Measuring trends in HIV testing and new HIV infections among female sex workers in Zimbabwe

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DECLARATION

I, Harriet Susan Jones, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

ABSTRACT

Female sex workers in sub-Saharan Africa are at increased risk of HIV acquisition and have a higher burden of HIV than women in the wider population. Despite this there remain gaps in our understanding of new HIV infections. Strengthening empirical data on key HIV indicators could improve the provision of targeted and equitable treatment and prevention services. The aim of my PhD is to understand trends in HIV testing and new infections among female sex workers in Zimbabwe and explore methods for the analysis of routinely collected clinic data to measure HIV indicators and inform programme delivery.

I conducted a systematic review exploring knowledge of HIV status and provided major contributions to a second review on HIV incidence, both among female sex workers in sub-Saharan Africa. In published literature, knowledge of HIV status ranged from 4% to 95.2% between 2002 and 2020, with wide heterogeneity in estimates and gaps in data unable to support the analysis of trends over time. Higher estimates were reported in East and Southern Africa, with a median knowledge of HIV status of 58.1% (IQR 38.1-73.1) compared to 41.0% (IQR 22.7-59.3) in West and Central Africa. Thirty two studies reported empirical estimates of HIV incidence between 1985 to 2020. Median incidence was 4.3 new HIV infections per 100py (IQR 2.8-7.0). Incidence among women who engage in sex work was nearly eight times higher than matched total population women (IRR 7·8, 95% CI 5.1-11.8). Both reviews demonstrated the wide variation in the definitions used for recruitment of female sex workers to studies, national gaps in data and the lack of longitudinal data or repeat measures in the same populations.

The main focus of my PhD is Zimbabwe. I analysed routinely collected programme data and recent HIV infection testing results from a nationally scaled programme for female sex workers (the KP Programme) run by the Centre for Sexual Health and HIV/AIDS Research. Among 86,197 FSW accessing programme services over 254,653 clinic visits between 2009 and 2019, 54,503 HIV tests were recorded for 39,462 women. HIV test-positivity declined from 47.9% to 9.6% (aOR 6.08 95% CI 5.52-6.70), partly explained by an increase from 18.2% to 56.7% of tests being among women testing within 6 months of a previous test. I calculated an overall seroconversion rate of 3.8 per 100py (95% CI 3.4-4.2) among 6665 women with >1 HIV test at a clinic during this period, which showed a steady decline over calendar time after accounting for an increase in younger women accessing services and HIV testing frequency. I estimated a higher seroconversion rate of 5.6 per 100py (95% CI 4.8-6.5) among younger women, and higher rates for women within the first year of service access at 5.8 per 100py (95% CI 5.0-6.7). The implementation of a recent HIV infection testing algorithm in the KP Programme between 2021 and 2023 classified 11.7% (95%

CI 10.0-13.5) of HIV-positive tests as newly acquired infections, and estimated an HIV incidence rate of 3.4 new HIV infections per 100py (95% CI 2.7-1.0).

HIV test-positivity and seroconversion rates show encouraging declines over time among female sex workers attending a targeted programme in Zimbabwe. Despite these declines, rates of new HIV infections remain high, particularly among younger women and those recently accessing services, demonstrating the need for intensifying and better targeting of prevention programming. Routinely collected and individually linked HIV testing data from programmes targeting female sex workers can provide valuable insights into epidemic indicators to inform programming strategies and enhance existing approaches to HIV surveillance among female sex workers in sub-Saharan Africa.

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My PhD is dedicated to Philip Jones, who saw me start this journey but sadly did not get to see me finish. His unwavering interest in everything I did has been deeply missed over the past few years. Dad, as promised, I finished. I think you would have been proud.

ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
AGSS	Adolescent girls who sell sex
AGYM	Adolescent girls and young women
ANC	Antenatal care
ART	Antiretroviral Therapy
ARV	Antiretroviral
CeSHHAR	Centre for Sexual Health and HIV/AIDS Research Zimbabwe
CI	Confidence Interval
CD4	Cluster of Differentiation 4 positive T cells
CRT	Cluster randomised trial
DHS	Demographic and Health Surveys
ELISA	Enzyme-Linked Immunosorbent Assay
HIV	Human Immunodeficiency Virus
HCT	HIV Counselling and Testing
IRR	Incidence rate ratio
IQR	Inter-quartile range
JAIDS	Journal of Acquired Immune Deficiency Syndrome
JIAS	Journal of the International AIDS Society
KP	Key Populations
LSHTM	London School of Hygiene and Tropical Medicine
MAR	Missing at random
MeSH	Measurement and Surveillance of HIV Epidemics Consortium
MOHCC	Ministry of Health and Child Care
MRCZ	Medical Research Council of Zimbabwe
NGO	Non-Governmental Organisation
OR	Odds ratio (aOR adjusted odds ratio)
PEP	Post-exposure prophylaxis
PEPFAR	President’s Emergency Plan for AIDS Relief
PHIA	Population-based HIV Impact Assessment
PITC	Provider-Initiated Testing and Counselling
PLOS	Public Library of Science
PMTCT	Prevention of mother to child transmission
PrEP	Pre-exposure prophylaxis
RCT	Randomised controlled trial

RCZ	Research Council of Zimbabwe
RDS	Respondent driven sampling
RDT	Rapid diagnostic test
RITA	Recent HIV Infection Testing Algorithm
STI	Sexually Transmitted Infection
STROBE	Strengthening Reporting of Observational studies in Epidemiology
TLS	Time-location sampling
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session
USAID	United States Agency for International Development
UTT	Universal test and treat
VCT	Voluntary Counselling and Testing
VLS	Viral load suppression
VMMC	Voluntary medical male circumcision
WHO	World Health Organisation

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1. INTRODUCTION

HIV remains a significant public health concern, with an estimated 39 million people living with HIV globally in 2022 and 25.6 million of these in sub-Saharan Africa.[1] Women, particularly those who engage in sex work, are disproportionately affected. The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated that in 2021 the relative burden faced by women who engage in sex work globally was 30 times that of other women of reproductive age.[2] In 2022, 1.3 million people acquired HIV globally, with half of all new infections estimated to be among key populations including female sex workers (FSW) and their sexual partners. Globally, new HIV infections had fallen by 38% in 2022 from 2.1 million in 2010, with greater declines in sub-Saharan Africa, up to 57% in Eastern and Southern Africa during the same period;[1] it is unknown if trends in new infections have followed a similar trajectory among FSW in the region. High numbers of HIV infections have been attributed to unprotected (condomless and in the absence of pre-exposure prophylaxis (PrEP)) sex work,[3,4] from 18% of all HIV infections in sub-Saharan Africa,[5] to 70% of all new infections in 2010 in Zimbabwe.[6] Modelling predicts 35-46% of cumulative HIV transmission will be directly or indirectly attributable to sex work up to 2036.[7] Preventing new HIV infections from unprotected sex work and supporting HIV-positive FSW to access services is critical to reducing new HIV infections by 2030 and beyond.[8]

We are now four decades into the HIV epidemic. While significant progress has been made, the 2020 target of reducing new HIV infections to below 500,000 per annum was not met, with 1.5 million new infections recorded that year and most countries still a way off reaching the 2016 goal to end AIDS by 2030.[9] Addressing the epidemic among FSW is fundamental to achieving both equitable access and reaching global targets.[10] However, despite evidence of the increased burden of HIV among FSW and known increased risks of HIV acquisition and transmission, the response to prevention and care for this population lags behind and the data needed to inform and drive this response is lacking. With declines in general population incidence, supporting key populations with HIV prevention and identifying new HIV infections becomes increasingly important.[11] In 2012, HIV prevalence data for FSW were only available in 16 of the 46 countries in sub-Saharan Africa, with a pooled regional prevalence estimate of 36.9% (95% CI 36.2–37.5).[4] Although 70% of countries globally had seroprevalence and testing data for FSW by 2010, only three countries in sub-Saharan Africa had data on HIV incidence.[12–14] The 2020 UNAIDS epidemic estimates were missing data on new HIV infections and testing targets for key populations due to a lack of data.[15] Questions on the proportion of undiagnosed HIV infections and HIV incidence among sex workers, identified as part of a proposed research agenda in a 2015 Lancet special

edition on HIV and sex work, are still relevant.[12,13] Beyond HIV surveillance, we need to continue to strengthen primary prevention through data driven programming.[16]

In the remainder of this introductory chapter I provide further background on FSW and sex work in the HIV epidemic, global HIV targets and programming for FSW, and HIV testing delivery as it relates to key epidemic metrics. Secondly, I present the gaps in knowledge and HIV epidemic measurement for FSW and the current context in which my PhD is set, along with the opportunities moving forward. Thirdly, I present background on sex work and HIV in Zimbabwe, where my PhD is based. Finally, I present the rationale for my PhD.

1.1. Background

1.1.1. Sex work and HIV

Sex workers are identified as one of the World Health Organisation's (WHO) five key populations[1] who are at increased risk of HIV. The UNAIDS definition is that *"sex workers include female, male and transgender adults (18 years of age and above) who receive money or goods in exchange for sexual services, either regularly or occasionally. Sex work is consensual sex between adults, can take many forms, and varies between and within countries and communities. Sex work may vary in the degree to which it is "formal" or organized".*[17] Sex work varies globally. In sub-Saharan Africa, sex work can take place in brothels, bars, hotels, road-side truck stops or at home, with clients predominantly solicited in bars or drinking venues, streets, or hotels. It is rare that sex work is through an intermediary, with money being exchanged directly between the client and the sex worker.[18] Sex work in sub-Saharan Africa is often defined by high mobility, either with displaced or migrant women entering sex work or mobility related to sex work demands such as seasonality.[18] [19] A 2016 review of studies in sub-Saharan Africa found that on average women engaged in sex work for less than 3-4 years.[18] However, transitions into and out of sex work are not uncommon.

Notwithstanding the definitions above, there is a still a certain level of ambiguity to the term 'sex work.' In this thesis I predominantly refer to FSW, reflecting the fact that the key data source for my main analyses is the Centre for Sexual Health and HIV/AIDS Research (CeSHHAR) Zimbabwe's Key Populations (KP) Programme, which serves (during the period of this PhD) predominantly cis-gender women accessing a programme targeted at FSW. The majority of these women will self-identify as a sex worker. However, the UNAIDS definition of sex work is broad and likely to include women who would identify as a sex worker, but still engage in transactional sex. Transactional sex has been described as *"non-commercial, non-marital sexual relationships*

[1] Men who have sex with men, trans and gender diverse people, sex workers, people who inject drugs and people in prisons and other closed settings

motivated by the implicit assumption that sex will be exchanged for material support or other benefits".[20] [21] This less formal exchange of goods or money for sex, often within relationships and more socially accepted, is widespread and likely to have considerable overlap with sex work in sub-Saharan Africa.[18] It is likely that women who engage in transactional sex will not identify as sex workers or be identified as such in the wider community, but women who identify as FSW may also engage in transactional sex. Sex work and transactional sex can be seen as sitting on a continuum, but are frequently conflated in definition[20] and measurement and will have overlapping HIV risks. UNAIDS also specifically identifies young people who sell sex or are sexually exploited as *"people 10-24 years of age, including children 10–17 years who are sexually exploited and 18–24-year-old adults who are sex workers."*[22]

The increased risk of HIV faced by FSW is related to context and circumstances. Unsafe sex, due to high rates of partner change and low rates of condom use are driven by social and structural factors. These include gender inequality,[23] client and intimate partner violence,[24,25] police violence and harassment,[18] poverty, economic inequality,[26] criminalisation and repressive policing,[27] stigma and discrimination,[26,28] marginalisation,[18] drug use and alcohol,[14] past history of STIs,[29] high rates of concurrent STIs and a lack of access to healthcare services.[30] The length of time women engage in sex work may also play a role in HIV risk, although evidence is less consistent.[18] Studies have repeatedly found that sex workers are paid more money for sex without a condom.[18] These risk factors are not all specific to sex work and may relate to transactional sex as well; this is thought to play an important role in the disproportionate burden of HIV among adolescent girls and young women more broadly in sub-Saharan Africa.[31] Women who engage in transactional sex may be younger than those engaging in sex work more formally,[32] have a lower perception of their HIV risk, and be less likely to access FSW-targeted HIV services.

1.1.2. Sex worker programmes

Many of the structural and societal factors that put FSW at increased risk of HIV also create barriers to accessing HIV services delivered for the general population. Programming guidance for key populations has been historically slow to emerge.[8,9,33–35] Despite an early focus on preventing HIV infections in sex work and evidence for the effectiveness of many programming approaches,[36] slow implementation[36,37] and low coverage, particularly in Africa, prompted a call in 2017 by WHO for more to be done in adopting and scaling up programmes for key populations.[38] Identifying populations and geographic locations with higher HIV burden and risk, and prioritising effective interventions for these populations,[39,40] could maximise the impact of HIV prevention.[41]

The WHO issued guidance on HIV services for key populations in December 2012 with a focus on HIV prevention and treatment for FSW in low and middle income countries.[42] Further updates in July 2014 and July 2016 on HIV prevention, diagnosis, treatment and care for key populations

brought together exiting guidance, including on the routine offer of voluntary HIV testing and counselling (HTC) to key populations in community and clinical settings and new recommendations on the offer of oral PrEP as a prevention option for key populations.[43] [44] The latest programming guidance was released in July 2022, again consolidating previous guidance on HIV prevention, diagnosis, treatment and care for key populations, but this time in consultation with global key population networks and expanded to include viral hepatitis and sexually transmitted infections (STIs).[45]

FSW-targeted programmes are frequently donor funded and implemented by non-governmental providers such as community-based organisations.[37] Programmes often have low coverage and are rarely implemented on a national scale, instead focusing on subnational locations such as cities and border towns or in specific sex work hotspots where there is a greater key population presence.[37] Services targeted specifically at FSW help mitigate some of the barriers FSW face accessing services from general health care facilities.[46,47] They address barriers including stigma and discrimination,[48] limited awareness of services, inconvenient service opening hours and issues of stock outs of condoms and PrEP.[49] Programming guidance on HIV and sex work[17,43,44,50] includes recommendations for community empowerment and community led services (with community involvement beyond peer education to implementation more broadly), the decriminalisation of sex work and favourable legal environments, integrated health and social services,[43] community based HIV testing by lay providers or peers,[44] HIV self-testing,[51] post-exposure prophylaxis (PEP) and PrEP.[44] Targeted HIV programmes for FSW, including periodic presumptive treatment for STIs,[52] have been shown to be effective and cost-efficient.[36,53] However, these programmes face challenges with implementation at scale[37] and national financing, and are rarely informed by a nuanced understanding of transmission dynamics or target women who do not self-identify as a sex worker.[53]

1.1.3. HIV testing and identifying new HIV infections

HIV testing is a fundamental part of HIV programming. High HIV testing coverage and the early identification of new HIV infections are fundamental for reducing the proportion of individuals with undiagnosed HIV and ensuring early treatment and the prevention of onward transmission, whilst providing a gateway for HIV prevention to those testing HIV-negative. A high proportion of undiagnosed HIV is likely to be undermining efforts to reduce HIV transmission.[54]

The first HIV antibody tests were developed in the mid-1980s, with more recently developed point of care testing with rapid diagnostic tests (RDTs) and self-testing making HIV testing increasingly accessible.[55,56] Testing delivery strategies have evolved alongside the changing availability of treatment and interventions (such as prevention of mother to child transmission (PMTCT), voluntary medical male circumcision (VMMC) and PrEP, to meet the challenges of reaching

declining proportions of HIV-positive individuals. Testing was initially client initiated and conducted in the absence of antiretroviral therapy (ART), known as voluntary counselling and testing (VCT). ART became available in the mid-1990s, and with it debate on whether the opt-in approach of VCT would support enough people to test and know their HIV status.[57–59] Testing subsequently saw a shift to provider-initiated testing and counselling (PITC) in the mid-2000s to address initially low ART coverage.[57] WHO guidance on PITC came out in 2007 after a number of countries had adopted this approach in their health care settings.[60] This shift normalised HIV testing and established it as a key part of the HIV response with the recommendation that testing was routinely offered in antenatal care and then in all health care facilities in generalised epidemics and to key populations. Evidence for test and treat emerged in 2013, and treatment as prevention was considered a key measure in preventing HIV by 2014. General HIV testing guidelines have evolved since 2009. Guidance in July 2015 brought together existing guidelines on HIV testing services (HTS), expanding testing to include HIV self-testing (HIVST) in order to increase access for groups including key populations.[51,61] These guidelines were updated in 2019 and incorporated into consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring in 2021. New recommendations were also added on more frequent retesting based on individual risk, 3-6 monthly, including for key populations presenting at services with an STI, social-network based testing approaches where testing is offered to social contacts of key populations and index testing (also described as provider-assisted referral or assisted partner notification) where service providers assist in contacting and testing the sexual partners and biological children of an HIV-positive individual.[62,63]

Tests can now differentiate recent from long standing HIV infection. In 1998, the first tests were developed to identify early HIV infection, these were proposed for estimating HIV incidence, supporting clinical care and guiding prevention programming.[64] Known as recent HIV infection testing, tests can be conducted in a laboratory or at point of care with a rapid test. Tests use limiting antigen to distinguish between recent (generally considered to be between 6-12 months) and established HIV infection.[65] On their own, recent HIV infection tests return a high proportion of false positives as they cannot necessarily distinguish between actual recent HIV infections and infections in people with controlled HIV (undetectable VL) or on ART.[66–68] Recent HIV infection testing conducted as part of a recent HIV infection testing algorithm (RITA), using additional clinical information to identify recent infections can reduce this false recent miscalssification.[69] Recent infection testing can help identify populations, defined by behaviour and/or geography, where current transmission is occurring.[70–72] In 2019, the President's Emergency Plan for AIDS Relief (PEPFAR) introduced recent infection testing for HIV surveillance and resource targeting in their programming. Recency testing is used in cross-sectional surveys, including in Population-based HIV Impact Assessment (PHIA) surveys to estimate HIV incidence. A 2021 review concluded that more research is needed on recency assays within HIV testing services to better understand

interpretation in these settings.[73] While recent HIV infection testing in a programme context can identify which infections are recent or not, the 2022 UNAIDS and WHO guidelines on recency assays suggest that the use of recency testing in programmatic settings for estimating the rate of new infections should only be done in the populations where existing HIV testing coverage of the population being studied is high in order to avoid selection bias.[74]

1.2. Measuring the HIV epidemic

1.2.1. Public health data

Data are the foundation of any public health response. HIV data, collected through epidemiological research, programmes and HIV surveillance, are used to monitor epidemic trends and inform resource allocation and decision making. Early in the epidemic, data were predominantly collected on AIDS cases, with some HIV prevalence estimates from facility based sentinel surveillance, mostly in antenatal care (ANC), based on WHO recommendations in the mid-1980's.[75] In response to improved HIV testing and ART rollout in high income countries in the mid-90s, data on HIV diagnoses started to be collected.[76] Since the early 2000s, countries have been required to provide national estimates on a range of key HIV epidemic indicators including HIV diagnoses, AIDS-related deaths and HIV incidence. Methods for obtaining these estimates include national probability sampled surveys and antenatal care surveillance (sentinel surveillance).[75] Country level processes now exist, with UNAIDS leading the estimates process each year so countries can report on the key epidemic indicators using empirical data and models, providing both national and subnational estimates of the epidemic. Estimates are reported by UNAIDS in their annual epidemic update. While estimates are provided for the general population disaggregated by age group and sex, data on key populations are lacking, generally not collected in population household surveys and in strategic information collected in health system data. Key population data are not currently fed into mathematical models in the same way as general population data.

Early HIV surveillance included cross-sectional serosurveys in sub-populations considered at risk, but often with convenience sampling and no clear indication of a sampling frame.[77] Key populations were not a focus of national surveillance activities until 2000, when UNAIDS recommended second generation surveillance which was tailored to the specific epidemics in each country, focusing more on trends over time, behaviours, sub-populations at higher risk of HIV infection and better use of surveillance data.[77] Despite this shift, where HIV prevalence was >1% in the female population the focus remained on stabilising overall HIV prevalence and not on key populations. Alongside recommendations for strengthening general population surveillance UNAIDS made recommendations in 2007 that annual bio-behavioural surveys should play an important role in monitoring epidemic trends, including analysis of STI surveillance data and additional sero-surveillance in groups considered high-risk.[77]

The concept of *"Know your epidemic, know your response"* came in the late 2000s on the back of recognition that HIV prevention needed to be intensified to achieve universal access.[78] This brought to light the need for more nuanced data on the epidemic in sub-populations. Countries were not required to report data on HIV among key populations until 2006. Key population surveillance-specific monitoring and evaluation guidelines came out in 2007,[79] and in 2008, global HIV reporting guidance recommended that countries consider their specific epidemic dynamics and potential concentrated sub epidemics in higher risk populations.[33] By 2010, 74 countries reported HIV surveillance estimates for sex workers.[80] Key population-specific surveillance guidelines were published in 2011.[81] By 2012, all countries were expected to report on key populations, with 58 countries reporting on the percentage of sex workers reached with HIV prevention programmes in 2012.[33] Since 2014, UNAIDS has published modelled estimates for the percentage of all new adult HIV infections acquired by key populations. However, by 2020, estimates were missing on new HIV infections and testing targets for key populations.[15]

1.2.2. HIV indicators

During the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS in June 2001, UN member states adopted the Declaration of Commitment on HIV/AIDS, providing a framework and core indicators to monitor progress towards the Millennium Development Goal of halting and beginning to reverse the HIV/AIDS epidemic by 2015.[82] In 2005, monitoring guidance and updates (including specific indicators for key populations, which remained largely unchanged until 2010) were: "Percentage who received HIV testing in the last 12 months and who know the results, percentage reached by prevention programs, percentage of most-at-risk populations who both correctly identify ways of preventing the sexual transmission of HIV and who reject major misconceptions about HIV transmission, and percentage of most at-risk populations who are HIV infected".[83] In 2008, 62% of these indicators were reported within the set timeframe.[84] Indicators in the UNAIDS 2016-2020 framework for key populations included HIV incidence, estimates of population size, HIV prevalence, coverage of HIV testing, ART coverage, active syphilis among sex workers, people receiving PrEP and condom use at last high-risk sex.[85]

Many of these indicators[86] have been incorporated into frameworks aimed at better characterising uptake and engagement in HIV services and monitoring global targets. One framework is the care cascade for monitoring sequential progression through services for those who are HIV positive, from knowledge of an HIV positive status to viral suppression.[87] The cascade has been established in the 95-95-95 targets (originally the 90-90-90 targets[87]) to ensure that 95% of people living with HIV have knowledge of their HIV status, 95% of those with knowledge of their HIV status are receiving ART, and 95% of those on treatment have a suppressed viral load (VLS).[54] Both longitudinal and cross-sectional measurement of the care cascade has been estimated with data

from various sources in the general population,[88,89] yet there is a lack of data for FSW, particularly from routine data sources.[90] The first 95 is particularly challenging to measure. In contexts including sub-Saharan Africa where the number of people with HIV and the number diagnosed are not directly counted, mathematical models are used to estimate the first 95 and aggregate test data are used, but often not deduplicated for retesting and re-diagnosis which may be high.[91] Estimates of the undiagnosed fraction come from data on HIV incidence using methods including CD4-depeletion models, biomarkers and test-retest and HIV prevalence from population surveys.[92] Frameworks for monitoring combination HIV prevention approaches are not so well established, in part due to the more complex nature of HIV prevention programming and the lack of obvious sequential stages as with HIV care. Prevention cascade frameworks have included indictors on individual perception of risk, adoption and adherence to HIV prevention tools, identification of populations at risk, and the demand and supply of prevention tools, [93–95] and linked HIV testing and retesting.[96,97]

1.2.3. Data gaps for female sex workers

Beyond the increased political will and shift in global focus on collecting key population data, substantial challenges and gaps in data collection and availability prevail. The efforts to obtain data on key populations and to include them in more targeted surveillance continue to face challenges due to the specific population characteristics. Female sex workers face social, structural, political and legal barriers to accessing services, which not only limits the provision of adequate health care but also the ability to research and monitor the HIV epidemic. Prohibitive legal environments,[27] and stigma and discrimination contribute to their often hidden nature and inability or unwillingness to self-identify, meaning women may not access services or be easily identified for research or surveillance. Sex workers are often transient, with cycles in and out of sex work in addition to significant geographical mobility.[19] The characteristics of sex work and sex workers are not uniform, with sex work varying greatly between and within countries. Defining sex work and sex workers and the conflation or separation of sex work and transactional sex is important for the delivery of HIV services, policy making and the measurement of HIV risk and key epidemic indicators.

1.2.4. Monitoring the HIV response among female sex workers

Monitoring the HIV epidemic and response among FSW is largely constrained by uncertainty around the size of FSW populations. Population size estimates (PSE) are needed to understand progress towards key epidemic indicators and estimate the scale of response required for targeting and recourse allocation, as well as the evaluation of programme impact.[98] A 2016 review of PSE in low and middle income countries found that while they were becoming increasing available for FSW, geographic coverage, extrapolation and methods varied widely.[99] A 2020 review identified

70 PSE for FSW in Africa, but limited use of these estimates to inform national key population programming.[100] While there is no gold standard, approaches to estimating the size of FSW populations include multiplier methods (service and object) and capture-recapture.[98,101,102] Challenges in enumerating FSW populations means that sampling frames do not exist. Approaches to sampling populations with no sampling frame include non-probability methods such as convenience sampling (e.g. using a clinic population), methods that utilise the networks such as snowball sampling and respondent driven sampling (RDS), and time-location sampling (TLS)[103] which uses a probability sampling approach by generating a sampling frame for locations and time when FSW frequent a venue or other location.[104] RDS is an adaptation of snowball sampling, using networks to recruit individuals to a study and statistical adjustments to account for potential bias.[105–111] Network approaches have limitations as they require individuals to be networked and those individuals are more likely to recruit others similar to themselves. TLS uses known locations for a population (e.g. a venue, bar) and the times when those venues will be frequented to sample eligible individuals for a survey. RDS methods have been used to obtain more representative samples for HIV surveillance among key populations,[109,110] as have Priorities for Local AIDS Control Efforts (PLACE), an adaptation on TLS, which is used to identify the locations of populations at higher risk of HIV infection to assess programme coverage, gaps and cascade indicators.[112–114] Other network and venue based sampling approaches are also used. Beyond identifying a representative sample and obtaining denominators, some measures require repeat or longitudinal follow up. While this is a challenge in general populations, it is more of a challenge where among highly mobile FSW populations.[115,116] Mobility may include migration both within and between countries, changes in locations where sex is sold and also temporal cycles into and out of sex work.

Methodological gaps in measuring specific HIV indicators also exist. UNAIDS 2008 monitoring guidance acknowledged the potential bias in reporting HIV prevalence indicators for key populations.[117] A 2019 review identified continued gaps in HIV prevalence data for key populations and only 6/123 countries with nationally representative data available for sex workers.[118] Data are not systematically collected on the numbers of key populations reached with services.[15] Programmatic data and medical record data continue to be insufficiently robust to provide estimates of the 95-95-95 targets for key populations.[119] The rate of new HIV infections is modelled for the general population mostly using HIV prevalence estimates from nationally representative population-based surveys, case-report surveillance (generally in high income settings) or recent HIV infection testing.[120–125] For key populations, the percentage of new adult infections is derived from modelled HIV incidence; in 2021, this was from the combined results of multiple models or imputed from other country estimates in the region.[126]

1.3. Current context and opportunities

Global commitments and HIV goals for key populations, along with efforts to collate key population data and the improvement of methods to obtain better epidemic metrics for key populations, have all seen substantial shifts over the past five years. Recognition of key populations at a global level is fundamental for leveraging political support and resources, and for driving country level programmatic responses. For sub-Saharan Africa, recognition of the importance of targeted HIV responses for key populations has been growing.[127] The UNAIDS 2021-2026 global strategy puts inequality clearly in focus, with a strategic priority to *"maximize equitable and equal access to HIV services and solutions"* and key results areas to address prevention needs, increase knowledge of HIV status and ensure human rights, equality, dignity and freedom from stigma and discrimination.[10] Utilising these commitments will be key to achieving better outcomes for FSW through programming and the leveraging of data to report back on these commitments.

Global efforts to collate key population surveillance data have increased over the past few years, with initiatives including the UNAIDS Key Population Atlas.[80] HIV surveillance, survey and programme data on FSW are increasing, however there are still gaps and challenges in data collection and availability, along with issues of comparability. Long running studies on key populations are yielding trend results, routine data sources are growing and population size estimates for FSW now exist for the majority of countries in sub-Saharan Africa.[80] Alongside these efforts to collate data, there have been continual advances in addressing some of the methodological challenges that exist and increasing calls for the use of routinely collected data in these populations. UNAIDS 2017 indicators guidance suggested that to address some of the data challenges that exist, not only in representative sampling but also logistical and cost challenges, programme monitoring data could be used as an option for certain indictors.[85] Also in 2017, the consolidated guidelines on person-centred case surveillance provided a major recommendation on collecting routine data on key populations, highlighting the issue of confidentiality and that records should not record key population categories (although probable route of transmission can be assessed and recorded for disaggregated data in routine systems).[128] In 2022, WHO published guidance on strategic information use, highlighting the role of routine data in measuring HIV prevalence and incidence for the first time.[76] These guidelines called for a better understanding of new HIV infections and missed prevention opportunities to enable efforts to be focused on the populations most in need of services.[76]

1.4. Zimbabwe

Zimbabwe is a landlocked country in Southern Africa, bordered by Zambia, Mozambique, South Africa, Botswana and Namibia. Zimbabwe recorded a population of >16 million in 2022, of whom 52.8% (8,614,935) were female.[129] Zimbabwe is made up of 10 provinces and 42 districts, although

district borders have changed over the past 10 years. The capital city, Harare, had a population of 1,578,000 in 2023. The second largest city, Bulawayo, had a population of 650,000 in the same year. Life expectancy in Zimbabwe was 56 years in 1980, but fell to 34 among women in 2004[130] due to the impact of HIV and AIDS. In 2023, life expectancy was 62 years. Health services are provided by the government overseen by the Ministry of Health and Childcare (MoHCC).

Zimbabwe has a complex economic history. After independence in 1980, droughts in 1992 and 1995 severely impacted the economy, along with the global economic downturn in the early 1990's. In the 1990s, the World Bank put an Economic Structural Adjustment Program (EASP) in place in Zimbabwe (and other African countries) to boost the economy. Economic declines from 1997 led to hyperinflation and the introduction of the USD. GDP was nearly halved by the political and economic crisis between 2000 and 2008, with poverty rates reaching over 72%. The economy recovered between 2009 and 2012 but slowed between 2012 and 2015.[129,131] Zimbabwe has seen another economic decline in more recent years with the Covid pandemic and other global financial crashes.

1.4.1. Sex work in Zimbabwe

FSW population size estimates were conducted in Zimbabwe in 2017 and in 2023. The number of FSW in Zimbabwe was estimated to be 40,491 (plausibility bounds 28,177-58,797), approximately 1.23% (plausibility bounds 0.86-1.79%) of all women aged 15-49 in 2017.[101,132] By 2023 this had increased to 70,423 (plausibility bounds 59,271–79,518) and 1.58% of women 15-49 (1.33%–1.79%).[133] In Zimbabwe sex work is not illegal in itself, but the solicitation of sex or facilitating sex work (e.g. running a brothel) are both criminal offences.[134] However, sex work is generally perceived to be illegal.

RDS surveys conducted in 2013 and 2016 found the median age for women starting sex work was 23 and 24 respectively. Approximately 50% of FSW surveyed in those years rely solely on sex for their income.[19] Women report having a median of 5 clients in the previous week and bars as the primary location for solicitation.[19] Changes in sex work in Zimbabwe are thought to be linked to changes in the economic context, with low demand for sex work and lower number of clients reported in the early 2000s with the economic downturn, and higher numbers of clients reported by sex workers from 2009 with economic recovery.[131] Mobility among FSW in Zimbabwe is high, with 81% of FSW surveyed in 2016 reporting some level of mobility in the preceding 12 months. This included travel away from the survey site or staying away from the survey site during that period, but was mostly within Zimbabwe. The main reason for mobility was to find clients with more money (57%) or to find more clients (39%).[19]

1.4.2. HIV in Zimbabwe

In 2022, adult HIV prevalence in Zimbabwe was 11.0% (9.8 - 12.0)[80] with variation by district.[135–137]. There were an estimated 750 000 (690 000 - 820 000) women living with HIV in Zimbabwe in the same year, translating to 13.7% (12.2 - 15.0) prevalence among women aged 15-49. Overall HIV prevalence has substantially declined from the height of the epidemic in Zimbabwe in 1997 when the adult HIV prevalence was estimated to be 26.5%. Among women accessing antennal care, HIV prevalence declined from 2.1% in 2000 to 23.9% in 2004.[138] Among women presenting for antenatal care in Harare, it was estimated that HIV incidence peaked at 5.5% per year in 1991, declining to 1% by 2010.[139] Recent HIV infection testing estimates for HIV incidence among 15-49 year old adults in Zimbabwe in the 2015-2016 PHIA survey of 0.44% (95% CI: 0.25–0.62) were similar to Spectrum estimates from the same year (0.54%, 95% CI: 0.49–0.66).[140] HIV incidence was 1.68 (1.17 - 2.32) per 1000 person years (py) in 2022, a decline from the 5.4 per 1000 reported in 2017.[80] In 2020, HIV incidence estimated from recency testing in a national household survey was higher among women at 0.68% per 100py (95% CI 0.34-0.99) than among men at 0.54% per 100py (95% CI 0.28-0.81).[137] Zimbabwe is on track to meet the 95-95-95 targets for the adult population, with an estimated 95% (87 - >98) of the population with knowledge of their HIV status, 94% (86 - >98) on ART, and 89% (82 – 97) with suppressed VL.[80] HIV prevalence among FSW has been estimated in RDS surveys at 57% in 2011, 54.8% in 2016 and 46.2% in 2021. Knowledge of HIV status was thought to be 75.4% and ART coverage 83.3% in 2020.[80] UNAIDS reported 34.5% coverage of FSW with prevention programmes in the same year.[80]

1.4.3. HIV policy and programmes in Zimbabwe

My PhD analysis uses data covering a 13-year period. During this time there have been global changes in policy recommendations for FSW service delivery and HIV testing, outlined earlier, and corresponding national changes in policy in Zimbabwe. Zimbabwe specific HIV policies have followed global guidelines, with key HIV testing strategy documents published in 2005,[141] 2014[142] and 2022.[143] National HIV strategic plans in 2011-2015,[144] 2015-2020[145] and 2021-2025[146] have guided Zimbabwe's HIV response. The 2011-2015 plan included priorities for targeting key populations through HTS, behaviour change communication and condom promotion and community strengthening through the provision of resources to non-governmental organisations working with key populations.[144] The 2015-2020 plan focused on prioritising sub-populations and geographical areas, under which there were priorities including key population size estimates, peer-led models to deliver comprehensive HIV prevention, treatment and support including the roll-out of microplanning (peer-led risk-differentiated service delivery for FSW, shown to have impact in FSW programmes in India[147,148], and now more widely implemented in Africa[149]) and tailored services for young women selling sex.[145] The latest strategic plan includes programming for key and vulnerable populations as one of its five key strategic priorities.[146]

Key population programmes are delivered by a number of providers across Zimbabwe. CeSHHAR has the widest coverage of any key population programme in the country. The second largest provider of services for FSW is Populations Solutions for Health (PSH) (formally Population Services International Zimbabwe (PSI)). PSH have a large key population focused HIV prevention and treatment programme covering Bulawayo (Bambanani), Harare (NAH), Chitungwiza, Mutare, Gweru and Masvingo. Other large organisations incorporate key populations in their programmes but are not necessarily targeted at them. These include: the Family AIDS Care Trust (FACT) who provide services mostly in Manicaland and Masvingo; the Organisation for Public Health Interventions and Development (OPHID); Zimbabwe Health Interventions (ZHI) (formally Family Health International (FHI)) which was established in 2019 and provides services for adolescent girls and young women; Pangaea Zimbabwe AIDS Trust (PZAT) who, funded by the CDC, provide programme coverage in provinces in including Bulawayo and Harare; and Médecins sans Frontières (MSF) who work with sex workers in Harare and have collaborated with CeSHHAR on transport to deliver services in less accessible geographic locations. Lastly, there are a number of smaller, community based and predominantly advocacy focused organisations working with key populations in Zimbabwe. These include Hands of Hope (who work with PSH) and Women against all forms of Discrimination (WAAD). An understanding of the other actors and services provided for FSW in Zimbabwe may provide insight into some of the service engagement patterns I later describe in my results chapters.

1.5. Rationale

Gaps exist in knowledge on HIV testing and on new HIV infections among FSW in Zimbabwe and across sub-Saharan Africa, with a limited understanding on how these have changed over time. Knowing where new and recent HIV infections are occurring will help us better target HIV services to those in most need. This can be done through the measurement of key HIV indicators on HIV testing and new infections, which help monitor progress towards global HIV targets and inform programmatic and policy decisions. As approaches such as cohort studies become increasingly impractical, alternatives to obtaining these estimates for FSW populations need to be explored. Routinely collected programme data is one source that could be used more effectively. Understanding the type of information that can be obtained from programme data and the bias that exists can give us a clearer indication of how useful these data are for monitoring key HIV indicators and informing programmatic decisions. Further research on the use and approaches to the analysis and interpretation of these data are needed if we are to improve our understanding of the HIV epidemic among FSW, reduce inequalities and the number of new HIV infections.

2. AIMS AND OBJECTIVES

The aim of my PhD is to understand trends in HIV testing and in new and recent HIV infections among female sex workers in Zimbabwe and explore methods for the analysis of routinely collected clinic data to measure HIV epidemic indicators and inform programme delivery. To meet this aim I addressed the following objectives:

1. To review existing published literature to understand trends over time in knowledge of HIV status among female sex workers in sub-Saharan Africa;
2. To review existing estimates of HIV incidence among women who engage in sex work in sub-Saharan Africa and explore levels and trends over time;
3. To analyse trends in HIV testing and test-positivity among female sex workers accessing targeted HIV testing services between 2009 and 2019 in CeSHHAR's KP Programme in Zimbabwe;
4. To analyse levels and temporal trends in the rate of HIV seroconversion among female sex workers accessing targeted HIV testing services between 2009 and 2019 in CeSHHAR's KP Programme in Zimbabwe;
5. To explore recent HIV infections using a recent HIV infection testing algorithm among female sex workers testing HIV-positive in CeSHHAR's KP Programme in Zimbabwe and estimate HIV incidence.

My PhD contributes knowledge on HIV testing and on new and recent HIV infections among female sex workers in Zimbabwe and how these have changed over time. By appraising the methods used to obtain epidemic metrics for FSW in sub-Saharan Africa in my reviews and by using quantitative methods to analyse programme data in Zimbabwe, my PhD makes an important contribution to discussions on the opportunities for using routinely collected clinic data to understand epidemiological trends in this context. More broadly, my thesis contributes to a growing body of work on epidemic surveillance and monitoring of HIV among key populations in sub-Saharan Africa.

2.1. Thesis structure

2.1.1. Chapter 1 Introduction

My first chapter provides the introduction to my thesis, with a background to the HIV epidemic and sex work, specifically in Zimbabwe. I introduce the historical and current context around measuring the HIV epidemic; exploring the use of HIV indictors and how globally the HIV response has been monitored for key populations, including FSW. I give an overview of the current HIV targets and commitments for key populations and the opportunities that exist. Lastly I provide a rationale for the research I have undertaken for my PhD.

2.1.2. Chapter 2 Aims and objectives

In this chapter I summarise the overall aims and objectives of my PhD and the contribution my thesis makes to knowledge in this area of research. I outline the overall structure of my thesis, and provide a summary of each chapter.

2.1.3. Chapter 3 Literature reviews

My first chapter includes two reviews of literature relevant to my first two research objectives. Both reviews are for sub-Saharan Africa and provide context for my subsequent chapters analysing data from Zimbabwe. The first is a systematic review of knowledge of HIV status among FSW in sub-Saharan Africa in which I aim to identify empirical estimates and understand temporal trends in this metric up to November 2023. The second is a literature review and meta-analysis of HIV incidence estimates for FSW in sub-Saharan Africa. I co-authored this review with colleagues at Imperial College London with the aim of synthesising and appraising empirical estimates of HIV incidence up to December 2022 among women who engage in sex work (WESW) in sub-Saharan Africa, estimate relative HIV incidence between WESW and the total female population for West and Central Africa (WCA) and East and Southern Africa (ESA), and estimate the change in relative HIV incidence over time. This was a collaborative piece of work and details of the specific contributions I made are summarised in chapter 3. This review was published in *The Lancet Global Health* in August 2024.

2.1.4. Chapter 4 Methods

In this chapter I give a summary of my PhD methods with additional details on the delivery of CeSHHAR's KP Programme in Zimbabwe, the main source of data for my thesis. I provide detail on the programme's data collection processes and the data management that I conducted to obtain an analysable dataset. I also give a summary of the methods I used for my analysis. Further details of my analytical approaches are presented in each of my results chapters.

2.1.5. Chapter 5 Results: HIV test-positivity

In my first results chapter I address research objective two and present an analysis of HIV testing patterns and test-positivity among FSW accessing sexual and reproductive health services though the KP Programme between 2009 and 2019. The aim of this analysis was to understand trends in HIV test-positivity during this period and identify the individual and service delivery factors influencing them. I sought to identify how trends in seroconversion among repeat testers could build on our interpretation of test-positivity as an indicator of programme performance. This paper was published in the *Journal of the International AIDS Society* (JIAS) in June 2022.

2.1.6. Chapter 6 Results: HIV seroconversion rates

In this chapter I meet objective four, presenting work on the identification of new HIV infections in the KP Programme data through use of repeat HIV test data for individual FSW. The aim was to understand trends in HIV seroconversion among women who underwent repeat testing within the KP Programme between 2009 and 2019, to identify risk factors associated with seroconversion, and to assess and minimise potential biases of measuring seroconversion rates from programme data. Here I estimate HIV seroconversion rates over the 10-year period of implementation. This analysis was published in *The Lancet HIV* in June 2023.

2.1.7. Chapter 7 Results: Recent HIV infections

In this final results chapter I analyse data from a 24-month study of a recent HIV infection testing algorithm in the KP Programme and calculate incidence for the period of programme implementation between October 2021 and March 2023. Here I present the findings of RITA implementation and explore the opportunities and programmatic benefits of identifying recently acquired HIV infections in the context of a national sex worker programme. This paper has been revised based on a first round of reviewer comments and is currently under a second review at the *Journal of the International AIDS Society*.

2.1.8. Chapter 8 Discussion

In my discussion chapter I summarise the key findings from my literature reviews and each of my results chapters on HIV test positivity, HIV seroconversion rates calculated from repeat HIV testing data, and recent HIV infection testing in a Key Population programme context. I reflect on the strengths and limitations of my PhD focusing on the generalisability of my findings, potential bias in the data, and my analytic assumptions. I discuss the interpretation of my PhD as a whole, linking my work from each chapter to discuss HIV test-positivity and knowledge of HIV status, identifying

new and recent HIV infections, and the use of routinely collected clinic data for HIV surveillance among FSW. I consider the implications of my findings for informing sex worker programmes and the collection and use of routine programme data and suggest areas for future research. I lastly draw some overall conclusions from my PhD.

3. LITERATURE REVIEWS

In this chapter I present two reviews of current literature on FSW in sub-Saharan Africa to situate the analysis I have done in Zimbabwe in what we know about FSW in the region. The first is on knowledge of HIV status among FSW in sub-Saharan Africa with searches up to November 2023. The second is a review I contributed to on HIV incidence among FSW in sub-Saharan Africa, with searches up until December 2022; this review includes some of the Zimbabwe data I have analysed in my PhD. In both reviews the quantitative findings are of interest, as well as the wide variation in how estimates are obtained.

How have trends in knowledge of HIV status changed over time among female sex workers in sub-Saharan Africa? A systematic review of the literature between 2009 and 2023

Harriet S Jones, Henry Cust, Frances M Cowan, Lucy Platt, Bernadette Hensen, James R Hargreaves

PLOS Global Public Health (in submission)

3.1. Review 1: Knowledge of HIV status

There are gaps in current knowledge and a lack of systematic reviews of existing research on the identification of HIV infections among FSW in sub-Saharan Africa, specifically the proportion of FSW that have been diagnosed and are aware that they are HIV positive. Understanding the first 95% of the UNAIDS 95-95-95 targets is fundamental if we are to get a grasp on how well we are doing at closing the gap of those yet to be diagnosed. Similarly we know very little about the rate of new HIV infections among FSW in the region and, for both of these metrics, how things may have changed over time. As I highlighted at the start of my introduction, the calls for more data on HIV among FSW are still very relevant.

Reviews synthesising existing data have focused on the burden on HIV among FSW and either uptake of HIV testing, the availability of cascade data or later components of the care cascade. Three reviews highlight the lack of cascade data for FSW. Mountain *et al* characterised the care cascade globally for FSW in 2014. They identified 24 cascade estimates in 5 countries in Africa (Benin, Burkina Faso, Kenya, Rwanda and Zimbabwe). They looked at HIV treatment, but found a

lack of published data for FSW. The limited data they were able to find suggested that uptake, retention and adherence were good. They conclude that *"more routine programme data on HIV treatment among FSWs across settings should be collected and disseminated."*[90] Risher *et al* also characterised the care cascade for key populations globally in 2015. They identified only 3 countries in Africa with FSW cascades (Zimbabwe, Burkina Faso and Togo and Malawi) and found poor cascade outcomes.[150] Hakim *et al* published a commentary in 2018 on the availability of care cascade data for key populations, searching published and BBS survey data and identifying only 5 countries in Africa with cascade data for FSW. They highlight the gaps in survey-derived cascade data for FSW and other key populations.[151]

I sought to augment my understanding of the availability of data on the first 95 in my literature review and see if more data were available and we could move towards an understanding of how knowledge of HIV status among FSW has changed over time. I synthesise data on the percentage of HIV-positive FSW aware of their HIV-status in sub-Saharan Africa from 43 estimates collected between 2002 and 2020. Awareness of HIV status ranged from 4% to 95.2% with substantial heterogeneity across studies. Median knowledge of HIV status was lower at before 2013 but showed no difference between 2013-2016 and from 2017 onwards. Evidence of heterogeneity with time periods made further interpretation of trends over time challenging. Regional differences were more apparent although still not clear to ascertain, with higher knowledge of HIV status reported in East and Southern Africa compared to West and Central Africa. The review I present in this chapter is the version I am in the process of submitting to PLOS Global Public Health.

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Student ID Number	378549	**Title**	Ms
First Name(s)	Harriet		
Surname/Family Name	Jones		
Thesis Title	Measuring trends in HIV testing and new HIV infections among female sex workers in Zimbabwe		
Primary Supervisor	Professor James Hargreaves		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

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Stage of publication	**Undergoing revision**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceived and conducted the systematic review. Henry Cust was a second reviewer supporting with screeing and reviewing included papers. I wrote the manuscript and incoprtated peer reviewer commnets. Co-authors provided input on this work by way of progress meetings and review of the manusript.

SECTION E

Student Signature	[redacted]
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Supervisor Signature	[redacted]
Date	28/02/2024

How have trends in knowledge of HIV status changed over time among female sex workers in sub-Saharan Africa? A systematic review of the literature between 2009 and 2023

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Keywords: Sex Workers, Africa, HIV epidemiology, HIV status, Key and vulnerable populations

3.2. Abstract

HIV testing and subsequent knowledge of HIV status is critical for linkages to care and provision of targeted prevention services. In sub-Saharan Africa, female sex workers (FSW) bear a disproportionate burden of HIV, yet it is unclear if we are on track to meet the UNAIDS first 95 target, knowledge of HIV status, for FSW in the region. We systematically reviewed published literature to identify empirical estimates and understand trends in knowledge of HIV status among FSWs in sub-Saharan Africa.

We searched Medline, EMBASE, Popline, Web of Science and Global Health for studies published between 1990 and 2023 using medical subject headings (MeSH) and text words for: 'Female sex worker', 'HIV' and 'sub-Saharan Africa'. Eligible studies reported the proportion of HIV-positive women who exchanged sex for goods or money aware of their HIV status in any sub-Saharan African country. We conducted meta-analyses by region and time-period and appraised studies on inclusion criteria and study recruitment.

Our review included 35 papers published over 18 years. We identified 43 estimates of knowledge of HIV status from 23 countries for 37,438 FSW. Median knowledge of HIV status was 54.9% (IQR 29.3-68.6), with estimates ranging from 4% to 95.2% and no clear trend over time. Regional differences were more apparent with a higher median of 58.1% of FSW with knowledge of their HIV status in East and Southern Africa, compared to 41.0% in West and Central Africa. There was considerable variation in study aims, recruitment and inclusion criteria, making further interpretation challenging.

Despite an increasing number of studies reporting knowledge of HIV status among FSW there remain country level gaps and a limited number of repeat studies in the same geographic locations and study populations. Our review highlights the heterogeneity in estimates of the first 95 and need for improved HIV surveillance among FSW to understand if we are on track to meet global targets.

3.3. Background

HIV testing and subsequent knowledge of HIV status are essential for initiating individuals on antiretroviral therapy (ART) for their own health and reducing HIV transmission.[152] Female sex workers (FSW), defined by UNAIDS as women who receive money or goods in exchange for sexual service*s,* bear a disproportionate burden of HIV. [4,17] Globally, FSW were estimated to have 30 times the risk of acquiring HIV than adult women in the same population in 2021.[2] Modelling estimates have attributed high numbers of HIV infections to unsafe sex work.[3,4] Preventing new HIV infections in sex work and supporting HIV-positive FSW to access services is critical for reducing new HIV infections by 2030 and beyond.[8]

In 2014 UNAIDS introduced the 90-90-90 targets,[87] now 95-95-95, with the aim of the first 95 to reach 95% of people with HIV aware of their HIV-positive status by 2030.[54] Estimating the proportion of people aware of their HIV status is challenging and requires estimates of the number of people are living with HIV and how many are diagnosed. In sub-Saharan Africa knowledge of HIV status is typically estimated from testing data and serology in nationally representative population-based surveys, including Demographic and Health Surveys (DHS), AIDS Indictor surveys,[153] and more recently from direct questions on knowledge of HIV status in Population-based HIV Impact Assessment (PHIA) surveys. Measuring knowledge of HIV status among FSW presents additional challenges. FSW face social and structural barriers including stigma, discrimination, and prohibitive legal environments,[27,47] reducing access to HIV services. Nationally representative surveys do not exist for FSW and robust estimates of HIV status awareness much harder to ascertain due to imprecise population size estimates[154] and a lack of systematic HIV testing and routine data collection systems.

Global efforts to collate key population surveillance data include resources such as the Joint United Nations Program on HIV/AIDS (UNAIDS) Key Population Atlas. However, gaps remain and understanding the nuances in data sources and the extent to which data are comparable or representative of the wider FSW population from which they are sampled. Consequently it is unclear if we are on track to meet global targets on knowledge of HIV status for FSW populations, essential if we want to address HIV testing and programming gaps, initiate HIV-positive FSW on treatment and reduce HIV transmission. We conducted a systematic review of published literature between 1990 and 2023 to identify empirical estimates and understand temporal trends in knowledge of HIV status among FSWs living with HIV in sub-Saharan Africa.

3.4. Methods

3.4.1. Searches

Medline, EMBASE, Popline, Web of Science and Global Health were searched in June 2019 using medical subject headings (MeSH) and text words covering three concepts: 'Female sex worker', 'HIV' and 'sub-Saharan Africa', searched for together. MeSH terms, syntax and Boolean operators were adapted for each database (Appendix 1). Searches were updated using the same search terms on 8th November 2023. We used broad searches acknowledging that there are several terms used to describe sex work. Our search strategy was peer reviewed by a librarian. A study protocol was registered with PROSPERO, the National Institute for Health Research International prospective register of systematic reviews on 2 January 2020 (registration number CRD42020162769).

3.4.2. Study inclusion

Studies were eligible for inclusion if they: reported an estimate of the proportion of FSW with knowledge of their HIV status, defined as the proportion of HIV-positive women who self-reported knowing they were HIV-positive among those testing HIV-positive in the study; presented the numerator and denominator for the outcome; were published in English between 1990 and 2023 and were conducted in sub-Saharan Africa. All study designs were included, but needed to include a biological HIV test and a sample of HIV-positive FSW greater than 20. Where the same estimate was reported in multiple publications a main paper was selected for inclusion and papers with duplicate estimates, or data on a sub-set of the full study population excluded.

