

OPERATIONS RESEARCH METHODOLOGY OPTIONS

Assessing Integration of Sexual and
Reproductive Health and HIV Services
for Key Affected Populations





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1 INTRODUCTION

1.1 Context

The Asia-Pacific region has seen impressive progress, including a 20% reduction in new HIV infections since 2001, yet the epidemic still outpaces the response—there are almost two new HIV infections for every person on treatment (UNAIDS 2011). The vast majority of epidemics in the Asia-Pacific region remain concentrated among key affected populations (KAPs) at higher risk of HIV: sex workers, men who have sex with men (MSM), transgender people and people who inject drugs (PWID) (UNAIDS 2011). Given that the region comprises 60% of the global population—including three of the four most populous nations in the world, China, India, and Indonesia—even relatively low HIV prevalence translates into a large absolute number of HIV-positive people (Population Reference Bureau 2012). In 2011, some five million people were living with HIV across South Asia, Southeast Asia, and East Asia. Of those, approximately one-third were women, and three-fourths were concentrated among KAPs (UNAIDS 2011).

HIV programs among KAPs often focus on access to condoms and STI diagnosis and treatment and have largely missed the opportunity to address the broader reproductive health needs of female KAPs. However, the same risk behavior – unprotected intercourse – can lead to HIV infection and unwanted pregnancy, and an integrated approach to addressing both sexual and reproductive health (SRH) and HIV among these populations is urgently needed. Furthermore, linked SRH-HIV programs are an effective and efficient strategy for improving coverage and uptake of both SRH and HIV services, reducing HIV-related stigma and discrimination, reducing redundancies in vertical programs, and reducing vertical HIV transmission (Kennedy et al. 2010).

While there is strong policy commitment to integration of SRH and HIV services (WHO et al. 2005; IATT 2011), there is limited experience in how to tailor integration of services in concentrated epidemics so that they reach women at higher risk of HIV, especially female sex workers (FSWs), women who inject drugs and female partners of men who inject, including those living with HIV (Petruney et al. 2012; UNFPA 2012).

There is a growing body of evidence demonstrating that FSWs in the region are at elevated risk of both HIV and unwanted pregnancy. For example, 60% of FSWs in Bangladesh reported an unmet need for family planning (FP) (Katz et al. 2011), and in studies of Indian and Laotian FSWs, one-fourth had ever had an abortion (Morineau et al. 2011; Wayal et al. 2011). Although condom use among FSWs with clients has increased dramatically in Asia (UNAIDS 2011), correct and consistent usage with clients is not the norm (Lau et al. 2007; Katz et al. 2011; Morineau et al. 2011). Condom use is even less consistent with regular intimate partners of FSWs, such as boyfriends or husbands (Lau et al. 2007; Minichiello et al. 2011; Wayal et al. 2011). Use of FP methods other than condoms among FSWs is also low in Asia. For example, prevalence of use of non-barrier FP methods was 53% in India (Wayal et al. 2011), 65% in Afghanistan (Todd et al. 2010), and 1.6%–5.2% in Cambodia (Delvaux et al. 2003).

Greater attention is needed to ensure female KAPs have access to the full range of contraceptive methods to enable them to use condoms and another form of contraception, that are most effective for preventing HIV and unwanted pregnancy and that best meet their needs (Petruney et al. 2012). Dual method contraception is important given the greater efficacy of contraceptive methods other than condoms in preventing pregnancy (Hatcher et al. 2007; Trussell 2011). So too, pregnant

female KAPs also need access to antenatal, delivery, and postnatal care, including PMTCT services.

HIV programs for KAPs provide critical entry points to enable:

- Provision of counseling and the full range of contraceptive methods
- Access to HIV testing, to know their HIV status and as central to planning pregnancy and HIV prevention, treatment and care
- Access to antenatal, delivery and post natal care including access to antiretroviral drugs both for the mothers' own health and to prevent infection to their children during pregnancy, delivery and breastfeeding
- Access to safe abortion, subject to legal context, and post abortion care
- Access to services and support to respond to GBV including emergency contraception, post exposure prophylaxis (PEP), effective referral for diagnosis and treatment of STIs and counseling and legal support.

Criminalization of KAPs and/or high levels of stigma and discrimination against sex workers, MSM, transgender people compound their vulnerability to HIV and undermine access to services. Legal barriers, stigma and discrimination, and programmatic limitations are formidable barriers to effective integrated SRH-HIV services for female KAPs. For example, all countries in the Asia-Pacific region criminalize aspects of sex work, except New Zealand and New South Wales (Australia) (UNDP, UNFPA 2012). FSWs are heavily stigmatized, and discrimination in service delivery settings is pervasive, including refusal of service, abusive treatment, or coercive abortion, all of which further hinder access to SRH services and frequently violate their reproductive rights (Delvaux et al. 2003; Todd et al. 2010; Chakrapani et al. 2011).

Despite the recognition of the importance of integrating SRH and HIV services to effectively prevent HIV transmission and unwanted pregnancy, programmatic experience remains largely focused on integration suited to generalized HIV epidemics (Petruney et al 2012). For example, there has been considerable progress integrating HIV prevention of mother-to-child transmission

(PMTCT) within maternal and child health (MCH) services. However, this has led to a focus on HIV testing of pregnant women who attend MCH services, which female KAPs often do not access. There is substantial need for integration between HIV and SRH services tailored to the epidemiological context in this region.

This report describes an operations research agenda to assess integration of SRH and HIV services to meet the needs of female KAPs. (See Scope below for details).

1.2 Report overview

Purpose

This OR methodology report provides a generic guide to support operations research (OR) in countries in the Asia-Pacific region. It provides options for OR to assess the quality and impact of HIV and SRH integrated and linked services to meet the HIV and SRH needs of female KAPs, especially female sex workers.

Scope

The focus of this report is on female KAPs, as the sexual health needs of MSM and transgender people, such as ensuring non-discriminatory access to STI diagnosis and treatment services and psychosocial support to increase self-esteem and improve health-seeking behavior, are already key elements of the HIV response. However, integration of the reproductive health needs of female KAPs is often neglected. Although the report focuses primarily on female sex workers, it can be adapted and used for other key affected populations such as women who inject drugs and the female partners of men who inject drugs.

Structure

The report provides an overview of study designs for country level operations research, and a set of indicators that can be adapted to countries needs to measure quality and uptake of integrated or linked services. It sets out approaches to country level implementation and options for regional level support to country level OR. The report will be used to advocate for, design, and implement operations research studies in countries in the region and in doing so will contribute to building the evidence base about what works in integrating SRH and HIV services in concentrated epidemics.

2 PROPOSED STUDY DESIGNS FOR COUNTRY OPERATIONS RESEARCH

This OR methodology report provides a guide to support operations research (OR) in countries in the Asia-Pacific region to assess the impact of integration of and linkages between HIV and SRH services on the uptake of services and change in knowledge and behaviors among female sex workers. Given that different countries will implement SRH-HIV integration models in different ways and over different time periods, we envisage that the design of the OR will be adapted to each country's needs. In this section we provide an outline of proposed approaches for studies in different country settings.

Integration of SRH and HIV to provide comprehensive services involves brokering partnerships between sex-worker communities/community-based HIV programs and health services and implementing a variety of strategies to:

- promote demand-generation strategies and uptake of services, e.g., tailored IEC materials, peer outreach, and education;
- reduce stigma and discrimination in healthcare settings;
- facilitate effective referral (e.g., protocols, accompanied referral mechanisms); and
- facilitate service delivery in community based settings (e.g., contraceptive counseling and access to a full range of contraceptive methods in community-based settings).

Operations research allows these strategies to be evaluated to assess their effectiveness and the extent to which SRH and HIV integration has taken place. Various research methodologies are available for country programs to select from based on the population of interest and the research question being asked; these include both quantitative and qualitative research techniques.

Quantitative methods allow programs to measure performance progress, to evaluate services/interventions and to provide results that can be generalized to other settings. Quantitative study designs include experimental designs (gold standard), quasi-experimental designs, and non-experimental study designs; each of these may be appropriate for different settings. Experimental and quasi-experimental designs are generally preferred over non-experimental study designs. Experimental designs control for confounding variables through random assignment and are the gold standard for demonstrating causality, i.e., the change in the outcome of interest has resulted from an exposure to the intervention. Quasi-experimental designs also provide a fairly robust evaluation by including a comparison group without random assignment. Qualitative methods, on the other hand, provide detailed and in-depth information examining the 'how' and 'why' of a situation or problem. Qualitative methods provide supplementary and explanatory data to augment the findings from quantitative surveys. The most frequently used qualitative methods include focus group discussions (FGDs), in-depth interviews (IDIs), and direct observation. Details on various quantitative and qualitative methods are provided in Annex 1.

A study design is a basic plan or strategy for investigating the research question. Selecting a study design requires careful consideration of ethical issues, technical requirements, and available resources. Factors that should be considered while selecting a study design include:

- **Purpose of the study:** Whether the question is to monitor trends in output and outcome indicators or to determine whether the changes in the output or outcome indicators are due to the program. Is the aim of the study to explore or obtain an in-depth understanding of the reasons behind certain behaviors?
- **Appropriateness:** Can the study design answer the specific question?
- **Causality:** Does causality need to be ascertained? If yes, then with what confidence can cause and effect be inferred from the study?
- **Comparison group:** Is there a possibility of identifying/having a comparison group or control group?
- **Ethical issues:** The study design should not violate people's rights or deny services that are proven to be effective.
- **Resources:** Availability of funds, time, and personnel.
- **Threats to validity:** The extent to which the design is able to capture what it is intended to measure.¹

A decision tree is provided in Figure 1 to help country program managers decide on an appropriate design for their population and field setting. Detailed information

on various research methodologies and sampling strategies are provided in Annex 1: Research methodology.

