BMJ Open Incidence of unintended pregnancy among female sex workers in lowincome and middle-income countries: a systematic review and meta-analysis

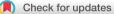
Frances H Ampt,^{1,2} Lisa Willenberg,¹ Paul A Agius,^{1,3} Matthew Chersich,⁴ Stanley Luchters,^{1,2,5} Megan S C Lim^{1,2,6}

ABSTRACT

To cite: Ampt FH, Willenberg L, Agius PA, *et al.* Incidence of unintended pregnancy among female sex workers in lowincome and middle-income countries: a systematic review and meta-analysis. *BMJ Open* 2018;**8**:e021779. doi:10.1136/ bmjopen-2018-021779

Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi. org/10.1136/bmjopen-2018-021779).

Received 22 January 2018 Revised 14 May 2018 Accepted 11 June 2018



© Author(s) (or their employer(s)) 2018. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to

Professor Stanley Luchters; stanley.luchters@burnet.edu.au **Objectives** To determine the incidence of unintended pregnancy among female sex workers (FSWs) in lowincome and middle-income countries (LMICs). **Design** We searched MEDLINE, PsychInfo, Embase and Popline for papers published in English between January 2000 and January 2016, and Web of Science and Proquest

for conference abstracts. Meta-analysis was performed on the primary outcomes using random effects models, with subgroup analysis used to explore heterogeneity. **Participants** Eligible studies targeted FSWs aged 15–49

years living or working in an LMIC.

Outcome measures Studies were eligible if they provided data on one of two primary outcomes: incidence of unintended pregnancy and incidence of pregnancy where intention is undefined. Secondary outcomes were also extracted when they were reported in included studies: incidence of induced abortion; incidence of birth; and correlates/predictors of pregnancy or unintended pregnancy.

Results Twenty-five eligible studies were identified from 3866 articles. Methodological quality was low overall. Unintended pregnancy incidence showed high heterogeneity ($l^2>95\%$), ranging from 7.2 to 59.6 per 100 person-years across 10 studies. Study design and duration were found to account for heterogeneity. On subgroup analysis, the three cohort studies in which no intervention was introduced had a pooled incidence of 27.1 per 100 person-years (95% Cl 24.4 to 29.8; $l^2=0\%$). Incidence of pregnancy (intention undefined) was also highly heterogeneous, ranging from 2.0 to 23.4 per 100 personyears (15 studies).

Conclusions Of the many studies examining FSWs' sexual and reproductive health in LMICs, very few measured pregnancy and fewer assessed pregnancy intention. Incidence varied widely, likely due to differences in study design, duration and baseline population risk, but was high in most studies, representing a considerable concern for this key population. Evidence-based approaches that place greater importance on unintended pregnancy prevention need to be incorporated into existing sexual and reproductive health programmes for FSWs.

PROSPERO registration number CRD42016029185

Strengths and limitations of this study

- This is the first study to systematically review and analyse the incidence of pregnancy or unintended pregnancy among female sex workers (FSWs) in low-income and middle-income countries.
- Broad inclusion criteria meant that the review allowed for the inclusion of a large proportion of the studies that have collected data on pregnancy or unintended pregnancy rates in this population.
- However, limitations of broad inclusion criteria are that only one study had an a priori objective of measuring pregnancy incidence, and studies were highly varied in terms of their methodology, settings and study populations.
- High heterogeneity prevented pooled analysis of all studies but allowed for subgroup analysis for cohort studies and for studies in which no intervention was introduced.
- Pregnancy rates among FSWs could not be compared with the background general population rates because of the lack of availability of those data.

INTRODUCTION

Unintended pregnancy affects a large number of women in low-income and middle-income countries (LMICs) and can have significant impacts on maternal and child health.^{1–3} Unintended pregnancy is a high priority issue for many female sex workers (FSWs)^{4 5} who usually have dependents to support and for whom pregnancy may increase financial dependence on sex work and add to already high levels of stigmatisation.⁵ This has been confirmed by consultation with FSWs in Kenyaⁱ and workshops with FSWs to inform development of a pregnancy prevention intervention.⁶ Participants expressed considerable

ⁱOur research group has worked closely with a local NGO (International Centre for Reproductive Health, Kenya) which has a long history of collaborating with and providing services for sex workers in Mombasa.

fear and anxiety about pregnancy, related personal and peer experiences of pregnancy scares and emphasised the importance of improving knowledge of family planning in their community (unpublished qualitative data, Mombasa, Kenya).

FSWs can face elevated risks of unintended pregnancy due to a high frequency of intercourse and a high number of sexual partners.^{7 8} Risks are exacerbated by concurrent paying and non-paying partnerships⁸ and by sexual and gender-based violence, gender inequalities and stigma towards sex work, which reduce women's power to negotiate within sexual relationships.⁹⁻¹¹ While gains have been made in terms of condom use with paying clients,¹² rates of condom and other contraceptive use are consistently lower with emotional (non-paying) partners.^{5 13 14} In many countries, particularly in sub-Saharan Africa, few FSWs use long-acting reversible contraceptives (intrauterine devices and implants), and methods such as injections, condoms and pills may be used inconsistently or incorrectly, rendering them less effective.^{5 15} Limited knowledge and misunderstandings, particularly in relation to contraceptive side effects and impacts on fertility, are significant demand-side barriers to contraceptive uptake.4516

Family planning services are often neglected as part of FSW-specific service provision, which have focused largely on preventing HIV and other sexually transmitted infec-tions (STIs).^{12 17-19} Stigma of health workers towards sex workers can also limit access to contraception.^{20 21} FSWs have the same reproductive rights as all women, and their desires and needs in relation to pregnancy have often been neglected,²²⁻²⁴ similar to other marginalised populations, which have historically been subjected to reproductive coercion.^{25 26} It is important that those who do desire pregnancy are provided with non-judgemental care and that those who do not are given the opportunity and resources to prevent it. Moreover, many FSWs who become pregnant may be reluctant to enter maternal health services, given their previous experiences of discrimination and abuse from health workers.²⁰ FSW programmes need to make concerted efforts to facilitate timely attendance of FSW at antenatal clinic and childbirth services. Importantly, FSWs often have remarkably high levels of HIV, and maternal health services are a key entry point for them to access antiretroviral treatment, which secures their health and reduces HIV in infants.

Despite a clear rationale for addressing unintended pregnancy in this population, it is important to acknowledge that intention is a problematic concept, which is more accurately represented as a spectrum than a dichotomy.^{3 27} Indeed, many women feel positive about pregnancy despite not intending to conceive, or may simultaneously desire both pregnancy and its avoidance, for different reasons. The degree to which women accept or welcome a pregnancy once it has occurred has been hypothesised to be a more important predictor of adverse outcomes than prepregnancy intentions.²⁷ Fertility preferences are also likely to be less stable over time in LMICs

undergoing fertility transition compared with high-income countries.³ FSWs' intentions also differ between types of partner, requiring them to adapt contraceptive use accordingly.²² Furthermore, as a stigmatised group, FSWs may feel pressure not to disclose their intention. Despite these limitations, we have continued to use the term 'unintended pregnancy' in this paper for the sake of consistency with other literature and the lack of a feasible alternative.

The primary objective of this study was to determine the pooled incidence of unintended pregnancy among FSWs in LMICs. Given the expected low number of eligible studies, we also aimed to determine the incidence of pregnancy where intention is not known. Secondary aims were to examine the correlates and predictors of pregnancy and the incidence of induced abortion and childbirth in this population.

METHODS

All stages of this systematic review and meta-analysis have been reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.²⁸ The protocol for this review was registered with the international prospective register of systematic reviews (PROS-PERO): number CRD42016029185.

Inclusion and exclusion criteria

Studies were included if they met key criteria in terms of population, outcomes and study design. FSWs had to account for at least two-thirds of the sample, unless data could be disaggregated by sex work status. We employed a broad definition of sex work, including women who self-identified as sex workers, those who engaged in transactional sex or part-time sex work and communities of women known to practice commercial or transactional sex. Study participants had to live or work in an LMIC²⁹ and be of reproductive age (15–49 years). Studies targeting women with reduced fertility (eg, women in the first 6 months postpartum and those exclusively breast feeding or undergoing fertility treatment) were excluded.

Studies had to measure or report one of the following primary outcomes:

- 1. Cumulative incidence (proportion of women who became pregnant in a defined time period) or incidence rate (per person-time) of unintended pregnancy.
- 2. Cumulative incidence or incidence rate of pregnancy (where intention is not measured).

Unintended pregnancy was defined as any pregnancy considered by the woman to be not planned, intended or desired at the time of conception,³⁰ as reported either prior to pregnancy or retrospectively. Such pregnancies may be described by the authors as unintended, unwanted, undesired, unplanned or mistimed.

Any study design that was able to measure one or more of the primary outcomes was considered, including both observational and intervention studies. Case studies, ecological studies, qualitative studies, editorials and commentaries were excluded. We planned to expand the inclusion criteria if insufficient studies measuring the primary outcomes were identified to include studies reporting prevalence of pregnancy in the previous 12 months. Cross-sectional studies were included in the initial screen for this purpose but were subsequently excluded as there were sufficient longitudinal studies measuring incidence. The addition of period prevalence in the last 12 months as an outcome would have required additional subanalyses; in addition, measurement of retrospective pregnancy intention in cross-sectional studies differs from prospective measurement as women may change their minds during the course of their pregnancy. Only studies published in English since 1 January 2000 were included.

Search strategy

A systematic electronic search of MEDLINE, Embase, PsychINFO and Popline was undertaken to identify relevant peer-reviewed articles. Search syntax included, as both subject headings and keywords: synonyms for 'sex work'; list of LMICs from the World Bank²⁹ and synonyms for 'low- and middle-income'; and study design and descriptor terms, for example, 'cohort studies' or 'controlled trials' (full search strategy in online supplementary file).

A search for unpublished grey literature was also undertaken, including conference proceedings and abstracts (via Web of Science and Proquest databases), research theses and the websites of relevant non-government organisations, including the Population Council, FHI 360 and Guttmacher Institute.

The last search was performed on 20 January 2016. Up to two attempts were made to contact authors when further information was required. Eligible studies recommended by contacted authors were also included.

