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A multivariate analysis of social, demographic, and behavioral factors associated with gonorrhea and chlamydia prevalence among men who have sex with men and transgender women in Papua New Guinea

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Abstract

A multivariate analysis of social, demographic, and behavioral factors associated with gonorrhea and chlamydia prevalence among men who have sex with men and transgender women in Papua New Guinea

By Chelsea Iwamoto

Introduction: Globally, there are an estimated 87 million gonorrhea infections, 127 million chlamydia infections, and 6 million syphilis infections annually among people aged 15-49. These STIs have significant implications for the HIV epidemic due to epidemiologic synergy driven by biological and behavioral mechanisms. Key populations, including men who have sex with men (MSM) and transgender women (TGW) are particularly vulnerable as a result of sociocontextual barriers to care that include stigma, discrimination, and violence. With the highest prevalence of HIV in the Western Pacific region, population estimates of STI prevalence among MSM and TGW in Papua New Guinea (PNG) have yet to be realized. This study estimates the population prevalence of gonorrhea and chlamydia among MSM and TGW in Papua New Guinea and explores demographic, social, and behavioral factors associated with prevalence.
Methods: Response driven sampling was used to recruit participants for an integrated biobehavioral survey between June 2016 and December 2017. Logistic regression procedures were used to conduct multivariate analyses. Variables were selected for models based on associations with STI infections seen in the literature and significance in bivariate models.
Results: Controlling for all variables found to be significant in the bivariate analysis, age, education level, cut foreskin, and presence of an active syphilis infection were associated with gonorrhea and/or chlamydia prevalence among MSM and TGW in Port Moresby, PNG. In Lae, total number of male partners in the last six months and an active syphilis infection were positively associated with prevalence (Table 4.). Presence of an active syphilis infection was the strongest association across sites with an aOR of 3.9 (95% CI 2.6-5.7, $p<0.0001$) in Port Moresby and an aOR of 2.5 (95% CI 1.3-4.8, $p=0.0116$) in Lae.
Conclusion: Based on previous studies that syphilis, gonorrhea, and chlamydia coinfection are associated with increased incident HIV among MSM, the results here suggest these infections may play a critical role in PNG's HIV epidemic moving forward. Given the burden of HIV and STIs among MSM and TGW, there is a tangible need to address testing and treatment access, engagement, and programming issues among MSM and TGW.

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I. Introduction

There are an estimated 376 million new cases annually of one of the four curable sexually transmitted infections (STIs) among people ages 15-49 (World Health Organization [WHO], 2016). These bacterial infections include an estimated 87 million Neisseria gonorrhea infections, 127 million Chlamydia trachomatis infections, 6 million syphilis infections, and 156 million Trichomonas vaginalis infections, respectively (Rowley et al., 2018). The global burden of these four STIs disproportionately affects low and middle income countries with 78% of infections occurring in these regions as of 2012 (Newman et al., 2015). In addressing the epidemic, public health practitioners have an opportunity to not only minimize the harm caused by STIs in and of themselves, but to address larger themes in global health including issues of health equity.

The WHO's Global Health Sector Strategy on Sexually Transmitted Infections for 2016-2021 prioritizes the global STI response as a critical health sector contribution to achieving Goal 3 of the 2030 Sustainable Development Goals (SDG)—"To ensure healthy lives and promote well-being for all at all ages" (WHO, 2016). Additionally, the health sector response to the STI epidemic may function as a significant driver towards the achievement of universal health coverage, a key SDG health goal. Characterizing the STI epidemic, as well as understanding how STIs affect both individual and population health and contribute to other epidemics, plays a crucial role in achieving these goals.

Consequences of the STI epidemic

While short-term reductions in quality of life in the form of urogenital pain and discomfort are associated with gonorrhea, chlamydia, syphilis, and trichomoniasis infections, psychosocial consequences such as stigma mediated shame, anxiety, and disruption of

relationship status are an additional public health concern that may also serve as drivers of the epidemic (Scoular, 2001; Fortenberry, 2002; Gottlieb, 2011). Although curable with specified courses of antibiotics, long-term consequences of untreated infections range in severity dependent upon the pathogen.

Untreated chlamydia and gonorrhea are both strongly associated with pelvic inflammatory disease (PID) which may lead to scarring of the fallopian tubes and subsequent infertility in women (Haggerty & Ness, 2006). This is especially concerning considering that 70-95% of women, and as many as 90% of men, experience asymptomatic chlamydia infection and may go without treatment for long stretches of time (Korenromp, 2002; Farley, 2003). Epididymitis, an inflammation of the ducts located behind the testes involved in sperm maturation, transportation, and storage, may result from gonorrhea infection and lead to decreased fertility in men (Ndowa & Lusti-Narasimhan, 2012). Additional complications affecting both men and women include chlamydia-induced reactive arthritis (Carter & Inman, 2011) and a potentially life-threatening blood infection, disseminated gonococcal infection (DGI) (Holmes, Counts, & Beaty, 1971). Untreated syphilis, regardless of sex, may invade the nervous system (neurosyphilis) or eye, (ocular syphilis) with consequences including changes in behavior, difficulty with muscle coordination, paralysis, and dementia for neurosyphilis and permanent blindness as a result of ocular syphilis. In its most severe form, and resulting from untreated syphilis infections of 10-30 years in duration, tertiary syphilis can lead to multiple organ system damage including permanent conditions affecting the brain, heart, liver, and eye (Centers for Disease Control and Prevention [CDC], 2017).

Severe health outcomes associated with STIs is not limited to infected adults, the presence of active sexually transmitted infections also compromises infant and newborn health.

Newborns exposed to gonorrhea while passing through the birth canal of an untreated woman may suffer blindness, joint infection, or a life threatening blood infection (Thadepalli, Rambhatla, Maidman, Arce, & Davidson, 1976). Similarly, chlamydia infection in pregnant women is associated with pre-term delivery as well as conjunctivitis and pneumonia in infants and newborns (Rours et al., 2011). Premature birth and low birthweight are both associated with active trichomoniasis infection at the time of delivery (Cotch et al., 1997). Women infected with syphilis while pregnant are at a high risk for stillborn pregnancy and untreated congenital syphilis infections, a syphilis infection passed to a baby while still in the womb, may lead to delays in development, seizures, or death (CDC, 2017).

A relationship to the HIV epidemic

As evidenced above, the health consequences of the STI epidemic far surpass the immediate ramifications of infection with the STIs themselves. The most significant example, with respect to global health, is the epidemiologically synergistic relationship existing between sexually transmitted infections and HIV infection whereby infection with one alters the manifestations or transmission of the other (Wasserheit, 1992). This relationship has allowed for the two epidemics to become mutually reinforcing and for this reason should be considered in tandem.

When considering behavioral similarities between those at risk for STIs and those at risk for HIV, without a codom, sex with multiple partners, and sex with anonymous partners are some practices that link the two epidemics. In addition to these behavioral elements there are biological pathways that contribute to this relationship. Ulcerative STIs, such as syphilis, can increase the risk for infection with HIV due to disruptions of the mucosal membrane that allow the virus to be more easily transmitted from an HIV positive partner. Additionally, genital ulcers

may increase the presence and activation of cells susceptible to HIV, increasing the likelihood of infection (Mayer & Venkatesh, 2011). Among HIV positive individuals, HIV has been cultured from genital ulcers suggesting the possibility of an increased risk of transmissibility as well (Kreiss et al., 1989).

Non-ulcerative STIs, such as gonorrhea and chlamydia, increase the risk of HIV infection through disruption of the mucosal membrane, local inflammatory responses that recruit HIV target cells and cellular chemicals that upregulate HIV replication, and by increasing viral shedding of HIV in genital secretions such as semen or vaginal fluid (Moss, 1995). Studies among HIV positive men have shown that those co-infected with gonorrhea and HIV were three times more likely to have detectable levels of HIV in semen, and that HIV seminal plasma levels could be eight to ten times higher in those with concomitant gonorrhea infections than those who did not have gonorrhea. After treatment for gonorrhea, the percentage of men with detectable levels of virus and those with elevated levels of HIV in seminal plasma fell to similar levels of those not previously infected with gonorrhea (Cohen, 1997).

Key populations and HIV

Understanding the synergistic relationship between HIV and other STIs is particularly important considering that HIV disproportionately affects subsets of the population, known as key populations, and that these groups are also most affected by STIs. Key populations are defined as a subset of the population at a high risk for HIV "regardless of the epidemic type or local context" (WHO, 2016). They include men who have sex with men (MSM), sex workers, injection drug users (IDUs), transgender people, and people in prisons. People belonging to these groups are particularly vulnerable to HIV due to a high degree of social, legal, and structural challenges. Stigma, discrimination, poverty, violence, and laws criminalizing key population

behaviors impede the ability of people in these populations to access services. As a result, while generalized HIV epidemics may have stabilized or declined, HIV among key populations continues to rise. An additional consequence has been persistent gaps in service provisions and programming targeted towards key populations as the above issues also hinder population size estimation efforts (WHO, 2016).

MSM, transgender women, gonorrhea, syphilis and chlamydia

Based on current epidemiology, incidence of gonorrhea, chlamydia, and syphilis among MSM appear to be increasing. However, there is a lack of sufficient evidence to fully characterize the epidemic (Stenger et al., 2017). Evidence from the United States does suggest that MSM are particularly vulnerable to multidrug resistant strains of gonorrhea, an especially concerning finding given the relationship between this STI and HIV (Kirkcaldy et al., 2013). Similarly, evidence from high-income countries suggests significant increases of syphilis and chlamydia among this key population with MSM accounting for two thirds of primary and secondary syphilis cases diagnosed in the United States (Chesson, Sternberg, Leichliter, & Aral, 2010). While HIV incidence among transgender women (TGW) appears to be high, and syphilis infection associated with HIV infection among this population as it is within the MSM community (Solomon et al., 2014), rates of infection with bacterial STIs vary globally (CDC, 2017).

Outside of behavioral and social-network determinants, there is evidence to suggest that at least a portion of increases in gonorrhea and chlamydia incidence are “artefacts of enhanced screening” (Stenger et al., 2017). Enhanced screening refers to testing of other regions of the body, such as the throat or rectum, known to have localized and frequently asymptomatic infections of gonorrhea and chlamydia. Given the marked increases in syphilis among MSM and

TGW globally, it is likely that apparent increases in incidence is a combined effect of enhanced screening as well as actual increases in gonorrhea and chlamydia infections.

STIs among MSM and TGW in Papua New Guinea

To date, estimates of STI prevalence among key populations in Papua New Guinea have been limited to HIV and syphilis in male and TGW sex workers, most of whom sell sex to other men. Among male sex workers, HIV prevalence has been estimated to be 8.8% and syphilis prevalence 6.5%. Among TGW sex workers HIV prevalence is estimated to be 23.7% and syphilis prevalence 25% (Kelly et al., 2011). Pooled chlamydia prevalence estimates among men in Papua New Guinea vary between 20-30%, dependent upon whether data was obtained from community or clinic based settings, with pooled gonorrhea prevalence estimates from clinic based settings around 10% (Vallely et al., 2010). Estimates for gonorrhea and chlamydia specifically among MSM and TGW, as well as an analysis of factors contributing to gonorrhea and chlamydia prevalence, have not been reported.

Problem Statement

Currently, there is a paucity of knowledge of the extent to which the STI epidemic impacts key populations globally. The potentially severe health consequences, synergistic relationship between STIs and HIV, and the similarities in behavioral determinants exemplify the need to characterize the STI epidemic among key populations. MSM and TGW in Papua New Guinea face a variety of social, legal, and economic challenges including the criminalization of sexual relationships between men. As a result, incidence of HIV continues to increase in these populations despite decreases among the general population. Gonorrhea and chlamydia prevalence remains unknown as do the social, demographic, and behavioral factors associated

with these infections. In filling this knowledge gap a contextualized understanding of the STI epidemic in Papua New Guinea will be realized. Additionally, public health entities will better be able to address the health needs of MSM and TGW in Papua New Guinea through more appropriately tailored services and programming.

Purpose statement

Through conducting a secondary analysis of bio-behavioral survey data collected between June 2016 and December 2017 among MSM and TGW in Papua New Guinea, this project will endeavor to contextualize the gonorrhea and chlamydia epidemic and address the following questions:

Question 1: What is the prevalence of gonorrhea and chlamydia among MSM and TGW in Port Moresby, Lae, and Mt. Hagen, Papua New Guinea?

Question2: What are the demographic, social, and behavioral factors associated with having a positive gonorrhea or chlamydia test among MSM and TGW in Papua New Guinea?

Significance statement

As a result of socioeconomic and legal disenfranchisement, key populations have remained hard to reach using interventions designed for the general population. Through constructing data driven models and integrating the complex factors that make key populations particularly vulnerable to negative health outcomes, future education, prevention, and treatment efforts will be more thoughtful and effective.