3.4.3. Reference screening

References were screened in two stages. An initial title and abstract screening was conducted by the first author (HJ) to exclude articles that clearly did not meet the inclusion criteria, including conference abstracts, studies not in sub-Saharan Africa and those on topics other than HIV and FSW. Abstracts of the remaining references were subsequently screened by the first author (HJ) and independently by a second reviewer (HC). Eligible references were selected for full text review. The agreed references for full text review were screened by the first author (HJ), and approximately 25% (n=40) selected at random and screened independently by the second reviewer (HC) to check if inclusion matched. Any discrepancies in the two independent review stages were discussed between the two authors. We judged there to be good agreement on inclusion based on this sample, and therefore did not do a second independent screening for the remaining 75% of articles.

3.4.4. Data Extraction

Standardised forms were developed in Excel to record study characteristics and provide a template for data extraction. We first extracted data on the study design, sample size, sample recruitment, inclusion criteria (including definition of sex work), study setting (geographical location and programmes context), data collection dates and methods. Data were then extracted on the sample characteristics including age, HIV testing history, the percentage of HIV positive FSW in the study and the outcome of interest: the percentage of FSW with knowledge of their HIV status. We recorded the weighted study percentage where this was presented and where a percentage was not presented this was calculated from the available data. Data extraction of the main outcomes was carried out independently by two reviewers (HJ, HC) for a randomly selected 20% of included papers and all included papers from the updated search (n=18) to check agreement.

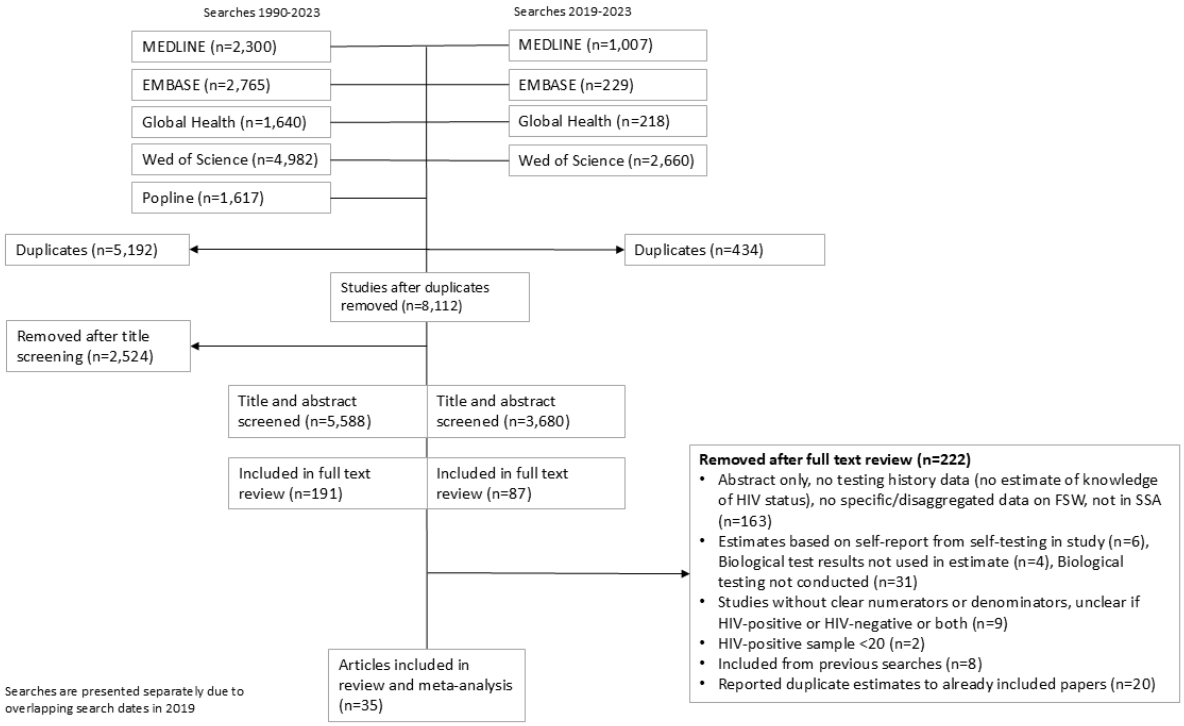
3.4.5. Data Synthesis

We first summarised the main study characteristics, including study period (data collection dates), location (region, country), and study context (e.g., whether there was a targeted FSW programme in the study location), inclusion criteria and study aims. For each study we summarised the percentage of HIV positive FSW included in the study and HIV testing history. We conducted a meta-analysis for proportions with random effects using Metaprop in STATA SE/18.0 by geographic region (East and Southern Africa, and West and Central Africa) and by time period (≤2013, 2013-2016, ≥2017). We further explored estimates of knowledge of HIV status by narratively describing our findings in the context of differences in study populations (age and inclusion criteria), sampling strategies and implementation and study context.

3.5. Results

We retrieved 11,792 references (Figure 1). After excluding 2,524 references on title screening, we reviewed 9,268 abstracts and included 278 (3.0%) papers in our full text review. Papers were excluded at full text review if they did not include estimates on FSW populations (67.1%, n=163), reported knowledge of HIV-status without biological HIV testing (14.4%, n=35), presented unclear numerators and denominators (3.7%, n=9), had fewer than 20 HIV-positive FSW in the study (<1%, n=2), or presented duplicates estimates of included papers (8.2%, n=20) (Figure 3.1).

Figure 3.1.1 PRISMA flow diagram of included studies



3.5.1. Study characteristics

Our review included 35 published papers, reporting 43 estimates of knowledge of HIV status from studies conducted between 2002 and 2020. Only two studies started before 2010[155,156], with study frequency increasing to ≥3 each year between 2010 and 2019. Included studies reported on 37,438 FSW, with sample size ranging from 106 to 5390. Over two thirds of study estimates were in East and Southern Africa (n=33), with the majority in Zimbabwe (n=6) and then three in each of South Africa, Malawi, Mozambique and South Sudan. Ten estimates of knowledge of HIV status were from West and Central Africa. Estimates were mostly from sub-national studies conducted in urban locations. Exceptions included studies in Zimbabwe, South Africa and Benin which conducted surveys in multiple locations nationally.

Twelve publications explicitly aimed to present data on the care cascade. Twelve focused on measuring HIV prevalence and risk factors for HIV. Other papers presented analyses of substance use and HIV infection[157] sexual violence[158] and family planning, antenatal care, pregnancy, or motherhood.[159–162] Study inclusion criteria varied by age, the length of time living in a specific geographic location and the time since last selling sex (Table 3.1). Most studies included FSW ≥18 years old (n=12), seven included FSW ≥15 years old, and one FSW ≥14 years old. Two studies included girls from the age of 13 years old and another three stipulated young age ranges (14-24 years, 16-19 years and 18-24 years). In three cases age was not stipulated,[29,155,163] and one study excluded women over 49 years old.[160,161,164] In all but two studies inclusion criteria gave parameters stipulating the period of time for selling sex.[29,163] Most studies included women who had sold sex in the preceding six (n=11) or 12 months (n=8). Others stipulated the past month (n=6), three months (n=2), currently (n=2), ever (n=2) or as a participant's main source of income (n=2).

Table 3.1.1 Characteristics of included studies

Author (publication date)	Country (location)	Inclusion criteria	Study design and sampling	Study setting
Abrahim (2023)[165]	Ethiopia (Addis Ababa)	Females aged ≥15yrs receiving money or other benefits in exchange for sex in the last 30 days, lived in the city for at least 1 month, provided consent for participation, possessed a valid coupon	Cross-sectional RDS survey. All FSW residing in Addis Ababa were targeted for study enrolment. Seed selection (number/type) determined by a formative assessment	Drop in centres providing comprehensive HIV prevention, care, and treatment services for FSW were established in Addis Ababa in 2016
Augusto Ado (2016)[166] [c]	Mozambique (Maputo, Beira, Nampula)	Biologically female, ≥15yrs, received money in exchange for sex from someone other than a steady partner past 6 months, resided or socialised in the survey area [a]	Cross-sectional biobehavioural RDS survey. Formative research (ethnographic mapping/key informant interviews) conducted to identify FSW networks and inform peer recruitment	No report of an existing programme. Only small convenience sampled surveys previously carried out
Bolo (2023)[167]	South Sudan (Wau, Yambio)	Females ages ≥13 years, who exchanged sex for goods or money in the previous 6 months, residing in Wau or Yambio for at least one month, and had a valid recruitment coupon	Cross-sectional bio-behavioural RDS survey. Seeds were peers selected based on their nationality, age, influence, and residence duration in the towns	HIV service providers report sex workers being active but no bio-behavioural surveys have previously been conducted
Bossard (2022)[168]	Malawi (Fatima, Bangula, Nsanje Mboma)	Women ≥13 years, living and/or working in the district for the previous six months, who had sexual intercourse with someone (other than their main partner) in exchange for money or goods in the last 30 days	Cross-sectional RDS survey. 3/5 study sites purposively selected. Seed selection conducted through community outreach to represent ≤19 and >19 year olds and those with/ without previous engagement in MSF activities or care	Since 2013, MSF has provided HIV, TB, and sexual and reproductive health (SRH) prevention and care services to FSWs in all study sites
Bowring (2019a)[169] [d]	Cameroon, (Bamenda, Bertoua, Douala, Kribi, Yaounde)	Sex work as main source of income in the past year, assigned female at birth, ≥18yrs, speaks and understands French or English, and lived in the city of recruitment for at least 3 months	Cross-sectional RDS study. Seeds selected through formative research and mapping which considered their understanding of recruitment, ability to recruit and interest in being recruited	FSW recruited for the study as part of the Continuum of Prevention, Care and Treatment (CoPCT) of HIV/AIDS with most at risk Populations (CHAMP) project
Coetzee (2017)[170]	South Africa (Soweto)	Biologically female, >18yrs, currently engaged in the sale of sexual services in Soweto, tested HIV-positive and had a successful viral load measure	A sub-sample of participants with successful viral load testing from the larger cross-sectional RDS survey	Study nested in an existing sex work programme at a perinatal HIV research unit in Soweto

Cowan (2019)[6] [e]	Zimbabwe (national)	FSW that had exchanged sex for money in the past 30 days, were aged ≥18, and had been working in the interview site for at least six months (30 days for Harare, Bulawayo and one rural site)	Multiple pooled cross-sectional RDS surveys. Mappings conducted in all sites with purposive selection of seeds representing a mix of ages, sex work types and geographic locations.	Surveys conducted in communities were targeted FSW programming had been implemented since 2009
Doshi (2018)[171]	Uganda (Kampala)	≥15yrs at the time of recruitment, living in greater Kampala, and sold sex to men in the preceding 6 months	Cross-sectional RDS survey. Seeds identified and enrolled by survey staff, FSW well-connected within networks, well regarded by peers, sympathetic to the survey goals, diverse in education, socioeconomic status, age, residence	Standalone survey to assess uptake of services by FSW in Kampala. Unclear if a specific FSW programme was in place
Goldenberg (2016)[172] [f]	Uganda (Gulu)	≥14 years and commercially exchanged sex for money or resources in the previous month	Cross-sectional TLS survey. Conducted through peer/SW led outreach to bars/clubs, lodges, hotels and truck stops. Sampling frame generated from ethnographic mapping and outreach planning (places sampling unit). IDP camps sampled to supplement the other locations	Survey conducted though The AIDS Support Organisation (TASO) and in IDP camps. Part of the Gulu Sexual Health Study
Hakim (2022)[173] [g]	South Sudan (Juba, Nimule)	Girls and women aged ≥15 years; spoke English, Juba Arabic, or Kiswahili; received money, goods, or services in exchange for sex in the past 6 months; resided, worked, or socialized in the survey city for at least the last 1 month	Cross-sectional RDS bio-behavioural survey. Seeds selected on age, neighbourhood, nationality, and influence among peers. Additional seeds added to reach underrepresented populations	Stand-alone survey conducted by the South Sudan Ministry of Health (MOH) - The Eagle Survey. Unclear if there was an existing programme
Hensen (2019)[174]	Zimbabwe (6 sites)	Aged 18 to 24, had sold sex (defined as sex in exchange for money and/or material support, and that the sex act would not have happened in the absence of an exchange) in the past month, and were not planning to move from the site within the next six months [b]	Cross-sectional RDS survey. Seeds selected through community mapping in four comparison sites and two DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored and Safe) Partnership sites to be representative of the population of young women who sell sex in each site	A national HIV prevention and treatment programme for FSW, “Sisters with a Voice,” provides support and services, including HIV testing, community mobilization activities and condoms
Herce (2018)[175]	Malawi (Lilongwe) Angola	≥15 years old (≥18 years in Malawi), new to the study and not intoxicated. Female, received money for sex in the last 6 months or identified as a FSW	Cross-sectional survey. Venue based sampling using the PLACE methodology	PEPFAR-funded LINKAGES programme in place to improve access to prevention & care

Holland (2016)[176] [h]	Burkina Faso (Ouagadougou, Bobo Dioulasso) Togo (Lome, Kara)	Female at birth, ≥18yrs, majority of income from sex work in past 12 months, lived in city for past 3 months	Cross-sectional RDS survey. Separate RDS sampling at each site. Seeds purposively selected to be demographically diverse	Standalone survey. Unclear if existing programme in place
Ingabire (2019)[163]	Rwanda (Kigali, Kasane in Chobe district)	Any woman exchanging sexual favours for money	Cross-sectional survey. Recruitment in known hotspots in neighbourhoods surrounding the Kigali research centre by a community health worker (formerly a FSW) and additional snowball sampling	PSF initiated programme to provide reproductive health services to FSW from Kigali's urban areas
Johnston (2013)[177]	Mauritius (Port Louis, Curepipe)	Females who reported having vaginal, anal or oral sex with a man in exchange for money or goods in the last 6 months, ≥15yrs, living in Mauritius and in possession of a valid coupon	Cross-sectional RDS bio-behavioural survey. Seeds identified through key contacts to reflect geographic, age, type of sex work, levels of risk behaviour, marital status and educational diversity	Standalone survey. Unclear if existing programme in place
Jonas (2020)[178]	Namiba (Katima Mulilo,Oshikango, Swakopmund/ Walvis Bay, Windhoek)	Persons who self-identified as female, were aged 18 years or older, exchanged sex for money in the past 30 days, and resided in one of the study cities for at least the past 6 months	Cross-sectional RDS survey. Seeds well-connected to FSW, diverse in marital status, sexual identity, engagement in sex work, age, employment status, income, and known access to FSW-friendly services	Study cities chosen on data indicating high concentrations of FSW and organizations working with FSW able to receive referrals for HIV care and prevention
Kerrigan (2017)[179]	Tanzania (Iringa)	Women ≥18yrs who reported exchanging sex for money in the last month	Phase II community RCT baseline survey. TLS used to recruit workers from entertainment venues identified from an updated mapping exercise across two communities	Baseline survey for a phase II trial of a community-based model of combination HIV prevention among FSW - Project Shikamana
Lancaster (2016a)[157] [i]	Malawi (Lilongwe)	Someone who had received money in exchange for sex either regularly or occasionally up to 12 months prior to the survey. ≥18 years old, self-reported FSW	Cross-sectional evaluation using purposive venue-based sampling with systematic recruitment of individuals. Venues identified through community mapping across Lilongwe in locations where women solicited sex	Standalone survey. Unclear if existing programme in place.
Lindman (2020)[180]	Guinea-Bissau (Six cities and Bissau)	Biologically female, ≥16yrs, self-reported engagement in selling sex in last 12 months, giving oral and written informed consent to participate	Cross-sectional survey. Venue-based recruitment (Bissau) and peer-based chain-referral (six cities outside Bissau) Participants required to come to a mobile clinic in the daytime	Standalone survey. Unclear if existing programme in place. Limited information exists on the HIV care continuum among FSW in Guinea-Bissau

Longo (2018)[29]	Central African Republic (Bagui)	Sexually active women in well-known areas of sexual transactions in Bangui having more the 2 sexual partners during the last 3 months and reporting receiving money or gifts in return for sexual relationships	Cross-sectional survey. Peer educator recruitment to a clinic in pre-identified locations where women were known to engage in transactional sex (dance halls, secondary schools, universities - identified in an earlier survey)	Standalone survey conducted through the Centre National deRéférence desMaladies Sexuellement Transmissibles etduSIDA (CNRMST/SIDA) – main clinic for HTS/STI management
Lyons (2018)[158] [j]	Cote d'Ivoire (Abidjan)	≥17yrs, assigned female at birth, engaged in sex work as a primary source of income within the past year. Lived primarily in Abidjan for at least 3 months, able to provide informed consent, spoke French or English	Cross-sectional RDS survey	Standalone survey. Unclear if existing programme in place
Ma (2020)[181]	Kenya (Mombasa)	Cis-gender female aged 14–24yrs who reported engaging in vaginal or anal sex at least once in their lifetime. Classified as YFSS if they self-identified as a sex worker or reported ever soliciting and receiving money, gifts, or other goods in exchange for sex, such that the price or commodity was negotiated before sex	Cross-sectional biobehavioural survey. Self-weighting sample using probablity proportional to size at hotspots. Mapping and enumeration of hotspots to estimate the number of AGYW and generate a sampling frame. Outreach workers or a peer-educator invited potential participants to the survey	Existing programmes in Kenya designed for all AGYW or FSW, not specifically high-risk AGYW. Venue-based HIV testing at hotspots not implemented before 2018 and sex worker programs not allowed to provide services for women <18
Milovanovic (2023)[182] [k]	South Africa (national)	≥18 years of age, actively engaged in the sale/transaction of sex for financial benefit at the time of the study, had sold/transacted in sex in the six months preceding the study and were cis-gender female	Cross-sectional survey of FSWs using chain referral sampling and peer recruitment. Each FSW was issued with 3 coupons with which to recruit other FSW. A stratified random sample of 12 districts from the 22/54 districts with an active sex work programme (≥ one district per province)	Districts selected for survey had an active sex worker programme
Morin (2021)[183]	Benin (national)	Self-identification a FSW, being ≥15yrs and providing informed consent to participate in the survey	Cross-sectional survey with proportional cluster sampling at randomly selected sex work hotspots. Sex work sites in urban and rural areas identified through mapping	Standalone survey. Unclear if existing programme in place. First survey to look at the treatment cascade in Benin

Mulholland (2022)[184]	Border sites (Kenya, Uganda, Rwanda, Tanzania)	Adult women, ages ≥18yrs, who reported that they had received money in exchange for sex in the preceding 12 months	Cross-sectional bio-behavioural survey. TLS (PLACE). Locations selected with cross border movement and trade, high STI prevalence, known gaps in health services, and presence of key populations	Part of The East Africa Cross-Border Integrated Health Study (CBIHS)
Musyoki (2015)[185]	Kenya (Nairobi)	≥17yrs, reported selling sex for money, drugs, or goods to a man at least once in the past 3 months and who lived in Nairobi or adjacent urban areas	Cross-sectional RDS survey	Standalone survey. Unclear if existing programme in place
Parmley (2019)[186] [l]	South Africa (Port Elizabeth)	Women ≥18yrs, assigned female at birth, currently living in Nelson Mandela Bay Municipality, reported sex work as their principal form of income in the past year, spoke English or Xhosa	Cross-sectional RDS survey	Standalone survey. Data collected in partnership with a programme providing health services for FSW in Port Elizabeth.
Peitzmeier (2014)[187]	The Gambia	A woman, ≥16yrs, reported exchanging sex for money, goods or favours in the last 12 months and able to provide verbal informed consent in English, Wolof or Mandinka	Cross-sectional survey using a mix of chain referral and venue based sampling. Seeds were clients of services provided by community based organisations under the AIDS Services Organisation (NASO)	Standalone survey. Existing FSW organisations were involved in recruitment
Rhead (2018)[155]	Zimbabwe (Manicaland)	Self-identified as a sex worker, had ever gone to bars/beer halls to meet clients or had exchanged sex for money/ goods	Cross-sectional survey using a combination of PLACE and snowball sampling (a modified RDS approach to reach sex workers outside venues)	Survey run parallel to a household survey for non-FSW. Unclear if existing programme in place
Rice (2022)[188]	Zimbabwe (4 sites: 2 largest cities, 1 rural farming/mining community, 1 border town)	Adolescent girls were eligible if they exchanged sex for money in the past 30 days, were aged 16–19 years, and were living or working in 1 of the 4 study areas	Cross-sectional RDS survey. Rapid social mapping to identify sex work locations and typologies in each site. Sites selected to represent different types of communities where sex is sold. Seeds selected based on sex work typologies	Targeted sex worker services delivered in survey sites by CeSHHAR Zimbabwe
Rwema (2019b)[189]	Senegal (Dakar, Mbour)	Assigned female at birth, ≥18yrs, had engaged in sex work as their primary source of income in the year preceding the study	Cross-sectional RDS survey	Standalone survey. Unclear if existing programme in place

Schwartz (2014)[164]	Burkina Faso (Kara, Lome), Togo (Ouaga, Bobo)	≥17yrs, sold sex with the past 3 months and able to provide informed consent in French, Ewe or Kabiya, lived in Togo for at least the past 3 months	Cross-sectional bio-behavioural RDS survey. Seeds identified with the sex worker community and selected if connected with the study community	Standalone survey. Unclear if existing programme in place
Schwartz (2015a)[161] [m]	Swaziland (Manzini, Mbabane, Piggs Peak, Lavumisa), Burkina Faso (Ouaga, Bobo), Togo (Kara, Lome)	Born female, ≥16yrs and ≤49yrs, sex work in the past 12 months (not necessarily the primary source of income)	Cross-sectional bio-behavioural RDS survey. Seeds identified with the sex worker community and selected if connected with the study community	Standalone survey. Unclear if existing programme in place
Tun (2019)[190]	Tanzania (Njombe, Mbeya)	≥18yrs, sold sex for money or goods in the past 6 months, HIV-positive and not currently on ART, planning to reside in the region for 12 months (or willing to return every 3 months for refills/check-ups) WHO clinic stages 3 & 4 (symptomatic) excluded	Implementation science cross-sectional study using clinic recruitment. Participants diagnosed through community based HTC services in hotspots and in targeted health facilities where brochures and announcements were used for recruitment	Existing services and NGOs in study locations
Wang (2007)[156]	Senegal (Dakar, Mbour, Sebikotane)	≥21yrs currently working as a registered sex worker and able to provide verbal informed consent	Cross-sectional survey. Convenience sample of consecutively presenting sex workers at 3 STI clinics in the 3 locations	Survey part of a longitudinal study. Unclear if existing programme in place

a. FSW status determined by questions assessing familiarity with terminology, relationship to the recruiter and how much they charged for sex
b. Included women who did not self-identify as FSW, but who considered themselves involved in sex work

Publications with duplicate estimates of knowledge of HIV status

c. Boothe (2021)[191]
d. Bowring (2019b)[192]
e. Chabata (2019)[193], Cowan (2018)[194] (2017)[195], Davey (2019)[196], Napierala (2022)[197] (2018)[198]
f. Goldenberg (2019)[199]
g. Hakim (2020)[200],
h. Papworth (2015)[159], Schwartz (2015a)[161], Schwartz (2014)[164]
i. Lancaster (2016b)[201]
j. Schwartz S (2015b)[160]
k. Jaffer (2022)[202]
l. Rao (2016)[203] Rwema (2019a)[162] Schwartz (2017)[161] Wells (2018)[204]
m. Schwartz S (2015b)[160]

3.5.2. Knowledge of HIV status

Knowledge of HIV status was directly measured from survey questions in all studies, as the proportion of HIV-positive participants aware of their HIV status. A median of 26.8% (IQR 15.9-52.6) of study participants were HIV-positive, ranging from 3.2% in Senegal to 100% in Tanzania.[156,190] Median knowledge of HIV status was 54.9% (IQR 29.3-68.6). Knowledge of HIV status ranged from 4% to 95.2%, exceeding 90% in two studies, with only one of these reporting over 95%.[168,182] In meta-analysis there was strong evidence of heterogeneity between estimates (I^2=100%) (Figure 3.2).

Knowledge of HIV status was higher in East and Southern Africa (median 58.1%, IQR 38.1-73.1) than in West and Central Africa (median 41%, IQR 22.7-59.3), although there remined strong evidence of regional heterogeneity (East and Southern Africa, I^2=100%; West and Central Africa I^2=95%) (Figure 3.2). In East and Southern Africa, two thirds of studies (22/33) reported knowledge of HIV status greater than 50%, including >75% in seven studies in Zimbabwe, Malawi, and South Africa and South Sudan. East and Southern Africa saw the highest estimate of any study at 95.2% in Malawi in 2019,[168] but also some of the lowest estimates, with two sub-national surveys in Mozambique reporting 10% and 20% in 2011-2012 and an estimate of 4% in Angola in 2016-2017.[166,175] Five out of 10 studies in West and Central Africa reported knowledge of HIV status over 50%, with the highest estimate of 67.5% in Senegal in 2014-2015.[189] The remaining five studies reported knowledge of HIV status below 30%.

The earliest study in our review was in Senegal which estimated that 29.3% of FSW living with HIV in knew their HIV status between 2000 and 2004.[156] The latest was in Ethiopia in 2020, which estimated 58.1% of FSW were aware of their HIV status.[165] Estimates of knowledge of HIV status from studies conducted between 2002-2012 (n=12) were lower (median 43.1% (IQR 23.5-55.05)) than those from studies conducted between 2013-2016 and from 2017 onwards (2013-2016: median 59.4% (IQR 28.75-76.4); 2017-2020: median 58.1% (IQR 46.1- 73.0)). Stratified meta-analysis showed wide ranging estimates within each time period with evidence of heterogeneity (Figure 3.3). In Zimbabwe, repeat estimates in the same study population showed increasing knowledge of HIV status between 2011 to 2017 in the context of surveys implemented in sites with an established national sex worker programme.[6,193–198]

Figure 3.1.2 Meta-analysis of knowledge of HIV status by region

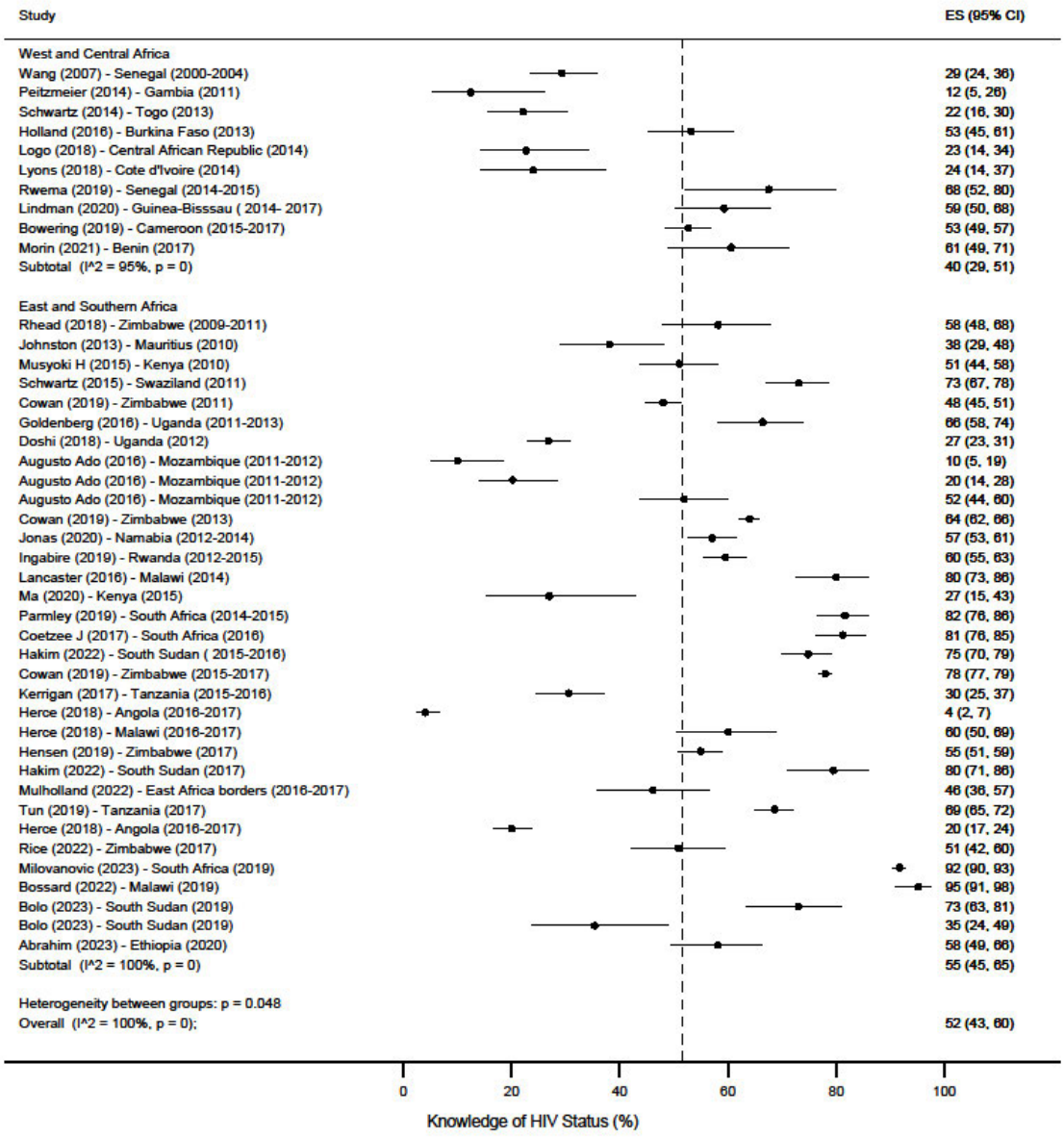


Figure 3.1.3 Meta-analysis of knowledge of HIV status by time period

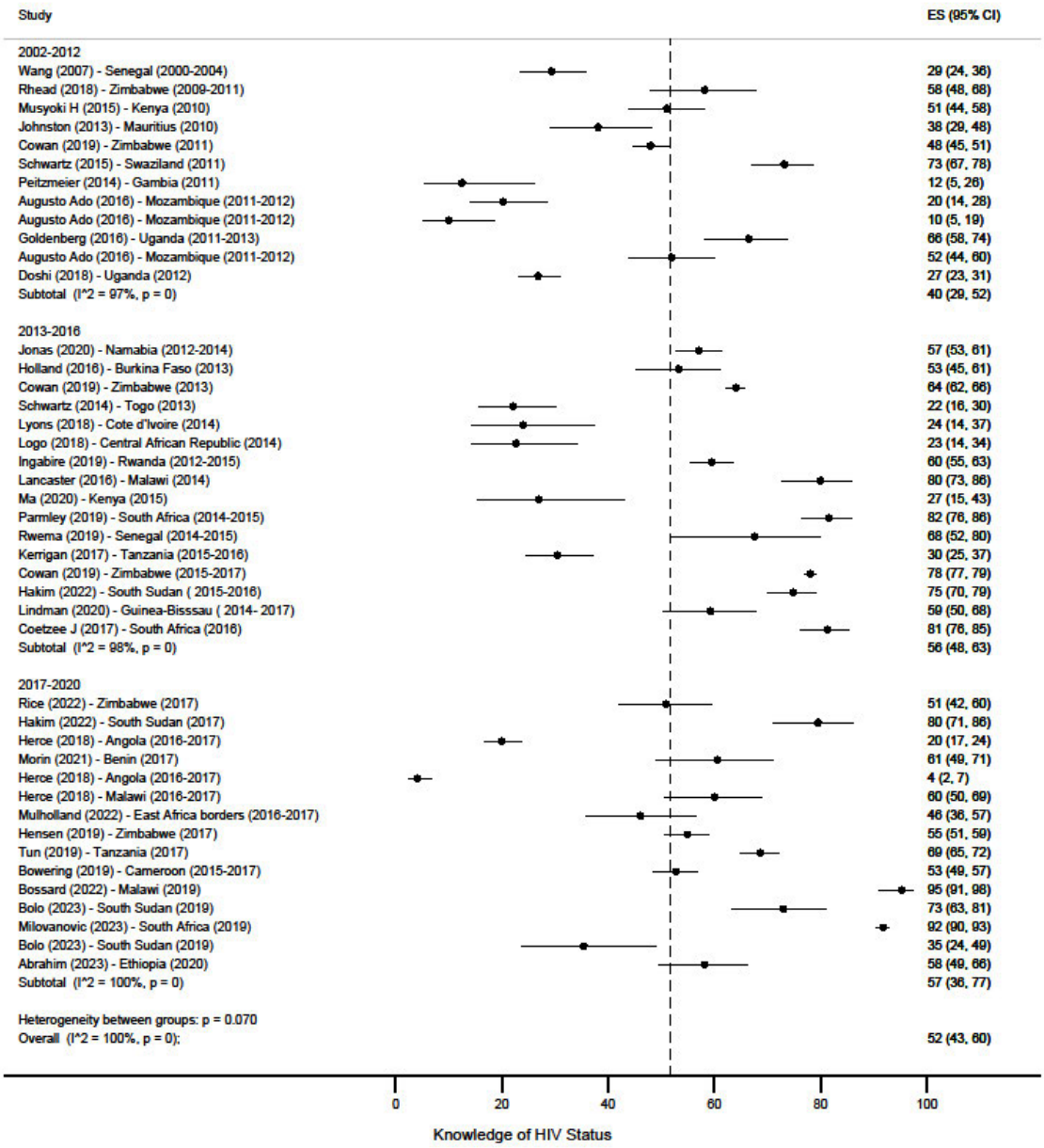


Table 3.1.2 Estimates of knowledge of HIV status

Author (date)	Country (location)	Data collection dates	Sample size (number HIV tested)	Ever tested (%)	HIV-positive N (%)	Knowledge of HIV Status N (%)	Sample age (years)
Abrahim (2023)[165]	Ethiopia	2020	822	93.1	129 (15.7)	75 (58.1)	63.4% 20–29
Augusto Ado (2016)[166]	Mozambique (Beira)	2011-2012	411 (410)	68.0	116 (23.6)	21 (20.2)	77% ≤24
Augusto Ado (2016)[166]	Mozambique (Maputo)	2011-2012	400 (398)	76.4	143 (31.2)	47 (51.9)	60% ≤24
Augusto Ado (2016)[166]	Mozambique (Nampula)	2011-2012	429	60.5	80 (17.8)	8 (10.0)	77% ≤24
Bolo (2023)[167]	South Sudan (Wau)	2019	679	⋯	52 (3.7)	23 (35.4)	Median 24; IQR 20-30
Bolo (2023)[167]	South Sudan (Yambio)	2019	605	⋯	94 (11.8)	68 (73.0)	Median 21; IQR 19-25
Bossard (2022)[168]	Malawi (Fatima,Bangula, Nsanje Mboma)	2019	363	⋯	173 (52.6)	⋯ (95.2)	Median 26; IQR 20–34
Bowering (2019a)[169]	Cameroon	2015-2017	2255 (2248)	88.6	550 (25.8)	290 (52.7)	Median 28
Coetzee (2017)[170]	South Africa (Soweto)	2016	508	⋯	269 (55.1)	220 (81.2)	Median 32; IQR 20-51
Cowan (2019)[6]	Zimbabwe (2013)	2013	2722	91.0[a]	⋯ (59.0)	... (64.0)	Mean 31; range 18–65
Cowan (2019)[6]	Zimbabwe (2015-2017)	2015-2017	5390	⋯	⋯ (54.0)	⋯ (78.0)	20% - 28% <25
Cowan (2019)[6]	Zimbabwe (3 sites)	2011	836	⋯	⋯ (58.0)	⋯ (48.0)	20% - 28% <25
Doshi (2018)[171]	Uganda (Kampala)	2012	1497	71.9	485 (32.4)	123 (26.8)	Median 27
Goldenberg (2016)[172]	Uganda (Gulu)	2011-2013	400	⋯	134 (35.5)	89 (66.4)	Median 21
Hakim (2022)[173]	South Sudan (Juba)	2015-2016	838	78.8	333 (39.7) (c)	233 (74.8)	11.1% 15–24 [e]
Hakim (2022)[173]	South Sudan (Nimule)	2017	409	⋯	108 (26.4) (c)	82 (79.5)	14.6% 15-24 [e]
Hensen (2019)[174]	Zimbabwe (DREAMS)	2017	2367	66.6[c]	543 (23.6)	299 (54.9)	20.9% (15.3-28.5) 18
Herce (2018)[175]	Angola (Benguela)	2016-2017	343	58.0	⋯ (5.0)	⋯ (4.0)	55% >25
Herce (2018)[175]	Angola (Luanda)	2016-2017	505	53.0	⋯ 8.0)	⋯ (20.0)	55% >25
Herce (2018)[175]	Malawi (Zomba)	2016-2017	106	88.0	⋯ (62.0)	⋯ (60.0)	55% >25
Holland (2016)[176]	Burkina Faso (Burkina)	2013	696	79.0	146 (20.1)	78 (53.2)	Median 25; IQR 22-32
Ingabire (2019)[163]	Rwanda	2012-2015	1168	93.0	587 (50.0)	349 (59.5)	Mean 30.4
Johnston (2013)[177]	Mauritius	2010	299	60.3	97 (28.9)	37 (38.1)	Median 31

Jonas (2020)[178]	Namibia	2012-2014	1188	⋯	487 (...)[b]	278 (57.1)	22.4% - 46.7% <25
Kerrigan (2017)[179]	Tanzania (Iringa)	2015-2016	496	92.0	203 (40.9)	62 (30.5)	Median 27
Lancaster (2016a)[157]	Malawi (Lilongwe)	2014	200	96.0	138 (69.0)	111 (80.0)	Median 24; IQR 22-28
Lindman (2020)[180]	Guinea-Bissau	2014- 2017	440	⋯	118 (26.8)	70 (59.3)	Median 28; IQR 22-35
Logo (2018)[29]	Central African Republic	2014	252	⋯	66 (19.2)	15 (22.7)	Median 23; IQR 15-47
Lyons (2018)[158]	Cote d'Ivoire	2014	466	81.3	50 (11.0)	12 (24.0)	38.4% 18–24
Ma (2020)[181]	Kenya (Mombasa)	2015	404 (365)	93.8	37 (10.1)	10 (27.0)	71.0% 19-24
Milovanovic (2023)[182]	South Africa (national)	2019	3005	99.7	1862 (62.1)	1708 (91.7)	13.3% ≤24
Morin (2021)[183]	Benin	2017	1037	79.2	71 (7.7)	⋯ (60.6)	307/1086 <25
Mulholland (2022)[184]	East Africa (Cross-border)	2016-2017	786 (715)	13.3[d]	85 (10.8)	37 (46.1)	Median 25; IQR 21-30
Musyoki H (2015)[185]	Kenya (Nairobi)	2010	596	89.3	181 (29.5)	116 (51.0)	Median 30; IQR 25-38
Parmley (2019)[186]	South Africa (Port Elizabeth)	2014-2015	410	99.0	261 (61.5)	213 (81.6)	Median 28; IQR 24-33
Peitzmeier (2014)[187]	Gambia	2011	251	⋯	40 (15.9)	5 (12.5)	Mean 31; SD 17-51
Rhead (2018)[155]	Zimbabwe (Manicaland)	2009-2011	174	81.6	91 (52.3)	53 (58.2)	20.7% 19–29
Rice (2022)[188]	Zimbabwe (AGSS)	2017	605	86.3	122 (20.2)	62 (50.8)	61.3% 18-19
Rwema (2019b)[189]	Senegal	2014-2015	410 (410)	71.4	40 (3.3)	27 (67.5)	29.8% 18–24
Schwartz (2014)[164]	Togo (Kara, Lome)	2013	684	74.3	122 (18.3)	27 (22.1)	Median 26; IQR 22-32
Schwartz (2015a)[161]	Swaziland	2011	317	⋯	223 (70.3)	163 (73.1)	Median 27; IQR 22-32
Tun (2019)[190]	Tanzania (Njombe, Mbeya)	2017	617	⋯	617 (100.0)	423 (68.6)	Median 30; IQR 25-37
Wang (2007)[156]	Senegal, (Dakar, Mbour, Sebikotane)	2000-2004	1052	70.3	208 (19.8)	61 (29.3)	Mean 35

a. calculated from reported 9 never tested
b. only provided by site
c. tested within the last 6 months
d. among the 48 testing HIV positive and unaware of their status
e. only for those who were HIV positive

3.5.3. Study design and implementation

Cross-sectional surveys were used in every study, with only one country with repeat surveys in the same FSW population.[194] Two studies reported baseline findings, one from a longitudinal cohort study[156] and one from a community randomised trial[179] (Table 3.1). We synthesised aspects of each study relating to study quality, including sampling and the likelihood that the approach taken would ensure adequate representation of the source population. Study recruitment was predominantly through chain referral (n=22) including 19 studies specifically using respondent driven sampling (RDS). Time location sampling (TLS), including Priorities for Local AIDS Control Effort (PLACE), was used in five studies and the reminder used venue or sex work location based peer recruitment (n=5). Three studies used more purposive sampling approaches, less likely to be representative of the source population (clinic recruitment (n=2) or a sub-sample of a larger RDS survey (n=1)). Knowledge of HIV status did not appear to vary with approaches to sampling and study recruitment. Studies recruiting through RDS had estimates of knowledge of HIV status ranging from one of the lowest at 10%, to two of the highest estimates of knowledge of HIV status in South Africa and Malawi.[166] Studies using TLS also presented a wide range of estimates from 4% in Angola to 66.4% in Uganda.[172,175] Studies taking more purposive approaches to sampling also presented a range of estimates from 29.3% in Senegal in 2014 to 81.2% in Soweto, South Africa in 2016.[156,170,190]

3.5.4. Study populations

Studies varied in terms of the age of recruited women and the definition of sex work used for study inclusion as previously described. In twelve studies the majority of FSW were ≤24 years old. Of these, three were in Mozambique which reported knowledge of HIV status below 21% in two sites.[166] Another was in the Central African Republic (CAR) and reported 22.7% of HIV-positive FSW were aware of their HIV status.[29] Two studies specifically conducted in younger FSW populations in Zimbabwe reported lower knowledge of HIV status at 50.8% and 54.9% than studies including older women in Zimbabwe from a similar time period.[174,188] In contrast, a study among adolescent girls and young women in South Africa reported much higher knowledge of HIV status at 91.7%.[182] All but three studies provided specific inclusion criteria which defined the age of women eligible for recruitment.[29,155,163] Of the three studies not stipulating age, two did not clearly specified the period of time for selling sex.[29,163]

3.5.5. Study context

Sixteen studies were conducted alongside targeted FSW programmes or as part of implementation studies and 19 reported findings from stand-alone surveys, not clearly

linked or in the context of a specific programme. Some of the highest estimates of knowledge of HIV status were reported in studies conducted in the context of FSW targeted programme implementation, although the extent of implementation in each study population was not always clear or reported. The only study in which knowledge of HIV status exceeded 95.2% was conducted in Malawi in 2019 in the context of a Médecins sans Frontières (MSF) programme providing HIV and sexual and reproductive health services to FSWs since 2013.[168] The second highest estimate was 91.7% reported in South Africa from a survey conducted in districts with a sex worker programme established for a minimum of 6 months.[182,202] Also in South Africa, knowledge of HV status reached 81.2% among FSW surveyed in an existing sex work programme at a perinatal HIV research unit in Soweto.[205] One of West Africa's higher estimates was 53.4%, reported in Cameroon in 2015-2017, in the context the Continuum of Prevention, Care and Treatment (CoPCT) of HIV/AIDS with Most At-Risk Populations (CHAMP) project.[169,192] It was unclear if the highest estimates of knowledge of HIV status in West Africa, in Senegal, Guinea-Bissau and Benin were in the context of a sex worker programme. Knowledge of HIV status was also measured in very specific contexts including through a programme in war-affected Gulu in Uganda[172,199] which reported 66.4% but would not necessarily be representative of other contexts in Uganda.

3.6. Discussion

Our systematic review of the literature identified 43 estimates of the percentage of HIV-positive FSW aware of their HIV-status in sub-Saharan Africa between 2002 and 2020. Median knowledge of HIV status was 54.9% and only exceeded 90% in only two studies, with one reporting over 95%. Higher knowledge of HIV status was seen in East and Southern Africa with a median knowledge of HIV status of 58.1% compared to 41.0% in West and Central Africa. Studies after 2013 also saw a higher median knowledge of HIV status of >58%, compared to a median of 43.1% from studies conducted between 2002 and 2013. There was some indication that knowledge of HIV status was higher in contexts with established FSW programmes. Wide variation in study focus, study population characteristics and recruitment, made further interpretation challenging. Despite an increasing number of studies reporting knowledge of HIV status among FSW there remain gaps and a limited number of repeat studies in the same geographical locations and study populations.

Our review had both strengths and limitations. We systematically searched the published literature using broad search terms across five databases to identify the greatest number of studies reporting knowledge of HIV status during this period. It is unlikely that we missed studies were knowledge of HIV status was a primary outcome during this period. While we identified a

large number of studies, knowledge of HIV status was frequently measured as a secondary outcome or described as one of many variables making it challenging to immediately identify in many studies and possible to miss at abstract review. Our review may have been subject to publication bias as we did not to search unpublished or grey literature. It is possible that we would have identified additional estimates from programme reports and behavioural surveillance surveys, but did not believe including these would enable detailed comparisons of methods or study context. We only included studies published in English, potentially excluding studies from regions including West Africa which may have been published in French. Studies were excluded if numerators and denominators were not presented, and if publications presented a duplicate estimate of knowledge of HIV status to another study. While we excluded duplicate estimates from same study populations, aiming to present only one estimate for each, duplication may have occurred where overlapping survey data were presented in different publications. There were occasionally small discrepancies between publications leaving room for error.

Our approach to data synthesis was conservative, acknowledging the limitations in pooling estimates from observational studies.[206–208] We found strong evidence of heterogeneity across all studies, within regions and within time periods making it inappropriate to present pooled estimates. We did not formally assess study quality, however synthesised data on aspects of study quality including definitions of the study population, study recruitment and knowledge of HIV status outcome definitions. While there was no study that stood out as weak in all of these factors, including studies with samples less likely to be representative of the population from which they were sampled may have biased our findings if these studies recruited FSW more or less likely to be aware of their HIV positive status. We chose not to exclude studies with less specific inclusion criteria. Inclusion criteria already varied widely between studies, making these studies no less likely to be recruiting different women to other studies.

In 2022 UNAIDS reported that globally, one in four FSW were thought to be unaware of their HIV status, including those who knew they were HIV-positive and those who had tested in the past 12 months and knew their test was negative.[2] Although the studies in our review looked at knowledge of an HIV positive status, only eight reported knowledge of HIV status over 75% and only one exceeded the UNAIDS 2030 target of 95%.[168] Notable increases over time in knowledge of HIV status have been modelled at population level in sub-Saharan Africa, from 5.7% (4.6-7.0) in 2000 to 84% (82-86) in 2020, with Southern Africa reaching 90% (88-92) in the same year.[91] In our review, median knowledge of HIV status increased from 43% in earlier studies to over 58% after 2013, although median estimates for 2013-2016 and 2017 onwards were similar. While some of the higher estimates of knowledge of HIV status were from studies conducted after 2013, the wide variation in studies and study contexts, and repeat measures of

knowledge of HIV status in only one FSW population in Zimbabwe[6,193–198] limited the identification of any trends over time in our review. In early 2000, a shift in focus from targeted HIV prevention programming for FSW, to more general population HIV prevention, may be the reason for lower knowledge of HIV status in earlier studies.[209] Recently renewed attention on sex worker programming is possibly driving some of the higher estimates in later studies, particularly in those where there is clear evidence of a targeted programme presence.[6,210,211] Our findings of a lower median knowledge of HIV status in West and Central Africa are in line with modelled estimates showing much lower population levels of knowledge of HIV status in these regions.[91]

We did not present pooled estimates of knowledge of HIV status in our review due to evidence of heterogeneity. A review of the care cascade for non-FSW populations also found that differences in data sources restricted comparability of over time or geographic location and created uncertainty around differences in cascades being due to real difference or differences in data sources.[212] The studies included in our review varied in terms of study aims, recruitment approaches and inclusion criteria. Surveys asking about HIV testing history and knowledge of the result are commonplace, regardless of the overall study aim, however variation in study aims may influence knowledge of HIV status among study participants. For example, a series of studies examined primary outcomes around family planning, antenatal care, pregnancy, and motherhood,[159–162] selecting a group of FSW who would have been likely to have greater service engagement and consequently knowledge of HIV status than other FSW in the same population.

Differences in study context and age of recruited women may have influenced the variation in estimates across studies. Younger age is likely to be a factor in lower knowledge of HIV status. Two studies in Zimbabwe[174,188] among younger FSW reported lower knowledge of HIV status than studies at a similar time among older FSW, however in contrast, a study among adolescent girls and young women in South Africa reported one of the highest estimates of knowledge of HIV status.[182] The level of programme implementation in a study setting was not always reported or easy to establish. Studies conducted alongside established FSW programmes would be likely to have higher test coverage and report greater knowledge of HIV status than exploratory surveys measuring HIV prevalence or scoping for project implementation. We found higher knowledge of HIV status in some studies with clear programme implementation, however this was not universal. The wider context in which studies were conducted may have additionally influenced the degree to which study populations would be able to access services and consequently influence knowledge of HIV status in that population. A study in the war-affected location of Gulu, Uganda was one example where service access may have been harder.[172,199]

Sampling and recruitment methods varied between studies. Different sampling approaches may achieve different levels of representativeness of the study population.[213] Without a sampling frame traditional probablity sampling methods are not possible, and instead RDS[109,110] and TLS commonly used to obtain a population sample FSW populations where weighting can be applied to reduce bias. While the majority of studies used RDS, not all reported weighted estimates and RDS reporting varied making it difficult to determine the degree to which some estimates would be representative of the wider FSW population. Other approaches to recruitment were through programmes, clinics or sex-work venues including bars, with some studies including only those attending clinics, while others used more active peer recruitment to engage FSW. A study comparing snowball vs venue-based sampling found RDS samples were younger than those recruited through venue-based snowball sampling, demonstrating the potential for sample differences with different methods.[213]

While the findings of our review indicate that in many contexts we are a long way off the 2030 goal of 95% awareness of knowledge of HIV status among FSW populations, limited data availability and heterogeneity in estimates make further interpretation difficult. Our review highlights the gaps and disparities in studies reporting on knowledge of HIV status among FSW in sub-Saharan Africa. Estimates will always be geographically and context specific but understanding trends more broadly was challenging with the available data. Addressing data gaps with moves towards improved surveillance among key populations, including continuity in approaches, will give us a clearer indication of whether we are on track to meet global targets. Reaching FSW with targeted programmes including HIV testing to increase knowledge of HIV status and support to HIV-negative FSW to access HIV prevention will be critical for reaching the first 95.

Declarations

Ethics approval and consent to participate

This review includes published data only and therefore ethical approval was no sought.

Availability of data and materials

Papers included in this review are publicly available. Data extraction tools can be made available on request to the corresponding author.

Competing interests

The authors declare no competing interests.

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Authors' contributions

HSJ conducted the searches and initial title and abstract screening and the full text review. HC conducted abstract screening and full text review on a sub-set of the literature. HSJ and HC carried out the data extraction. All authors contributed to the design and development of the review. HSJ wrote the manuscript with input and review from all authors.

HIV incidence among women engaging in sex work in sub-Saharan Africa: a systematic review and meta-analysis

Harriet S Jones and Rebecca L Anderson, Henry Cust, R. Scott McClelland, Barbra A. Richardson, Harsha Thirumurthy, Kalonde Malama, Bernadette Hensen, Lucy Platt, Brian Rice, Frances M Cowan, Jeffrey W. Imai-Eaton, James R Hargreaves, Oliver Stevens

The Lancet Global Health (published 2024)

3.7. Review 2: HIV incidence in sub-Saharan Africa

Where care cascade data for FSW are lacking, there has been even less data on new HIV infections.[14] A commonly cited statistic on the burden of HIV among FSW comes from a systematic review and meta-analysis published by Baral *et al* in 2011 on HIV prevalence and incidence among FSW globally. For sub-Saharan Africa, the authors present a pooled HIV prevalence estimate of 36·9% (95% CI 36·2–37·5) from 16 countries, and an OR of 12·4 (95% CI 8·9–17·2) for prevalence compared to the wider population. They did not identify any incidence estimates for FSW in sub-Saharan Africa, although in their discussion they comment that incidence has fallen among FSW in Kenya.[4]

The second review, which I include here, originated from additionally searching the papers included for abstract screening in my first review for those reporting HIV incidence for FSW. This resulted in a conference abstract in the 23rd International AIDS Conference in 2020: "*A systematic review of HIV incidence measurement among female sex workers in Africa: a strategic information gap to be filled if we are to achieve epidemic control*"[214] (Appendix 3). I identified 13 studies including 10,342 women from 8 countries: Benin, Burkina Faso, Cote d'Ivoire, Kenya, Rwanda, Tanzania, Uganda and Zimbabwe. Most studies recruited populations accessing clinical services. HIV incidence estimates ranged from 0/100py among a population enrolled in an oral PrEP demonstration project in Burkina Faso 2009-2011 to 13.1/100py in a study in Kenya which enrolled women from 1993-1997. Overall, 1131 FSW seroconverted during a total of 25,263.35 person years. HIV incidence was higher in Eastern Africa (3.55 per 100py, 8 studies) than Western Africa (1.4 per 100py, 5 studies), with only 1 study in Southern Africa (Zimbabwe, 9.8 per 100py). Follow up time ranged from nine months to fifteen years. Four studies showed decreased incidence over participation follow-up time, but overall temporal patterns were difficult to detect.

