transcripts with inability to induce productive infection *in vitro*.

**Conclusion:** Viral 'blips' reflect higher transcriptional activity from the reservoir despite viral suppression, and slightly higher HIV-1 DNA over time. Viral 'blips' are therefore significant. This sensitive assay can be used in monitoring the size and activity of the HIV-1 reservoir and will be useful in research into HIV-1 cure strategies.

### Disclosure of interest statement:

This study was supported by a St Vincent's Clinic Foundation Research Grant and AMR Translational Research Grant, with partial support from NHMRC grant (APP1105808). KS receives research funds from Denka Co. Ltd.

## 12 BALANCING STATISTICAL POWER AND RISK IN HIV CURE CLINICAL TRIAL DESIGN

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**Background:** Analytical treatment interruptions (ATI) are closely monitored, temporary pauses of antiretroviral therapy (ART) in the context of an HIV cure clinical trial. They are currently the gold standard in determining if the intervention being tested can achieve sustained virological control in the absence ART. However, withholding ART comes with risks and discomforts to the trial participant including rebound viremia, and frequent blood sampling. We used mathematical models to explore how ATI study design can be improved to maximise statistical power, while minimising risks to participants.

**Methods:** Using previously observed dynamics of time to viral rebound (TVR) post ATI, we modelled estimates for optimal sample size, timing of sampling and duration to follow up required to detect a significant difference in the time to detection of virus between control and intervention groups. Control and intervention groups were compared using a log-rank test, and analytical and stochastic techniques.

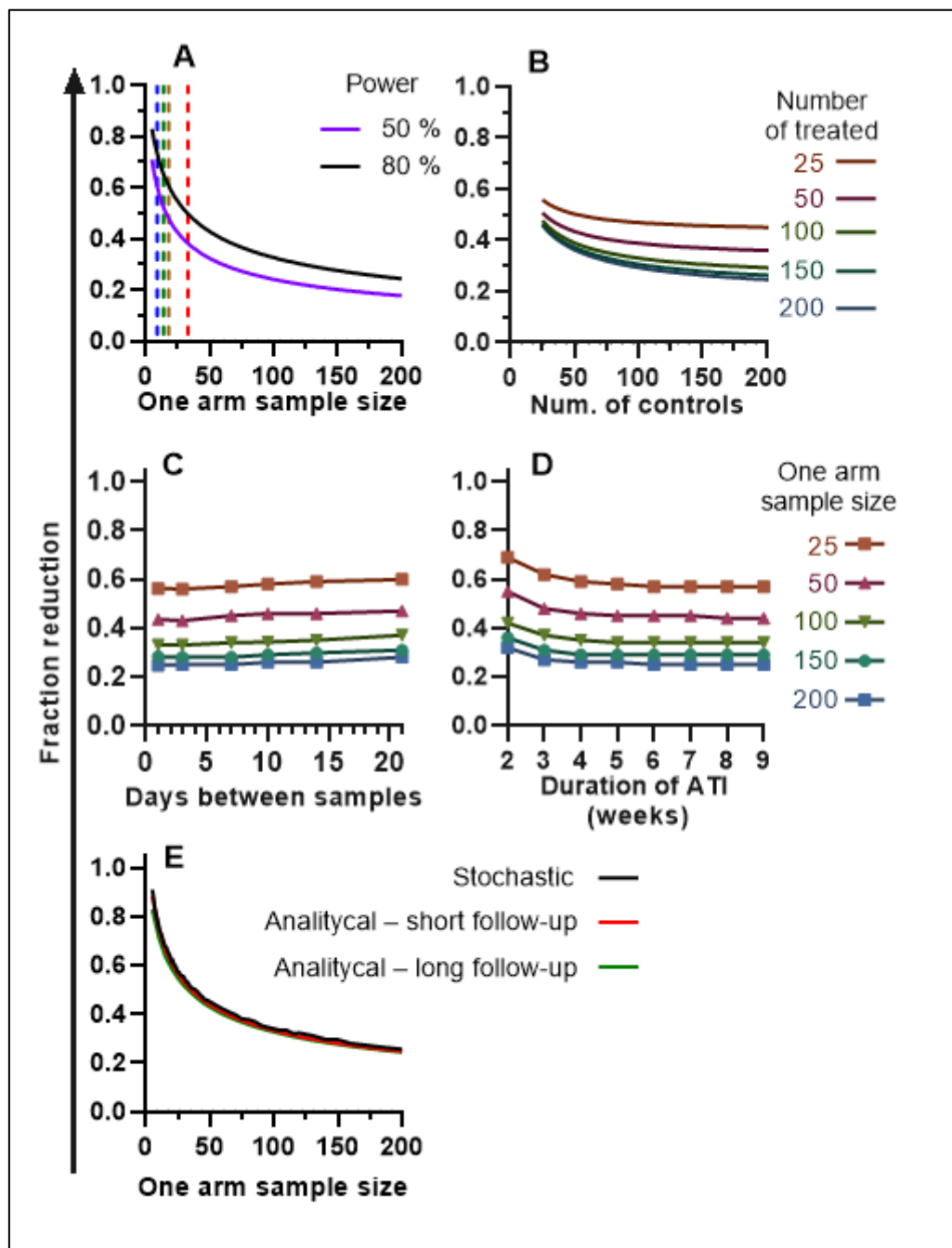
**Results:** In placebo-controlled TVR studies, 120 participants are required in each arm to detect a 30% difference in the size of the viral reservoir at 80% power (Fig. 1A). Using historical controls instead of placebo arms could reduce the number of participants required to test the intervention (Fig. 1B). Regardless of sample size, there was little statistical advantage to measuring viral load more frequently than weekly (Fig. 1C), or interrupting ART beyond 5 weeks (Fig. 1D). Fig. 1E demonstrates that a 5-week ATI study with weekly viral load monitoring is almost identical in terms of statistical power compared to continuous monitoring for an indefinite period.