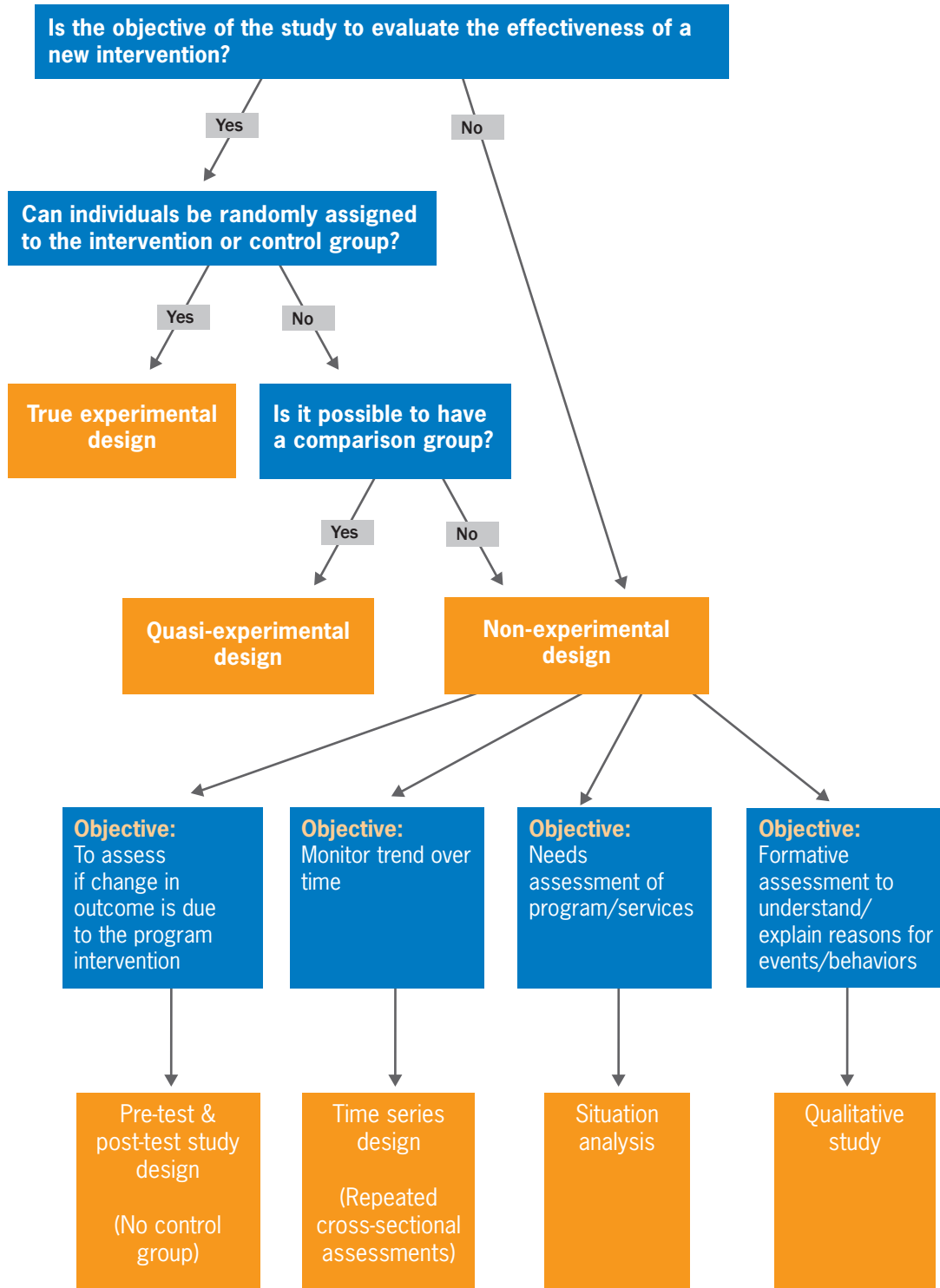
Country program managers would find it beneficial to select a study design only after a careful review of field settings, the target population, and related needs and gaps. A formative assessment is often essential to obtain information on the local population, services available, health provider views, and barriers to and to some extent the future acceptability of proposed interventions. Therefore, in all settings we propose undertaking a short qualitative formative assessment as a first step, to understand health-facility settings and services and the utilization of services by female sex workers. The formative assessment may be undertaken as a formal research study with ethical approvals or informally as discussions with providers or the target population. For a qualitative assessment the following activities are proposed:

- Focus group discussions (FGDs) with health providers at selected health facilities,
- Focus group discussions/in-depth interviews (IDIs) with female sex workers, and/or
- Key informant interviews (KIs) with key program managers and site managers.

The number of FGDs and KIs will depend on the geographic area in which the project is being planned. Findings from these interviews will be used to finalize the study design. For instance, a randomized controlled trial typically requires a cohort of study participants to be followed over time. FGDs with health providers and FSWs will allow the researchers to decide if it is feasible to follow a cohort of FSWs or whether the study design should consider a survey with two different random samples of FSWs to assess change in behaviors or uptake of services. Similarly, FGDs or KIs will also allow researchers to explore the acceptability of the proposed interventions; for instance would FSWs be willing to visit specific SRH services or what specific SRH services such as family planning might be feasible to deliver within existing HIV programs for KAPs in a given context. Researchers will prepare a detailed OR proposal with study design, sample size calculations, research staff requirements,

1 Threats to validity include **History:** events occurring concurrently during the project can influence the outcome; **Maturation** of people and programs can produce changes that are independent of the program; **Testing:** earlier measurements can affect the results of the later measurement; **Instrumentation:** changes in instruments, observers, or scorers can change the outcome; **Regression to the mean:** a tendency for persons or groups who scored at the extreme low end of a range of scores to achieve a higher score on a subsequent measurement; **Selection:** when participants selected in the control group differ greatly from participants in the intervention group; and **Differential mortality:** in longitudinal cohort studies (where the same group of people are followed over time) when participants who are lost to follow up differ greatly from those who continue, the difference observed in the outcome at posttest may be due to the loss of cases rather than the effect of intervention.

Figure 1: Decision tree for program managers



data collection instruments, and an analysis plan using findings from the formative assessment. The formative assessment and proposal writing should be completed in approximately two to three months for each study.

Following the formative assessment, country program managers could select a study in consultation with relevant stakeholders. The following section describes different country settings and provides suggestions on suitable study designs.

2.1 Settings with SRH-HIV integration pilot projects

Proposed methodology

In settings where SRH-HIV integration is to be initiated as a **pilot project** to demonstrate feasibility and where program managers would like to assess effectiveness of the proposed intervention model, a **pretest-posttest group quasi-experimental design** is proposed. Wherever possible a true experimental design will be considered, that is if randomization of study sites (health facilities within districts) or study participants is possible. The study will use mixed methods; both quantitative and qualitative data will be collected to assess effectiveness (Grissmer et al. 2009). As SRH-HIV integration activities cannot be delayed in the control sites beyond a reasonable period and programs need effectiveness results to be made available at the earliest opportunity so that an effective intervention can be scaled up, the duration of the study will be a key consideration.

An illustrative example:

An 18-month study is proposed to assess the effectiveness of an integrated SRH-HIV services pilot model for FSWs in a large province. Two to four FSW drop-in centers/health facilities assigned to the intervention group provide integrated SRH-HIV services while 2–4 health facilities assigned to the control arm provide routine services (randomization of study sites to be done if possible).

Successful integration will be evaluated at three project levels: (i) provision of comprehensive SRH-HIV services

on site or through linkages with other service delivery points (SDPs), (ii) improved health provider attitudes at SDPs, and (iii) increased uptake of SRH services such as family planning and MCH by FSWs in the community in the geographical coverage area of the health facilities. These indicators will be compared at baseline and end-line to assess the level of positive change.

Recruitment of study participants

Health provider interviews: To assess provider training (process indicators), provider knowledge (output indicators), and provider attitudes toward FSWs (outcome indicators) interviews will be conducted with health providers at the drop-in center and at referral SDPs such as MCH and FP services. A simple random selection of participants will be made from a list of providers and the same participants will be interviewed at two time points.

FSW client exit interviews: To assess client perspectives on quality of services, to identify gaps in services, and to assess knowledge (output indicator) and uptake of services such as FP (outcome indicator), FSW clients accessing services at participating health facilities will be interviewed before they leave the health facility (exit interviews). Systematic random sampling will be used and a separate sample of FSWs will be interviewed at two data collection points.

FSW community survey: To assess the impact of SRH-HIV integration in the FSW population in the larger community, that is, documented change in behaviors and increased uptake of services by FSWs, a survey will be conducted among a representative sample of FSWs recruited from the FSW population in the coverage area of the health facilities using time location cluster sampling since lists are difficult to obtain or compile for hard-to-reach marginalized populations. Two different representative samples of FSWs will be interviewed in the community, as it may be logistically difficult and expensive to follow a large cohort of FSWs in the community.

In the intervention arm, regular monitoring of the intervention is planned to ensure that the model is implemented as planned. As illustrated in Table 1, facility-level indicators drawn from service statistics (5 data points),

Table 1: Proposed activities and data collection pretest-posttest group (QED)

Activities	Intervention sites					Control sites				
	SRH-HIV Integration Model					Routine services (no intervention)				
	BL	4 months	9 months	12 months	EL	BL	4 months	9 months	12 months	EL
Facility assessment Service statistics (5 rounds of data collection in intervention and 2 rounds in control sites)	√	√	√	√	√	√		√		√
Provider interviews (3 rounds of data collection)	√		√		√	√		√		√
Client exit interviews (3 rounds of data collection)	√		√		√	√		√		√
Community survey with FSWs (2 rounds of data collection)	√				√	√				√

BL: Baseline at 0 months; EL: Endline at 18 months

provider-level indicators (3 data points), and client-level indicators (3 data points) will be collected at regular intervals through facility assessments, provider interviews, and FSW client exit surveys. This information will be used to feed back into model development and refinement through discussion with program managers. Monitoring data will be available as panel data that will also be linked to the evaluation of the intervention.

In the control sites, monitoring data will be collected at three time points to provide comparative data for analysis. Data will be analyzed to compare the two groups on key outcomes at endline.

Illustrative timeline

Formative assessment and finalization of study proposal	1–2 months
Study set up (site selection, hiring and training staff)	1–2 months
Implementation of the 18 month study	18 months
Data cleaning, data analysis, and final report writing	3–4 months

2.2 Settings with phased-in introduction of SRH-HIV integration activities

Proposed methodology

In settings where SRH-HIV integration is to be introduced in a phased manner across different districts or provinces and program managers want to consider assessing effectiveness of the proposed intervention model, we propose a quasi-experimental method.

Phased-in pretest-posttest control design.

A district where the intervention is introduced in the first phase will serve as the intervention district and a district where a delayed roll out of the intervention is planned will serve as the control group. A key consideration will be planning the study within the time period before activities are rolled out in the control district.

An illustrative example

An 18-month study is proposed to assess the effectiveness of provision of a model of integrated SRH-HIV services for FSWs in two districts. Six to eight FSW drop-in centers/health facilities providing integrated SRH-HIV services in the district where the intervention is being rolled out in phase 1 will be assigned to the intervention group while 6–8 health facilities from the district where

a delayed roll out is planned will be assigned to the control arm. In both groups, where possible, a random selection of study sites is envisaged.

Successful integration will be evaluated at three levels: (i) provision of comprehensive SRH-HIV services on site or through linkages with other SDPs, (ii) improved health provider attitudes at SDPs, and (iii) increased uptake of SRH services such as family planning and MCH by FSWs in the community in the geographical coverage area of the health facilities. FSWs in the community will be recruited using time location cluster sampling or respondent-driven sampling to obtain a representative sample of the target population. All data will be collected at baseline, end of phase 1, and at endline.

Recruitment of study participants

Health provider interviews: To assess provider training (process indicators), provider knowledge (output indicators), and provider attitudes toward FSWs (outcome indicators) interviews will be conducted with health providers at the drop-in center and at referral SDPs such as MCH and FP services. A simple random selection of participants will be made at each site; the same providers will be interviewed at all three data collection time points.

FSW client exit interviews: To assess client perspectives on quality of services, to identify gaps in services, and to assess knowledge (output indicator) and uptake of services such as FP (outcome indicator) FSW clients accessing services at participating health facilities will be interviewed before they leave the health facility (exit interviews). Systematic random sampling will be used and a separate sample of FSWs will be interviewed at three data collection points.

FSW community survey: To assess the impact of SRH-HIV integration in the FSW population, that is, documented change in behaviors and increased uptake of services by FSWs, a survey will be undertaken with a representative sample of FSWs recruited from the FSW population in the coverage area of the health facilities using time location cluster sampling since lists are difficult to obtain or compile for hard-to-reach marginalized populations. Three cross-sectional surveys will be conducted with different representative samples of FSWs as it may be logistically difficult and expensive to follow a large cohort of FSWs in the community.

Data analysis will be possible at three levels (see Table 2).