On the back of the AIDS 2020 abstract and through the Measurement and Surveillance of HIV Epidemics Consortium (MeSH) I collaborated with Oliver Stevens (OS) and Rebecca Anderson (RA) at Imperial College London to update the review and write a manuscript for publication. My contribution to the review was in the original searches, collaboratively developing the overall

framing of the paper (specifically in looking at trends in HIV incidence over time), developing the data extraction forms, supporting with data extraction, and conducting the quality assessment. RA conducted the updated searches and we collectively agreed the final included papers. RA led the data extraction and I supported the development of data extraction forms and conducted data extraction on aspects of publications included in the quality assessment. I selected the approach to quality assessment and conducted the quality assessment. The quantitative aspects of the review, which involved area-matching the FSW incidence estimates to estimates among women in the wider population, was conceived and conducted by RA and OS. RA and OS followed up with authors to obtain unpublished data. We co-wrote the submitted manuscript which was published in *The Lancet Global Health* in August 2024. The published version of the manuscript is below, along with scoring details from the quality assessment. The full quality assessment is in Appendix 4.

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SECTION A – Student Details

Student ID Number	378549	**Title**	Ms
First Name(s)	Harriet		
Surname/Family Name	Jones		
Thesis Title	Measuring trends in HIV testing and new HIV infections among female sex workers in Zimbabwe		
Primary Supervisor	Professor James Hargreaves		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	Lancet Global Health		
When was the work published?	August 2024		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Yes	Was the work subject to academic peer review?	Yes

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Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	Harriet S Jones & Rebecca L Anderson, Henry Cust, R. Scott McClelland, Barbra A. Richardson, Harsha Thirumurthy, Kalonde Malama, Bernadette Hensen, Lucy Platt, Brian Rice, Frances M Cowan, Jeffrey W. Imai-Eaton, James R Hargreaves, Oliver Stevens

Stage of publication	**Undergoing revision**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	My contribution to the review was in the original searches, collaboratively developing the overall framing of the paper (specifically in looking at trends in HIV incidence over time), developing the data extraction forms, supporting with data extraction, and conducting the quality assessment. Rebecca Anderson (RA) conducted the updated searches and we collectively agreed the final included papers. RA led the data extraction and I supported the development of data extraction forms and conducted data extraction on aspects of publications included in the quality assessment. I selected the approach to the quality assessment and conducted this. The quantitative aspects of the review, which involved area-matching the FSW incidence estimates to estimates among women in the wider population, was conceived and conducted by RA and Oliver Stevens (OS). RA and OS followed up with authors to obtain unpublished data. We co-wrote the submitted manuscript which is currently being revised for resubmission to The Lancet Global Health on the back of reviewer comments. The pre-print of the manuscript is below, along with additional details of the quality assessment.

SECTION E

Student Signature	[redacted]
Date	28/02/2024

Supervisor Signature	[redacted]
Date	28/02/2024

HIV incidence among women engaging in sex work in sub-Saharan Africa: a systematic review and meta-analysis

Harriet S Jones, Rebecca L Anderson*, Henry Cust, R Scott McClelland, Barbra A Richardson, Harsha Thirumurthy, Kalonde Malama, Bernadette Hensen, Lucy Platt, Brian Rice, Frances M Cowan, Jeffrey W Imai-Eaton, James R Hargreaves, Oliver Stevens*

Summary

Background Women who engage in sex work in sub-Saharan Africa have a high risk of acquiring HIV infection. HIV incidence has declined among all women in sub-Saharan Africa, but trends among women who engage in sex work are poorly characterised. We synthesised data on HIV incidence among women who engage in sex work in sub-Saharan Africa and compared these with the total female population to understand relative incidence and trends over time.

Methods We searched MEDLINE, Embase, Global Health, and Google Scholar from Jan 1, 1990, to Feb 28, 2024, and grey literature for studies that reported empirical estimates of HIV incidence among women who engage in sex work in any sub-Saharan Africa country. We calculated incidence rate ratios (IRRs) compared with total female population incidence estimates matched for age, district, and year, did a meta-analysis of IRRs, and used a continuous mixed-effects model to estimate changes in IRR over time.

Findings From 32 studies done between 1985 and 2020, 2194 new HIV infections were observed among women who engage in sex work over 51 490 person-years. Median HIV incidence was 4·3 per 100 person years (IQR 2·8–7·0 per 100 person-years). Incidence among women who engage in sex work was eight times higher than matched total population women (IRR 7·8 [95% CI 5·1–11·8]), with larger relative difference in western and central Africa (19·9 [9·6–41·0]) than in eastern and southern Africa (4·9 [3·4–7·1]). There was no evidence that IRRs changed over time (IRR per 5 years: 0·9 [0·7–1·2]).

Interpretation Across sub-Saharan Africa, HIV incidence among women who engage in sex work remains disproportionately high compared with the total female population. However, constant relative incidence over time indicates HIV incidence among women who engage in sex work has declined at a similar rate. Location-specific data for women who engage in sex work incidence are sparse, but improved surveillance and standardisation of incidence measurement approaches could fill these gaps. Sustained and enhanced HIV prevention for women who engage in sex work is crucial to address continuing inequalities and ensure declines in new HIV infections.

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For the French translation of the abstract see Online for appendix 1

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Introduction

Among women in sub-Saharan Africa, women who engage in sex work are disproportionately affected by HIV.[1,2] Women who engage in sex work comprise an estimated 1·2% of women aged 15–49 years in sub-Saharan Africa, but an estimated 3·5% of women living with HIV in the region.[2] Despite evidence of substantially higher HIV prevalence,[2–4] HIV incidence among women who engage in sex work is poorly characterised. HIV prevention programmes for women who engage in sex work were a core component of the early HIV response in sub-Saharan Africa; however, reduced funding and a shift to general population programming reduced programmes focused on women who engage in sex work from the early 2000s.[5] More recently, renewed attention on focused approaches for key populations has re-expanded programming for women who engage in sex work.[6–8] Assessing the success of these efforts at preventing new HIV infections is challenging. Although new HIV infections have steadily declined among all women in sub-Saharan Africa,[1] whether HIV incidence among women who engage in sex work has declined at a similar rate is unknown.

Despite increasing surveillance and programmes for women who engage in sex work, studies of HIV incidence in sub-Saharan Africa remain infrequent and challenging. Identifying and following up women who engage in sex work is often difficult due to the heterogeneous, informal, and hidden nature of sex work, commonly driven by stigma and criminalisation.[9] For these reasons, women who engage in sex work are largely unidentified in population-based household surveys, and constructing a representative national sampling frame for women who engage in sex work is impractical. Sex work encompasses a broad spectrum of sexual transactions occurring in multiple settings,

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Research in context

Evidence before this study

Women who engage in sex work are disproportionately affected by HIV across sub-Saharan Africa, comprising an estimated 1·2% of woman aged 15–49 in the region, but an estimated 3·5% of women living with HIV. Empirical estimates of HIV incidence among women who engage in sex work are limited, with individual studies often narrow in geographical scope and rarely repeated in the same populations. Despite overall declines in HIV incidence among all women in sub-Saharan Africa, it is unclear whether incidence among women who engage in sex work is declining at a similar rate. Previous efforts to synthesise data on HIV incidence among women who engage in sex work have assessed global differences in incidence by age, with limited focus on sub-Saharan Africa or on changes in incidence over time.

Added value of this study

We systematically searched and meta-analysed studies published between Jan 1, 1990 and Feb 28, 2024 reporting empirical measurements of HIV incidence among women who engage in sex work in sub-Saharan Africa. Our review identified a greater number of empirical estimates and substantially increased the geographical reach and time period covered by any previous review of HIV incidence among women who engage in sex work in sub-Saharan Africa. Our analysis quantified the discrepancy between incidence in women who engage in sex work and total population women, estimating rates among women who engage in sex work to be 7·8 times higher (incidence rate ratio 7·8, 95% CI 5·1–11·8), with a greater disparity in western and central Africa compared with eastern and southern Africa. Our work addresses methodological challenges synthesising heterogeneous studies by accounting for the geographical and age variation in recruited populations. The review contributes to improving characterisation of HIV incidence among women who engage in sex work in the region by assessing trends over time and situating these findings within the context of the HIV epidemic among age-matched women in the wider population.

Implications of all the available evidence

Our study underscores the need to continue expansion of effective prevention and treatment programming for women who engage in sex work. Our study also highlights the geographical and methodological gaps that remain in surveillance activities and the need to ensure a more standardised approach to obtaining empirical estimates of incidence among women who engage in sex work. Improved incidence measurement will strengthen and guide data-driven HIV programming. Quantifying and broadening our understanding of the inequalities that persist in the HIV epidemic provides a practical assessment for programmatic need and progress towards targets to be reached through continued and sustained HIV prevention.

from on streets, to in homes, brothels, or hotels.[10] Women who exchange sex for money and goods might not self-identify as sex workers; for surveillance, this presents challenges, as those not identifying as sex workers are unlikely to present at sex worker dedicated programmes. Additionally, mobility among women who engage in sex work is high,[11] and repeated initiation and cessation of sex work common, precipitating commonly high loss to follow-up for programmes and cohort studies.[12,13] To mitigate these challenges, methods have been developed leveraging cross-sectional data to estimate incidence,[14,15] and recruitment approaches such as respondent-driven sampling and time-location sampling are increasingly used to capture more representative samples of women who engage in sex work.

As countries seek to reach the global goal of ending AIDS as a public health threat by 2030 through ending inequalities, quantifying HIV incidence trends among women who engage in sex work is required to guide national HIV programme planning and delivery. In this study, we aimed to synthesise and appraise empirical estimates of HIV incidence in women who engage in sex work in sub-Saharan Africa, estimate relative HIV incidence with the total female population for western and central Africa and eastern and southern Africa, and estimate the change in HIV incidence over time among women who engage in sex work, relative to incidence trends among all women.

Methods

Study design

We searched published and grey literature to identify empirical estimates of HIV incidence among women who engage in sex work in sub-Saharan Africa. We conducted our searches with no language restrictions for peer-reviewed literature published between Jan 1, 1990, and Feb 28, 2024, and replicated searches in French to identify any additional publications. Our initial screening was from a preliminary search of papers identified through an earlier review of HIV testing among women who engage in sex work.[16] MEDLINE, Embase, POPLINE, Web of Science, and Global Health were searched on June 19, 2019, by authors HSJ and HC using medical subject headings and text words adapted for each database covering three domains: "female sex workers", "HIV", and "sub-Saharan Africa". Full texts were subsequently searched for those reporting HIV incidence by HSJ. An updated search and screening was conducted by RLA on Feb 28, 2024 in MEDLINE, Embase, Global Health, and Google Scholar using text words addressing four domains: "sex workers", "sub-Saharan Africa", "HIV", and "incidence" (appendix 2 p 4). RLA checked

See Online for appendix 2

that the second search included all papers identified in the initial search. RLA additionally searched key population biobehavioural surveillance reports (grey literature), which was collated during an earlier key population data collation exercise.[2] All papers were selected for final inclusion based on consensus between authors HSJ, RLA, and OS.

This study received ethical approval from the Imperial College Research and Ethics Committee (6412027). For use of the Centre for Sexual Health and HIV/AIDS Research Zimbabwe (CeSHHAR) Key Populations programme data, ethical approval was obtained from the London School of Hygiene and Tropical Medicine (16543) and the Medical Research Council of Zimbabwe (MRCZ/A/2624).

Study inclusion

Included studies were required to report an empirically measured estimate of serologically confirmed HIV incidence among women who engage in sex work in any sub-Saharan Africa country or report the number of HIV events and total person-years at-risk to calculate incidence. Women who engage in sex work could be cisgender or transgender women either self-reporting being a sex worker, engaged in a sex worker programme, or reporting selling or exchanging sex for money or goods. For multicountry studies, nationally disaggregated data were required. For closed cohort studies reporting annual estimates, only the overall estimate of incidence from the study was extracted to avoid artificial declines in observed incidence with follow-up of the same individuals. Studies were excluded if the study cohort was exposed to an intervention specifically intended to affect HIV incidence—eg, HIV pre-exposure prophylaxis. Data from the control group in randomised control trials and from early or pre-intervention periods in interventional cohort studies were included, as these were likely to be more representative of the wider population of women who engage in sex work from which data were collected. Conference abstracts or published short communications were excluded. When multiple papers

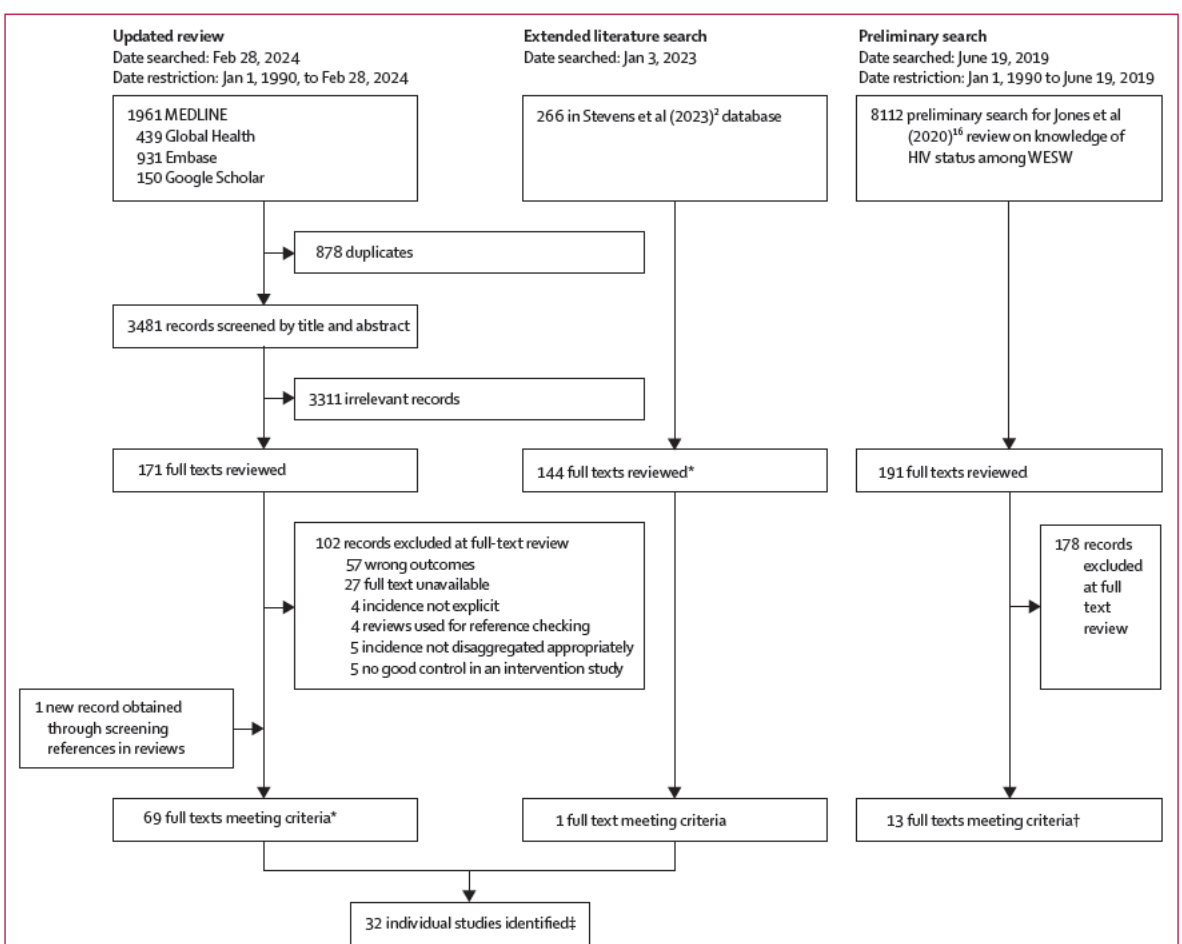

Figure 1: **Trial profile**
WESW=women who engage in sex work. *Full texts meeting criteria include multiple papers reporting on the same study. †All papers identified in the preliminary search were identified in the updated review. Individual studies identified are the primary texts from which data were extracted from.

reported incidence estimates for the same study population, the paper reporting the greatest number of person-years of follow-up was selected as the primary study (figure 1).

Procedures

From each study, two authors extracted the study location (country, subnational area), time period, study population definition, recruitment strategy, mean or median age and eligible age range, incidence measurement method (eg, repeat HIV tests, recent infection testing), study type (eg, cohort, randomised controlled trial), sample size, person-years of follow-up, number of seroconversions, incidence rate per 100 person-years, and CIs, disaggregated by age-group when available. We contacted study authors when estimates were not clearly available in existing publications (n=1),[17] not disaggregated to women who engage in sex work (n=1),[18] or from studies reporting data for extended time periods that could provide annual estimates to assess temporal trends (n=2).[19,20]

Quality assessment

We appraised studies using the Global HIV Quality Assessment Tool for Data Generated through Non-Probability Sampling (GHQAT).[21] The tool comprises three domains: study design, study implementation, and a measurement specific domain for HIV incidence. Domain-specific assessment criteria are in the appendix 2 (p 10). A score of 1 was assigned if studies met the assessment criteria and 0 if they did not. Each study was classified as good, fair, or poor for each domain, and then overall. Scoring was agreed between HSJ, RLA, and OS based on the narrative assessment findings. Studies scoring 70% or more were classified as good, 30–70% as fair, and less than 30% as poor. We excluded assessment criteria on follow-up time and participant retention when these were not relevant (ie, for cross-sectional estimates of HIV incidence using recent HIV infection testing or HIV prevalence).

Data synthesis and meta-analysis

HIV incidence observations among women who engage in sex work were matched to HIV incidence in the total female population by district (subnational location where each study was conducted), age, and year. Estimates for missing age information were matched to ages 15–39 years, reflecting the age distribution observed in women who engage in sex work in studies that reported age data. District-level estimates for the total female population in 2022 were extracted from UNAIDS subnational HIV estimates created using the Naomi small-area estimation model.[22] District-level incidence estimates for 1985–2021 were created by extrapolating 2022 estimates backwards in time parallel to age-matched UNAIDS national-level female incidence trajectories, assuming the proportional change in incidence at district level mirrored that at national level.[23,24] For studies without annual incidence estimates, the midpoint study year was used for matching. When a subnational location was not specified in the text (n=3), national total population incidence was used as the comparator. One study reported incidence for a control group of women not engaged in sex work,[25] which was used as the total population comparator instead of matching to UNAIDS' district estimates.

We assessed correlation between women who engage in sex work and matched total population female incidence and calculated incidence rate ratios (IRRs). We meta-analysed IRRs, with study-district nested random effects to account for variation in study type, and regional fixed effects to stratify the pooled IRRs by region (eastern and southern Africa and western and central Africa). The I^2 statistic was used to assess heterogeneity. Due to high heterogeneity, we also calculated median IRRs with IQRs by region. We estimated time trends in log IRRs with a Bayesian mixed-effects log-linear model. The regression model included a linear trend for calendar year, and study-level random effects. Log total female population incidence and person-years of follow-up were specified as offsets such that model coefficients reflected log IRRs relative to matched population female incidence (appendix 2 p 6). We also conducted case studies for the two countries with the most available data. We used data from an open cohort in Mombasa, Kenya[19] and from a national key populations programme in Zimbabwe run by the Centre for Sexual Health and HIV/AIDS Research Zimbabwe (CeSHHAR),[20] to descriptively assess temporal trends between women who engage in sex work and total female population incidence.

We conducted sensitivity analyses. To address uncertainty about district-level total population incidence estimates we repeated the meta-analysis using national age–sex matched population incidence as the denominator for IRRs. To assess the effect of study quality, we repeated the meta-analysis restricted to higher quality studies (those scoring 60% or above on the GHQAT). Finally, as the majority of empirical incidence estimates for women who engage in sex work were from populations in Kenya and Zimbabwe, we refit the mixed-effects model to data from both countries. Analyses were implemented in R v4.2.1 using the *metafor* v3.8.1[26] and *R-INLA* v22.5.7[27] packages.

For more on **R** see https://www.r-project.org/

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

We extracted 83 estimates of HIV incidence among women who engage in sex work in sub-Saharan Africa from 32 studies reported in 69 peer-reviewed papers and one surveillance report (tables 1, 2). 65 (78%) of 83 estimates were from eastern and southern Africa,

	Study period	Study location*	Midpoint year	Age group (years)†	Women who engage in sex work new HIV infections	Person years	Women who engage in sex work incidence per 100 person years	Total female population incidence per 100 person years‡	IRR§
Ali et al (2022)[15]§									
Zimbabwe	2011–17	Zimbabwe	2014	15–24	7	105	6·3 (5·3–7·6)	1·07	5·90
Zimbabwe	2011–17	Zimbabwe	2014	25–39	6	175	3·3 (1·3–4·2)	0·88	3·74
Botswana Ministry of Health (2013)[28]¶									
Botswana	2012	Gaborone–Francistown–Kasane	2012	15–39	46	450	12·5 (7·3–17·1)	1·80	6·93
Braunstein et al (2011)[29]									
Rwanda	2006–08	Kigali	2007	15–39	3	91	3·3 (0·0–7·0)	0·47	7·05
Chabata et al (2021)[30]									
Zimbabwe	2017–19	Chinhoyi	2018	15–24	16	226	7·1 (4·3–11·5)	0·49	14·39
Zimbabwe	2017–19	Karoi	2018	15–24	11	193	5·7 (3·2–10·3)	0·46	12·44
Zimbabwe	2017–19	Kwekwe	2018	15–24	12	278	4·3 (2·5–7·6)	0·69	6·29
Zimbabwe	2017–19	Zvishavane	2018	15–24	9	210	4·3 (2·2–8·2)	0·65	6·54
Chersich et al (2014)[31]									
Kenya	2006–07	Mombasa (Kisauni and Chaani)	2007	15–39	10	381	2·6	0·62	4·20
Diabaté et al (2018)[32]									
Benin	2008–12	Cotonou	2010	15–39	6	425	1·4 (0·3–2·5)	0·33	4·26
Faini et al (2022)[33]									
Tanzania	2018–19	Dar es Salaam	2019	15–24	12	278	4·3	0·05	80·58
Tanzania	2018–19	Dar es Salaam	2019	25–34	5	234	2·1	0·07	32·60
Tanzania	2018–19	Dar es Salaam	2019	35–44	4	97	4·1	0·05	79·31
Forbi et al (2011)[34]									
Nigeria	2006	Nasarawa State	2006	15–34	71	590	12·0 (8·5–15·4)	0·47	25·53
Fowke et al (1996)[35]									
Kenya	1985–94	Nairobi	1990	15–39	239	569	42·0	3·21	13·07
Ghys et al (2001)[36]									
Côte d'Ivoire	1994–98	Abidjan	1996	15–39	11	68	16·3	2·07	7·88
Gilbert et al (2003)[37]									
Senegal	1985–99	Dakar	1987	15–24	34	1628	2·1	0·01	235·63
Senegal	1985–99	Dakar	1987	25–34	91	5474	1·7	0·02	82·60
Senegal	1985–99	Dakar	1987	35–44	58	1939	3·0	0·01	216·60
Senegal	1985–99	Dakar	1987	45–49	12	260	4·6	0·01	639·76
Jones et al (2023)[20]‖									
Zimbabwe	2010–19	Zimbabwe	2010	15–39	3	56	5·4 (3·2–10·9)	1·28	4·20
Zimbabwe	2010–19	Zimbabwe	2011	15–39	6	139	4·3 (2·2–14·6)	1·20	3·60
Zimbabwe	2010–19	Zimbabwe	2012	15–39	15	264	5·7 (1·9–22·8)	1·11	5·10
Zimbabwe	2010–19	Zimbabwe	2013	15–39	12	410	2·9 (1·5–8·1)	1·04	2·81
Zimbabwe	2010–19	Zimbabwe	2014	15–39	33	731	4·5 (2·5–8·2)	0·97	4·66
Zimbabwe	2010–19	Zimbabwe	2015	15–39	62	1402	4·4 (3·6–5·4)	0·89	4·99
Zimbabwe	2010–19	Zimbabwe	2016	15–39	58	1857	3·1 (2·5–4·1)	0·79	3·98
Zimbabwe	2010–19	Zimbabwe	2017	15–39	94	2422	3·9 (3·3–4·7)	0·68	5·69
Zimbabwe	2010–19	Zimbabwe	2018	15–39	114	2946	3·9 (3·3–4·7)	0·55	7·02
Zimbabwe	2010–19	Zimbabwe	2019	15–39	44	1432	3·1 (2·1–5·0)	0·47	6·56
Kasamba et al (2019)[38]									
Uganda	Cohort 1: 2008–17; cohort 2: 2013–17	Kampala	2010	15–39	59	2007	2·9	1·15	2·53
Uganda	Cohort 1: 2008–17; cohort 2: 2013–17	Kampala	2014	15–39	46	1394	3·3	0·93	3·53
Uganda	Cohort 1: 2008–17; cohort 2: 2013–17	Kampala	2016	15–39	65	2138	3·0	0·84	3·59

(Table 1 continues on next page)

	Study period	Study location*	Midpoint year	Age group (years)†	Women who engage in sex work new HIV infections	Person years	Women who engage in sex work incidence per 100 person years	Total female population incidence per 100 person years‡	IRR§
(Continued from previous page)									
Kassanjee et al (2022)[14]¶									
South Africa	2019	South Africa	2019	15–49	190	4130	4·6 (1·5–8·5)	1·21	3·81
Kaul et al (2004)[39]									
Kenya	1998–2002	Nairobi	2000	15–39	16	495	3·2	1·29	2·47
Kerrigan et al (2019)[40]									
Tanzania	2015–17	Mafinga	2002	15–39	10	144	6·9	2·54	2·73
Kilburn et al (2018)[25]									
South Africa	2012–15	Mpumalanga	2014	15–19	41	1273	3·2	1·85	1·74
Laga et al (1994)[41]									
Democratic Republic of Congo	1988–91	Kinshasa	1988	15–39	70	880	11·7	0·34	34·68
Lyons et al (2020)[42]									
Senegal	2015–17	Dakar-Mbour-Theis	2016	15–39	4	303	1·3 (0·5–3·5)	0·01	161·67
Malama et al (2022)[17]									
Zambia	2012–17	Ndola–Lusaka	2015	15–44	24	884	2·7	1·84	1·49
McClelland et al (2015)[19]‖									
Kenya	1993–2017	Mombasa	1993	15–39	20	335	6·0	3·24	1·84
Kenya	1993–2017	Mombasa	1994	15–39	36	228	15·8	2·92	5·42
Kenya	1993–2017	Mombasa	1995	15–39	24	213	11·3	2·46	4·57
Kenya	1993–2017	Mombasa	1996	15–39	29	325	8·9	2·01	4·45
Kenya	1993–2017	Mombasa	1997	15–39	41	364	11·3	1·68	6·71
Kenya	1993–2017	Mombasa	1998	15–39	31	271	11·4	1·41	8·13
Kenya	1993–2017	Mombasa	1999	15–39	24	207	11·6	1·21	9·52
Kenya	1993–2017	Mombasa	2000	15–39	16	188	8·5	1·06	8·01
Kenya	1993–2017	Mombasa	2001	15–39	8	216	3·7	0·95	3·91
Kenya	1993–2017	Mombasa	2002	15–39	19	251	7·6	0·88	8·65
Kenya	1993–2017	Mombasa	2003	15–39	14	245	5·7	0·79	7·23
Kenya	1993–2017	Mombasa	2004	15–39	13	263	5·0	0·74	6·69
Kenya	1993–2017	Mombasa	2005	15–39	14	271	5·2	0·70	7·39
Kenya	1993–2017	Mombasa	2006	15–39	8	228	3·5	0·65	5·36
Kenya	1993–2017	Mombasa	2007	15–39	7	244	2·9	0·62	4·60
Kenya	1993–2017	Mombasa	2008	15–39	4	211	1·9	0·58	3·24
Kenya	1993–2017	Mombasa	2009	15–39	9	163	5·5	0·56	9·91
Kenya	1993–2017	Mombasa	2010	15–39	3	187	1·6	0·52	3·09
Kenya	1993–2017	Mombasa	2011	15–39	3	283	1·1	0·48	2·19
Kenya	1993–2017	Mombasa	2012	15–39	2	334	0·6	0·44	1·36
Kenya	1993–2017	Mombasa	2013	15–39	4	280	1·4	0·40	3·55
Kenya	1993–2017	Mombasa	2014	15–39	5	225	2·2	0·37	6·08
Kenya	1993–2017	Mombasa	2015	15–39	5	222	2·3	0·33	6·71
Kenya	1993–2017	Mombasa	2016	15–39	4	216	1·9	0·30	6·28
Kenya	1993–2017	Mombasa	2017	15–39	3	237	1·3	0·26	4·88
McKinnon et al (2015)[43]									
Kenya	2008–11	Nairobi	2010	15–39	34	1514	2·2 (1·6–3·1)	0·63	3·49
Nagot et al (2005)[44]									
Burkina Faso	1998–2002	Bobo-Dioulasso	2000	15–39	19	594	3·2 (1·9–4·9)	0·20	15·87
Naicker et al (2015)[45]									
South Africa	2004–06	Durban	2005	25–49	10	248	4·0 (1·9–7·4)	2·09	1·93
South Africa	2004–06	Durban	2005	15–24	8	59	13·5 (5·8–26·6)	2·93	4·62

(Table 1 continues on next page)

	Study period	Study location*	Midpoint year	Age group (years)†	Women who engage in sex work new HIV infections	Person years	Women who engage in sex work incidence per 100 person years	Total female population incidence per 100 person years‡	IRR§
(Continued from previous page)									
Nouaman et al (2022)[46]									
Cote d'Ivoire	2016–17	San Pedro	2017	15–39	4	188	3·3	0·09	37·94
Cote d'Ivoire	2016–17	Abidjan	2017	15–39	3	293	1·6	0·17	9·60
Price et al (2012)[47]									
Kenya	2008	Kilifi	2007	15–39	9	339	2·7 (1·4–5·1)	0·39	6·94
Kenya	2008	Nairobi	2007	15–39	2	527	0·4 (0·1–1·5)	0·76	0·53
Priddy et al (2011)[48]									
Kenya	2008	Nairobi (Mukuru District)	2008	15–39	5	89	5·6 (1·6–12·0)	0·71	7·88
Riedner et al (2006)[49]									
Tanzania	2000–03	Mbeya Region	2002	15–39	19	99	19·2	1·47	13·08
Roddy et al (1998)[50]									
Cameroon	1994–96	Yaounde–Douala	1995	15–39	46	698	6·6	0·84	7·87
Thirumurthy et al (2021)[18]‖									
Kenya	2017–20	Siaya County	2018	15–39	0	939	0·0	0·44	0·00
Van Damme et al (2002)[51]									
South Africa	1996–2000	KwaZulu-Natal	1998	15–39	30	182	16·5	3·45	4·78
Benin	1996–2000	Cotonou	1998	15–39	10	121	8·3	0·90	9·21
Cote d'Ivoire	1996–2000	Abidjan	1998	15–39	5	67	7·4	1·62	4·57
van der Loeff et al (2001)[52]									
Guinea-Bissau	1989–98	Guinea-Bissau	1994	15–39	3	126	2·4 (0·7–7·4)	0·44	5·39
Guinea-Bissau	1989–98	Guinea-Bissau	1994	40–49	7	160	4·4 (2·1–9·2)	0·24	18·55
Guinea-Bissau	1989–98	Guinea-Bissau	1994	50–59	5	67	7·5 (3·1–18·0)	0·13	56·66

The referenced study was taken as the primary study from which estimates were extracted from, or from which unpublished estimates were received. Unpublished incidence estimates among women who engage in sex work and person-years of follow-up were obtained through personal communications with study authors. IRR=incidence rate ratio. *Area used to match women who engage in sex work incidence to total female population incidence estimates to calculate IRRs. †Age group used to match women who engage in sex work incidence to total female population incidence estimates; when no age information was specified, a default of age 15–39 years was used. ‡Incidence matched to women who engage in sex work estimate by subnational location, midpoint year, and age group. §IRR calculated by dividing study-reported women who engage in sex work incidence by area-year matched total population female incidence. Total population female incidence in 2022 was extracted from Naomi, the UNAIDS-supported district-level estimation model,[22] and extrapolated parallel to national-level female HIV incidence trajectories from UNAIDS Global HIV Estimates 2022, National Spectrum estimates.[23,24] ¶Incidence estimate were derived from serial cross-sectional prevalence testing with no estimate of person-years or number of new infections. The number of person-years was imputed using the median number of person-years across all studies and split proportionally according to the denominator in each age group. Imputed person-year values were then multiplied by the study-reported HIV incidence to back-calculate the number of HIV infections. ‖Incidence estimate derived from recent HIV infection testing. The number of person-years was derived by multiplying the number of tested individuals by 0·5.

Table 1: **Annual incidence estimates for women who engage in sex work and women from the general population matched for area, year, and age**

predominantly from Kenya and Zimbabwe (49 [59%] of 83). In western and central Africa, 18 incidence estimates were reported from eight countries. Median study year was 2008 (IQR 2000–15). Between 1985 and 2020, 2194 new HIV infections were observed from 51490 person years with median HIV incidence of 4·3 per 100 person years (IQR 2·8–7·0 per 100 person years; eastern and southern Africa: 4·3 per 100 person years [2·9–6·3]; western and central Africa: 3·8 per 100 person years [2·2–7·5]).

19 of 32 studies were cohort studies, seven were randomised control trials or intervention studies, five were cross-sectional studies, and one used routine clinic data (table 2). Seven studies included women who self-identified as sex workers, 13 included women who exchanged sex for money or goods (either over a defined period or as a primary or secondary source of income), two studies included women who worked in a known sex work location. No studies were identified on transgender women who engage in sex work or stratified by gender identity. Six study populations were women linked to clinics or sex worker programmes. Study reach varied widely, from studies in single clinics to single towns, cities, or regions, and multiple locations nationally in South Africa and Zimbabwe. Recruitment methods included network sampling approaches (seven studies), time location sampling (four), clinic recruitment (seven), or convenience samples from peer outreach activities or community meetings (nine). Study participant ages ranged from a median of 15 years (IQR 14–17)[27] to a mean of 38 years (30–45),[93] with 11 (34%) studies reporting mean or median ages between 25 and 30 years. Incidence estimates were predominantly derived from inference of a seroconversion date between HIV tests (27 studies). Most of these studies used the midpoint between first positive test result and last negative test result (14 [52%] of 27), two used the HIV-positive test date, and ten did not report a clear seroconversion date estimation

	Country	Study population age, years	Definition of women who engage in sex work	Study design and recruitment	Incidence estimation method	Additional papers identified*
Ali et al (2022)[15]	Zimbabwe	18–39	Women who self-reported exchanging sex for money in the past 30 days and had been living or working in the survey site for at least 6 months	Cross-sectional respondent-driven sampling surveys conducted between 2011 and 2017 at sex work hotspots	Prevalence back calculation, pooling data from RDS surveys; estimation of HIV incidence from analysis of HIV prevalence patterns	NA
Braunstein et al (2011)[29]	Rwanda	Median: 24, range: 18–46	Women who had exchanged sex for money at least once in the past month or were currently having sex with multiple partners plus having sex at least twice per week (all enrolled women self-identified as sex workers)	Cohort recruited through community meetings conducted by community mobilisers	Seroconversion at follow-up 6–12 months after baseline survey; midpoint estimation between last HIV-negative and first-HIV positive test	Braunstein et al (2012),[53] Braunstein et al (2011)[54]
Botswana Ministry of Health (2013)[28]	Botswana	≥18	Women who received either money or a gift or incentive in exchange for sexual favours within the past 3 months	Time-location sampling at hotspots for recruitment to cross-sectional IBBS survey	Recent infection testing algorithm; BED incidence assay	NA
Chabata et al (2021)[30]	Zimbabwe	18–24	Young women who had exchanged sex for money or material support in the past month, and explicitly stated that sex acts with men would not have happened in the absence of an exchange, and if they were not planning to move from the site within the next 6 months	Non-randomised plausibility evaluation of DREAMS on HIV incidence; respondent-driven sampling with seeds selected from sex-work hotspots identified through a community mapping	Seroconversion at follow-up 24 months post-recruitment; midpoint estimation between an HIV-negative and HIV-positive test	NA
Chersich et al (2014)[31]	Kenya	≥16; mean 25·1 (SD 5·2)	Women reporting receipt of money in exchange for sex as part of their livelihood in the past 6 months, sexually active in the past 3 months, and not pregnant at the time of enrolment	Cohort recruited in locations with existing community links through long-standing service provision by implementers and peers through snowball sampling	Seroconversion between quarterly follow-ups; midpoint estimation between an HIV-negative and HIV-positive test	NA
Diabeté et al (2018)[32]	Benin	≥18	Women attending Dispensaire IST, the main clinic dedicated to women who engage in sex work in Cotonou	Clinic recruited cohort; all women attending invited to participate	Seroconversion between quarterly follow-ups; midpoint estimation between an HIV-negative and HIV-positive test	NA
Faini et al (2022)[33]	Tanzania	18–45	Women self-identifying as sex workers who resided within Dar es Salaam, reported to have exchanged sexual intercourse for money within the past month, considered themselves to be at increased risk for HIV infection and willing to undergo pregnancy testing	Respondent-driven sampling recruited cohort	Seroconversion follow-up visits at 3, 6, 9, and 12 months; midpoint estimation between an HIV-negative and HIV-positive test	NA
Forbi et al (2011)[34]	Nigeria	18–35	Active women who engage in sex work living in brothels within Nasarawa state of North Central Nigeria (results show all reported >1 partner per week)	Cross-sectional cohort recruited from brothels	Recent infection testing algorithm; BED assay; calculation used Hargrove adjustments[55] and McWalter and Welte's correction[56]	NA
Fowke et al (1996)[35]	Kenya	..	Women who engage in sex work of lower socioeconomic status (from a slum area in Nairobi) who engage in sex work from their home	Cohort recruited from an existing community-based cohort established in 1985	Seroconversion between follow-ups every 6 months; midpoint estimation	NA
Ghys et al (2001)[36]	Côte d'Ivoire	Median 27, (IQR 22–32)	Women who engage in sex work attending the Clinique de Confiance, a HIV/STD clinic only available for those who are women who engage in sex work or their stable sex partners	Intervention study—peer educator recruited for a survey before recruitment of HIV-negative women who engage in sex work for the study	Seroconversion between follow-ups every 6 months (HIV negative to HIV-1 seropositive; HIV-2 seropositive to both HIV-2 and HIV-1 seropositive; HIV-negative to HIV-2 seropositive); midpoint estimation	NA
Gilbert et al (2003)[37]	Senegal	Mean 30·4 (range 19–56)	Registered sex workers (self-identifying sex workers were required by government to register and regularly attend a health clinic)	Clinic-recruited cohort	Seroconversion between follow-ups every 6 months; midpoint estimation	Travers et al (1995),[57] Kanki et al (1994),[58] Kanki et al (1999)[59]
Jones (2023)[20]	Zimbabwe	Median age at first test: 27	Women attending programme clinics (predominantly cisgender women who self-identify as selling sex)	Routinely collected clinic data from CeSHHAR Zimbabwe's Key Populations Programme, which encompasses a national sex worker programme including community outreach	Seroconversion between two tests after first attending the programme; midpoint estimation	Jones et al (2022),[60] Hargreaves et al (2016)[61]

(Table 2 continues on next page)

	Country	Study population age, years	Definition of women who engage in sex work	Study design and recruitment	Incidence estimation method	Additional papers identified*
(Continued from previous page)						
Kasamba et al (2019)[38]	Uganda	≥18 (<18 included if pregnant, had children, or provided for their own livelihood)	Women who reported engaging in commercial sex (self-identified women who engage in sex work or received money, goods, or other favours in exchange for sex) or employed in an entertainment facility; analysis only included those who reported at follow-up that their sole source of income was sex work, or sex work and another job (results excluded those who did not engage in sex work)	Peer-recruited cohort at mapped sex work hotspots	Seroconversion between 3-monthly follow-ups; random estimation with uniform distribution	Vandepitte et al (2014),[62] Redd et al (2014),[63] Kasamba et al (2019),[64] Abaasa et al (2021),[65] Abaasa et al (2019)[66]
Kassanjee et al (2022)[14]	South Africa	≥18; median 32 (IQR 27–38)	Cisgender women who had sold or transacted in sex in the past 6 months and worked in one of the districts that were studied	Cross-sectional respondent driven sampling survey recruitment at hotspots visited by outreach programmes	Recent infection testing algorithm; Kassanjee method for incidence calculation; MDRI 145, FRR 0·50%	NA
Kaul et al (2004)[39]	Kenya	≥18; mean 29·1 (SD 7·8)	Women who reported having received money or gifts in exchange for sex over the past month	RCT recruited through a series of community visits assisted by peer educators	Seroconversion between follow-ups every 6 months	Kaul et al (2004),[67] Peterson et al (2013),[68] Plummer et al (1991),[69] Willerford et al (1993),[70] MacDonald et al (2000)[71]
Kerrigan et al (2019)[40]	Tanzania	≥18; mean 27·8	Women who reported exchanging sex for money in the past month	RCT recruited through time location sampling at entertainment venues	Seroconversion between baseline and follow-up at 18 months	NA
Kilburn (2018)[35]	South Africa	Recruited ages 13–20, enrolled in high school; median 15 (IQR 14–17)	Young women who reported transactional sex (where they felt that they had to have sex with a male partner as he gave them money or gifts) with any partner in the past 12 months	RCT recruited through the Agincourt Health and Social Demographic Surveillance System; participants visited at home to check eligibility for enrolment	All participants were assessed before random assignment and then reassessed annually at 12, 24, and 36 months until they graduated from high school or the study ended	Ranganathan et al (2020)[72]
Laga et al (1994)[41]	Democratic Republic of Congo	..	Women who self-identified as sex workers	Cohort study (recruitment method not reported)	6-monthly HIV-1 incidence rates were computed assuming that seroconversion had occurred at midpoint between the first positive HIV-1 serological test and the last negative one	Laga et al (1993)[73]
Lyons et al (2020)[42]	Senegal	≥18; mean 38·5 (IQR 30–45)	Women assigned female at birth and having engaged in sex work as a primary source of income during the year before enrolment	Cohort recruited through respondent-driven sampling with additional purposive sample recruitment	Time to event survival analysis (seroconversion date was the diagnosis date); 4-month follow-up visits	NA
Malama et al (2022)[17]	Zambia	18–45	Women who reported currently exchanging sex for money	Community-recruited cohort through peers and health-care workers at bars, lodges, and on streets	First visit 1 month after enrolment, then 2 months later, then quarterly	NA
McClelland et al (2015)[19]	Kenya	≥18; median 31 (IQR 26–37)	Participants self-reported exchanging sex for cash or in-kind payment; most women reported working in bars, where they met local male clients	1993–97: clinic recruited cohort with outreach meetings in bars; 1998–2017: cohort recruited through peer-led community outreach meetings at bars	Seroconversion estimated between monthly follow-ups; for women who acquired HIV and a viral load was first detected at or after seroconversion, the date of infection was estimated at the midpoint between the last seronegative and first seropositive test; for women with a detectable viral load before seroconversion (ie, HIV RNA detected but antibodies were not), infection date was estimated as 17 days before the positive viral load	Baeten et al (2007),[74] Baeten et al (2005),[75] Graham et al (2014),[76] Graham et al (2013),[77] Lavreys et al (2000),[78] Lavreys et al (2002)[79] Martin et al (1998),[80] Martin et al (2005),[81] Martin et al (1999),[82] McClelland et al (2006),[83] McClelland et al (2006),[84] McClelland et al (2005),[85] McClelland et al (2007),[86] McClelland et al (2018),[87] Richardson et al (2001),[88] Sabo et al (2019),[89] Willcox et al (2021)[90]

(Table 2 continues on next page)

	Country	Study population age, years	Definition of women who engage in sex work	Study design and recruitment	Incidence estimation method	Additional papers identified*
(Continued from previous page)						
McKinnon et al (2015)[43]	Kenya	..	Anyone enrolled at the SWOP-City clinic, a sex worker outreach programme offering integrated HIV prevention, care, and treatment services	Community-recruited cohort at hotspots through peers and health-care workers	Seroconversion between quarterly follow-ups	NA
Nagot et al (2005)[44]	Burkina Faso	15–56	Professional sex workers ("seaters" and "roamers", averaging 18–28 clients per week) and non-professional sex workers (waitresses, fruit/beer sellers, students) who did not identify as a sex workers but reported an average of 2–3 clients per week	Community-recruited cohort at workplaces through peers	Seroconversion during follow-up visits which took place every 3 months	NA
Naicker et al (2015)[45]	South Africa	≥18	Self-identifying sex workers	Purposively recruited cohort through community liaison partners	Seroconversion during monthly follow-ups; midpoint estimation	van Loggerenberg et al (2008)[91]
Nouaman et al (2022)[46]	Côte d'Ivoire	≥18; median 25 (IQR 21–29)	Women who engage in sex work working at a site of prostitution at the time of the study	Cross-sectional convenience sample recruitment by CBO staff	Recent infection testing algorithm; MDRI 0·3 years, FRR 0·013	NA
Price et al (2012)[47]	Kenya	Kilifi: median 25 (range 18–65); Nairobi: median 28 (range 18–59)	Women who had received goods or money for sex	Cohort recruitment through hotspots, VCT centres, and peer recruitment	Seroconversion between quarterly follow-ups	NA
Priddy et al (2011)[48]	Kenya	Mean 28 (range 18–55)	Women aged 18–60 years who were HIV negative and not pregnant, and who reported exchanging sex for money or gifts at least three times in the past month	Cohort recruited HIV-negative women who attended education sessions for female sex workers in the Mukuru neighbourhood of Nairobi	Seroconversion at follow-up 6 months after baseline	NA
Riedner et al (2006)[49]	Tanzania	16–39	Women working in modern and traditional bars, guesthouses, and hotels	Cohort recruited from project sites (seem to be hotspots)	Seroconversion between 3-monthly follow-ups; midpoint estimation	NA
Roddy et al (1998)[50]	Cameroon	18–45; mean 26	Female sex workers residing in Yaoundé or Douala, Cameroon, who averaged at least four sexual partners per month	RCT recruitment not clear	Seroconversion at yearly follow-up	NA
Thirumurthy et al (2021)[18]	Kenya	≥18; median 25 (IQR 22–31)	Women who reported sex work as their primary or secondary source of income with ≥2 male sexual partners in the past 4 weeks	Cohort recruited through random sampling in beach and hotspot clusters from a list of all eligible women who engage in sex work	Seroconversion between 6-monhtly follow-ups	NA
Van Damme et al (2002)[51]	Benin, Côte d'Ivoire, South Africa	≥18 (≥16 South Africa)	No explicit sex work definition provided	RCT clinic recruitment	Seroconversion between follow-ups occurring every 2 months; midpoint estimation	Auvert et al (2011)[92]
van der Loeff et al (2001)[52]	Guinea Bissau	≥15; median 28·5 (IQR 21·2–43·5)	Commercial sex workers (no further definition given)	Cohort recruited from a string of villages in northwest Guinea-Bissau	Seroconversion between first survey (occurring between 1989 and 1992) and second survey (occurring between 1996 and 1998)	NA

CBO=Community-based organisation. CeSHHAR=The Centre for Sexual Health and HIV/AIDS Research Zimbabwe. DREAMS=Determined Resilient Empowered AIDS-free Mentored and Safe women. FRR=False recency rate. IBBS=Integrated bio-behavioural survey. MDRI=Mean duration of recent infection. RCT=randomised controlled trial. RDS=Respondent driven sampling. STD=sexually transmitted disease. SWOP=Sex Workers Outreach Project. VCT=Voluntary counselling and testing. *Instances where multiple papers from the same study were identified; these papers were not used for quality assessment or incidence estimate extraction. Note that language used in this table is taken directly from the cited studies.

Table 2: **Study characteristics**

approach. Four studies estimated incidence from recency assays, and one used back calculation from age-specific HIV prevalence.

Assessment with the GHQAT classified 17 studies as good quality and the remaining 15 as fair (appendix 2 p 10). Studies all scored well in terms of study design, with study objectives and study populations clearly defined. 26 studies either had robust approaches to sampling or did not seek to generalise their findings beyond their study population so were considered adequately representative. Power calculations were presented in nine studies. Scores for study implementation varied, with ten studies reporting participation rates, of which six reported over 85% participation. For 19 studies, it was likely that participants enrolled were representative of the source population. Scoring for measurement of HIV incidence was variable. Among longitudinal studies, 12 report over 70% participant retention at 12 months or study endpoint and 15 assessed reasons for dropout or described methods to address loss to follow-up.

Incidence among women who engage in sex work was correlated with matched female incidence (Pearson's correlation coefficient=0·6 [95% CI 0·5–0·8]; p<0·0001; figure 2). In meta-analysis, HIV incidence among women who engage in sex work was almost eight times higher than in matched total population women (IRR 7·8 [95% CI 5·1–11·8]; figure 3). IRRs were greater in western and central Africa (19·9 [9·6–41·0]) than in eastern and southern Africa (4·9 [3·4–7·1]). Heterogeneity across IRR estimates was high (sub-Saharan Africa I^2 96·9%, eastern and southern Africa I^2 94·7%, western and central Africa I^2 94·9%; figure 1), although median IRRs were similar to pooled IRRs from meta-analysis (sub-Saharan Africa median IRR: 6·1, IQR 3·9–9·4; appendix 2 p 12). Sensitivity analysis using the 20 studies scoring above 60% in the quality assessment yielded a pooled IRR of 7·0 (95% CI 4·1–12·0; appendix 2 p 7). Sensitivity analysis using nationally matched incidence resulted in higher IRR (9·5 [95% CI 6·6–13·7]; appendix 2 p 8).

There was no evidence for a change in IRR over time (IRR per 5 years 0·9 [95% CI 0·7–1·2]; figure 4). Incidence in women who engage in sex work was nearly five times higher than in the total female population in 2003 estimated from the log-linear mixed-effects model (IRR 4·9 [95% CI 3·3–7·3]; figure 3; appendix 2 p 13).

In separate models fitted to data from Kenya and Zimbabwe, log IRR did not change over time in Kenya (IRR per 5 years: 1·0 [95% CI 1·0–1·1]) but increased in Zimbabwe between 2009 and 2019 (1·6 [1·3–2·1]; appendix 2 p 12). Two studies from these countries provided annual incidence estimates (appendix 2 p 9). In the Kenyan cohort, incidence among women who engage in sex work peaked at 15·8 per 100 person years in 1994 and declined to 1·3 per 100 person years in 2017. However, the declines in incidence among women who engage in sex work were matched by reductions in total female population incidence, resulting in a stable IRR over the cohort period. In the Zimbabwean cohort, the HIV incidence rate in women who engage in sex work also declined from 5·4 per 100 person years to 3·1 per 100 person years from 2010 to 2019, but the IRR increased due to faster relative declines in total population female incidence.

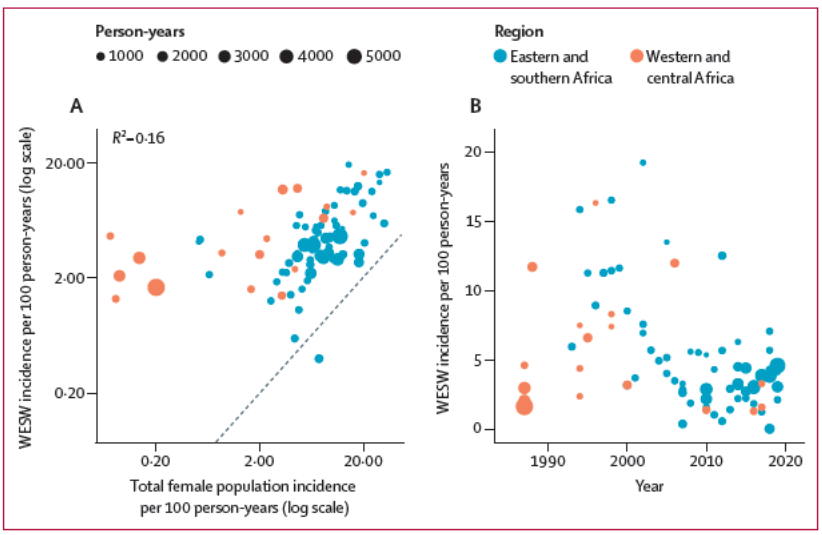

Figure 2: **Empirical estimates of HIV Incidence among women who engage in sex work**
Association between HIV incidence in WESW and in the district-year-sex matched total population (A) and empirical estimates of HIV incidence in WESW over time (B). Black dashed line represents the line of equality. WESW=women who engage in sex work.