As key populations are often hidden populations, funding streams are not commonly targeted towards nor sufficiently large enough to reasonably meet programmatic needs. Centering the experiences and qualities of these populations within the context of the HIV epidemic will also demonstrate the need for more focused funding into provisions of care and increased research. Additionally, while this study seeks to fill gaps in the existing literature, it is likely other blind-spots will be identified throughout its course. This will serve the purpose of identifying best practices as well as shortcomings in the research tools that may be utilized in projects to come.

Definition of terms

Coupon: An invitation to enrol in the study that a participant can give to people in their social network. Coupons allow study staff to determine which participant recruited each participant and are essential to network size calculations.

Homophily: The tendency for people to share social ties with others who exhibit similar behavioral, social, demographic characteristics.

Integrated bio-behavioral survey (IBBS): A survey tool with standardized indicators developed to survey HIV prevalence among populations most vulnerable to the HIV epidemic.

Key populations: A group of people including men who have sex with men, transgender women, injection drug users, people in prisons or other closed settings, and sex workers, who due to high-risk behaviors have increased vulnerability to the HIV epidemic.

Men who have sex with men (MSM): A male identified individual who was assigned male and has had oral or anal sex with another man or transgendered woman, irrespective of sexual identity.

Participants: Priority population members who have provided consent and completed the survey.

Peer-recruited participant: A participant that is recruited by a seed a member of the priority population.

Population estimate: An estimate of a characteristic of the study population that accounts for response driven sampling design.

Priority population: A group of individuals about whom researchers wish to make estimates.

Point of care testing (POC): Self-contained biological assays that can be used in the field and do not require the presence of an off-site laboratory.

Recruitment chain: The group of all participants linked to a specific seed. Recruitment chains are also called "recruitment trees."

Reimbursement: Money, goods, and/or services provided to participants for completing the main interview.

Response Driven Sampling (RDS): A sampling method that utilizes "snowball sampling" (where one participant refers people they know as potential future participants) and weighted mathematical models to account for issues of non-randomness within the sample.

Seed: A participant that is recruited by a researcher and meets all eligibility criteria with the exception of possessing a valid coupon.

Sexually transmitted infections (STI): A group of infections caused by bacteria, viruses, or parasites, where the primary route of transmission is through sexual contact with another person.

Transgender woman (TGW): An individual who was assigned male at, but identifies as a woman and has had oral or anal sex with men, irrespective of sexual identity.

II. Methodology

Introduction

Surveying key populations requires complex sampling designs and methods as conventional sampling frames either do not exist or are inadequate for use among these populations (WHO, CDC, United Nations Joint Programme on HIV/AIDS [UNAIDS], 2017). For this reason, response driven sampling (RDS) was used to recruit participants for the first integrated bio-behavioral survey (IBBS) conducted among MSM and TGW in Papua New Guinea. IBBSs are cross-sectional surveys that incorporate behavioral assessments with biomarker testing to generate population-level estimates particularly useful in estimating HIV burden and risk-factors among key populations. Between June 2016 and December 2017 an IBBS was conducted among MSM and TGW in Port Moresby, Lae, and Mt. Hagen, Papua New Guinea to assess the HIV epidemic and inform HIV/STI programmatic needs among these populations. A secondary data analysis to estimate gonorrhea and chlamydia prevalence among MSM and TGW as well as assess the demographic, social, and behavioral factors associated with prevalence was then performed.

Population and Sample

MSM and TGW residing in the capital district (Port Moresby) the Morobe Province (Lae), and the Western Highlands Province (Mt. Hagen) were the priority populations and locations for this secondary analysis. Study sites were determined during a stakeholder meeting

coordinated by the National AIDS Council Secretariat (NACS) and included members from the MSM and TGW communities, donors, and civil society. Agreement on study sites was achieved through an examination of regionally available epidemiologic data, knowledge of sexual networks within and around the MSM and TGW communities, understanding of risk behaviors, and capacity to achieve ideal sample size. Local areas determined to be safe and effective recruitment sites for MSM and TGW were identified through stakeholder consultations led by the Papua New Guinea Institute of Medical Research (IMR).

The population of focus for this analysis was chosen based on compelling evidence suggesting that MSM and TGW in Papua New Guinea are at a high-risk for HIV and STIs (Kelly-Hanku, Rawstorne, Kupul, & Worth, 2013). Additionally, recommendations from the midterm review of Papua New Guinea's national HIV strategy included strengthening the connection between HIV and STIs with particular attention devoted to detecting and treating asymptomatic STIs. The report also acknowledged a pressing need to scale up HIV and STI prevention, treatment, and access to services for key populations where the effect of the epidemic has yet to be fully contextualized (Godwin & the midterm review team, 2013).

Eligibility for inclusion in the overall study required that participants were born biologically male, were 12 years of age or older at the time of recruitment, engaged in oral or anal sex with a male in the previous 6 months, spoke English or Tok Pisin, and presented to the study site with a valid study coupon. Participants who lacked the ability to understand or provide informed consent, were a duplicate recruit, exhibited violent behavior during the interview process, were under the influence of alcohol or drugs during the interview, or presented to the study site without a valid study coupon were excluded from the study.

Research Design

Population size estimation was a central objective of the original study design and utilized both unique object multiplier and service multiplier methods. These two methods are collectively considered multiplier methods and are significant to the secondary analysis in that, in concert with the IBBS, they allowed for the weighted estimation of priority populations for which gonorrhea and chlamydia prevalence was estimated (Fearon, Chabata, Thompson, Cowan, & Hargreaves, 2017).

Response driven sampling (RDS) was an ideal recruitment strategy for IBBS participants as MSM and TGW face a high degree of stigma and risk legal prosecution in Papua New Guinea as a result of sexual behaviors. As such, reliance on time location sampling (TLS) of venues is problematic in that it may pose privacy concerns for key population members. Additionally, RDS has been previously utilized by the Papua New Guinea IMR to successfully recruit key populations.

RDS is a type of chain referral sampling method that utilizes a coupon based referral system where reimbursements are distributed to both the recruiting participant, the seed, and the participants recruited by a previous participant, the peer recruited participant. A cohort of MSM and TGW were identified via consultations with gatekeepers, key community members, service providers, and other key population focused organizations, to serve as potential seeds. Criteria for seeds included being well-connected amongst their respective social networks as well as representative of diverse sexual or gender identities, socioeconomic status, age, region of residence, ethnicity, marital status, HIV status, access to services, and profession. Seeds who wished to participate were asked to recruit up to three or four peers, depending on site location, by giving each a coupon to be presented to study staff at the time of the survey. Coupon

recipients who chose to participate in the IBBS were in-turn given three to four coupons at the time of their participation and asked to recruit potential participants within their social network. This referral and coupon process was repeated until sample size was achieved.

A key component of this sampling method is that it can mitigate biases that may be associated with chain referral methods, generating a final sample of participants that are independent of the initially recruited sample (Heckathorn, 1997).

Procedure

Following a brief eligibility assessment conducted by study staff, all participants were given a detailed description of study procedures including the interview process, STI testing, and follow-up. Eligible individuals who provided informed consent to participate in the study were tested for gonorrhea, chlamydia, and/or TB using point of care (POC) tests and administered the IBBS by a trained study staff. HIV pre-test counseling took place post-interview and prior to HIV, hepatitis B, and/or syphilis POC testing. While waiting to receive test results, participants received peer recruitment training, reimbursement, and an exit interview. Test results and HIV post-test counseling were provided prior to participants leaving the clinic. A second visit was also scheduled during which participants were interviewed about their recruitment efforts and provided secondary reimbursements dependent upon the number of participants they had recruited.

Biological samples included blood, urine, and rectal and vaginal swabs. All samples were self-collected with the exception of blood samples that were collected by a qualified health care worker. Participants who returned a positive test result for gonorrhea, chlamydia, or syphilis were treated on site with syphilis treatment administered by a qualified health care worker.

Participants who tested positive for HIV were referred into treatment services separate from the study site.

Instruments

Survey tools

The IBBS utilized in this study was developed with guidance from the bio-behavioral Survey Guidelines for Populations at Risk for HIV, generally known as the Blue Book. This tool was developed by the U.S. Centers for Disease Control and Prevention (CDC), Family Health International (FHI360), the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) to provide a standardized method for conducting IBBS whilst remaining adaptable to local context. Open data kit (ODK) is the open access data collection tool that was used to administer the IBBS. RDS Coupon Manager allowed study staff to track coupons, identify duplicate recruits, confirm that coupons correctly represented the recruit possessing the coupon, and to re-establish recruits who attended follow-up without a coupon.

STI testing materials

POC genital and rectal gonorrhea and chlamydia testing was conducted using the GeneXpert real-time polymerase chain reaction (PCR) platform (Cepheid, Sunnyvale, CA). This test has been validated to be as accurate as in-lab PCR tests and is recommended for use in settings where delays to treatment are a concern (Causer et al., 2014). HIV testing using venous blood was performed using two rapid POC tests in conjunction to determine HIV status—Alere Determine HIV-1/2 Ag/Ab Combo, (Abbott, Lake Bluff, Illinois) and Chembio HIV 1/2 Stat-Pak, (Chembio Diagnostic Systems Inc., Medford, NY). Although testing limitations have been reported with the Alere Ag/Ab Combo, it has been found to perform well in detecting established

HIV infections (Rosenberg et al., 2012). The Chembio HIV 1/2 Stat-Pak (Chembio Diagnostic Systems Inc., Medford, NY) has been found to perform well in the field with a high positive predictive value (Kagulire et al., 2011). If rapid HIV testing returned a positive result, CD4 and viral load testing were conducted using the Alere Pima CD4 test (Abbott, Lake Bluff, Illinois) and Xpert HIV-1 Viral Load (Cepheid, Sunnyvale, CA). Validation studies found both tests were easily conducted by a variety of medical personal, performed as well as in-lab testing, and were accurate and precise (Mtapuri-Zinyowera et al., 2010; Malagun et al., 2014).

Syphilis POC testing using venous blood was performed with the Chembio DPP Syphilis Screen & Confirm Assay (Chembio Diagnostics Systems Inc., Medford, NY) and the Alere Determine HBsAg lateral flow rapid test (Alere Inc., Waltham, MA, USA) was used for POC rapid hepatitis B (HBV) testing. The Chembio DPP Syphilis Screen & Confirm Assay has been identified as highly specific and able to effectively differentiate past infections from active infections, thereby minimizing overtreatment (Causer et al., 2015). The POC lateral flow rapid test used for the detection of HBV was recently found to have the highest pooled specificity and sensitivity of currently available HBsAG rapid tests (Chevaliez & Pawlotsky, 2018).

Data analysis

Data for this secondary analysis was obtained using RDS methods and required adjustment for homophily and social network size. This was accomplished through the use of Response Driven Sampling Analyst (RDS-A Version 7.0, www.respondentdrivensampling.org) and SAS (Version 9.4, Cary, NC). RDS-A is a statistical software package specifically developed for the analysis of RDS data and, subsequent to cleaning of data in SAS, was used to produce population point prevalence estimates and 95% confidence intervals for variables of interest. RDS-A was

also utilized to produce survey weights using Gile's Successive Sampling Estimator and a cluster variable reflective of seed generated recruitment chains.

Weighted data was imported into SAS and logistic survey procedures were used to conduct bivariate analyses of the relationship between independent variables of interest and the outcome of positive biomarker data for gonorrhea and/or chlamydia in Port Moresby, Lae, and Mt. Hagen. Given the epidemiologic link and close association between gonorrhea and chlamydia, the main outcome variable of interest in this analysis was a combined variable that reflected testing positive for gonorrhea and/or chlamydia.

An alpha level of 0.10 and a relative standard error (RSE) of <0.30 was selected as the maximum levels for entry of dependent variables into the final multivariate model for each study site. Adjusted odds ratios for the final models were reported using an alpha level of 0.05 as the cut-off for statistical significance. A multivariate analysis was not conducted for Mt. Hagen due to small sample size. Multicollinearity diagnostics conducted using correlation and regression procedures in SAS determined that dependent variables were non-collinear.

Data presented in the results section are RDS-adjusted population estimates unless otherwise noted. Wilson intervals for binomial proportions based on RDS-adjusted data were used to estimate uncertainty for population prevalence of STIs where indicated.

Ethical considerations

This analysis was determined to be exempt from review by the Emory Institutional Review Board as it is an analysis of secondary data and all data were de-identified prior to analysis (Appendix). Project approval was granted previously by Papua New Guinea Institute for Medical Research Institutional Review Board, the Papua New Guinea Medical Research

Advisory Committee, the National AIDS Council Secretariat Research Advisory Committee, and the Human Research Ethics Committee at University of New South Wales (Appendix). Although considered research, upon study protocol review by the the CDC human research protection procedures it was determined that CDC was not engaged in a manner requiring IRB approval (Appendix).