Screening and data extraction

Screening of all abstracts, removal of duplicates and selection of full-text articles was conducted by one researcher, with a random selection of 10% screened in duplicate. Data from a random sample of 50% of included full-text manuscripts were extracted in duplicate. Discrepancies in eligibility and data extraction were resolved by discussion, with a third researcher arbitrating when necessary.

Summary estimates were sought rather than individual subject data. Data were extracted relating to: eligibility criteria; study aims, population and methods; setting and participant characteristics at baseline; primary and secondary outcome data for each time point reported; and quality assessment criteria. In addition to the primary outcomes, the following secondary outcomes were extracted: incidence of induced abortion (termination of pregnancy); incidence of birth; and correlates/predictors of pregnancy or unintended pregnancy. Authors were contacted to provide data relating to the primary outcome when it was not reported in the paper, for example, the total person-years of exposure.

Quality assessment

Methodological quality of the included studies was assessed using a modified version of the Joanna Briggs Institute Prevalence Critical Appraisal Tool³¹ (online supplementary file). This tool was designed to assess studies measuring prevalence or incidence and can be applied to multiple study designs. The tool was modified to address specific methodological concerns of our research question. Given measurement bias could result from infrequent or irregular pregnancy detection methods, items on these methods were specifically included. We also documented whether pregnancy incidence was an a priori study objective.

Quality assessment was undertaken in duplicate for 50% of studies, with discrepancies resolved by discussion. Studies were given a score out of 15 if they measured unintended pregnancy incidence, and a score out of 14 if they measured pregnancy incidence (the latter did not include an item on measurement of intention). Scores were then reported as percentages.

Analysis

We undertook a qualitative narrative synthesis of both primary and secondary outcomes and quantitative analysis of primary outcomes using Stata V.13.1.

Incidence rate (per 100 person-years) was taken as the unit of analysis. In studies reporting only cumulative incidence, we estimated person-time, censoring women at their first pregnancy and assuming that they became pregnant halfway through the study.

The Mantel-Haenszel I² statistic was over 95% for both primary outcomes, so meta-analysis and meta-regression were not performed for all eligible studies, as had been planned. Instead, sources of heterogeneity were explored using subgroup analyses, and pooled incidence rates were calculated using DerSimonian & Laird random effects models for subgroups containing more than two studies and with I^2 of less than 75%. The explored subgroups were clustered as covariates that may explain heterogeneity (geographic region and intervention vs non-intervention) and potential methodological explanations of heterogeneity: study design (cohort vs randomised controlled trial (RCT); study duration; and frequency of pregnancy measurement (measured regularly vs only when indicated). Interventions included any introduced by the study with the aim of improving sexual and reproductive health, including contraceptive provision and behavioural or biomedical interventions to prevent HIV/STIs.

We assessed study quality as a source of heterogeneity by examining scatter plots and Pearson correlation coefficients of quality score against incidence rate. We also qualitatively explored characteristics of different studies, including the following baseline population characteristics that may have impacted on pregnancy rates: age; contraceptive prevalence; consistent condom use; number of sex partners; coital frequency; STI prevalence; indicators of gender-based violence; and alcohol and other drug use.

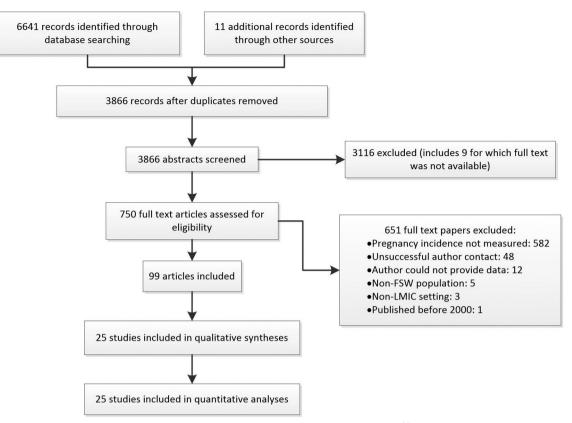


Figure 1 PRISMA flow diagram of search results and inclusion of studies after review.²⁸ FSWs, female sex workers; LMICs, low-income and middle-income countries; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Patient and public involvement

The research question and outcome measures were informed by previous qualitative work with FSWs conducted by the International Centre for Reproductive Health, Kenya. This confirmed that unintended pregnancy was an important issue for this population group. Patients and members of the public were not otherwise involved in the design or conduct of this study.

RESULTS

The initial search yielded 6523 peer-reviewed and 118 grey literature articles and 11 identified by hand-searching (eg, due to recommendations from contacted authors). After removal of duplicates, this resulted in 3866 articles (figure 1). Based on title and abstracts, 750 manuscripts remained for full-text screening.

Pregnancy incidence was reported in 12 studies and was obtained for a further 13 studies after contacting authors. These 25 studies were reported in 99 papers. Ten studies measured *unintended* pregnancy (outcome 1), and 15 studies measured pregnancy *without specifying intention* (outcome 2); none measured both outcomes.

Fourteen cohort studies and 11 RCTs were included (table 1). Pregnancy incidence was not an a priori primary objective for any but was a secondary objective for a Rwandan HIV incidence study.³² The majority of studies aimed to test interventions to prevent HIV or STIs (n=11) or measure HIV incidence (n=8). Six

undertook substudies in which they reported pregnancy incidence.^{33–38} Thirteen studies included any intervention: three involved provision of diaphragms or female condoms,^{39–41} and 10 studies were biomedical or behavioural interventions to prevent HIV/STIs (table 1). The latter included four studies that reported providing contraceptive counselling^{35 36 42 43} and one which offered free contraception when needed.⁴⁴

Most RCTs in this review required women to remain non-pregnant for continuation.^{36 40 42 44–48} The majority of studies (n=19) took place in sub-Saharan Africa, most frequently in Kenya (n=8; table 1). There were also studies from the Americas (Mexico and the Caribbean) and East Asia (China, Thailand and Cambodia). All except three^{36 44 49} took place in urban settings. The study areas were frequently informal housing settlements, low-income areas or environments known for sex work and/or drug use.

Sex work was mainly defined as exchange of sex for money or goods (n=12) or money alone (n=4). In five studies, sex workers were self-identified, in two studies they were members of communities or working in areas known for commercial sex work^{36 46} and in two studies no definition was provided.^{48 50} Eighteen studies involved FSWs exclusively; the remainder targeted women with high-risk sexual practices or at high risk of HIV. These studies either reported pregnancy incidence in the sex work subgroup^{36 42 44 51} or FSWs constituted more than

Table 1 Cha	aracteristics	Characteristics of included studies	studies										
Study (first author, year)	Additional sources	Y Country st	Year started	Design	Aim	Population	N (FSWs) at baseline	Age (median)†	Current contraceptive use‡ (%)	Consistent condom use§	Number of sex partners/ frequency of sex¶	Gender-based violence (GBV)/ alcohol/other risk factor	HIV/STI prevalence
Outcome 1: unintended pregnancy	ided pregnancy												
Benets, ³⁹ 2005		Madagascar 21	2004	Prospective cohort (with intervention).	Assess acceptability and feasibility of diaphragm use.	FSWs who use condoms inconsistently.	91	5 28	Any: 47% LARC or permanent: <1%.	0% with clients in last month (inconsistent use was an inclusion criterion).	Five partners. Six sex acts.	N/A.	Vaginitis/Pelvic inflammatory disease (PID): 8%. TP (RPR): 27%.
Behets, ⁴⁰ 2008	Author†† Khan <i>et</i> af ⁴ Perman-Aguilar et al ⁷²	Madagascar	2005	RCT (pilot).	Assess acceptability and feasibility of diaphragm and microbicide use for STI prevention.	Women with high-risk sex behaviours (sex work self-reported: 81% current, 100% ever).	192	50	Any (excl. condoms): 24%.	0% in last 2 weeks (inconsistent use was an inclusion criterion).	Six casual partners. 10 sex acts.	Ever violence from casual partner for suggesting condom: 21%. Ever received more money for no condom: 38%.	WA.
Braunstein, ³² 2011	1 Braunstein et al ⁷³	2 Rwanda	2006	Prospective cohort.	Measure HIV incidence (secondary aim: measure pregnancy incidence).	HIV- uninfected women at hilgh risk of HIV exposure (94% reported current sex work).	265	24	Any: 91%. LARC or permanent: 0%.	21% with clients 18% with non- paying partners.	90 partners in past 3 months. 10 clients per week. 40 vaginal sex acts in last month.	Forced sex ever: 19%. Alcohol before sex: 52%.	CT: 5%. GN: 12%. TV: 17%. (RPR+TPHApos): 7%. HSV2: 54%.
Chersich, ³⁴ 2014	Author†† Luchters <i>et af</i>	Kenya (Mombasa).	2006	Prospective cohort.	Assess HIV incidence and microbicide trial feasibility. This substudy: investigate This between alcohol use, and unsafe sex and incident HIV infection.	HIV- uninfected FSWs.	386	Mean 25.1	Any (incl. <i>consistent</i> condom use): 57.1%. LARC: 3.0%. Permanent: 0%.	21.3% in last 3months.	N/A.	Hazardous or hamrful drinking: 26.8%. Ever had abortion: 21%.	N/A.
Deschamps, ³³ 2016	Deschamps et al ^{r4}	Haiti, Puerto 21 Rico and Dominican Republic	5009	Prospective cohort.	Assess feasibility of establishing a high-risk cohort for HIV vaccine trials. This substucy: assess retention, HIV and pregnancy incidence and risk behaviours.	HIV- uninfected FSWs.	634	24‡‡	Permanent: 10.0% (excluded from pregnancy analysis). Others not reported.	0.5% in last 6months.	last 6months#4.	Forced sex by client N/A in last 6months: 37.1%. Heavy drinker: 38.8%. Drug use: 14.0%.	N/A.
Gaffoor, ⁴² 2013	Author†† Skoler-Karpoff et a/ ⁷⁵	South Africa (one site of a multisite trial)	2004	RCT (phase 3, double blind, placebo- controlled).	Test safety and efficacy of the microbicide. Carraguard for HIV prevention. This substucy: describe prevalence and associations of forced sex.	HIV- uninfected sexuallyactive women (3% FSWs).	41	ŝ	ŝ	N/A.	ŝ	N/A.	Ś
Lara, ⁴¹ 2009	Author 11	Dominican Republic	2006	Prospective cohort (with intervention).	Assess acceptability of the female condom and diaphragm, determinants of use, and impact on unprotected sex.	FSWs.	243	58.8% aged 20–29 years	Any (excl. condoms): 22.2%. Permanent: 0%.	66% in last month.	N/A.	Ever had abortion: 70%.	HIV: 1%. CT: 13%. GN: 2%. TP (VDRL): 8%.
McClelland, ⁵ 2008	Author†† Martin <i>et al</i> ⁷⁵ McClelland <i>et al</i> ⁷⁷ McClelland <i>et al</i> ⁷⁸	Kenya 21 (Mombasa)	2003	RCT (placebo- controlled, nested in an open cohort study).	Test efficacy of monthly periodic presumptive autibiotic treatment at reducing incidence of vaginal infections and promoting vaginal Lactobacillus colonisation.	HIV- uninfected FSWs.	310	33	Any (excl. condoms): 35.5%. LARC: 3.6%. Permanent: 2.9%.	Median 100% coverage of sex acts in past week.‡‡	One partner. One sex act.##	N/A.	GN: 0.3%. TV: 1%. Cervicitis (microscopy): 0.6%. HSV2: 74%. BV: 34.5%.
													Continued