- At the first level, data from the two groups will be compared at the end of phase 1 to assess effectiveness of the intervention (two independent group comparative analyses).

Table 2: Proposed activities and data collection for the phased-in pretest-posttest control group, duration 18 months

Activities	Intervention sites			Control sites		
	SRH-HIV Integration Model (rolled out from baseline)			Routine services (no intervention) SRH-HIV Integration Model rolled out		
	Baseline	Midline	Endline	Baseline	Midline	Endline
Facility assessment Service statistics (3 rounds of data collection)	√	√	√	√	√	√
Provider interviews (3 rounds of data collection)	√	√	√	√	√	√
Client exit interviews (3 rounds of data collection)	√	√	√	√	√	√
Community survey with FSWs (3 rounds of data collection)	√	√	√	√	√	√

Baseline at 0 months; Midline at 9 months; Endline at 18 months.

Table 3: Proposed activities and data collection for pretest-posttest one-group study design, duration 12 months

Activities	Intervention sites	
	SRH-HIV Integration Model (rolled out at all sites from baseline)	
	Baseline	Endline
Facility assessment Service statistics (2 rounds of data collection)	√	√
Provider interviews (2 rounds of data collection)	√	√
Client exit interviews (2 rounds of data collection)	√	√
Community survey with FSWs (2 rounds of data collection)	√	√

Baseline at 0 months; Endline at 12 months.

- At the second level a pretest-posttest analysis of data from the control group is proposed (same group pre-intervention and post-intervention comparative analysis) to document within-group change in a separate district.
- At the third level an endline comparative assessment will be undertaken to document differences in behavior change and uptake of services among FSW clients and health providers in the two groups; comparative analysis of a mature longer duration intervention vs. a newly introduced intervention.

Illustrative timeline:

Formative assessment and finalization of study proposal	2 months
Study set up (site selection, hiring and training staff)	1–2 months
Implementation of the 18-month study	18 months
Data cleaning, data analysis and final report writing	3–4 months

2.3 Settings with large-scale roll out of SRH-HIV integration activities

In settings where SRH-HIV integration is to be introduced across all health centers in selected districts or provinces and where program managers would like to document change in behaviors or uptake of services as a result of the intervention we propose a non-experimental **pretest-posttest one-group study design.**

An illustrative example

A 12-month study is proposed to document change in behaviors of providers and FSW clients and an increase in uptake of services by FSWs as a result of an SRH-HIV integrated service delivery intervention. As there is no likelihood of obtaining a control group, or in cases where the effectiveness of an intervention is known and program managers would like to document the magnitude of change, we propose to use the pre-intervention phase as the control period measurement and the post-intervention measurement as the posttest measure. In a district 8–10 FSW-focused drop-in-centers/health facilities would be randomly selected to participate in the study. A baseline assessment and data collection would be followed with the roll out of SRH-HIV integration activities; a second endline assessment and data collection

would be undertaken at the end of the stipulated duration of the intervention.

Successful integration will be evaluated at three levels: (i) provision of comprehensive SRH-HIV services on site or through linkages with other SDPs, (ii) improved health provider attitudes at SDPs, and (iii) increased uptake of SRH services such as family planning and MCH by FSWs in the community in the geographical coverage area of the health facilities. FSWs in the community will be recruited using time location cluster sampling of the target population. All data will be collected at baseline and at endline.

Service statistics and health facility data will be used as monitoring indicators to feed back into the intervention model to ensure that it delivers the intervention as planned. Data analysis would entail a repeated measure analysis to assess change in uptake of services and behaviors among FSWs and providers.

Illustrative timeline

Formative assessment, finalization of study proposal, and study set up (site selection, hiring and training staff)	3 months
Implementation of the 11-month study	12 months
Data cleaning, data analysis and final report writing	3 months

3 CORE INDICATORS

To assess project performance and facilitate comparison across activities and geographic contexts, the scope of this OR methodology includes tracking a set of core indicators. These core indicators comprise a common monitoring and evaluation framework that is potentially applicable for all country initiatives.² The service delivery interventions focus on generating demand for and delivery of quality SRH and HIV services to female sex workers. Therefore, the primary core indicators measure *individual-level* and *provider-level* changes in outputs (i.e., skills and knowledge of FSWs and service providers) and outcomes (i.e., behaviors of FSWs and service providers). In addition, *facility-level* indicators assess the availability and quality of SRH-HIV service provision for FSWs. Finally, *policy-level* indicators track the extent to which laws and policies create an enabling environment to promote access to quality HIV and SRH services for FSWs and are most useful to track at the country level. *Country program indicators*, a subset of policy indicators, track the extent to which evaluated programs have been used to advocate for uptake and scale up among decisionmakers. Figure 2

2 Because interventions are designed in collaboration with local implementation partners with the input of local KAPs, the specific aims and design of activities varies across countries and regions. Due to the context-specific nature of program implementation, individual activities may call for tailored programmatic indicators in addition to the core indicators. Program implementers and KAPs identify these local programmatic indicators during the initial planning and conceptualization phase of each country-specific initiative and, therefore, are not the focus of this discussion of the overarching core indicators.

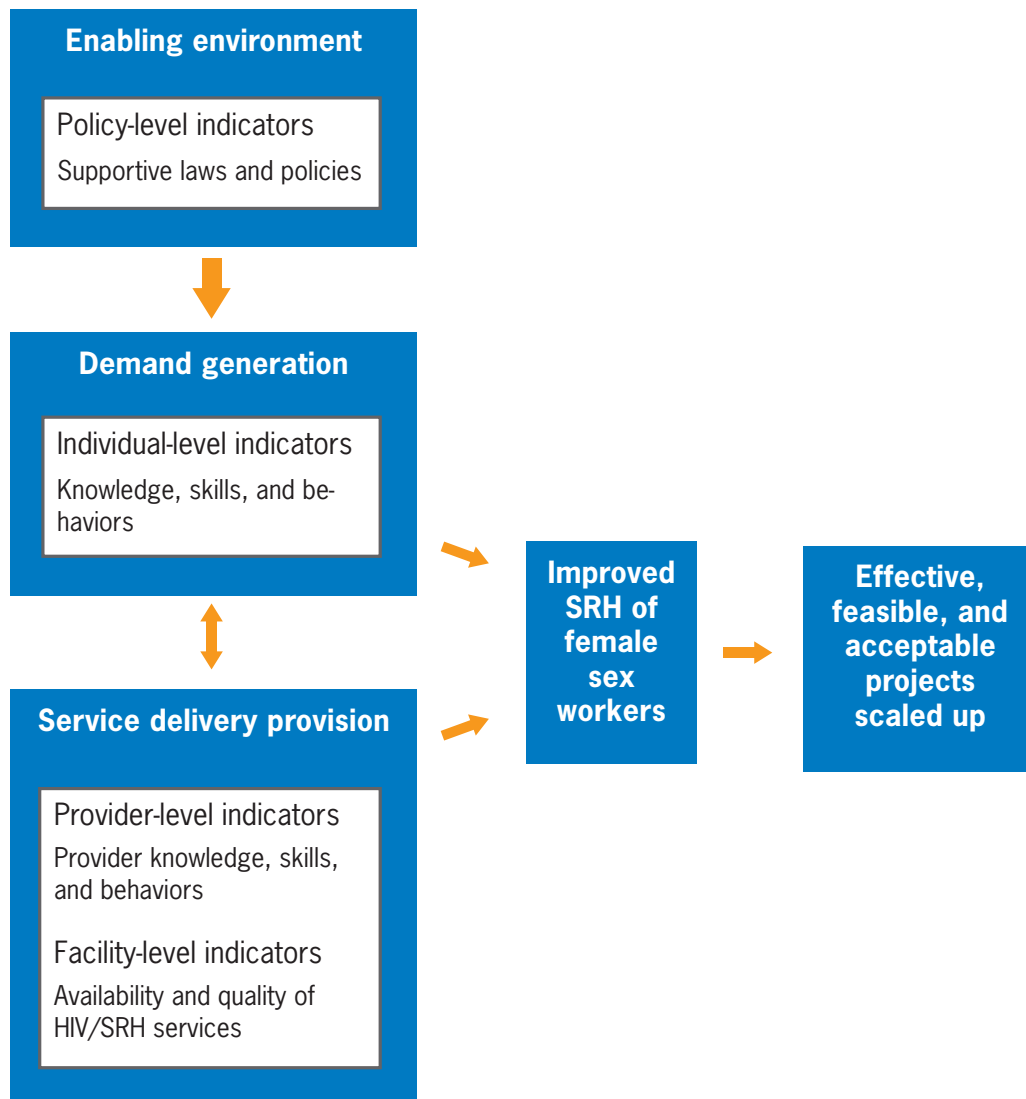
displays how these four broad categories of indicators assess demand generation, service delivery provision, and enabling environments, all of which are connected in causal pathways that can lead to the improved SRH of FSWs.

3.1 Enabling environment: Policy-level indicators

These indicators assess the extent to which policies, laws, and programs support an enabling environment for FSWs to access quality confidential SRH and HIV services and information. Although HIV policies often mention FSWs as KAPs in terms of their HIV risk, few policies explicitly address the SRH needs of these women, above and beyond HIV prevention. For the purposes of documenting the extent to which an enabling environment exists to address both HIV and SRH among FSWs, ideally the policy-level indicators for this regional project refer specifically to those policies that explicitly address linkages between HIV and SRH services for FSWs. Examples of such policies include – but are not limited to – international declarations or commitments, national laws, donor policies, and facility service-delivery protocols.

Specifically, these policies might address key issues related to FSWs' sexuality and reproduction, such as:

- human rights,
- stigma and discrimination,
- gender equality,

Figure 2: Project indicators conceptual framework

- integrated provision (either directly or through referrals) of both HIV and SRH services,
- age-of-consent laws,
- informed consent for services and treatment,
- availability of condoms/contraceptives/commodities,
- geographic access to services, or
- financial access to services (IPPF et al. 2009).

The specific nature and content of these policies will vary across countries, unique to local legal contexts, political climates, and donor priorities. Therefore, the core indicators at the policy level are general, encompassing a potentially broad range of issues. Relevant policies can be identified through desk reviews of pertinent policies and regulations, as well as through communication with key informants such as health officials and policymakers. Table 4 provides a list of policy-level indicators.