Limitations and delimitations

As a cross-sectional study, models generated through analysis of IBBS are limited to identifying associations that may inform future studies, programming, and prevention efforts--they are not sufficient to establish causal links between variables. Another limitation may be found within the survey design itself. While an objective of the IBBS was to aggregate biomarker data for a range of STIs to be used in epidemiologic models, the survey was designed to estimate HIV burden among MSM and TGW. Survey questions related to STIs were in service to this objective and therefore lacked a degree of specificity that could have been used to estimate more complex relationships between gonorrhea and chlamydia prevalence and internal and external contexts.

A concern among IBBS implementers has been the length of surveys and the subsequent time it takes for participants to complete the process. The IBBS totaled 187 questions, and although not all questions were asked to all participants, a substantial amount of time was needed to complete the survey. It is plausible this impacted the speed at which participants sought to move through the survey, resulting in intentionally skipped questions. There are several variables in the IBBS that could have provided relevant information, but due to small cell size, could not be included as part of the models.

Another limitation to this study is one inherent of all quantitative studies that seek to characterize complex public health issues. Although questions were designed to capture some sociodemographic determinants of gonorrhea and chlamydia prevalence, complex psychosocial elements that influence risk taking behaviors are not easily measured nor able to be captured through quantitative methods alone. Integration of qualitative methods provide a richer perspective of individual experiences and may allow for the identification of more subtle drivers of the STI epidemic.

III. Results

A total of 863 participants were recruited across three sites, Port Moresby (N=400), Lae (N=352), and Mt. Hagen (N=111), to take part in the integrated bio-behavioral survey. Population-level estimates for prevalence of chlamydia and/or gonorrhea ranged from 22.2% (19.2-27.2) to 26.5% (16.5-36.6) with the highest prevalence found in the Mt. Hagen, Western Highlands province (Table 1.). Population size estimation of MSM and TGW revealed that while TGW make up a small fraction of the population in Port Moresby, Lae, and Mt. Hagen respectively, this population experienced an elevated prevalence of gonorrhea and chlamydia. Multivariate analysis of data from Port Moresby and Lae confirmed a relationship between prevalence of gonorrhea and/or chlamydia infection among MSM and TGW collectively and the presence of an active syphilis infection (Table 4.). Several relationships with well-established sociodemographic and behavioral characteristics were seen in this analysis, but were not found to be statistically significant. Examples of this include a positive association with experiencing an STI symptom in the last twelve months and having a concomitant HIV infection (Table 4.).

Demographics

The age distribution of MSM and TGW in Port Moresby and Lae are quite similar with just over 50% of the MSM and TGW population falling between the ages of 20-29 (Table 1.). The median age in Mt. Hagen was slightly lower, 21 (IQR 19-25), with over 70% of the MSM and TGW population below the age of 25. The majority of the MSM and TGW population across all sites have at least a primary-level education with an estimated 40% having received a high school-level education or higher in Port Moresby and Lae. 60% of MSM and TGW in Mt. Hagen have received a high school-level education or higher (Table 1.). Monthly income levels were similar across Port Moresby and Lae, with Mt. Hagen showing a slightly larger percentage of the population making more than 1,000 Kina per month. 62.4% (56.1–68.8) to 77.9% (68.0–87.9) of MSM and TGW have never been married and three in five across all sights have not disclosed their MSM and TGW status to friends or family (Table 1.). MSM and TGW experienced a high degree of violence, including sexual violence, during their lifetime with three in five experiencing such incidences in Port Moresby and Mt. Hagen and four in five experiencing violence in Lae. An overwhelming majority experienced such episodes of violence in the past twelve months (Table 1.).

Sexual behaviors

Upwards of 80% of MSM and TGW across all sites have had vaginal or anal sex with a woman in the last six months and a majority have had sex with one to two male partners in the same time period (Table 2.). A majority of the population were between the ages of fifteen and nineteen when they first had anal sex. The use of mobile applications to find sex partners was not widely reported in Port Moresby and Lae, but at 42.6% (33.2-52.0), use of this technology in Mt. Hagen was two times that of either site (Table 2.). A sizeable proportion of MSM and

TGW have engaged in transactional sex in the last six months including half of this population in Port Moresby, 42.2% in Lae, and 35.9% in Mt. Hagen.

STI prevalence

STI prevalence, excluding HIV, ranged from about 30% (25.6-37.2) in Port Moresby to just below 40% (33.6-45.4) in Lae and Mt. Hagen, and between 13% to 14% of all MSM and TGW across all sites tested positive for more than one infection (Table 3.). Syphilis prevalence varied by site with Lae reporting both the highest percentage of active syphilis, 8.2% (4.9-11.6), and the highest lifetime prevalence of syphilis at 21.2% (16.1-26.3)—over double that of the other sites (Table 3.). HIV prevalence was highest in Port Moresby, with the lowest prevalence found to be in Mt. Hagen (Table 3.).

Among MSM and TGW in the capital district of Port Moresby, population prevalence of gonorrhea and/or chlamydia was estimated at 22.2% (19.2-27.2). Of those who tested positive for gonorrhea and/or chlamydia, 37.6% (24.6-50.9) experienced coinfection with both gonorrhea and chlamydia. In Lae, estimates were similar with a cumulative gonorrhea and/or chlamydia prevalence of 23.9% (18.6-29.2) estimated among MSM and TGW. Population estimates for gonorrhea and chlamydia coinfection in Lae were 19.2% (9.7-28.4), slightly lower than the Port Moresby estimate and Mt. Hagen estimate of 27.9% (22.8-33.6). Mt Hagen had the highest population prevalence of gonorrhea and/or chlamydia infection of 26.5% (16.5-36.6). At 20%, chlamydia prevalence was twice that of gonorrhea prevalence across all sites.

Results from the multivariate analysis

Controlling for all variables found to be significant in the bivariate analysis, age, education level, having cut foreskin, and presence of an active syphilis infection were associated

with gonorrhea and/or chlamydia prevalence among MSM and TGW in Port Moresby (Table 4.). Although increased age was associated with increased gonorrhea and/or chlamydia prevalence across all age categories, the odds decreased as age increased with the exception of an increase among those aged 35 or older. However, it should be noted that in this category the relative standard error is well above 0.30 indicating some instability in the estimate. The odds of gonorrhea and/or chlamydia prevalence among individuals aged 20-24 was 8.9 (95% CI 6.1-13.0, $p<0.0001$) times that of individuals aged 12-19 and dropped to 4.9 (95% CI 2.8-8.5) for individuals aged 25-29 and 2.3 (95% CI 1.3-4.1) for those aged 30-34. Having a primary-level education as well as having cut foreskin were associated with decreased gonorrhea and/or chlamydia prevalence, aOR=0.4 (95% CI 0.3-0.6, $p<0.0001$) and aOR=0.6 (95% CI 0.4-0.9, $p=0.0184$). Having an active syphilis infection was associated with an increase in prevalence, aOR=3.9 (95% CI 2.6-5.7, $p<0.0001$). Although testing positive for HIV was significantly associated with increased prevalence in the bivariate model, the adjusted model produced a statistically insignificant aOR of 2.7 (95% CI 0.5-23.9, $p=0.3660$). No other sexually transmitted infections had statistically significant associations with increased gonorrhea and/or chlamydia prevalence.

In Lae, total number of male partners in the last six months and an active syphilis infection were positively associated with gonorrhea and/or chlamydia prevalence. Adjusted prevalence odds among those having three to four partners in the last six months was 1.9 (95% CI 1.2-3.1, $p<0.0001$) times the odds of those who had one to two partners in the last six months. Having an active syphilis infection was associated with gonorrhea and/or chlamydia prevalence 2.5 (95% CI 1.3-4.8, $p=0.0116$) times that of those without an active syphilis

infection. As in Port Moresby, prevalence and having a positive HIV diagnosis was found to have a positive, yet statistically insignificant association, aOR=1.7 (95%CI 0.9-3.3, p=0.1055).

IV. Discussion

Population-level estimates for gonorrhea and chlamydia prevalence among MSM and TGW are similar to pooled prevalence values previously estimated when we consider the two STIs separately (Vallely et al., 2010). However, when combined gonorrhea and/or chlamydia prevalence is separated by gender identity we see that these STIs disproportionately affect TGW with 42.4% (95% CI 26.0-56.7) estimated prevalence in Port Moresby, 53.9% (95% CI 26.4-81.4) prevalence estimated in Lae, and 38.7% (95% CI 0.0-85.6) estimated in Mt. Hagen. While the multivariate analysis showed no significant relationship between gonorrhea and/or chlamydia prevalence and current gender identity, a positive bivariate association for TGW was seen in Port Moresby, as well as in Lae, and insignificance may be attributable to small sample size (Table 4.). Given the high degree of stigma and challenges in accessing competent care faced by TGW (Castillo et al., 2015; Bayrer et al., 2010), these somewhat unstable prevalence estimates may be an indicator that the gonorrhea and chlamydia burden, much like that of HIV, is high in this insufficiently studied population. Additionally, this may hint at the sociocontextual factors affecting TGW differently than MSM, despite studies routinely evaluating the two populations together. A meta-analysis and systematic review of the global burden of HIV in transgender women (Baral et al, 2013) suggests that social network-level factors and high-risk behaviors, such as receptive anal sex without a condom, do not sufficiently explain the high acquisition risk that face this group in particular. Instead, the authors implicate

a high degree of stigma, discrimination, violence, and a lack of competency within healthcare systems as potential drivers.

Data analysis in both Port Moresby and Lae revealed a strong association between active syphilis infection and gonorrhea and/or chlamydia prevalence. Syphilis prevalence at both sites was estimated to be 4.0% (95% CI 1.7-6.4) in Port Moresby and 8.2% (95% CI 4.9-11.6) in Lae. Syphilis incidence in high-income countries has been increasing among MSM and is a significant predictor of HIV risk (Pathela, Braunstein, Blank, Shepard, & Schillinger, 2015). Global prevalence of this infection has been reported as 5-10% (WHO, 2016) with low-to-middle income countries reporting the highest prevalence of syphilis globally (Newman et al., 2015). Prevalence estimates from this study appear to reflect this current trend and highlights the role that social networks play in STI transmission, where high prevalence of an STI in a given network may also increase the likelihood of exposure to other infections within that same network (Pathela et al., 2015).

The most concerning outcome of this relationship is the ability for gonorrhea, chlamydia, and syphilis coinfections to increase the likelihood of HIV infection. The complimentary role syphilis plays in the MSM HIV epidemic, both biologically and behaviorally, is well documented (CDC, 2018; Advisory Committee for STD and HIV Prevention [ACHSP], 1998). However, MSM with subsequent or concurrent infections with gonorrhea and/or chlamydia have been found to have as much as a two-fold increased risk of incident HIV than those with only an active syphilis infection (Pathela et al., 2015). Given the often asymptomatic nature of syphilis, gonorrhea, and chlamydia infections, as well as Papua New Guinea's frequent use of syndromic management for STIs (A. Vallely, et al. 2010; L. Vallely, et al., 2016), there is potential for a missed opportunity to curb the HIV and other STI epidemics. Syndromic management of STIs is

a method that is particularly useful in settings where expensive assays are not available and/or treatment delays are prevalent. It involves determination of treatment based on commonly associated symptoms, but does not perform well when infections are asymptomatic. It is important to note that in this study having experienced STI symptoms in the last twelve months produced no significant association with gonorrhea and/or chlamydia prevalence, aOR=1.9 (95% CI 0.9-3.9, p=0.0890) in Port Moresby and aOR=1.6 (95% CI 1.0-2.6, p=0.0699), despite being previously associated with prevalence in the literature (Benn et al., 2006). Awareness of STI symptoms, both what symptoms STIs may cause and the ability to recognize the presence or absence of symptoms, may influence care-seeking behavior. As such, asymptomatic infections combined with stigma and marginalization experienced by MSM and TGW may lead to delays in testing and treatment.

Although having vaginal and/or anal sex with a woman in the last six months was not significantly associated with gonorrhea and/or chlamydia infection in the bivariate analysis, given the sizeable estimates of female sex partners within the last six months it is important to discuss the potential for MSM and TGW communities to serve as bridge populations with non-key population female partners. Maternal syphilis in Papua New Guinea is one of the highest globally (Vallely et al., 2016) and chlamydia prevalence among women remains elevated. Syndromic management in Papua New Guinea has been found to be poor performing among women especially and may encourage persistent infections that cause infertility or serious complications during a pregnancy. Infections have been significantly linked to male partner risk factors which may suggest that effectively addressing prevalence among key populations may have an unforeseen impact of mitigating prevalence among the general population including neo-natal infections (Wangnapi et al., 2015).