6

Table 1 Con	Continued												
Study (first author, year)	Additional sources	Country	Year started	Design	Aim	Population	N (FSWs) at baseline	Age (median)†	Current contraceptive use‡ (%)	Consistent condom use§	Number of sex partners/ frequency of sex¶	Gender-based violence (GBV)/ alcohol/other risk factor	HIV/STI prevalence
Peterson, ⁴⁶ 2007	Author†† Macqueen et al ⁶⁶	Ghana, Cameroon and Nigeria	2004	RCT (phase 2, double bilind, placebo controlled).	Investigate safety and preliminary effectiveness of tenofovir disoproxil fumarate in preventing HIV infection.	HIV- uninfected women women ho work in hotels, bars, markets in high HIV high HIV high HIV areas (areas known for sex work).	936	Mean 23.6‡‡	Any (excl. condoms): 1.22%. LARC: <2%. Permanent: <2%.	NVA.	Mean 21 partners in 30 days. Mean 12 coital acts per week.	N/A.	Any STI in last 6 months (self- reported): 41.2%.
Watson-Jones, ⁴⁴ 2008	Author†† Odutola <i>et al</i> ⁷⁹	Tanzania	2004	RCT (double blind, placebo controlled).	Determine whether HSV2 suppressive therapy reduces the risk of HIV acquisition and genital shedding of HIV.	Female workers at food and recreational facilities at risk of HIV (38% FSWs).	499	ŝ	ŝŝ	<i>8</i>	ŝ	33	90 207
Outcome 2: pregnancy (intention undefined)	intention unde	fined)											
Bazzi, ^{sel} 2015	Authorff Syvertsen et a ^{ph}	Mexico	2010	Prospective cohort.	Identify time varying risk factors for STI acquisition within FSWs' intimate partnerships.	FSWs with drug use history and their steady male partners.	212	ŝ	Any (excl. condoms): 53.3%. LARC: 12.3%. Permanent: 25.5%.	Often or always: 56%.	N/A	In last year: physical assault by pathers 41%. Sexual coercion in relationship 9%. In last 6 months: hazardous drinking: 23%. Intravenous drug use: 62%.	HIV: 2.6%. CT: 5.9%. GN: 1.2%. TP (active): 1.4%. Any STI: 8%.
Page. ³⁸ 2013	Author†† Duff <i>et al⁶⁵</i> Couture <i>et al⁶¹</i>	Cambodia	2009	Prospective cohort.	Estimate HIV and STI prevalence, incidence and associated factors. This substudy: decorbe contraceptive utilisation and correlates of incident pregnancy.	Young women 220 who practice SW and/or have multiple partners (all those recruited had practiced SW).		60.3% aged 25-29 years	Any hormonal (not LARC): 10.8%. LARC: <1.0%.	WA.	Four partners in last month.	In last year: physical or sexual violence by clience and the second- thimate partner: 20.1%. In last 3 months: stimulard chug use: 27.0%. Abortion: 11.3%.	HIV: 16.2%.
Feldblum, ³⁵ 2007	Feldblum <i>et alst</i> Madagascar Hoke <i>et alst</i>	Madagascar	2001	RCT.	Assess impact of two condom promotion interventions. This substudy: estimate pregnancy incidence rate and predictive factors.	FSWs.	935	Mean 28.3	Any highly effective (excl. condoms): 16.3%.	No unprotected sex with any partners: 13.2%.	Mean 5–6 partners.	N/A.	CT: 14.6%. GN: 21.7%. TV: 11.7%. Any STI: 36.1%. ‡‡
Kaewkungwal, ³⁶ 2013	Rerks-Ngarm et al ⁸³	Thailand (two provinces)	2003	RCT (multisite double blind placebo controlled).	Assess the efficacy of two vaccines to prevent HIV. This substudy: determine the qualities and outcomes of women's participation.	HIV- uninfected women (5% FSWs).	318	A/A	WA.	SS	N/A.	ŞŞ	N/A.
Kaul, ⁴⁷ 2004	Yadav <i>et al⁸⁴</i> Fonck <i>et al⁸⁵</i>	Kenya (Nairobi)	1998	RCT (double blind placebo controlled).	Assess impact of monthly PPT on HIV and STI incidence.	HIV- uninfected FSWs.	430	28.6‡‡	Any hormonal (not LARCs): 39.1%.	17.2% with casual partner:‡‡	15.4 partners.##	Daily alcohol: 47.6%. Ever intravenous drug use: 4.1%.	CT: 9.9%. GN: 10.3%. TV: 12.2%. TP: 4.4%. HSV2: 73.9%. BV: 51.1%.
													Continued

6

6

	HIV/STI prevalence	CT: 14.0%. GN: 3.3%. TP: 1.3%. Any STI: 16.9%.	NA	Any non- ulcerative STI: 9.1%. Genital ulcers: 1.5%. TP: 0.6%. Any STI: 10.6%.	CT: 5.5%. GN: 6.0%. TY: 9.0%. HSV2 (antibody): 72.0%. BV: 38.0%.	WA.	CT: 12.0%. GN: 2.2%. TV: 33.6%. TP (active): 8.4%.	CT: 4.4%. GN: 5.1%. TV: 3.5%. TP: 11.2%.	Continued
	Gender-based violence (GBV)/ alcohol/other risk F factor p	N/A.	2 VIV	3	Sexual/physical C violence related to C Sex work (SW) in 1 last month: 19.59, 1 Sometimes/always F paid more for no 7 paid more for no 7 paid more for no 7 sometimes/always has sex while intoxicated: 31.59,	Abortion in last 3 months: 0.43%.	N/A.	. A.N	
	Number of v v sex partners/ a frequency of sex f	Mean 8.3 clients.#	Two sex acts.	w.A.	Mean per day: 2.4 regular clients. 1.9 casual clients.	A.A.	30 clients per nonth. 51 paid sex acts per month.		
	Consistent condom use§	43.6% in past month.	55% in past week.	N/A.	N/A (only reported sometimes/ always use).	32.6% with clients. 20.3% with non- paying partners.	14.9% with regular clients. 11.7% with casual clients.	N/A (only reported Three partners use of condom per day. in ≥50% of sex acts).	
	Current contraceptive t uset (%)	LARC: 29.9%.	Any (excl. condoms): 43.0%. Parmanent: 2.67%.	N/A.	Any non-barrier method: 52.0%. LARC: 3.0%. 1.0%.	Any hormonal (incl. implant): 36.5%. IUD: 0.5%. Permanent: 0.5%.	Any (excl. condoms): 39.3%. LARC: 25.3%. Permanent: 17.8%.	N/A.	
	Age (median)†	Mean 27.8‡‡	£	ŝ	Mean 28	N/A	33	26	
	N (FSWs) at baseline	750	80	515	500	1463	584	892	
	Population	FSWs.	HIV-infected FSWs.	HIV- uninfected women and men at risk of HIV (75% of women were FSWs).	HIV- uninfected FSWs.	HIV- uninfected women and men at high risk for HIV (64% FSWS).	HIV- s uninfected FSWs who inject drugs.	HIV- uninfected FSWS.	
	Aim	Assess the impact of a preventive intervention for FSWs on condom use with clients and partners.	Assess HIV-1 incidence and relationships between hormonal contraception, STIs and HIV. This substudy: examine relationship between risk behaviour and biologic outcomes (STI, pregnancy, seminal fulud deposition) among HIV-positive FSWs.	Describe populations at risk of HIV, including HIV incidence, in preparation for HIV trials.	Assess HIV risk behaviour and incidence, STI prevalence, vaginal practices and retention.	Describe the trajectory of acute HIV infection.	Determine effectiveness of two behavioural interventions to reduce sexual and injecting risk.	Determine effectiveness of monoxynol-9 microbicide in prevention of HIV-1.	
	Design	Cluster RCT.	Open cohort.	Prospective cohort.	Prospective cohort.	Prospective cohort.	RCT (four-arm factorial).	RCT (multisite triple blind placebo- controlled; open cohort design).	
	Year started	2009	1993	2005	2008	2009	2008	1996	
	Country	China	Kenya (Mombasa)	Kenya (Nairobi, Kilifi)	Kenya (Nairobi)	Kenya, Tanzania and Uganda	Mexico	Benin, Cote d'Ivoire, South Africa and Thailand	
Continued	Additional sources	Author 11	Author†† Martin <i>et al</i> ⁷⁸ McClelland <i>et al</i> ⁴⁸	Author17		Author†† Rono et a ⁶⁷	Author†† Vera <i>et al</i> / ⁸⁸ Gaines <i>et al</i> ⁸⁹	Author†† Vandebosch et al ⁶⁰ Ramjee et al ⁶¹	
Table 1 Con	Study (ffirst author, year)	Liu, ⁸⁸ 2015	McClelland, ³⁷ 2011	Price, ⁴⁹ 2012	Priddy, ^{se} 2011	Robb, ⁵¹ 2016	Strathdee, ⁴³ 2013	Van Damme, ⁴⁸ 2002	