Table 4: Policy-level indicators

	Definition	Reference (if applicable)
[1] Score on the Enabling Environment Index for FSWs	Sum of score from 1–16 based on the following questions (Yes/No).	MEASURE Evaluation. (2012). <i>Operational Guidelines for Monitoring and Evaluation of HIV Programmes for Sex Workers, Men who have Sex with Men, and Transgender People.</i>
	1) Has the country developed a national multisectoral strategy to respond to HIV that addresses sex workers?	
	2) Has the country ensured “full involvement and participation” of civil society (including sex workers) in the development of the multisectoral strategy?	
	3) Does the country have a mechanism to promote interaction between government, civil society organizations (including organizations of sex workers), and the private sector for implementing HIV strategies/programs?	
	4) Does the country have non-discrimination laws or regulations that specify protections for sex workers?	
	5) Does the country have laws, regulations or policies that present obstacles to effective HIV prevention, treatment, care, and support for sex workers? <i>[To be reverse scored]</i>	
	6) Does the country have a policy or strategy to promote information, education, and communication and other preventive health interventions for key or other vulnerable subpopulations [such as sex workers]?	
	7) Does the country have a policy or strategy that addresses condom promotion for sex workers?	
	8) Does the country have a policy or strategy that addresses HIV testing and counseling for sex workers?	
	9) Does the country have a policy or strategy that addresses stigma and discrimination reduction for sex workers?	
	10) Does the country have a policy or strategy that addresses targeted information on risk reduction and HIV education for sex workers?	
	11) Does the country have a policy or strategy that addresses vulnerability reduction (e.g., income generation) for sex workers?	
	12) Has the country identified the specific needs for HIV prevention programs [for sex workers]?	
	13) To what extent has HIV prevention been implemented? Do the majority of [sex workers] in need have access to risk reduction?	
	14) Is there a central national database with HIV-related data on key populations [such as sex workers]?	
	15) Does the country have a policy to ensure equal access for sex workers to HIV prevention, treatment, care, and support?	
16) Does the country have municipal-level comprehensive HIV prevention, treatment and care programs implemented for and with sex workers?		
[2] Are there specific policy commitments or sources of funding dedicated to improving linkages between HIV and SRH services for FSWs? (Yes/No)		
[3] Within the broader HIV operational plan or strategy, are there any explicit activities to improve access, coverage, and quality of SRH services for female sex workers? (Yes/No)		IPPF, UNFPA, WHO UNAIDS, GNP+, ICW and Young Positives. (2009). <i>Rapid Assessment Tool for SRH and HIV linkages: A Generic Guide.</i>
[4] Within the broader SRH operational plan or strategy, are there any explicit activities to improve access, coverage, and quality of HIV services for female sex workers? (Yes/No)		

Country program indicators

Pilot initiatives that address HIV and SRH needs of KAPs and have been designed, evaluated, costed and found to be effective, feasible, and acceptable should be presented to key decisionmakers in government for consideration to take to scale. Country program indicators inform the national country program about projects that could be scaled up or replicated across other provinces. Commitment to take to scale could be defined as a change in budget allocation by the government or donor; an endorsement/approval to replicate or scale up the pilot project; or approval of a policy, legislation, or law that could affect replication or uptake of the pilot initiative. Table 5 provides key indicators on country program uptake.

3.2 Service delivery: Facility-level indicators

Core indicators addressing service delivery include facility-level and provider-level indicators. **Facility-level indicators** focus on the availability, access, and quality of HIV and SRH care at service delivery points. In selected facilities, these indicators assess:

- the range of HIV and SRH services offered,
- availability of equipment and commodities for comprehensive HIV and SRH services,
- recordkeeping,
- confidentiality, and
- hours of operation.

In addition to these assessments of service delivery infrastructure, other facility-level indicators assess FSW views on the quality of care and satisfaction with services from a **client-side perspective**. These client-side facility-level indicators assess client satisfaction regarding:

- waiting time,
- intended services received,
- respectful treatment,
- comprehension of information given,
- ability to ask questions and have questions answered,
- time with provider, and
- privacy.

Table 5: Country program uptake indicators

	Definition	Data source
Output indicators		
Number of pilot initiatives that address the HIV and SRH needs of KAPs that have been designed, evaluated, costed, and presented to key decisionmakers in the government for consideration to take to scale	Track number of projects being implemented	To be collected from UNFPA and MOH
Output indicators		
Number of pilot models that address the HIV and SRH needs of KAPs pilot models in which the key stakeholders have demonstrated a commitment to replicate or take them to scale	Track number of projects being implemented	To be collected from UNFPA and MOH

Data can be collected for the facility-level infrastructure indicators through site assessments and interviews with service providers, and the client-side perspectives can be based on client exit interviews at selected service delivery points. Table 6 describes facility-level output and outcome indicators.

3.3 Service delivery: Provider-level indicators

In addition to the facility-level indicators, the provider-level indicators assess a second aspect of service delivery: the knowledge, skills, attitudes, and behaviors of service providers regarding the provision of SRH and HIV services for FSWs. Provider-level indicators will address their knowledge, skills, attitudes, and behaviors regarding:

- modern contraceptive methods in addition to condoms;
- antenatal, delivery, and postnatal care;
- prevention of mother-to-child transmission (PMTCT);
- antiretroviral drugs (both for mother's health and to prevent vertical transmission to children);
- stigma and discrimination toward FSWs; and
- attitudes about FSWs' reproductive rights.

Service providers may not be facility-based, and they do not necessarily have a clinical background. Therefore, the core indicators for the project are not intended to assess comprehensive expertise of all of the pertinent SRH and HIV issues. Rather, the focus of the indicators is to ascertain the extent to which service providers possess a basic level of competence in both SRH and HIV, as opposed to just one or the other. Table 7 describes provider-level output and outcome indicators.

Table 6: Facility-level indicators

	Definition	Data source
Number of targeted FSW service delivery points (SDPs) in the project area	Number of SDPs that target FSWs in the project area	Collected from district authorities
% of targeted FSW SDPs offering HIV and SRH services on site or through linkages with other SDPs ^a (Composite indicator can be constructed)	To be tracked for each of the following individual services: HIV services <ul style="list-style-type: none"> • % providing HIV testing and counseling • % providing condom distribution • % providing HIV treatment SRH services <ul style="list-style-type: none"> • % providing family planning • % providing MCH, including PMTCT • % providing STI diagnosis and treatment 	To be collected from site assessments and interviews with site managers
% of targeted FSW HIV SDPs in project area providing SRH services for FSWs ^a (For stand-alone HIV services)	Tracked for each of the following individual services: <ul style="list-style-type: none"> • % providing family planning • % providing MCH, including PMTCT • % providing STI diagnosis and treatment 	To be collected from health facility assessments and interviews with site managers

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	Definition	Data source
% of targeted FSW SDPs providing alcohol use and drug use related services ^a	Tracked for each of two services <ul style="list-style-type: none"> • % providing alcohol-use-related services • % providing drug-use-related services 	To be collected from health facility assessments and interviews with site managers
Service utilization indicators – Service statistics		
Number of FSWs provided FP counseling and services during a fixed time period	The number of FSWs at an intervention facility who received FP counseling and services during a fixed time period	Service statistics
Number of pregnant FSWs who were provided/referred to antenatal care/MCH during a fixed time period	The number of pregnant FSWs at an intervention facility who were provided/referred to antenatal care/MCH during a fixed time period	Service statistics
Number of FSWs who were tested for HIV during a fixed time period	The number of FSWs at an intervention facility who were tested for HIV during a fixed time period	Service statistics
Number of eligible HIV-positive FSWs who were provided with/referred to HIV treatment services during a fixed time period	The number of eligible HIV-positive FSWs at an intervention facility who were provided/referred to HIV treatment services during a fixed time period	Service statistics
Number of FSWs diagnosed with an STI who were provided with/referred for treatment during a fixed time period	The number of FSWs at an intervention facility who were diagnosed with an STI who were provided with/referred for treatment during a fixed time period	Service statistics
% of FSWs reporting that they received FP counseling and services during a fixed time period	The proportion of FSWs at an intervention facility who received FP counseling and services during a fixed time period	FSW exit interviews
% of pregnant FSWs reporting antenatal referral during a fixed time period, among FSWs who were pregnant during a fixed time period	The proportion of pregnant FSWs at an intervention facility who were provided with/referred for antenatal care/MCH during a fixed time period	FSW exit interviews
% FSWs offered HIV testing during a fixed time period	The proportion of FSWs at an intervention facility who were tested for HIV during a fixed time period	FSW exit interviews
% of eligible HIV-positive FSWs reporting referral to HIV treatment during a fixed time period	The proportion of eligible HIV-positive FSWs at an intervention facility who were provided/referred to HIV treatment services during a fixed time period	FSW exit interviews
% of FSWs with an STI reporting that they received/were referred for treatment during a fixed time period	The proportion of FSWs at an intervention facility who were diagnosed with an STI who were provided/referred for treatment during a fixed time period	FSW exit interviews

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Facility assessment		
% FSW focused facilities providing quality care (Composite indicator can be constructed)	To be tracked for the following: <ul style="list-style-type: none"> • % facilities with required number of health workers per staffing guidelines • % facilities with standard operating procedures (SOPs) in place • % facilities with a waiting room • % open during work hours per clinic guidelines • % facilities with arrangements for keeping records confidential • % facilities with commodities available on day of assessment: Condoms, HIV testing kits, Pregnancy test kits, STI treatment kits 	From facility assessments

^aSelected references describing services provided at specified HIV and SRH service delivery points: (1) *HIV TESTING AND COUNSELING*: WHO. (2011). "Guide for Monitoring and Evaluating National HIV Testing and Counseling (HTC) Programs." (2) *CONDOM PROVISION*: Population Council and UNFPA. (2010). "Planning and implementing an essential package of sexual and reproductive health services: Guidance for integrating family planning and STI/RTI with other reproductive health and primary health services." (3) *HIV TREATMENT*: Population Council and UNFPA. (2010). "Planning and implementing an essential package of sexual and reproductive health services: Guidance for integrating family planning and STI/RTI with other reproductive health and primary health services." (4) *FAMILY PLANNING: MEASURE* Evaluation Family Planning and Reproductive Health Indicators Database. (5) *MCH: ANTENATAL, DELIVERY, AND POSTNATAL CARE*: WHO. (1997). "Monitoring Reproductive Health: Selecting a Short List of National and Global Indicators." (6) *PREVENTION OF MOTHER-TO-CHILD TRANSMISSION*: USAID. (2000). "Handbook of Indicators for HIV/AIDS/STI Programs"; WHO. (2013). "Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: Recommendations for a public health approach." (7) *STI DIAGNOSIS AND TREATMENT*: USAID. (2000). "Handbook of Indicators for HIV/AIDS/STI Programs."

Table 7: Provider-level indicators

	Definition	Data source
Process indicators		
Number of providers at FSW-targeted HIV SDPs trained to provide FP counseling and services and/or % of providers reporting training on FP services	The number of providers at an intervention facility who were trained to provide FP counseling and services during a fixed time period ^a The proportion of providers at an intervention facility who report being trained on FP services during a fixed time period	Surveys of facility managers and/or Survey of health providers
Number (%) of service providers at FSW-targeted HIV SDPs trained to provide STI diagnosis and treatment per national guidelines and/or % of providers reporting training on STI services	The number/proportion of providers at an intervention facility who were trained to provide STI diagnosis and treatment during a fixed time period The proportion of providers at an intervention facility who report being trained on STI services during a fixed time period	Surveys of facility managers and/or Survey of health providers
Number (%) of FSW-targeted HIV SDP service providers trained to provide HIV testing and counseling services and/or % of providers reporting training on HIV counseling and testing services	The number/proportion of providers at an intervention facility who were trained to provide HIV testing and counseling services during a fixed time period The proportion of providers at an intervention facility who report being trained on HIV counseling and testing services during a fixed time period	Surveys of facility managers and/or Survey of health providers
Number (%) of service providers at FSW-targeted SDPs trained on PMTCT and/or % of providers reporting training on PMTCT services	The number of providers at an intervention facility who were trained on PMTCT during a fixed time period The proportion of providers at an intervention facility who report being trained on PMTCT services during a fixed time period	Surveys of facility managers and/or Survey of health providers
Number of service providers at FSW-targeted SDPs trained on HIV treatment and/or % of providers reporting training on HIV treatment services	The number of providers at an intervention facility who were trained on HIV treatment during a fixed time period The proportion of providers at an intervention facility who report being trained on HIV treatment services during a fixed period of time	Surveys of facility managers and/or Survey of health providers
	Definition	Reference (if applicable)
Output indicators		
% of providers with correct knowledge about HIV/AIDS prevention	The proportion who, in response to prompting, 1) correctly identify using condoms and having sex only with one faithful uninfected partner as means of protection against HIV infection; 2) correctly reject the two most common local misconceptions about AIDS transmission or prevention; and 3) correctly respond that a person who looks healthy can have HIV.	MEASURE DHS HIV/AIDS Survey Indicator Database
% of providers with knowledge of modern methods of family planning	The proportion who can name at least three modern contraceptive methods.	USAID. (2004). <i>Health and Family Planning Indicators</i> .