Discussion

In sub-Saharan Africa, HIV incidence among women who engage in sex work was nearly eight times higher than in the total female population; this disparity was larger in western and central Africa, where incidence was almost 20 times higher, compared with five times higher in eastern and southern Africa. Between 1985 and 2020, incidence in women who engage in sex work declined at a similar rate to incidence in matched women in the total population; however, case studies of Kenya and Zimbabwe illustrated that these trends might vary between countries. Sensitivity analyses using national incidence estimates and restricted to high-quality studies did not alter the interpretation of our findings.

Our analysis adds to existing evidence that women who engage in sex work are disproportionately affected by HIV. High relative incidence echoes the five-fold higher HIV prevalence among women who engage in sex work compared with all adult women in sub-Saharan Africa.[2] Relative incidence was higher in western and central Africa, where overall HIV prevalence and incidence are lower than eastern and southern Africa. These findings mirror similar findings of a larger HIV prevalence gap between women who engage in sex work and the total female population in western and central Africa than in eastern and southern Africa.[2] The regional differential in

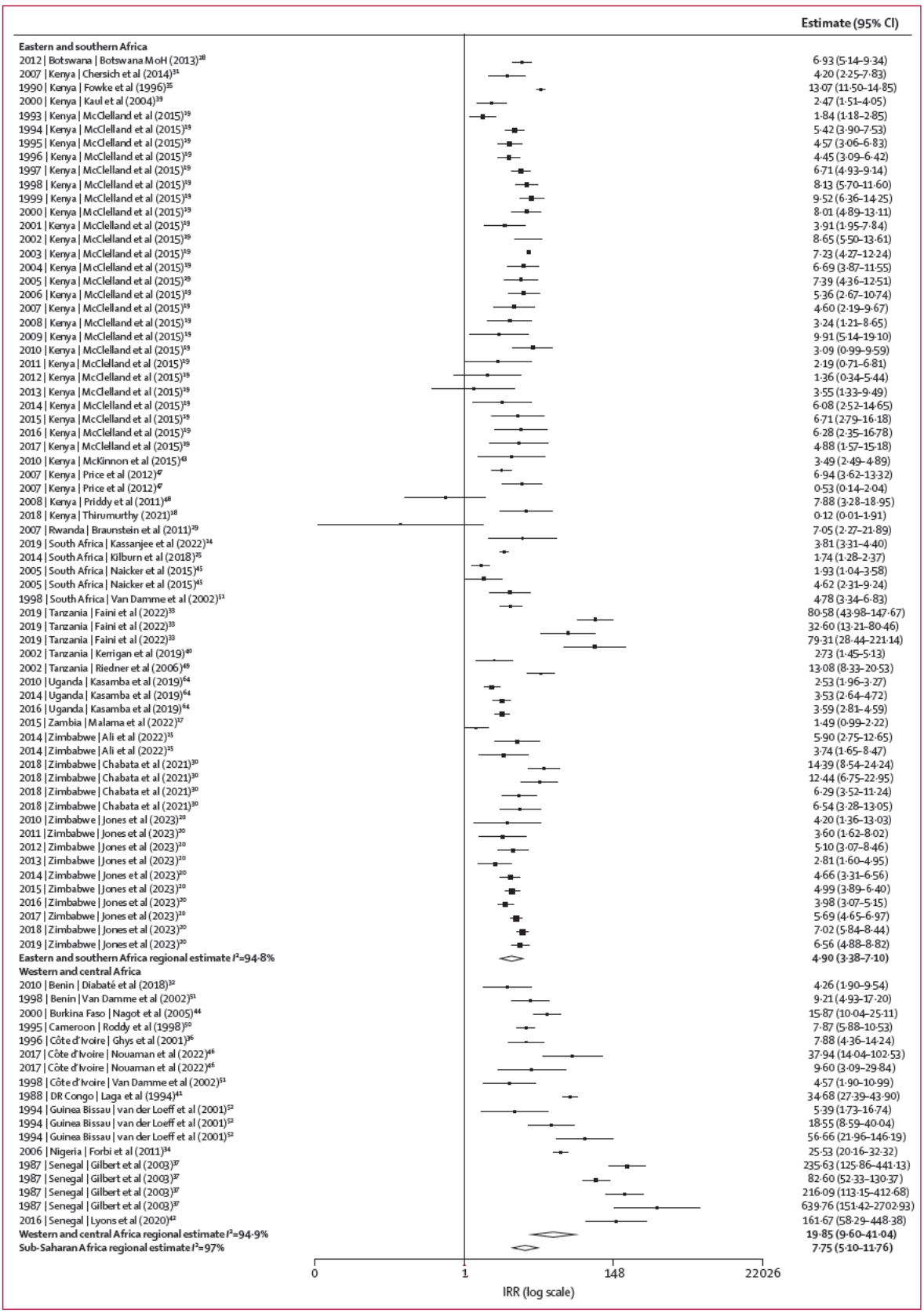

Figure 3: **Meta-analysis of HIV incidence in women who engage in sex work relative to the total female population in sub-Saharan Africa**

IRRs calculated by dividing empirical estimates of HIV incidence in women who engage in sex work by HIV incidence among total population of women matched for age, district, and year derived from the district-level estimation model Naomi,[22] and synthesised by use of meta-analysis with study-district random effects. Figure shows year of data collection, country, and study.

IRRs primarily reflects differences in population HIV incidence (the denominator for the IRR) and transmission dynamics between the regions, rather than differential incidence among women who engage in sex work.[93] Despite higher relative incidence in western and central Africa, median incidence was modestly lower than in studies in eastern and southern Africa. HIV transmission in western and central Africa tends to be more concentrated among key populations such as women who engage in sex work, resulting in larger incidence differences with the total population.[94]

The declining HIV incidence among women who engage in sex work observed in this analysis was consistent with mathematical modelling studies from western and central Africa that estimate the proportion of total new HIV infections attributable to commercial sex has fallen over time.[95,96] These parallel declines contrast HIV incidence trends among men who have sex with men in sub-Saharan Africa for whom a recent systematic review found no evidence of incidence decline.[97] Initial reductions in incidence in women who engage in sex work probably resulted from implementation of sex worker dedicated prevention programmes and health services in sub-Saharan Africa.[5] More recently, declines might reflect the effect of HIV treatment as prevention, including increasing treatment coverage among men.[1]

Studies identified in this review varied in their geographical scope, recruitment, and definition of women who engage in sex work. Inclusion criteria often defined the age range and duration or frequency of selling sex, or enrolled women self-identifying as women who engage in sex work, leading to a range of study populations with heterogeneous HIV acquisition risk. This variation is reflected by the heterogeneity in our findings. Studies among women linked to sex worker focused programmes or clinics might have recruited women at lower risk of HIV acquisition, who might be older or have sold sex for longer, potentially missing younger women, those not identifying as selling sex, and those in the highest risk period immediately following sex work initiation.[98] Data from South Africa suggest that sex work dynamics are changing, with the mean age of sex workers and durations at-risk both increasing,[99] while young women who engage in sex work remain at highest incidence risk.[100] Different sampling and recruitment approaches are also likely to have identified different women for study inclusion. Studies have shown that participants recruited through respondent-driven sampling are younger than those recruited through venue-based snowball sampling.[101] Using IRRs matched for district and age in our analysis probably mitigated some of the bias that would have come from geographical and age differences if raw estimates of incidence were analysed independently.

Our study has limitations. Data were available from less than half of sub-Saharan Africa countries, with western and central Africa particularly under-represented, and estimates for eastern and southern Africa disproportionately from Kenya and Zimbabwe. This limitation precluded estimation of country-specific IRRs and non-linear time trends and limited the generalisability of our findings. Despite the heterogeneity reported, data were insufficient to disaggregate the meta-analysis beyond region to explore factors that might have contributed to this variation; for example, age-disaggregated IRRs could have provided further insights, given evidence of higher incidence among younger women who engage in sex work.[100] For all but one study that provided a comparator group of women not engaging in sex work,[25] our IRR denominators were based on extrapolations of subnational estimates backwards in time parallel to national female incidence trajectories. Although this approach aimed to capture spatial variation over time, there is substantial uncertainty in these subnational incidence denominators, particularly for older studies, which is not reflected in the calculated IRRs. Additionally, given high mobility among women who engage in sex work,[11] matching on district boundaries might not yield the most comparable total female population denominator. However, sensitivity analysis with nationally matched IRRs gave similar results to the district-matched analysis, alleviating concerns around subnational uncertainties.

Most studies did not make inferences beyond the study population they recruited and scored positively in the quality assessment on adequately representing the wider population of women who engage in sex work. However,

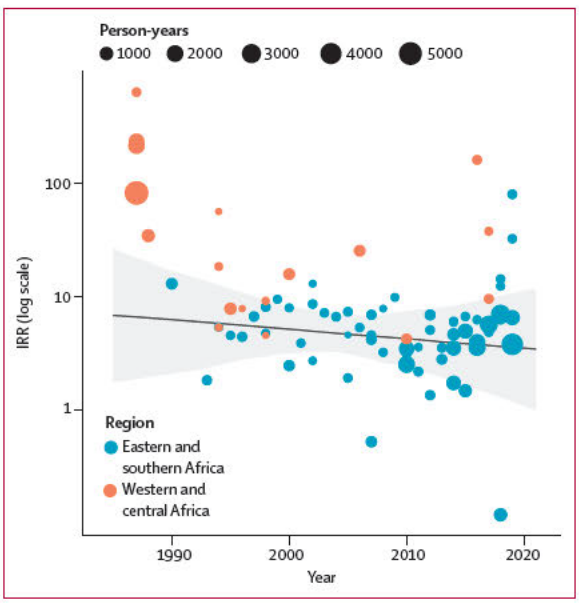

Figure 4: **HIV IRRs modelled over time, presented on the logarithmic scale**
Points represent IRRs calculated by dividing study-reported HIV incidence in WESW by age–district–year matched total population HIV incidence derived from the Naomi model.[22] The solid line represents the estimated IRR for sub-Saharan Africa, with the grey shading capturing the 95% uncertainty range. IRR=incidence rate ratio. WESW=women who engage in sex work.

it is unlikely that many studies would have been representative had they made these inferences. Ascertaining the degree of bias associated with sample recruitment posed challenges. There is no standardised approach to sampling individuals from key populations, and although respondent-driven sampling is widely accepted as a gold standard to achieving a representative sample,[102] there was variation in implementation and reporting across studies.

Our review highlights that while HIV incidence data are available for women who engage in sex work, geographical gaps remain, and temporal trends are difficult to ascertain from empirical estimates alone, particularly at country level. Individual studies were challenging to compare due to large variation in study design and the limited generalisability of findings beyond individual study populations. Standardisation in definitions for women who engage in sex work and reporting of age ranges could improve comparability of estimates. Applying consistent methodological standards for measuring incidence in key populations would improve comparability, generalisability, and ability to estimate trends. Data gaps could be addressed by incorporating incidence measurements into survey and routine programmatic data analysis via serial cross-sectional prevalence data from biobehavioural surveys and recency testing.[14,15,20,28] Increasing dissemination and use of these data where they are already collected could facilitate more robust country-level estimation and support real-time data-driven programming.

The declining HIV incidence among women who engage in sex work in sub-Saharan Africa parallel to incidence trends among all adult women represents progress, but the persistently large disparity in HIV incidence highlights the need to sustain and continue to expand effective HIV prevention options and support for women who engage in sex work. Preventing new HIV infections though focused programmes for key populations, including options and preferences for different prevention technologies, will become increasingly important as incidence further declines in the general population.[103] Counterfactual-based modelling shows that fully meeting HIV prevention and treatment needs of women who engage in sex work would substantially affect the HIV epidemic in sub-Saharan Africa, and that averting HIV transmission associated with sex work should remain a programmatic priority to achieve, and sustain, epidemic control.[6,8,96] Transitioning from continent-level summaries to location-specific and programme-specific monitoring to ensure inequalities are identified and addressed in a timely and efficient manner will require expanded future surveillance activities with more standardised approaches to obtaining empirical estimates and repeat measures in the same populations.

Contributors

OS, RLA, and HSJ conceptualised the study. JRH and HSJ conceived and conducted the initial literature review with HC. RLA updated the review and identified additional unpublished data. RLA led the quantitative data extraction and HSJ led data extraction of study methods. RSM, HT, BAR, KM, FMC, and HSJ provided unpublished data. RLA and OS led the quantitative analysis. HSJ led the quality assessment. JWI-E and JRH provided technical input throughout the study. HSJ, RLA, and OS wrote the manuscript. All other coauthors contributed to the interpretation of results and reviewed the manuscript for intellectual content. RLA and OS directly accessed and verified the underlying quantitative data and RLA and HSJ directly accessed and verified the underlying qualitative data reported in the manuscript. All authors read and approved the final version of the manuscript for submission.

Declaration of interests

We declare no competing interests.

Data sharing

Data collected for this study did not include individual participant data. All aggregate data extracted from published literature or provided by co-authors and analysed in meta-analysis are reported in table 1. Data in spreadsheet format and R code to reproduce analysis are available from: https://github.com/rebecca-and/WESW-incidence.git.

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Table 3.1.3 Global HIV Quality Assessment Tool Summary Table

	Was the research question or objective in this study clearly stated?	Was the study population clearly defined?	Will the study population defined answer the research question proposed?	Was the sample size justified either through a power description, or variance and effect estimates?	Was the proportion of people who agreed to participate reported?	Was the proportion who agreed to participate at least 85%?	Is there reason to believe that the participants enrolled are a representative sample of the source population?	Are the numerator (number newly infected with HIV) and total amount of person-time at risk reported?	Was the HIV outcome clearly defined? [a]	Were the statistical methods used to assess HIV outcome appropriate?	Have actual confidence intervals been reported?	Was the time frame sufficient so that one could reasonably expect to incident infections representative of the underlying incidence? [b]	By the end of the study, was retention reasonable? [c]	If dropout was greater than or equal to 10%, did the authors assess reasons for dropout or compare those who dropped out to those who remained in follow-up? [d]	TOTAL (N)	TOTAL (%)
Ali (2020) ‡	1	1	1	0	0	0	1	1	1	1	1	-	-	-	8	73%
Botswana MoH (2013) ‡	1	1	1	1	0	0	1	1	1	1	1	-	-	-	9	82%
Braunstein (2011)	1	1	1	1	0	0	1	1	1	1	1	1	1	0	11	79%
Chabata (2021)	1	1	1	1	1	1	1	1	1	1	1	1	0	1	13	93%
Chersich (2014)	1	1	0	0	1	1	1	1	1	1	1	1	1	1	12	86%
Diabete (2018)	1	1	1	0	0	1	1	1	1	1	1	1	1	1	12	86%
Faini (2022)	1	1	1	0	0	0	1	1	1	0	0	1	1	0	8	57%
Forbi (2011) ‡	1	1	0	0	0	0	0	1	1	1	1	-	-	-	6	55%
Fowke (1996)	1	1	1	0	0	0	0	1	1	0	0	1	0	0	6	43%
Ghys (2001)	1	1	1	0	1	0	1	1	0	1	1	1	0	1	10	71%
Gilbert (2003)	1	1	1	0	0	0	1	1	1	1	1	1	0	0	9	64%
Jones (2023)	1	1	1	0	1	0	1	1	1	1	1	1	0	0	10	71%
Kasamba (2019)	1	1	1	0	0	0	1	1	1	1	1	1	1	1	11	79%
Kassanjee (2022) ‡	1	1	1	1	0	0	1	1	1	1	1	-	-	-	9	82%
Kaul (2004)	1	1	1	1	1	0	0	1	0	1	0	1	1	1	10	71%
Kerrigan (2017)	1	1	1	1	0	0	1	0	0	1	0	1	0	0	7	50%

Kilburn (2018)	1	1	0	0	0	0	0	1	1	1	0	1	0	1	7	50%
Laga (1994)	1	1	0	0	0	0	0	1	1	1	0	1	0	0	6	43%
Lyons (2020)	1	1	1	0	0	0	1	1	1	1	1	1	0	0	9	64%
Malama (2022)	1	1	1	0	1	0	1	1	0	1	0	1	0	0	8	57%
McClelland (2006)	1	1	1	0	0	0	1	1	1	1	1	1	0	1	10	71%
McKinnon (2015)	1	1	1	0	0	0	0	1	0	1	1	1	0	1	8	57%
Nagot (2005)	1	1	0	0	0	0	0	1	0	1	1	1	1	1	8	57%
Naicker (2015)	1	1	1	0	1	1	0	1	1	1	1	1	0	0	10	71%
Nouaman (2022) ǂ	1	1	1	0	0	0	0	1	1	1	0	-	-	-	6	55%
Price (2012)	1	1	1	0	1	1	1	1	0	1	1	1	1	1	12	86%
Priddy (2011)	1	1	1	0	0	0	0	1	0	1	1	0	1	0	7	50%
Riedner (2006)	1	1	1	0	0	0	0	1	1	1	1	1	1	1	10	71%
Roddy (1998)	1	1	1	1	1	0	0	1	1	1	0	1	1	1	11	79%
Schim van der Loeff	1	1	1	0	0	0	1	1	1	1	1	1	0	1	10	71%
Thirumurthy (2021)	1	1	1	1	1	1	1	1	1	1	0	1	1	1	13	93%
Van Damme (2002)	1	1	0	1	0	0	0	1	1	1	0	1	0	0	7	50%
TOTAL (N)	32	32	26	9	10	6	19	31	24	30	21	26	12	15		
TOTAL (%)	100%	100%	81%	28%	31%	19%	59%	97%	75%	94%	66%	96%	44%	56%		

a. additional criteria: reporting approach to seroconversion date estimation
b. additional criteria: minimum 12 months follow up
c. additional criteria: 70% retention
d. additional criteria: approaches addressing loss to follow up

3.8. Chapter summary

Collectively, these reviews have highlighted the continued gaps in data on FSW in relation to diagnosis and rates of HIV infection, as well as the challenges around synthesising these data to get a broader understanding for sub-Saharan Africa and identifying any trends over time. Both reviews indicate that data in this area is becoming less sparse and we are moving towards being able to identify regional trends with FSW data alone. They both highlight the need for repeat measures in the same population or for longitudinal data tracking these metrics over time. Beyond a paucity of data, the challenge for data synthesis lies in the heterogeneity in estimates and variance in studies that measure these metrics. This is mostly in terms of who they include, for example and how they describe FSW, plus the wide variation in how well these women may represent the wider FSW population in relation to both definition and sampling approaches. These are all important considerations in the interpretation of my findings and in relation to other literature, particularly considering they are from a programme where women will predominantly identify as a FSW. I aim to address and explore some of gaps identified in my reviews among FSW in Zimbabwe

4. METHODS

In this section I provide an overall summary of the methods I have used throughout my PhD, giving additional context and details where these have not been provided in my results chapters. In my introduction I offer an overview of the context in which CeSHHAR's KP Programme data are collected, giving a picture of where FSW in Zimbabwe may or may not be accessing services and consequently appear in the analysis datasets I use in my PhD. Here I describe the CeSHHAR KP Programme and give details of service delivery and how this has changed over time, to provide insight into where programme reach and access may have varied both temporally and geographically. I discuss the process of data collection and management, and how this has developed, to highlight where inaccuracies or bias may exist. I provide a rationale for the approaches I took to minimise these biases and outline the approaches and assumptions I make in my analyses.

4.1. Involvement in data collection

This section outlines where I have led and developed the methodological aspects of my PhD and where this was more collaborative or led by others. My PhD has not taken place in isolation and without the staff at CeSHHAR implementing the KP Programme, developing the data systems and collecting the data that I analyse here my PhD would not exist.

The main data source for my PhD is the CeSHHAR KP Programme dataset, which is collected alongside the delivery of routine sexual and reproductive health services to FSW accessing the programme since 2009. I was not involved in primary data collection. These data have been collected and managed by the programmes and data teams in Zimbabwe. These data include the results and dates of HIV tests done through the programme. When I refer to "programme data" from this point forward I am referring to a de-identified, individual level dataset including at least the results and dates of HIV tests and some socio-demographic data that has been shared with me by the KP Programme for the purposes of analysis for my PhD. I also use recent HIV infection testing data from a study conducted within the KP Programme by the KP research team at CeSHHAR Zimbabwe. These data were collected between 2021 and 2023. Throughout my PhD I have spent time in Zimbabwe, I have visited programme sites and spent time with staff at CeSHHAR to familiarise myself with service delivery and data collection processes. I have worked closely with the data and programme teams at CeSHHAR to inform the steps I have taken in the management and merging of data to generate suitable datasets for an analysis. My contribution

has been in conceiving and conducting the analysis of these data and making recommendations for their potential use.

4.2. CeSHHAR's Key Populations (KP) Programme

CeSHHAR's KP Programme, formerly Sisters with a Voice, is a nationally scaled programme delivered on behalf of the Zimbabwe MoHCC providing free services to predominantly cis-gender women who sell sex and are at least 16 years old. Key programme terms are presented in table 4.1. The programme was set up as a demonstration project in 5 sites (locations where services are delivered through clinics and in the community) in September 2009 and has expanded significantly over the past 13 years, providing services from 86 sites in 40 districts across all 10 provinces of Zimbabwe by 2023. From its inception, the KP Programme has formed part of a programme-research platform. Through the KP Programme, data has been routinely collected on the delivery of comprehensive sexual health and HIV services, research has been conducted on enhanced service delivery through cluster-randomised intervention trials, and estimates have been made on the size of the FSW population. Population impact has been measured through RDS surveys conducted since 2011. As a consequence, service delivery has not remained static, with changes in sites and modes of delivery, enhanced services delivered in sites linked to research projects and standard of care delivered in others. I outline these changes below and in Figure 4.1. to provide further context for my PhD.

Table 4.1 KP Programme definitions

Term	Definition
Static site	A clinic site operating 5 days a week. Linked and reporting into government health facilities. Most are based in government health facilities (~65%) but some in other locations, e.g. border sites.
Mobile outreach site	A clinic site delivering clinical services once a week (previously once every two weeks). These include local mobile sites linked to a static site hub and running mobile clinical services within public sector facilities/clinic/hospital spaces in the same city. Highway mobile sites are linked to a static hub in a different city, going across district lines to deliver services (always within the same province).
Out of facility services	Clinical services delivered in the community including HIV testing, ART and PrEP refills. These are run out of a static site with teams including a nurse and outreach worker going to homes or delivering services from a mobile van when needed.

Peer-led outreach	All community based outreach activities where non-clinical services are provided. Outreach is done as and when needed, sometimes at night or over weekends. This includes outreach for condom distribution, self-test kits. A large component of peer-led outreach is microplanning. Microplanners identify where to go (e.g. bars).
CeSHHAR clinic staff	Staff at a clinic include nurses, outreach workers, drivers and strategic information officers. Nurses deliver clinical services.
Outreach workers	These are CeSHHAR staff that coordinate and support peer-led microplanning. They provide screening in clinics when a FSW first accesses services. They provide some of the counselling. They are mostly social workers and not clinically trained.
Mircroplanners	FSW peer-outreach workers, formally (briefly) empowerment workers. They lead community microplanning under the coordination of the outreach workers.

4.2.1. Programme delivery

The KP Programme delivers services through static and mobile clinic sites. Statics sites are open from 8am to 4.30pm, mostly housed within Ministry of Health facilities, delivering services five days a week. Mobile sites deliver services at least once a week, also mostly from government facilities, but with staff travelling to a site each day to provide services. Sites are based in a range of geographical locations, including urban, rural and highway locations (Figure 4.2). Sites have also occasionally moved, for example, in Harare the KP clinic moved out of the City of Harare (Mbare) between 2013 and 2016 to the Central Business District.[6] Early implementation was at 5 sites in locations with high volumes of sex workers. By the end of 2017 the KP Programme was operating in 36 sites and the delivery of services had intensified with outreach being delivered every week instead of every two weeks. By 2018 the KP Programme was well established with 57 clinic sites (12 static) and by 2023 with 86 sites. Throughout there have been disruptions in funding and in service delivery. There was a funding gap of 6 months in the second and third quarters of 2012 followed by elections during 2013 which disrupted service delivery, and funding interruptions forced closures of 18 outreach sites during 2016 and again in 2017[6] (Figure 4.1). The latest significant disruptions were in 2020 due to Covid-19 which are described in more detail at the end of this chapter.

Figure 4.1: Timeline of KP Programme implementation, policies and research initiatives

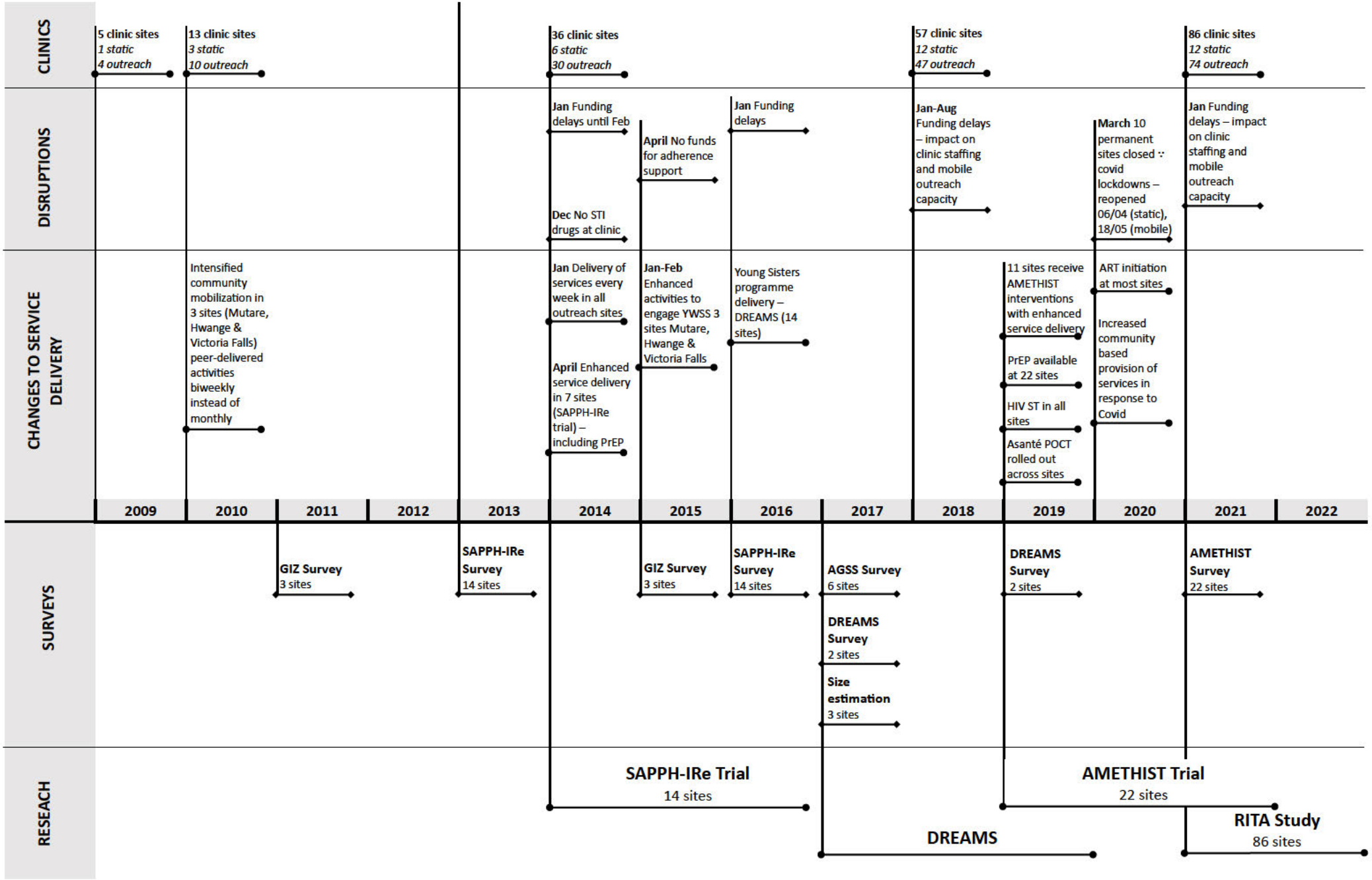
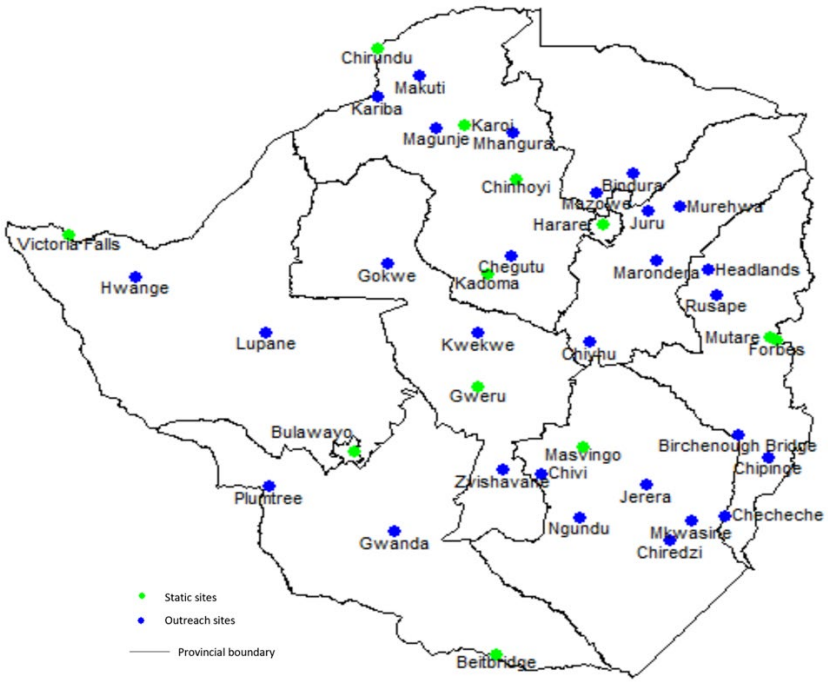

CLINICS
5 clinic sites
1 static
4 outreach
13 clinic sites
3 static
10 outreach
36 clinic sites
6 static
30 outreach
57 clinic sites
12 static
47 outreach
86 clinic sites
12 static
74 outreach
DISRUPTIONS
Jan Funding delays until Feb
Dec No STI drugs at clinic
April No funds for adherence support
Jan Funding delays
Jan-Aug Funding delays – impact on clinic staffing and mobile outreach capacity
March 10 permanent sites closed ∵ covid lockdowns – reopened 06/04 (static), 18/05 (mobile)
Jan Funding delays – impact on clinic staffing and mobile outreach capacity
CHANGES TO SERVICE DELIVERY
Intensified community mobilization in 3 sites (Mutare, Hwange & Victoria Falls) peer-delivered activities biweekly instead of monthly
Jan Delivery of services every week in all outreach sites
April Enhanced service delivery in 7 sites (SAPPH-IRe trial) – including PrEP
Jan-Feb Enhanced activities to engage YWSS 3 sites Mutare, Hwange & Victoria Falls
Young Sisters programme delivery – DREAMS (14 sites)
11 sites receive AMETHIST interventions with enhanced service delivery
PrEP available at 22 sites
HIV ST in all sites
Asanté POCT rolled out across sites
ART initiation at most sites
Increased community based provision of services in response to Covid
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
SURVEYS
GIZ Survey
3 sites
SAPPH-IRe Survey
14 sites
GIZ Survey
3 sites
SAPPH-IRe Survey
14 sites
AGSS Survey
6 sites
DREAMS Survey
2 sites
Size estimation
3 sites
DREAMS Survey
2 sites
AMETHIST Survey
22 sites
RESEACH
SAPPH-IRe Trial
14 sites
AMETHIST Trial
22 sites
DREAMS
RITA Study
86 sites

Figure 4.2 Map of CeSHHAR's KP Programme sites in Zimbabwe



In a clinic the first point of contact is usually an outreach worker; these are non-clinical CeSHHAR staff, often social workers who conduct a verification (checking if the woman has previously accessed services) and screening (to identify if the woman is a sex worker) and then referral (to the nurses). The outreach worker will run awareness sessions, condom demonstrations and distribute condoms at the clinics. After an initial screening, nurses offer general STI exams, family planning, HIV testing, initiation on PrEP (since 2019), referrals to MoH clinics for ART and more recently ART initiation on site (since 2021), and other referrals. For family planning women have the option of long-term family planning (implants) or shorter-term family planning (oral or injectable). Clinics treat other illnesses such as respiratory tract infections. When needed, clinical staff and outreach workers will deliver services outside a facility, either from a mobile van or in individuals' homes.

Community outreach services are also delivered from each site. Outreach is led by peer mircroplanners and coordinated and supported by outreach workers. Outreach involves peer-led mircroplanning, weekend and night outreach. FSW peer microplanners are employed by the KP Programme to deliver outreach in the community. In 2017, peer-led microplanning was introduced in Harare. The mircroplanners have a caseload of 50-80 other FSW in a designated hotspot who they risk assess and support with different levels of intensity dependent of their level of risk. In

2019, microplanning was implemented in 11 sites as part of the AMETHIST trial (described in more detail later) and scaled up nationally in 2021.[215]

4.2.2. HIV testing

HIV testing is offered in line with Zimbabwe's national HIV testing algorithm.[142] Since 2014 initial screening has been performed with Determine HIV-1/2 (Abbott Diagnostics, Tokyo, Japan) antibody testing or OraQuick self-test kits. Confirmatory antibody testing is performed with SD Bioline HIV-1/2 (Abbott Diagnostics, Tokyo, Japan). HIV testing is offered at a first clinic visit to women who are HIV negative or of unknown HIV status and to HIV-negative women revisiting a clinic who have not tested in the previous six months. For women confirmed HIV positive a referral is made to MoHCC clinics in line with ART initiation guidance at the time of testing. In static sites ART clinics are often in the same government facility as the KP clinic. Since 2021 women have been initiated on ART on site at 11 KP clinics. Women testing newly HIV-positive are asked to provide contacts for the KP Programme to undertake index (sexual and family contacts) and social (social network contacts) network testing, who clinic staff then attempt to locate (either directly or indirectly) and offer voluntary HIV testing.

4.2.3. Recent HIV infection testing

In 2019, CeSHHAR's KP Programme began delivering rapid point of care (Asanté) recent HIV infection testing on behalf of the MoHCC. This was conducted in all sites for surveillance purposes without results of the recency tests being returned to individuals. In 2018 a pilot study to explore the implementation of laboratory recent HIV infection testing was carried out by the programme in six static sites.[70] The study identified challenges with implementation related to sample collection and handling, integrating the delivery of recency testing into routine services, and returning the results to clients.[70] On 5th October 2021, as part of the Bill and Melinda Gates funded MeSH consortium, laboratory recent HIV infection testing was rolled out across the KP Programme. Implementation of recent infection testing for the full study is described in more detail in chapter 7. In brief, all women 18 years and older with a confirmed HIV positive test in the KP Programme, with no history of an HIV-positive test within the past year, or who were not on ART, were eligible for enrolment in the study. Dried blood spot (DBS) samples were collected from each consenting woman, and in pre-selected sites plasma samples were also collected (plasma results not included as part of this PhD). All samples were delivered to the Flow Cytometry Laboratory in Harare for testing. Results were not returned to individual women. The overall aim of the study was to explore the utility of assessing recency of HIV infection among female sex workers to guide their individual management and to target HIV prevention more effectively.

4.2.4. Implementation during Covid

While my first two analysis chapters pre-date Covid-19 with data up to the end of 2019, my final analysis uses data collected during this period. Covid-19 had implications for both service delivery and routine programme data collection. Lockdown restrictions were introduced in Zimbabwe in late March 2020. CeSHHAR's KP Programme had to close 10 permanent sites for one week and all mobile clinics for six weeks. Permanent sites were reopened on 6th April 2020 and mobile services resumed on 18th May 2020. Routine clinic visits were discouraged for a time after this to ease the burden on facilities.[216] Between October and December 2020 there were significant commodity shortages in the country impacting the delivery of services such as PrEP.[216] Challenges with travel authorisation and the financial implication of the pandemic also impacted the ability of FSW to access services.[217]

4.2.5. Research implementation

Alongside programme implementation a series of research projects have been conducted (Figure 4.1). These have generated enhanced service delivery at specific sites for varying periods of time. In 2011 a GIZ funded project in Hwange, Mutare and Vic Falls supported enhanced community mobilisation which was then rolled out across the programme.[218] RDS surveys were conducted in 2011 and 2015 to assess the impact of these services. In 2014 additional services were provided to engage young women who sell sex (YWSS) through the Young Sisters programme.[219] Between 2014 and 2016 the Sisters Antiretroviral Programme for Prevention of HIV – an Integrated Response (SAPPH-IRe) cluster-randomised trial was conducted in 14 sites alongside KP Programme services. The intervention was designed to strengthen engagement of FSW in HIV prevention and care. Sites were randomised 1:1, with normal service delivery in control sites and enhanced services, including additional HIV testing, ART initiation at sites, PrEP, adherence, and intensified community mobilisation in trial sites. At the time this was the only access to PrEP for FSW in Zimbabwe. Rates of HIV diagnosis and treatment initiation increased due to the intervention.[6] From 2016 the Young Sisters programme, part of the PEPFAR funded DREAMS partnership, offered services to young women who sell sex in 14 sites.[220] The DREAMS implementation was evaluated among FSW 18-24 years old in a non-randomised plausibility study in which service uptake and HIV incidence were compared between sites implementing and not implementing DREAMS.[221] In 2017 a survey was conducted among adolescent girls who sell sex (AGSS) (16–19 year olds) to explore the risks and patterns of selling sex among younger women.[188] Most recently CeSHHAR implemented the AMETHIST trial (Adapted Microplanning: Eliminating Transmissible HIV In Sex Transactions) through which enhanced services were delivered at 11/22 sites enrolled in the study. Enhanced services consisted of a combination of microplanning and self-help groups (SHG) to increase the uptake of existing HIV prevention

options and HIV treatment to reduce the proportion of FSW at risk of acquiring or transmitting HIV.[215]

4.3. Data collection

The main source of data for my PhD are individual-level records generated through service delivery in CeSHHAR's KP Programme (programme data). These programme data are routinely collected by clinical staff (nurses) through a series of clinical and sociodemographic questions asked of woman as they access clinical services, and a record of the services delivered. Here I describe the systems and processes of data collection in the programme. Data have been collected in different formats and across different systems, many of which have been upgraded over time. In Table 4.2 I summarise the data sources and analysis methods I use against each of my research questions.

Table 4.2 Research questions, data sources and analysis methods

Research objective	Data Sources	Methods
1. To analyse trends in HIV testing and test positivity between 2009 and 2019 among female sex workers accessing targeted HIV testing services in CeSHHAR's KP programme in Zimbabwe	KP programme data 2009-2019 (Demographic, clinical and HIV testing data)	Quantitative analysis of HIV test results using adjusted Logistic regression with interaction terms and robust standard errors to account for clinic and individual level clustering (Chapter 5).
2. To analyse trends in HIV testing and test positivity between 2009 and 2019 among female sex workers accessing targeted HIV testing services in CeSHHAR's KP programme in Zimbabwe	KP programme data 2009-2019 (Demographic, clinical and HIV testing data)	Quantitative analysis of repeat HIV testing data for individual FSW, seroconversion rates estimates by two-year time period accounting for clinic level clustering. Poisson regression to compare differences over time (Chapter 6).
3. To explore recent HIV infections using a recent HIV infection testing algorithm among female sex workers testing HIV-positive in CeSHHAR's KP Programme in Zimbabwe and estimate HIV incidence.	Programme data 2021-2023, ICT/SNT data, recent HIV infection testing laboratory data.	Quantitative analysis of recent HIV infection testing data (Chapter 7).

4.3.1. Clinic registration and unique identifying information

Since 2009, KP Programme staff have registered each new FSW presenting at a KP clinic using the LinkLog (up to Jan 2021, now the register app), a secure database locally held on a Structured Query Language (SQL) server. Through the LinkLog each FSW is assigned a Sisters number, a chronological number with a prefix to indicate the site where the SW was first registered, e.g. xx-00001. The Sisters number can be used by the FSW across all clinic sites. In 2017, an algorithm for a unique identifier (UIC) was introduced to help uniquely identify FSWs accessing clinic services. Information collected through questions asked of a FSW by clinic staff on their mother's name, their surname, district of birth, date of birth and gender is used to generate and assign the UIC alongside the Sisters number on her first clinic visit. With the introduction of microplanning in 2018, the allocation of a Sisters number and UIC may predate a first clinic visit, with microplanners allocating a number when they come into contact with women in the community. When women are referred to the clinic they come with their unique number; if they do not have this they are allocated a new one. The purpose of the LinkLog is to securely store contact details and all unique identifying information, to generate the UIC and allocate Sisters numbers. Client registration in the LinkLog is possible without women receiving any clinical services.

Each time a woman accesses clinical services she is asked if she has previously visited the KP Programme. LinkLog data are accessed by clinic staff (either manually to get the Sisters number or automatically to generate a new clinic form for entry on a tablet) to ensure that the new clinical record is assigned to the correct woman or existing records are linked. If the LinkLog is not accessible at the time due to internet issues this is sometimes done through WhatsApp messages between the clinical staff and staff in CeSHHAR's main office to see if they are able to access the Sisters number. This is then recorded by clinic staff on paper records. Some FSW come with their numbers, others will provide their name or other identifying information so their record can be identified.

4.3.2. Demographic and clinical data

Basic demographic information on date of birth, marital status, level of education, religion and number of biological children are collected by clinical staff at a first clinic visit (demographic form). Staff ask a series of demographic questions and record the responses during a woman's first clinical consultation. A word version of the demographic form with these questions is in Appendix 5. Clinical information is then collected through a series of questions asked of the FSW by clinic staff, and from a record of the services delivered at the first visit and each subsequent clinic visit. Data are collected on the reason for the visit and on self-reported sexual and HIV testing history. The services delivered and the results of any STI examination, HIV testing delivery and test results from that visit are recorded. The full set of clinic visit questions (also known as the STI form) are

in Appendix 6. Questions have been added to the STI form over time, including updates for questions on PrEP and from 2020 questions on length of time in sex work, the cost of selling sex and impact of Covid-19 on sex work. Details of the questions and response options to the main variables used in my PhD alongside the variables and categories that I have generated from these and any logical checks are in Table 4.5. Alongside these two forms, data are routinely collected on the number of sexual and social network contacts of women testing newly HIV positive. This information is obtained through a conversation initiated by clinical staff where information on the number of contacts, as well as the contact details are collected. Subsequently, the number of individuals reached and tested from those contacts and the number of those tests that are HIV positive is recorded. These data are recorded by clinic staff in MoHCC paper registers and were only captured electronically for the purposes of analysis for the RITA study. In addition to individual level data, staff at each clinic record daily summary data as daily logs with aggregate numbers of visits, HIV tests and abbreviated data collected in the STI forms. HIV testing data are also captured in the MoHCC HTS register.

4.3.3. Recent HIV infection testing data

Additional data were collected by clinic staff between 2021 and 2023 for the RITA study. For women enrolled in the study a unique identification code (RITA ID) was assigned using site codes and a unique number, e.g. xxx-xx-A001. A paper form was completed by clinic staff with details of Sisters ID, sample collection date and clinic for each woman enrolled. This information was collected by the head office to complete the study enrolment register (excel spreadsheet). A centrally held database was kept with anonymised enrolment details and RITA ID and updated with RITA results when they were returned from the laboratory. A separate centrally held register was kept with RITA and Sisters ID so these were linkable for analysis. Laboratory data were entered into the Maxim spreadsheet in excel by laboratory staff under the RITA ID (Table 4.3).

Table 4.3 RITA study datasets, collection mode and data systems

Dataset	Description	Collection	Database
RITA enrolment data	Details of sample collection data	Clinic staff	Excel
RITA linkage data	Sisters ID and RITA ID	Study coordinator	Excel
Laboratory data	Batch processing date, sample analysis data, final result	Laboratory staff	Maxim spreadsheets

4.3.4. Programme data systems

Data on demographic characteristics, clinic visit information and HTS data have been collected and stored in three different electronic systems since 2009. A Microsoft Access database was initially used, with Access databases held separately for demographic data, clinic visit data and HTS data, all linkable through a Sisters ID. Data were collected on paper forms by nursing staff and then single-entered into the Access database retrospectively by a data entry clerk (Table 4.4).

Table 4.4 KP programme datasets, collection mode and data systems

Dataset	Description	Collection	Database
Link log	A secure database holding details of a woman's UIC and Sisters number	Direct entry by clinic or programme staff	LInklog SQL secure server
Demographic	Demographic details collected at a first Sisters clinic visit.	Clinic staff enter directly into tablets or onto paper forms	Microsoft Access, Coconut, DHIS2
STI & clinic visit	Details of a specific clinic visit. Each visit identifiable by a date and Sisters number	Clinic staff enter directly into tablets or onto paper forms	Microsoft Access, Coconut, DHIS2
HIV testing data	Data on HIV testing and test results (between 2009-2014) HTS data afterwards collected in the STI form	Clinic staff	HTS Access database, Coconut
ICT & SNT (Index & Social network testing)	Data recorded on MoHCC registers.	Clinic staff, SIEs	MoHCC registers, entered from into Excel for RITA study

In 2014 electronic data capture was introduced through an electronic record system, RTI International's Coconut Surveillance Case Management system (Coconut). The application was supported for use on android based mobile devices where data was stored on the device when working offline and synced to a cloud server when there was internet connectivity. The Coconut system was adopted to minimise double-counting sex workers who registered at a different clinic by enabling data sharing of patient records across the clinics, and to provide continuity of care for individual women. In Coconut, demographic data and clinic visit data were held separately, with HTS data now included in the electronic clinic data collection system. Data has intermittently been

collected on paper forms when internet connectivity was poor and paper records were faster. The data collection forms are in Appendix 5 and 6.

From October 2020 to the end of the period of data collection covered in my PhD, data was captured from all clinics on paper forms while a new DHIS2 system was being set up. This period of data collection is relevant to my last PhD objective on recent HIV infection testing in the KP Programme. During this period there were two versions of the printed data capture forms. The older Coconut version and the newer DHIS2 version. The new DHIS2 system included updated questions and a new data collection format. When DHIS2 was up and running in 2022 the backlog of data captured on paper forms was entered. This was challenging. There was nothing to ensure that the paper form was fully filled in so there was frequently incomplete information, the forms were often faint and poorly photocopied or printed and some of the questions hard to read. For data entry, handwriting was sometimes a challenge to interpret and the order of questions on the forms did not match the online data entry forms. With the import of historical data and direct system data entry DHIS2 holds CeSHHAR's programme records.

4.3.5. Data storage and management in Zimbabwe

In Zimbabwe data from the relevant databases between 2009 and 2019 were synced weekly to a central secure cloud server. The flow of data in Zimbabwe, from clinics to head office can be followed in the flow diagram (Appendix 7). Data that were shared with me for my PhD, for the purposes of analysis outside CeSHHAR, were first downloaded from the cloud server in Zimbabwe, stored securely locally and cleaned. Data cleaning and checks are conducted regularly for the KP Programme data by the team in Zimbabwe. Checks are done against the daily log sheets to identify any discrepancies in numbers. If these are identified, then the appropriate action is taken to identify whether there was a syncing issue or a data entry issue. Checks for duplicate records are conducted in STATA, using identifiable data stored in the Linklog to check that women with the same identifiable data have not been issued more than one Sisters number. For this PhD, I only had access to de-identified data after these processes had taken place, except for a short period during the RITA study which will be described in more detail later.

4.3.6. Data sharing agreements and processes

On 9th December 2019 a data sharing agreement outlining procedures for transfer and use of clinical records and other routine programmatic data collected by the KP Programme in Zimbabwe was drawn up by me and others. This covered data to be shared between CeSHHAR and the London School of Hygiene and Tropical Medicine (LSHTM). The agreement stated that to share the agreed datasets, data managers at CeSHHAR would upload anonymised data files to SharePoint, a shared platform that will initially be hosted by the LSHTM, with plans to move hosting

to Zimbabwe at a later date. Data would be uploaded as three separate STATA files for 1) demographic data, 2) STI data and 3) HIV testing data. Any data hosted on SharePoint will be anonymised. Where SharePoint was not accessible, data have been shared through the LSHTM Filr system which also enables secure sharing of data. The final signed data sharing agreement is in Appendix 8.

4.4. PhD Data Management

The data management decisions I made throughout my PhD have been informed by the service delivery, data collection processes and databases I have just described. Here I outline the data management I carried out with the programme dataset and the data management and linkage for the RITA study. Further details of data management and assumptions made for each study are provided in the relevant chapters. Here I describe the rationale for each substantial decision I made.

Table 4.5 Variables in the KP Programme dataset

Variable	Question response	Variable coding & data management
Date of birth	DD/MM/YY	<25/ 25+, also used as continuous variable with age at clinic visit. Updated for each clinic visit using visit year & adding years to age
Age	Years	Used if DOB was missing
Marital status	Never married or have never lived together, Divorced/separated, Married or Cohabiting, Widowed	
Level of education	None/Primary School/Secondary school/ tertiary education	None or primary Secondary or tertiary
Gender based violence *In the past six months have you experienced any of the following?*	Legal issues/Domestic Violence/Police violence/Client violence/Rape/Other	Ever experienced GBV (0/1), any of 1=Client violence 1=Domestic violence 1=Rape
Clinic visits - visit date (staff entry)	DD/MM/YY	Not required (system generated)
Condom use at last sex (regular/client) *During the most recent sex with your regular partner did you use a condom? During the most recent sex with your most recent client did you use a condom?*	No/Yes	Recent condom use (0/1) - either 1=recent with partner 1=recent with client

Ever HIV tested (self-report) Have you ever had an HIV test	Yes/No	0,1, . If HIV test date has valid data and ever hiv tested ==0 or ==. change to ==1
Last HIV test date (self-report) *Do you know the day of your last HIV test/what is the day of your last HIV test; Do you know the month of your last HIV test/what is the month of your last HIV test; Do you know the year of your last HIV test/what is the year of your last HIV test*	number between 1 and 31, month, year (sperate variables)	2 stages of data management 1) against visit date 2) against previous test dates
Clinical diagnosis	Genital Herpes, VDS,PID, Genital Warts, Candida, Genital Ulcer, Bartholin Abscess	STI dx (0/1) = 1 if any of gen herpes=1, vds=1, pid=1, gen warts=1, candida=1, gen ulcers=1, babsess=1 None needed
Presenting complaint	None/ARV/DUB/Family Planning/HIV Test/LAP/PrEP/PV Ulcers/PV Warts/Reproductive Health Issues/Vaginal Discharge/Vulval Itchiness/Other	Family planning 0/1

4.4.1. Programme data structure

I received all the KP Programme data as de-identified STATA files, initially as three separate files for the demographic, clinical and HTS data (although as described, the HTS data was later incorporated in the STI data so the separate HTS data only covered the period from 2009 to 2014). These are the data that I used for objectives 3 and 4 for the period up until end 2019 (programme dataset 1). I received an updated programme dataset for my final analysis for objective 5, as two STATA files, the clinical data, now including the HTS data, and the demographic data. This dataset included programme data up until March 2023 (programme dataset 2).

In the demographic dataset, one record was held per woman, and multiple records per woman held in the clinical dataset, each representing a clinic visit. For the period of time the HIV testing dataset was separate, each record represented one HIV test; a women could have multiple HIV tests in the dataset. The files for programme dataset 1 included data from both Access and Coconut databases, each with different variable names and coding. The first stage in data management was to update a STATA *do* file previously generated by other staff at LSHTM and CeSHHAR to append data from Access to Coconut databases and ensure variable names and coding were consistent. I then merged the appended Access/Coconut database, the demographic data and the HTS data using the merge function in STATA on Sisters ID. I went through a similar

process with programme dataset 2 although did not need to merge Access and Coconut data and only had datasets for the demographic database and the clinical database as the HTS data were already included. This dataset did not include clinical data from the Access database so starts at a later date.

4.4.2. Programme HIV testing data

Clinic HIV test data comprised of test date (the same as clinic visit date) and test results (positive, negative or inconclusive). Women could have multiple tests in the data and I conducted checks using test dates to identify any potential duplicate test records. I excluded tests that were <7 days after another test with the same Sisters ID and the same test result. HIV tests may have been close together because they were duplicates, a Sisters number allocated twice by mistake, or simply because a woman tested close together. As data syncing and any data entry from paper forms was conducted weekly this was an appropriate timeframe as these weekly processes may have generated duplicates. Beyond excluding potential duplicate tests there were database discrepancies between the STI and HTS databases for test numbers after datasets were merged. Some HIV tests seemingly appeared in both databases so I made the decision to use the primary source of data collection for HIV testing for each time period. From 2009-2014 I used data from the HTS dataset only and from 2014 onwards HIV test data from the STI dataset only. To double check that I was not missing anything by selecting test data from only one of the datasets I re-ran my exploratory analysis using only the HTS test dates and obtained similar proportions to those obtained after data management.