**Conclusion:** We propose that mathematical models can be used to improve ATI trial design. Most recent HIV cure trials are underpowered to detect changes in the viral reservoir. TVR studies can be shortened to 5 weeks with weekly viral load monitoring while maintaining statistical power. This has implications on future ATI trial development.

### **Disclosure of interest statement:**

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*(Figure 1 next page)*



**Figure 1.** Detectable reduction of the rate of virus rebound using time-to-detection method in a model of a controlled study. A) Number of participants in a single arm needed to detect a given reduction in reactivation rate with power of both 80% and 50%. B) Reduction in reactivation rate that could be detected with 80% power, given a treatment group size of 25, 50, 100, 150 and 200 participants and variable number of historical controls. C and D) The effect of frequency of sampling and duration of ATI on detecting a reduction in reactivation rate with 80% power. E) Short-course ATI with weekly sampling maintains statistical power (80%). The green curve shows the analytical relationship that assumes continuous detection of reactivation and a long time window (all participants are detected). Red curve shows the analytical relationship corrected for the number of participants that are expected to be detected within 5 weeks of stopping ART. Black curve shows a stochastic simulation assuming weekly sampling and 5 weeks ATI.

### 13 HIGH LEVELS OF HIV RNA TRANSCRIPTS IN CSF CELLS DESPITE SUPPRESSIVE ART

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**Background:** HAND persists despite suppressive cART, and we aimed to study HIV RNA transcripts in CSF cells and characterize CD4 T cells that may contribute to this CNS HIV reservoir, using high-dimensional flow cytometry and our highly-sensitive Double-R assay of HIV RNA transcripts.

**Methods:** CSF cells and PBMC were compared by 18-colour flow cytometry. DNA and RNA were extracted in 20 paired samples of CSF and blood from HIV+ subjects on cART, with both plasma and CSF HIV RNA (Roche) <50 copies/ml. HIV-1 transcripts and DNA were determined by the Double-R  $\pi$ Code MicroDiscs assay, as copies/106 CD4. *In vivo* brain injury was assessed with MR spectroscopy in the frontal white matter (FWM) and posterior cingulate cortex (PCC).

**Results:** CSF cells were 91% memory T cells, comprised equally of memory CD4 (median 3,605 cells recovered) and CD8 T cells (3,507). Other CSF cells were 3.1% CD14+CD16+ monocytes, 2.0% NK cells and 0.4 % B cells. Memory CXCR3+CD49d+integrin $\beta$ 7-cells were 76% of CD4 T cells in CSF (vs 17% in PBMC); 51% were CCR5+ (vs 16%); and 18% expressed CD38 and/or HLA-DR activation markers (vs 11%). 18/20 patients' CSF cells had significantly higher cell-associated HIV-1 RNA transcripts vs PBMCs (8,331 vs 680;  $P < 0.0001$ ), but levels were significantly correlated between CSF cells and PBMC ( $r = 0.46$ ;  $P = 0.029$ ). 16/20 patients also had significantly higher HIV-1 DNA levels in CSF cells vs PBMC (median 3,940 copies/106 cells vs 885;  $P < 0.0001$ ). CSF transcripts were inversely correlated with the neuronal integrity biomarker N-acetyl aspartate in FWM ( $P = 0.04$ ) and PCC ( $P = 0.055$ ).