Table 1 Continued	ntinued												
Study (first author, year)	Additional sources	Country	Year started	Design	Aim	Population	N (FSWs) at Age baseline (med	Age (median)†	Current contraceptive use‡ (%)	Consistent condom use§	Number of sex partners/ frequency of sex¶	Gender-based violence (GBV)/ alcohol/other risk factor	HIV/STI prevalence
van Loggerenberg, ⁶² 2008	Author†† Naicker et al ⁸²	South Africa (Durban)	2004	Prospective cohort.	Understand HIV-1 subtype C acquisition, pathogenesis and disease progression. This substudy: describe obhort characteristics and HIV-incidence rates, and HIV-incidence rates, and HIV-incidence rates, the cohort.	HIV- uninfected women who practice SW (79%) and/or have multiple partners.	193	Mean 34.3	N/A.	53.9% with casual partners. 20.4% with steady partners.	Two partners per week.	N/A.	Any STI (CT, GN, TV, MG, TP, HSV2): 31.3%.
Vandepitte, ^{%2} 2013 Authorff Vandepit et al ^{%4}	3 Author11 Vandepitte et al ⁹⁴	Uganda (urban slum).	2008	Prospective cohort.	Understand dynamics of HIV FSWs. and STI infections among FSWs. This substudy: investigate patterns of clearance and recurrence of untreated <i>Mycoplasma genitalium</i> infection.	FSWs.	1027	Mean 26	N/A.	59.8% in last month.	At least daily sex for money: 50.5%.	Froblem drinking: 55.7%.	MG: 14%.
Vielot, ^{so} 2015	Author11	Kenya (Nairobi)	2009	Prospective cohort.	Compare the duration of high FSWs. risk HPV infection among FSWs by exposure to STIs, using a highly sensitive biomarker assay.		350	28	LARC: 15.5%. Permanent: 2.1%.	Most of the time/ always: 73.8% with clients. 24.6% with non- paying partners.	10 partners per week.	N/A.	HIV: 24.0%. CT: 3.8%. GN: 2.3%. TV: 7.3%. MG: 12.8%.
†Median unless specified. ‡Any=modern contracept §Always uses condoms (u ¶Median number per wee	†Median unless specified. ≵Any=modern contraceptive method inclu §Always uses condoms (unless specified) ¶Median number per week unless specifie	ncluding condom ed). cified. Sex partne	ns, unless ers may b	specified; LARC= e paying, non-pay	†Median unless specified. ‡Any=modern contraceptive method including condoms, unless specified; LARC=long-acting reversible contraception (implants or IUDs); Permanent=any method of permanent contraception, for example, tubal ligation or hysterectomy, §Always uses condoms (unless specified).	otion (implants o ecified.	r IUDs); Perma	nent=any me	thod of permaner	it contraception, for	example, tubal ligati	on or hysterectomy.	

If Median number per week unless specified. Sex partners may be paying, non-paying, regular or casual, unless specified.
If Median number per week unless specified. Sex partners may be paying, non-paying, regular or casual, unless specified.
If Author¹ indicates additional data were obtained from the author. Other references listed here reported on the same study and were used for data extraction.
If Author¹ indicates additional data were obtained from the author. Other references listed here reported on the same study and were used for data extraction.
SSNbt disaggregated by sub-group: data presented here are overall estimates.
SSNbt disaggregated by sex work status.
BV, bacterial vaginosis: CT. Charnydia trachomatis; FSW, female sex worker, HSV2, herpessimplex virus type 2; MG, Mycoplasma genitalium; N/A, not measured or reported, data not available from author, NG, Neisseria gonorrhoeae; RCT, randomised controlled trial; STI, sexually transmitted infection; TP, Treponema palifour (syphilis); TV, Trichomonas vaginalis.

two-thirds of the sample.^{32 40 49 52} Fourteen studies were restricted to women without HIV at baseline, and one study to women living with HIV.³⁷

Most studies (n=15) were conducted for 1–2 years, although they ranged from a 1 month pilot RCT⁴⁰ to a 15-year open cohort study.³⁷ The studies reporting pregnancy (intention undefined) tended to be of longer duration than those reporting unintended pregnancy (median duration 24 and 12 months, respectively; table 2).

Baseline population characteristics

Most study populations had a median of 5–8 years of education, and the majority of women were supporting at least one financial dependent (data not shown). Median duration in sex work was 3–5 years for most study populations, with one notable exception of 14 years in a study in Mexico.⁴³ Concurrent non-paying sex partners were common, reported by 30%–100% of women in 12 studies.

Permanent and long-acting reversible contraceptive use was around 1% in most studies in Africa, with only one study in Kenya reporting significantly higher coverage (17.5%).⁵⁰ By contrast, coverage of these methods was greater than 30% in China⁵³ and Mexico.^{43 54} Consistent condom use was measured using diverse metrics but was generally low and very low with non-paying partners. Most studies reported frequent sex with multiple partners, and few reported a median of less than five partners per week.^{37 45 52 55} High rates of gender-based violence were noted in all studies in which this was measured, as well as physical or financial pressure not to use condoms.^{40 56}

While the factors described generally contributed to high baseline pregnancy risk, several studies included FSW with notably lower risk profiles. For example, two studies were part of a large Kenyan open cohort, in which participants had few partners and sex acts per work, and older median age and lower STI prevalence than the other studies.^{37 45} In addition, a number of studies provided insufficient information to assess population risk for pregnancy.

HIV prevalence was reported in four studies and varied from 24 % in Kenya⁵⁰ to less than 3 % in Mexico⁵⁴ and Dominican Republic. ⁴¹ STIs other than HIV were prevalent, with one study reporting up to 36% of the study population having at least one STI on biological testing.^{35 57}

Methodology and quality assessment

Quality scores, as percentages of the available total, are presented in table 2. The median quality score was 40% (IQR=36%-50%). Four studies scored 60% or greater; three of these measured unintended pregnancy³²⁻³⁴ and one measured pregnancy (undefined).⁵³ Most studies scored poorly in the external validity and selection bias categories.

Measurement bias was an issue for some studies. Pregnancy was tested regularly in all but one⁴⁴ of the unintended pregnancy studies; in contrast, five pregnancy (undefined) studies only measured it if suspected by the clinician or participant. Five of the pregnancy (undefined) studies measured pregnancy using self-report rather than a biological test.

Incidence of pregnancy

Incidence rate was reported by 14 studies and calculated for the remainder based on the available data, with the number of women who became pregnant as the numerator and person-years as the denominator. Women were censored at the time they became pregnant. The one exception was Deschamps *et al*,³³ who counted multiple pregnancies and subtracted pregnancy time from total person-time.

Unintended pregnancy incidence rate (outcome 1) varied widely between studies, ranging from 7.2 to 59.6 pregnancies per 100 person-years (table 2; figure 2). The median rate of the 10 studies was 26.8, and seven reported a rate of greater than 20 per 100 person-years.

Incidence rate of pregnancy (intention undefined – outcome 2) also varied widely, but rates were lower overall than unintended pregnancy, ranging from 2.0 to 23.4 per 100 person-years (table 2). The median rate of the 15 studies was 13.5, and only two reported a rate of greater than 20 per 100 person-years.

Meta-analyses

Random effects meta-analyses were performed for the two primary outcomes. Heterogeneity was high, with I^2 statistic over 95% for both outcomes.

Incidence of unintended pregnancy

Explored covariates that may explain the high heterogeneity of unintended pregnancy incidence showed that geographical region did not explain this, whereas presence/absence of an intervention seemed important. The three cohort studies that did not involve an intervention had very low heterogeneity ($I^2=0\%$), and the pooled estimate for these studies was 27.1 unintended pregnancies per 100 person-years (95% CI 24.4 to 29.8; figure 3). These three studies scored at least 60% on quality assessment (table 2).

Assessment of potential methodological explanations showed that study design (RCT vs cohort) and study duration seemed important sources of heterogeneity, while pregnancy measurement method did not explain the high heterogeneity. The cohort studies were more homogenous than the RCTs (I²=63.9% and 96.8% respectively), and had higher pooled incidence of unintended pregnancy (figure 4). The three studies of less than 1 year duration were more homogenous (I²=59.1%) and had higher incidence (44.5 per 100 person-years) than longer studies (figure 5).

Quality was not found to be a source of heterogeneity, as no relationship was demonstrated between study quality score and unintended pregnancy incidence rate (Pearson correlation coefficient 0.01; scatter plot not shown).

 Table 2
 Results of included studies reporting unintended pregnancy and pregnancy (intention undefined) in ascending order of incidence