4.4.3. Demographic and other clinical data

Women were asked for their main presenting complaint (reason for their visit) and responses recorded by clinic staff. Options include LAP (Lower Abdominal Pain), genital warts, reproductive health issues, vaginal discharge, DUB (dysfunctional uterine bleeding), Other, vulval itchiness, family planning, ulcers. More recently reasons for a visit could include HIV testing (added in 2014), ART and PrEP (added in 2017). The original options are in the questionnaire in Appendix 5 and 6. As I was using STI diagnostic data as another variable I chose to split the presenting complaint data into a binary variable coded 1 (yes) if a woman was presenting for family planning and 0 (no) if not. At a clinic visit FSW are asked a range of questions on sexual history and condom use. I selected to use data from the following two questions as these had the most complete data: *During the most recent sex with your regular partner did you use a condom? During the most recent sex with your most recent client did you use a condom?* I combined responses to form a binary 1/0 (yes/no) variable on condom use with a recent partner. Lastly, I combined data from possible syndromic STI diagnoses (genital herpes, vaginal discharge, pelvic inflammatory disease (PID),

genital warts, candida, genital ulcer, Bartholin abscess) to form a binary variable identifying whether an STI was diagnosed at that visit of not.

For self-report HIV testing history data I took the following approach to ensure that data were as complete and logical as possible. I firstly managed a variable on ever-testing, where a woman was asked if she had ever had an HIV test. I checked that every woman reporting they were HIV positive also reported that they had ever tested at the visit they reported their HIV positive status and at subsequent visits. If there was missing data on ever HIV testing on the visit they reported an HIV-positive status or on subsequent visits, I imputed this to say they had ever HIV tested so she could not be 'ever tested' at one visit and then not 'ever tested' at a later visit. I then checked this variable against the programme data and if she had received a programme test all her subsequent visits had to be 1 (yes) to ever HIV tested. On 254,653 clinic records 90.5% (230,526 clinic records for 76,894 individual FSW) had data on a self-reported previous HIV test date. Of these test dates, 3,487 were after the visit date they were reported at, which I considered inaccurate. 1,023 were reported as the same date as the visit date. I used self-reported test date and programme test date information from other clinic visits to impute self-reported testing dates where these were missing or inaccurate. Firstly, I imputed self-reported previous test dates to subsequent visits where dates were missing. Secondly, I dropped test dates that fell before the previously reported test date. I then used programme HIV test dates to impute a test date that was missing on subsequent visits as this was considered the last HIV test. I replaced previous test dates with programme test dates if the reported last test date was before the last programme test date. Lastly, I checked any more test dates that fell before a previous test date by imputing these so tests all fell in order. After data management 70.4% (162,213/230,526) of the test date data was the same as originally recorded. The remaining 29.6% (68,313//230,526) was updated to reflect the most accurate date of a last HIV test. I imputed 6,413 test dates. When a woman was asked about the result of a previous test I used the response she gave and did not check it against previous responses or clinic test results. I believed the response given was what she wanted to tell the clinic staff, even if this was not the true test result.

4.4.4. Time and HIV testing frequency

The KP Programme dataset is longitudinal, with repeat clinic visits from the same women over time. The data can be viewed as a kind of 'open cohort' with women entering and leaving the dataset at different times. The analyses for my first two papers used both calendar time and individual follow-up time. For each I used the clinic visit date for each woman to identify the calendar time period that visit was in, or the length of time between visits for follow-up time. For calendar time in my first analysis (Chapter 5), I used three pre-specified periods representing broad variations in the intensity of programme implementation (2009-2013, 2014-2017, 2018-2019). For my main seroconversion analysis (chapter 6) I used two-year calendar periods (2009-2011, 2012-

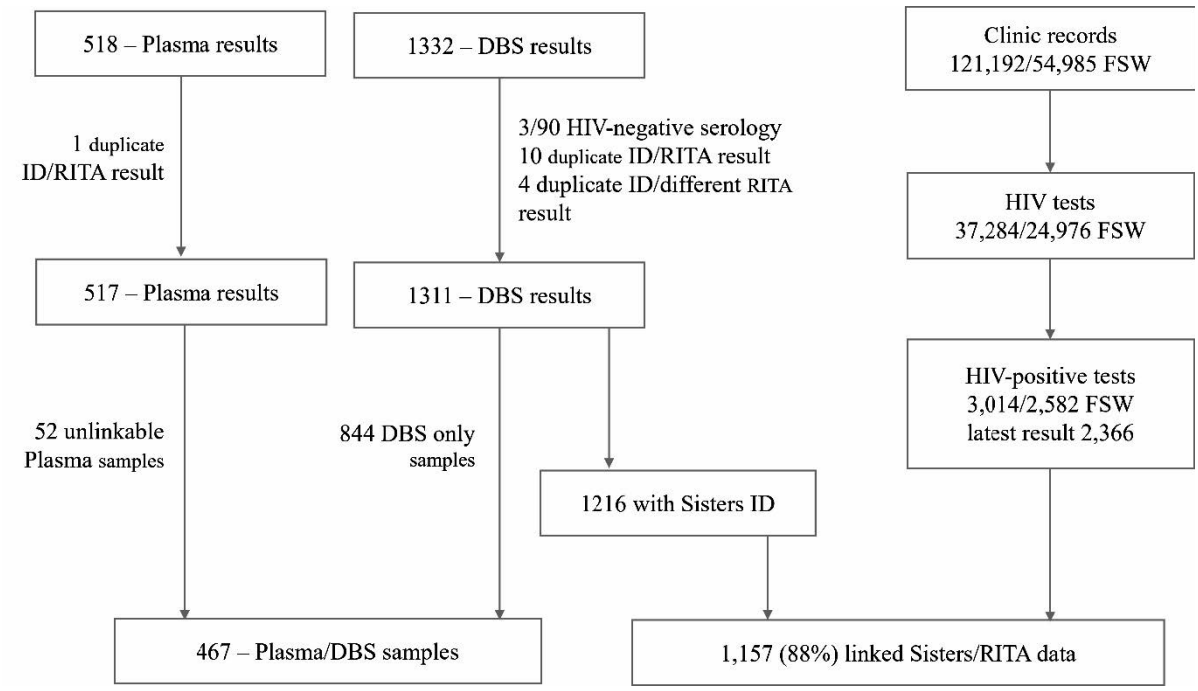
2013, 2014-2015, 2016-2017, 2018-2019). For individual follow-up time I assigned a number to each clinic visit for each woman to calculate the number of clinic visits and the time between her first and last clinic visit, as well as the intensity of her visits (how many visits over the whole period of time she had visited the programme). I also considered if a woman tested for HIV at a clinic visit and took the same approach for testing, to get a measure of HIV testing frequency, using a first test in the programme and a last test in the programme and then the time and number of tests in between.

4.4.5. RITA study data

For the RITA study I had access to three additional study datasets: the RITA study enrolment data, recent infection laboratory testing data and index testing (ICT) and social network testing (SNT) data (Table 4.3). These were deidentified and shared in Excel files. Firstly, I imported the laboratory data spreadsheets into STATA (17 spreadsheets for the separate laboratory sample batches that were run). I then ran checks on the batch run dates as some of these were in DD/MM/YYYY format and others in MM/DD/YYYY format. Women were identifiable in the laboratory data through their RITA study number. I identified any duplicate IDs in the data and checked the recency results to make sure these matched and were unlikely to be a duplicate. Separately, I imported the study enrolment data, also where women were identified by their RITA ID. I again identified duplicate study IDs, checked the rest of the data and removed duplicates. Lastly, I imported the linking study register which held Sisters IDs and RITA IDs so women could be linked back to any demographic information. I worked with staff in Zimbabwe to identify missing IDs in the linking dataset from paper records.

Data on index and social network testing (ICT/SNT) was also shared in excel spreadsheets; a separate workbook was completed for each clinic site collecting these data. These spreadsheets held data extracted from MoHCC registers which do not hold information on Sisters ID or RITA study ID. These data are not usually kept electronically by the programmes team. For some of the spreadsheets, Sisters ID were linked by staff at clinic sites but for some these were not included. To be able to link the data to identify whether women were also enrolled in the RITA study I needed to identify Sisters IDs and then link these to RITA study IDs. To firstly link data to Sisters ID I was granted access to a STATA dataset of identifiable data from the LinkLog for the duration of my time in Zimbabwe. I used names linked to the ICT/SNT data (usually held in paper records). There were challenges with linkage as names are not always recorded in the same way and the LinkLog was not up to date for the whole study period. Details of record linkage are in Figure 4.3.

Figure 4.3 Flow diagram: RITA data linkage and missing data



4.5. Statistical Analysis

Details of the analysis methods used for each of my objectives are outlined in the relevant results chapters. Here I summarise the main methods I used and any preliminary analysis and provide more explanation on my choice of methods where this is not covered in the results chapter. For my analyses I used STATA 18 SE—Standard Edition.

4.5.1. Paper 2: Test-Positivity Analysis

The main focus of my first analysis was to describe the trends over time in testing patterns and test-positivity. I used data on 54,503 HIV tests for 39,462 FSW (Figure 4.4). The outcome for this analysis was an HIV-positive test result from a programme delivered HIV test (not self-report test result). I firstly used logistic regression to examine factors associated with an HIV-positive test result. I used robust standard errors to account for clustering by clinic site. To explore any differences in factors associated with an HIV-positive test result over time I included my three time periods (2009-2013, 2013-2017, 2018-2019) as interaction terms in my models. I used time period as my exposure variable to explore changes in test-positivity over time. I adjusted my models for age, marital status, education, and rural/urban location as potential confounders. I further adjusted my model for time of last HIV test to explore the potential mediating role of individual testing history. To test my time period assumptions, I re-ran my models with calendar year instead of time period. I re-ran my unadjusted and partially adjusted model on a complete case analysis to check if this

approach had introduced any bias. I additionally summarised the programme testing data to look at missed testing opportunities. I categorised women as eligible or not eligible for testing based on time since last reported or actual HIV test date and result of the HIV test. I categorised those not reporting an HIV-positive status and not reporting or being tested at a KP Programme clinic in the previous 6 months as eligible for a test. I present proportions for women missed for testing and present these data for each year at the end of chapter 5.

4.5.2. Papers 2 and 3: Seroconversion Analysis

To set up the KP Programme data for the analysis of seroconversion rates, only women with an HIV-negative test and then at least one subsequent programme HIV test were eligible for inclusion. Women with no tests, or one HIV test in the programme were excluded from analysis. Clinic visits with no HIV test data were also excluded. I applied further restrictions to the data used in analysis. As described in my data management section I looked at the order of HIV test results, selecting to exclude any women with an HIV-negative test after an HIV-positive test. I excluded women with fewer than 31 days between their first and last test due to minimal follow up and the possibility that women were already seroconverting by the time of their first test. I also excluded tests that were within 7 days of a previous test as these were potential duplicates (Figure 4.4). To run the analysis, I set up the data as survival data using *stset* in STATA. I defined the entry date as the first test date and exit date as the last test date or an estimated seroconversion date using the midpoint between the last negative test and the positive test. I then calculated a seroconversion rate using *strate* accounting for clustering by clinic site.

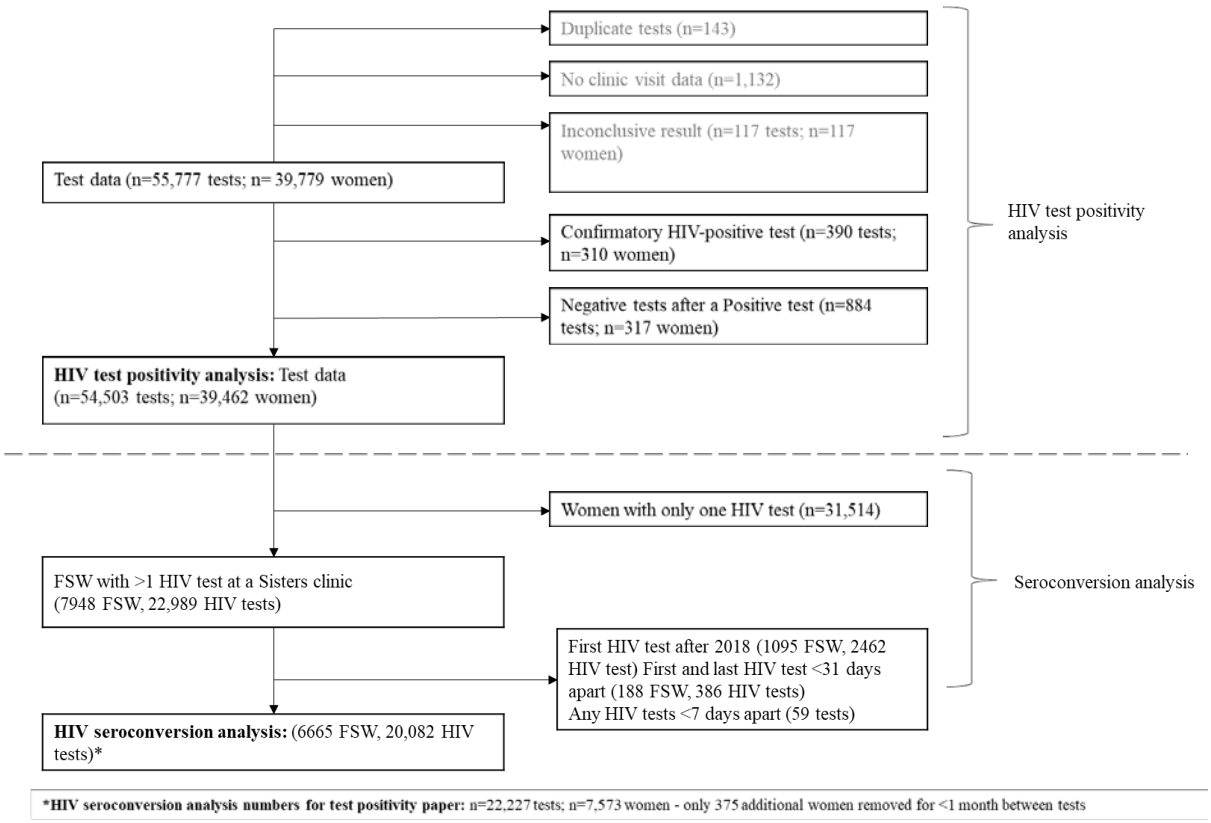
In exploratory analysis I recreated an earlier analysis looking at seroconversion in these data.[222] The earlier analysis presents an overall incidence estimate for the period 21st September 2009 and a last exit data of 3rd May 2013. Firstly, after setting up my data I cut (using *stsplit*) the data at 3rd May 2013 so my analysis had follow-up data for the same period. This gave me very different results to the earlier analysis. I identified that this was because some women had come back to the programme after 3rd May 2013, and by splitting the data on calendar time they were now contributing additional HIV-negative follow-up time to the analysis where they had not previously. I subsequently dropped all clinic visits after this date to recreate the earlier dataset before setting the data up for survival analysis. I then calculated a rate for this period to get the same findings as had been previously published. I describe the findings in more detail in Chapter 5.

In my test-positivity paper (chapter 5) I present seroconversion rates by the time periods 2009-2013, 2014-2017 and 2018-2019 used for my test-positivity analysis. In my seroconversion paper (chapter 6) which builds on this analysis I use biennial time periods. For both, I used *stsplit* to calculate rates by follow-up time and time period. Based on findings from my exploratory analysis

I additionally excluded women first testing after 31 December 2018 in my second paper to prevent the artificial inflation of rates towards the end of the reporting period.

My second analysis goes into more detail, looking at demographic and behavioural risk factors associated with seroconversion, comparing rates and associated characteristics by time period and incorporating individual follow-up time. I used Poisson regression to identify risk factors for seroconversion, including demographic factors and time since a first HIV-negative test. I describe in more detail how I assigned risk factors to visit dates in Chapter 6, but as some were time-varying, I used the outcome for the last recorded HIV-negative test (the penultimate visit for women who seroconverted and the final test for those who remained HIV-negative). I then used Poisson regression to compare differences in seroconversion rates over time. I ran crude and then adjusted models with age as a continuous variable and HIV testing-frequency. I conducted sensitivity analyses to explore the impact of follow-up time on seroconversion rates and to explore options for different seroconversion date estimation. In my first sensitivity analysis, I restricted each woman to two years follow-up to reflect a more traditional cohort and also the knowledge that rates may be artificially skewed over longer follow-up periods. I also explored different ways of estimating seroconversion dates, running my analysis 1) one month before an HIV-positive test to address the potential for testing to be risk motivated, 2) two weeks after a last HIV-negative test to address the potential that women had already been exposed at their last HIV-negative test but were testing too early, 3) randomly assigned, using the mean of 100 random runs of seroconversion date estimation.

Figure 4.4 Flow diagram of data merges for KP Programme datasets



4.5.3. Paper 4: Recent Infection Testing Analysis

For my final objective I used recent HIV infection testing data from a study implemented at 86 sites in the KP Programme between October 2021 and January 2023. I firstly summarised the recent HIV infection testing algorithm (RITA) results, presenting an overall proportion of recent HIV infections for all sites and then by province. I then used an approach developed by Kassanjee *et al*[223,224] to estimate HIV incidence in line with other recency estimates from Zimbabwe.[225] This approach uses the following calculation, where n_R is the number of recently infected individuals, n_+ is the number of HIV-positive individuals in the data, n_s is the number of HIV-negative individuals in the data, β_T is the false recency rate, Ω_T is the mean duration of recent infection, and T is the cut-off time for recency classification.

$$\hat{I}_T = \frac{n_R - \beta_T n_+}{n_s(\Omega_T - \beta_T T)}$$

The number of HIV-positive FSW was the number who underwent recent HIV infection testing. To obtain the number of HIV-negative individuals I used an updated version of the programme dataset to March 2023, using data for the period of study implementation. Due to data complexities I opted

to treat all clinics as implementing for the same period of time, whereas in reality this was unlikely. I also included the overall enrolment rate in the study (55.5%) in the calculation, but this was also a crude approach due to differences in enrolment between sites and province being as much as 30%.

The mean duration of recent infection (MDRI), which is the average number of days since infection that the biomarkers identified by the assay are detectable, and the false recent rate (FRR) which gives the proportion of those classified as recent infections likely to be long standing infections are important parameters for the calculation. Both are challenging to ascertain and are subject to much debate. Biomarkers vary substantially between individuals making the characterisation of an MDRI difficult. Including an incorrect FRR can impact the resulting incidence calculation,[122] particularly in high prevalence populations. Using a RITA should remove some misclassification of falsely recent infections but is unlikely to remove this completely. I used an MDRI of 130 days, in line with pervious analysis of sex worker recency data in Zimbabwe and the 2020 PHIA survey. Unlike previous analysis in Zimbabwe and PHIA I selected an FRR of 0.2%, because it is highly unlikely even using a RITA that none of the results were false recent results. These recommendations for estimating HIV incidence from recent HIV infection testing come from WHO technical guidelines.[74]

Lastly, I used index and social network testing data from the KP Programme from October 2021 to January 2023 to understand if there was a difference in HIV-positive contacts between FSW testing recent compared to those with long term infections. For the social and index testing data I was able to link to FSW enrolled in the RITA study (Figure 4.3). I collated the data to calculate the percentage of new HIV-positive individuals identified through either social or index testing and whether this differed by recency result. Due to the limitations of linkage and small numbers I simply summarise these data and present percentages.

4.6. Ethics

4.6.1. Informed consent

As the KP Programme data are collected for clinical management during service delivery, and not for research purposes, consent was not obtained at the point of data collection. Retrospective consent for this research was not sought. Current phone numbers and contact details are not available for the majority of women in the dataset and so retrospectively contacting them to obtain consent would not have been possible.

4.6.2. Ethical approval

Permission to use these data was granted by the Centre for Sexual Health and HIV/AIDS Research (CeSHHAR) in Zimbabwe who collect this information for clinical purposes and have ownership of the data. CeSHHAR has a waiver from the Medical Research Council of Zimbabwe (MRCZ) to undertake secondary analyses of these data for programme improvement and research purposes (MRCZ/E/266, approval date 5th February 2020). Ethical approval was obtained for my PhD from the London School of Hygiene and Tropical Medicine on 19th December 2019 (16543). Approval was granted by the MRCZ on 26th August 2020 (MRCZ/A/2624), on condition that approval was obtained from the Research Council of Zimbabwe (RCZ) after registration as foreign researcher. Approval was obtained from the RCZ on 11th July 2022. Study termination was approved by MRCZ on 22nd January 2024. All ethical approval documents are in Appendix 9-11.

5. RESULTS: HIV TEST-POSITIVITY

Interpreting declines in HIV test-positivity: an analysis of routine data from Zimbabwe's national sex work programme, 2009–2019

Jones, H.S., Hensen, B., Musemburi, S., Chinyanganya, L., Takaruza, A., Chabata, S.T., Matambanadzo, P., Rice, B., Cowan, F.M. and Hargreaves, J.R.

Journal of the International AIDS Society (published 2022)

In this chapter I address my first objective, to analyse trends in HIV testing and test-positivity between 2009 and 2019 among FSW accessing targeted HIV testing services in CeSHHAR's KP Programme in Zimbabwe. I contribute to discussions on this metric used to monitor HIV testing, and explore its use in assessing changes in the programme over time. High HIV test-positivity, the percentage of HIV-positive tests from all tests delivered (also referred to HIV testing yield), has been suggested by some to be indicative of programme efficiency. There is a predominantly donor-driven trend to report high test-positivity from HIV programmes, reflecting greater resource efficiency. In this analysis I found a >50% decline in test-positivity among women accessing services over the 10-year period, with evidence that this decline was in part driven by increased individual level HIV testing in the programme and likely to be the result of earlier tests identifying a much greater proportion of undiagnosed longer-term HIV infections. The implications of these findings are that while test-positivity remains high in this population, HIV testing has substantially increased both in the KP Programme and at other locations in Zimbabwe over this period and test-positivity is likely to reflect the identification of newer HIV infections in later years.

I presented some of the work in this chapter in an oral presentation 11th IAS Conference on HIV Science (IAS 2021), July 2021: *Trends in HIV testing yield need to be interpreted within the context of changing testing patterns: analysis of individual-level programme data from Zimbabwe's national sex work programme, 2009-2019* (Appendix 12).

In addition to my published work, I present a short descriptive analysis at the end of this chapter to increase understanding of what this analysis means in practice in terms of missed opportunities to test women who access KP Programme services. These analyses have implications for my PhD in that they provide further insights into testing patterns for FSW in Zimbabwe, providing contextual knowledge on how to interpret measures using these data.

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SECTION A – Student Details

Student ID Number	378549	**Title**	Ms
First Name(s)	Harriet		
Surname/Family Name	Jones		
Thesis Title	Measuring trends in HIV testing and new HIV infections among female sex workers in Zimbabwe		
Primary Supervisor	Professor James Hargreaves		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	Journal of the International AIDS Society		
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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	My role in this research was in devising and conducting the analysis, writing, submitting and revising the manuscript. HSJ devised and conducted the analysis with input from BH, JRH, FMC and BR. SM, AT and STC provided support with data management and interpretation. PM and LC supported in understanding programme implementation, data collection and interpretation. HSJ wrote the manuscript with input from BH, JRH, FMC and BR and review from all authors. HSJ made reviewer revisions with input from coauthors.

SECTION E

Student Signature	[redacted]
Date	28/02/2024

Supervisor Signature	[redacted]
Date	28/02/2024

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JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

RESEARCH ARTICLE

Interpreting declines in HIV test positivity: an analysis of routine data from Zimbabwe's national sex work programme, 2009–2019

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Abstract

Introduction: Early diagnosis of HIV is critical for epidemic control. To achieve this, successful testing programmes are essential and test positivity is often used as a marker of their performance. The aim of this study was to analyse trends and predictors of HIV test positivity over time and explore how an understanding of seroconversion rates could build on our interpretation of this indicator among female sex workers in Zimbabwe.

Methods: We analysed HIV test data from Zimbabwe's nationally scaled sex work programme between 2009 and 2019. We defined test positivity as the proportion of all tests that were HIV positive and measured new diagnoses by estimating seroconversion rates among women with repeat tests, defined as an HIV-positive test after at least one HIV-negative test in the programme. We used logistic regression to analyse test positivity over three time-periods: 2009–2013, 2014–2017 and 2018–2019, adjusting for potential confounding by demographic factors and the mediating effects of time since last HIV test. We calculated the seroconversion rates for the same time-periods.

Results: During the 10-year study period, 54,503 tests were recorded in 39,462 women. Between 2009 and 2013, 18% of tests were among women who reported testing in the previous 6 months. By 2018–2019, this had increased to 57%. Between 2018 and 2019, test positivity was 9.6%, compared to 47.9% for 2009–2013 (aOR 6.08 95% CI 5.52–6.70) and 18.8% for 2014–2017 (aOR 2.17 95% CI 2.06–2.28). Adjusting for time since last test reduced effect estimates for 2009–2013 (aOR 4.03 95% CI 3.64–4.45) and 2014–2017 (aOR 1.97 95% CI 1.86–2.09) compared to 2018–2019. Among 7573 women with an initial HIV-negative test in the programme and at least one subsequent test, 464 tested HIV positive at a rate of 3.9 per 100 pyar (95% CI 3.5–4.2).

Conclusions: Test positivity decreased among women testing through the programme over time, while seroconversion rates remained high. These declines were partly driven by changes in individual testing history, reflecting comprehensive coverage of testing services and greater knowledge of HIV status, but not necessarily declining rates of seroconversion. Understanding testing history and monitoring new HIV infections from repeat tests could strengthen the interpretation of test positivity and provide a better understanding of programme performance.

Keywords: Africa; HIV epidemiology; HIV prevention; key and vulnerable populations; sex workers; testing

Additional information may be found under the Supporting Information tab of this article.

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1 | INTRODUCTION

Early diagnosis of HIV is critical for epidemic control. Female sex workers (FSW) in sub-Saharan Africa are at greater risk of HIV infection than other women of reproductive age, and sex work an important driver of HIV transmission [1–3]. Yet, globally, the proportion of FSW diagnosed fell short of UNAIDS 2020 targets of 90% [4]. In Zimbabwe, UNAIDS report 75.4% of FSW knew their HIV-positive status in 2020, compared to 96% of all adult women [5]. Annual HIV testing is recommended for FSW in all settings, and testing every 3–6 months if indicated by individual risk [6]. Successful testing strategies are fundamental for identifying individuals with HIV, but where incidence remains high, even intensive

strategies may fail to identify enough cases to reach the UNAIDS 2030 target of 95% of those with HIV knowing their HIV-positive status [7].

The performance of testing programmes is often monitored using HIV test yield or test positivity, defined as the proportion of tests that are HIV positive [8, 9]. Funding constraints have made it necessary for programmes to balance resource efficiencies with identifying a decreasing proportion of individuals with undiagnosed HIV [9, 10]. Test positivity has been used to evaluate differentiated HIV testing approaches being implemented to achieve this, such as community-based testing, self-testing, index-testing and partner notification [11–16]. Individual testing history and repeat testing among HIV-negative individuals [17, 18] will play a role in test positivity but have less frequently been explored. Test positivity will be influenced by all of these factors, as well as HIV incidence and prevalence, testing coverage and re-diagnosis [16, 17, 19, 20], and should be interpreted in the context of these complexities to understand programme effectiveness and gauge progress towards global targets.

In Zimbabwe, the Sisters with a Voice programme (Sisters) offers HIV testing, alongside other sexual and reproductive health services for FSW nationally. In 2017, Sisters reached 57% of the estimated 40,000 FSW in Zimbabwe with clinical services [3]. Since 2009, the programme has collected routine service delivery data, providing a unique opportunity to explore long-term trends in HIV testing. The aim of this analysis was to understand trends in HIV test positivity between 2009 and 2019, and identify the individual and service delivery factors influencing these. We further sought to identify how trends in seroconversion among repeat testers could build on our interpretation of test positivity as an indicator of programme performance.

2 | METHODS

2.1 | Study setting

The Sisters programme delivers free sexual and reproductive health services through static and mobile sites across Zimbabwe to women aged ≥16 years self-identifying as selling sex [21]. HIV testing is offered at a first clinic visit if an HIV negative or unknown HIV status is reported. In line with national guidance, women revisiting a clinic are offered an HIV test if they have not tested within the previous 6 months. Since 2014, Determine HIV-1/2 has been used as a first screening test with SD Bioline HIV-1/2 to confirm HIV-positive results.

At each visit, a woman is seen by clinic staff and data are collected on demographic variables (first visit only), the reason for her visit, self-report STI and HIV test and test result history, a sexual risk behaviour history, the services provided at that visit, and the results of any syndromic STI diagnosis and HIV test. Data are electronically kept and centrally held for each woman, linked by a unique identification number and a Sisters number assigned at first visit. Women are subsequently identified by their Sisters number or unique identifying information if this is not known. Further checks are carried out during regular data syncing to ensure that multiple records do not exist for the same woman. HIV test results, clinical and demographic data are held in separate databases, which were merged for this analysis, matching records on Sisters number and clinic visit date. We excluded tests if results were inconclusive, duplicated (defined as a second test within 7 days of a previous programme test) or confirming an existing HIV-positive result within the programme. We excluded women from our analysis if they had an HIV-negative test after an HIV-positive test as we could not guarantee data accuracy (Figure 1).

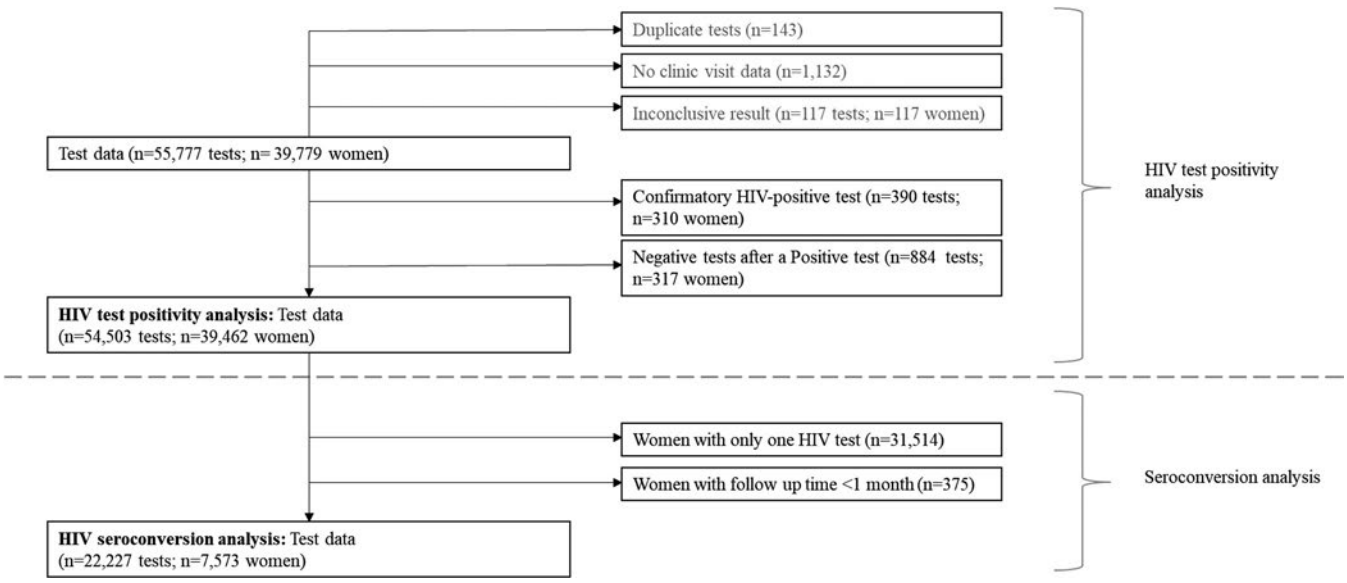

Figure 1. Flow diagram of women included in HIV test positivity and seroconversion analysis.

2.2 | Measures

Our main outcome was HIV test positivity, defined as the proportion of all HIV tests delivered by the programme that were HIV positive. We then restricted our analysis to women with >1 test to explore trends in new HIV diagnoses in the programme by estimating seroconversion rates. We defined seroconversion as an HIV-positive test after at least one HIV-negative test at a Sisters clinic.

Our main exposure was calendar time. We analysed changes over three pre-specified periods of varying programme implementation. Our first period covered early implementation from 2009 to 2013. Five Sisters sites were established in areas known for high numbers of sex workers, but there were delays in funding continuation for much of 2012 and disruption of services in 2013 due to elections (static sites: 1 in 2009, 3 between 2010 and 2012, 6 in 2013; outreach sites: 4 between 2009 and 2010; 10 between 2010 and 2013, 30 in 2013). The number of clinic sites increased to 36 by the end of 2017 (static: 6 between 2014 and 2017, outreach: 30 between 2014 and 2017), and outreach had gone from once every 2 weeks to once a week, representing significant programme expansion, financial input and increased recruitment of FSW through intensified peer outreach. The third period, 2018–2019, represents a more established programme with 57 clinic sites (12 static) but funding disruptions, forcing periodic clinic closures [3].

We analysed demographic (age, education and marital status), self-report HIV testing history (time since last test at a Sisters clinic or externally) and HIV status and clinic visit (clinic location and type, reason for a clinic visit and STI diagnoses) variables. Age was calculated from date of birth to reflect age at the date of each clinic visit, and categorized as <25 and ≥25 years old. A self-reported test history, including date and result of last test, was also collected at each visit and categorized as never tested, tested in the previous 6 months, 6–12 months or >12 months. To address missing or implausible data on testing history (e.g. when a date was in the future), we used self-report or programme test data from earlier visits to complete records where possible.

2.3 | Analysis

We described women visiting and HIV testing in the programme and plotted test positivity and testing history by year quarter to understand trends over time. Using logistic regression, we estimated the crude association between time-period and test positivity, and explored potential associations with FSW characteristics (demographics, test history and clinic visit information) to identify predictors of positivity. Our models included time-period as an interaction term to understand if associations varied over time.

We adjusted our test positivity and time-period logistic regression model for FSW characteristics to explore confounding. We analysed the mediating role of HIV testing history in the relationship between time-period and test positivity by further adjusting for time of last HIV test. Our models included robust standard errors to account for clustering by site and repeat tests on the same women. We conducted a sensitivity analysis with calendar year as our exposure to assess the impact of our time-period assumptions on our findings. Our models included the maximum number of records available at each stage to obtain the least biased estimate. We conducted a final analysis using the subset of data included in our fully adjusted model to understand if this approach had biased our results.

We estimated HIV seroconversion among women returning to Sisters clinics for an HIV test using an approach previously applied to a subset of our data [22]. We established a retrospective cohort of women to include in our analysis. Women were eligible if they had more than one HIV test at a Sisters clinic, their first test was HIV negative and their last HIV test with the programme was more than 1 month after their first. Date of entry was a woman's first HIV test at a Sisters clinic. Date of seroconversion was estimated at the midpoint between a woman's last HIV-negative test and her HIV-positive test. Exit date was either the estimated date of seroconversion or last HIV-negative test (if no HIV-positive result). We used lexis expansion to split our data by time-period and calculated seroconversion rates for each using robust standard errors to account for clustering by site. Lastly, we compared our findings with those previously published from these data by looking at the seroconversion rate between September 2009 and May 2013.

2.4 | Ethics

Ethical approval was obtained from the London School of Hygiene and Tropical Medicine (16543) and the Medical Research Council of Zimbabwe (MRCZ/A/2624). All data in this analysis were collected as part of routine clinical care and, therefore, consent was not obtained. Data were de-identified and anonymized before databases were shared for analysis.

3 | RESULTS

Between September 2009 and December 2019, 86,197 women made 254,653 visits to a Sisters clinic. Half of all women visited once (44,852/86,197; 52.0%), 17.6% (15,186/86,197) visited twice, 17.9% (15,468/86,197) had between 3 and 5 visits and 12.4% (10,691/86,197) >5. At first visit, median age was 28 years (IQR 23–34), 68.7% (59,245/86,197) reached secondary education and 60.9% (52,491/86,197) were divorced. Just under half of all clinic visits were attended by women self-reporting an HIV-positive status (Table 1).

During the study period, 55,777 HIV tests were conducted and data on 54,503 tests among 39,462 women included in the analysis (Figure 1). Overall, missing data on demographic and testing history variables did not exceed 10%, with small variations in the proportion missing between HIV-positive and HIV-negative tests, and slightly more between time-periods. Tests among women reporting having never tested fell from 38.7% (1563/4039) between 2009 and 2013 to 11.3% (2102/27,024) between 2018 and 2019. In later time-periods, most tests were among women self-reporting or having tested at a Sisters clinic in the previous 6 months. Between 2018 and 2019, this was 56.7% (14,453/27,024), compared to 17% (702/4039) between 2009 and 2013 (Figure 2). Over time, an increasing percentage of tests were among women

Table 1. Characteristics of women visiting and HIV testing at Sisters clinics between 2009 and 2019 by time-period

	All clinic visits and HIV tests 2009–2019		Time-period 1 2009–2013		Time-period 2 2014–2017		Time-period 3 2018–2019	
	Total clinic visits	Total HIV tests	Clinic visits *N* (col%)	HIV tests *N* (col%)	Clinic visits *N* (col%)	HIV tests *N* (col%)	Clinic visits *N* (col%)	HIV tests *N* (col%)
Tota (row %)	*n* = 254,653	*n* = 54,503	*n* = 36,426	*n* = 4039 (11.1)	*n* = 139,199	*n* = 23,440 (16.8)	*n* = 79,028	*n* = 27,024 (34.2)
Demographic								
Age (at first c inic visit)								
<25	57,659 (23.4)	19,343 (37.0)	6595 (18.2)	1047 (26.0)	31,658 (23.5)	8281 (36.8)	19,406 (25.8)	10,015 (39.0)
25+	188,422 (76.6)	32,885 (63.0)	29,693 (81.8)	2980 (74.0)	102,986 (76.5)	14,246 (63.2)	55,743 (74.2)	15,659 (61.0)
missing	*8572*	*2275*	*138*	*12*	*4555*	*913*	*3879*	*1350*
Education								
None	1635 (0.7)	295 (0.6)	34 (0.2)	4 (0.2)	1137 (0.9)	186 (0.8)	464 (0.6)	105 (0.4)
Primary	51,364 (23.3)	9642 (19.3)	5371 (27.4)	620 (24.6)	31,821 (24.9)	4900 (22.2)	14,172 (19.5)	4122 (16.3)
Secondary	165,565 (75.2)	39,267 (78.7)	14,076 (71.9)	1883 (74.7)	94,414 (73.7)	16,795 (76.2)	57,075 (78.5)	20,589 (81.3)
Tertiary	1754 (0.8)	687 (1.4)	96 (0.5)	14 (0.6)	697 (0.5)	168 (0.8)	961 (1.3)	505 (2.0)
missing	*34,335*	*4612*	*16,849*	*1518*	*11,130*	*1391*	*6356*	*1703*
Marita status								
Current y married	4955 (2.2)	1494 (2.9)	521 (1.4)	64 (1.6)	2608 (2.0)	583 (2.6)	1826 (2.5)	847 (3.3)
Divorced	156,536 (64.0)	32,031 (61.7)	21,372 (59.1)	2473 (61.7)	88,557 (66.1)	14,667 (65.4)	46,607 (62.5)	14,891 (58.4)
Never married	47,634 (19.5)	14,415 (27.8)	5892 (16.3)	748 (18.7)	22,690 (16.9)	5071 (22.6)	19,052 (25.6)	8596 (33.7)
Separated	2985 (1.2)	360 (0.7)	930 (2.6)	108 (2.7)	1726 (1.3)	205 (0.9)	329 (0.4)	47 (0.2)
Widowed	32,614 (13.3)	3622 (7.0)	7457 (20.6)	618 (15.4)	18,419 (13.7)	1891 (8.4)	6738 (9.0)	1113 (4.4)
missing	*9929*	*2581*	*254*	*28*	*5199*	*1023*	*4476*	*1530*
Clinic site								
Location								
Urban	196,473 (77.2)	37,135 (68.1)	28,795 (79.1)	2969 (73.5)	100,538 (72.2)	12,882 (55.0)	67,140 (85.0)	21,284 (78.8)
Rura	58,180 (22.9)	17,368 (31.9)	7631 (21.0)	1070 (26.5)	38,661 (27.8)	10,558 (45.0)	11,888 (15.0)	5740 (21.2)
Type								
Static	149,740 (58.8)	45,021 (82.6)	22,469 (81.7)	3445 (85.3)	68,284 (49.1)	23,880 (88.4)	58,987 (74.6)	17,696 (75.5)
Mobi e	104,913 (41.2)	9482 (17.4)	13,957 (38.3)	594 (14.7)	70,915 (51.0)	3144 (11.6)	20,041 (25.4)	5744 (24.5)
HIV testing history								
Time since ast HIV test								
Never tested	12,051 (4.9)	5974 (11.5)	5381 (15.3)	1563 (40.5)	4162 (3.0)	2309 (10.2)	2508 (3.3)	2102 (8.3)

(*Continued*)

Table 1. (Continued)

	All clinic visits and HIV tests 2009–2019		Time-period 1 2009–2013		Time-period 2 2014–2017		Time-period 3 2018–2019	
	Total clinic visits	Total HIV tests	Clinic visits *N* (col%)	HIV tests *N* (col%)	Clinic visits *N* (col%)	HIV tests *N* (col%)	Clinic visits *N* (col%)	HIV tests *N* (col%)
Tested >12 months ago	82,030 (33.1)	9088 (17.5)	13,338 (37.8)	882 (22.9)	45,634 (33.4)	4514 (19.9)	23,058 (30.4)	3692 (14.5)
Tested 6–12 months ago	35,898 (14.5)	10,808 (20.8)	5552 (15.7)	711 (18.4)	19,621 (14.4)	4844 (21.3)	10,725 (14.1)	5253 (20.6)
Tested <6 months ago	117,913 (47.6)	26,168 (50.3)	11,002 (31.2)	702 (18.2)	67,296 (49.2)	11,031 (48.6)	39,615 (52.2)	14,435 (56.7)
missing	6761	2465	1153	181	2486	742	3122	1542
Se f-report HIV status								
HIV negative	127,785 (54.1)	46,241 (97.1)	11,088 (39.3)	1939 (92.2)	72,072 (54.5)	20,136 (97.0)	44,625 (59.1)	24,166 (97.6)
HIV positive	108,322 (45.9)	1370 (2.9)	17,105 (60.7)	164 (7.8)	60,286 (45.5)	611 (3.0)	30,931 (40.9)	595 (2.4)
missing	*18,546*	*6892*	*8233*	*1936*	*6841*	*2693*	*3472*	*2263*
Sisters clinic engagement								
C inic visits								
First visit	168,456 (66.2)	31,288 (57.4)	22,568 (62.0)	2514 (62.2)	92,481 (66.4)	13,470 (57.5)	53,407 (67.6)	15,304 (56.6)
Repeat visit	86,197 (33.9)	23,215 (42.6)	13,858 (38.0)	1525 (37.8)	46,718 (33.6)	9970 (42.5)	25,621 (32.4)	11,720 (43.4)
STI diagnosed at c inic visit								
No	159,619 (62.7)	35,556 (65.2)	22,157 (60.8)	2212 (54.8)	80,034 (57.5)	13,794 (58.9)	57,428 (72.7)	19,550 (72.3)
Yes	95,034 (37.3)	18,947 (34.8)	14,269 (39.2)	1827 (45.2)	59,165 (42.5)	9646 (41.2)	21,600 (27.3)	7474 (27.7)
Visit for fami y p anning								
No	212,160 (83.3)	45,053 (82.7)	33,236 (91.2)	3616 (89.5)	117,350 (84.3)	19,997 (85.3)	61,574 (77.9)	21,440 (79.3)
Yes	42,493 (16.7)	9450 (17.3)	3190 (8.8)	423 (10.5)	21,849 (15.7)	3443 (14.7)	17,454 (22.1)	5584 (20.7)
Testing de ivery								
First programme test	39,462 (72.4)	39,462 (72.4)	3560 (88.1)	3560 (88.1)	17,992 (76.7)	17,992 (76.7)	17,910 (66.3)	17,910 (66.3)
Repeat programme test	15,041 (27.6)	15,041 (27.6)	479 (11.9)	479 (11.9)	5448 (23.2)	5448 (23.2)	9114 (33.7)	9114 (33.7)

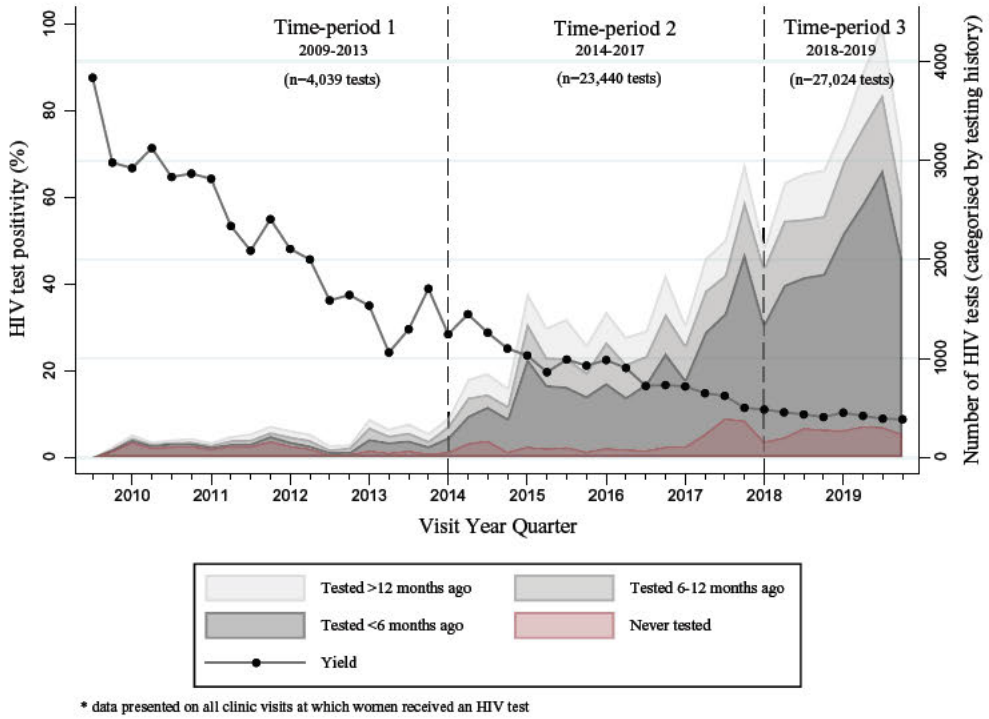

Figure 2. HIV test positivity and testing coverage at Sisters clinics in Zimbabwe between 2009 and 2019.

<25 years old, from 26.0% (1047/4039) between 2009 and 2013 to 39.0% (10,015/27,024) between 2018 and 2019. A small percentage of tests (1370/54,503, 2.9%) were among women self-reporting an HIV-positive status (Table 1).

Between 2009 and 2019, 16.4% (8959/54,503) of programme tests were HIV positive. Test positivity decreased from 47.9% (1934/4039) between 2009 and 2013, to 18.8% between 2014 and 2017 (4417/23,440; OR 2.2 95% CI 2.1–2.3 $p<0.001$) and 9.7% between 2018 and 2019 (2608/27,024; OR 8.6 95% CI 7.9–9.3 $p<0.001$) (Table 3). In all time-periods, test positivity was higher among women ≥25 years old than <25 years old (OR 1.50 95% CI 1.4–1.7 $p<0.001$). However, test positivity declined more steadily among women <25 years old who made up an increasing proportion of women testing HIV positive over time, from 20.8% (403/1934) between 2009 and 2013 to 31.4% (819/2608) between 2018 and 2019. Test positivity was higher among women with primary than secondary education (OR 1.33 95% CI 1.22–1.46), and those diagnosed with an STI at a Sisters clinic compared to those who were not (OR 1.91 95% CI 1.75–2.09 $p<0.001$). For 2009–2013, test positivity was higher among women visiting for family planning than those who visited for other reasons (OR 2.2 95% CI 1.73–2.85), but the opposite in later time-periods. Test positivity was also higher at first-time programme tests than repeat tests at a Sisters clinic (OR 7.88 95% CI 6.62–9.38 $p<0.001$) (Table 2).

Test positivity was lower among women either self-reporting or testing at a Sisters clinic within the previous 6 months (2187/26,168; 8.4%) than among those who had never tested (2067/5974; 34.6%; OR 0.17 95% CI 0.16–0.18). Findings were similar for positivity among women testing in the previous 6–12 months (1531/10,808; 17.2% OR 0.31 95% CI 0.29–0.34) and >12 months (2705/9088; 29.8% OR 0.80 95% CI 0.75–0.86). This trend was the same for all time-periods; however, in 2018–2019, test positivity among women who had tested >12 months ago was higher than positivity among women who had never tested (OR 2.02 95% CI 1.72–2.36) (Table 2).

After adjusting for age, marital status, education and urban/rural site, higher positivity remained associated with earlier time-periods (2009–2013 vs. 2018–2019: aOR 6.08; 95% CI 5.52–6.70 and 2014–2017 vs. 2018–2019: aOR 2.15; 95% CI 2.04–2.28). After further adjusting for testing history, effect estimates decreased (2014–2017: aOR 4.03 95% CI 3.64–4.45 and 2014–2017: 1.97 95% CI 1.86–2.09) (Table 3). Similar results were obtained using the subset of data from our fully adjusted model, only with a smaller reduction in effect estimates for 2009–2013 between our crude and demographically adjusted models (OR 6.5 95% CI 5.7–7.2 to aOR 6.1 95% CI 5.5–6.7). A sensitivity analysis showed declining odds of test positivity by calendar year and the same trend with smaller effect estimates when adjusted for time since last test, in line with our findings for time-period categories (Supplementary Table S1).