**Conclusion:** CSF cells have high transcription activity despite ART, most likely in the predominant CXCR3+CD49d+integrin $\beta$ 7-CCR5+ memory CD4+T cells. Ligands for CXCR3+ cells, especially IP-10, likely induce trafficking of circulating infected CD4 T cells into the CNS. Therapies targeting transcription should be developed, to reduce compromised neuron integrity.

#### Disclosure of interest statement:

K.S. receives research funds from Denka Co. Ltd. K.S. is the original inventor under WO2018/045425 (PTC/AU2017/050974) patent, titled 'Methods of detecting Lentivirus' of HIV-1 detection targeting 'R' region.



## Sexual Health – Social, political and cultural aspects of HIV and sexual and reproductive health in the Australasian region

### 14 LOST IN TRANSLATION: PREVENTING THE MEANINGS OF SEXUAL AND REPRODUCTIVE HEALTH FROM BEING LOST DURING THE TRANSLATION OF NATIONAL SURVEYS

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**Background:** In multicultural Australia, the translation of sexual and reproductive health (SHR) surveys into community languages has become a standard practice. Nevertheless, translation is often viewed as a supplementary or last-minute activity, and by translators who are outside of the study team. Few studies have examined how the meanings of SRH terminology can be lost in the translation process and the implications of this for the quality for the research.

**Methods:** Guided by best practice for cross-cultural survey adaptation, the Australian Study of Health and Relationships (ASHR) survey was translated into Simplified-Chinese. To examine question acceptability and comprehension, six focus groups were conducted with 39 Mandarin-speakers in Australia. Group transcripts were analysed thematically and triangulated with meeting documents and fieldnotes.

**Results:** Three themes that captured how meanings were lost in the process of survey translation were identified: 1) linguacultural differences in sexuality and relationships between English and Chinese; 2) the clash of everyday and professional discourses; and 3) translation challenges associated with source questionnaire design. Western concepts such as ‘sexuality’, ‘gender’ and ‘relationship expectations’ were subtly altered or became incomprehensible to the target population during translation. Maintaining linguistic and cross-cultural equivalence was particularly challenging when translating questions with ‘explicit’ reference to genitals and sexual acts. Everyday Chinese translations of some SRH terms were problematic due to their inherent stigmatizing connotations [e.g. ‘HIV’ = aizibingdu (AIDS virus)]. Translation errors were likely to be introduced if translators were not well-informed about the skip logics and definitions of terms with similar meanings (e.g. ‘steady’/‘regular’ partners). The intended mode of survey administration (e.g. paper/phone interviews) also affected translation style and word choice.

**Conclusion:** Meanings of SRH terminology can be lost easily in the translation process. To improve cross-cultural comparability of SRH data, translation should be planned carefully and integrated into earlier stages of survey design, to ensure that quality is maintained.

#### Disclosure of interest statement:

The Sex in Translation project is funded by the Department of Health. The authors declare no conflict of interest in the development of this study.

## 15 ADOLESCENT ACCESS AND EXPERIENCE OF ABORTION CARE IN NSW – ADOLESCENTS’ PERSPECTIVE

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**Background:** There is a lack of adolescent focused evidence concerning the experience and trajectories of adolescents seeking access to abortion care. This is the second and third stages of a multi-stage mixed method study to determine the care trajectories and experiences of adolescents, aged 16- to 19-years-old, seeking an early induced abortion in New South Wales.

**Methods:** Stage 2 was a quantitative cross-sectional online survey of adolescents aged 16- to 19-years-old in NSW. Stage 3 was case studies with adolescents aged 16- to 25-years-old who had accessed an abortion in NSW when aged 16 to 19 years.

**Results:** In the online survey of 576 respondents, 14 adolescents identified accessing an abortion. These respondents reported they were provided with comprehensive information, space and time to ask the questions that they needed and were likely to recommend the service to others. Treatment by the staff working in abortion services was also highly rated. Four case study interviews took place. The overarching theme was the abortion trajectory was a profound personal crisis for adolescents. Participants found the experience of an unplanned pregnancy and the decision to have an abortion brought their fertility into acute focus and led to reflection on their sense of identity. A sense of agency and resourcefulness emerged as participants navigated their trajectory to resolve their personal crisis and access an abortion. Some participants became empowered by navigating the system.