Limitations of findings

Foreskin cutting has previously been associated with a reduction in syphilis and HIV prevalence in Papua New Guinea if cutting took place prior to sexual debut and was a full dorsal longitudinal cut (Vallely et al., 2017). Having cut foreskin had a significant negative association with gonorrhea and/or chlamydia prevalence in Port Moresby, but this association was not significant in Lae. The nature of the IBBS question regarding cut foreskin did not allow for specification of type of cutting and therefore, despite recognition that this was a significant characteristic supported by the literature and possesses biological plausibility, this finding should be regarded with caution.

An important limitation to note was a lack of reliability of two risk indicator variables that were unable to be incorporated into the models. Condom use and sexual positioning although identified as risk factors associated with HIV and other STIs by proxy (Pathela,, Jamison, Braunstein, & Schillinger, 2017), was not able to be adequately evaluated due to small cell sizes.

Similarly, small sample size in Mt. Hagen necessitated site exclusion from multivariate analysis. While Port Moresby and Lae had similar sociodemographic and behavioral characteristics among participants, Mt. Hagen revealed that some key difference, such as higher income, a younger population, and an increased use of mobile technology to meet potential partners (Table 1, Table 2). Mobile application use for finding sexual partners, in particular, has been significantly associated with an increase in STIs including positive associations with gonorrhea, chlamydia, and syphilis in high-income countries (Allen, Mansergh, Mimiaga, Holman, & Herbst, 2017). Having an adequate sample size to explore these differences in

demographics relative to prevalence would have added additional dimensions to this study, and allowed us to compare emerging trends across sites.

V. Recommendations

Criminalization and stigmatization of MSM and TGW have limited research efforts in low and middle income countries, leaving a paucity of literature on the global health status of these populations and hindering appropriately targeted funding (Beyrer et al., 2010). While Papua New Guinea is making a substantial effort to address the HIV and STI epidemic among key populations, decriminalization of the sexual practices of MSM and TGW community members is a key step to improving access and engagement to care, dispelling stigma, and ultimately combating the HIV and STI epidemic.

As the standard of care shifts towards point of care testing as the predominant diagnostic model for STIs, it is imperative that resources be diverted towards building such access in low-to-middle income countries such as Papua New Guinea. While syndromic management minimizes treatment delays, it is also missing substantial portions of the population with asymptomatic infections. Extragenital infections, such as pharyngeal or rectal gonorrhea and chlamydia, are frequently asymptomatic and have been increasing in key populations (Reno, Brethauer, Spear, Knaup, & Stoner, 2013). Rapid POC testing would allow for the identification and treatment of such infections and help to minimize the spread of infections by individuals unaware of their STI status.

As a result of social, behavioral and biological risk factors for HIV and STIs common to both TGW and MSM, TGW are generally aggregated with MSM in research cohorts. This has

had the effect of both highlighting and perpetuating underrepresentation of this key population in both literature and programming. TGW sample sizes in this study were too small to draw meaningful conclusions about associations between gonorrhea and/or chlamydia prevalence and known risk factors. Further research should focus on additional methods that may aid in reaching this hidden population. The experience of TGW and the subsequent sociocontextual barriers to care they face will not be well understood until sufficient funding streams are allotted to this end.

As a region previously documented as undergoing a "resource boom" and subject to the changes in economic drivers known to fuel the HIV epidemic (Godwin et al., 2013), future research into key populations in the Mt. Hagen region should be undertaken. Unique population characteristics, as well as the high gonorrhea and chlamydia prevalence, differentiate this region from both Port Moresby and Lae, and may reveal as yet known associations between STIs and the emerging HIV epidemic not able to be assessed in this study.

VI. Conclusion

The national HIV prevalence for Papua New Guinea is estimated to be 0.9% among individuals between the ages of 15-49 with a total of 45,795 individuals living with HIV/AIDS (UNAIDS, 2016). Papua New Guinea remains the country with the highest prevalence of HIV in the Western Pacific region as well as the country with the highest estimated incidence of gonorrhea, chlamydia, and syphilis. With 40-50% of all new cases of HIV globally occurring among key populations and their partners (UNAIDS, 2016) the HIV epidemic cannot be adequately addressed without addressing the STI epidemic and the specific needs and challenges of key populations.

The tools, technologies, and resources to identify and mitigate the STI and HIV epidemic and achieve global health targets such as the SDGs and the UN 90-90-90 exist, but are not readily available to all populations. Point of care tests regularly utilized in high-income countries remain inaccessible on a large scale in low-to-middle income countries such as Papua New Guinea. Although financial feasibility is a significant barrier, social and structural barriers are equally as challenging. As an example, anti-retroviral therapy (ART) for the treatment of HIV is free and available across Papua New Guinea, but shortcomings in the effective engagement of key populations obscures resource access.

Achievement of global health goals relies on the successful engagement of these populations and necessitates the maximizing of resource availability and access. This will require rapid, yet focused scale-up of interventions that address the health needs of key populations as well as investment in research and programming that centers their experiences.

Disclaimer and a note to collaborators and funders

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References

Advisory committee for HIV and STD prevention. (1998). HIV prevention through early detection and treatment of other sexually transmitted diseases–United States. Recommendations of the Advisory Committee for HIV and STD prevention. *Morbidity and Mortality Weekly Report*. 47(RR-12), 1-24. Retrieved from: https://www.cdc.gov

Baral, S.D., Poteat, T., Strömdahl, S., Wirtz, A.L., Guadamuz, E., & Beyrer, C. (2013). Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. *The Lancet Infectious Diseases,* 13(3), 214-222. https://doi.org/10.1016/S1473-3099(12)70315-8

Benn, P. D., Rooney, G., Carder, C., Brown, M., Stevenson, S. R., Copas, A., … Ridgway, G. L. (2006). Chlamydia trachomatis and neisseria gonorrhoeae infection and the sexual behaviour of men who have sex with men. *Sexually transmitted infections,* 83(2), 106–112. doi:10.1136/sti.2006.021329

Beyrer, C., Baral, S.D., Walker, D., Wirtz, A.L., Johns, B., & Sifakis, F. (2010) The expanding epidemics of HIV type 1 among men who have sex with men in low- and middle-income countries: Diversity and consistency. *Epidemiologic Reviews*, 32(1), 137–151. https://doi-org.proxy.library.emory.edu/10.1093/epirev/mxq011

Carter, J.D. & Inman, R.D. (2011). Chlamydia-induced reactive arthritis: Hidden in plain sight? *Best practice & research Clinical rheumatology*, 25(3), 359-374. https://doi.org/10.1016/j.berh.2011.05.001

Castillo, R., Konda, K.A., Leon, S.R., Silva-Santisteban, A., Salazar, X., Klausner, J.D., Coates, T.J. & Cáceres, C.F. (2015). HIV and sexually transmitted infection incidence and associated risk factors among high-risk MSM and male-to-female transgender women in Lima, Peru. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, 69(5), 567–575. doi: 10.1097/QAI.0000000000000667.

Causer, L. M., Hengel, B., Natoli, L., Tangey, A., Badman, S.G., Tabrizi, S.N., . . .Guy, R.J. (2014) A field evaluation of a new molecular-based point-of-care test for chlamydia and gonorrhoea in remote Aboriginal health services in Australia. *Sexual Health,* 12(1), 27-33. https://doi.org/10.1071/SH141

Causer, L.M., Kaldor, J. M., Conway, D.P., Leslie, D.E., Denham, I., Karapanagiotidis, T., . . .Guy, R.J. (2015). An evaluation of a novel dual treponemal/nontreponemal point-of-care test for syphilis as a tool to distinguish active from past treated infection. *Clinical Infectious Diseases,* 61(2), 184-191. doi: 10.1093/cid/civ243.

Centers for Disease Control and Prevention. (2018). Sexually Transmitted Disease Surveillance, 2017. Atlanta, GA: Department of Health and Human Services. Retrieved from: https://www.cdc.gov

Centers for Disease Control and Prevention. (2017). Syphilis. Retrieved from: https://www.cdc.gov/std/syphilis/stdfact-syphilis-detailed.htm

Chesson, H.W., Sternberg, M., Leichliter, J.S, & Aral, S.O. (2010). Changes in the state-level distribution of primary and secondary syphilis in the USA, 1985-2007. *Sex Transmitted Infections,* 86(Suppl 3), iii58–62.

Chevaliez, S. & Pawlotsky, J.M. (2017). New virological tools for screening, diagnosis, and monitoring of hepatitis B and C in resource-limited settings. *Journal of Hepatology.* 69(4), 916-926. https://doi.org/10.1016/j.jhep.2018.05.017

Cohen, M.S., Hoffman, I.F., Royce, R.A., Kazembe, P., Dyer, J.R., Daly, C.C., . . .Eron, J.J. (1997). Reduction of concentration of HIV-1 in semen after treatment of urethritis: implications for prevention of sexual transmission of HIV-1. *Lancet,* 349(9069), 1868–1873. https://doi.org/10.1016/S0140-6736(97)02190-9

Cotch, M.F., Pastorek, J.G., Nugent, R.P., Hillier, S.L., Gibbs, R.S., Martin, D.H., . . . Eschenbach, D.A. (1997). Trichomonas vaginalis associated with low birth weight and preterm delivery. *Sexually Transmitted Diseases,* 24(6), 353–360. Retrieved from: https://oce-ovid-com.proxy.library.emory.edu/journals/stds/199707000

Emory Institutional Review Board. (2019). Does my project need IRB review? Retrieved from Emory IRB website: http://www.irb.emory.edu/forms/review/index.html

Farley, T.A., Cohen, D.A., & Elkins, W. (2003). Asymptomatic sexually transmitted diseases: The case for screening. *Preventive Medicine,* 36(4), 502-509. https://doi.org/10.1016/S0091-7435(02)00058-0

Fearon, E., Chabata, S. T., Thompson, J. A., Cowan, F. M., & Hargreaves, J. R. (2017). Sample size calculations for population size estimation studies using multiplier methods with respondent-driven sampling Surveys. *JMIR Public Health and Surveillance,* 3(3), e59. doi:10.2196/publichealth.7909

Fortenberry, J.D., McFarlane, M., Bleakley, A., Bull, S., Fishbein, M., Grimley, D.M., Malotte, C.K., & Stoner, B.P. (2002). Relationships of stigma and shame to gonorrhea and HIV screening. *American Journal of Public Health,* 92(3), 378-381. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/journals/258/

Godwin, P., & the midterm review team. (2013). Midterm review of Papua New Guinea HIV strategy (2011-2015). Retrieved from FHI360 website: https://www.fhi360.org

Gottlieb, S.L., Stoner, B.P., Zaidi, A. A., Buckel, C., Tran, M., Leichliter, J.S., Berman, S. M., & Markowitz, LE. (2011). A prospective study of the psychosocial impacy of a positive chlamydia trachomatis laboratory test. *Sexually Transmitted Diseases,* 38(11), 1004-1011. doi:10.1097/OLQ.0b013e31822b0bed

Haggerty, C.L. & Ness, R.B. (2006). Epidemiology, pathogenesis and treatment of pelvic inflammatory disease. *Expert review of anti-infective therapy,* 4(2), 235-247. https://doi.org/10.1586/14787210.4.2.235

Heckathorn, D.D. (1997). Respondent-driven sampling: A new approach to the study of hidden populations. *Social Problems,* 44(2), 174–199. https://doi.org/10.2307/3096941

Holmes, K.K., Counts G.W., & Beaty, H.N. (1971). Disseminated gonococcal infection. *Annals of Internal Medicine,* 74(6), 979-993. doi**:** 10.7326/0003-4819-74-6-979

Kagulire, S.C., Opendi, P., Stamper, P.D., Nakavuma, J.L., Mills, L.A., Makumbi, F., … Reynolds, S.J. (2011). Field evaluation of five rapid diagnostic tests for screening of HIV-1 infections in rural Rakai, Uganda. *International Journal of STD & AIDS,* 22(6), 308–309. https://doi.org/10.1258/ijsa.2009.009352

Kelly, A., Kupul, M., Man, W.Y.N., Nosi, S., Lote, N., Rawstorne, P., . . . & Worth, H. (2011) Askim na save (Ask and understand): People who sell and/or exchange sex in Port Moresby. Key Quantitative Findings. Papua New Guinea Institute of Medical Research and the University of New South Wales: Sydney, Australia. Retrieved from: https://aidsdatahub.org

Kelly-Hanku, A., Rawstorne, P., Kupul, M., & Worth, H. (2013). Anal sex, vaginal sex and HIV risk among female sex workers in Papua New Guinea. *AIDS and Behavior,* 18(3), 573-582. doi: 10.1007/s10461-013-0624-8

Kirkcaldy, R.D., Zaidi, A., Hook, E.W., Holmes, K.K., Soge, O., del Rio, C., . . .Weinstock, H.S. (2013). Neisseria gonorrhoeae antimicrobial resistance among men who have sex with men and men who have sex Exclusively with women: The gonococcal isolate surveillance project, 2005–2010. *Annals of Internal Medicine*, 158(5 Pt 1), 321–328. doi: 10.7326/0003-4819-158-5-201303050-00004