Between 2009 and 2019, 7573 women had an HIV-negative test followed by at least one repeat HIV test at a Sisters clinic and were included in our seroconversion analysis. These women made 22,227 clinic visits and contributed 11,974 person-years at risk (pyar). The last entry into our cohort was 19 November 2019. Median follow-up time was 291 days (IQR 152–553) and median number of HIV tests per woman was 2 (IQR 2–3). Median time between a final negative test before a positive test among women who seroconverted was 273 days (IQR 140–529). The longest time

Table 2. Univariable and stratified logistic regression analysis of time, demographic, HIV testing history and clinic and service engagement factors with HIV test positivity

	All HIV tests between 2009 and 2019				HIV-positive tests									
					2009–2013			2014–2017			2018–2019			Interaction
	Total tests	HIV-positive tests (row%)	OR (95% CI)	*p*-value	Total	HIV-positive tests (row%)	OR (95% CI)	Total	HIV-positive tests (row%)	OR (95% CI)	Total	HIV-positive tests (row%)	OR (95% CI)	*p*-value (Wald)
All H V tests	54,503	8959 (16.4)	2.2 (2.1–2.3)		4039	1934 (47.9)		23,440	4417 (18.8)		27,024	2608 (9.7)		
Demographic														
Age (at first clinic visit)														
<25	19,343	2560 (13.2)	1 (baseline)		1047	403 (38.5)	1 (baseline)	8281	1338 (16.2)	1 (baseline)	10,015	819 (8.2)	1 (baseline)	0.10
25+	32,885	6139 (18.7)	1.50 (1.37–1.65)	<0.001	2980	1522 (51.1)	1.67 (1.39–2.00)	14,246	2966 (20.8)	1.36 (1.19–1.57)	15,659	1651 (10.5)	1.32 (1.17–1.49)	
missing	*2275*	*260 (11.4)*			12	9 (75)		913	113 (12.4)		1350	138 (10.2)		
Education														
None	295	60 (20.3)	1.47 (0.94–2.29)	<0.001	4	2 (50.0)	1.42 (0.24–9.46)	186	43 (23.1)	1.33 (0.81–2.18)	105	15 (14.3)	1.57 (0.69–3.56)	0.004
Primary	9642	1814 (18.8)	1.33 (1.22–1.46)		620	287 (46.3)	1.31 (1.19–1.43)	4900	1088 (22.2)	1.27 (1.13–1.42)	4122	439 (10.6)	1.13 (1.00–1.27)	
Secondary	39,267	5814 (14.8)	1 (baseline)		1883	749 (39.8)	1 (baseline)	16,795	3092 (18.4)	1 (baseline)	20,589	1973 (9.6)	1 (baseline)	
Tertiary	687	41 (6.0)	0.37 (0.25–0.52)		14	5 (35.7)	0.84 (0.21–3.40)	168	13 (7.7)	0.37 (0.20–0.69)	505	23 (4.6)	0.45 (0.32–0.64)	
missing	*4612*	*1230 (26.7)*			*1518*	*891 (58.7)*		*1391*	*181 (13.0)*		*1703*	*158 (9.3)*		
Marital status														
Currently married	1494	169 (11.3)	0.60 (0.50–0.71)	<0.001	64	23 (35.9)	0.63 (0.35–1.15)	583	73 (12.5)	0.56 (0.38–0.83)	847	73 (8.6)	0.85 (0.51–1.41)	<0.001
Divorced	32,031	5621 (17.6)	1 (baseline)		2473	1162 (47.0)	1 (baseline)	14,667	2968 (20.2)	1 (baseline)	14,891	1491 (10.0)	1 (baseline)	
Never married	14,415	1794 (12.5)	0.67 (0.63–0.71)		748	302 (40.4)	0.76 (0.67–0.87)	5071	736 (14.5)	0.67 (0.56–0.79)	8596	756 (8.8)	0.87 (0.76–0.99)	
Separated	360	66 (18.3)	1.05 (0.77–1.45)		108	31 (28.7)	0.45 (0.32–0.64)	205	33 (16.1)	0.76 (0.47–1.22)	47	2 (4.3)	0.40 (0.09–1.73)	
Widowed	3622	1018 (28.1)	1.84 (1.68–2.01)		618	397 (64.2)	2.03 (1.76–2.33)	1891	481 (25.4)	0.35 (1.11–1.62)	1113	140 (12.6)	1.29 (1.05–1.59)	
missing	*2581*	*291 (11.3)*			*28*	*19 (67.9)*		*1023*	*126 (12.3)*		*1530*	*146 (9.5)*		
Clinic site														
Location														
Urban	45,021	7425 (16.5)	1 (baseline)		3445	1629 (47.3)	1 (baseline)	17,696	3408 (19.3)	1 (baseline)	23,880	2388 (10.0)	1 (baseline)	0.007
Rural	9482	1534 (16.2)	0.98 (0.72–1.33)	0.88	594	305 (51.4)	1.18 (0.70–1.97)	5744	1009 (17.6)	0.89 (0.68–1.18)	3144	220 (7.0)	0.68 (0.52–0.88)	
Type														
Static	37,135	6007 (16.2)	1 (baseline)		2969	1455 (49.0)	1 (baseline)	12,882	2425 (18.8)	1 (baseline)	21,284	2127 (10.0)	1 (baseline)	0.23
Mobile	17,368	2952 (17.0)	1.06 (0.74–1.53)	0.75	1070	479 (44.8)	0.84 (0.44–1.60)	10,558	1992 (18.9)	1.00 (0.75–1.35)	5740	481 (8.4)	0.82 (0.62–1.09)	

(Continued)

Table 2. Continued

	All HIV tests between 2009 and 2019				HIV-positive tests									
					2009–2013			2014–2017			2018–2019			Interaction
	Total tests	HIV-positive tests (row%)	OR (95% CI)	*p*-value	Total	HIV-positive tests (row%)	OR (95% CI)	Total	HIV-positive tests (row%)	OR (95% CI)	Total	HIV-positive tests (row%)	OR (95% CI)	*p*-value (Wald)
HIV testing history														
Time since last H V test														
Never tested	5974	2067 (34.6)	1 (baseline)	<0.001	1563	1125 (72.0)	1 (baseline)	2309	705 (30.5)	1 (baseline)	2102	237 (11.3)	1 (baseline)	<0.001
Tested >12 months ago	9088	2705 (29.8)	0.80 (0.75–0.86)		882	396 (44.9)	0.32 (0.27–0.38)	4514	1556 (34.5)	1.20 (1.08–1.33)	3692	753 (20.4)	2.02 (1.72–2.36)	
Tested 6–12 months ago	10,808	1531 (17.2)	0.31 (0.29–0.34)		711	143 (20.1)	0.10 (0.08–0.12)	4844	859 (17.7)	0.49 (0.44–0.55)	5253	529 (10.1)	0.88 (0.75–1.04)	
Tested <6 months ago	26,168	2187 (8.4)	0.17 (0.16–0.18)		702	160 (22.8)	0.11 (0.09–0.14)	11,031	1127 (10.2)	0.26 (0.23–0.29)	14,435	900 (6.2)	0.52 (0.45–0.61)	
missing	*2465*	*469 (19.0)*			*181*	*110 (60.8)*		*742*	170 (22.9)		*1542*	*189 (12.3)*		
Self-report H V status														
H V negative	46,241	5689 (12.3)	1 (baseline)		1939	463 (23.9)	1 (baseline)	20,136	3124 (15.5)	1 (baseline)	24,166	2102 (8.7)	1 (baseline)	<0.001
H V positive	1370	825 (60.2)	10.79 (9.14–12.74)	<0.001	164	155 (94.5)	54.90 (21.91–137.55)	611	438 (71.7)	13.79 (10.31–18.43)	595	232 (39.0)	6.71 (5.12–8.81)	
missing	*6892*	*2445 (35.5)*			*1936*	*1316 (68.0)*		*2693*	*855 (31.8)*		*2263*	*274 (12.1)*		
Sisters clinic engagement														
Clinic visits														
First visit	31,288	6508 (20.8)	1 (baseline)		2514	1395 (55.5)	1 (baseline)	13,470	3134 (23.3)	1 (baseline)	15,304	1979 (12.9)	1 (baseline)	0.07
Repeat visit	23,215	2451 (10.6)	0.45 (0.40–0.51)	<0.001	1525	539 (35.3)	0.44 (0.38–0.50)	9970	1283 (12.9)	0.49 (0.41–0.57)	11,720	629 (5.4)	0.38 (0.32–0.45)	
ST diagnosed at clinic visit														
No	35,556	4692 (13.2)	1 (baseline)		2212	993 (44.9)	1 (baseline)	13,794	2063 (15.0)	1 (baseline)	19,550	1636 (8.4)	1 (baseline)	0.01
Yes	18,947	4267 (22.5)	1.91 (1.75–2.09)	<0.001	1827	941 (51.5)	1.3 (1.05–1.61)	9646	2354 (24.4)	1.84 (1.64–2.05)	7474	972 (13.0)	1.64 (1.49–1.80)	
Visit for family planning														
No	45,053	8075 (17.9)	1 (baseline)		3616	1658 (45.9)	1 (baseline)	19,997	4080 (20.4)	1 (baseline)	21,440	2337 (10.9)	1 (baseline)	<0.001
Yes	9450	884 (9.4)	0.47 (0.36–0.61)	<0.001	423	276 (65.3)	2.22 (1.73–2.85)	3443	337 (9.8)	0.42 (0.37–0.48)	5584	271 (4.9)	0.42 (0.36–0.48)	
Testing delivery														
First programme test	39,462	8456 (21.4)	7.88 (6.62–9.38)		3560	1905 (53.5)	17.86 (11.07–28.81)	17,992	4210 (23.4)	7.73 (6.17–9.69)	17,910	2341 (13.1)	4.98 (4.08–6.09)	<0.001
Repeat programme test	15,041	503 (3.3)	1 (baseline)	<0.001	479	29 (6.1)	1 (baseline)	5448	207 (3.8)	1 (baseline)	9114	267 (2.9)	1 (baseline)	

Table 3. Crude and adjusted logistic regression models for HIV test positivity

	Total tests	HIV-positive tests row%	cOR (95% CI)	aOR (95% CI)[a]	aOR (95% CI)[b]
All HIV tests	54,503	8959 (16.4)	*n* = 54,503	*n* = 49,756	*n* = 47,529
Period 1: 2009–2013	4039	1934 (47.9)	8.60 (7.93–9.32)	6.08 (5.52–6.70)	4.03 (3.64–4.45)
Period 2: 2014–2017	23,440	4417 (18.8)	2.17 (2.06–2.29)	2.15 (2.04–2.28)	1.97 (1.86–2.09)
Period 3: 2018–2019	27,024	2608 (9.6)	1 (baseline)	1 (baseline)	1 (baseline)

[a]Adjusted for demographic variables (age, marital status, education and rural/urban).
[b]Adjusted for demographic variables and HIV testing history.

between an HIV-negative and an HIV-positive test was >7 years.

A total of 464 women tested HIV positive after an initial HIV-negative test; at a rate of 3.9 (95% CI 3.5–4.2) HIV infections per 100 pyar. Between 2009 and 2013, 36 women seroconverted at a rate of 4.2 per 100 pyar (95% CI 3.0–5.8). A further 247 women seroconverted in 2014–2017 at a rate of 3.9 per 100 pyar (95% CI 3.4–4.4) and 181 women in 2018–2019 at a rate of 3.8 per 100 pyar (95% CI 3.3–4.5).

We calculated a seroconversion rate of 4.7 per 100 pyar (95% CI 2.9–8.0) between September 2009 and May 2013. Our analysis included follow-up data for 413 women who first tested before May 2013 but were either not included (269/413) in earlier analysis [22] because they only had one test during that period, or contributed less follow-up time (144/413) because they later returned for subsequent tests. The seroconversion rate among these women was 1.6 per 100 pyar.

4 | DISCUSSION

Among FSW accessing HIV testing services through the Sisters programme in Zimbabwe, we report high but declining test positivity between 2009 and 2019. Our findings suggest that this trend was mediated by an increase in more frequent individual testing both within and outside the programme. Over time, new diagnoses remained consistently high among repeat testers, at a rate between 4.2 and 3.8 per 100 pyar. Despite high seroconversion rates, the decrease seen in test positivity is likely to have been the consequence of testing saturation and increased knowledge of HIV status, which need to be factored into the interpretation of test positivity as an indicator of programme performance.

The decrease in test positivity seen at Sisters clinics is unsurprising and comparable to a decrease from 13% to 2.2% between 2000 and 2020 in non-FSW populations across sub-Saharan Africa [23], and 20–6% in Zimbabwe between 2011 and 2018 [24]. Although test positivity trends have not been reported for other FSW populations, similar changes were seen in HIV prevalence among women accessing FSW-dedicated services in Kenya over a 10-year period from 2008, which fell from 44% to 12% [25]. Our seroconversion rates were lower than 12.5 per 100 pyar (95% CI 6.9–21.2), previously reported from a subset of our data [22], due to the availability of additional follow up of women with low seroconversion rates. Estimates for our last time-period need to be interpreted with caution as they may also be inflated and likely to become more accurate with longer follow up. Despite this, our findings reflect the minimal reduction in annual incidence seen among women 15+ years in Zimbabwe's PHIA surveys (0.5 in 2016 to 0.54 in 2020) [26, 27], and in later time-periods are similar to rates of 3.1 and 5.3 per 100 pyar reported for young women selling sex in Zimbabwe in 2017 [28].

The HIV testing trends we observed reflect increases in testing across Zimbabwe [24]. Zimbabwe's Ministry of Health and Child Care HIV testing strategy [24, 29], UNAIDS 90-90-90 targets [30] and initiatives, including PEPFAR 3.0 [31], have influenced national testing coverage and targeting. Changes in World Health Organization testing guidance for key populations [6] and expansion of the Sisters programme have ensured increased testing, specifically among FSW. Resulting increases in knowledge of HIV status [21, 32, 33] leading to declines in undiagnosed HIV will reduce test positivity. Although we did not include a direct measure of knowledge of HIV status, we can infer increased knowledge from the testing expansion we observed, and from other studies in Zimbabwe [21, 32, 33]. A 2009–2011 study reported 58.2% of FSW knew their HIV-positive status [32] compared to estimates closer to 80% in 2016 [21, 33]. Additionally, knowledge of HIV status has increased among all women of childbearing age in Zimbabwe, with over 95% of women tested in pregnancy by 2020 [5]. The rollout of pre-exposure prophylaxis is also likely to have influenced testing trends; however, our analysis predates the widespread delivery in Zimbabwe. Higher test positivity earlier in the programme was likely due to the diagnosis of longer standing infections or women previously diagnosed. This was indicated by greater proportions of women never tested, longer periods since a previous test and more HIV-positive tests among older women and those self-reporting an HIV-positive status. New infections in the programme also made up a greater proportion of HIV-positive tests over time, further supporting these findings. Re-diagnosis has been reported in other contexts. An analysis of provincial health records in South Africa found 51.3% of HIV-positive tests to be previously diagnosed between 2017 and 2018 [34]. Other studies have restricted test positivity measures to newly identified HIV-positive cases, excluding known positives from the denominator [16].

We found that HIV testing history mediated the association between time and test positivity; however, the interpretation of our findings is likely to be more complicated. A 2003–2007 US study found that testing history was associated with

earlier diagnosis, but not with an HIV-positive result, citing the potential interaction between HIV risk and testing behaviours [17]. A UK study of chlamydia testing also showed that reasons for seeking a test and individual HIV risk played a role in test positivity [19]. In our analysis, decreasing test positivity and an increasing proportion of younger women testing over time was likely to reflect reduced risk of seropositivity in younger age groups. In a Zimbabwean study among FSW, prevalence estimates were 1.5 times lower for FSW aged 18–19 years than 20–24 year olds [35]. Changing test positivity may have also been influenced by lower testing coverage in earlier years of the Sisters programme. This was seen in a study of antenatal care in Malawi, where suboptimal testing coverage led to underestimates of HIV prevalence [36].

Our study had limitations. Firstly, we used routine clinic data, introducing the potential for duplicate records and limiting the number of variables with which to explore confounding and interaction. Our analysis relied on self-report testing history, requiring socially motivated responses to questions which may have introduced bias. The accuracy of our data improved over time as subsequent clinic visit data became available to update existing clinic records, and as observations became less reliant on self-report. Although ultimately a strength of our analysis, this could have introduced bias and created disparity between earlier and later years. Although data were missing on demographic and test history variables, this did not appear to affect our findings. Despite adjusting for site location, we could not fully account for the changing catchment areas incorporated over time with the addition of new sites in our analysis. Mobility, transitions into and out of sex work and transfers to antenatal care and ART services, as well as testing availability through other providers, may contribute to women only receiving one HIV test at a Sisters clinic and, therefore, not included in our seroconversion analysis. Additionally, our seroconversion analysis used the midpoint between a woman's last HIV-negative test and her first positive test as an estimated seroconversion date. This may have introduced bias in our estimates due to the length and variation in time between tests, clustering seroconversions in the middle of the reporting period and showing inaccurate declines towards the end [37], as well as ignoring the potential for seroconversion dates to be skewed towards the date of the HIV-positive test [38]. We calculated seroconversion rates for the time-periods used in our test positivity analysis, but may have observed different rates with alternative calendar intervals, depending on which side of a time split the estimated seroconversion date fell.

Our findings have implications for the interpretation of test positivity in tracking programme performance. Funding constraints have necessitated a drive for testing efficiencies, and higher positivity is often thought to reflect resource efficiency [9]. However, in our study, lower test positivity was driven by more frequent individual testing, which has been shown to be cost-saving among FSWs [7, 17]. The increasing proportion of new and recent infections identified over time reflects greater awareness of HIV status and fewer re-diagnoses, signalling a shift towards test positivity more closely approximating incident HIV infections. Testing less than every 6 months could delay HIV diagnosis or result in missed opportunities to test women who may disengage from services. Among non-FSW populations in Kenya, more frequent testing in outpatient departments increased HIV diagnosis and reduced numbers of missed cases [18]. In Swaziland, a screening tool, including testing interval, to identify individuals at risk of being HIV positive and undiagnosed would have missed 25% of HIV-positive cases [39].

5 | CONCLUSIONS

Declining test positivity among FSW over time is likely to reflect changing testing patterns and demonstrate resource efficiencies. Understanding testing history and monitoring new HIV diagnoses from repeat tests could strengthen the interpretation of test positivity and provide a more nuanced understanding of programme performance. These insights are possible with routine HIV programme data and critical to informing testing delivery and ensuring we reach 95% of FSW diagnosed by 2030.

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COMPETING INTERESTS

The authors declare no competing interests.

AUTHORS' CONTRIBUTIONS

HSJ devised and conducted the analysis with input from BH, JRH, FMC and BR. SM, AT and STC provided support with data management and interpretation. PM and LC supported in understanding programme implementation, data collection and interpretation. HSJ wrote the manuscript with input from BH, JRH, FMC and BR and review from all authors. HSJ made reviewer revisions with input from co authors.

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DATA AVAILABILITY STATEMENT

Data are available upon request to the Centre for Sexual Health and HIV/AIDS Research Zimbabwe.

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SUPPORTING INFORMATION

Additional information may be found under the Supporting Information tab for this article:

Table S1: Sensitivity analysis with crude and adjusted logistic regression models for HIV test positivity by visit year

5.1. Missed testing opportunities

To support the interpretation of testing data in the KP Programme I summarised data on where it was potentially missing opportunities to test women. I categorised FSW as eligible for a test if they did not report a HIV-positive status or had been tested at KP site in the previous 6 months. In total, 39,765/85,880 FSW were eligible for HIV testing at 52,687 clinic visits. At 17,257 clinic visits, 33% (13,156/39,765) of FSW were never tested. There were an additional 4,925/39,765 (12%) women who were eligible for testing but not tested at one or more of their clinic, although were tested in a KP clinic during their engagement with the programme. Table 5.4 shows the number of tests that were conducted among eligible FSW. By 2018-2019 testing was delivered at 83.0% of visits where FSW were eligible, and in the same year 77.4% of eligible FSW were HIV tested. These percentages of eligible FSW reached with HIV testing were substantially higher than in earlier years of programme delivery. These data do not take into account where an FSW may have been offered but declined HIV testing.

Table 5.4 HIV testing delivery in the KP Programme by year

Year	Eligible visits†	No. HIV tests delivered at eligible visits (row %)		Eligible women‡	No. HIV tests at any clinic visit (row %)	
	N	n	%	N	n	%
2009	238	124	62.1	264	164	52.1
2010	3,242	688	43.5	2,296	999	21.2
2011	3,618	846	43.9	2,171	954	23.4
2012	2,070	654	54.3	1,310	711	31.6
2013	2,766	919	54.2	2,008	1,088	33.2
2014	4,999	1,716	54.3	4,366	2,369	34.3
2015	5,618	2,905	69.5	4,556	3,166	51.7
2016	5,946	3,064	68.1	4,463	3,041	51.5
2017	8,831	4,344	63.9	7,295	4,661	49.2
2018	6,443	5,281	89.4	4,685	4,188	82.0
2019	8,916	6,899	83.0	6,351	5,268	77.4
Total	52687	27440	66.9%	39765	26,609	52.1%

† A clinic visit with no report of a HIV-positive status or HIV test, or tested at KP site in the previous 6 months

‡ An FSW with no report of a HIV-positive status or HIV test, or tested at KP site in the previous 6 months

6. RESULTS: HIV SEROCONVERSION RATES

Temporal trends in, and risk factors for, HIV seroconversion among female sex workers accessing Zimbabwe's national sex worker programme, 2009–19: a retrospective cohort analysis of routinely collected HIV testing data

Harriet S Jones, Bernadette Hensen, Sithembile Musemburi, Lilian Chinyanganya, Albert Takaruza, Sungai T Chabata, Primrose Matambanadzo, Lucy Platt, Brian Rice, Frances M Cowan, James R Hargreaves

The Lancet HIV (published 2023)

In this chapter I address objective four, to analyse levels and temporal trends in the rate of HIV seroconversion among FSW accessing targeted HIV testing services in CeSHHAR's KP Programme Zimbabwe. The HIV incidence review that I co-authored identified gaps in measurement of the rate of new HIV infections among FSW in sub-Saharan Africa, specifically repeat measures in the same population over time or the reporting of any temporal trends. In a 15 year cohort study among of FSW in Mombasa, Kenya, a downward trend in HIV incidence was seen, falling from 11.4 per 100py in 1998 to 0.6 per 100py in 2012.[226] Other than this, longitudinal data on HIV infection rates among FSW in sub-Saharan Africa have not been published. Earlier work on HIV seroconversion rates, using the KP Programme data until 3rd May 2013, identified 24 women seroconverting over 193 person years follow-up, translating to a seroconversion rate of 12.5 per 100py (95% CI 6.9-21.2). My seroconversion analysis builds on this and on the work I did for my first analysis, using testing patterns and the HIV test data to look at women who seroconverted when they engaged in the KP Programme between 2009 and 2019. Here I provide further analysis of testing patterns for women with repeat HIV tests in the programme. This analysis also has implications for estimating seroconversion rates more broadly and how well the programme is performing in terms of identifying recent HIV infections. From repeat test data I calculated an overall seroconversion rate of 3.8 per 100py (95% CI 3·4–4·2), with seroconversion rates falling over time, when accounting for changes in age and testing frequency among the women accessing HIV services. Seroconversion rates remain high, with evidence that rates are particularly high, reaching 5.8 per 100py (95% CI 5.0–6.7) within the first year of first engaging with KP Programme services.

I had part of this work accepted as a poster presentation at AIDS 2022, the 24th International AIDS Conference, in July- August 2022: The impact of seroconversion date estimation on

seroconversion rates: Analysis of routine HIV test data among female sex workers in Zimbabwe (A-AIDS-2022-08699) (Appendix 14). The methods I have taken to looking at seroconversion date estimation were referenced as exploratory work in the WHO consolidated guidelines on person-centred HIV strategic information: Strengthening routine data for impact.[76]

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Student ID Number	378549	**Title**	Ms
First Name(s)	Harriet		
Surname/Family Name	Jones		
Thesis Title	Measuring trends in HIV testing and new HIV infections among female sex workers in Zimbabwe		
Primary Supervisor	Professor James Hargreaves		

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Where was the work published?	The Lancet HIV		
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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	My role in this research was in planning and conducting the analysis. I prepared the manuscript for publication and addressed revisions. HSJ planned and did the analysis, with input from JRH, BH, FMC, BR, and LP. JRH conceived the original HIV seroconversion analysis in the Sisters cohort. SM, AT, and STC had full access to the programme data and supported data management and interpretation. AT and SM accessed and verified all study data. PM is the Key Populations programme director and leads implementation of the Sisters with a Voice programme. PM and LC provided support with understanding programme HIV testing and data collection and interpretation. HSJ wrote the Article, with input from JRH, BH, FMC, LP, and BR. All authors reviewed the Article, had access to the anonymised subset of programme data included in this analysis, and accept responsibility for the decision to submit for publication.

SECTION E

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Date	28/02/2024

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Date	28/02/2024

Temporal trends in, and risk factors for, HIV seroconversion among female sex workers accessing Zimbabwe's national sex worker programme, 2009–19: a retrospective cohort analysis of routinely collected HIV testing data

Harriet S Jones, Bernadette Hensen, Sithembile Musemburi, Lilian Chinyanganya, Albert Takaruza, Sungai T Chabata, Primrose Matambanadzo, Lucy Platt, Brian Rice, Frances M Cowan, James R Hargreaves

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See Comment page e423

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Summary

Background The frequency of new HIV infections among female sex workers in sub-Saharan Africa is poorly understood. We used routinely collected data that enable unique identification of repeat HIV testers to assess temporal trends in seroconversion and identify associated risk factors for female sex workers accessing Sisters with a Voice, Zimbabwe's national sex worker programme.

Methods We pooled HIV testing data gathered between Sept 15, 2009, and Dec 31, 2019, from 36 Sisters programme sites in Zimbabwe. We included female sex workers aged 16 years or older with an HIV-negative test and at least one subsequent programme test. We calculated HIV seroconversion rates (using the midpoint between the HIV-positive test and the last negative test as the seroconversion date) and estimated rate ratios to compare 2-year periods by using Poisson regression, with robust SEs to account for clustering by site and adjusting for age and testing frequency to assess temporal trends. We did sensitivity analyses to explore assumptions about seroconversion dates and the effects of variation in follow-up time on our conclusions.

Findings Our analysis included data for 6665 female sex workers, 441 (7%) of whom seroconverted. The overall seroconversion rate was 3·8 (95% CI 3·4–4·2) per 100 person-years at risk. Seroconversion rates fell with time since first negative HIV test. After adjustment, there was evidence of a decrease in seroconversion rates from 2009 to 2019 (p=0·0053). In adjusted analyses, being younger than 25 years, and having a sexually transmitted infection diagnosis at a previous visit, were significantly associated with increased seroconversion rates. Our findings were mostly robust to sensitivity analyses, but when 1 month before an HIV-positive test was used as the seroconversion date, seroconversion rates no longer fell with time.

Interpretation We identified high rates of seroconversion shortly after linkage to programme services, which emphasises the need to strengthen HIV prevention programmes from first contact with female sex workers in Zimbabwe. New infections among female sex workers remain challenging to measure, but longitudinal analysis of routine testing data can provide valuable insights into seroconversion rates and associated risk factors.

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Introduction

Understanding trends in new HIV infections and risk factors for seroconversion is essential for the optimisation of programmes aiming to sustainably control the epidemic.[1] The number of new HIV infections has plateaued at 1·5 million globally, with 58% of these infections in sub-Saharan Africa.[2] A focus on preventing new HIV infections among key populations rather than more broadly in lower risk networks will have a larger effect on overall HIV transmission.[3,4] Female sex workers are one such key population: they bear a disproportionally high burden of HIV,[5] and have a 30 times greater risk of infection than non-sex-working women of reproductive age.[2] Female sex workers indirectly accounted for an estimated 15% of new infections in sub-Saharan Africa in 2021.[2]

Female sex workers are often mobile, transient, stigmatised, and criminalised,[6,7] which creates barriers to accessing HIV services[8] and difficulties in recruiting and following up cohorts over time. As a result, measurement of new HIV infections in this population is challenging. Uncertainty around population size and challenges with reaching female sex workers have prompted the use of alternative methods, such as network sampling or

Research in context

Evidence before this study

We searched MEDLINE, EMBASE, POPLINE, Web of Science, and Global Health with the medical subject headings and text words "female sex worker", "HIV", and "sub-Saharan Africa" for articles published in English between Jan 1, 1990, and June 4, 2019. We updated our search to include articles published up to Dec 15, 2022, and also searched unpublished literature for a review of estimates of HIV incidence among female sex workers in sub-Saharan Africa. Estimates of incidence ranging from 0·4 per 100 person-years to 42 per 100 person-years were identified for 31 independent study populations of female sex workers in 14 countries between 1987 and 2020. Very few studies were nationally representative and inclusion criteria, recruitment methods, and analytical approaches varied widely. As a result, comparison of estimates and pooling of data is challenging. Only two study populations provided estimates from more than one timepoint, making temporal trends difficult to ascertain.

Added value of this study

This study—which is based on data from Sisters with a Voice, a nationally representative sex worker programme in Zimbabwe—contributes new estimates of the frequency of new HIV infections among female sex workers to the scarce empirical data available for this population in sub-Saharan Africa. The comprehensive longitudinal dataset provided by Sisters enabled analysis of seroconversion rates in the same population over 10 years, which has not been possible elsewhere in the region. This study additionally showed the methodological limitations of the use of routine data for analyses of HIV incidence and provided a nuanced overview of the effect of the various analytical decisions that need to be made to draw robust conclusions from these data.

Implications of all the available evidence

Among female sex workers accessing sexual and reproductive health services from Sisters in Zimbabwe, rates of HIV seroconversion remain high, but there is evidence of a steady decline over time. High seroconversion rates soon after initial service engagement are consistent with previous evidence of increased acquisition risk before and during formal entry into sex work, suggesting the need for earlier intervention and enhanced HIV prevention services from first contact. As HIV surveillance transitions to routine-dominated surveillance, the development of methods to estimate the frequency of new HIV infections in key populations from programme data is becoming increasingly important—particularly approaches that address challenges in follow-up and that provide insight into new infections among people who do not access services. Empirical estimates of new HIV infections are crucial to tracking and ensuring future progress in the HIV response to achieve sustainable epidemic control.

respondent-driven sampling.[6,9] Despite these advances, data for new HIV infections among female sex workers in sub-Saharan africa and temporal trends are poorly understood.[10,11] Leveraging routinely collected data among repeat testers in which each person is assigned a unique identifier could provide an opportunity to explore HIV seroconversion and associated risks among female sex workers accessing HIV testing services over time, and provide insights not obtained by other approaches.

In Zimbabwe, the prevalence of HIV among female sex workers is estimated to be 57·5%.[12] HIV testing data from Zimbabwe's national sex work programme, Sisters with a Voice (referred to hereafter as Sisters), provides a unique opportunity to understand trends in HIV seroconversion in a programme context. We aimed to understand trends in HIV seroconversion among women who underwent repeat testing within the Sisters programme between 2009 and 2019, to identify risk factors associated with seroconversion, and to assess and minimise potential biases.

Methods

Study setting and data sources

We did a retrospective cohort analysis of HIV testing data routinely collected by Sisters, a national sexual and reproductive health programme in Zimbabwe that provides free services mainly to cisgender women and girls aged at least 16 years who self-identify as a sex worker. Between the programme's intiation in September, 2009, and Dec 31, 2019, Sisters operated at 36 sites, including static clinics delivering services 5 days a week and mobile clinics delivering services once a week. Community outreach is done at each site by peer educators. HIV testing is offered at the first clinic visit to woman who are HIV negative or of unknown HIV status. HIV-negative women revisiting any Sisters clinic are offered an HIV test if they have not been tested within the previous 6 months, in line with national guidance. Zimbabwe's national HIV testing algorithm is followed at all Sisters clinics, with Determine HIV-1/2 antibody testing (Abbott Diagnostics, Tokyo, Japan) for initial screening and confirmatory antibody testing with SD Bioline HIV-1/2 (Abbott Diagnostics, Tokyo, Japan). Until 2018, female sex workers who tested positive for HIV were referred for treatment at Government health facilities, in line with national treatment guidelines at the time of diagnosis. Antiretroviral therapy (ART) is now provided by Sisters clinics in 11 districts.

A unique identifier code and a Sisters number are assigned to each woman when they first engage with the programme, either at the first clinic visit or during community outreach. Personal identifying information, including phone numbers and current location, are collected by clinic staff during registration and kept

electronically. At subsequent visits, women are identified by their Sisters number or unique identifying information. To minimise duplicate records (ie, the assignment of more than one Sisters number to the same individual), checks of personal identifying information provided at registration are done by clinic staff. At the first clinic visit, staff also collect data for age, marital status (married, divorced, never married, separated, or widowed), education (none or primary education, or secondary or tertiary education), and whether the client has ever experienced gender-based violence. At each clinic visit, data are collected for self-reported HIV testing history and sexual risk behaviour, including condom use with most recent sex partner. A record is kept of services provided at each visit, including HIV test results and diagnosis of sexually transmitted infections (STIs; based on verbal report of symptoms and a physical examination only).

Ethical approval for our study of Sisters data was obtained from the London School of Hygiene & Tropical Medicine (16543) and the Medical Research Council of Zimbabwe (MRCZ/A/2624). Because the data were collected as part of routine clinical care, consent was not obtained. Data were de-identified and anonymised before databases were shared for analysis.

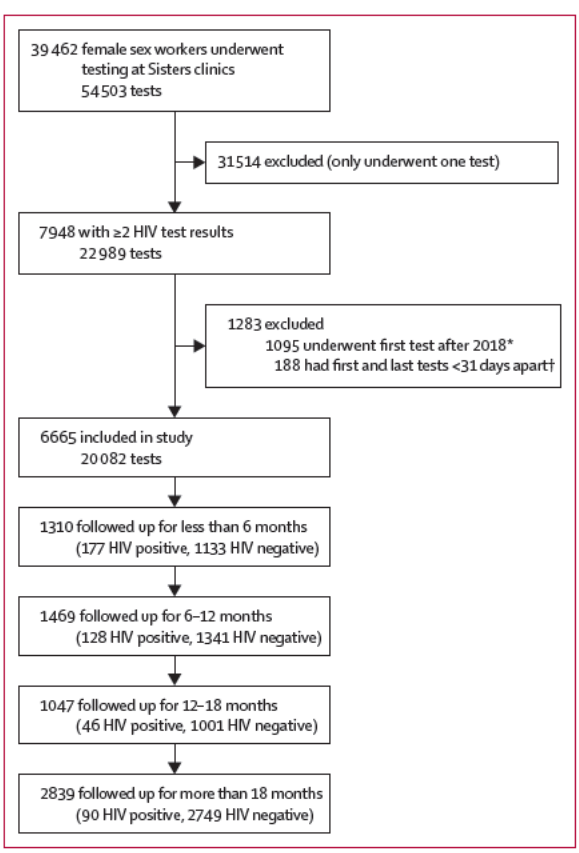

Figure 1: **Flow diagram of cohort inclusion and follow-up**
Follow-up was defined as the time from the date of participants' first HIV test to seroconversion (or date of last negative test if no positive HIV test was recorded). *35 of 2462 HIV tests were positive. †27 of 386 HIV tests were positive; a further 59 tests were excluded because they were done less than 7 days after the previous test (two of these were positive, and the previous negative result was excluded).

Procedures

To study seroconversion rates, we formed a retrospective cohort comprising women visiting Sisters who had an initial HIV-negative test and who underwent one or more subsequent HIV tests as part of the programme between Sept 15, 2009, and Dec 31, 2019. We excluded women with fewer than 31 days between their first and last HIV test (because of the minimal follow and the possibility that those testing HIV positive could have been seroconverting at the time of their first test). We excluded HIV tests that were done with 7 days of a previous test and people who tested HIV negative after a previous positive test result, because we could not guarantee the accuracy of these data. Finally, to ensure equal opportunity for at least 1 year's follow-up and to prevent artificially inflating seroconversion rates by limiting the potential to return for subsequent testing,[13] we excluded women whose first HIV test was after Dec 31, 2018. Cohort entry was the date of a woman's first HIV test at a Sisters clinic. Cohort exit was either an estimated seroconversion date or the date of the last HIV-negative test. The date of seroconversion was estimated as the midpoint between a woman's last negative HIV test and her HIV-positive test.

Our main exposure was time. We used lexis expansion to split data into 2-year periods (2009–11 [slightly longer than 2 years because it also contained data for the end of 2009], 2012–13, 2014–15, 2016–17, and 2018–19) and by time since first HIV test (<6 months, 6 to <12 months, 12 to <18 months, and ≥18 months). Other explanatory variables included demographic and behavioural factors, HIV testing, and clinic visit characteristics—ie, the results of any other assessment at the clinic, such as syndromic STI diagnoses, and the location (urban *vs* rural) and type (mobile *vs* static) of clinic. We calculated individual HIV testing frequency by using the mean time between a woman's Sisters tests (<6 months, 6 to <12 months, 12 to <18 months, and ≥18 months). Testing frequency was not treated as time-varying and was thus calculated once for the duration of individual follow up. Time-varying factors were collected at each visit (except for age, which was calculated on the basis of data collected at the first visit). We used lexis expansion to split data on age at HIV test for age (<25 years and ≥25 years). Other variables were not treated as time-varying, because data were collected at first visit only, or there was minimal individual-level variation over time (eg, clinic site).

Statistical analysis

We described our cohort by HIV test and clinic visit characteristics and demographic and behavioural risk factors, and stratified data by whether or not participants tested positive for HIV. We described these characteristics

for the whole analysis period (ie, 2009–19) and then for 2009–11, 2012–13, 2014–15, 2016–17, and 2018–19. We calculated seroconversion rates overall and then by study period and follow-up time (ie, time since a first HIV-negative test), using clustered robust SEs to account for within-site correlation. We assessed correlation

	2009–11 (n=239)		2012–13 (n=431)		2014–15 (n=1745)		2016–17 (n=2639)		2018–19 (n=1611)	
	HIV negative (n=209)	HIV positive (n=30)	HIV negative (n=397)	HIV positive (n=34)	HIV negative (n=1604)	HIV positive (n=141)	HIV negative (n=2479)	HIV positive (n=160)	HIV negative (n=1535)	HIV positive (n=76)
Site location										
Urban	150 (72%)	24 (80%)	371 (93%)	31 (91%)	1123 (70%)	105 (74%)	2044 (82%)	142 (89%)	1398 (91%)	71 (93%)
Rural	59 (28%)	6 (20%)	26 (7%)	3 (9%)	481 (30%)	36 (26%)	435 (18%)	18 (11%)	137 (9%)	5 (7%)
Site type										
Static	128 (61%)	19 (63%)	283 (71%)	27 (79%)	718 (45%)	76 (54%)	1880 (76%)	121 (76%)	1363 (89%)	67 (88%)
Mobile	81 (39%)	11 (37%)	114 (29%)	7 (21%)	886 (55%)	65 (46%)	599 (24%)	39 (24%)	172 (11%)	9 (12%)
Median age at first HIV test, years	29 (24–36)	25 (22–31)	29 (24–33)	26 (23–30)	28 (23–34)	24 (21–31)	26 (22–32)	26 (21–31)	26 (22–31)	26 (22–30)
Education										
None or primary	20 (30%)	1 (7%)	84 (22%)	8 (25%)	390 (25%)	39 (28%)	412 (18%)	25 (16%)	244 (17%)	13 (18%)
Secondary or tertiary	46 (70%)	13 (93%)	292 (78%)	24 (75%)	1170 (75%)	99 (72%)	1906 (82%)	127 (84%)	1180 (83%)	60 (82%)
Missing	143	16	21	2	44	3	161	8	111	3
Marital status										
Married	1 (1<%)	0 (0)	14 (4%)	0 (0)	44 (3%)	1 (1%)	63 (3%)	3 (2%)	59 (4%)	1 (1%)
Divorced	134 (64%)	22 (73%)	231 (59%)	24 (71%)	1094 (69%)	96 (70%)	1518 (65%)	102 (67%)	876 (61%)	47 (64%)
Never married	36 (17%)	8 (27%)	87 (22%)	7 (21%)	285 (18%)	26 (19%)	604 (26%)	41 (27%)	442 (31%)	21 (29%)
Separated	3 (1%)	0 (0)	29 (7%)	1 (3%)	20 (1%)	2 (1%)	4 (<1%)	0 (0)	2 (<1%)	0 (0)
Widowed	34 (16%)	0 (0)	33 (8%)	2 (6%)	135 (9%)	13 (9%)	142 (6%)	6 (4%)	48 (3%)	4 (5%)
Missing	1	0	3	0	26	3	148	8	108	3
Condom used with most recent sexual partner										
No	95 (53%)	7 (39%)	224 (59%)	15 (47%)	1024 (66%)	82 (59%)	1758 (75%)	120 (75%)	1088 (75%)	53 (75%)
Yes	84 (47%)	11 (61%)	155 (41%)	17 (53%)	533 (34%)	58 (41%)	596 (25%)	39 (25%)	361 (25%)	18 (25%)
Missing	30	12	18	2	47	1	125	1	86	5
STI diagnosis*										
No	134 (64%)	20 (67%)	267 (67%)	20 (59%)	1146 (71%)	77 (55%)	1749 (71%)	85 (53%)	1138 (74%)	45 (59%)
Yes	75 (36%)	10 (33%)	130 (33%)	14 (41%)	458 (29%)	64 (45%)	730 (29%)	75 (47%)	397 (26%)	31 (41%)
Gender-based violence (ever)										
No	188 (90%)	25 (83%)	278 (70%)	23 (68%)	1149 (73%)	103 (74%)	1882 (81%)	121 (80%)	1231 (87%)	57 (79%)
Yes	21 (10%)	5 (17%)	119 (30%)	11 (32%)	432 (27%)	36 (26%)	436 (19%)	30 (20%)	187 (13%)	15 (21%)
Missing	0	0	0	0	23	2	161	9	117	4
HIV tests										
Median number	3 (2–4)	2 (2–3)	3 (2–5)	2 (2–3)	3 (2–4)	2 (2–3)	2 (2–3)	2 (2–3)	2 (2–3)	2 (2–3)
Median time between last two tests	426 (210–1134)	365 (182–761)	308 (157–736)	477 (247–1086)	305 (146–651)	301 (155–652)	246 (122–470)	298 (176–546)	175 (101–280)	203 (86–351)
Time between first and last HIV test										
0 to <6 months	15 (7%)	4 (13%)	35 (9%)	3 (9%)	219 (14%)	28 (20%)	427 (17%)	26 (16%)	437 (28%)	25 (33%)
6 to <12 months	18 (9%)	2 (7%)	48 (12%)	7 (21%)	220 (14%)	27 (19%)	442 (18%)	43 (27%)	613 (40%)	27 (36%)
12 to <18 months	15 (7%)	7 (23%)	32 (8%)	2 (6%)	170 (11%)	23 (16%)	392 (16%)	35 (22%)	392 (26%)	22 (29%)
≥18 months	161 (77%)	17 (57%)	282 (71%)	22 (65%)	995 (62%)	63 (45%)	1218 (49%)	56 (35%)	93 (6%)	2 (3%)
Mean testing frequency										
0 to <6 months	17 (8%)	4 (13%)	61 (15%)	4 (12%)	372 (23%)	35 (25%)	743 (30%)	41 (26%)	804 (52%)	35 (46%)
6 to <12 months	40 (19%)	9 (30%)	114 (29%)	12 (35%)	538 (34%)	46 (33%)	905 (37%)	48 (30%)	551 (36%)	25 (33%)
12 to <18 months	42 (20%)	5 (17%)	70 (18%)	5 (15%)	268 (17%)	22 (16%)	399 (16%)	39 (24%)	158 (10%)	16 (21%)
≥18 months	110 (53%)	12 (40%)	152 (38%)	13 (38%)	426 (27%)	38 (27%)	432 (17%)	32 (20%)	22 (1%)	0 (0)

Data are n (%), median (IQR), or n. For percentage calculations, we used available data as the denominator rather than the total N. STI=sexually transmitted infection. *Diagnosed with an STI at the last recorded HIV-negative test (the penultimate visit for women who seroconverted and the final test for those who remained HIV negative).

Table 1: **Characteristics of repeat HIV testers in the Sisters programme, by seroconversion status and time**

between follow-up time and mean testing frequency by calculating correlation coefficients for participants with more than two HIV tests. We calculated seroconversion rates for each demographic and behavioural risk factor. For time-varying factors, we used the outcome at the last recorded HIV-negative test for each participant (ie, the penultimate visit for women who seroconverted and the final test for those who remained HIV negative). To explore temporal trends in seroconversion, we used Poisson regression to estimate rate ratios and compared rates by study periods. We also estimated rate ratios for all other variables. We adjusted our model of seroconversion rates for age and HIV testing frequency to account for the changing demographic and testing patterns of people accessing services over time.

See Online for appendix

We did sensitivity analyses to assess our analytical decisions about cohort inclusion and seroconversion date estimation. In exploratory analysis, follow-up time was a strong predictor of seroconversion. Thus, we first restricted follow-up for each participant to a maximum of 2 years. We subsequently ran our analysis three more times, each time applying a different approach to estimating seroconversion dates. First, we used 1 month before a positive test as the seroconversion date to address the possibility that attending Sisters for HIV testing could be motivated by potential risk of exposure. Second, we used 2 weeks after a last negative test to address the potential that women had already been exposed at that time but had tested too early. Finally, we randomly assigned seroconversion dates by using the mean of 100 random runs of estimated seroconversion dates. We used Poisson regression to estimate rate ratios and compare seroconversion rates by time and adjusted our models as in our main analysis. We used Stata (version 17.0) for all statistical analyses.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Sept 15, 2009, and Dec 31, 2019, 39 462 female sex workers underwent 54 503 HIV tests at a Sisters clinic. However, 31 514 had only one HIV test (8456 [27%] of which were positive) and were excluded from further analysis. A further 1283 participants with an initial HIV-negative test and at least one subsequent HIV test were excluded (accounting for 2907 tests; figure 1). Our analysis cohort thus comprised 6665 female sex workers, who underwent 20 082 HIV tests.

Median age at first HIV test in the analysis cohort was 27 years (IQR 23–32). The median age of women who were excluded because they underwent only one HIV test was 26 years (22–33). Among these women, median age was 25 years (21–32) among those who tested negative for HIV and 28 years (24–34) for those who tested positive. Other demographic characteristics and risk factors were similar between women who tested for HIV only once (and were thus excluded from our analysis) and those in the analysis cohort (appendix p 1).

During the study, 441 (7%) participants seroconverted. Median time between the first and last test was 409 days (IQR 222–702) among women who seroconverted compared with 476 days (239–896) among those who remained HIV negative. Both those who seroconverted and those who remained HIV negative did a median of two tests (IQR 2–4). Overall, the median between HIV tests was 266 days (159–452). In all study periods, education and marital status were similar between those who seroconverted and those who did not (table 1). 86 (20%) of the 441 women who seroconverted had less than 6 months between their first and last HIV test, compared with 1133 (18%) of the 6224 who remained HIV negative throughout the study. Overall, women who seroconverted were less likely to have more than 18 months between their first and last HIV test (160 [36%] *vs* 2749 [44%]) and were younger at first HIV test (median 25 years [IQR 22–31] *vs* 27 years [23–32]) than those who did not seroconvert (table 1).

Women contributed 11 657 person-years at risk, and the overall seroconversion rate during the study was 3·8 (95% CI 3·4–4·2) per 100 person-years at risk. Seroconversion rates were highest within 12 months of a first HIV-negative test, and fell among women who were followed up for more than a year (table 2). The rate ratio for seroconversion at least 18 months after an HIV test compared with in the first 6 months after an HIV test was 0·34 (95% CI 0·27–0·44; table 2). Seroconversion rates fell from 4·6 per 100 person-years at risk in 2009–11 to 3·6 per 100 person-years at risk in 2018–2019, but this difference was not significant in unadjusted analyses (table 2). Rates of seroconversion by follow-up time were similar in each 2-year study period (figure 2).

For 3504 (53%) participants, the mean time between HIV tests was the same as the length of follow-up because they underwent only two tests. The mean time between tests was correlated with follow-up time among women who underwent more than two tests (0·46; p<0·0001). Seroconversion rates were higher among women with a mean of less than 6 months between HIV tests than among those with a mean of more than 18 months between tests (rate ratio 0·29 [95% 0·23–0·37]; table 2).

In adjusted analyses, seroconversion rates were higher among participants younger than 25 years than those aged 25 years or older, among those with a syndromic STI diagnosis at their previous visit than among those without an STI diagnosis (table 2), and among those who reported using a condom during their most recent sexual encounter than among those who reported not using condoms (table 2). Seroconversion rates did not differ significantly between urban and rural sites or static and mobile sites, or between women who had ever

	Seroconversions	Person-years at risk/100	Seroconversion rate per 100 person-years (95% CI)	Rate ratio (95% CI)	Adjusted rate ratio* (95% CI)	p value
Period	..	..	..	..	..	0·0053
2009–11	9	1·9	4·6 (2·6–12·7)	1·28 (0·80–2·04)	1·78 (1·15–2·75)	..
2012–13	27	6·7	4·0 (2·8–6·3)	1·11 (0·72–1·70)	1·61 (1·02–2·55)	..
2014–15	95	21·3	4·5 (3·5–5·7)	1·23 (0·93–1·63)	1·54 (1·20–1·97)	..
2016–17	152	42·8	3·5 (3·1–4·1)	0·98 (0·79–1·23)	1·15 (0·92–1·43)	..
2018–19	158	43·7	3·6 (2·9–4·6)	1 (ref)	1 (ref)	..
Follow-up time†	..	..	..	..	..	<0·0001
0 to <6 months	177	30·7	5·8 (5·0–6·7)	1 (ref)	1 (ref)	..
6 to <12 months	128	23·1	5·5 (4·6–6·5)	0·95 (0·80–1·14)	0·94 (0·76–1·16)	..
12 to <18 months	46	16·6	2·8 (2·1–3·7)	0·48 (0·33–0·71)	0·50 (0·33–0·75)	..
≥18 months	90	46·1	2·0 (1·6–2·4)	0·34 (0·27–0·44)	0·37 (0·28–0·51)	..
Mean time between tests	..	..	..	..	..	<0·0001
0 to <6 months	119	15·1	7·9 (6·8–9·3)	1 (ref)	1 (ref)	..
6 to <12 months	140	37·8	3·7 (3·2–4·4)	0·47 (0·37–0·60)	0·50 (0·39–0·63)	..
12 <18 months	87	22·9	3·8 (2·8–5·3)	0·48 (0·36–0·63)	0·49 (0·38–0·64)	..
≥18 months	95	40·8	2·3 (1·8–3·0)	0·29 (0·23–0·37)	0·31 (0·23–0·40)	..
Site location	..	..	..	..	..	..
Urban	373	92·9	4·0 (3·6–4·5)	1 (ref)	1 (ref)	..
Rural	68	23·7	2·9 (2·3–3·6)	0·72 (0·57–0·91)	0·81 (0·64–1·02)	0·067
Site type	..	..	..	..	..	..
Static	310	77·0	4·0 (3·6–4·5)	1 (ref)	1 (ref)	..
Mobile	131	39·6	3·3 (2·7–4·0)	0·82 (0·66–1·01)	0·93 (0·76–1·14)	0·48
Age	..	..	..	..	..	..
<25 years	177	31·7	5·6 (4·8–6·5)	1 (ref)	1 (ref)	..
≥25 years	251	81·8	3·1 (2·7–3·5)	0·55 (0·45–0·67)	0·59 (0·48–0·73)	<0·0001
Education	..	..	..	..	..	..
None or primary	86	22·3	3·9 (3·2–4·7)	1·03 (0·82–1·29)	0·96 (0·76–1·22)	0·73
Secondary or tertiary	323	81·7	4·0 (3·5–4·6)	1 (ref)	1 (ref)	..
Marital status	..	..	..	..	..	0·0044
Married	5	3·2	1·6 (0·4–23·2)	0·40 (0·17–0·95)	0·38 (0·16–0·90)	..
Divorced	291	73·3	4·0 (3·4–4·7)	1 (ref)	1 (ref)	..
Never married	103	25·2	4·1 (3·6–4·7)	1·03 (0·82–1·29)	0·86 (0·68–1·08)	..
Separated	3	1·7	1·8 (0·6–7·0)	0·46 (0·15–1·35)	0·53 (0·17–1·63)	..
Widowed	25	9·4	2·7 (1·8–4·0)	0·67 (0·45–1·01)	0·84 (0·56–1·26)	..
Condom used with most recent sexual partner	..	..	..	..	..	..
No	277	79·9	3·5 (3·0–4·1)	1 (ref)	1 (ref)	..
Yes	143	31·1	4·6 (4·0–5·2)	1·33 (1·06–1·65)	1·33 (1·07–1·64)	0·0086
STI diagnosis‡	..	..	..	..	..	..
No	247	84·4	2·9 (2·6–3·3)	1 (ref)	1 (ref)	..
Yes	194	32·2	6·0 (5·3–7·0)	2·06 (1·84–2·30)	2·16 (1·97–2·35)	<0·0001
Gender-based violence (ever)	..	..	..	..	..	..
No	329	87·3	3·8 (3·3–4·4)	1 (ref)	1 (ref)	..
Yes	97	25·4	3·8 (3·3–4·6)	1·02 (0·81–1·27)	1·08 (0·87–1·35)	0·47
Time from last negative test to seroconversion	..	..	..	..	..	..
≤365 days	261	60·6	4·3 (3·8–4·9)	1 (ref)	1 (ref)	..
>365 days	180	55·9	3·2 (2·8–3·8)	0·75 (0·64–0·88)	1·50 (1·16–1·94)	0·0021

STI=sexually transmitted infection. *Adjusted for age and mean time between HIV tests. †Time from first programme test to midpoint estimated seroconversion date (or date of last HIV-negative test date if no HIV-positive result). ‡Diagnosed with an STI at the last recorded HIV-negative test for each woman (the penultimate visit for women who seroconverted and the final test for those who remained HIV-negative).

Table 2: **Seroconversion rates by demographic and HIV testing characteristics (n=441)**

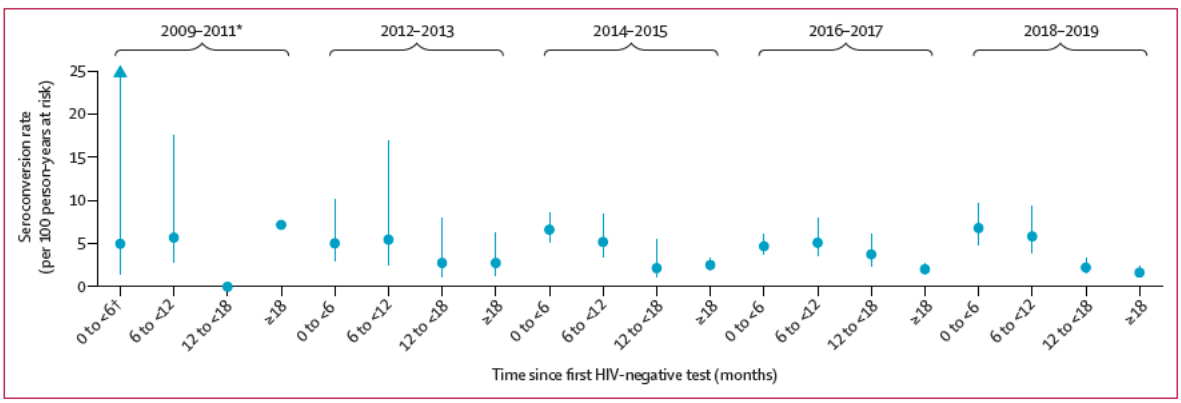

Figure 2: **HIV seroconversion rates among female sex workers (n=6665) accessing Zimbabwe's Sisters programme, by time since first HIV test**
Rates are shown for 2-year periods between 2009 and 2019: 2009–11 (nine seroconversions and 195 person-years at risk), 2012–13 (27 seroconversions and 674 person-years at risk), 2014–15 (95 seroconversions and 2132 person-years at risk), 2016–17 (152 seroconversions and 4283 person-years at risk), and 2018–19 (158 seroconversions and 4374 person-years at risk). Error bars represent 95% CIs. *Data for 2009 are from Sept 15 to Dec 31 only; 95% CIs could not be calculated for the 13–18 months' follow-up and the >18 months' follow-up groups. †95% CI=1·5–56·3.

experienced gender-based violence and those who had not (table 2).