**Conclusion:** Though barriers and experiences that emerged are similar to findings around adult abortion experience, adolescents’ age exasperates these barriers and creates greater emotional and physical burden. The unique needs of adolescent’s need to be acknowledged. Empathetic person-centred care, comprehensive information and support through health services, school-based sexuality and healthy literacy education needs to be provided to improve adolescents’ accessibility and overall experience of care.

### **Disclosure of interest statement:**

This research has been funded by the University of Technology Sydney.

## 16 FEASIBILITY AND ACCEPTABILITY OF USING VIDEOCONFERENCING FOCUS GROUPS IN SEXUAL HEALTH RESEARCH WITH CULTURALLY AND LINGUISTICALLY DIVERSE COMMUNITIES IN AUSTRALIA

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<sup>6</sup>Faculty of Health Sciences, Simon Fraser University

**Background:** While videoconferencing focus groups (VFGs) have emerged as a popular data collection method during the pandemic, the literature on the use of VFGs to collect sexual health data is still very much in its infancy. It is unclear from the limited literature whether this method is considered acceptable by people from culturally and linguistically diverse backgrounds for research exploring ‘sensitive’ issues, such as sexual and reproductive health.

**Methods:** As a part of a larger sexual health study, VFGs were conducted with a total of 39 Mandarin-speaking migrants recruited from six Australian cities. Discussions covered various issues pertaining to sexual and reproductive health which were relevant to the Australian Chinese community. Participants were asked to comment on their experience of VFGs to discuss sexual health. The analysis focused on describing participants’ experiences and reflecting on the contributions in planning and facilitating future videoconferencing focus groups.

**Results:** Feedback on the VFGs was overwhelmingly positive. Participants felt more comfortable disclosing and discussing sexual experiences with strangers in a virtual setting, especially when they could turn off their cameras during discussions. Nevertheless, some non-verbal data were sacrificed, and new concerns regarding facilitation and research ethics were introduced. There was also a gender-based difference throughout the research process. Women appeared to be less willing to turn on their cameras, but their discussions tended to be more engaging and dynamic. Heterosexual men and non-heterosexual women also appeared to be less responsive to recruitment messages.

**Conclusion:** VFGs appeared to be a highly feasible and acceptable way to collect ‘sensitive’ sexual health data with the Australian Chinese community. Whether participants should be allowed to turn off their cameras is an important decision that researchers have to make when planning VFGs. Researchers also need to be aware of the potential differences in relation to participants’ gender and sexuality throughout the research process.

### Disclosure of interest statement:

The Sex in Translation project is funded by the Department of Health. The authors declare no conflict of interest in the development of this study.

## Sexual Health – Clinical management and therapeutics: managing HIV and/or sexual health, related infections and co-morbidities

### 17 TREATMENT EFFICACY OF 1G AZITHROMYCIN VERSUS 100MG DOXYCYCLINE BI-DAILY FOR SEVEN DAYS FOR ASYMPTOMATIC RECTAL *CHLAMYDIA TRACHOMATIS*

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**Background:** Rectal chlamydia is the most commonly diagnosed bacterial sexually transmissible infection among men who have sex with men (MSM) and there is increasing concern about rectal chlamydia in women. The absence of randomised controlled trial (RCT) evidence means there is ongoing debate about the most efficacious treatment.

**Methods:** We conducted a double-blind RCT to compare the efficacy of azithromycin 1g single-dose with 7-days doxycycline 100mg twice daily for the treatment of asymptomatic rectal chlamydia. MSM diagnosed with asymptomatic rectal chlamydia infection at five sexual health clinics in Australia were randomly assigned to receive either doxycycline or azithromycin. The primary outcome was rectal chlamydia microbiological cure defined as a negative nucleic acid amplification test at four weeks post-treatment. Logistic regression was used to calculate the difference in microbial cure within a modified intention to treat population that excluded L2 serovar diagnoses post-recruitment.