Study	Incidence rate (per 100 person-years)	95% CI	Person- years of exposure	Duration (months)	Measurement of pregnancy	Frequency of measurement	Quality (%)
Unintended pregna	ancy			<u> </u>			. ,
McClelland et al ⁷⁷	7.2	4.5 to 10.9	305.4	12	Urine test	Monthly	40
Watson-Jones <i>et al</i> ⁴⁴	11.8	9.7 to 14.5	796	30	Urine test	Quarterly on suspicion only	53
Gaffoor <i>et al</i> ⁴²	13.4	6.1 to 25.4	67.2	24	Urine test	Quarterly	20
Behets <i>et al</i> ⁴⁰	20.7	4.3 to 60.5	14.5	1	Urine test	Weekly	27
Braunstein et al ³²	26.3	21.9 to 30.7	528.5	24	Serum test	6 monthly for 1 year+1 measurement in second year	60
Deschamps <i>et al³³</i>	27.3	23.3 to 31.7	615.6	18	Test (unspecified)	6 monthly	67
Chersich <i>et al³⁴</i>	28.0	22.6 to 34.3	335.8	12	Urine test	Quarterly	60
Peterson <i>et al</i> ⁴⁶	51.7	44.9 to 59.3	400	12	Urine test	Monthly	40
Behets <i>et al³⁹</i>	53.0	21.0 to 110.0	13.2	2	Urine test	Monthly	40
Lara et al ⁴¹	59.6	41.7 to 82.5	60.4	4	Urine test	Monthly	40
Pregnancy (intentio	on undefined)						
Robb <i>et al⁵¹</i>	2.0	1.4 to 2.9	1619.6	24	Self-report	Quarterly on suspicion only	21
McClelland <i>et al³⁷</i>	2.7	2.1 to 3.5	2259.3	15-year open cohort *	Urine test	Monthly on suspicion only	21
Bazzi et al ⁵⁴	3.3	1.4 to 5.2	359.6	24	Self-report	6 monthly	43
Strathdee <i>et al</i> ⁴³	5.9	4.1 to 8.4	540.1	12	Self-report	4 monthly	36
van Loggerenberg <i>et al⁵²</i>	8.5	5.6 to 11.5	376.5	24	Urine test	Monthly on suspicion only	36
Van Damme <i>et al⁴⁸</i>	8.6	6.7 to 10.8	837.5	≤24 [*]	Urine test	Quarterly	29
Vielot <i>et al⁵⁰</i>	12.6	9.7 to 16.1	500.8	24	Urine test	Quarterly on suspicion only	50
Kaul et al ⁴⁷	13.5	11.3 to 16.1	968.0	≤48 [*]	N/A	N/A	21
Priddy <i>et al⁵⁶</i>	14.2	7.6 to 24.3	91.5	6	Urine test	Quarterly	36
Price <i>et al</i> ⁴⁹	14.5	12.0 to 17.5	784.0	48	Urine test	Quarterly	43
Liu et al ⁵³	15.2	10.4 to 21.5	210.3	6	Self-report	Quarterly	71
Kaewkungwal et al ³⁶	15.8	13.0 to 19.0	721.0†	42	Urine test	N/A	43

Continued

Table 2 Continued

Study	Incidence rate (per 100 person-years)	95% CI	Person- years of exposure	Duration (months)	Measurement of pregnancy		Quality (%)
Vandepitte <i>et al⁹³</i>	18.3	16.2 to 20.6	1467.0	≥24 [*]	Urine test	N/A	50
Page et al ³⁸	22.0	16.3 to 30.1	186.4	12	Self-report	Quarterly	50
Feldblum <i>et al³⁵</i>	23.4	20.6 to 26.5	1067.5	18	Urine test	6 monthly on suspicion only	43

*Duration varied for different participants.

†Person-time estimated by: (n_FSWs * yrs * retention) – (n_preg * yrs/2); where: n_FSWs, number of FSWs enrolled; yrs, study duration in years; retention, retention rate; n_p reg, number of women who became pregnant. We could not use the approach advocated by Vandenbrou c ke *et al* ⁹⁵ as average follow-up time among FSWs was not known.

FSWs, female sex workers; N/A, not measured or reported, data not available from author.

Incidence of pregnancy (intention undefined)

Subgroup analyses showed that study duration and geographic region were sources of heterogeneity for rates of pregnancy where intention was not known. Pregnancy measurement method and study design characteristics did not account for any heterogeneity for this outcome.

There were only two studies of less than 1-year duration^{53 56} (I² 0%). As with the unintended pregnancy outcome, these studies had a higher pooled incidence than studies of more than 1 year duration (14.9 vs 11.4 per 100 person-years).

A subanalysis of geographic region showed that studies from Asia and the Americas (both in Mexico) were more homogenous ($I^2=29.8\%$ and 68.1%, respectively) than those from sub-Saharan Africa ($I^2=98.3\%$). The pooled incidence of pregnancy was higher in Asia (16.8 per 100 person-years) and lower in Mexico (4.8 per 100 person-years; figure 6).

A scatter plot demonstrated a weak positive relationship between quality score and incidence rate (plot not shown; Pearson correlation coefficient 0.55).

Secondary outcomes

Three studies assessed pregnancy outcomes for FSWs (table 3). In two of the studies, outcomes were unknown for about 25% of pregnancies (in the Caribbean³³ and Madagascar,³⁵) resulting in underestimates of birth and abortion incidence. Abortion accounted for less than 20% of pregnancies with known outcomes. In contrast, in the third study, a multicountry study,⁴⁸ 62 abortions were recorded as adverse events (author correspondence), compared with only 10 reported as withdrawing from the

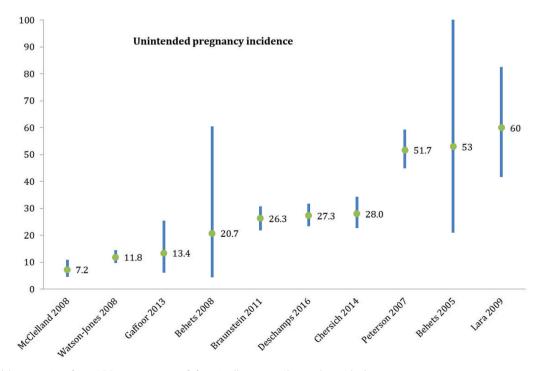


Figure 2 Incidence rates (per 100 person-years) for studies reporting unintended pregnancy.

Study		Incidence rate (95% CI)	Weight %
No intervention			
Braunstein 2011	+	26.30 (21.90, 30.70)	37.55
Chersich 2014	+	28.00 (22.62, 34.26)	21.47
Deschamps 2016	-	27.29 (23.32, 31.74)	40.98
Subtotal (I-squared = 0.0% , p = 0.893)	\$	27.07 (24.37, 29.77)	100.00
Intervention			
McClelland 2008	•	7.20 (4.51, 10.91)	18.69
Watson–Jones 2008	•	11.81 (9.65, 14.45)	18.79
Behets 2005		53.00 (21.00, 110.00)	5.54
Behets 2008	-	20.72 (4.27, 60.54)	9.63
Lara 2009		59.59 (41.73, 82.49)	12.56
Gaffoor 2013		13.40 (6.13, 25.43)	16.99
Peterson 2007		51.75 (44.94, 59.30)	17.80
Subtotal (I-squared = 96.0%, p = 0.000)	\Diamond	27.47 (15.01, 39.92)	100.00

Figure 3 Forest plot showing subgroup analysis of unintended pregnancy incidence rates (per 100 person-years) by intervention versus no intervention.

study due to pregnancy, suggesting that over 85% of the total women who became pregnant reported an abortion.

Four studies developed multivariate regression models to determine the predictors of pregnancy^{35 37} or unintended pregnancy.^{5 33} Common findings were that

younger age was associated with higher pregnancy incidence^{5 33 35} and that highly effective contraceptive use³⁵ and consistent condom use^{35 37} were protective; however, one study in Kenya found that using condoms at the exclusion of other methods was a risk factor.⁵ Having a

	Incidence	%
Study	rate (95% Cl)	Weigh
RCT		
McClelland 2008	7.20 (4.51, 10.91)	23.09
Watson–Jones 2008 +	11.81 (9.65, 14.45)	23.23
Gaffoor 2013	13.40 (6.13, 25.43)	20.72
Behets 2008	20.72 (4.27, 60.54)	11.12
Peterson 2007	→ 51.75 (44.94, 59.30)	21.84
Subtotal (I–squared = 96.8%, p = 0.000)	20.79 (7.84, 33.74)	100.00
Cohort	_	
Braunstein 2011 🔸	26.30 (21.90, 30.70)	31.98
Deschamps 2016	27.29 (23.32, 31.74)	32.53
Chersich 2014 -	- 28.00 (22.62, 34.26)	27.78
Behets 2005	53.00 (21.00, 110.00)	1.49
Lara 2009	• • • • • • • • • •	6.23
Subtotal (I–squared = 63.9% , p = 0.026)	29.57 (24.03, 35.10)	100.00

Figure 4 Forest plot showing subgroup analysis of unintended pregnancy incidence rates (per 100 person-years) by RCT versus cohort study design. RCT, randomised controlled study.

Study	Incidence rate (95% CI)	Weight %
12 months and over		
McClelland 2008	7.20 (4.51, 10.91)	14.81
Watson–Jones 2008	11.81 (9.65, 14.45)	14.92
Braunstein 2011 -	- 26.30 (21.90, 30.70)) 14.58
Gaffoor 2013	13.40 (6.13, 25.43)	12.98
Chersich 2014	► 28.00 (22.62, 34.26	i) 14.24
Peterson 2007	51.75 (44.94, 59.30) 13.84
Deschamps 2016	► 27.29 (23.32, 31.74	4) 14.62
Subtotal (I–squared = 97.0%, p = 0.000)	> 23.54 (14.21, 32.88	3) 100.00
Less than 12 months		
Behets 2005 —	53.00 (21.00, 110.0	00) 22.04
Behets 2008	20.72 (4.27, 60.54)	34.98
Lara 2009	59.59 (41.73, 82.49	9) 42.98
Subtotal (I–squared = 59.1%, p = 0.087)	44.54 (17.93, 71.14	4) 100.00

Figure 5 Forest plot showing subgroup analysis of unintended pregnancy incidence rates (per 100 person-years) by study duration (cut-off 1 year).

main or emotional partner increased the odds of unintended pregnancy^{5 33} but not of pregnancy (intention undefined).^{35 37} Deschamps *et al* noted some additional

associations, including recreational drug use and male partners having other sex partners being protective against pregnancy. Only one study assessed reproductive

	3.	.34 (1.45, 5.22)	52.10
-	5.	.92 (4.05, 8.36)	47.90
\diamond	4.	.58 (2.04, 7.11)	100.00
	8.	.50 (5.60, 11.50)	10.10
			7.32
		. , ,	10.00
) 10.18
	8.	.60 (6.73, 10.83)	10.39
	1	3.53 (11.31, 16.06) 10.30
	22	3.42 (20.61, 26.51) 10.10
•			10.64
•	2.	.70 (2.07, 3.47)	10.64
\diamond	1	1.68 (7.65, 15.71)	100.00
	• 2	2.00 (16.30, 30.10) 18.48
+			
	1		
~ ~		6.80 (13.52, 20.08) 100.00
	*		3.34 (1.45, 5.22) 5.92 (4.05, 8.36) 4.58 (2.04, 7.11)

Figure 6 Forest plot showing subgroup analysis of pregnancy (intention undefined) incidence rates (per 100 person-years) by geographic region.