When our model was adjusted for age and mean time between HIV tests, the risk of seroconversion was greater in 2009–11, 2012–13, and 2014–15 than in 2018–19 (table 2), and overall the risk of seroconversion between 2009 and 2019 decreased (p=0·0053). After adjustment for age and time between HIV tests, when seroconversion dates were randomly generated, seroconversion rates fell with time (p=0·0093; table 3). When 1 month before seroconversion was used as the seroconversion date, seroconversion rates fell between 2009 and 2017, but were highest in 2018–19 (table 3). In this sensitivity analysis, seroconversion rates were associated with calendar time in our adjusted model (p=0·0007). When 2 weeks after the last negative test result was used as the seroconversion date, seroconversion rates were higher between 2009 and 2015 than when either midpoint or random estimation were used to ascertain the seroconversion date (table 3). By 2018–19, seroconversion had fallen to 2·6 per 100 person-years at risk, with a strong downward trend in both crude and adjusted models (p<0·0001; table 3).

When follow-up time was restricted to 2 years, 6665 participants contributed 8268·9 person-years at risk and 386 seroconverted (rate 4·7 per 100 person-years at risk). Seroconversion rates in this restricted cohort showed little variation over time (table 3).

Discussion

In our study, seroconversion rates were high among female sex workers accessing HIV services through Zimbabwe's Sisters programme, but there was evidence of a steady decline over time after adjustment for age and individual HIV testing frequency. Seroconversion rates were higher within 6 months of a first HIV-negative test, among those testing more frequently, among those younger than 25 years, and among those diagnosed with an STI at a previous visit. Our findings were generally robust to sensitivity analyses, but when we simulated testing strongly motivated by recent risk (by using 1 month before a negative test as the seroconversion date), seroconversion rates no longer decreased over time.

Seroconversion rates in our study were similar to those previously reported for female sex workers accessing HIV services through the Sisters programme.[13,14] Rates for individual periods reflect those reported in other studies of female sex workers[15–17] in southern Africa between 2009 and 2019, although the rate for 2018–19 in our study was lower than the 4·6 per 100 person-years at risk reported in South Africa for 2019.[18] The decline in seroconversion rates over time that we report reflects both modelled and empirical estimates reported for the general population in southern Africa.[11,19,20] We identified variables commonly associated with increased risk of HIV infection, including younger age and diagnosis with an STI.[21]

Our findings are consistent with the age-specific prevalence of HIV reported among female sex workers recruited for respondent-driven sampling surveys in Zimbabwe,[16] in which the incidence of HIV was higher among female sex workers aged 18–24 years than among those aged 25–39 years (6·3 per 100 person-years at risk compared with 3·3 per 100 person-years at risk). A similar incidence of 5·3 per 100 person-years at risk was also reported for young women selling sex in non-intervention sites in the DREAMS study.[17] Studies suggest a higher frequency of new HIV infections before formal entry into sex work[22] compared with already being a sex worker and soon after first selling sex compared with having been a sex worker for longer,[16] aligning with the higher seroconversion rates we reported close to first testing for HIV at a Sisters clinic. Although a first HIV test could be a proxy for recent entry into sex work, we could have underestimated incidence by excluding the period before formal entry into sex work and engagement

	Overall cohort						Cohort restricted to 2 years' follow-up				
	Seroconversions	Person-years at risk/100	Seroconversion rate per 100 person-years (95% CI)	Rate ratio (95% CI)	Adjusted rate ratio* (95% CI)	p value	Seroconversions	Person-years at risk/100	Seroconversion rate per 100 person-years (95% CI)	Adjusted rate ratio* (95% CI)	p value
Midpoint	..	..	..	..	..	0·0053	..	..	..	..	0·054
2009–11	9	1·9	4·6 (2·6–12·7)	1·30 (0·82–2·04)	1·78 (1·15–2·75)	..	9	1·9	4·6 (2·7–12·7)	1·57 (0·98–2·50)	..
2012–13	27	6·7	4·0 (2·8–6·3)	1·13 (0·73–1·73)	1·61 (1·02–2·55)	..	24	5·4	4·4 (2·9–7·4)	1·51 (0·88–2·60)	..
2014–15	95	21·3	4·5 (3·5–5·7)	1·26 (0·95–1·67)	1·54 (1·20–1·97)	..	88	16·7	5·3 (4·3–6·6)	1·44 (1·11–1·87)	..
2016–17	152	42·8	3·5 (3·1–4·1)	0·99 (0·80–1·23)	1·15 (0·92–1·43)	..	130	30·5	4·3 (3·5–5·5)	1·06 (0·79–1·43)	..
2018–19	158	43·7	3·6 (2·9–4·6)	1 (ref)	1 (ref)	..	135	28·2	4·8 (3·8–6·1)	1 (ref)	..
1 month before seroconversion	..	..	..	..	..	0·0007	..	..	..	..	0·0002
2009–11	8	2·0	4·1 (1·7–20·7)	0·84 (0·49–1·46)	1·11 (0·65–1·89)	..	8	2·0	4·1 (1·8–20·7)	1·64 (1·06–2·52)	..
2012–13	21	6·8	3·1 (1·7–6·3)	0·64 (0·35–1·19)	0·87 (0·45–1·70)	..	17	5·5	3·1 (1·5–8·4)	1·25 (0·54–2·91)	..
2014–15	71	21·7	3·3 (2·4–4·5)	0·68 (0·49–0·96)	0·81 (0·59–1·11)	..	61	16·9	3·6 (2·6–5·2)	1·02 (0·73–1·41)	..
2016–17	127	43·6	2·9 (2·4–3·6)	0·61 (0·45–0·83)	0·68 (0·50–0·94)	..	101	30·9	3·3 (2·6–4·2)	0·83 (0·58–1·18)	..
2018–19	214	44·6	4·8 (3·9–5·9)	1 (ref)	1 (ref)	..	149	28·7	5·2 (4·1–6·6)	1 (ref)	..
2 weeks after last negative test	..	..	..	..	..	<0·0001	..	..	..	..	<0·0001
2009–11	20	1·9	10·8 (8·1–14·2)	4·20 (2·76–6·40)	5·98 (3·84–9·32)	..	20	1·8	10·8 (8·1–14·2)	4·43 (2·53–7·76)	..
2012–13	34	6·5	5·3 (4·1–7·4)	2·05 (1·41–2·98)	3·06 (2·02–4·63)	..	34	5·2	6·6 (5·3–9·0)	2·71 (1·65–4·44)	..
2014–15	122	20·7	5·9 (4·4–7·8)	2·30 (1·58–3·36)	2·85 (2·04–3·99)	..	119	16·1	7·4 (6·0–9·1)	2·58 (1·75–3·79)	..
2016–17	154	41·9	3·7 (3·0–4·6)	1·43 (1·11–1·86)	1·62 (1·23–2·14)	..	146	29·6	4·9 (3·9–6·5)	1·55 (1·08–2·23)	..
2018–19	111	43·3	2·6 (1·9–3·6)	1 (ref)	1 (ref)	..	95	27·8	3·4 (2·5–4·9)	1 (ref)	..
Random	..	..	..	..	..	0·0093	..	..	..	..	0·069
2009–11	9	1·9	4·6 (2·6–12·6)	1·27 (0·79–2·04)	1·77 (1·13–2·76)	..	9	1·9	4·6 (2·7–12·7)	1·55 (0·97–2·48)	..
2012–13	27	6·7	4·0 (2·8–6·3)	1·10 (0·72–1·68)	1·60 (1·02–2·52)	..	24	5·4	4·4 (3·0–7·4)	1·49 (0·87–2·57)	..
2014–15	96	21·3	4·5 (3·5–5·8)	1·24 (0·94–1·63)	1·54 (1·21–1·97)	..	86	16·7	5·2 (4·1–6·5)	1·45 (1·12–1·90)	..
2016–17	151	42·8	3·5 (3·1–4·2)	0·96 (0·78–1·18)	1·13 (0·92–1·38)	..	127	30·5	4·2 (3·3–5·5)	1·07 (0·79–1·45)	..
2018–19	158	43·7	3·6 (3·0–4·5)	1 (ref)	1 (ref)	..	136	28·2	4·8 (3·9–6·0)	1 (ref)	..

*Adjusted for age and mean time between HIV tests; 6414 people were included in adjusted models because data were missing for age for the other 251 participants.

Table 3: **Seroconversion rates by method of estimation of seroconversion date (n=6665)**

with the Sisters programme and prevention services.[23] Our data give some indication of this potential underestimation, with 27% of tests positive among female sex workers with only one Sisters HIV test result. Given the median age of 27 years at a first test in our study, and that access to Sisters services requires self-identification as a sex worker, it is unlikely that our findings fully account for this period of recent entry into sex work before self-identification as a sex worker.

A key strength of our study was the large programme dataset, which enabled analysis of HIV test data for 6665 female sex workers over 10 years. As a result, we could report temporal trends in the incidence of new HIV infections, which have not been previously reported for female sex workers in southern Africa.[10] Our study had several limitations. The generalisability of our findings could be limited by the decision to include only sex workers who accessed Sisters clinic services and returned for repeat HIV testing. However, with programme coverage increasing substantially over time through expanded community outreach and clinic referral and the use of peer educators and networks within the sex worker community, our cohort was probably increasingly representative of female sex workers in Zimbabwe. In 2017, the programme's clinical services were thought to have reached 57% of the estimated 40 000 female sex workers in the country,[24] and our findings are similar to those reported in respondent-driven sampling surveys, which reached female sex workers who had not accessed Sisters services. Female sex workers excluded from our study because they had only one HIV test result available were slightly younger than those included in the analysis, but were similarly distributed across clinic sites and had similar demographic characteristics. Our findings might be less generalisable to women and young girls who do not identify as sex workers. Although we included time-varying risk factors in our analysis, we could not do this for all variables, which limited our ability to adjust for confounding by variables that were measured only at the first clinic visit. We used proximity to a last HIV-negative test for STI diagnoses and condom use, but variation in time between HIV tests meant that proximity varied for individual women, and could have greater relevance when measured closer to HIV-positive test results. Our analysis did not include variables for which data were not collected, including time in sex work and HIV test refusal, or variables for which over 40% of data were missing, including number of condomless sex partners, which could have helped with interpretation. Our analysis pre-dated widespread rollout of pre-exposure prophylaxis in Zimbabwe.

Identification of the time of HIV infection at diagnosis is challenging.[25] In our study, imputation of seroconversion dates either at the midpoint between testing positive for HIV and the last negative test result or randomly gave similar results, as has been reported elsewhere.[17,26] Unlike more conventional cohorts that have set follow-up times, the continuous enrolment of women in our cohort means that midpoint estimation is unlikely to have caused clustering of seroconversions around the middle of the reporting period, and therefore is unlikely to have suggested inaccurate declines in seroconversion frequency towards the end of the study.[27] However, despite the exclusion of women testing for the first time after 2018, seroconversion rates at the end of our reporting period could have been inflated if HIV test data were not available for women who later returned to the programme.[13,14] In other populations, studies have shown that HIV infection is not independent of testing patterns in public health testing services[28] and have suggested that seroconversion occurs closer to an HIV-positive test than midpoint estimation sometimes suggests.[25] In sensitivity analyses in our study, use of 1 month before testing positive for HIV as the seroconversion suggested that seroconversion rates were not declining with time. However, female sex workers are recommended to test more frequently than non-sex workers, which makes the relevance of assumptions about risk exposure driving testing less clear.

Our study identified the effect of wide variation in follow-up time and time between HIV tests on our findings. As follow-up time and time between tests were correlated, we chose to adjust for mean time between HIV tests as an indicator of testing engagement and reduced certainty around seroconversion dates with longer time between tests. Regular HIV testing could indicate high-risk behaviour and potential HIV exposure. Testing patterns among female sex workers accessing Sisters have changed over time,[13] as have testing guidelines,[29] and the availability and acceptability of testing have increased. HIV-exposure-driven testing might have become more common with expansion of the Sisters programme. Our model adjusted for increased testing frequency and age showed evidence of decreasing seroconversion rates over time by accounting for potential confounding caused by increased testing and for bias introduced by early testing among individuals with recent infections.[30] We restricted follow-up to 2 years in a sensitivity analysis to reduce potential bias introduced by the disproportionate contribution of HIV-negative follow-up from a small group of long-term engaged participants. The results of this analysis suggest that there are potential biases in our approach, and that our results are sensitive to analytical choices for estimation of seroconversion rates over shorter periods. Restriction of follow-up to 2 years increased seroconversion rates in later periods. Our overall interpretation of falling seroconversion rates over time remained, although this sensitivity analysis shows that inclusion of all possible follow-up time could underestimate seroconversion rates in later periods.

Our study suggests that, although seroconversion rates remain consistently high among female sex workers

accessing services, seroconversion risk has decreased overall. Through peer outreach, Sisters has worked to reach women and girls at high risk of acquiring HIV over time; the proportion of younger women accessing Sisters services has increased, as have engagement with services and HIV testing frequency. Although our study supports previous evidence that younger women are at increased risk of HIV infection, we also found that women are twice as likely to seroconvert within 6 months of first testing compared with those whose first test was more than 18 months ago. This finding suggests that women at higher risk for HIV, potentially new to sex work, are being reached, but need to be engaged in prevention interventions earlier—ie, before or as they transition into sex work—to maximise the effect of interventions on new infections.

Our findings have implications for the delivery of HIV testing for female sex workers. Increasing the recommended testing frequency to every 3 months for the first year of programme engagement could be an important intervention during this period of increased seroconversion risk. For women who remain HIV negative after a year, testing frequency could be reduced in line with published guidelines. Future analysis should include data for initiation of sex work to account for the period of transition into sex work and early sex work. WHO has advocated for better use of routinely collected data to inform programming,[31] and risk factors identified in this study could be used to provide more intensive and targeted support to specific groups of female sex workers, as is done with risk-differentiated microplanning.[32]

New HIV infections remain challenging to measure, although longitudinal analysis of routine HIV testing data with linkage of individuals over time can provide valuable insights into seroconversion rates and associated risk factors. Our findings highlight the potential to draw biased conclusions when estimating HIV incidence from routine data as a result of testing patterns, and thus there is a need to strengthen HIV surveillance approaches among female sex workers and other key populations. Our findings also show the continued need to intensify HIV prevention among female sex workers in Zimbabwe, given the high rates of seroconversion identified. Both measurement approaches and programming need to be strengthened to reduce new HIV infections and achieve sustainable epidemic control.

Contributors

HSJ planned and did the analysis, with input from JRH, BH, FMC, BR, and LP. JRH conceived the original HIV seroconversion analysis in the Sisters cohort. SM, AT, and STC had full access to the programme data and supported data management and interpretation. AT and SM accessed and verified all study data. PM is the Key Populations programme director and leads implementation of the Sisters with a Voice programme. PM and LC provided support with understanding programme HIV testing and data collection and interpretation. HSJ wrote the Article, with input from JRH, BH, FMC, LP, and BR. All authors reviewed the Article, had access to the anonymised subset of programme data included in this analysis, and accept responsibility for the decision to submit for publication.

Declaration of interests

We declare no competing interests.

Data sharing

A de-identified dataset with variables included in this analysis can be made available on request to the Centre for Sexual Health & HIV/AIDS Research Zimbabwe, subject to ethical approval of a proposal.

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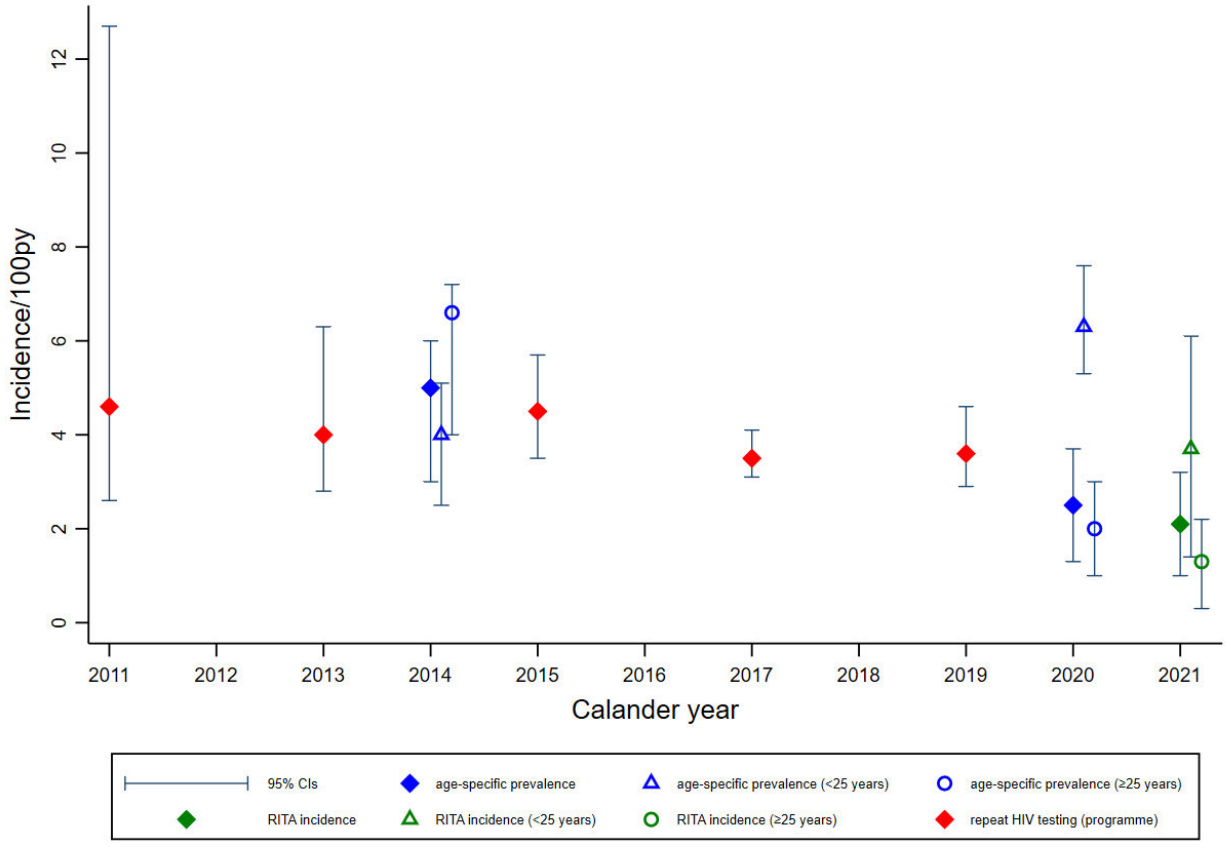
6.1. HIV incidence in Zimbabwe

In my manuscript on HIV seroconversion I describe my findings in the context of other HIV incidence estimates in Zimbabwe.[227] Here these estimates are shown together over time in a graph presented at the MeSH 2023 Scientific Symposium III. The additional estimates are from an analysis of pooled data from cross-sectional RDS surveys conducted between 2011 and 2017, which used changes in age-specific HIV prevalence to calculate HIV incidence,[227] and from a 2021 RDS survey where incidence was estimated from recent HIV infection testing.[225]

Figure 6.3 HIV incidence estimates for FSW in Zimbabwe (2009-2022): Data from RDS surveys (n=14,350) and KP Programme data (n=6665, 11,657py)



7. RESULTS: RECENT HIV INFECTION TESTING

Recent infection testing to inform HIV prevention responses and surveillance in a programme context: Lessons from implementation within a nationally scaled female sex worker programme in Zimbabwe

Harriet S Jones, Fortunate Machingura, Leah Gaihai, Memory Makamba, Thomas Chanyowedza, Panganai Masvikeni, Edward Matsikire, Primrose Matambanadzo, Sithembile Musemburi, Phillip N Chida, Jeffery Dirawo, Owen Mugurungi, Sarah Bourdin, Bernadette Hense[4], Lucy Plat[1], Gary Murphy, James R Hargreaves, Frances M Cowan, Brian Rice

Journal of the International AIDS Society (under review 2024)

In my last results chapter I cover objective five, to explore the proportion of recent HIV infections among women testing HIV-positive in CeSHHAR's KP Programme in Zimbabwe and estimate HIV incidence. This last study uses data from the programme between 2021 and 2023 and specifically data from the implementation of a study looking at recent HIV infection testing using a RITA. The overall aim of the study was to explore the utility of assessing recency of HIV infection among FSW accessing services in the KP Programme over 86 sites to guide their individual management and to target HIV prevention more effectively. I use recent infection testing data from this study and combine it with routinely collected programme data to build on my previous analyses around the identification of HIV infections in the programme, but look more specifically at the identification of recent HIV infections.

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Student ID Number	378549	**Title**	Ms
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Surname/Family Name	Jones		
Thesis Title	Measuring trends in HIV testing and new HIV infections among female sex workers in Zimbabwe		
Primary Supervisor	Professor James Hargreaves		

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	Platt, Gary Murphy, James R Hargreaves, Frances M Cowan, Brian Rice
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	My role in the research included in this paper was in compiling the different datasets and formulating and conducting the analyis. I wrote the manuscript. I had no role in implementing the study. FMC, BR, and FM conceived and planned the RITA study. HSJ conducted the analysis and wrote the manuscript with input from BR, FMC, GM, FM, PM, and JRH. FM is the Key Populations research director at CeSHHAR and, with LG, MM, PM, EM, implemented the study. FMC and BR provided technical guidance on implementation. GM provided technical guidance on laboratory procedures. PM is the Key Populations programme director at CeSHHAR, overseeing implementation of the Key Populations programme. JD, SM, PNC, and TC oversaw and managed the programme and study data. Co-authors reviewed the manuscript and provided input on analysis, interpretation of results and writing. All authors have approved the final manuscript.

SECTION E

Student Signature	[redacted]
Date	28/02/2024

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Recent infection testing to inform HIV prevention responses and surveillance in a programme context: Lessons from implementation within a nationally scaled female sex worker programme in Zimbabwe

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7.1. Abstract

In the context of key population HIV testing programmes, identifying new HIV acquisitions, tracking incidence, and responding with prevention and treatment interventions will be critical for achieving HIV epidemic control. Laboratory tests for recently acquired HIV used as part of a “recent infection testing algorithm” (RITA), offer a potential tool to support this work. We implemented a RITA for female sex workers (FSW) in Zimbabwe to explore opportunities and programmatic benefits.

Between October 2021 and January 2023, recency testing was offered to FSW attending the Centre for Sexual Health and HIV/AIDS Research (CeSHHAR) Zimbabwe’s key populations programme. Dried blood spot (DBS) samples were taken at 86 clinic sites across 10 provinces and Laboratory LAg Avidity and viral load (VL) testing conducted. RITA results were analysed and linked to programme data to explore geographical differences and calculate HIV incidence. We describe concurrent efforts in HIV testing for social (SNT) and sexual (ICT) contacts of those testing HIV-positive.

Among 24,976 FSW tested at programme sites, 9.5% (2,363/24,976) were confirmed HIV-positive. We enrolled 55.5% (1311/2363) of eligible HIV-positive FSW to our study. 11.7% (153/1311) were identified as having recently acquired HIV. It took a median of 37 days (IQR 20-67) for samples to be processed. Enrolment rates varied between provinces but the proportion of recently acquired HIV was similar (range: 18.4% to 4.0%). Overall HIV incidence was 3.4 (95% CI 2.7-4.0) per 100py. Where results could be linked to routinely collected data we found higher test-positivity from ICT among FSW with recently acquired HIV (22.7% (5/22) vs 13.8% (4/29)) and among FSW with long-term HIV from SNT (24.1% (13/54) vs 10.2% (12/118)).

Implementation of a RITA was possible within a nationally scaled sex worker programme, and while challenging to implement, can provide an understanding of transmission dynamics and HIV incidence in this context. Sub-optimal recruitment and data linkage limited the interpretation of our findings and opportunities for strategic gains though focusing HIV prevention efforts.

7.2. Introduction

Data on HIV transmission dynamics will better inform HIV prevention and treatment programmes and enable tracking of newly acquired HIV over time to assess the impact of HIV control measures. Female sex workers (FSW) are at high risk of HIV aquisition[4,6]. Understanding transmission is critical to improve service delivery and achieve and sustain epidemic control[228]. One method for improving our understanding is recent HIV infection surveillance.

HIV-1 Limiting Antigen Avidity Enzyme Immunoassay (LAg-Avidity-EIA) can distinguish recently acquired from long-standing HIV, when combined in a Recent Infection Testing Algorithm (RITA) to reduce the number of false positive results. When conducted as part of a RITA, recency testing can identify those that are likely to have been recently infected and help define where current transmission is occurring[70–72]. More research is needed on recency assays within HIV testing services, to better understand interpretation in these settings[73]. The 2022 UNAIDS/WHO guidelines on recency assays highlight the potential bias in interpreting recency results in a non-randomly selected population accessing HIV testing services[69].

The Centre for Sexual Health and HIV/AIDS Research (CeSHHAR) Key Populations (KP) Programme in Zimbabwe provides free sexual and reproductive health services to women who sell sex. Since its initiation in 2009, programme coverage has increased and those attending services are likely to be representative of FSW in Zimbabwe[195]. We implemented a RITA across the programme between October 2021 and January 2023. Here we present the findings of RITA implementation, estimate HIV incidence, and explore the opportunities and strategic benefits of identifying recently acquired HIV in the context of a national FSW programme.

7.3. Methods

7.3.1. Study Setting

CeSHHAR's KP Programme delivers free sexual and reproductive health services across Zimbabwe. The programme predominantly serves cisgender women and girls aged at least 16 years old who sell sex, operating in 86 sites across all 10 provinces in Zimbabwe during the study period. Sites are based in urban, rural and highway locations and are a range of static clinics delivering services five days a week and drop-in centres and mobile clinics delivering services at least one day a week. Community outreach services are delivered at each site by FSW peer educators known as microplanners[215 6]. HIV testing is offered at a first clinic visit to women who are HIV negative or unaware of their HIV status and to HIV-negative women revisiting a clinic who have not tested in the previous 6 months. In line with Zimbabwe's national HIV testing algorithm initial screening is performed with Determine HIV-1/2 (Abbott Diagnostics, Tokyo, Japan) antibody

testing or OraQuick self-test kits. Confirmatory antibody testing is performed with SD Bioline HIV-1/2 (Abbott Diagnostics, Tokyo, Japan). Pre-exposure prophylaxis (PrEP) is offered to FSW testing HIV-negative. All women testing positive and not on ART are either initiated on, or referred for, antiretroviral treatment as part of Zimbabwe's national HIV treatment programme. Index case testing (ICT) and social network testing (SNT) are conducted for all consenting FSW testing HIV-positive[62,229]. Through tailored discussions clinic staff record contact details for recent sexual partners (clients and regular/permanent) for ICT and for friends and acquaintances engaged in sex work for SNT. Where consent is obtained, clinic staff identify and offer voluntary HIV testing to individual contacts, or conduct wider community testing where direct contact is not considered safe.

7.3.2. Study enrolment

On 5th October 2021 a RITA was introduced as part of our study across the programme. All FSW testing newly HIV-positive were eligible for enrolment if they were 18 years and older and received a confirmatory HIV-positive result. Those with an indeterminate HIV test result, a history of testing HIV-positive >1 year ago, or on ART were excluded. Informed consent was sought from all eligible women. Sample size was calculated based on an estimated annual HIV incidence of 6%-10% and 25,000 FSW undergoing HIV testing in the programme, with 10% test-positivity, of which 10% would test RITA positive.

A Dried Blood Spot (DBS) sample was collected for each consenting woman. Samples were stored at clinic sites at room temperature in gas impermeable plastic bags with desiccant sachets to keep them dry and collected from sites every 14 days by a designated study driver and delivered to the Flow Cytometry Laboratory in Harare. Clinic staff informed the study coordinator when a new participant was enrolled so sample delivery to the laboratory could be arranged and tracked. In line with UNAIDS/WHO guidance, laboratory results were not returned to study participants.[69]

7.3.3. Laboratory procedures

DBS samples were tested using the Maxim HIV-1 Limiting Antigen Avidity (LAg Avidity) Enzyme Immunoassay (EIA) in accordance with the product insert (DBS KIT CAT NO. 92003).[230] After initial testing samples with a normalized optical density (ODn) less than 0.4 underwent serology confirmation with an HIV-1 ELISA test to confirm an HIV-positive result. Samples with an ODn >2.0 were immediately classified as long-term HIV. Those with an ODn ≤2.0 underwent retesting in triplicate from a fresh dilution of the specimen to confirm the results. Final determination of recently acquired or long standing HIV for samples with a screening ODn of ≤2.0 was based on the median ODn value of the three retests. A final interpretation of recently acquired HIV required an ODn of ≤1.5, and an ODn of >1.5 for long standing HIV. A laboratory specialist examined the relationship

between the screening and confirmatory results to determine a final classification, undertaking further testing if necessary.

Viral load testing was performed with a NucliSens assay on samples with an ODn ≤1.5. Samples with an ODn ≤1.5 and a viral load <1000 copies/ml denoted long-term HIV, and those with an ODn ≤1.5 and a viral load ≥1000 copies/ml were classified as recently acquired HIV. Based on resources and the number of samples expected over the period of study implementation testing of DBS samples was conducted when 85 samples reached the laboratory. Laboratory staff were trained in specimen handling and testing prior to implementation. For quality control measures, we engaged in external proficiency testing and validated results via the Maxim spreadsheet and sought external technical support for each run.

7.3.4. Data collection

All women accessing CeSHHAR's KP services are assigned a unique identification number on first contact with the programme. Programme data are routinely collected on demographic and clinic visit characteristics and centrally held in an anonymised DHIS2 database. Study participants were assigned an additional unique identification code and data were collected on study enrolment site and sample collection date. A centrally held database was kept with anonymised enrolment details and updated with RITA results when they were returned from the laboratory. For every woman testing newly HIV-positive in the programme, data are also routinely collected on the number of ICT and SNT contacts for that individual, the number of contacts reached and tested and the number of those tests that are HIV-positive. These data are held in Ministry of Health and Childcare (MoHCC) registers and were anonymised and electronically captured for the period of study implementation. Study and programme data were linked using a separate register holding individual study identification codes and unique programme identification numbers for each study participant. RITA study data were incorporated with other programmatic data, and an anonymised data set generated for analysis.

7.3.5. Data analysis

We firstly present results of the RITA, showing the classification of samples. We present these overall and at provincial level. Using the number of women tested by the programme during study implementation we estimated HIV incidence among programme attenders[223]. The calculation takes into consideration all those at risk of recently acquired HIV, using the number of women testing HIV-negative and the number recently acquiring HIV; as well as the proportion of FSW testing HIV-positive and enrolled in the study and recency testing. For our main analysis we used a mean duration of recently acquired HIV (MDRI) of 130 days. We applied a false recency rate (FRR) of 0.2%. We also calculated incidence using an MDRI of 161 days and an FRR of 0.2% in line with

the updated test product insert[230]. For provinces enrolling ≥70% of HIV-positive FSW in the study we calculated province specific incidence. Lastly, we describe the results of concurrent efforts to offer HIV testing to sexual and social contacts of FSW testing positive. We were able to obtain unique identification data to retrospectively link 250 individual FSW enrolled in the RITA study to their programmatic ICT and SNT data to explore the number of HIV-positive contacts identified from FSW with recently acquired and long-term HIV.

7.3.6. Ethics

Ethical approval was granted by the Medical Research Council of Zimbabwe (MRCZ/A/2244) and the London School of Hygiene & Tropical Medicine (14542 - 1).

7.4. Results

Between 5th October 2021 and 10th January 2023, 24,976 uniquely identified individual FSW HIV tested at CeSHHAR programme clinics. Overall, 9.5% (2,363/24,976) newly tested HIV-positive. Among women testing HIV-positive during this period, 55.5% (1311/2,363) gave consent for a DBS sample to be taken and were enrolled in the study. Study enrolment varied nationally, from 92.2% (188/204) in Bulawayo to 29.4% (25/85) in Matabeleland North (Table 1). The median age of 28 years (IQR 23-35) (data from 11,910 FSW) among FSW testing during this period was slightly lower than that of women testing positive (data for 1,374/2,366) at 30 years (IQR24-36), and higher than that of HIV-positive women enrolled in the study at 27 years (IQR23-24).

It took a median of 37 days (IQR 20-67) for DBS samples to reach the laboratory in Harare and be processed (data from 1,186 samples). No samples were rejected due to quality issues. LAg Avidity test results were obtained for 1311 confirmed HIV-positive women of which 89 had an ODn threshold <0.4 and underwent serology testing. 1028/1311 samples had a final ODn of >1.5 and were classified as long-term HIV. The remaining 283/1311 samples had a final ODn ≤1.5 and underwent VL testing, of which 130 had a VL <1000 copies/ML and were also classified as long-term HIV, with the likelihood of being a woman on ART. The remaining 153/1311 (11.7%, 95% CI 10.0-13.5) samples had a VL ≥1000 copies/ML and were classified as recently acquired HIV (Figure 1). The proportion of recently acquired HIV varied between provinces, ranging from 18.4% (9/49; 95% CI 8.8-32.0) in Midlands to 4.0% (1/25; 95% CI 0.1-20.4) in Matabeleland North, with overlapping 95% CIs (Table 1).

Table 7.1 HIV testing, RITA study enrolment and results by province in Zimbabwe

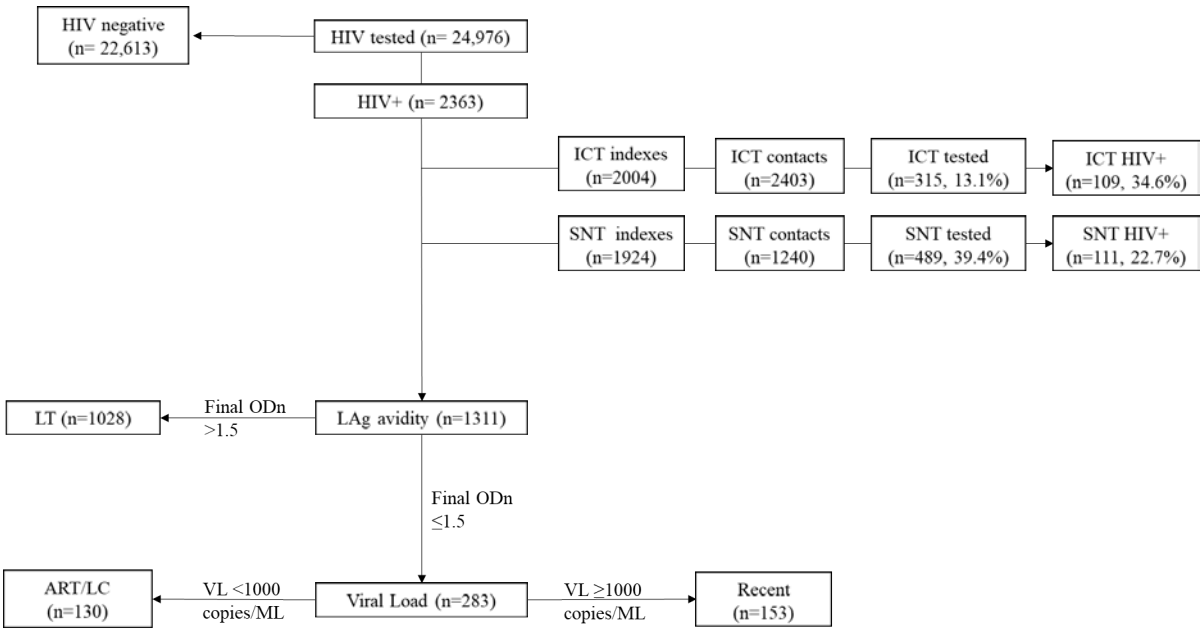
Province	FSW[a] tested	HIV+	%	RITA[b] enrolled	%	Recent HIV	%	95% CI
Bulawayo	2,357	204	9%	188	92%	17	9.0%	(5.4% - 14.1%)
Harare	3,313	378	11%	310	82%	33	10.6%	(7.4% - 14.6%)
Manicaland	7,124	482	7%	194	40%	18	9.3%	(5.6% - 14.3%)
Mashonaland Central	1,358	61	4%	34	56%	3	8.8%	(1.9% - 23.7%)
Mashonaland East	446	107	24%	47	44%	5	10.6%	(3.5% - 23.1%)
Mashonaland West	3,222	480	15%	183	38%	32	17.5%	(12.3% - 23.8%)
Masvingo	2,214	197	9%	108	55%	14	13.0%	(7.3% - 20.8%)
Matabeleland North	1,025	85	8%	25	29%	1	4.0%	(0.1% - 20.4%)
Matabeleland South	2,216	246	11%	172	70%	21	12.2%	(7.7% - 18.1%)
Midlands	1,695	119	7%	49	41%	9	18.4%	(8.8% - 32.0%)
Missing	9	4	-	1	-	0		-
Total	24,979	2,363	9%	1,311	55%	153	11.7%	(10.0% - 13.5%)

a. FSW= female sex workers
b. RITA=recent HIV infection testing algorithm

7.4.1. HIV incidence

During the period of study implementation 22,610 individual women tested HIV-negative in the programme. Using an MDRI of 130 days and a FRR of 0.2% we calculated an incidence of 3.4 (95% CI 2.7-4.0) per 100py. We applied the same method using an MDRI of 161 days[230], which gave an incidence of 2.7 (95% CI 2.2-3.2) per 100py. For Harare we calculated an incidence of 3.8 (95% CI 2.4-5.1) per 100py and for Bulawayo 2.4 (95% CI 1.2-3.5) per 100py (Table 2).

Figure 7.1 Recent infection testing algorithm flow diagram



ICT=Index Case Testing; SNT=Social Network Testing; LT=Long term HIV; ART/LC=Long term HIV with likely ART, VL=Viral load

Table 7.2 HIV incidence calculations

Incidence calculation	Incidence/100py (95% CI)	Details
All data MDRI 130[a] days, FRR[b] 0.2%	3.35 (2.73-3.96)	2020 ZIMPHIA, Zimbabwe RDS
All data MDRI[a] 161 days, FRR[b] 0.2%	2.70 (2.21-3.20)	In line with updated test insert (DBS KIT CAT NO. 92003)
Matabeleland South[c]	4.17 (2.36-5.95)	12.2% recent HIV
Bulawayo[c]	2.35 (1.19-3.50)	9% recent HIV
Harare[c]	3.75 (2.42-5.06)	10.6% recent HIV

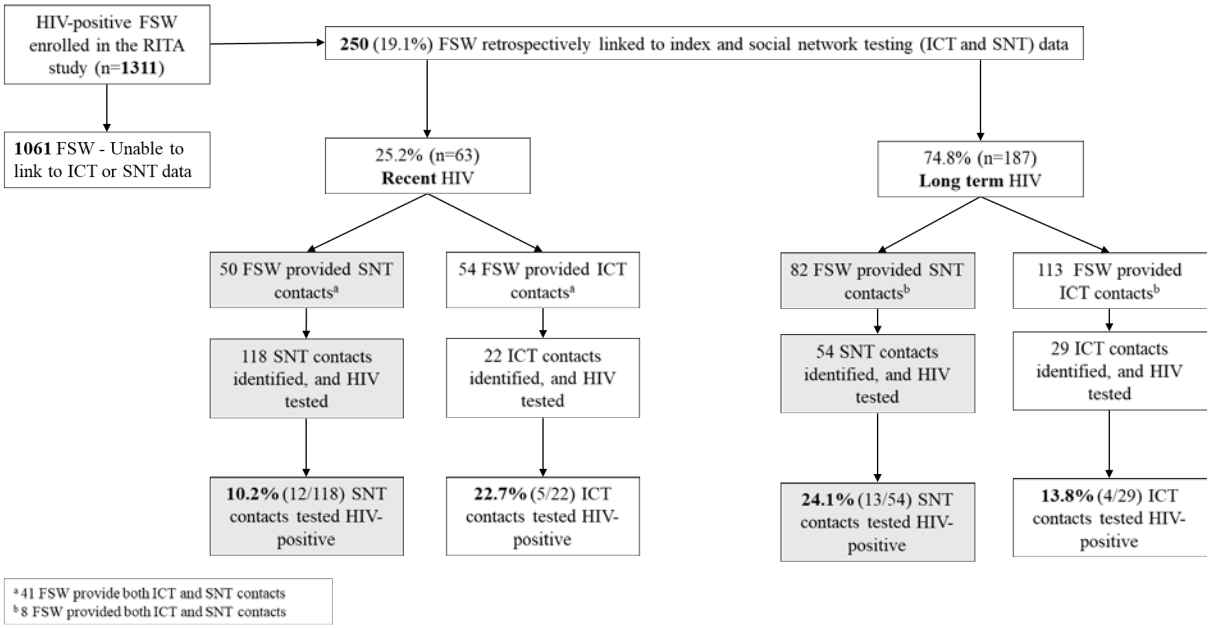
a. mean duration of recent infection (MDRI)
b. False recency rate (FRR)
c. Province incidence calculations - MDRI of 130 days and FRR of 0.2%

7.4.2. Sexual and social network testing

Between October 2021 and January 2023 ICT and SNT were conducted as part of routine programme implementation. Data were collected from March 2022 in static sites, with mobile sites starting data collection later in 2022. Highway sites did not collect these data. During this period, 2004 FSW (84.8%; 2004/2363) gave details of 2403 sexual contacts (1.2 contacts per FSW), of whom 315 (13.1%) were identified and tested with 109 (34.6%) testing HIV-positive. 1924 FSW (81.4%; 1924/2363) gave details for 1240 social network contacts (0.64 contacts per FSW), of whom 489 (39.4%) were identified and agreed to an HIV test and 111 (22.7%) subsequently tested HIV-positive (Figure 1).

We were only able to link a sub-set of 250 FSW enrolled in the RITA study to their routinely collected ICT and SNT data (Figure 2). 167 FSW had provided ICT contacts of whom 51 were identified and tested, with 9 (17.6%) testing HIV-positive. 132 provided SNT contacts of whom 172 were identified and tested and 25 (14.5%) tested HIV-positive. 25.2% (63/250) of the women linked to their ICT and SNT data had recently acquired HIV. Test-positivity for SNT contacts among FSW with recently acquired HIV was 10.2% (12/118) compared to 24.1% (13/54) among those with long-term HIV. For ICT contacts identified and tested for FSW with recently acquired HIV, 22.7% (5/22) were HIV-positive compared to 13.8% (4/29) among those with long-term HIV.

Figure 7.2 Index and social network testing by recent HIV infection test results



7.5. Discussion

Our study provides insights into the novel application of laboratory recent infection testing in a national sex worker programme in Zimbabwe. We recruited 55.5% of all newly HIV-positive women accessing HIV testing services over 14 months, with higher recruitment in urban sites delivering services five days a week. We found 11.7% had recently acquired HIV, with recency at province level ranging from 18.4% to 4.0%. National differences in study recruitment made it challenging to determine the extent to which province level recency was due to implementation differences or real differences in recently acquired HIV. We used individual programme testing data to calculate an HIV incidence of 3.4 per 100py. For a sub-set of FSW we were able to link programmatic ICT and SNT data, finding higher test-positivity among ICT contacts for FSW with recently acquired HIV and higher test-positivity among SNT contacts of FSW with long-term HIV.

Our study had several strengths. We present approaches to the implementation and analyses of recency testing data that speak to current gaps in knowledge on the use of recency assays in routine HIV testing services[73] and previously identified limitations and challenges with recency testing in a programmatic context.[72] Our study contributes to the limited understanding of how to interpret findings from recency testing in routine HIV testing services[73] and to a growing body of knowledge on HIV incidence among FSW in Southern Africa.[231] We implemented our study in a high testing frequency setting with good programme coverage, speaking to recommendations that it is only in high coverage settings where inferences can be made.[69] In 2017, CeSHHAR's KP programme reached 57% of the estimated 40,000 FSW in Zimbabwe,[6] and with expansion since, will be reaching many more. An earlier analysis of programme testing data showed increased testing frequency among FSW over time, with 56.7% of tests among women reporting they had tested in the preceding 6 months by 2018-2019,[232] in line with WHO recommendations for testing every 3-6 months for key populations.[62]

Our study also had limitations. The national reach of CeSHHAR's KP programme presented challenges for implementation. Training clinic staff across 10 provinces and 86 sites on recruitment, sample storage and data collection required substantial coordination and oversight. Variations in recruitment between sites may have been due to challenges in training roll-out across a wide geographical area and study initiation during the Covid-19 pandemic. As part of a national MoHCC initiative there was concurrent implementation of point of care testing with Asanté HIV-1 rapid recency assay as a surveillance tool in programme sites. Asanté implementation and messaging varied between provinces, potentially leading to conflicting information, test refusal and the additional burden of conducting two recency tests on the same individuals. Sub-optimal recruitment is likely to have introduced bias in our findings, however without data on whether non-enrolment was due to delayed implementation, tests not being offered, or test refusal it is difficult to assess the direction of any bias. It is likely that within clinic sites non-enrolled FSW did not systematically

differ from those enrolled, but differences in enrolment between clinics may have led to bias if recruitment varied between areas with higher or lower HIV transmission. Limitations in data linkage meant we were unable to fully characterise the women recruited to our study and make comparisons with those not recruited to further explore potential bias.

Turnaround of samples took over a month. Regular sample collection from programme sites was reliant on clinic staff informing the study coordinator on the day the sample was taken. Delays were possible at sites with service delivery only one day a week or with high client to staff ratios. At the laboratory, samples were stored until the minimum number for batch testing was reached so they were not all tested on arrival. Dual data collection systems with different individual identification numbers meant integration of study data into routine systems was not always possible and full datasets not always available. ICT and SNT data were electronically captured from paper registers for this study; however, data were not collected for the entire period of implementation or at highway sites, and so linkage was not always possible. Routinely, only aggregate, and not individual level, ICT and SNT data are captured electronically. The small proportion of data we were able to link limits the extent to which we can draw conclusions from our findings.

We identified a similar proportion of recently acquired HIV to the 10.5% (33/313) found in an earlier pilot in CeSHHAR Zimbabwe's large static programme sites.[70–72] We identified higher recency than the 6% (18/306) found in a 2021 RDS among FSW in Zimbabwe,[225] and the 1.6% (95% CI 0.9–2.4) among FSW surveyed in South Africa in 2019.[233] While our findings show that we are identifying >80% FSW with long-term HIV, an MDRI of 130 days is only a small window for identifying recently acquired HIV and may be shorter than the testing frequency of many FSW. Testing practices will influence the identification of recent HIV during routine service delivery. FSW testing may not be driven by as specific risk exposure if risk is considered constant. Testing for PrEP may increase testing frequency, but periods of disengagement from sex work may be mirrored by disengagement from HIV testing services. An earlier analysis of CeSHHAR's KP programme data showed higher HIV test-positivity among first time testers (13.1% compared to 2.9% among repeat testers) where testing history is less certain and there is a higher potential of a previous diagnosis.[232] An analysis of health records in South Africa between 2017 and 2018 identified 51.3% of HIV-positive tests were among individuals retesting.[234]

Any national variation in recency was hard to determine and may in part reflect differences in study implementation between sites. Although overall enrolment was lower than the 72% reported in the earlier Zimbabwe pilot,[70] enrolment at static sites was higher. Provinces such as Mashonaland East, with large urban sites delivering services five days a week and regular mobile outreach achieved higher recruitment than provinces with smaller sites, often with lower staffing ratios, delivering services only once a week and no static site presence. Despite the wide reach of

CeSHHAR's KP programme, sub-optimal recruitment in many study sites limits the inferences that can be made nationally about recently acquired HIV among FSW in Zimbabwe. Findings from sites with high numbers of FSW and levels of recruitment, such as Harare and Bulawayo, are likely to have been more representative of the wider FSW population.

We estimated higher HIV incidence than the 2.1 per 100py, calculated from a RITA in a 2021 RDS survey conducted among FSW in Zimbabwe,[225] but similar to 3.6 (95% CI 2.9–4.6) per 100py from repeat test data in the Sisters programme between 2018-2019.[235] Estimating seroconversion rates from repeat tests requires subsequent testing with reduced certainty around estimates where there is limited time for individuals to return.[235] We linked programme testing records to obtain individual level test data and calculated incidence using the proportion of recent HIV among those at risk of HIV acquisition, likely to be more indicative of HIV incidence than using only HIV-positive tests.[236] While we used data from all sites for the period of study implementation, the accuracy of our estimates may have improved by specifying geographical variation in study implementation, applying site specific implementation periods and varying study enrolment. We used an MDRI of 130 days for our main incidence calculation in line with the Zimbabwe 2020 PHIA survey[137] and previous estimates from cross-sectional FSW RDS surveys.[225] Following expert consultation, we applied an FRR of 0.2% in contrast to 0 which suggests no false recent results and is unlikely, even with a RITA .[237]

Through retrospective linkage of programme ICT and SNT data, we identified a greater proportion of HIV-positive ICT contacts among FSW with recent HIV, although with a minimal difference in total numbers. The opposite was true in SNT where we identified a greater proportion of HIV-positive contacts among contacts reached and tested for FSW with long term HIV. Recently acquired HIV infections could indicate geographic areas or sexual networks with active HIV transmission. Identifying and testing the sexual contacts of women with recently acquired HIV could optimise HIV testing strategies and improve HIV case finding, potentially of other recent HIV infections. Testing other FSW within the social networks of those with recently acquired HIV could support case finding among women at higher risk, where they may have the same sexual partners or clients within a geographic location or network. A 2021 study in Nigeria identified additional HIV-positive cases through ICT among recent positives, although did not make comparisons between participants with recently acquired or long-term HIV.[238] A 2018 study of recency testing in routine services in Kenya found a greater proportion of HIV-positive ICT contacts previously unaware of their HIV status among participants with recently acquired HIV, although overall similar numbers of HIV-positive contacts for those with recent and long term HIV.[72,239] As with our study, neither the Nigeria or Kenya studies provide conclusive evidence of strategic gains from focusing resources on ICT among those with recently acquired HIV.

With documented challenges in the implementation and interpretation of rapid recency assays in field settings,[70,240] our study explored whether laboratory based recency testing could provide an alternative. Whilst we demonstrate that DBS sample collection, storage, transport, and laboratory analysis were feasible, implementing a RITA across a nationally scaled programme requires substantial resources. The turnaround time from sample collection to laboratory processing and linkage of results has implications for informing a programmatic response. Operationalising recency testing requires data systems that can link HIV test and recency results back to clinics, whilst ensuring confidentiality. While UNAIDS/WHO do not recommend the use of recency assays for clinical management,[69] we hypothesised that recency assays could be useful for the identification of geographic clusters of recent HIV, and inform more targeted approaches to ICT and SNT, which when unguided takes substantial resources to identify a relatively small number of new HIV acquisitions. Our findings were unable to support this, with little variation in recent HIV between provinces or evidence of higher test-positivity for SNT or ICT among FSW with recently acquired HIV. Further exploration of recency testing to guide ICT and SNT would be needed to draw any robust conclusions. We were however able to estimate HIV incidence which could have advantages over estimation of seroconversion rates through individual test linkage for repeat testers, providing more up to date information.

RITAs are challenging to implement in a programmatic context and integrate within existing data systems, limiting the interpretation of findings and opportunities for a programmatic response. Our study demonstrates that implementation within a nationally scaled sex worker programme is possible and while substantial programme capacity is required, understanding transmission dynamics through a RITA could support efforts to estimate HIV incidence.

Declarations

Data availability statement

A de-identified dataset with variables included in this analysis can be made available on request to the Centre for Sexual Health & HIV/AIDS Research Zimbabwe, subject to ethical approval of a proposal.

Conflicts of interest

The authors declare no conflicts of interest.

Authors' contributions

FMC, BR, and FM conceived and planned the RITA study. HSJ conducted the analysis and wrote the manuscript with input from BR, FMC, GM, FM, PM, and JRH. FM is the Key Populations research director at CeSHHAR and, with LG, MM, PM, EM, implemented the study. FMC and BR

provided technical guidance on implementation. GM provided technical guidance on laboratory procedures. PM is the Key Populations programme director at CeSHHAR, overseeing implementation of the Key Populations programme. JD, SM, PNC, and TC oversaw and managed the programme and study data. Co-authors reviewed the manuscript and provided input on analysis, interpretation of results and writing. All authors have approved the final manuscript.

Acknowledgments

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8. DISCUSSION

Female sex workers in sub-Saharan Africa have long been recognised to be at increased risk of HIV acquisition and have a higher burden of HIV than women in the wider population. However, data to track trends and quantify the size and determinants of this risk have largely been absent, poorly characterised and at risk of bias. Targeted programmes for FSW need to be data informed, have wide coverage and strategically deliver HIV testing if we are to achieve equitable service provision and reach and sustain a downward trend in new HIV infections. The aim of my PhD is to investigate HIV testing patterns and the identification of new and recent HIV infections among FSW accessing clinical services in Zimbabwe, to contribute to understanding epidemiological trends and inform discussions on the use and interpretation of routinely collected data for epidemic surveillance and for operationalising these data to inform programme implementation.