**Results:** We enrolled 625 men and randomly assigned 314 to doxycycline and 311 to azithromycin between August 2016 and August 2019. Primary outcome data were available for 290 (92%) assigned to doxycycline and 297 (96%) assigned to azithromycin. In the modified intention to treat population, the observed microbiological cure was 281/290 (96.9%; 95%CI: 94.9 to 98.9) for doxycycline and 227/297 (76.4%; 95%CI: 73.8 to 79.1) for azithromycin, with an adjusted risk difference of 19.9% (95% CI: 14.6 to 25.3) in favour of doxycycline. Adverse events including nausea, diarrhoea and vomiting were reported by 33.8% (98/290) receiving doxycycline and 45.1% (134/297) azithromycin (risk difference = -11.3%; 95%CI: -19.5 to -3.2). Chlamydial load at baseline was greater for those in the azithromycin arm who failed treatment compared to those who did not.

**Conclusion:** The efficacy of doxycycline was found to be 20% higher compared to azithromycin in the treatment of asymptomatic rectal chlamydia infection among MSM. Doxycycline must replace azithromycin as first-line treatment for asymptomatic rectal chlamydia.

#### Disclosure of interest statement:

The authors have no conflicts of interest to declare.

## 18 AUDIT OF VIRTUAL AND FACE-TO-FACE PSYCHOSEXUAL GROUP INTERVENTIONS FOR MEN WITH ERECTILE DYSFUNCTION IN AN INNER-CITY SEXUAL HEALTH CLINIC: ADAPTING THE DELIVERY OF CARE IN RESPONSE TO THE COVID-19 PANDEMIC

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**Background:** The use of group-based interventions in managing erectile dysfunction (ED) is increasingly recognised as feasible and cost effective. The use of face-to-face psychosexual group interventions for ED has been implemented in the clinic since 2017. However, the COVID-19 pandemic has accelerated the adoption of virtual delivery. An audit was performed to compare the outcomes of men who participated in the face-to-face and virtual groups.

**Methods:** An audit was conducted on all participants of the ED groups between January 2019–2021. Demographic and clinical characteristics were reviewed. Outcome measures included The National Sexual Outcomes Group measure (NSOG), International Index of Erectile Function 5-item score (IIEF-5), Generalised Anxiety Disorder Scale-7 (GAD-7) and Patient Health Questionnaire-9 (PHQ-9). Outcomes of the face-to-face versus virtual groups were compared using Chi-squared & Wilcoxon rank-sum tests.

**Results:** 38 men were included in the audit; 42% participated in virtual groups. The median age was 46.3 years (IQR 34–57 years). 29% experienced ED for more than ten years. Mean changes in scores were as follows: IIEF-5 2.43 (IQR 0–1), NSOG 10.0 (IQR 3–16), GAD-7 –1.74 (IQR –4–1) and PHQ-9 –0.96 (IQR –3–1). Overall, 60.5% completed four or more of the five group sessions and face-to-face participants were more likely to complete all sessions (45% vs 12.5%,  $P = 0.031$ ). Comparing the two modalities, there were no significant differences in changes of NSOG ( $P = 0.33$ ), IIEF-5 ( $P = 0.089$ ), GAD-7 ( $P = 0.97$ ) or PHQ-9 ( $P = 0.75$ ). 68% had used an ED medication before or during the group and this was significantly associated with greater improvement in NSOG ( $P = 0.002$ ).

**Conclusion:** This audit suggests that among participants who completed all sessions there was no significant difference in outcomes between face-to-face and virtual ED groups. Both modalities showed significant improvements in erectile dysfunction and sexual confidence. This suggests that adopting ‘digital first’ care for ED can be effective and sustainable during the COVID-19 pandemic.

### Disclosure of interest statement:

None.

## 19 RESISTANCE-GUIDED COMBINATION THERAPY FOR *MYCOPLASMA GENITALIUM*

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**Background:** *Mycoplasma genitalium* (MG) is challenging to cure. While resistance-guided sequential monotherapy (doxycycline followed by azithromycin for macrolide-susceptible infections or moxifloxacin for macrolide-resistant infections) increased cure to 95.4% (95%CI: 89.7–98.0) for macrolide-susceptible and 92.0% (95%CI: 88.1–94.6) for macrolide-resistant infections, selection of resistance and rising antimicrobial resistance remains a concern. In an effort to further increase cure and reduce de novo resistance, we evaluated the efficacy and tolerability of combination therapy with doxycycline+azithromycin or doxycycline+moxifloxacin.