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% of providers with knowledge of prevention of mother to child transmission of HIV	The proportion who say that maternal to child transmission of HIV can be prevented through antiretroviral therapy during pregnancy <i>and</i> avoiding breastfeeding.	MEASURE DHS HIV/AIDS Survey Indicator Database
% of providers with knowledge of STI diagnosis and treatment	The proportion who know the symptoms of the five most common STIs and their treatment (per national guidelines – syndromic or diagnostic testing).	
% of providers with knowledge of ART	The proportion who know about ART eligibility (CD4 counts per national guidelines) and ART (HAART: 3 ARV medications to be taken regularly; adherence >90%).	
Outcome indicators		
% of providers expressing accepting attitudes toward people with HIV	The proportion who report an accepting or supportive attitude on all four component questions: 1) would be willing to care for a family member who became sick with the AIDS virus; 2) would buy fresh vegetables from a vendor whom they knew was HIV+; 3) female teacher who is HIV+ but not sick should be allowed to continue teaching in school; 4) would not want to keep the HIV+ status of a family member a secret.	MEASURE DHS HIV/AIDS Survey Indicator Database
% of providers who possess non-discriminatory attitudes toward female sex workers	The proportion who respond affirmatively to the following: 1) agree that FSWs deserve the same quality of care as anyone else; <i>and</i> 2) feel comfortable providing services to FSWs.	Abstracted from: Feyissa et al. 2012. "Validation of an HIV-related stigma scale among health care providers in a resource-poor Ethiopian setting." <i>Journal of Multidisciplinary Healthcare</i> , 5: 97–113. <i>Additional stigma scale items can be added if desired.</i>

3.4 Demand generation: Individual-level indicators

On the demand side, the interventions aim to affect positive changes in FSWs' SRH and HIV knowledge, behaviors, and practices. Specifically, individual-level indicators assess women's knowledge, behaviors, and practices regarding:

- modern contraceptive methods in addition to condoms;
- antenatal, delivery, and postnatal care;
- PMTCT; and

- antiretroviral drugs (both for mother's health and to prevent vertical transmission to children).

When possible, to facilitate data collection and harmonize efforts with existing monitoring and evaluation systems, individual-level indicators for this project draw upon existing measures, such as the core indicators of the UN General Assembly Special Session (UNGASS). In many cases, the individual-level knowledge indicators will be the same as the provider-level knowledge indicators, intended to assess general topical knowledge in the key issue areas. Table 8 describes individual-level process, output and outcome indicators.

Table 8: Client-level indicators

	Definition	Data source
Process indicators		
% of FSWs reporting that they received FP counseling and services during a fixed time period ^a	The proportion of FSWs at an intervention facility who received FP counseling and services during a fixed time period ^a	FSW exit interviews
% of pregnant FSWs reporting antenatal referral during a fixed time period, among FSWs who were pregnant during a fixed time period ^a	The proportion of pregnant FSWs at an intervention facility who were provided with/referred to antenatal care/MCH during a fixed time period ^a	FSW exit interviews
% FSWs offered HIV testing during a fixed time period ^a	The proportion of FSWs at an intervention facility who were tested for HIV during a fixed time period ^a	FSW exit interviews
% of eligible HIV-positive FSWs reporting referral to HIV treatment	The proportion of eligible HIV-positive FSWs at an intervention facility who were provided/referred to HIV treatment services during a fixed time period ^a	FSW exit interviews
% of FSWs with an STI reporting that they received/were referred for treatment during a fixed time period ^a	The proportion of FSWs at an intervention facility who were diagnosed with an STI who were provided/referred for treatment during a fixed time period ^a	FSW exit interviews
Number (%) of FSWs in the community reached by HIV and SRH services Composite indicator could be drawn up	The number/proportion of targeted FSWs who received or were exposed to HIV and SRH services. The precise definition of this indicator will vary by context and intervention (for example, FP peer outreach as opposed to facility-based antenatal care services). To be tracked separately for each of the following services: HIV services: <ul style="list-style-type: none"> • HIV testing and counseling • Condom distribution • HIV treatment SRH services: <ul style="list-style-type: none"> • Family planning • MCH, including PMTCT • STI 	FSW community surveys

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	Definition	Reference (if applicable)
Output indicators		
% of FSWs with correct knowledge about HIV/AIDS prevention	The proportion who, in response to prompting, 1) correctly identify using condoms and having sex only with one faithful uninfected partner as a means of protection against HIV infection; 2) correctly reject the two most common local misconceptions about AIDS transmission or prevention; and 3) correctly respond that a person who looks healthy can have HIV.	MEASURE DHS HIV/AIDS Survey Indicator Database
% of FSWs with knowledge of modern methods of family planning	The proportion who can name at least three modern contraceptive methods	USAID. (2004). Health and Family Planning Indicators.
% of FSWs with knowledge of prevention of mother to child transmission of HIV	The proportion who say that maternal to child transmission of HIV can be prevented through antiretroviral therapy during pregnancy <i>and</i> avoiding breastfeeding.	MEASURE DHS HIV/AIDS Survey Indicator Database
% of FSWs reached with HIV prevention programs	The proportion who respond affirmatively to both of the following questions. Sex workers are asked: 1. Do you know where you can go if you wish to receive an HIV test? 2. In the last three months, have you been given condoms (e.g., through an outreach service, drop-in center or sexual health clinic)?	UNGASS Indicator 1.7
% of FSWs who are satisfied with the care received (Composite indicator for overall satisfaction can be constructed)	To be tracked for each of the following items. Among FSWs in intervention sites: <ul style="list-style-type: none"> • % satisfied with facility hours of operation • % satisfied with waiting time • % satisfied with services received • % satisfied with respectful treatment • % satisfied with ability to ask questions and have them answered • % satisfied with time with provider • % satisfied with privacy 	Client exit survey
Outcome indicators		
% of FSWs who use a non-barrier modern contraceptive method	Among FSWs who are not trying to get pregnant: The proportion who report currently using any of the following: oral contraceptive pill, IUD, injectable, implant, sterilization	Survey with FSWs and Exit survey with clients
% of FSWs who use condoms consistently	The proportion who always used a condom during vaginal or anal sex in the past month	Survey with FSWs and Exit survey with clients
% of FSWs who used a condom with their most recent client	The proportion who report that they used a condom with their most recent new client	UNGASS Indicator 1.8 Since condom use varies across partners, this indicator should be complemented by the following three additional indicators. Survey with FSWs and Exit survey with clients
% of FSWs who used a condom with their most recent non-commercial partner	The proportion who report that they used a condom with their most recent noncommercial partner	Survey with FSWs and Exit survey with clients

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% of FSWs who are dual method users	Among FSWs who are not trying to get pregnant: The proportion who always used condoms in the past month and are currently using a non-barrier modern contraceptive.	Survey with FSWs and Exit survey with clients
% of FSWs who have received a recent HIV test and know their results	The proportion who received an HIV test and received the results within the past 12 months.	UNGASS Indicator 1.9 Shorter/longer time periods can be assessed by asking women how long ago they last received an HIV test and received the result. Survey with FSWs and Exit survey with clients
% of eligible HIV-positive FSWs who are receiving antiretroviral therapy	Among HIV-positive FSWs who are eligible (as defined by country guidelines): The proportion who are receiving antiretroviral therapy,	Survey with FSWs and Exit survey with clients
Proportion of pregnant FSWs who received antenatal care	Among FSWs who had a live birth during a fixed time period (e.g., past year): The proportion who were attended, at least once during their pregnancy, by skilled personnel (excluding traditional birth attendants) for reasons related to pregnancy,	WHO. (2006). Reproductive Health Indicators: Guidelines for their generation, interpretation and analysis for global monitoring Survey with FSWs and Exit survey with clients
Proportion of pregnant FSWs who received HIV testing during pregnancy	Among FSWs who were pregnant during a fixed time period: The proportion who 1) were tested for HIV during pregnancy, and 2) received the test result.	Survey with FSWs and Exit survey with clients
Proportion of births to FSWs attended by skilled health personnel	Among births to FSWs during a fixed time period (e.g., past year): The proportion of births attended by skilled health personnel.	WHO. (2006). Reproductive Health Indicators: Guidelines for their generation, interpretation and analysis for global monitoring
Proportion of HIV-positive, pregnant FSWs who received treatment to prevent mother to child HIV transmission	Among FSWs who were pregnant and HIV-positive within the past year: The proportion 1) who received maternal antiretroviral treatment and 2) whose infants received treatment to prevent maternal transmission	Survey with FSWs and Exit survey with clients

^a Time periods to be standardized by Regional Steering Committee.

4 ETHICAL CONSIDERATIONS

Ethical conduct and regard for the welfare of those involved in research under the regional OR project are of utmost importance. Female sex workers and other key affected populations are socially vulnerable and often marginalized for their behaviors; hence, all efforts will be made to maintain confidentiality and prevent any adverse impact with regard to stigma and discrimination. The project will follow the UNEG Ethical Guidelines for Evaluation (UNEG 2008) and NIH standard for ethical research. For all OR undertaken, the necessary ethics clearance and approvals will need to be obtained in line with country requirements.

All study participants will provide informed consent that will be obtained at the time of recruitment and prior to any data collection. The informed consent forms will be designed as per internationally accepted standards and include the following components:

- An explanation of the purpose of study and a description of study procedures
- Information on the sponsors supporting the study and the agencies conducting the study
- A description of possible the risks or discomfort to the participants and a description of steps to be taken to bring relief
- A description of any compensation to be given
- A statement on the benefits accruing from the study to the participant and to the field in general
- A statement about the confidentiality of records
- Information with contact phone numbers of two persons who the participant could contact with questions
- A statement that participation is voluntary, that it may be discontinued at any time, and that discontinuation will in no way affect access to care or services

Participants will be allowed to read the consent form in private or have the consent form read out to them in private. Consent will be obtained by study staff after allowing sufficient time for clarifications and questions. Participants who are not comfortable writing or signing the informed consent will be offered the alternative of using a thumb print or making a mark in the presence of a witness. All signed consent forms will be stored in a secure locked cabinet accessible only to authorized study staff.

Research study staff will be trained in ethical conduct of research and data collection in a nonjudgmental manner. They will receive intense training on participant confidentiality, data collection, and data management. The research staff will be required to undertake ethics training for research and obtain certification from the FHI or NIH ethics training program. Standard Operating Procedures (SOPs) for conducting informed consent with potential participants will be developed and used by all field investigators.

All data collected in the research study will be confidential and based on unique ID numbers. The data will not be linked to names or addresses or any other identification. Data will be stored in a safe, password-protected database and paper-based data collection will be stored in a safe, locked cabinet. Data will be retained by the project for a period of at least three years after the completion of the study; the duration would be determined based on individual country policies and legal requirements.