Table 3 Incidence of abortion and birth

Study	Site	Outcome	Incidence of pregnancy	Incidence of birth	Incidence of abortion	Abortion (as proportion of pregnancies with known outcome)
Deschamps <i>et al³³</i>	Haiti, Puerto Rico and Dominican Republic	Unintended pregnancy	27.3	15.1	3.1	16%
Feldblum <i>et al³⁵</i>	Madagascar	Pregnancy (intention undefined)	23.4	11.9	3.0	17%
Van Damme <i>et al⁴⁸</i>	Benin, Cote d'Ivoire, South Africa and Thailand	Pregnancy (intention undefined)	8.6	Not measured	7.4	>85%

history and income,⁵ and none considered HIV status as potential predictors or confounders.

DISCUSSION

This review found that of the many studies examining FSWs' sexual and reproductive health in LMICs, very few have measured pregnancy and even fewer have assessed pregnancy intention. While incidence varies widely between the included studies, it is sufficiently high in most low-income and middle-income contexts to constitute a significant health and social issue for FSWs.

Study design impacted on unintended pregnancy rates, with a lower rate seen in RCTs (20.8 per 100 person-years) than cohort studies (29.6 per 100 person-years). Most of the RCTs in this review required women to remain non-pregnant for continuation^{36 40 42 44–48} and although only six RCTs specifically mentioned providing contraceptive counselling or methods, others may have offered a larger package of services that was not reported.

To better understand the influence of services provided by studies, we compared studies that provided any intervention with those that did not and found that the three studies in the latter category had very low heterogeneity and high pooled unintended pregnancy incidence (27 per 100 person-years). As non-intervention cohort studies with quality scores of at least 60%, these were arguably the best designed to answer the review question.

The included studies may have underestimated population incidence of pregnancy, for several reasons. First, studies that only tested for pregnancy on suspicion could have missed early pregnancies or failed to ascertain the need to test. Second, pregnancies occurring between study visits and ending in spontaneous or induced abortion may have been missed. Third, social desirability bias is likely to influence self-reporting of pregnancy in studies using that measure. Fourth, participants may have joined some studies in order to access services, potentially receiving superior family planning services than would otherwise be accessible.⁵⁸ Finally, there may be selective loss to follow-up among women who become pregnant, particularly in drug trials requiring women to remain non-pregnant for continuation.^{36 40 42 44-48} It is possible that these factors were more prominent in the studies measuring pregnancy without defining intention, contributing to the surprising finding that this outcome had generally lower incidence rates than unintended pregnancy.

Some 'unintended' pregnancies may in fact have been intended, because women may have been unsure about their intention or it changed over time.²⁷ Only one study assessed intention repeatedly,³⁴ and none used a validated instrument designed to measure this complex latent construct.⁵⁹ Some participants may have wanted a pregnancy but felt pressure to say otherwise, depending on the social environment, external and internal stigma and the study design, for example, if they wanted to access HIV prevention and other services through the study but inclusion was restricted to those not wanting to get pregnant.

Conversely, it is likely that most women in the undefined intention category (outcome 2) who became pregnant may not have intended to do so. During recruitment for a pregnancy prevention intervention trial with FSWs in Kenya,⁶ less than 1% of those interested in taking part were planning to get pregnant in the next year (unpublished data). Similarly, in a cohort study included in this review, only 4% of participants expressed an intention to get pregnant at some point during the 12-month follow-up.⁵³⁴ A study in South Africa found a higher proportion (10%) wishing to conceive, but this is still a small minority of FSWs. While immediate pregnancy intentions may be low, however, future fertility preferences may be comparable with other women,⁶⁰ and several authors have highlighted the need for appropriate services that promote safe conception and address FSWs' need for different forms of protection with different partners.^{22–24 60}

Quality scores were low, but it is important to note that we were assessing how well the studies answered *our* research question, rather than their own stated objectives. However, there was a notable absence of well-described sampling and recruitment techniques, suggesting that study populations may have been poorly representative of local FSW populations. This may have underestimated pregnancy incidence, as more marginalised members of the population, who are at greater sexual risk, are harder to reach and recruit by convenience or snowball methods. Indeed, the only study to use a random sampling approach found moderately high incidence of pregnancy (intention undefined; 15 per 100 person-years), despite 30% IUD coverage in this population.53 Furthermore, inclusion criteria limiting more than half of the studies to HIV negative women contributed to selection bias, particularly in sub-Saharan African studies, where HIV prevalence among FSWs is estimated at 37%.⁶¹ This may partly explain the observation that pregnancy incidence in sub-Saharan Africa was lower than Asia, despite the fact that total population fertility rates are lower in Asia. Higher quality scores seen in the Asian studies may also account for this discrepancy.

Quantitative analysis identified study duration as a clear contributor to heterogeneity in both outcomes. Incidence was lower in shorter studies and decreased over time within studies that reported incidence at multiple time points.^{32 35} This is due in part to the analytical approach, taken by all but one study,³³ of censoring women's persontime when they first become pregnant. As study subjects at highest risk fall pregnant early, they are censored early and cannot contribute additional pregnancies to the numerator. The remaining lower risk women are less likely to experience the outcome. The same phenomenon has been observed in closed cohorts with the outcome of HIV incidence.⁶² In addition, sexual risk behaviours often reduce over time in longitudinal studies, because of social desirability bias or health education from study participation,^{33 36} or attrition bias,⁶³ which may have been a factor for 12 studies in this review with low or unreported retention rates among FSWs.

While measurement bias did not emerge as a significant source of heterogeneity, there was ambiguity in the reporting of pregnancy measurement, and it was often dependent on authors' recollections. There was a weak positive association between study quality and incidence rates in the pregnancy (intention undefined) group. The lack of a clear relationship may be because quality issues can result in either an underestimate or overestimate of incidence.

Limitations

This review had a number of limitations. Foremost was the inclusion of studies in which (unintended) pregnancy incidence was not an a priori objective, which was the case for all but one. This likely resulted in methodological issues affecting participant selection and pregnancy measurement.

We also adopted a broad approach to other inclusion criteria. Several studies conducted in the late 1990s and early 2000s were included, which may be problematic as family planning coverage has grown and fertility rates declined since that time. The heavy reliance on authors to provide unreported data was a limitation and may have introduced bias, and older data often could not be accessed.

We used a broad definition of sex work, which may have increased the heterogeneity of the outcomes. However, this definition reflects the reality that there are many reasons for women to sell sex, which depend on local laws, culture and economies, and to arbitrarily limit to full-time sex workers, for example, may exclude studies of 'hidden' FSWs who are often especially vulnerable.^{64 65}

Our analysis was limited by high heterogeneity, which prevented us from pooling overall rates or performing meta-regression to tease out the influence of different variables. Heterogeneity was not fully explained by explorative subanalyses and may in part be due to the low number of studies, low quality and incomplete data on risk factors. It should be noted that interpretation of these descriptive heterogeneity statistics require a certain level of caution, specifically where the number of cases is small. Variations in baseline population risk probably contributed significantly to heterogeneity, but these could not be quantified due to the incomplete and/or inconsistent measurement of risk factors between studies. Cultural, legal and economic contexts, such as cultural norms around motherhood and abortion law, also vary considerably between the different settings in which the studies took place, and influence fertility preferences, expression of pregnancy intention and access to prevention methods and abortion. These contextual factors could not be accounted for in our analysis.

Another limitation was that we were unable to directly compare rates of pregnancy between FSWs and other populations. Very high pregnancy incidence has been observed in HIV studies among women not categorised as sex workers^{66 67}; however, these women were at high risk for HIV for other reasons (eg, multiple partners). Among the general population, unintended pregnancy incidence is estimated at 5.4 per 100 person-years in the developing world, and eight in Africa,⁶⁸ substantially lower than the rates among FSWs presented here. Of the three studies in this review, which reported incidence for a broader study population as well as an FSW subgroup, two reported higher incidence^{36 42} and one reported approximately equal incidence⁴⁴ in the FSW subgroup compared with the whole study population.

CONCLUSION

Ultimately, this review demonstrates a concerning lack of research on an issue which is a priority for many FSWs in low-resource settings. This is surprising as we found many studies on HIV incidence and prevention in this population, for which unintended pregnancy is both relevant to the primary outcome and may indicate overall sexual risk. There has been

a modest increase in family planning availability for women in many countries since the early 2000s^{69 70}; however, this has not been accompanied by research on whether these additional services have reached FSW populations or impacted on pregnancy rates. Access to family planning, particularly long-acting reversible contraceptives, may be improved by better targeting of FSWs through mobile outreach⁷¹ and integration with existing FSW-specific HIV prevention services, and by careful training of health workers and community workers in contraceptive counselling and follow-up.⁷¹ Also, it is important that concerted efforts are made to link FSWs who become pregnant with maternal health services, including services for antiretroviral treatment and preventing HIV transmission to infants.

This review found that studies measuring pregnancy incidence among FSWs were of low overall methodological quality and had highly varied results but that unintended pregnancy incidence was high overall and, based on available data, higher than the general population. There is an urgent need for quality research on unintended pregnancy incidence, the effectiveness of interventions to reduce it and the best models of reproductive health service provision for this large and stigmatised population.

Author affiliations

¹Burnet Institute, Melbourne, Victoria, Australia

²Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Victoria, Australia

³Judith Lumley Centre, La Trobe University, Melbourne, Victoria, Australia

⁴Faculty of Health Sciences, Wits Reproductive Health and HIV Institute, University of the Witwatersrand, Johannesburg, South Africa

⁵Department of Obstetrics and Gynaecology, International Centre for Reproductive Health, Universiteit Gent, Ghent, Belgium

⁶Melbourne School of Global and Population Health, University of Melbourne, Melbourne, Victoria, Australia

Acknowledgements We would like to acknowledge the many study authors who responded to our queries, in particular the following who provided additional data (in alphabetical order): Daniela Abramovitz, Kathy Baisley, Frieda Behets, Liviana Calzavara, Putu Duff, Paul Feldblum, James Iveniuk, Rupert Kaul, Diana Lara, Qun Li, Kate MacQueen, R. Scott McClelland, Mark Milazzo, Kimberly Page, Matt Price, Barbra Richardson, Merlin L. Robb, Steffanie Strathdee, Douglas Taylor, Abigail Norris Turner, Lut Van Damme, Francois Van Loggerenberg, Judith Vandepitte, Nadja Alexandra Vielot, Handan Wand, Deborah Watson-Jones and Helen Weiss. We would also like to thank senior librarian Lorena Romero at the lan Potter library, who assisted with building the search strategy, and Professor Rory Wolfe, who provided additional statistical advice.