Through systematic reviews of the literature, I have identified that we are still a long way from reaching the UNAIDS first target of 95%, with continuing gaps in data on knowledge of HIV status for FSW in sub-Saharan Africa and significant heterogeneity in study findings making trends over time difficult to establish (objective 1). I have jointly contributed to new evidence that HIV incidence among FSW in sub-Saharan Africa is declining in real terms and at a similar trajectory to women in the wider population (objective 2). My PhD demonstrates the feasibility of using routinely collected programme data to address important epidemiological questions. I have shown that test-positivity, a commonly used metric to monitor programme success, is declining in the context of a national key population programme in Zimbabwe, in part due to increased testing frequency, and likely to be indicating that we are seeing fewer undiagnosed HIV infections over time (objective 3). I have generated new evidence on HIV incidence among FSW accessing services in Zimbabwe, demonstrating declines since the KP Programme's inception in 2009 and that incidence remains high among younger FSW, particularly when women first access services (objective 4). Lastly, I identify the proportion of recent HIV infections among FSW accessing key population programme services and demonstrate the potential for recent HIV infection testing to inform programme responses and estimate HIV incidence in a programme context. However, I caution that any gains using recent HIV infection testing need to be balanced against the additional programmatic inputs and resources required for implementation (objective 5).

8.1. Key findings

8.1.1. Objectives 1 and 2: Literature reviews

Through two literature reviews I contributed to a growing body of work to collate data on HIV among key populations. My focus was on the synthesis of existing data to understand regional trends in sub-Saharan Africa, appraise data sources and identify gaps in existing knowledge. I conducted the first review on trends in knowledge of HIV status and how this has changed over time among FSW in sub-Saharan Africa. I contributed to a second review on levels and trends in HIV incidence among women who engage in sex work in sub-Saharan Africa compared to women in the wider female population. Empirical data on the percentage of HIV-positive FSW who are aware of their HIV-status in sub-Saharan Africa were available from 43 independent study populations between 2002 and 2020. Estimates ranged from 4% to 95.2%, with evidence of heterogeneity and gaps in data making it difficult to identify any trends over time. Differences between regions were more apparent, with higher estimates of knowledge of HIV status reported in East and Southern Africa. In a collaborative review on HIV incidence among women who engage in sex work in sub-Saharan Africa, we identified 83 empirical estimates of HIV incidence from 32 studies conducted between 1985 to 2020. The median incidence for FSW was 4.3 new infections per 100py (IQR 2·8-7·0). Our review found evidence of parallel declines in incidence between women who engage in sex work and age-district-year matched women in the wider population over time. Both reviews identified national gaps in studies reporting on these indicators for FSW and very few studies with repeat measures in the same populations. They also highlighted the variation in inclusion criteria used to enrol women in studies and how these differences makes comparisons challenging.

8.1.2. Objective 3: HIV test-positivity

For the remaining objectives of my PhD I focused on Zimbabwe, through the analysis of data from Zimbabwe's national sex worker programme. My first objective was to understand how trends in HIV test-positivity have changed over time among FSW accessing HIV testing services and to identify any individual and service delivery factors influencing these. HIV testing coverage and individual testing patterns have changed over time among FSW in Zimbabwe. Among the 54,000 women testing between 2009 and 2019, fewer women were first time testers in the latter part of the study period, with only 11.3% having never tested in 2018-2019 compared to 38.7% in 2009-2013. More women reported having tested or had an HIV test recorded at a key population clinic in the preceding 6 months, with 57% of women testing within 6 months of a previous test in 2018-2019 compared to 17% in 2009-2013. Test-positivity was lower among women who had tested in the past 6 months compared to those who had never tested (OR 0.17 95% CI 0.160.18), falling over time with the lowest test-positivity among women testing less than 6 months previously in 2018-2019. Overall, HIV test-positivity fell from 47.9% in 2009–2013 to 9.6% in 2018-2019 (aOR

6.08 95% CI 5.52–6.70) in 2009–2013 when compared to 2018-2019. Differences over time were partly, but not wholly, explained by increases in recent testing.

8.1.3. Objective 4: HIV seroconversion rates

My third objective was to measure and understand trends and risk factors for HIV seroconversion among women who underwent repeat testing within the KP Programme between 2009 and 2019. I first explored seroconversion rates in paper 1, doing an initial assessment to identify how trends in seroconversion among repeat testers could build on our interpretation of test-positivity as an indicator of programme performance. I conducted a comparative analysis with previous work on seroconversion rates in the KP programme data. I calculated a seroconversion rate of 4.7 per 100py (95% CI 2.9–8.0) between September 2009 and May 2013, much lower than earlier estimate of 12.5 per 100py (95% CI 6.9-21.2) because an additional 413 FSW had returned to the KP programme after this date and were included in my analyses.[222] This demonstrated the importance of factoring time for women to return for a follow-up test to prevent inflating seroconversion estimates at the end of the reporting period. I built on my initial findings in paper 2, further exploring the methods that were used to assess seroconversion and risk factors that would help understand trends and support programme guidance and targeting. Among 6665 women with repeat HIV tests in the KP Programme, 441 seroconverted at a rate of 3.8 new HIV infections per 100py (95% CI 3·4–4·2). Seroconversion rates were higher among women <25 years (5.6 per 100py (95% CI 4.8–6·5) compared to 3.1 per 100py (95% CI 2.7–3.5) for women ≥25 years, and within the first 12 months of women first testing HIV negative in the programme (5.8 per 100py (95% CI 5.0–6.7) compared those with ≥18 months follow-up (2.3 per 100py (95% CI 1.8–3.0). Using the midpoint between a last HIV-negative test and an HIV-positive test as the seroconversion date, there was evidence that seroconversion rates fell with calendar time after adjusting for changes in HIV testing frequency and an increase in HIV testing among younger women aged <25 (IRR 1·78 (1·15–2·75) in 2009-2013 compared to 2018-2019). Estimates were sensitive to analytical decisions on the date of seroconversion. Seroconversion dates estimated closer to the HIV-positive test could reflect a plausible pattern of risk driven testing that is not the midpoint between two tests, with rates increasing from 3.1 per 100py (95% CI 1.7–6.3) in 2012-2013 to 4.8 per 100py (95% CI 3.9–5.9) in 2018-2018, (IRR 0.87 (95% CI 0.45–1.70) in 2012-2013 compared to 2018-2019). The trends over time were also sensitive to analyses limiting follow-up time to two years for each woman: this provided weaker evidence of a downward trend in seroconversion rates.

8.1.4. Objective 5: Recent HIV infection testing

For my last objective I used data from a study implementing a recent HIV infection testing algorithm in the KP Programme to determine the frequency of recent HIV infections and obtain estimates of HIV incidence among this cohort. Half (55.5%) of all newly diagnosed HIV-positive women

accessing HIV testing services over 14 months were enrolled, with enrolment higher in large urban sites delivering services five days a week (92% in Bulawayo and 82% in Harare). Among all women enrolled in the study, 11.7% (95% CI 10.0-13.5) had recently acquired HIV, with provincial level differences ranging from 4.0% (95% CI 0.1 - 20.4) to 18.4% (95% CI 8.8 - 32.0) although with overlap in 95% confidence intervals. Provincial differences in study enrolment made it challenging to determine the extent to which national variation in recency was due to implementation differences or reflected real differences in recent infections. I used all programme testing data during the period of study implementation, regardless of study enrolment, to calculate an HIV incidence of 3.35 per 100py (95% CI 2.73-3.96).

8.2. Strengths and Limitations

8.2.1. Literature reviews

My reviews highlight the gaps in data for UNAIDS' first 95% target, knowledge of HIV status, and HIV incidence for FSWs in sub-Saharan Africa. For my review on knowledge of HIV status, estimates were difficult to synthesise and regional and temporal trends difficult to ascertain. I was unable to explore heterogeneity effectively by FSW definition or by the level of programme implementation in a study context due to overlapping definitions used to include women and a lack of clarity on the extent to which FSW programmes were implemented in many contexts. For the incidence review, these challenges in synthesis and pooling estimates for FSW alone were addressed through my co-authors' work to match estimates of FSW incidence with incidence in the wider female population. This enabled the assessment of relative trends over time by plotting general population age-location matched IRRs.

For the incidence review I evaluated study quality using the Global HIV Quality Assessment Tool for Data Generated through Non-Probability Sampling (GHQAT).[241] The tool is subjective and, depending on the detail reported in each publication, often challenging to complete. The tool comprises three domains: study design, study implementation and a measurement specific domain for HIV incidence. Two domains that were particularly challenging to score were on study populations (*will the study population defined answer the research question proposed (adequately represent the target population)?*) and representativeness of the source population (*is there reason to believe that the participants enrolled are a representative sample of the source population (the population from which participants were recruited)?*) The first domain required the study to stipulate the population they wished to extrapolate to, and the second domain, for papers to provide enough information on their sampling approach which was not always clear. While the quality assessment scoring was discussed with my co-authors, there was room for subjectivity.

8.2.2. Generalisability

National coverage of CeSHHAR's KP Programme was a key strength of the data I analysed for my PhD. In 2017, the programme reached 57% of the estimated 40,000 FSW in Zimbabwe.[6] The number of sites delivering services increased from 36 to 57 between 2013 and 2019, reaching a programme presence in every province in Zimbabwe. The number of women reached and receiving an HIV test more than doubled over the same period. The increasing intensity of service delivery, with expanded community outreach through microplanning and adaptability to run mobile outreach in locations with new sex work hotspots, is likely to have reached FSW who were not previously accessing services. While I did not seek to generalise my findings beyond FSW accessing services, it is clear that the programme was increasingly reaching a large proportion of FSW in the country making findings increasingly likely to be representative of those in the wider FSW population.

Despite increasing programme coverage, there has always been geographical and time specific variation in service delivery. The nuances of this variation, whether at clinic level (e.g. due to specific gaps in implementation with funding delays, how close the clinic may be to a receiving ART clinic, or being included in enhanced service delivery as a trial site) or provincial level (e.g. due to provincial differences in service delivery guidance) were challenging to capture in analysis of the whole programme. To account for site level differences, I used clustered robust standard errors in all of my analyses. While this approach accounts for correlation between observations within clusters by increasing standard errors, it does not allow for any exploration of these differences. In my recent HIV infection testing analysis (by which time there were 86 clinic sites), I presented the data by province; however, numbers were small. I was able to explore broader changes in the programme over time by using time periods representative of stages in the development of the programme, but this still does not account for all the site level nuances in programme delivery and reach.

Generalisability, as with all research among FSW, is limited by fact that we are unable to fully characterise the underlying FSW population. However, an understanding of the KP Programme data can provide some insight into who may be missed and where there may be limitations in our understanding of what is going on for some FSW. Women accessing a targeted FSW programme are likely to self-identify as an FSW and be less likely to solely engage in transactional sex where they may not self-identify as a sex worker. RDS surveys conducted in 2017 in Zimbabwe found that women who self-identify as an FSW had better service engagement and HIV testing practices, with 70.1% compared to 59.7% who did not identify as an FSW having tested in the previous 6 months, and were also more likely to have heard of the KP Programme.[174] Studies have found low levels of service engagement among younger women who sell sex in sub-Saharan African countries.[242] However, since 2016 the KP Programme has provided safe spaces for younger

women who sell sex and increased community engagement with the aim of identifying women who may not have previously sought services or identify as an FSW. The median age of FSW accessing services has decreased over time, with proportionately more young women being reached. In 2009-2013, 25.9% (1047/4039) of tests were among FSW <25 years old; this had increased to 37.1% of tests (10,015/27,024) among women <25 years old by 2018-2019. Encouragingly, survey data using RDS to obtain a population based sample of FSW in Zimbabwe in 2013 found no difference in the characteristics of surveyed women and KP Programme attendees,[102] indicating that the programme data are potentially as representative of women as RDS surveys in these sites.

8.2.3. Data collection, data linkage and missing data

Multiple records for the same woman under different unique IDs are likely to have been minimal. Robust practices at clinics now identify women who had previously accessed services, linking them to their existing records and to data management in Zimbabwe to check for women who appeared in the data with more than one unique identification number. While it is uncertain how many women may be recorded under different IDs, a study using machine learning and the KP Programme data from 2017 identified 8% of sex workers registered more than once (with a different ID), with >50% of these in Harare, the highest volume clinic. The appearance of the same women under multiple IDs would have introduced correlation between individual observations in the data and potentially reduced the availability of data on repeat HIV tests for my seroconversion analysis. The identification of an existing ID for FSW returning for a repeat visit is likely to have improved over time, with the introduction of the UIC in 2014 and roll-out of electronic systems.

Overall, less than 10% of data were missing for the main demographic and testing history variables used for analysis. Although this was not possible to ascertain, it is likely that missing data were a combination of missing not at random (where missingness is related to the variable being measured) and missing at random (missingness is not related to the missing information but can be predicted from other characteristics of that individual).[243] For HIV test data it is possible that women at higher risk of HIV infection either did or did not want an HIV test, or to provide HIV test data. While data collection processes and system changes over time may have led to variations in data quality and missingness, these were not related to my research questions and changes in patterns of missingness over time were unlikely to be linked to key confounders.

For my main outcome variable, HIV test data, I addressed missing HIV test data by combining approaches of carrying the last observation forward and using the more reliable result of a test conducted in the programme over a self-report test date or result. It is likely that the accuracy of the testing data improved over time with more clinic-visit data and observations becoming less reliant on self-report. This may have introduced disparities in data accuracy and bias across years

of implementation. While I improved accuracy of the data for analysis, making test dates reflective of the latest or most accurate account of testing history in the programme (the programme test), this would not necessarily have been reflective of what was shared by the FSW at her clinic visit.

One limitation in my study was the availability of data on other potential risk factors, which although not one of the main aims of my PhD, could have provided further insight into my main findings. Data were not collected or had >50 missing data on more than half of the variables or their response options, including number of condomless sex partners. Test refusal rates were not possible to ascertain from the data, as the variable to on the offer of testing had >70% missing data. Knowing whether a woman was offered, but refused a test could have been incorporated into measures of test-positivity and, if reasons for testing or not testing ascertained, given some indication of whether testing was risk-driven. Understanding the frequency of risk motivated testing would also be useful when making assumptions on assigning a seroconversion date between repeat tests.

8.2.4. Selection bias

The internal validity of my findings is important to consider due to the exclusion of women at different stages in my analysis for reasons of data linkage, HIV test data and repeat HIV test data availability. Excluding women at any stage of my analysis could have introduced bias if included individuals were systematically different from other women accessing services through the KP Programme.

Exclusions due to data linkage for my test-positivity and seroconversion analyses were minimal. Overall data linkage between clinical and demographic data was good, with ~98% of HIV test and clinic records linked for analysis of test-positivity and seroconversion. The exclusion of records with no test data was more substantial. Between 2009 and 2019, 86,197 women made 254,653 clinic visits to the programme. I excluded 53.9% (46,418/86,197) of FSW because they had clinic records with no testing data, records where there was uncertainty around duplicate tests, no clinic visit data (only demographic) or an inconclusive test result. By exploring testing history, I estimated that a possible 33% of women eligible for testing (reporting an HIV-negative or unknown HIV status and had not tested in the past 6 months) were not tested between 2009-2019 after accessing programme services. This percentage fell over time from 57% in 2010 to 17% by 2019. It is likely that many of the women who were not tested either self-reported being HIV positive or refused an HIV test, but it was not possible to explore these reasons in detail due to missing data. Among these women, those who did not self-report an HIV-positive status, were not offered a test or refused a test may have been systematically different from women who did test in the programme.

Beyond the exclusion of women and clinic records with no test data, women without repeat test data were excluded from my seroconversion analysis and could be considered lost to follow-up. Repeat test data were available for 6665 FSW, with 20 082 HIV tests in the KP Programme. FSW with only one HIV test in the programme were slightly younger than those with repeat tests but were similarly distributed across clinic sites and had similar demographic characteristics. Bias will have been introduced if having only one HIV-negative test in the programme, and no follow-up data, was related to risk of seroconversion. The reasons for women not returning for repeat tests could include no longer working as a sex worker, returning but using a different name and therefore registered under a different ID, or seeking services from other providers. These reasons may have changed over time, with changes in testing and service availability by other providers changing and potentially influencing this. For example, coverage of PMTCT programmes has increased progressively. A tracing study conducted in Zimbabwe among FSW who had not accessed KP Programme services for a 6 to 18 month period was able to trace half of the women lost to the programme, the vast majority of whom were still engaged in sex work (unpublished). Depending on the HIV risk of those without follow-up tests, my seroconversion estimates could have either increased or decreased. The tracing study indicates that with at least half of the women traced still in sex work, this risk could remain very high among women who disengage from services.

Data availability and data linkage were more challenging for the RITA study, leading to a greater proportion of FSW excluded from analyses. Only 55.5% of all women testing HIV-positive during the period of study implementation were enrolled in the RITA study. While this varied between sites, with much higher enrolment in large urban sites, overall it is likely that bias was introduced by non-enrolment. The reasons for this were not captured so it is unclear if this was due to refusal or not being offered a test. For women that were enrolled in the study, data linkage was complicated by dual data collection systems using different individual identification numbers, meaning integration of study data into routine systems was not always possible and full datasets not available. 88.3% (1157/1311) of DBS results were linked to clinical data, but only 21.6% (250/1157) linked to ICT/SNT data.

8.2.5. Measurement error

HIV testing in the KP Programme follows Zimbabwe's national testing algorithm using rapid point of care testing[142] While rapid tests have been shown to be accurate in controlled settings, studies have found misdiagnosis in implementation. A systematic review of HIV testing and misdiagnosis found a median of 3.1% false-positive and 0.4% false-negative results, with suboptimal testing strategies being a predominant reason for this misclassification across 64 studies between 1990 and 2017.[244] A study of HIV testing misclassification in Zimbabwe found a high rate of false-negative results (10.6%) and 0.34% false-positive results. An estimated 3.5% of HIV-negative women were taking ART among those attending PMTCT services in 2017,[245] although another

study of retesting before ART initiation in Zimbabwe in the same year found no adults had been misdiagnosed.[246] The reasons for misclassification may be due to changing algorithms leading to uncertainties on testing procedures and high burden work settings meaning inadequate time to accurately use and record test results.[247,248] Fully ascertaining where there may have been misdiagnoses was not possible with the programme data but we can get some indication from repeat test data and self-report testing history. In the programme, 317 women with repeat HIV tests had an HIV-negative test recorded after an HIV-positive test; this could indicate potential misdiagnoses, although it could be also explained by data entry or data linkage issues with test records incorrectly assigned to the wrong women. Self-report test history could also give an indication of earlier misdiagnoses outside of the KP Programme. A total of 2.9% (1370/47,611) of the women with self-report test history data testing in the programme reported a prior HIV-positive diagnosis, but only 60.2% (825/1370) had this HIV-positive result confirmed by their programme test. While these numbers are small in the context of all women testing in the programme, and would have had limited impact on our findings, they indicate that these data are not exempt from errors in test results. In the context of the KP Programme, it is possible that test accuracy fluctuated over time and between clinics, with periods when algorithms changed or at clinics with high provider-patient ratios.

Test accuracy could also be a limitation in my recent HIV infection testing analysis. Here I report results from testing DBS samples which have been shown to overestimate recent HIV infections when compared to plasma testing.[249] In a comparison of DBS and plasma samples in the same study, for 467 FSW with paired samples, plasma testing classified 10.3% (48/467) and DBS 12.2% (57/467) as recent infections, with 78.0% (46/59) agreement (unpublished: IAS 2024 – abstract submitted) (Appendix 16). Overestimating recent infections would also overestimate HIV incidence.

Risk factors in the programme data were also subject to potential measurement error. The KP Programme uses syndromic STI diagnosis which may give a less accurate result that STI testing.[250,251] Other variables relied on self-report. Self-reported testing history relies on socially motivated responses to questions which may have introduced bias. Reporting an HIV-positive status also relies being willing to disclose your HIV status and believing an earlier result or understanding that this is a lifelong diagnosis. Studies in Africa have shown good accuracy on self-report HIV status, but not in FSW populations and with lower accuracy among younger people.[252,253] Self-reported sexual and HIV-related risk behaviour will be subject to social desirability bias, with the mode of questionnaire delivery likely to influence this bias. [254–256] In the KP Programme clinic staff ask face to face questions of FSW on condom use and sexual partners when they access services, in order to assess HIV and STI risk and provide clinical care. In research settings, studies have found underreporting of sexual behaviours in interviewer

administered surveys which will have implications on the validity (how accurately the measure actually records the event) of responses on sexual behavioral.[255,257,258]

In my analysis of seroconversion rates, temporality may have been an issue when measuring risk factors for seroconversion. I used the date of the HIV-positive test to measure clinic visit risk factors (other than STI diagnosis) but used the midpoint between the HIV-positive test and the previous HIV-negative test as the seroconversion date. For some women the seroconversion interval was short, but for others it was much longer meaning the risk factor may have been inaccurate at the estimated time of seroconversion. For example, questions on recent condom use would not have been relevant for the whole period between a last HIV-negative test and the test this was measured at. For FSW testing HIV-positive, it is possible that seroconversion happened before the last time she had sex, and therefore a report of condom use would not be relevant in the same way to whether she seroconverted or not. Variation in the time between tests for individual women also meant that there were different degrees of proximity to a seroconversion for the measurement of risk factors, even if temporality had not been an issue. I used the outcome of an STI diagnosis from the visit prior to an HIV-positive test, but the diagnosis may have had greater relevance when measured closer to the HIV-positive test if it was within the previous six months compared to the previous two years. Variables including education, marital status and experiences of gender-based violence were only measured at a first visit, meaning that they may not have been correct at the time of a follow-up test or at the time of an HIV-positive test result or seroconversion. The implication is that this may have biased our risk factor analysis for test-positivity or seroconversion leading to spurious results, but it is hard to know in which direction.

8.2.6. Analytic assumptions

I explored a range of assumptions in my analyses on individual testing frequency, the date of seroconversion and follow-up time for FSW included in my seroconversion analysis. The median time between HIV tests was 266 days (IQR 159–452). To address the wide variation in time between HIV tests I assigned a measure of average testing frequency to each FSW to assess for the contribution of these differences in testing patterns to my overall estimates. As the majority of women only tested twice, and there was a strong correlation between overall test time (time between first and last HIV test) and number of tests, assigning one measure made sense. However, this would not have accounted for potential variation over time in testing frequency for FSW with >2 tests; patterns that may have been reflective of changes in HIV risk.

The variation in testing intervals was also relevant for the seroconversion interval, the time between the last negative and first positive HIV test. In sensitivity analyses I identified my estimates were sensitive to the analytic decisions that I made. Estimating a seroconversion date either at the midpoint or randomly between testing positive for HIV and the last negative test result gave similar

results, as has been reported elsewhere.[220,259] At odds with this, estimating a seroconversion date one month before a positive HIV test (suggesting that testing was motivated by seroconversion risk) gave higher incidence estimates in 2018-2019 than in earlier years, indicating that rates were not declining over time. As many sex workers are at ongoing HIV risk and therefore test regularly, testing motivated by a specific risk exposure may have been less common.[62] My assumptions around seroconversion soon after a negative test were a less likely scenario, but demonstrated the difference if estimates were earlier in the seroconversion interval. In reality it will have been a range of these factors, so taking the midpoint or random point is the most realistic approach. My analysis was limited in the extent to which I could ascertain which assumptions I made about seroconversion date are likely to be closest to reality.

Another factor was overall follow-up time for women in my seroconversion analysis. There was wide variation in follow-up time among women with repeat HIV tests. I adjusted for mean time between HIV tests which would have accounted for some of this variation. I also restricted follow-up to 2 years in a sensitivity analysis to reduce potential bias introduced by the disproportionate contribution of HIV negative follow-up from a small group of long-term engaged participants. Restriction of follow-up to 2 years increased seroconversion rates in later periods and, while my overall interpretation of falling seroconversion rates over time remained, the evidence for this was weaker and demonstrates that the inclusion of all possible follow-up time could underestimate seroconversion rates in later periods. FSW with long term engagement in HIV services may be at lower risk than those with shorter term engagement and less access to HIV services. Related to this was the assumption that women remained at high HIV risk for all analytic follow-up time and continued to engage in sex work. In reality this may not have been the case, with the likelihood that women to cycle in and out of sex work and during periods of not actively engaged in sex work, and possibly being at lower risk, they did not engage in services. Accounting for this in analysis by cutting follow-up time for lower risk periods may have increased estimates of HIV incidence.

Calculating HIV incidence from recent HIV infection testing requires making an assumption on the mean duration of recent infection (MDRI) and false recency rate (FRR). For my analysis I used an MDRI of 130 days in line with the Zimbabwe 2020 PHIA survey[137] and previous estimates from cross-sectional FSW RDS surveys.[225] I applied an FRR of 0.2% in contrast to 0 used by the Zimbabwe 2020 PHIA. Zero suggests there are no false recent results and is unlikely, even when using a RITA.[237] Both the MDRI and the FRR are challenging to ascertain and are subject to much debate. Biomarkers vary substantially between individuals making the characterisation of an MDRI difficult and including an incorrect FRR can have a big impact on the resulting incidence calculation,[122] particularly in high prevalence populations. A study in Uganda identified the importance of using an HIV subtype specific MDRI to prevent overestimating HIV incidence.[260] Most of the evidence on calculating HIV incidence from recent HIV infection testing comes from

nationally representative surveys (PHIA). Facente *et al* identified less than half (20/51) of studies using recent HIV infection testing to calculate incidence did so in key or sentinel populations, including in HIV testing services.[73] Weak evidence exists for the value in only using the proportion testing recent and not calculating HIV incidence.[73] A study in Côte d'Ivoire, Malawi, and Mozambique compared recency testing with modelled incidence estimates, to explore the use of different denominators in interpreting recency data. The study found that for recent infection testing in routine HIV testing services, using the proportion of all those at risk of HIV acquisition was a better proxy for HIV incidence than the proportion among HIV-positive tests .[236] For my analysis I linked all programme testing records and not just HIV-positive test records for the study period to reflect this.[236]

8.3. Interpretation

The findings from my PhD contribute collectively to evidence on HIV testing patterns, test-positivity and new infections for FSW in Zimbabwe. They build on existing knowledge and provide a more nuanced understanding of the programming and policy gaps that remain and whether we are on track to achieving global targets. In the following section I will discuss the interpretation of these findings in relation to the wider literature and within the context of the limitations I have outlined. I will present this under two themes: 1) the data gaps that have been addressed for FSW in Zimbabwe and more broadly for sub-Saharan Africa and 2) the contribution this research has made to methodological approaches to filling these gaps for programme monitoring and HIV surveillance for FSW and other key populations.

8.3.1. HIV test-positivity and knowledge of HIV status

My analysis of HIV testing patterns in Zimbabwe's KP Programme showed declines in the proportion of FSW who had never tested and increased HIV testing frequency between 2009 and 2019. Declines in HIV test-positivity over the same period are likely to reflect declines in undiagnosed HIV. While unmeasured alternatives, such as reductions in HIV risk among women accessing services in later years are possible, these test-positivity declines are plausible and reflective of trends seen elsewhere. Test-positivity declines have been seen in non-FSW populations in sub-Saharan Africa from 13% to 2.2% between 2000 and 2020[91] and from 20% to 6% in Zimbabwe between 2011 and 2018.[6,261] These findings are also reflective of measured knowledge of HIV status among FSW in Zimbabwe. In line with the expansion of testing coverage for FSW in Zimbabwe,[155,194,196] 58.2% of FSW reportedly knew their HIV-positive status between 2009 and 2011[155] compared to estimates closer to 80% in 2016.[194,196] Knowledge of HIV status has increased among all women of childbearing age in Zimbabwe, with over 95% of women tested in pregnancy by 2020.[80] In sub-Saharan Africa there have been modelled increases in knowledge of HIV status in the wider population from 5.7% (95% CI 4.6-7.0) in 2000 to 84% (95% CI 82-86)

in 2020, with 12 countries in Southern Africa reaching at least 90% (95% CI 88-92) in the same year.[91] This has not reportedly been mirrored in FSW populations, with one in four FSW thought to be unaware of their HIV positive or negative status globally in 2021, including those who were HIV-negative at their last test when this was over 12 months previously.[2]

HIV test-positivity is suggested as a measure of programme performance and reflective of testing delivery and uptake. Whether an overall 16.4% test-positivity is an indicator of good programme performance, with temporal declines indicating that we are doing enough to reach global targets, is hard to interpret. This may be particularly true over a long period of time with changes in testing guidelines, testing criteria, delivery and access to treatment (and more recently PrEP). In the KP Programme, women are likely to have been more motivated to seek testing services with the increasing availability of ART and the introduction of PrEP in intervention sites during the SAPPH-IRe trial (now at all sites). Changes in test-positivity may be hard to disentangle from changes in testing behaviours and programme engagement where these are not independent from HIV risk;[262,263] and may be less clear cut in a population that tests frequently. The KP Programme has seen significant expansion and reached many more women over >10 years of implementation, with increases in national testing coverage and in the proportion of women undergoing testing when they access services. It is likely that by 2019 the programme was testing >80% of eligible FSW at clinic visits. These increases mirror findings in a global review which identified increased testing rates with rapid test delivery.[264]

In an era of resource constraints and a drive to reach a decreasing undiagnosed fraction, more narrowly targeted testing, with the aim of achieving higher test-positivity, may be at odds with identifying those yet to be undiagnosed.[265] My analysis suggests that declining test-positivity in the programme is not necessarily reflective of inefficiency, but rather the likelihood of an increase in newer HIV infections being identified through increased individual testing frequency, instead of the identification of longer term infections and potentially more existing diagnoses. As an indicator of programme performance, higher rates of testing and test-positivity declines are likely to be encouraging and reflective of greater testing accessibility and better service engagement.

8.3.2. New HIV infections

The findings from my PhD all point to the persistence of disproportionately high rates of new HIV infections among FSW, even when accessing targeted services. The seroconversion rates I estimated from repeat HIV test data are high at 3.8 new HIV infections per 100py (95% CI 3·4–4·2) and consistent with the estimate of incidence I calculated from recency testing in the programme at 3.4 per 100py (95% CI 2.7-4.0) for the period of 2021 to 2023. These seroconversion rates are also comparable, although marginally lower than our pooled review estimates for sub-Saharan Africa of 4.3 per 100py (IQR 2·8-7·0). Other estimates of HIV incidence

for FSW in Zimbabwe have been calculated using HIV prevalence data from RDS surveys at 4.4 per 100py in 2011-2017 and 2021-2023.[227] Incidence calculated from recent infection testing in RDS survey data was lower in 2021 at 2.1 per 100py (95% CI 1.0-3.2).[225] Other estimates in Zimbabwe are for young women aged 18-24 years who sell sex and were 5.29 per 100py (95% CI 3.99-7.02) in absence of DREAMS interventions, and 3.14 per 100py (95% CI 2.21-4.46) where DREAMS was implemented.[220] Earlier estimates from the KP Programme data in Zimbabwe were higher, but these discrepancies can be explained by the characteristics of the data which are discussed in the following section. Seroconversion rates in the KP Programme were more than five times higher than the annual incidence of 0.57% (95% CI 0.29–0.85) reported among adult women 15-49 years in the 2016 Zimbabwe Population-based HIV Impact Assessments (PHIA).[137,266]

The rate of new HIV infections is likely to be declining among FSW accessing HIV services in Zimbabwe and more broadly among FSW in sub-Saharan Africa. Incidence trends over calendar time have only been published for one other FSW population in Kenya. A downward trend was also seen here, albeit over a longer period of time and steeper, from 11.4 per 100py (95% CI 16.2-7.8) to 0.6 per 100py (95% CI 2.2-0.1).[267] Over the 15 year period between 1998 and 2012, declines were attributed to increased population ART coverage.[226] With the scale-up of programming and HIV prevention for FSW in Zimbabwe and across the region, these findings in Zimbabwe are encouraging. A 2017 call from the WHO for more to be done in adopting and scaling up key population programmes,[38] plus the development of programming that works and meets the needs of FSW,[36,37,53,268] should be driving a decline in new HIV infections. Specifically in Zimbabwe, the SAPPH-IRe cluster-randomised trial was conducted in 14 sites alongside existing services to strengthen engagement of FSW in HIV prevention and care. While there was normal service delivery in 7 sites, enhanced services including additional HIV testing, ART initiation at sites, PrEP, adherence and intensified community mobilisation were delivered in intervention sites. At the time this was the only access to PrEP for FSW in Zimbabwe. Rates of HIV diagnosis and treatment initiation increased due to the intervention.[6] From 2016 the Young Sisters programme, which later became part of the PEPFAR funded DREAMS Partnership, offered services to young women who sell sex in the KP Programme.[220] Evaluation of the intervention found it was plausible that incidence had declined in two major cities where DREAMS for YWSS was implemented (compared to those where it was not), but only found weak evidence of this decline as it was lower than an anticipated 40%.[220]

HIV transmission in sex work does not happen independently of the HIV epidemic in the wider population. FSW are part of the female population and are likely to be captured in general estimates of incidence, even if data are not stratified. In our incidence review, modelled age-year matched estimates for Zimbabwe showed a decline in adult female incidence from 0.76 per 100py

in 2016 to 0.45 per 100py in 2019. Declines in the KP Programme were not as steep, indicated by a greater IRR in 2019 at 6.83 compared to IRRs closer to 4 in 2010 and 2011. PHIA estimates, which use recent HIV infection testing, show no such decline in incidence over a similar time period. Incidence among adult women was 0.57 per 100py (95% CI 0.29–0.85) in 2016 compared to 0.67 per 100py (95% CI 0.34-0.99) in 2020 and among all adults in Zimbabwe, 0.44 per 100py (95% CI 0.25–0.62) in 2016, compared to 0.45 per 100py (95% CI 0.45-0.65) in 2020.[137,266] For adolescent girls and young women, incidence declines were indicated in 10 high HIV prevalence countries in Africa, all receiving DREAMS funding, but with limited evidence to suggest that transmission was slowing by 2016 in some of the highest risk settings in Uganda and South Africa.[269] Approaches to measuring HIV incidence including recent HIV infection testing and age specific prevalence among FSW have yielded generally consistent results.[270] However, when interpreting trends over time there seem to be discrepancies when using different approaches for the general population. Based on my sensitivity analyses cutting follow-up time to 2 years, I may not have drawn the same conclusions on declines in seroconversion when using either a midpoint or random allocation of a seroconversion date.

The high rates of seroconversion in the first 12 months of FSW accessing services are challenging to interpret, although other studies have reported similar declines in seroconversion with follow up. A study in Mombasa, Kenya between 1993 and 1997 compared HIV incidence by follow-up time (to replicate a closed cohort) and incidence density by calendar time (open cohort). They found that 50% of new HIV infections occurred within the first 6 months of enrolment, and 73% in the first 12 months, with incidence falling from 17.4 per 100py in the first 6 months to 1.7 per 100py in the last 6 months of a potential 3 year follow-up period. When analysing the data as an open cohort they also found that incidence density fell over time.[271] In a similar way in my analysis, it is possible that after excluding the highest risk FSW, who seroconvert early in engagement, it is the lower risk FSW who return to the programme and continue to contribute data to the analysis. The Mombasa study found that no repeatedly HIV-negative women were leaving the cohort and the cohort was accumulating lower risk individuals, magnified by lower recruitment rates in later years. The KP Programme is likely to represent an even more open cohort, running for a longer period of time and with increasing, not decreasing, rates of new entrants into the programme. It is possible that a continual influx of high-risk women keeps seroconversion rates in the programme high, and with less of a decline over time than that seen in the Mombasa cohort.[267]

The high rates of seroconversion early programme engagement could be related to a higher risk period before women identify as an FSW, and access programme services. When interpreting these early high infection rates, it must be considered that the HIV-positive tests we knew to be new HIV infections (because we had testing history data on these women) made up only 5.6% (503/8959) of all HIV positive tests in the programme. The remaining HIV-positive tests were

among women when they first tested at a programme clinic. For these women we do not know if these were new diagnoses, and we have no information about previous negative results. This has implications for our interpretation as the women included in our seroconversion analysis make up a very small proportion of all HIV-positive tests.

8.3.3. Identifying recent HIV infections

More frequent individual testing in later years of KP Programme implementation (with more women testing within 6 months of a previous test), as well as decreasing seroconversion intervals, point to the earlier identification of HIV infections over time. However, recency testing in the KP Programme between 2021 and 2023 indicates that we are still reaching many women later in their HIV infection. Recency findings show that among HIV-positive women enrolled in the study, 88.3% had long term HIV infection. Data from repeat testing show that among women accessing KP Programme services between 2009 and 2019, we may be identifying infections sooner, with 40.8% (180/441) of FSW seroconverting, with a seroconversion interval of >12 months. The fact that women enrolled in the RITA study may have been first-time testers in the programme, whereas FSW with repeat tests were already engaged in services, potentially explains some of this difference. Knowing whether we are identifying previously undiagnosed HIV-positive FSW, and how long after they become HIV infected, has epidemiological, clinical and programmatic importance. However, unpacking where HIV infections are re-diagnoses and the identification of the time of HIV infection at diagnosis is challenging. With seroconversion rates remaining high and frequent testing among FSW, we would ideally expect be picking up new infections within 12 months of seroconversion. The recency study in 2021 identified a similar proportion of recently acquired infections to the 10.5% (33/313)[70] found in an earlier pilot in CeSHHAR Zimbabwe's large static programme sites in 2017, but higher recency than the 5.9% (18/306) found in a 2021 RDS among FSW in Zimbabwe.[225] Studies in South Africa have shown that 33.8% of HIV positive tests in one cohort were re-diagnoses.[272] In the KP Programme approximately 3% of tests were conducted among women recorded as self-reporting an HIV positive status and of these women 60% tested HIV positive in the programme. While it is likely that we are identifying women engaged in services earlier in their HIV infection, my findings also indicate that we may be missing opportunities to test FSW and identify recent HIV infections. At 52.1% of KP Programme visits, women reporting an HIV-negative or unknown HIV status and not testing in the preceding six months were not tested. This percentage fell over time, indicating that the programme was missing fewer opportunities to test and likely to be identifying new infections earlier.

8.3.4. Risk factors

I identified clinical and demographic factors associated with HIV infections in the programme that could provide insights to support programme delivery. As with many studies, age was a risk factor

for HIV test-positivity, seroconversion and recent HIV infection. Overall, women accessing services had a median age of 28. Over time, younger age groups made up an increasing proportion of women testing and new diagnoses in the programme. Test-positivity was associated with older age, with FSW ≥25 years old 50% more likely to test HIV-positive (OR 1.50, 95% CI 1.4-1.7), although younger women made up a larger proportion to HIV-positive tests in later years. Women who seroconverted were younger at their first HIV test in the programme than FSW who did not seroconvert (25 years old compared to 27 years old). There were similar findings in the DREAMs study where new infections did not decline as expected in intervention sites and remained very high in younger age groups.[269] A pooled analysis across nine African countries among young women who sell sex found high HIV prevalence by 18-19 years old, indicating the need for earlier intervention in this age group.[242] The 2023 UNAIDS epidemic update cited analysis by the Global HIV Prevention Coalition which identified that in 2021 in sub-Saharan Africa, dedicated HIV prevention programmes for adolescent girls and young women were only delivered in 42% of districts with high HIV incidence.[1]

The frequency and reason for women accessing HIV testing services could some indication of their HIV risk, with HIV testing frequency associated with test-positivity and seroconversion. HIV test-positivity was higher among women visiting a clinic for family planning in earlier years, 2009–2013 (OR 2.2, 95% CI 1.73–2.85), but the opposite in later time-periods. Test-positivity was also higher among those diagnosed with an STI (OR 1.91, 95% CI 1.75–2.09). Seroconversion rates were twice as high among FSW diagnosed with an STI at the previous clinic visit at 6.0 per 100py (95% CI 5.3–7.0) compared to 2.9 per 100py (95% CI 2.6–3.3) among those with no STI diagnosis. STIs are a known risk factor for HIV infection and treatment of curable STIs is likely to have a big impact on HIV.[273,274] Understanding the geographical distribution of new HIV infections could help in understanding where transmission may be higher and support the targeting of HIV prevention. However, this was difficult to ascertain from our data. Provincial level differences in recent infections demonstrated wide variability and potential difference in risk, but interpretation was limited by small numbers and widely varying recruitment rates. While I conclude that it is hard to disentangle recruitment from actual differences, it is likely that geographical differences exist. In a modelled study in the region, wide variation was seen with sub-national estimates in new HIV infections, with many not meeting the reductions that were reported at a national level.[275]

8.3.5. Data and HIV surveillance

There is increasing availability of HIV data for FSW in sub-Saharan Africa, with opportunities for the longitudinal analysis of programme data where programme coverage now exists or is expanding, and for understanding trends over time with repeat surveys in the same FSW populations. There seems to be a shift from studies measuring incidence in research cohorts among populations of women mostly accessing clinical services to population-based surveys using

approaches such as RDS. However, gaps and challenges remain in the synthesis and comparison of estimates, and in many contexts, national and longitudinal trends are not still possible to obtain.

In the context of a nationally scaled FSW targeted programme, routinely collected clinic data can provide a valid and useful source of information for HIV surveillance and programme targeting. The concept of '*know your epidemic, know your response'*,[78] becomes even more important as HIV incidence in the wider population goes down. The WHO called for routine data to be considered more for HIV surveillance,[76] however specific approaches to operationalising this for key populations need to be further explored. There is increasing recognition that using repeat testing data (in settings where repeat testing is encouraged) at specific periods to identify individuals who seroconvert may be an option for estimating HIV incidence and supporting the interpretation of incidence patterns.[76,276] Despite this, methodological gaps remain for surveillance in key populations. While routine data require a programme to be in place (and do not necessarily remove the challenges of HIV surveillance among key populations), they do provide an alternative data source that can be usefully analysed and triangulated with other data sources.

Before 2014, UNAIDS did not report on the number of new infections among key populations in their annual epidemic updates. A study by Stevens *et al* triangulating empirical and modelled estimates of HIV incidence for FSW (identified in our systematic review) for 2021 found that UNAIDS modelled estimates were potentially overestimating the distribution of new HIV infections among FSW, at 15% of new adult HIV infections compared to the 5% identified in their work.[126] The 2023 UNAIDS epidemic update presents an estimate for FSW HIV prevalence at 4 times that of the general population, substantially lower than the 30 times the risk reported in 2022. They also report that preliminary analysis in countries with available trend data suggests that between 2010 and 2022 new infections were declining in line with national trends.[1]

8.4. Implications

The findings from my PhD have implications for both programming and HIV surveillance among FSW populations. For programming I highlight the continued importance of HIV prevention for FSW by quantifying the high HIV risk among FSW in Zimbabwe, even when they are engaged in comprehensive targeted services. I strengthen existing knowledge around the increased risk among younger FSW and identify gaps in knowledge where groups of women that may be missed in programming and are potentially at higher risk of HIV infection. My findings highlight the strong potential for better use of programme data to identify and support women early after they access services, and for the use of tools such as recent HIV infection testing to better target HIV testing services. For HIV surveillance I present important considerations for using these data to estimate HIV seroconversion rates among FSW. I also highlight wide variation in empirical data currently

available with HIV estimates, which has implications for the interpretation of regional estimates and empirical data use in epidemic models.

8.4.1. Female sex worker programmes

For FSW who access targeted services, HIV infection rates remain unacceptably high, with the highest rates of seroconversion within 12 months of first accessing services. The implication is that there is more that could be done to identify these women when they first access services and intensify the delivery of services for FSW testing HIV-negative on first engagement in the programme. This could be by supporting women to access services more frequently soon after engagement, with interventions including PrEP now provided in all KP Programme sites. We remain unclear on what happens before FSW access services, and it is not known if there is a correlation between starting out in sex work and being a new entrant in the programme. The KP Programme data show that a substantial proportion of FSW are accessing HIV services after they become HIV-positive. This is in line with findings from a 2015 biobehavioural survey among adolescent girls and young women (AGYW) in Mombasa, Kenya which used viral sequencing to identify time since HIV infection. An estimated 74.1% (95% CI 53.7–88.9) of young women acquired HIV before self-identifying as a sex worker.[277] A large proportion of FSW who test HIV-negative in the programme also do not return for a subsequent test. These findings highlight potential missed opportunities to engage women earlier and retain HIV-negative women in services. However, there are complexities around this if women are not in sex work before they seroconvert, are therefore do not qualify for services and, if they leave sex work and consequently stop accessing services. Women who do not identify as an FSW, yet still sell sex, may not want to access FSW-dedicated services. We need to ensure that FSW-dedicated services are not the only option for them. Younger women, as shown in other settings, had lower test-positivity and a higher risk of HIV seroconversion in the KP Programme, further highlighting the need for earlier and more targeted prevention support. In Zimbabwe, despite programme services being offered to younger women through safe spaces, and to women who do not identify as an FSW, but who are identified through peer outreach in the community, there are still challenges in providing effective prevention to these younger women. Beyond the KP Programme and CeSHHAR there is a need to optimise services for adolescent girls and young women.

The implications of my findings on HIV test-positivity are that we are going to need to work harder to reach an ever-smaller proportion of undiagnosed FSW. This might mean using approaches including more extensive peer led outreach (which may include incentive linked outreach), offering services that are motivating for FSW to access, as well as incorporating recent HIV infection testing of newly identified HIV-positive women to help target index and social network testing. Recency testing in a programme context could also support efforts to understand patterns in new HIV diagnoses and estimate HIV incidence. Calculating incidence from a RITA could have advantages

over estimation of seroconversion rates through individual test linkage for repeat testers, providing more up-to-date information and not requiring that women access services more than once. The disadvantage is the significant effort that is required in terms of human resources to operationalise these and generate appropriate data that is useful.

8.4.2. Routine programme data

My PhD demonstrates the potential for routine programme data use among key populations where it exists, both for informing programming and for HIV surveillance. It also highlights the challenges and potential bias with these data, and where future work could make improvements. Strengthening data use with a minimum set of system and data requirements could improve HIV prevention. Data requirements could include good HIV testing and test history data ((details of both previous tests reported by women conducted outside of the of the KP programme, as well as details related to tests conducted by the KP programme) to support an understanding of seroconversion intervals and how quickly a programme may be identifying new HIV infections. Strengthening the collection of data on behavioural characteristics associated with higher HIV risk could enable more in depth research on risk factors that have the potential to be directly influenced by HIV prevention programming. These behavioural risk factors could include condom use or numbers of sexual partners. While I was able to include some analysis of condom use in my thesis, there were other data items on condom use and on numbers of sexual partners that had too much missing data to use, and known to be subject to social desirability bias. While the main purpose of collecting these data in the KP Programme is to identify risk and provide clinical care, where clinician administered questions during a clinic visit are needed, there may be opportunities to augment these data with anonymised data collection to improve response rates and reduce the bias to enhance future research. Approaches to strengthening self-reported sexual risk behaviours has been largely explored in the research space, where self-completion questionnaires including audio computer-assisted survey instruments (ACASI) and informal confidential voting interviews (ICVI) have been shown to increase reporting on sexual behaviors compared to face to face interviewing.[255,258,278,279] While ensuring the balance between service provision and research is maintained, there may be opportunities to introduced self-administered questions for a sub-set of consenting FSW when they attend clinic services to strengthen specific areas of research. System requirements would include the capacity to confidentially link individual records for analysis. It took a long time to obtain an analysable dataset for this PhD, which has implications for future research and more timely use of these data for HIV programming. Systems need to function well and be operationalizable; using analytics through dashboards, for example, is likely to be important for specific indicators around testing and new HIV infections, whilst ensuring data are aggregated and maintaining individual confidentiality.

The increased availability of empirical data and use of these data to inform epidemic models is encouraging, but it will be important to continue on this trajectory to build on a regional understanding of HIV among FSW and improve model validation. The differences in how empirical data are obtained, whether through studies among FSW accessing programme services, or recruited to population-based surveys; among women currently engaging in sex work or those who may have only sold sex once, are important considerations moving forward. There could be an opportunity for a more standardised approach to defining populations for HIV surveillance, although with the need to acknowledge contextual differences in sex work (and the importance of not deterring women who could benefit from programmes, accessing them). Synthesising existing estimates does not capture the heterogeneity in sex work and the women included in these estimates. They miss the differential risk for younger women who sell sex compared to older women, or for those who engage in transactional sex compared to those who self-identify as a sex worker. Understanding these differences could support a better understanding of risk and the provision of services.

8.5. Future research

Through my PhD I have identified important areas for further research. In the short term, I would like to update my seroconversion analysis for the past five years. With the continued expansion of the programme (now in 86+ clinics) and greater data availability this analysis would provide up to date estimates and longer trend data. It would also enable me to explore some of my assumptions around follow-up time and identify whether there is a continued downward trend in new HIV infections in the programme. We now have recent HIV infection testing estimates of HIV incidence from RDS surveys in 2021 and from the programme data; these would be interesting to compare to updated estimates from repeat tests in the programme as they are lower than previous incidence estimates. Understanding similarities or differences in FSW contributing data to these RDS survey and programme estimates could help identify how indicative programme estimates are of what may be happening outside the programme and if there is a way to quantify how much we may be under or overestimating seroconversion rates in the programme compared to population-based data in this context. Secondly, I would use the methods I have developed in my PhD to explore the impact of PrEP roll-out across the programme. Specifically, I would explore whether the time to seroconversion from a first HIV-negative test in the programme has changed in light of PrEP rollout across all clinic sites, addressing some of the implications of my work for intensified prevention services for FSW soon after they access services.

I would also like to use the work I have done through my PhD to inform discussions on a core set of clinical and demographic questions to be asked at a KP Programme clinic visit. The timely use of these data are fundamental for improving programme performance. Opportunities including the

introduction of data analytics platforms could support this work. Additionally, exploring the mode of data collection in the context of service delivery (to identify existing limitations and ways of strengthening data on sexual risk behaviours) could enhance research. I would be keen to ensure that enough information is gathered to address future research questions useful for informing programme delivery and wider knowledge on HIV among FSW. At the same time, it will be important to balance the information needed for clinical support and not overburden staff in order to ensure the most ethical use of these data and sustainability in their collection.

In the longer term, I would like to pursue my interest in who the women are who are reached with clinical services, compared to those who are not captured in these data. An important finding in my PhD was that a large proportion of women who access services are already HIV-positive and there are much higher seroconversion rates soon after women access HIV services. This has implications for both programme implementation when women first access services and for optimising prevention coverage to reach women earlier. A bigger piece of research I would be keen to undertake would focus on understanding the risk factors for early seroconversion or attending the programme already HIV-positive. We remain unaware of what happens before women access services. It is unclear whether they may not access services early in sex work, whether they do not access FSW-dedicated services because they do not identify as a sex worker, or whether they are HIV-positive before first engaging in sex work. CeSHHAR's KP Programme now collects data on length of time in sex work. Using these data combined with self-report testing history could help explore this further. There may also be scope to triangulate the KP Programme clinic data with risk score data that has been collected through AMETHIST to improve understanding of risk on first access to the programme. Understanding how best to optimise HIV prevention for these women, particularly in the period before they first access services, will be important if we want to see a continued decline in new HIV infections.

In the longer term, I would also like to explore the methodological gaps that I have identified through my PhD. We now have a period of time where repeat test data and recent HIV infection testing data are available in the programme. While it was not possible to explore repeat testing patterns of FSW enrolled in the RITA study at the time of my analysis due to limitations with the electronic data systems, this may now be possible as much more of these data have been captured electronically. Triangulating recent HIV infection testing data, testing history (self-report and programme) could help identify where recent infections are picked up as new HIV infections in the programme, or where these are among FSW newly accessing services. This type of analysis could also contribute to our understanding of when to estimate a seroconversion date between repeat HIV tests in programme data and on the validity of midpoint estimation assumptions.

8.6. Conclusions

My thesis on HIV testing and new HIV infections among FSW accessing targeted programme services over a 13 year period in Zimbabwe contributes to the empirical data available on FSW in sub-Saharan Africa and provides important contributions on the use of routinely collected programme data to obtain estimates of key HIV indicators. I have demonstrated that among women accessing dedicated FSW services, risk of HIV infection remains over five times higher than that of women in the wider population in Zimbabwe. We are likely to be seeing a decreasing fraction of undiagnosed HIV-positive FSW in Zimbabwe and new HIV infections are showing encouraging declines over time. Routinely collected programme data are valuable in supporting the increased need for HIV data for key populations, to inform epidemic models and consequent resource allocation and decision making. FSW in Zimbabwe remain at a disproportionate risk of HIV. While there are positive indications that new infections are falling, there are still substantial gaps in knowledge on new HIV infections and a lack of empirical data to target and drive much-needed efforts in HIV prevention.

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