Korenromp, E.L., Sudaryo, M.K., de Vlas, S.J., Gray, R.H., Sewankambo, N.K., Serwadda, D., Wawer, M.J., & Habbema, J.D. (2002). What proportion of episodes of gonorrhoea and chlamydia becomes symptomatic? *International journal of STD & AIDS*, 13(2), 91-101. doi:10.1258/0956462021924712

Kreiss, J., Coombs, R., Plummer, F., Holmes, K., Nikora, B., Cameron, W., . . . Corey, L. (1989). Isolation of Human Immunodeficiency Virus from Genital Ulcers in Nairobi Prostitutes. *The Journal of Infectious Diseases,* 160(3), 380-384. Retrieved from http://www.jstor.org.proxy.library.emory.edu/stable/30123203

Malagun, M., Nano, G., Chevallier, C., Opina, R., Sawiya, G., Kivavia, K., . . . Kalinoe, A. (2014). Multisite evaluation of Point of Care CD4 Testing in Papua New Guinea. *PLoS One,* 9(11), e112173. https://doi.org/10.1371/journal.pone.0112173

Mayer, K.H. & Venkatesh, K.K. (2011). Interactions of HIV, other sexually transmitted diseases, and genital tract inflammation facilitating local pathogen transmission and acquisition. *American Journal of Reproductive Immunology,* 65(3), 308–316. doi: 10.1111/j.1600-0897.2010.00942.x

Moss, G.B., Overbaugh, J., Welch, M., Reilly, M., Bwayo, J., Plummer, F.A., . . . Kreiss, J.K. (1995). Human immunodeficiency virus DNA in urethral secretions in men: association with gonococcal urethritis and CD4 cell depletion. *Journal of Infectious Disease,* 172(6), 1469–1474. Retrieved from: https://www.jstor.org/stable/i30134647?refreqid=excelsior%3A67fcc82e459da4e9f59a7bf405d89715

Mtapuri-Zinyowera, S., Chideme, M., Mangwanya, D., Mugurungi, O., Gudukeya, S., Hatzold K., . . .Peter,T. (2010) Evaluation of the PIMA Point-of-Care CD4 Analyzer in VCT Clinics in Zimbabwe. *Journal of Acquired Immunodeficiency Syndrome*, 55(1):1-7. doi: 10.1097/QAI.0b013e3181e93071.

Ndowa, F. & Lusti-Narasimhan, M. (2012). The threat of untreatable gonorrhea: implications and consequences for reproductive and sexual morbidity. *Reproductive Health Matters,* 20(40), 76-82. doi:10.1016/S0968-8080(12)40653-X

Newman, L., Rowley, J., Vander Hoorn, S., Wijesooriya, N.S., Unemo, M., Low, N., Stevens, G., Gottlieb,S., Kiarie, J., & Temmerman, M. (2015). Global estimates of the prevalence and incidence of four curable sexually transmitted infections in 2012 based on systematic review and global reporting. *PLoS One.* 10(12): e0143304. https://doi.org/10.1371/journal.pone.0143304

Pathela, P., Braunstein, S.L., Blank, S., Shepard, C., & Schillinger, J.A. (2015). The high risk of an HIV diagnosis following a diagnosis of syphilis: A population-level analysis of New York City men. *Clinical Infectious Diseases,* 61(2), 281–287. https://doi-org.proxy.library.emory.edu/10.1093/cid/civ289

Pathela, P., Jamison, K., Braunstein, S, & Schillinger, J. (2017) Lb3.261 Trends in condom use and sexual positioning among men-who-have-sex-with-men in the era of HIV pre-exposure prophylaxis, and risk for diagnoses of incident HIV and other sexually transmitted infections – New York City, 2011–2015. *Sexually Transmitted Infections,* 93(suppl 2), A191. http://dx.doi.org.proxy.library.emory.edu/10.1136/sextrans-2017-053264.496

Reno, H.E.L., Brethauer, C., Spear, D., Knaup, R., & Stoner, B.P. (2013). P3.069 Enhanced oropharyngeal and rectal testing for neisseria gonorrhoeae and chlamydia trachomatis at a public

STI clinic. *Sex Transmitted Infections,* 89**(**suppl 1)**,** A169. doi:10.1136/sextrans-2013-051184.0529

Rosenberg, N.E., Kamanga, G., Phiri, S., Nsona, D., Pettifor, A., Rutstein, S.E., . . . Miller, W.C. (2012). Detection of acute HIV infection: A field evaluation of the determine® HIV-1/2 Ag/Ab combo test. *The Journal of Infectious Diseases,* 205(4), 528-534, https://doi.org/10.1093/infdis/jir789

Rours, G.I., Duijts, L., Moll, H.A., de Groot, R., Jaddoe, V.W., Hofman, A.,…Verbrugh, H.A. (2011). Chlamydia trachomatis infection during pregnancy associated with preterm delivery: A population-based prospective cohort study. *European Journal of Epidemiology*, 26(6), 493-502. doi: 10.1007/s10654-011-9586-1

Rowley, J., Vander Hoorn, S., Korenromp, E., Low, N., Unemo, M., & Abu-Raddad, LJ. (2018). *Global and regional estimates of the prevalence and incidence of four curable sexually transmitted infections in 2016.* Geneva, World Health Organization. Retrieved from https://www.who.int/reproductivehealth/publications/stis-surveillance-2018/en/

Scoular, A., Duncan, B., & Hart, G. (2001). "That sort of place …where filthy men go …": a qualitative study of women's perceptions of genitourinary medicine services. *Sexually Transmitted Infections,* **77**(5)**,** 340-343. doi:10.1136/sti.77.5.340

Solomon, M.M., Mayer, K.H., Glidden, D.V., Liu, A.Y., McMahan, V.M., Guanira, J.V., . . . Grant, R.M. (2014). Syphilis predicts HIV incidence among men and transgender women who have sex with men in a preexposure prophylaxis trial. *Clinical Infectious Diseases*, 59(7), 1020–1026. https://doi.org/10.1093/cid/ciu450

Stenger, M. R., Baral, S., Stahlman, S., Wohlfeiler, D., Barton, J. E., & Peterman, T. (2017). As through a glass, darkly: the future of sexually transmissible infections among gay, bisexual and other men who have sex with men. *Sexual Health*, 14(1), 18–27. doi:10.1071/SH16104

Thadepalli, H., Rambhatla, K., Maidman, J., Arce, J.J., & Davidson, E.C. Jr. Gonococcal sepsis secondary to fetal monitoring. *American Journal of Obstetrics and Gynecologyl*, 126(4), 510–512. doi: https://doi.org/10.1016/0002-9378(76)90650-5

United Nations Joint Programme on HIV/AIDS. (2016). Country progress report—Papua New Guinea: Global AIDS monitoring 2016. Retrieved from: www.unaids.org

Vallely, A., MacLaren, D., David, M. , Toliman, P. , Kelly-Hanku, A. , Toto, B., . . . Kaldor, J. M. (2017). Dorsal longitudinal foreskin cut is associated with reduced risk of HIV, syphilis and genital herpes in men: a cross-sectional study in Papua New Guinea. *Journal of the International AIDS Society*, 20(1), 21358. doi:10.7448/IAS.20.01/21358

Vallely, A., Page, A., Dias, S., Siba, P., Lupiwa, T., Wilson, D.P., . . . Kaldo, J.M. (2010). The prevalence of sexually transmitted infections in Papua New Guinea: A systematic review and meta-analysis. *PLoS One*, 5(12), e15586. doi:10.1371/journal.pone.0015586

Table 1. Characteristics of men who have sex with men (MSM) and transgender women (TGW) in Port Moresby, Lae, and Mt Hagen, Papua New Guinea.

	PORT MORESBY				LAE				MOUNT HAGEN			
	Valid	Sample proportion (unweighted)	Population proportion (weighted)	Chlamydia /Gonorrhea Prevalence (weighted)	Valid	Sample proportion (unweighted)	Population proportion (weighted)	Chlamydia /Gonorrhea Prevalence (weighted)	Valid	Sample proportion (unweighted)	Population proportion (weighted)	Chlamydia /Gonorrhea Prevalence (weighted)
	N=400	%	% (95% CI)	%	N=352	%	% (95% CI)	%	N=111	%	% (95% CI)	%
Gender identity	400				352				111			
Male	354	88.5	89.3 (84.2-94.5)	19.9 (10.2-29.5)	325	92.6	93.8 (89.9-97.7)	21.4 (15.6-27.2)	104	93.7	94.3 (90.1–98.5)	25.8 (17.0-35.6)
TG	46	11.5	10.7 (5.5-15.8)	42.4 (26.0-56.7)	26	7.4	6.2 (2.3-10.1)	53.9 (26.4-81.4)	7	6.3	5.7 (1.5 – 9.9)	38.7 (0.0-85.6)
Age (years)	400				345				111			
Sample Median (IQR)			27 (23 – 33)				25 (22 – 30)				21 (19 – 25)	
12-19	36	9.0	11.4 (7.0–15.7)	6.8 (5.8-7.8)	45	13.0	14.2 (9.5 – 18.9)	18.3 (10.7-25.8)	32	28.8	24.3 (14.5–34.1)	37.2 (8.7-65.6)
20-24	107	26.8	26.3 (21.0–31.7)	34.0 (5.2-62.8)	107	31.0	32.1 (26.0–38.1)	29.1 (12.6-45.6)	51	46.0	48.1 (36.5– 59.7)	27.6 (18.7-36.5)
25-29	113	28.2	26.4 (21.0–31.7)	23.7 (9.4-37.9)	90	26.1	26.0 (20.5–31.4)	18.3 (6.7-30.0)	11	9.9	11.6 (4.9–18.3)	31.6 (16.4-46.8)
30-34	63	15.8	17.0 (12.2–21.8)	13.1 (5.5-20.8)	54	15.7	13.6 (9.6 – 17.7)	20.7 (10.2-31.1)	8	7.2	8.3 (1.8–14.9)	9.0 (0.5-17.5)
35 or older	81	20.2	18.9 (14.0–23.8)	21.3 (16.7-25.9)	49	14.2	14.2 (9.0 – 19.4)	26.0 (17.3-34.6)	9	8.1	7.7 (1.4–14.0)	0.0 (0.0-0.0)
Education	400				352				111			
No formal education	36	9.0	8.7 (5.4–12.0)	34.1 (19.4-48.7)	62	17.6	18.3 (13.1–23.4)	23.8 (12.5-35.0)	8	7.2	6.5 (2.1-10.9)	56.4 (4.0-100.0)
Primary	203	50.7	48.8 (42.7–55.0)	19.5 (15.8-23.1)	140	39.8	40.9 (34.6–47.1)	25.1 (17.7-32.4)	37	33.3	38.8 (28.3-49.3)	11.4 (3.8-18.9)
High school or higher	161	40.3	42.5 (36.3–48.7)	22.9 (1.3-44.6)	150	42.6	41.0 (34.2–47.3)	22.8 (9.1-36.4)	66	59.5	54.7 (43.8-65.5)	34.1 (19.4-48.7)
Marital status	400				352				111			
Never married	246	61.5	62.4 (56.1–68.8)	26.0 (8.2-43.7)	240	68.2	70.9 (65.2–76.6)	25.1 (16.8-33.4)	88	79.3	77.9 (68.0–87.9)	29.4 (23.0-35.7)
Married	77	19.2	18.2 (13.3–23.1)	17.7 (15.8-19.6)	53	15.1	13.8 (9.6–17.9)	20.8 (13.3-28.3)	14	12.6	13.6 (4.9–22.4)	10.8 (0.0-38.7)
Divorced, separated, or widowed	77	19.3	19.4 (14.6–24.1)	14.6 (11.2-17.9)	59	16.8	15.3 (11.0–19.6)	20.8 (10.7-30.7)	9	8.1	8.4 (1.6–15.3)	26.1 (0.0-64.2)
Main source of income	380				340				102			
Formal sector	94	24.7	23.6 (18.3–28.8)	30.5 (11.5-49.5)	94	27.6	26.5 (21.0–32.0)	35.4 (26.1-44.8)	14	13.7	15.7 (7.1–24.3)	25.6 (0.0-60.4)