Contributors FHA, SL and MSCL conceived of and designed the study. All authors contributed to the protocol. FHA performed the search, screening, data extraction and analysis and drafted the manuscript. MC advised on search strategy. LW performed duplicate screening and extraction. PAA advised on analytical methods. All authors reviewed drafts and approved the final manuscript.

Funding This work was supported by the Australian National Health and Medical Research Council, which provided funding for the study (Project Grant GNT 1087006), a Career Development Fellowship for SL and a Postgraduate Scholarship for FHA.

Competing interests None declared.

Patient consent Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement There are no additional data available.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

REFERENCES

- Singh S, Darroch JE, Ashford LS. Adding it up: the costs and benefits of investing in sexual and reproductive health. New York: Guttmacher Institute, 2014.
- 2. Hall JA, Benton L, Copas A, *et al*. Pregnancy intention and pregnancy outcome: systematic review and meta-analysis. *Matern Child Health J* 2017;21:670–704.
- Gipson JD, Koenig MA, Hindin MJ. The effects of unintended pregnancy on infant, child, and parental health: a review of the literature. *Stud Fam Plann* 2008;39:18–38.
- Khan MR, Turner AN, Pettifor A, et al. Unmet need for contraception among sex workers in Madagascar. Contraception 2009;79:221–7.
- Luchters S, Bosire W, Feng A, et al. "A Baby was an added burden": predictors and consequences of unintended pregnancies for female sex workers in mombasa, kenya: a mixed-methods study. PLoS One 2016;11:e0162871.
- Ampt FH, Mudogo C, Gichangi P, et al. WHISPER or SHOUT study: protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open* 2017;7:e017388.
- Morineau G, Neilsen G, Heng S, et al. Falling through the cracks: contraceptive needs of female sex workers in Cambodia and Laos,. *Contraception* 2011;84:194–8.
- Scorgie F, Chersich MF, Ntaganira I, et al. Socio-demographic characteristics and behavioral risk factors of female sex workers in sub-saharan Africa: a systematic review. AIDS Behav 2012;16:920–33.
- Okal J, Stadler J, Ombidi W, et al. Secrecy, disclosure and accidental discovery: perspectives of diaphragm users in Mombasa, Kenya. Cult Health Sex 2008;10:13–26.
- Okal J, Chersich MF, Tsui S, et al. Sexual and physical violence against female sex workers in Kenya: a qualitative enquiry. AIDS Care 2011;23:612–8.
- Erickson M, Goldenberg SM, Ajok M, et al. Structural determinants of dual contraceptive use among female sex workers in Gulu, northern Uganda. Int J Gynaecol Obstet 2015;131:91–5.
- Yam EA, Okal J, Musyoki H, et al. Kenyan female sex workers' use of female-controlled nonbarrier modern contraception: do they use condoms less consistently? *Contraception* 2016;93:222–5.
- Maher L, Mooney-Somers J, Phlong P, et al. Condom negotiation across different relationship types by young women engaged in sex work in Phnom Penh, Cambodia. *Glob Public Health* 2013;8:270–83.
- Chow EP, Muessig KE, Yuan L, et al. Risk behaviours among female sex workers in China: a systematic review and data synthesis. PLoS One 2015;10:e0120595.
- Lim MS, Zhang XD, Kennedy E, et al. Sexual and reproductive health knowledge, contraception uptake, and factors associated with unmet need for modern contraception among adolescent female sex workers in China. PLoS One 2015;10:e0115435.
- Williamson LM, Parkes A, Wight D, et al. Limits to modern contraceptive use among young women in developing countries: a systematic review of qualitative research. *Reprod Health* 2009;6:3.
- Dhana A, Luchters S, Moore L, et al. Systematic review of facilitybased sexual and reproductive health services for female sex workers in Africa. Global Health 2014;10:46.
- Moore L, Chersich MF, Steen R, et al. Community empowerment and involvement of female sex workers in targeted sexual and reproductive health interventions in Africa: a systematic review. *Global Health* 2014;10:47.
- Slabbert M, Venter F, Gay C, et al. Sexual and reproductive health outcomes among female sex workers in Johannesburg and Pretoria, South Africa: Recommendations for public health programmes. BMC Public Health 2017;17:442.
- Scorgie F, Nakato D, Harper E, et al. 'We are despised in the hospitals': sex workers' experiences of accessing health care in four African countries. Cult Health Sex 2013;15:450–65.
- Mtetwa S, Busza J, Chidiya S, et al. "You are wasting our drugs": health service barriers to HIV treatment for sex workers in Zimbabwe. BMC Public Health 2013;13:698.

<u>6</u>

Open access

- Beckham SW, Shembilu CR, Brahmbhatt H, et al. Female sex workers' experiences with intended pregnancy and antenatal care services in southern Tanzania. Stud Fam Plann 2015;46:55–71.
- 23. Center for Health and Gender Equity. *All women, all rights, sex workers included*. Washington, DC: CHANGE, 2016.
- Duff P, Shoveller J, Feng Č, et al. Pregnancy intentions among female sex workers: recognising their rights and wants as mothers. J Fam Plann Reprod Health Care 2015;41:102–8.
- Kendall T, Albert C. Experiences of coercion to sterilize and forced sterilization among women living with HIV in Latin America. *J Int AIDS Soc* 2015;18:19462.
- Zampas C, Lamačková A. Forced and coerced sterilization of women in Europe. Int J Gynaecol Obstet 2011;114:163–6.
- 27. Aiken AR, Borrero S, Callegari LS, *et al.* Rethinking the pregnancy planning paradigm: unintended conceptions or unrepresentative concepts? *Perspect Sex Reprod Health* 2016;48:147–51.
- Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. BMJ 2009;339:b2535.
- The World Bank Group. World bank country and lending groups. 2016 https://datahelpdesk.worldbank.org/knowledgebase/articles/ 906519 (accessed 10 Jan 2016).
- Santelli J, Rochat R, Hatfield-Timajchy K, et al. The measurement and meaning of unintended pregnancy. Perspect Sex Reprod Health 2003;35:94–101.
- Munn Z, Moola S, Riitano D, et al. The development of a critical appraisal tool for use in systematic reviews addressing questions of prevalence. Int J Health Policy Manag 2014;3:123–8.
- Braunstein SL, Ingabire CM, Kestelyn E, et al. High human immunodeficiency virus incidence in a cohort of Rwandan female sex workers. Sex Transm Dis 2011;38:385–94.
- Deschamps MM, Metch B, Morgan CA, et al. Feasibility of identifying a female sex worker cohort at high risk of HIV infection in the Caribbean for HIV vaccine efficacy trials: longitudinal results of HVTN 907. J Acquir Immune Defic Syndr 2016;71:70–7.
- Chersich MF, Bosire W, King ola N, et al. Effects of hazardous and harmful alcohol use on HIV incidence and sexual behaviour: a cohort study of Kenyan female sex workers. *Global Health* 2014;10:22.
- Feldblum PJ, Nasution MD, Hoke TH, et al. Pregnancy among sex workers participating in a condom intervention trial highlights the need for dual protection. *Contraception* 2007;76:105–10.
- Kaewkungwal J, Pitisuttithum P, Rerks-Ngarm S, *et al.* Issues in women's participation in a phase III community HIV vaccine trial in Thailand. *AIDS Res Hum Retroviruses* 2013;29:1524–34.
- McClelland RS, Richardson BA, Wanje GH, et al. Association between participant self-report and biological outcomes used to measure sexual risk behavior in human immunodeficiency virus-1seropositive female sex workers in Mombasa, Kenya. Sex Transm Dis 2011;38:429–33.
- Page K, Stein E, Sansothy N, *et al.* Sex work and HIV in Cambodia: trajectories of risk and disease in two cohorts of high-risk young women in Phnom Penh, Cambodia. *BMJ Open* 2013;3:e003095.
- Behets F, Turner AN, Van Damme K, et al. Acceptability and feasibility of continuous diaphragm use among sex workers in Madagascar. Sex Transm Infect 2005;81:472–6.
- 40. Behets FM, Turner AN, Van Damme K, *et al.* Vaginal microbicide and diaphragm use for sexually transmitted infection prevention: a randomized acceptability and feasibility study among high-risk women in Madagascar. *Sex Transm Dis* 2008;35:818–26.
- Lara DK, Grossman DA, Muñoz JE, et al. Acceptability and use of the female condom and diaphragm among sex workers in Dominican Republic: results from a prospective study. *AIDS Educ Prev* 2009;21:538–51.
- Gaffoor Z, Wand H, Daniels B, et al. High risk sexual behaviors are associated with sexual violence among a cohort of women in Durban, South Africa. <u>BMC Res Notes</u> 2013;6:532.
- 43. Strathdee SA, Abramovitz D, Lozada R, et al. Reductions in HIV/ STI incidence and sharing of injection equipment among female sex workers who inject drugs: results from a randomized controlled trial. PLoS One 2013;8:e65812.
- Watson-Jones D, Weiss HA, Rusizoka M, et al. Effect of herpes simplex suppression on incidence of HIV among women in Tanzania. N Engl J Med 2008;358:1560–71.
- McClelland RS, Richardson BA, Hassan WM, *et al.* Improvement of vaginal health for Kenyan women at risk for acquisition of human immunodeficiency virus type 1: results of a randomized trial. *J Infect Dis* 2008;197:1361–8.
- Peterson L, Taylor D, Roddy R, et al. Tenofovir disoproxil fumarate for prevention of HIV infection in women: a phase 2, double-blind, randomized, placebo-controlled trial. *PLoS Clin Trials* 2007;2:e27.