5 IMPLEMENTATION OF OPERATIONS RESEARCH

Consideration has been given to how regional support could be provided by the Asia–Pacific Regional Office (APRO) for OR implemented in countries in the Asia-Pacific region (see 5.2). Whether this is useful, feasible, and a priority for UNFPA APRO will be considered in the context of the development of UNFPA's Strategic Plan 2014–2017 and APRO's Regional Programme for this period.

As countries may be at varying stages of implementing targeted intervention programs for key affected populations, specifically FSWs, the OR will be adapted to the national context and need of the country.

5.1 Country-level implementation

In all countries, the OR will likely be conducted in partnership with in-country researchers from public or not-for-profit research organizations, including academic institutions or universities. The following criteria should be considered when recruiting suitable research partners:

- availability of qualified research personnel with the requisite skill sets,
- past experience with similar operations research projects,
- presence in the geographic area where projects may be implemented or ability to set up field offices, and
- experience in financial management of grants.

Country OR team

This section proposes what the Country OR Team would consist of and their roles, responsibilities, and qualifications.

The Country OR Team will consist of a Core Team and a Field Team of research assistants for data collection. The **Core Team** will comprise the following individuals:

- Country OR team leader or principal investigator (PI)
- Project coordinator
- Data manager and statistician
- Administrative and Finance Officer

Roles and responsibilities: The **Country OR team leader and PI** will be responsible for the overall implementation of the study and financial oversight, and will serve as a liaison with Department of AIDS officials and other relevant bodies including the local Ethics Committee. Specifically, s/he will undertake the following tasks:

- Undertake a desk review of reference materials
- Communicate electronically with the evaluation team prior to arrival in country
- Prepare and submit the inception report
- Set up the research team, including hiring and training of research staff, and set up of study sites
- Obtain ethical approval for the study from the national Ethics Committee
- Develop, pretest, and finalize data collection tools; supervise set up of data entry platforms
- Regularly monitor and supervise study activities through field visits
- Supervise data analysis and interpretation

- Prepare and submit the draft and final report
- Provide quality assurance and technical support during the design, implementation, analysis, and reporting/presentation of the study findings
- Present preliminary and final findings at national and international forums

Qualifications for the Country OR Team Leader:

- PhD in public health, social science, or related field, required.
- 10–12 years of experience in conducting OR nationally, required. Experience of working on projects in collaboration with the Department of AIDS Control or Ministry of Health, preferred. Experience in international research will be an advantage.
- Affiliated with or working for a Research Organization or University.
- Proven ability to lead multidisciplinary teams.
- Excellent oral and writing skills in English, required.

The **Project coordinator** will implement research activities in the field and be responsible for the day to day running of the research project. S/he will report to the Country OR Team Leader.

The **Data manager and Statistician** will be responsible for the quality of data entry, data cleaning, and drawing up data analysis plans.

The **Administrative and finance officer** will manage project accounts and finances, commodity procurement where required, HR, and financial reporting. S/he will report to the Country OR Team Leader.

The **Field team** will be hired for data collection in the field as per the study design. For example, repeated surveys may require staff hired for short periods while cohort studies for evaluation designs may require the team to be hired for extended periods. The Project Coordinator will be responsible for managing the team in the field.

Collaboration between Country OR team (CORT) and regional OR advisor/team

It is envisaged that there may be a specific role for APRO in providing regional coordination, where multiple OR at country level are undertaken and/or support to specific OR at the country level. See the proposed approach as set out in Subsection 5.2 below.

The Country OR Team (CORT) will work in close collaboration with the Regional OR Advisor and his/her team. Recognizing that there may be in-country needs for technical support in the areas of tool development, data entry and management, and data analysis and interpretation the Regional OR Team (RORT) will provide the required technical support to the CORT. The composition of the Regional OR Team is available on page 28. Experts from the RORT will be available and will participate actively in the development of tools, assist with pre-testing and finalization of data collection instruments, support training of the field research team, guide the development of data entry frames, and assist with data analysis and interpretation. Some of this technical support will be provided remotely through regular electronic communication—for instance, review of drafts of data collection tools, training plans, etc.—while at other times, experts will provide technical support through field visits—for instance, during training and study initiation and data analysis meetings/workshops. This collaboration will also ensure that projects undertaken in different countries, while distinct in nature depending on the country context, collect some data in a similar manner to facilitate the measuring of core indicators that can be used for cross-country comparisons.

Stakeholder involvement

Stakeholder involvement is critical for the successful conduct of any project, this is particularly relevant for key affected populations; special attention will be paid to this aspect. Key stakeholders, defined as people who play a political, scientific, or social role in enabling access to and provision of services for KAPs, specifically FSWs, will be involved throughout the project period. Although key stakeholders will be defined on a country-to-country basis, stakeholders will likely include, but are not limited to, MOH and District AIDS Control Officials

(DACO), community leaders in project districts, implementing partners, academic institutions working on similar topics, donor agencies, sex worker organizations active in project areas and at the national level, and networks of people living with HIV. Thus, stakeholders will be engaged at two levels: the national level and at the sub-national level where the study is being implemented. The process will be initiated very early in the project and key stakeholders (for instance, MOH and DACO, members of scientific advisory committees, donors, UNFPA Country Office Coordinator) will be asked to provide input into the study design. Community engagement with local district-level stakeholders will be undertaken prior to the roll out of the project and continuously throughout the project. Regular meetings are proposed with key stakeholders to share project progress and interim results. The Country OR Team Leader will be responsible for engaging key stakeholders at the national and sub-national levels, for sharing interim results and project updates, and for facilitating meetings with RORT and the Regional UNFPA Coordinator.

Dissemination and research utilization plans

Results and recommendations emerging from operations research studies will be disseminated nationally and internationally through the publication of reports on the UNFPA website and workshops targeting program planners and implementers. Findings from these studies will be presented at national and international conferences. To share cross-country experiences and OR findings we propose to hold webinars. Dissemination will also take place through publication of journal articles in peer-reviewed international journals targeting academics, researchers, and the donor community. The UNFPA Country Office will use the OR recommendations to prepare a Management Response as per the UNFPA evaluation procedures.

5.2 Regional OR coordination

As outlined above, this section explains how regional support could be provided by APRO for OR implemented in countries in the Asia-Pacific region. Whether this is useful, feasible, and a priority for UNFPA APRO will be considered in the context of the development of UN-

FPA's Strategic Plan 2014 – 2017 and APRO's Regional Program for this period.

As several countries in the Asia-Pacific region may conduct country OR studies, regional support will be critical for their successful implementation and for collating and sharing research findings and recommendations. It is envisaged that a Regional Steering Committee could be established to facilitate this process. If multiple, concurrent country OR studies are undertaken, this section proposes the approach, structure, and level of effort required to ensure strong regional coordination and support.

Regional steering committee (RSC)

The Regional Steering Committee will be responsible for overall coordination, and strategic and technical guidance for the regional project. The RSC would include the following persons:

- UNFPA Regional HIV Advisor
- UNFPA Regional M & E Advisor
- UNFPA Country Representative of all participating countries
- UNFPA APRO Program Advisor
- Population Council Representative, South Asia Office (India)
- Additionally 2–3 key stakeholders

The terms of reference for the RSC will be drawn up by UNFPA's Regional HIV Advisor; these terms will be endorsed by the RSC. The RSC will be responsible for overall coordination of the regional OR project and will:

- Provide overall technical guidance and quality assurance on the OR
- Review and endorse a regional inception report
- Provide guidance on Country OR terms of reference
- Provide support to establishing CORTs and endorse membership
- Review and comment on country inception reports
- Discuss and set the terms for data ownership and responsibility for country reports
- Review and approve final regional OR report

Regional OR advisor and regional OR team (RORT)

The regional OR advisor will be the team leader from the lead OR agency (Population Council) and will provide leadership and technical expertise for implementing and managing the regional OR project. While all OR projects will be implemented by in-country research organizations, the regional OR advisor will coordinate the projects to facilitate their implementation within the broad regional OR framework laid out in this document. As research capacities may be variable in country programs the Regional OR Advisor and his/her team will provide technical support to in-country researchers and build capacity for OR. The RORT will consist of the following key personnel:

- Regional OR advisor (team leader from Lead OR Agency)
- Program officer: study design, data collection, and monitoring
- Program officer: data management, analysis, and statistics

The Regional OR advisor will be responsible for the overall management of the regional OR project and will be:

- Responsible for the overall coordination of the country OR team including selection of in-country research agency.
- Responsible for overall quality assurance of the evaluation in accordance with UNFPA and UNEG Evaluation guidelines.
- Coordinate internal review and OR reporting processes (Review and comment on TOR, inception report and final report by UNFPA Country Office, UNFPA Regional Advisor and APRO)
- Coordinate with UNFPA Regional Office HIV Advisor on approval of all OR deliverables.

The Regional OR Advisor and his/her team will work closely with the UNFPA Country Office to identify and select an in-country research organization to undertake OR. The Regional Advisor and RORT will work closely with the in-country OR team and UNFPA Country Office to meet with key stakeholders and national program of-

ficers to understand the national program and research needs. The Advisor and technical expert will assist the country OR team to design the study, develop the pretest and finalize data collection instruments, and participate in the research training workshop as a part of capacity-building. Regular monitoring visits are envisaged to support the country team during the data collection phase (depending on duration and complexity of study design). The RORT technical expert on data management, will provide technical support on setting up data entry frames, data management and data analysis as required by the country OR team. In many countries where English is not widely spoken, researchers find it difficult to write reports in English; in such situations the RORT will support the national OR team in preparing the report, abstracts, and presentations for conferences.

Level of effort: It is envisaged that the Regional OR Advisor, as team leader of the Regional OR Project, will contribute around 25–30% of his/her time to the regional OR project. OR Program Officers (technical experts) will contribute between a 75–100% effort depending on the number of studies initiated in the region and overlap of study activities. This level of technical support is essential to build local capacity and ensure quality research.

Travel

Regional advisor: The regional OR advisor will visit UNFPA's Regional Office annually for consultations with the regional advisor (3 trips over 3 years). In addition, the advisor will visit each country to meet with stakeholders and identify a country research organization to partner with, followed by 1–2 trips per country to coordinate and provide oversight to the project.

Technical program officers: It is envisaged that a minimum of three visits will be undertaken by the program officers (technical experts) for each study: one at the time of study initiation and training, one monitoring visit, and a third for data analysis. For studies with multiple rounds of data collection and in countries with limited expertise in conducting OR, additional monitoring visits may be required.

Study timelines and indicative estimates for a selected study designs

Illustrative timelines are provided for proposed OR research studies in section 2.0.

Three different study designs have been proposed: (i) A pilot project to demonstrate feasibility and assess effectiveness using a pretest-posttest control group quasi-experimental design; (ii) phased-in pretest-posttest control design in two different districts; and (iii) a pretest-posttest one-group study design in one district.