Informal sector	153	40.3	39.3 (33.1–45.5)	19.5 (2.4-36.6)	149	43.8	45.7 (39.5–52.0)	17.7 (11.7-23.6)	40	39.2	43.0 (32.5–53.5)	26.3 (9.4-43.2)
Unemployed	133	35.0	37.1 (31.0–43.3)	18.7 (13-24.4)	97	28.5	27.8 (22.3–33.3)	22.7 (12.0-33.4)	48	47.1	41.4 (30.9-51.7)	29.6 (7.7-51.4)
Average monthly income	266				255							
< 200 kina (~USD 63)	34	12.8	11.8 (7.3–16.1)	17.1 (1.5-32.6)	17	6.7	7.6 (3.8 – 11.5)	19.0 (13.9-24.0)	10	15.9	14.1 (4.7–23.4)	34.7 (15.7-53.7)
200-499 kina	94	35.3	34.1 (26.9–41.3)	20.4 (5.8-35.1)	121	47.5	48.1 (40.0–56.3)	19.5 (14.2-24.7)	23	36.5	38.8 (20.9–56.9)	24.2 (10.2-38.3)
500-999 kina	94	35.3	39.1 (32.0–46.5)	25.4 (16.7-34.2)	80	31.4	29.8 (23.0–36.6)	38.4 (30.2-46.7)	15	23.8	21.2 (9.4–33.0)	16.7 (0.0-42.5)
≥ 1000 kina	44	16.5	15.0 (9.9–20.0)	35.0 (0.0-78.0)	37	14.5	14.5 (9.1–19.8)	13.8 (2.4-25.2)	15	23.8	25.8 (12.5–39.2)	27.1 (6.9-47.4)
Have cut foreskin	400				352				111			
Yes	240	60.0	59.5 (53.2–65.8)	18.6 (11.7-25.5)	291	82.7	83.4 (78.6–88.2)	22.4 (16.0-28.9)	85	76.6	73.4 (65.0–81.8)	27.4 (17.0-37.8)
No	160	40.0	40.5 (34.2–46.8)	27.6 (9.5-45.8)	61	17.3	16.6 (11.8–21.4)	31.2 (22.6-39.7)	26	23.4	26.6 (18.3–35.0)	24.2 (6.8-41.6)
Screened positive for depression	400				352				111			
Yes	37	9.3	8.0 (4.9-11.1)	25.9 (23.4-28.5)	18	5.1	5.7 (2.9-8.4)	1.1 (0.0-2.5)	5	4.5	3.8 (2.8-5.1)†	20.0 (5.7-34.3)
No	363	90.8	92.0 (88.9-95.1)	21.9 (8.3-35.6)	334	94.9	94.3 (91.6-97.1)	22.8 (9.9-35.6)	106	95.5	96.2 (94.9-97.3) †	32.7 (9.3-56.1)
Disclosed sexual behaviors to family or friends (non-MSM)	400				352				111			
Yes	160	40.0	38.1 (32.0–44.0)	23.1 (7.3-38.8)	140	39.8	35.7 (29.6– 41.8)	26.2 (10.9-41.5)	44	39.6	35.2 (25.9–44.5)	28.2 (6.4-50.0)
No	240	60.0	61.9 (55.7–68.0)	21.7 (10.6-32.8)	212	60.3	64.0 (58.1 – 70.4)	22.6 (20.1-25.0)	67	60.4	64.8 (55.5–74.1)	25.7 (16.5-34.9)
Hide sexual behavior or gender identity from healthcare worker	359				209				60			
Yes	173	48.2	48.0 (41.8–54.2)	25.3 (10.5-40.2)	89	42.6	45.0 (36.1 – 54.2)	25.4 (1.7-49.0)	20	33.3	39.6 (26.8–52.6)	37.1 (10.2-64.1)
No	186	51.8	52.0 (45.8–58.2)	21.2 (7.5-34.9)	120	57.4	55.0 (45.8 – 63.9)	30.5 (22.8-38.2)	40	66.7	60.5 (47.4–73.2)	26.9 (5.9-47.9)

Ever experienced violence/sexual violence	382				347				106			
Yes	251	65.7	63.6 (58.6-68.6)	20.5 (7.6-33.4)	270	77.8	78.3 (75.0-81.6)	22.7 (13.6-31.8)	66	62.3	63.6 (54.0-73.1)	22.2 (9.5-35)
No	131	34.3	36.4 (31.4-41.4)	26.4(11.0-41.8)	77	22.2	21.7 (18.4-25.0)	26.8 (18.6-35.1)	40	37.7	36.4 (26.9-46.0)	33.9 (20.6-47.2)
Experienced violence/sexual violence in last 12 months	179				128				27			
Yes	154	86.0	87.5 (80.7-94.4)	19.1 (9.1-29.0)	91	71.1	67.9 (57.2-78.3)	25.5 (4.4-46.7)	22	81.5	79.2 (65.7-92.4)	19.2 (3.9-34.5)
No	25	14.0	12.5 (5.6-19.3)	18.7 (0.0-52.4)	37	28.9	32.1 (21.7-42.8)	19.6 (0.0-41.0)	5	18.5	20.9 (7.6-34.3)	28.3 (0.0-95.7)
Can rely on other MSM and TGW to accompany them to doctor or hospital	373				334				103			
Yes	144	38.6	35.9 (30.0–41.8)	20.9 (2.9-39.0)	204	61.1	58.4 (52.3 – 64.5)	22.9 (12.2-33.7)	62	60.2	61.2 (51.0–71.3)	31.3 (13.9-48.7)
No	229	61.4	64.1 (58.2–70.0)	23.4 (14.1-32.7)	130	38.9	41.6 (35.5 – 47.7)	25.4 (20.5-30.2)	41	39.8	38.8 (28.7–49.0)	24.1 (12.2-35.9)

[†]Confidence intervals calculated using Wilson binomial proportion bounds

Table 2. Sexual behaviors of men who have sex with men and transgender women in Port Moresby, Lae, and Mt Hagen, Papua New Guinea

	PORT MORESBY				LAE				MOUNT HAGEN			
	Valid	Sample proportion (unweighted)	Population proportion (weighted)	Chlamydia /Gonorrhea Prevalence (weighted)	Valid	Sample proportion (unweighted)	Population proportion (weighted)	Chlamydia /Gonorrhea Prevalence (weighted)	Valid	Sample proportion (unweighted)	Population proportion (weighted)	Chlamydia /Gonorrhea Prevalence (weighted)
	N=400	%	% (95% CI)	%	N=352	%	% (95% CI)	%	N=111	%	% (95% CI)	%
Age first had anal sex with a man or TG (years)	376				332				103			
10-14	33	8.8	7.1 (4.2-10.0)	40.1 (18.2-61.9)	28	8.4	7.5 (3.8-11.1)	35.8 (25.1-46.5)	2	1.9	3.0 (2.1-4.3) †	0.0 (0.0-0.0)
15-19	143	38.0	37.7 (31.5-43.9)	19.3 (1.0-37.6)	123	37.1	41.0 (34.2-47.8)	21.3 (13.5-29.0)	54	50.0	47.8 (36.3-59.4)	39.3 (26.6-51.9)
20-24	108	28.7	30.2 (24.5-36.0)	24.5 (5.1-43.8)	103	31.0	29.3 (23.5-35.2)	27.3 (18.0-36.7)	56	33.3	32.9 (21.3-44.6)	22.0 (14.2-29.8)
25 or older	92	24.5	24.9 (19.1-30.7)	17.5 (15.0-19.9)	78	23.5	22.2 (16.7-27.8)	23.0 (13.0-33.1)	16	14.8	16.2 (7.5-25.0)	9.6 (2.9-16.2)
Total number of male or TGW partners in the last 6 months	378				339				103			
1-2 partners	167	44.2	45.9 (39.6-52.1)	20.3 (7.1-33.6)	185	54.6	58.4 (52.6-64.3)	23.1 (17.5-28.6)	60	58.3	62.2 (51.4-73.1)	29.8 (18.3-41.3)
3-4 partners	56	14.8	14.8 (10.4-19.1)	24.1 (10.5-37.8)	59	17.4	14.7 (10.5-18.9)	37.4 (24.9-49.9)	15	14.6	14.3 (7.7-20.9)	33.6 (17.8-49.3)
5-9 partners	42	11.1	10.7 (6.8-14.6)	32.4 (13.7-51.0)	30	8.9	7.6 (4.5-10.6)	15.5 (0.0-35.1)	6	5.8	5.0 (0.1-9.9)	0.0 (0.0-0.0)
10 or more partners	26	6.9	4.2 (2.1-6.2)	56.0 (12.8-99.2)	10	3.0	2.3 (0.7-3.9)	43.3 (11.6-75.0)	1	1.0	1.6 (1.0-2.6) †	0.0 (0.0-0.0)
Used internet or mobile apps to meet partners, last 6 months	399				351			351	111			
Yes	85	21.3	23.2 (16.8 – 29.6)	34.9 (5.1-64.7)	98	27.9	24.0 (18.6-29.3)	24.1 (13.4-34.7)	45	40.5	42.6 (33.2-52.0)	40.4 (19.9-60.9)
No	314	78.7	76.8 (70.4 – 83.2)	18.4 (14.1-22.7)	253	72.1	76.0 (70.7-81.4)	23.5 (17.8-29.2)	66	59.5	57.4 (48.0-66.8)	16.3 (7.2-25.5)
Had vaginal/anal sex with a woman in the last 6 months	361				327				106			

Yes	294	81.4	80.7 (75.5-85.9)	19.9 (11.4-28.3)	302	92.4	92.1 (88.8-95.4)	22.0 (17.9-26.1)	95	89.6	87.7 (80.5-94.9)	27.9 (18.7-37.2)
No	67	18.6	19.3 (14.1-24.5)	21.9 (4.2-39.6)	25	7.6	7.9 (4.6-11.2)	23.5 (0.0-47.8)	11	10.4	12.3 (5.1-19.5)	12.8 (0.0-30.1)
Has exchanged sex for money in the last 6 months	378				339				103			
Yes	195	51.6	51.6 (45.3 – 58.0)	21.2 (7.3-35.1)	143	42.2	38.2 (31.6-44.7)	23.8 (12.6-35.1)	37	35.9	33.0 (23.4-42.6)	29.0 (13.5-44.6)
No	183	48.4	48.4 (42.0 – 54.7)	23.1 (8.5-37.8)	196	57.8	61.8 (55.3-68.4)	25.5 (20.4-30.7)	66	64.1	67.0 (57.4-76.6)	26.4 (17.7-35.2)

[†]Confidence interval calculated using Wilson binomial proportion bounds

Table 3. Sexually transmitted infections among men who have sex with men and transgender women in Port Moresby, Lae, and Mt Hagen, Papua New Guinea.

	PORT MORESBY			LAE			MOUNT HAGEN		
	Valid	Sample proportion (unweighted)	Population proportion (weighted)	Valid	Sample proportion (unweighted)	Population proportion (weighted)	Valid	Sample proportion (unweighted)	Population proportion (weighted)
	N=400	%	% (95% CI)	N=352	%	% (95% CI)	N=111	%	% (95% CI)
Experienced STI symptoms in last 12 months	141	35.2	35.3 (29.6-40.9)	144	41.1	42.7 (36.4-49.1)	36	32.4	27.9 (18.1-37.7)
STI Prevalence ‡	132	34.9	31.4 (25.6-37.2)	141	40.4	39.5 (33.6-45.4)	38	35.5	38.9 (27.6-50.1)
Prevalence of STI coinfection *	43	14.9	13.4 (8.4-18.3)	38	15.4	14.8 (10.0-19.7)	8	10.4	14.1 (2.8-25.6)
Prevalence chlamydia	79	20.5	19.9 (15.2-24.7)	70	20.1	19.2 (14.4-23.9)	22	20.6	24.3 (13.9-34.7)
Anorectal	30	8.0	7.6 (4.4-10.9)	17	5.0	5.8 (2.2-7.4)	4	3.9	5.5 (4.2-7.1) †
Genital	42	10.8	10.5 (6.9-14.1)	46	13.4	12.9 (8.7-17.0)	14	13.2	15.0 (6.1-23.9)
Both	7	2.2	2.4 (0.1-4.6)	7	2.5	2.2 (0.4-4.0)	4	4.5	5.6 (0.4-10.8)
Prevalence gonorrhea	40	10.5	10.3 (6.4-14.2)	33	9.5	9.4 (6.0-12.8)	7	6.5	9.6 (2.4-16.9)
Anorectal	25	6.6	6.6 (3.5-9.7)	6	1.8	1.9 (0.4-3.4)	4	3.9	6.2 (4.8-7.9) †
Genital	13	3.3	3.2 (1.2-5.2)	17	5.0	4.9 (2.6-7.2)	0	0	0.0
Both	2	0.6	0.5 (0.3-0.8) †	10	3.1	3.0 (1.0-5.1)	3	2.9	4.0 (2.9-5.4)†
Prevalence of chlamydia and gonorrhea coinfection	30	35.3	37.6 (24.6-50.9)	19	22.6	19.2 (9.7-28.4)	5	20.8	27.9 (22.8-33.6)†
Prevalence of chlamydia or gonorrhea	89	23.1	22.2 (19.2-27.2)	84	24.1	23.9 (18.6-29.2)	24	22.4	26.5 (16.5-36.6)
Prevalence hepatitis B	56	14.1	11.7 (8.1-15.3)	50	14.2	13.8 (9.6-18.0)	15	13.5	13.6 (6.5-20.8)
Prevalence lifetime syphilis	47	11.8	10.1 (6.6-13.5)	70	19.9	21.2 (16.1-26.3)	7	6.3	8.3 (1.4-15.2)
Prevalence active syphilis	17	4.3	4.0 (1.7-6.4)	29	8.2	8.2 (4.9-11.6)	3	2.7	2.5 (1.7-3.7) †
Prevalence HIV	30	7.7	8.5 (4.3-12.6)	23	6.7	7.2 (3.8-10.7)	2	1.8	1.3 (0.8-2.2) †

‡ Excludes positive tests for HIV

*Tested positive for at least two of the following: hepatitis B, anorectal/genital chlamydia, anorectal/genital gonorrhea, and active syphilis.