- Kaul R, Kimani J, Nagelkerke NJ, *et al*. Monthly antibiotic chemoprophylaxis and incidence of sexually transmitted infections and HIV-1 infection in Kenyan sex workers: a randomized controlled trial. *JAMA* 2004;291:2555–62.
- Van Damme L, Ramjee G, Alary M, et al. Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-1 transmission in female sex workers: a randomised controlled trial. *Lancet* 2002;360:971–7.
- Price MA, Rida W, Mwangome M, et al. Identifying at-risk populations in Kenya and South Africa: HIV incidence in cohorts of men who report sex with men, sex workers, and youth. J Acquir Immune Defic Syndr 2012;59:185–93.
- Vielot N, Hudgens MG, Mugo N, et al. The role of chlamydia trachomatis in high-risk human papillomavirus persistence among female sex workers in Nairobi, Kenya. Sex Transm Dis 2015;42:305–11.
- Robb ML, Eller LA, Kibuuka H, et al. Prospective study of acute HIV-1 infection in adults in East Africa and Thailand. N Engl J Med 2016;374:2120–30.
- 52. van Loggerenberg F, Mlisana K, Williamson C, *et al.* Establishing a cohort at high risk of HIV infection in South Africa: challenges and experiences of the CAPRISA 002 acute infection study. *PLoS One* 2008;3:e1954.
- Liu J, Calzavara L, Mendelsohn JB, et al. Impact evaluation of a community-based intervention to reduce risky sexual behaviour among female sex workers in Shanghai, China. *BMC Public Health* 2015;15:147.
- 54. Bazzi AR, Rangel G, Martinez G, *et al.* Incidence and predictors of HIV and sexually transmitted infections among female sex workers and their intimate male partners in Northern Mexico: a longitudinal, multilevel study. *Am J Epidemiol* 2015;181:723–31.
- 55. Duff P, Evans JL, Stein ES, *et al.* High pregnancy incidence and low contraceptive use among a prospective cohort of female entertainment and sex workers in Phnom Penh, Cambodia. *BMC Pregnancy Childbirth* 2018;18:128.
- Priddy FH, Wakasiaka S, Hoang TD, et al. Anal sex, vaginal practices, and HIV incidence in female sex workers in urban Kenya: implications for the development of intravaginal HIV prevention methods. *AIDS Res Hum Retroviruses* 2011;27:1067–72.
- Feldblum PJ, Hatzell T, Van Damme K, et al. Results of a randomised trial of male condom promotion among Madagascar sex workers. Sex Transm Infect 2005;81:166–73.
- Stadler J, Scorgie F, van der Straten A, et al. Adherence and the Lie in a HIV prevention clinical trial. *Med Anthropol* 2016;35:503–16.
- Hall J, Barrett G, Mbwana N, et al. Understanding pregnancy planning in a low-income country setting: validation of the London measure of unplanned pregnancy in Malawi. *BMC Pregnancy Childbirth* 2013;13:200.
- Rao A, Baral S, Phaswana-Mafuya N, et al. Pregnancy intentions and safer pregnancy knowledge among female sex workers in Port Elizabeth, South Africa. Obstet Gynecol 2016;128:15–21.
- Baral S, Beyrer C, Muessig K, *et al.* Burden of HIV among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. *Lancet Infect Dis* 2012;12:538–49.
- Heyward WL, Osmanov S, Saba J, et al. Preparation for phase III HIV vaccine efficacy trials: methods for the determination of HIV incidence. AIDS 1994;8:1285–91.
- Graham SM, Raboud J, McClelland RS, et al. Loss to follow-up as a competing risk in an observational study of HIV-1 incidence. PLoS One 2013;8:e59480.
- Hawken MP, Melis RD, Ngombo DT, et al. Part time female sex workers in a suburban community in Kenya: a vulnerable hidden population. Sex Transm Infect 2002;78:271–3.
- Manopaiboon C, Prybylski D, Subhachaturas W, et al. Unexpectedly high HIV prevalence among female sex workers in Bangkok, Thailand in a respondent-driven sampling survey. Int J STD AIDS 2013;24:34–8.
- MacQueen KM, Johnson L, Alleman P, et al. Pregnancy prevention practices among women with multiple partners in an HIV prevention trial. JAIDS Journal of Acquired Immune Deficiency Syndromes 2007;PAP:32–8.
- Halpern V, Lie CC, Feldblum P, et al. Predictors of pregnancy in microbicide trials. *Contraception* 2011;83:436–40.
- Sedgh G, Singh S, Hussain R. Intended and unintended pregnancies worldwide in 2012 and recent trends. *Stud Fam Plann* 2014;45:301–14.
- 69. Wang W, Wang S, Pullum T, *et al.* How family planning supply and the service environment affect contraceptive use: findings from four East African Countries. *DHS Analytical Studies* 2012:26.
- Ross J, Smith E. Trends in national family planning programs, 1999, 2004 and 2009. *Int Perspect Sex Reprod Health* 2011;37:125–33.

- Rees H, Pillay D, Mullick S, et al. Strengthening implant provision and acceptance in South Africa with the 'Any woman, any place, any time' approach: An essential step towards reducing unintended pregnancies. S Afr Med J 2017;107:939–44.
- 72. Penman-Aguilar A, Legardy-Williams J, Turner AN, *et al.* Effect of treatment assignment on intravaginal cleansing in a randomized study of the diaphragm with candidate microbicide. *J Womens Health* 2011;20:187–95.
- Braunstein SL, Ingabire CM, Geubbels E, et al. High burden of prevalent and recently acquired HIV among female sex workers and female HIV voluntary testing center clients in Kigali, Rwanda. PLoS One 2011;6:e24321.
- Deschamps MM, Zorrilla CD, Morgan CA, et al. Recruitment of Caribbean female commercial sex workers at high risk of HIV infection. *Rev Panam Salud Publica* 2013;34:92–8.
- Skoler-Karpoff S, Ramjee G, Ahmed K, et al. Efficacy of Carraguard for prevention of HIV infection in women in South Africa: a randomised, double-blind, placebo-controlled trial. *Lancet* 2008;372:1977–87.
- Martin HL, Nyange PM, Richardson BA, et al. Hormonal contraception, sexually transmitted diseases, and risk of heterosexual transmission of human immunodeficiency virus type 1. *J Infect Dis* 1998;178:1053–9.
- McClelland RS, Richardson BA, Graham SM, et al. A prospective study of risk factors for bacterial vaginosis in HIV-1-seronegative African women. Sex Transm Dis 2008;35:617–23.
- McClelland RS, Richardson BA, Hassan WM, et al. Prospective study of vaginal bacterial flora and other risk factors for vulvovaginal candidiasis. J Infect Dis 2009;199:1883–90.
- Odutola A, Baisley K, Hayes RJ, et al. Pregnancy and contraceptive use among women participating in an HIV prevention trial in Tanzania. Sex Transm Infect 2012;88:436–43.
- Syvertsen JL, Robertson AM, Abramovitz D, *et al.* Study protocol for the recruitment of female sex workers and their non-commercial partners into couple-based HIV research. *BMC Public Health* 2012;12:1–16.
- Couture MC, Sansothy N, Sapphon V, et al. Young women engaged in sex work in Phnom Penh, Cambodia, have high incidence of HIV and sexually transmitted infections, and amphetamine-type stimulant use: new challenges to HIV prevention and risk. Sex Transm Dis 2011;38:33–9.
- Hoke TH, Feldblum PJ, Van Damme K, *et al.* Temporal trends in sexually transmitted infection prevalence and condom use following introduction of the female condom to Madagascar sex workers. *Int J STD AIDS* 2007;18:461–6.

- Rerks-Ngarm S, Pitisuttithum P, Nitayaphan S, et al. Vaccination with ALVAC and AIDSVAX to prevent HIV-1 infection in Thailand. N Engl J Med 2009;361:2209–20.
- Yadav G, Saskin R, Ngugi E, et al. Associations of sexual risk taking among Kenyan female sex workers after enrollment in an HIV-1 prevention trial. J Acquir Immune Defic Syndr 2005;38:329–34.
- Fonck K, Kaul R, Kimani J, et al. A randomized, placebo-controlled trial of monthly azithromycin prophylaxis to prevent sexually transmitted infections and HIV-1 in Kenyan sex workers: study design and baseline findings. *Int J STD AIDS* 2000;11:804–11.
- McClelland RS, Graham SM, Richardson BA, et al. Treatment with antiretroviral therapy is not associated with increased sexual risk behavior in Kenyan female sex workers. AIDS 2010;24:891–7.
- Rono K, Sanga E, Sekiziyivu A, et al. RV 217: The early capture HIV cohort study (ECHO): a prospective study of acute hiv infection among high risk populations. *AIDS Research and Human Retroviruses* 2010;26:A33.
- Vera A, Abramovitz D, Lozada R, *et al.* Mujer Mas Segura (Safer Women): a combination prevention intervention to reduce sexual and injection risks among female sex workers who inject drugs. *BMC Public Health* 2012;12:653.
- Gaines TL, Rudolph AE, Brouwer KC, et al. The longitudinal association of venue stability with consistent condom use among female sex workers in two Mexico-USA border cities. *Int J STD AIDS* 2013;24:523–9.
- Vandebosch A, Goetghebeur E, Ramjee G, et al. Acceptability of COL-1492, a vaginal gel, among sex workers in one Asian and three African cities. Sex Transm Infect 2004;80:241–3.
- Ramjee G, Williams B, Gouws E, et al. The impact of incident and prevalent herpes simplex virus-2 infection on the incidence of HIV-1 infection among commercial sex workers in South Africa. J Acquir Immune Defic Syndr 2005;39:333–9.
- Naicker N, Kharsany AB, Werner L, et al. Risk factors for HIV acquisition in high risk women in a generalised epidemic setting. *AIDS Behav* 2015;19:1305–16.
- Vandepitte J, Weiss HA, Kyakuwa N, et al. Natural history of Mycoplasma genitalium infection in a cohort of female sex workers in Kampala, Uganda. Sex Transm Dis 2013;40:422–7.
- Vandepitte J, Bukenya J, Weiss HA, et al. HIV and other sexually transmitted infections in a cohort of women involved in highrisk sexual behavior in Kampala, Uganda. Sex Transm Dis 2011;38:1–23.
- Vandenbroucke JP, Pearce N. Incidence rates in dynamic populations. *Int J Epidemiol* 2012;41:1472–9.