The cost of individual studies will depend on the number of research sites, duration of the study period, frequency of data collection, sample size proposed, skills of the in-country research team, technical support required, and cost of travel and stay. For all studies a preparatory phase of three months is envisaged; this period will be used to undertake a quick formative assessment followed by finalization of study design and data collection tools. A three-month period of time is required for data entry, data cleaning, data analysis, and report writing. An indicative cost estimate for a research study with an intervention and control group to be conducted in two districts/provinces with a two rounds of data collection (baseline and endline quantitative surveys) for a sample of 350 participants in each group (700 participants at each round) and qualitative interviews (around 50 at each round) to be conducted over 18 months is as follows:

- A study conducted by a country research organization over 18 months would be budgeted at around USD 150,000. The local agency will be responsible for all aspects of the study including research design, sample size calculation and protocol writing, data collection instrument development and pre-testing, training of research team, participant recruitment and follow-up, data entry and monitoring, data analysis, report writing, and manuscript preparation and submission to peer-reviewed journals.
- Regional technical support by a team of experts in qualitative and quantitative research over an 18-month consultancy would be budgeted at around USD 100,000. Technical support would include assistance with writing the proposal, data collection instrument development, training of research team, setting up data entry frames, monitoring and supervision, data analysis, report writing, and manuscript preparation. The consultant team would not manage the conduct of research activities or grants.
- A study conducted by the regional team through partnership with a local research organization would be budgeted at USD 300,000 for 18 months. The regional team would be responsible for developing the protocol and identifying a suitable in-country research organization. The regional team would work with local partners to develop data collection instruments, train the research team, monitor quality of data collection and data entry, monitor participant recruitment and follow up, conduct data analysis and write the report. The regional team would assist local partners in preparing manuscripts for submission to peer-reviewed journals.

UNFPA Country Office

The UNFPA Country Office, a key stakeholder, will provide in-country support for the project. The Country Office **point person** for the OR project will be the lead from the UNFPA Country Office to support the project as follows:

- Liaise with national MOH and AIDS department officials to facilitate collaboration.
- Identify provinces/districts where the project will be undertaken.
- Work closely with the Regional OR advisor to identify, shortlist, and select the country OR agency and team.
- Participate in national and subnational stakeholder interactions to endorse and support the project.
- Visit project sites.
- Review inception report and final report.
- Disseminate project lessons by placing the final report on UNFPA website, supporting workshops, and webinars.

6 REFERENCES

- Campbell, D. and J. Stanley. 1963. *Experimental and Quasi-experimental Designs for Research*. Chicago: Rand McNally.
- Chakrapani, V. et al. 2011. "Prevalence of and barriers to dual-contraceptive methods use among married men and women living with HIV in India," *Infectious Diseases in Obstetrics and Gynecology* (Article ID 376432).
- Delvaux, T. et al. 2003. "The need for family planning and safe abortion services among women sex workers seeking STI care in Cambodia," *Reproductive Health Matters* 11(21): 88–95.
- Dhanu, A. et al. 2011. "Do sex workers think beyond condoms for family planning? Experiences from Aastha, India," in *Proceedings of the International Conference on Family Planning*, Dakar, Senegal.
- Fisher, A. et al. 2002. *Designing HIV/AIDS Intervention Studies: An Operations Research Handbook*. Washington, DC: Population Council.
- Flaskerud, J. and A. Nyamathi. 1990. "Effects of an AIDS education program on the knowledge, attitudes and practices of low income black and Latina women," *Journal of Community Health* 15(6): 343–355.
- Grissmer, D. et al. 2009. "A guide to incorporating multiple methods in randomized controlled trials to assess intervention effects." Washington, DC: American Psychological Association. Available online at: <http://www.apa.org/ed/schools/cpse/activities/mixed-methods.aspx>.
- Human Rights Council. 2010. *Report of the Special Rapporteur on the Right to Health*. New York: United Nations.
- Interagency Working Group (IAWG) on SRH & HIV Linkages. 2012. "SRH & HIV Linkages Resource Pack." <www.srhivlinkages.org>.
- IPPF, UNFPA, WHO, UNAIDS, GNP+, ICW, Young Positives. 2009. *Rapid Assessment Tool for Sexual and Reproductive Health and HIV Linkages: A Generic Guide*.
- Jadhav, S. et al. 2011. "We have family planning needs too! Contraceptive needs and choices of female sex workers from Mumbai, India," in *Proceedings of the International Conference on Family Planning*, Dakar, Senegal.
- Katz, K. et al. (2011). "Assessing the need for family planning among female sex workers and female injecting drug users in Dhaka, Bangladesh," in *Proceedings of the International Conference on Family Planning*, Dakar, Senegal.
- Kennedy, C. et al. 2010. "Linking sexual and reproductive health and HIV interventions: a systematic review," *Journal of the International AIDS Society* 13: 26.
- Lau, J. et al. 2007. "Comparing prevalence of condom use among 15,379 female sex workers injecting or not injecting drugs in China," *Sexually Transmitted Diseases* 34(11): 908–916.
- Lusti-Narasimhan, M. et al. 2010. "Linking HIV and sexual and reproductive health services to enhance program outcomes," *International Journal of Gynecology & Obstetrics* 110(Supplement): S7–S9.
- Minichiello, S. et al. 2011. "Contraceptive needs among female sex workers in Yunnan, China," in *Proceedings of the International Conference on Family Planning*, Dakar, Senegal.
- Morineau, G. et al. 2011. "Falling through the cracks: Contraceptive needs of female sex workers in Cambodia and Laos," *Contraception* 84(2): 194–198.
- Petrunej, T. et al. 2012. "Meeting the contraceptive needs of key populations affected by HIV in Asia: An unfinished agenda," *AIDS Research and Treatment* Volume 2012, Article ID 792649, 6 pages. PP NOS?

- Population Reference Bureau (PRB). 2012. *2012 World Population Data Sheet*. Washington, DC: PRB.
- Rothwell, P. 2005. "External validity of randomised controlled trials: "to whom do the results of this trial apply?" *Lancet* 365(9453): 82–93.
- Todd, C. et al. 2010. "Contraceptive utilization and pregnancy termination among female sex workers in Afghanistan," *Journal of Women's Health* 19(11): 2057–2062.
- UNAIDS. 2011. "Asia Pacific Regional Review. HIV in Asia and the Pacific: Getting to Zero." New York: UNAIDS.
- United Nations. 2011. "World Contraceptive Use 2010 (POP/DB/CP/ Rev2010)," New York: United Nations, Department of Economic and Social Affairs, Population Division.
- UNDP and UNFPA. 2012. *Sex Work and the Law in Asia and the Pacific*. Geneva: UNDP.
- United Nations Evaluation Group (UNEG). 2005. "Standards for Evaluation in the UN System." UNEG /FN/ Standards.http://www.uneval.org/papersandpubs/documentdetail.jsp?doc_id=22.
- Walker, H. et al. (2009). "A randomized controlled trial of the First Step to Success early intervention. Demonstration of program efficacy outcomes in a diverse, urban school district," *Journal of Emotional and Behavioral Disorders* 17(4): 197–212.
- Wayal, S. et al. 2011. "Contraceptive practices, sexual and reproductive health needs of HIV-positive and negative female sex workers in Goa, India," *Sexually Transmitted Infections* 87(1): 58–64.
- Women of the Asia Pacific Network of People Living with HIV. 2012. *Positive and Pregnant—How Dare You: a study on access to reproductive and maternal health care for women living with HIV in Asia (Findings from six countries: Bangladesh, Cambodia, India, Indonesia, Nepal, Vietnam)*.

7 ANNEXES

A. RESEARCH METHODOLOGY

A1.1 Overview

In this section the report lists and summarizes commonly used quantitative research methods followed by a discussion on qualitative research methods used in OR. For each of the quantitative and qualitative methods the description adheres to the following structure:

- Brief description of the method
- Key outcomes that the method can address
- Suitable setting
- Strength and weaknesses
- Data collection – structured surveys, client exit interviews, facility assessments
- Data analysis plan

A1.2 Quantitative methods

This section describes a range of study designs used to measure performance progress and achievements of country initiatives. A study design is a basic plan or strategy for investigating the research question. These designs range from true experimental to non-experimental to quasi-experimental designs. The designs presented here are not exhaustive but are some of the more commonly used designs in operations research. Selecting a study design requires careful consideration of ethical issues, technical requirements, and available resources; factors that should be considered while selecting a study design include:

Purpose of the study: Whether the question is to monitor trends in output and outcome indicators or to determine whether the changes in the output or outcome indicators are due to the program.

Appropriateness: Can the study design answer the specific question?

Causality: Does causality need to be ascertained? If yes, then with what confidence can cause and effect be inferred from the study?

Comparison group: Is there a possibility of identifying/ having a comparison group or control group?

Ethical issues: The study design should not violate people's rights or deny services that are proven to be effective.

Resources: Availability of funds, time, and personnel.

Threats to validity: The extent to which the design is able to capture what it is intended to measure.³

³ Threats to validity include **History:** events occurring concurrently during the project can influence the outcome; **Maturation** of people and programs can produce changes that are independent of the program; **Testing:** earlier measurements can affect the results of the later measurement; **Instrumentation:** changes in instruments, observers, or scorers can change the outcome; **Regression to the mean:** a tendency for persons or groups who scored at the extreme low end of a range of scores to achieve a higher score on a subsequent measurement; **Selection:** when participants selected in the control group differ greatly from participants in the intervention group; and **Differential mortality:** in longitudinal cohort studies (where the same group of people are followed over time) when participants who are lost to follow up differ greatly from those who continue, the difference observed in the outcome at posttest may be due to the loss of cases rather than the effect of intervention.

Experimental study designs

True experimental designs are the gold standard of quantitative research for demonstrating causality. They produce the most accurate results in comparison to all other study designs. These study designs consist of two main types of study participants or study units (for example, health facility, villages, or districts): intervention group and control group. The intervention group receives the program intervention and the control group does not. In true experimental study designs the individuals or other study units are randomly assigned to the intervention or control group. The strength of randomization is that extraneous attribution or counterfactual factors that affect the success or failure of an intervention are controlled for in both groups, therefore the differences observed in the dependent variable (outcome or output indicators) are very likely to be due to the intervention. In addition, every eligible participant has equal chance of receiving the intervention. If the evaluator randomly selects a representative sample of units for evaluation, then the results can be generalized to the population of all eligible units. Randomization can be used when:

- It is feasible to assign participants to treatment and control group.
- Study participants can be randomized prior to the start of the intervention.
- It is easy for study participants to comply with the assignment.

However, as with all designs it is important to contextualize the findings when planning to generalize the findings more broadly, as sometimes the external validity of the findings to other populations may be limited, especially when the intervention is highly locally specific.

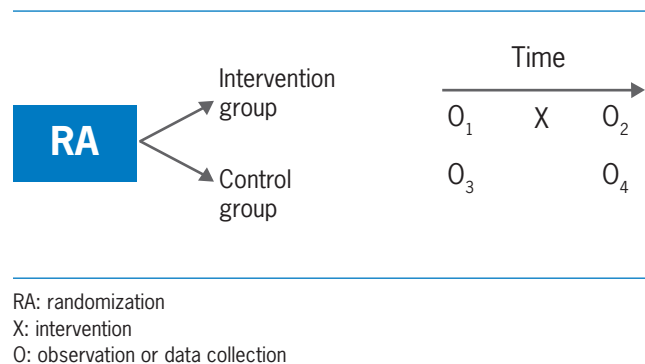
Two commonly used study designs include:

- Pretest-Posttest Control Group Design (randomized controlled trial)
- Multiple Treatment Design

Pretest-posttest control group design

This is also known as the randomized controlled trial (RCT). In this design both the intervention group and the control group receive an initial measurement observation (the pretest O_1 and O_3). The intervention group then receives the program intervention X , but the control group does not. Subsequently, after the intervention period is completed or after a specified period of time, a second set of measurement observations is made (the posttest O_2 and O_4). Since both the intervention and the control groups were randomly assigned, it is assumed that O_1 and O_3 would be equivalent in all the factors that might have an effect on the outcome of interest and any difference observed between the intervention and control group at the posttest can be attributed to the effect of the intervention. This study typically follows a cohort of study participants over the study period or randomly selected from the sampling frame.