†Confidence intervals calculated using Wilson binomial proportion bounds.

Table 4. Multivariate analysis for factors associated with gonorrhea or chlamydia infection among MSM and transgender women in Port Moresby and Lae, Papua New Guinea.

	PORT MORESBY				LAE			
	OR (95% CI)	**P Value**	**aOR (95% CI)**	**P Value**	**OR (95% CI)**	**P Value**	**aOR (95% CI)**	**P Value**
Gender identity		0.0002		0.1711		0.0345[†]		
Male	Ref		Ref		Ref			
TG	3.0 (1.8-4.8)		1.6 (0.8-3.3)		4.8 (1.1-20.4)			
Age (years)		<0.0001		<0.0001		0.1151		
12-19	Ref		Ref		Ref			
20-24	7.1 (1.8-27.0)		8.9 (6.1-13.0)		1.8 (0.5-6.6)			
25-29	4.3 (1.7-10.5)		4.9 (2.8-8.5)		1.0 (0.3-3.4)			
30-34	2.1 (1.0-4.6)		2.3 (1.3-4.1)		1.2 (0.8-2.6)			
35 or older	3.7 (2.8-4.9)		4.4 (1.5-12.5)		1.6 (0.9-2.9)			
Education		<0.0001		<0.0001		0.7628		
No formal education	Ref		Ref		Ref			
Primary	0.5 (0.0.3-0.8)		0.4 (0.3-0.6)		1.1 (0.4-2.6)			
High school or higher	0.6 (0.0.3-1.1)		0.7 (0.3-1.4)		0.9 (0.2-3.6)			
Monthly Income*		0.0037				0.0008		
< 200 kina (~USD 63)	Ref				Ref			
200-499 kina	1.3 (0.7-2.4)				1.0 (0.8-1.3)			
500-999 kina	1.7 (0.8-3.7)				2.7 (1.8-4.0)			
≥ 1000 kina	2.6 (0.8-8.9)				0.7 (0.3-1.5)			
Cut foreskin		0.0361		0.0184		0.0570		0.1048
Yes	0.6 (0.4-1.0)		0.6 (0.4-0.9)		0.6 (0.4-1.0)		0.7 (0.4-1.1)	
No	Ref				Ref			
Disclosed sexual behaviors to family/friends (non-MSM)		0.7334				0.5875		
Yes	1.1 (0.7-1.7)				1.2 (0.6-2.6)			
No	Ref				Ref			
Hide sexual behavior or gender identity from healthcare worker		0.1587				0.6958		
Yes	1.3 (1.0-1.8)				0.8 (0.2-3.0)			
No	Ref				Ref			
Experienced violence/ in last 12 months		0.9714				0.4561		
Yes	1.0 (0.2-5.8)				0.7 (0.3-1.9)			
No	Ref				Ref			

Age first had anal sex with a man or TG (years)		0.0011		<0.0092		0.3515		
10-14	Ref				Ref			
15-19	0.4 (0.2-0.6)		0.7 (0.4-1.2)		0.5 (0.2-1.1)			
20-24	0.5 (0.3-0.8)		1.6 (0.6-2.4)		0.7 (0.3-1.4)			
25 or older	0.3 (0.1-0.9)		0.9 (0.5-1.5)		0.5 (0.2-1.3)			
Total number of male/TG partners in last 6 months		0.0009		<0.0001		<0.0001		<0.0001
1-2 partners	Ref		Ref		Ref		Ref	
3-4 partners	1.2 (0.5-3.4)		1.3 (0.6-2.9)		2.0 (1.3-3.0)		1.9 (1.2-3.1)	
5-9 partners	1.9 (1.3-2.7)		1.0 (0.6-1.5)		0.6 (0.2-2.2)		0.5 (0.2-1.7)	
10 or more partners	5.0 (1.8-13.9)		1.5 (0.2-14.5)		2.5 (0.7-9.6)		1.9 (0.4-9.2)	
Used internet/mobile app to meet partners, last 6 months		0.1055				0.8720		
Yes	2.4 (0.8-6.9)				1.0 (0.7-1.5)			
No	Ref				Ref			
Exchanged sex for money in last 6 months		0.3383				0.7125		
Yes	0.9 (0.7-1.1)				0.9 (0.5-1.5)			
No	Ref				Ref			
Experienced STI symptoms in last 12 moths		0.0229		0.0890				0.0699
Yes	2.0 (1.1-3.7)		1.9 (0.9-3.9)		1.6 (1.0-2.5)	0.0325	1.6 (1.0-2.6)	
No	Ref				Ref			
Coinfection with HBV		0.7918				0. .3007		
Yes	1.1 (0.6-1.8)				0.7 (0.3-1.4)			
No	Ref				Ref			
Coinfection with Syphilis		<0.0001		<0.0001		0.0557		0.0116
Yes	2.7 (1.8-3.9)		3.9 (2.6-5.7)		2.3 (1.0-5.5)		2.5 (1.3-4.8)	
No	Ref				Ref			
Tested positive for HIV		0.0108		0.3660		0.0620		0.1055
Yes	4.7 (1.5-14.8)		2.7 (0.3-23.9)		1.8 (1.0-3.2)		1.7 (0.9-3.3)	
No	Ref				Ref			

*Income variable excluded from multivariate analysis at both sites due to small cell size

†Excluded from multivariate model due to high relative standard error

Appendix

Institutional Review Board

April 23rd, 2019

Chelsea Iwamoto
Rollins School of Public Health
Emory University

RE: **Determination: No IRB Review Required**
Title: *Secondary Analysis of Data from Papua New Guinea*
Responsible Party/Investigator: *Chelsea Iwamoto*

Dear Ms. Iwamoto:

Thank you for requesting a determination from our office about the above-referenced project. Based on our review of the materials you provided, we have determined that it does not require IRB review because it does not meet the definition of "research" with "human subjects" or "clinical investigation" as set forth in Emory policies and procedures and federal rules, if applicable. Specifically, in this project, you will try to find associations between social, demographic, and behavioral factors and gonorrhea and chlamydia prevalence among men who have sex with men and transgender women. All data has been de-identified and was provided by the Centers for Disease Control. There is no current systematic investigation taking place as part of this thesis work.

Please note that this determination does not mean that you cannot publish the results. This determination could be affected by substantive changes in the study design, subject populations, or identifiability of data. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

Sincerely,

Ashton Hughes
Research Protocol Analyst
Emory University IRB

CGH HSR Tracking #:

Request for Project Determination & Approval – Center for Global Health (CGH)

This form should be used to submit proposals to the CGH Office of the Associate Director for Science/Laboratory Science (ADS/ADLS) for research/nonresearch determination and requirements for IRB review/approval.
Approval Chain: Investigator → Branch Chief/Country Director →Division ADS → CGH Human Subjects Mailbox

☐ **New Request** ☒ **Amendment** ☐ **Laboratory Submission**

Project Title:: A respondent driven sampling study of female sex workers and men who have sex with men in in Papua New Guinea (PNG)		Project Location/Country(ies): Port Moresby, Lae and Mt. Hagen, PNG.
CDC Principal Investigator(s): Avi Hakim		
CDC Project Officer(s): Steven Terrell-Perica	Division: DGHA	Telephone: 404-259-4426
Proposed Project Dates: Start: late July 2015	End: Dec 2016	

Please check appropriate category and subcategory:

☐ **I. Activity is NOT human subjects research. Primary intent is public health practice or a disease control activity (Check one)**
- ☐ A. Epidemic or endemic disease control activity; if applicable, Epi-AID #
- ☐ B. Routine surveillance activity (e.g., disease, adverse events, injuries)
- ☐ C. Program evaluation activity
- ☐ D. Public health program activity*
- ☐ E. Laboratory proficiency testing

*e.g., service delivery; health education programs; social marketing campaigns; program monitoring; electronic database construction and/or support, development of patient registries; needs assessments; and demonstration projects intended to assess organizational needs, management, and human resource requirements for implementation.

☐ **II. Activity is research but does NOT involve human subjects (Check one)**
- ☐ A. Activity is research involving collection or analysis of data about health facilities or other organizations or units (NOT persons).
- ☐ B. Activity is research involving data or specimens from deceased persons.
- ☐ C. Activity is research involving unlinked or anonymous data or specimens collected for another purpose.
- ☐ D. Activity is research involving data or specimens from animal subjects.*

*Note: Approval by CDC Institutional Animal Care and Use Committee (IACUC) may be required.

☒ **III. Activity is research involving human subjects but CDC involvement does not constitute "engagement in human subject research." (Check one)**
- ☒ A. This project is funded under a grant/cooperative agreement/contract award mechanism. Award # TBD
  ALL of the following 3 elements are required:
  - ☒ 1. CDC employees or agents will not intervene or interact with living individuals for research purposes.
  - ☒ 2. CDC employees or agents will not obtain individually identifiable private information.
  - ☒ 3. Supported institution must have a Federalwide Assurance (FWA) and project must be reviewed by a regis IRB linked to the supported institution's FWA.

Supported Institution/Entity Name:	Oil Search Foundation, PNG		
Supported Institution/Entity FWA #	FWA00023381	FWA Expiration Date (mm/dd/yyyy):	0.0
Expiration Date of IRB approval:		(Attach copy of the IRB approval letter)	

- ☐ B. CDC staff provide technical support that does not involve possession or analysis of identifiable data or interaction participants from whom data are being collected (No current CDC funding).
- ☐ C. CDC staff are involved only in manuscript writing for a project that has closed. For the project, CDC staff did not with participants and were not involved with data collection (No current CDC funding).
- ☐ D. Activity is research involving linked data, but CDC non-disclosure form 0.1375B is signed.*

*Access to linked data is permitted under any of the above sub-categories if CDC investigators and the holder of the key linking the data to identifiable subjects enter into an agreement using CDC form 0.1375B, prohibiting the release of the key to CDC investigators under any circumstances. The purposes of the planned research do not contradict the terms of consent under which the information or specimens were collected, whether that consent was documented or not documented.

☐ **IV. Activity is research involving human subjects that requires submission to CDC Human Research Protection Office (Check one)***
- ☐ A. Full Board Review (Use forms 0.1250, 0.1370-research partners)
- ☐ B. Expedited Review (Use same forms as A above)
- ☐ C. Exemption Request** (Use forms 0.1250X, 0.1370-research partners)
- ☐ D. Reliance**
  - ☐ 1. Request to allow CDC to rely on a non-CDC IRB (Use same forms as A above, plus 0.1371)
  - ☐ 2. Request to allow outside institution to rely on CDC IRB (Use same forms as A above, plus 0.1372)

*There are other types of requests not listed under category IV, e.g., continuation of existing protocol, amendment, incident reports.
**Exemption and reliance request is approved by CDC Human Research Protection Office (HRPO).

CGH HSR Tracking #:

Amendment: If this request is an amendment to an existing project determination. Please include a brief description of the substantive change or modification below and attach both clean and marked copies of the amended protocol or project outline.

HIV, CD4, and viral load as well as all STI and TB testing will be done at POC.

Submission: Attach a protocol or project description (See standard format below) in enough detail to justify the proposed category. Submit your request to your branch chief (or country director for DGHA country staff).

Approval Chain
Investigator → Branch Chief/Country Director →Division ADS → CGH Human Subjects Mailbox

CGH ADS/ADLS Review **Date received in CGH ADS /ADLS office:**

☐ **Project does not require human subject research review beyond CGH at this time.**

☐ **Project constitutes human subject research that must be routed to CDC HRPO.**

Comments/Rationale for Determination:

Approvals/Signatures:	**Date:**	**Remarks:**
Avi Hakim Investigator	**06/03/2015**	**Approved**
Steven Terrell-Perica Branch Chief/Country Director	**06/03//2015**	**Approved**
Division Human Research Protection Coordinator Division ADS/ADLS or Director	11/4/15	
CGH Human Research Protection Coordinator CGH ADS/ADLS or Deputy ADS/ADLS		

Note: Although CDC IRB review is not required for certain projects (categories I,II & III) approved under this determination, CDC investigators and project officers are expected to adhere to the highest ethical standards of conduct and to respect and protect to the extent possible the privacy, confidentiality, and autonomy of participants. All applicable country, state, and federal laws must be followed. Informed consent may be appropriate and should address all applicable elements of informed consent. CDC investigators should incorporate diverse perspectives that respect the values, beliefs, and cultures of the people in the country, state, and community in which they work.