**Methods:** We conducted a prospective evaluation of patients treated with resistance-guided combination therapy at Melbourne Sexual Health Centre between August 2019 and December 2020. All patients received doxycycline for 7 days followed by either combination doxycycline+azithromycin (1g day 1, 500mg daily for 3 days) for macrolide-susceptible infections or combination doxycycline+moxifloxacin (400mg daily for 7 days) for macrolide-resistant infections. Adherence and adverse effects were recorded at test of cure, which was recommended 14–28 days after completing antimicrobials. Sequencing was performed to determine the prevalence of parC mutations in macrolide-resistant infections.

**Results:** Of 101 patients treated with doxycycline+azithromycin, 93 were cured (92.1% [95%CI: 85.0–96.5%]). Of 247 patients treated with doxycycline+moxifloxacin, 210 were cured (85.0% [95%CI: 80.0–89.2%]). Sequencing was available for 119 (48%) of the doxycycline+moxifloxacin group; parC S83 mutations were detected in 26%. Doxycycline+moxifloxacin cured 97.6 % (91.5–99.7%) of cases without and 32.2% (16.7–51.1%) of cases with parC S83 mutations. Almost half of patients (46% and 44%, respectively) reported adverse effects, predominantly mild gastrointestinal.

**Conclusion:** Combination doxycycline+azithromycin was not more effective than sequential monotherapy. Overall combination doxycycline+moxifloxacin achieved 85% cure in macrolide-resistant infections, where the prevalence of S83 mutations was 26%. Absence of parC S83 mutations was associated with 98% cure for doxycycline+moxifloxacin. High levels of quinolone resistance has significantly impacted on the efficacy of moxifloxacin and this was not improved with combination therapy. Adverse effects were common.

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### Potential conflicts of interest:

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## Sexual Health – Prevention, epidemiology and health promotion on HIV and/or sexual health in the Australasian region

### 20 RISK FACTORS FOR OROPHARYNGEAL GONORRHOEA AMONG FEMALE SEX WORKERS ATTENDING SEXUAL HEALTH CLINICS IN MELBOURNE AND SYDNEY: A CASE-CONTROL STUDY

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**Background:** Tongue kissing is a risk factor for oropharyngeal gonorrhoea in men who have sex with men and is commonly reported by female sex workers (FSWs) with their clients. The aim of this study was to determine the risk factors for oropharyngeal gonorrhoea in FSWs.

**Methods:** A case-control study involving 83 FSWs diagnosed with oropharyngeal gonorrhoea (cases) and 603 FSWs without oropharyngeal gonorrhoea (controls). Participants were recruited at two sexual health clinics in Melbourne and Sydney in November 2018–March 2020. The survey asked basic demographic questions, location of sex work, sex practices with male clients in an average working week and sex with not-at-work male partners in the last week. Nucleic acid amplified test was used for oropharyngeal gonorrhoea diagnosis. Univariable and multivariable logistic regression were performed to examine the factors associated with oropharyngeal gonorrhoea.

**Results:** The median age of 686 FSWs was 30 (interquartile range [IQR]: 26–36). Most performed sex work exclusively in one type of venue (578; 84.3%), most commonly brothels (352; 51.5%) followed by massage parlours (153; 22.4%). Almost 40% were newly arrived in Australia (within 3 years). There were 417 (60.8%) who tongue kissed clients and 198 (28.9%) who performed condomless oral sex on clients in an average working week. There were 251 (36.6%) who had not-at-work sexual partners. After adjusting for site of recruitment, age, length of time in Australia, tongue kissing clients, performing condomless oral sex with clients and having a not-at-work sexual partner, only performing condomless oral sex at work was associated with oropharyngeal gonorrhoea (adjusted odds ratio [aOR]: 3.5; 95%CI: 1.8–6.8;  $P < 0.001$ ).

**Conclusion:** Almost 30% of FSW reported performing condomless oral sex on clients and this practice was associated with oropharyngeal gonorrhoea diagnosis. Tongue kissing with male clients was not associated with oropharyngeal gonorrhoea in FSWs.

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## 21 GENITAL WARTS TRENDS IN AUSTRALIAN AND OVERSEAS-BORN PEOPLE IN AUSTRALIA: MEASURING PROGRESS TOWARDS CONTROL AND ELIMINATION

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**Background:** Substantial declines in genital warts (GW) have been observed in countries with quadrivalent/nonavalent HPV (q/n HPV) vaccination programs, with Australia showing the most pronounced and long-term reductions. Yet, no study has assessed progress towards elimination of GW among migrants, and their contribution to population-level control of GW. We assessed Australia's progress towards GW elimination by examining trends in diagnoses in Australian- and overseas-born attendees of sexual health clinics (SHCs) across Australia.