[√] **Has been forwarded to the Papua New Guinea Medical Research Advisory Council (MRAC). You must not commence this study until the MRAC has also indicated their approval.**

Date of committee review: 08 February 2018

Date of Approval: 08 February 2018

Ethical clearance from other institutions involved (PI's) [√] No [ ] Yes [ ] N/A

Source of support: [ ] None [ ] Institutional [√] Outside Funding

Are the following involved: [ ] No [√] Yes

[√] Minors [ ] Neonates [ ] Fetus [ ] Prisoners [ ] Pregnant women [ ] Mentally Disabled

The PNGIMR IRB operates under the HHS Federal Wide Assurance of Compliance number FWA # 00000123, IRB # 00005517 and IORG registration # 0004625

Prof. Mark SOLON
Chairman, IMR Institutional Review Board
09 March 2018

General Information

Information including details of reporting requirements can be found on the IMR IRB website www.pngimr.org.pg/imrirb. We strongly advise you to access this website regularly, for updates to and information on the IMR IRB. In particular however we would like draw your attention to the need to report to the IMR IRB all:

1. deviations from or changes to this protocol that are required to eliminate immediate hazards to the study participants;
2. deviations and changes increasing the risk to participants and/or affecting significantly the conduct of the study;
3. adverse drug reactions that are both serious and unexpected; and
4. New information that may affect adversely the safety of the participants of the conduct of the study.
5. Provide **annual report** (or sooner for short projects).

PAPUA NEW GUINEA INSTITUTE OF MEDICAL RESEARCH

PO Box 60, Goroka, Eastern Highlands Province (EHP) Papua New Guinea (PNG)

Tel: + (675) 532 2800 Fax: + (675) 532 1998 Director: + (675) 532 1469
IRB Deputy Chairman/Secretary: + (675) 531 4206

Website: www.pngimr.org.pg/imrirb Email: general@pngimr.org.pg

IMR Institutional Review Board

[ ] **New Protocol** [√] **Protocol Amendment** [ ] **Progress Report**

The IMR Institutional Review Board (IMR IRB) has reviewed your proposal

Name of amendment protocol: Key population integrated bio-behavioural survey (KP IBBS). A respondent driven sampling study of female sex workers and men who have sex with men and transgender in Papua New Guinea "Kauntim mi tu" (IRB # 1508, MRAC # 15.12)

Submitted by: Dr Angela Kelly-HANKU

Date of submission: 05 February 2018

The Board's considers this proposal:

[√] **Fully acceptable, without reservation**

Amendment requested for were:-

1. As per the approved protocol researchers plan to validate the sensitivity and specificity of anorectal CT/MG sample collected during the IBBS study. This means researchers have tested samples using the CT/NG Xpert assay at the point of care and now want to compare those results using another commercial CT/NG assay. Researchers have had to change the testing venue for the validation study because the lab leader and AI has gone on sabbatical. The same commercial (Cobas 4800) assay for comparison purposes will be used at the new testing venue located at the Molecular Diagnostic Medicine Laboratory, SydPath, St Vincent's Public Hospital, Victoria Street, Darlinghurst, NSW 2010 and supervised by Philip Cunningham from the Kirby Institute - UNSW Sydney.
2. On completion of Point 1 there will be remnant sample extracts available that could be used to undertake molecular gonorrhoea (NG) AMR (antimicrobial drug resistance) testing and researchers would like to run several molecular PCR assays across the extracts to detect NG AMR strains. Doing so would give researchers valuable insight into strain types present in Papua New Guinea. Doing so would also complement any other NG AMR work within PNG being conducted now or planned for the future. Results would also provide preliminary data on key populations, which other studies have not focused on to date. All samples in Sydney AU for this validation are approved to be stored and undergo further testing of this kind. If researchers do not test these extracts they will be disposed of in accordance with biohazard safety procedures in Sydney AU as we do not have the capacity to return them.

3. In the survey researchers would also like to offer participants the opportunity to answer up to 8 other sensitive questions themselves on the tablets, especially about their HIV status. This would be an optional extra and not mandatory.

[ ] **Acceptable with minor changes.** All corrections must be sent to IRB for direct approval by the Chairman (no need to resubmit the proposal).

[ ] **Put on HOLD until next IRB meeting.** Proposal must be resubmitted to the next IRB meeting with following clarifications/changes requested by the Board:-

[ ] **Definitely rejected** for the following reasons

[√] Was allocated **IRB number:** 1508

[√] **Has been forwarded to the Papua New Guinea Medical Research Advisory Council (MRAC). You must not commence this study until the MRAC has also indicated their approval.**

Date of committee review: 08 February 2018

Date of Approval: 08 February 2018

Ethical clearance from other institutions involved (PI's) [√] No [ ] Yes [ ] N/A

Source of support: [ ] None [ ] Institutional [√] Outside Funding

Are the following involved: [ ] No [√] Yes

[ ] Minors [√] Neonates [ ] Fetus [ ] Prisoners [√] Pregnant women [ ] Mentally Disabled

The PNGIMR IRB operates under the HHS Federal Wide Assurance of Compliance number FWA # 00000123, IRB # 00005517 and IORG registration # 0004625

Prof. Mark SOLON
Chairman, IMR Institutional Review Board
09 March 2018

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[√] Was allocated **IRB number:** 1508

[√] **Has been forwarded to the Papua New Guinea Medical Research Advisory Council (MRAC). You must not commence this study until the MRAC has also indicated their approval.**

Date of committee review: 08 February 2018

Date of Approval: 08 February 2018

Ethical clearance from other institutions involved (PI's) [√] No [ ] Yes [ ] N/A

Source of support: [ ] None [ ] Institutional [√] Outside Funding

Are the following involved: [ ] No [√] Yes

[ ] Minors [√] Neonates [ ] Fetus [ ] Prisoners [√] Pregnant women [ ] Mentally Disabled

The PNGIMR IRB operates under the HHS Federal Wide Assurance of Compliance number FWA # 00000123, IRB # 00005517 and IORG registration # 0004625

Prof. Mark SOLON
Chairman, IMR Institutional Review Board
09 March 2018

General Information

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1. deviations from or changes to this protocol that are required to eliminate immediate hazards to the study participants;
2. deviations and changes increasing the risk to participants and/or affecting significantly the conduct of the study;
3. adverse drug reactions that are both serious and unexpected; and
4. New information that may affect adversely the safety of the participants of the conduct of the study.
5. Provide **annual report** (or sooner for short projects).

PAPUA NEW GUINEA INSTITUTE OF MEDICAL RESEARCH

PO Box 60, Goroka, Eastern Highlands Province (EHP) 441, Papua New Guinea

IRB Deputy Chairman/Secretary: Tel: + (675) 531 4206
Tel: + (675) 532 2800 Fax: + (675) 532 1998 Director: + (675) 532 1469
Website: www.pngimr.org.pg/imrirb Email: general@pngimr.org.pg

IMR Institutional Review Board

[√] New Protocol **[ ] Protocol Amendment** **[ ] Progress Report**

The IMR Institutional Review Board (IMR IRB) has reviewed your proposal

Name of protocol: KP IBBS: Respondent driven sampling study of female sex workers and men who have sex with men and transgender in Papua New Guinea (Kauntim Mi Tu)

Submitted by: Dr Angela KELLY-HANKU

Date of submission: 21 May 2015

The Board's considers this proposal:

[√] **Fully acceptable, without reservation**

[ ] **Acceptable with minor changes.** All corrections must be sent to IRB for direct approval by the Chairman (no need to resubmit the proposal).

[ ] **Definitely rejected** for the following reasons

[√] Was allocated **IRB number:** 1508

[√] **Has been forwarded to the Papua New Guinea Medical Research Advisory Council (MRAC). You must not commence this study until the MRAC has also indicated their approval.**

Date of committee review: 05 June 2015

Date of Approval: 05 June 2015

Ethical clearance from other institutions involved (PI's) [ ] No [√] Yes [ ] N/A

Source of support: [ ] None [ ] Institutional [√] Outside Funding

Are the following involved: [ ] No [√] Yes

[√] Minors [ ] Neonates [ ] Fetus [ ] Prisoners [√] Pregnant women [ ] Mentally Disabled

The PNGIMR IRB operates under the HHS Federal Wide Assurance of Compliance number FWA # 00000123, IRB # 00005517 and IORG registration # 0004625

for

Prof. Michael MEL
Chairman, IMR Institutional Review Board
17 June 2015

General Information

Information including details of reporting requirements can be found on the IMR IRB website www.pngimr.org.pg/imrirb. We strongly advise you to access this website regularly, for updates to and information on the IMR IRB. In particular however we would like draw your attention to the need to report to the IMR IRB all:

1. deviations from or changes to this protocol that are required to eliminate immediate hazards to the study participants;
2. deviations and changes increasing the risk to participants and/or affecting significantly the conduct of the study;
3. adverse drug reactions that are both serious and unexpected; and
4. New information that may affect adversely the safety of the participants of the conduct of the study.
5. Provide **annual report** (or sooner for short projects)

Government of Papua New Guinea
Medical Research Advisory Committee
National Department of Health

PO Box 807
WAIGANI 131, NCD
Papua New Guinea

Phone: + (675) 301 3650
Fax: + (675) 3251825
Email:urarang_kitur@health.gov.pg

FILE: 54-6-2
DATE: 30/07/2015

Dr.Angela Kelly-Hanku
P.O Box 60
GOROKA 441
Eastern Highlands

Dear Dr.Angela Kelly-Hanku

Subject: MRAC ethics review

Your proposal, "Respondent Driven Sampling Study of Female Sex Workers and Men Who Have Sex with Men and Transgender in Papua New Guinea (Kauntim Mi Tu) has been reviewed by the MRAC. **The proposal is approved and given ethical clearance to be done in PNG and is assigned MRAC No. 15.12**

MRAC would like to thank you for your submission and looks forward to the successful implementation of your study.

Investigators are reminded of the importance of keeping relevant authorities including the MRAC on the progress of and outcomes of their study.

Best Wishes.

.....
Dr.UrarangKitur
MRAC Chairman

Cc: Professor Peter Siba- Director, PNGIMR

Human Research Ethics Committee (HREC)
The University of New South Wales
UNSW Sydney, NSW, Australia, 2052
E: humanethics@unsw.edu.au
W:https://research.unsw.edu.au/human-research-ethics-home

14-Jul-2015

Dear Dr Angela Kelly,

Project Title	KauntimMi Tu: Key Population Integrated Bio-Behavioural Survey in Papua New Guinea
HC No	HC15355
Re	Notification of Ethics Approval
Approval Period	14-Jul-2015 - 13-Jul-2020

Thank you for submitting the above research project to the **Human Research Ethics Committee** for ethical review. This project was considered by the **Human Research Ethics Committee** at its meeting on 14-Jul-2015.

I am pleased to advise you that the **Human Research Ethics Committee** has granted ethical approval of this research project, subject to the following conditions being met:

Conditions of Approval Specific to Project:
N/A

Conditions of Approval – All Projects:

- The Chief Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Chief Investigator will notify the **Human Research Ethics Committee** of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the **Human Research Ethics Committee**. These instructions can be found at https://research.unsw.edu.au/research-ethics-and-compliance-support-recs.
- The Chief Investigator will submit any necessary reports related to the safety of research participants in accordance with **Human Research Ethics Committee** policy and procedures. These instructions can be found at https://research.unsw.edu.au/research-ethics-and-compliance-support-recs.
- The Chief Investigator will report to the **Human Research Ethics Committee** annually in the specified format and notify the HREC when the project is completed at all sites.
- The Chief Investigator will notify the **Human Research Ethics Committee** if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Chief Investigator will notify the **Human Research Ethics Committee** of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Iinstructions for obtaining an extension of approval can be found at https://research.unsw.edu.au/research-ethics-and-compliance-support-recs.

- The Chief Investigator will notify the **Human Research Ethics Committee** of his or her inability to continue as Coordinating Chief Investigator including the name of and contact information for a replacement.

A copy of this ethical approval letter must be submitted to all Investigators and sites prior to commencing the project.

The **Human Research Ethics Committee** Terms of Reference, Standard Operating Procedures, membership and standard forms are available from https://research.unsw.edu.au/research-ethics-and-compliance-support-recs.
Should you require any further information, please contact the, Ethics Administrator on:
E: humanethics@unsw.edu.au
W:https://research.unsw.edu.au/human-research-ethics-home

The **Human Research Ethics Committee** wishes you every continued success in your research.

Kind Regards

Professor Heather Worth
HREC Presiding Chairperson