**Methods:** A cross-sectional trend analysis of new GW diagnoses among first-time attendees of 34 SHCs between 2004 and 2018. Rate ratios (RR) and their 95% confidence intervals (CI) were used for comparing GW trends among Australian- and overseas-born patients by 2018 relative to the pre-vaccination era 2004–2007.

**Results:** A total of 439,957 new patients (Australian-born: 230,230; overseas-born: 209,727) were seen at SHCs, 6.4% were diagnosed with GW (Australian-born: 7.1%; overseas-born: 5.6%). By 2018, there had been a 64% reduction in the proportion of all SHC patients with a GW diagnosis relative to 2004–2007 (RR: 0.36, 95% CI: 0.35 to 0.38,  $P < 0.01$ ). The decline was more pronounced at 72% (RR: 0.28, 95% CI: 0.27 to 0.30,  $P < 0.01$ ) among Australian-born patients, with the greatest reduction in women and men aged <21 years, at 98% (RR: 0.02, 95% CI: 0.01 to 0.02,  $P < 0.01$ ) and 92% (RR: 0.08, 95% CI: 0.06 to 0.11,  $P < 0.01$ ), respectively. There was a 49% reduction in the proportion of overseas-born patients diagnosed with GW (RR: 0.51, 95% CI: 0.48 to 0.54,  $P < 0.01$ ), and a 21% reduction in overseas-born patients from countries with no/bivalent HPV (bHPV) vaccination program (RR: 0.79 95% CI: 0.71 to 0.90,  $P < 0.01$ ).

**Conclusion:** Although reductions in genital warts diagnoses have reached near elimination levels in young Australian-born people, population-wide elimination of genital warts is dependent on other countries initiating and expanding their HPV vaccination programs.

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## 22 TRENDS AND RISK FACTORS OF INFECTIOUS SYPHILIS AMONG WOMEN AND HETEROSEXUAL MEN IN MAJOR AUSTRALIAN CITIES: ANALYSIS OF NATIONAL SENTINEL SURVEILLANCE DATA 2011–2019

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**Background:** In Australia, infectious syphilis notifications have increased from 1280 in 2009 to 5078 in 2018. Although historically concentrated among urban men who have sex with men and remote Indigenous communities, a rise in syphilis notifications among women in major cities and cases of congenital syphilis have been observed. We analysed trends in infectious syphilis positivity among women and heterosexual men in major Australian cities and identified associated risk factors.

**Methods:** De-identified data were extracted from 34 sexual health clinics within ACCESS. Included patients were 52,221 women and 36,341 heterosexual men  $\geq 15$  years who lived in major cities who had attended a sexual health clinic for the first time during the study period. Infectious syphilis positivity was defined as the proportion of attendees per calendar year with recorded syphilis testing who had recorded diagnoses of infectious syphilis. Poisson regression determined annual trends in positivity (rates per 1000 tests) and risk factors for infectious syphilis (rate ratios [95% CIs]).

**Results:** Between 2011 and 2019, infectious syphilis positivity increased by 63% in women (1.82 [1.01–2.02] to 2.98 [2.76–4.34]) and 24% in heterosexual men (6.06 [2.74–4.92] to 7.56 [5.37–8.13]). For both men and women, infectious syphilis was higher in those reporting lifetime injecting drug use (women: 4.87 [2.18–10.86]; men: 1.96 [0.96–3.99]) and those from disadvantaged areas (women: 2.01 [1.37–2.93]; men: 2.57 [1.44–4.57]). For women only, infectious syphilis was higher among Indigenous women (2.39 [1.22–4.70]) and women from culturally and linguistically diverse backgrounds (3.72 [1.41–9.81]), and lower in bisexually active women (0.48 [0.29–0.89]) and female sex workers (0.35 [0.29–0.44]). Among men only, it was higher among those aged 40–49 years (2.08 [1.38–3.13]) and  $\geq 50$  (2.33 [1.50–3.61]).

**Conclusion:** Increasing syphilis in women and heterosexual men in major Australian cities requires enhanced prevention, including integration of culturally appropriate sexual and reproductive health care into harm reduction programs.

### Disclosure of interest statement:

Nothing to declare.