Figure 3: Pretest-posttest control group design



Application

The pretest-posttest control group design has been used widely in social science research and is most suitable for effectiveness studies where a new intervention or health service strategy is compared to standard of care or routine services (Fisher et al. 2002; Walker et al. 2009). Participants in the standard care or control group receive the intervention at the end of the study, especially when the intervention is found successful or involves capacity-building.

Illustrative example:

Assessing the effectiveness of a 'computer based on-line stigma reduction training program' to train service providers to improve their attitude and practices toward sex workers compared to the control group of service providers who do not receive this online training.

Strengths

- Most of the extraneous attribution or counterfactual factors or confounders are balanced between the intervention and control group.
- High interval validity.
- Investigators can assess the effect of the intervention at several levels in addition to the overall effect. For example the evaluator can assess the effect at each stratification level, in addition to the overall impact.
- Fewer assumptions are required, which translates into fewer threats to internal validity as this design distributes the confounders equally between the intervention and the control group.
- External influences affect both groups equally.
- Randomized designs are easy to analyze.

Limitations

- It may not be ethical to assign the intervention to only one group when proven effective (for example, sex workers cannot be randomly assigned to use female condoms).
- In some situations randomization might not be possible.
- The design sometimes lack generalizability or external validity; the findings are limited to the sample population and may not be applicable to other settings or populations (Rothwell 2005).

Caution/concerns

- More expensive (often 10% to 20% higher) to conduct than designs that do not include a control group
- Contamination of the control group (for example, if a mass media campaign is introduced during the research period, it might be difficult to prevent the control group from receiving the campaign)

Data collection

Data collection is an important part of any study design. For the pretest-posttest control group design, quantitative data is most often collected through a structured interview administered by a trained interviewer. This approach uses a standardized questionnaire to ensure that all respondents are asked exactly the same set of questions in the same order. The exact wording of each question is standardized in advance and the interviewer simply reads each question to the respondent. The questionnaire is pretested in the field several times before finalizing.

Data analysis

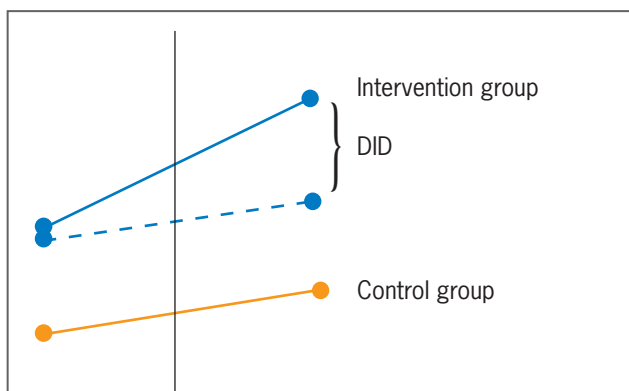
This study design would permit analysis to determine the following:

- Confirm the equivalence of the two groups at pretest; generally randomization ensures that confounders are equally distributed between the two groups.
- Is there a measurable change in the output and outcome indicators over time?
- Is the change over time observed in both the intervention and control group?
- Is the change observed in the intervention group more than the change observed in the control group?
- What is the magnitude of difference in the dependent variable between different interventions and the control group and is this difference statistically significant?

The pretest-posttest control group design allows for inferences to be drawn with regard to the direction and extent of the effect of the intervention tested. A description of the characteristics of the groups being studied includes descriptive statistics such as frequency distribution, percentages, means, and standard deviations which can be calculated at pretest for all socio-demographic covariates. Most often, while studying an intervention we want to know whether there are any differences between the intervention, and control groups in factors that might have an impact on the effect of the intervention. Therefore bivariate relationships can be examined using chi-square tests for categorical variables and t-tests

for continuous variables.⁴ Analysis of variance (ANOVA) can be used to test whether or not the means of more than two groups are equal. When there are more than two measurements for the same subject, repeated measures ANOVA is used to assess change over time. Multiple regression techniques can be applied to assess the relationship between exposure to intervention and the outcome of interest. Techniques such as generalized estimating equation (GEE) can be used to analyze the effect of time and intervention on the outcomes of interest. Figure 4 is an example of a graph presenting the effect of program difference-in-difference (DID). The blue line presents the change observed in the outcome of interest in the intervention group, the red line presents the change in the control group and the dotted line presents the change in the outcome in the intervention group in the absence of the intervention. The key assumption is that in the absence of intervention the change in the outcomes for the intervention group is similar to the change in the outcomes for the control group. Structural equation modeling can be used to assess the effect of intervention variables on the outcome of interest.

Figure 4: Graph of difference-in-difference

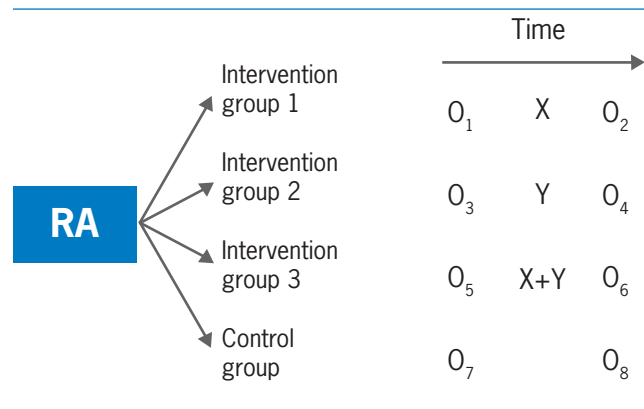


4 **Frequency distribution:** number of cases in each category. **Mean:** average. **Standard deviation:** measure of dispersion, informs how close the data is to the mean value. **Covariate:** a variable that is possibly predictive of the outcome under study. **Bivariate analysis:** examining the relationship between two variables. **Chi-square test:** statistical test of association for nominal or ordinal variables that examines whether there is a significant difference between distributions. **T-test:** a statistical test to determine whether the difference between the two means is statistically significant. **GEE:** multivariate statistical analysis used for longitudinal data (repeated measures).

Multiple treatment design

This design is an extension of the pretest-posttest control group design or RCT and compares the relative effectiveness of two or more interventions alone and in combination (Fisher et al. 2002). It is also called the factorial design. The presence of the control group permits determination of the counterfactual or what would be the outcome of not having the intervention. This design is more complex than the pretest-posttest control group design. In this design individuals or study units are randomly assigned to different intervention groups or to the control group. Measurements are taken for all the groups including the control group before and after the start of the intervention.

Figure 5: Multiple treatment design



RA: randomization
X and Y: two different interventions
O: observation or data collection

Application

There are practical difficulties in conducting this research study, such as retaining the integrity of the intervention to limit contamination between groups and setting up separate delivery systems for each intervention tested. This design, does however, increase the alternatives available for researchers when examining the effectiveness of several different types of interventions. For example, this design is useful when there are more than one intervention options and the researcher would like to determine the effectiveness of both the individual interventions when offered separately and when offered together.

Illustrative examples:

The multiple treatment design can be used when there is more than one viable way to effect change such as improving quality of care through training services providers (X), or generating demand through target beneficiary outreach (Y), or the combination of both (X + Y).

Strengths

- Random assignment of individuals or study units to different groups makes the intervention groups equivalent in most extraneous attributive or counterfactual factors that might influence intervention outcomes.
- This provides comparative effectiveness estimates for more than one intervention.

Limitations

- It may sometimes be unethical to randomize intervention.
- In some situations randomization may not be feasible. However, multiple treatment design can be applied using a comparison group instead of a control group (as a quasi-experimental design).

This design has high internal validity but in some instances may not have high external validity as sometimes the intervention is very locally specific; but if the researcher selects a representative sample of units and then randomly assigns them to different interventions or the control group, the results can be generalized to population of all eligible units.

Caution/concerns

- This design requires more time, effort, human resources, participants, and finances.
- Contamination is a concern if the study units—such as health facilities that receive different interventions—are in close proximity.

Data collection

For the multiple treatment design, quantitative data are most often collected through a structured interview administered by a trained interviewer using a standardized questionnaire to ensure that all respondents are asked

exactly the same set of questions in the same order. The questionnaire is pretested in the field several times before finalizing.

Data analysis

This study design permits analyses to determine the following:

- Are all the groups equivalent in all factors that can influence the effect of the intervention, at pretest?
- Are there changes in the output and outcome indicators over time in all the groups?
- How is the effect of each intervention compared to the control group?
- What is the magnitude of difference in the dependent variable between different interventions and control group and is this difference statistically significant?
- Is it more effective to offer individual intervention separately or together?

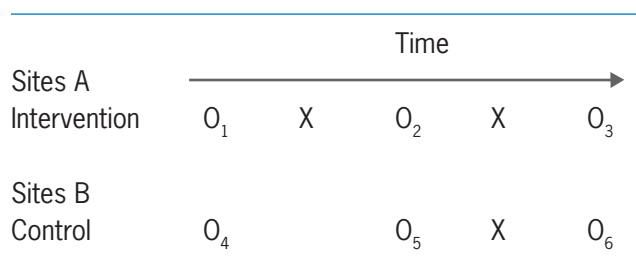
Descriptive statistics would be calculated at pretest and posttest for all socio-demographic covariates. The degree of equivalence between the intervention and control group is determined at pretest and posttest, as some covariates may vary overtime such as income, habits, marital status. Bivariate relationships can be examined using chi-square tests for categorical variables and t-tests for continuous variables (see footnote 4, page 35). ANOVA can be used to test whether or not the means of different groups are equal. Repeated measures ANOVA can be used to assess if the change over time is significant or not. All factors on which the groups differ significantly are included in the multivariate analysis. Multilevel modeling and GEE analysis can be used to analyze the effect of time and different interventions on the outcomes of interest (see footnote 4, page 35) .

Phased-in pretest-posttest control design

This design is a variation of the pretest-posttest control design, the difference being that the intervention is initiated later in the control group. This design involves doing a baseline pretest with randomly selected individuals from the study population in the intervention and control groups. This is particularly suitable in settings

where new programs are initiated in a phased manner in different geographic locations; this is seen most commonly in the roll out of national health programs across districts or provinces. Randomization can be used to phase in the intervention over time by introducing the intervention to one small group at one time. The sites where the intervention is rolled out first serve as the intervention group and sites where the intervention is yet to roll out serve as the control group. A pretest is conducted at both sites prior to the roll out of the program. Subsequently, an intervention is introduced and then a posttest is done with randomly selected individuals from the same study population. There is a pretest measure of the outcome prior to the start of the intervention, that provides a benchmark against which the posttest measure can be compared.

Figure 6: Phased-in pretest-posttest design



X: intervention
O: observation or data collection

Application

This design is often used where the intervention needs to be provided to all and when due to logistics it needs to be rolled out in phased in manner.

Illustrative example:

An information campaign to change community attitudes toward HIV and AIDS is being initiated in a few districts in the first year (district 1, 3, 5, and 7) and after six months the intervention will be upscaled to other districts (district 2, 4, 6, and 8) of the state. Sites in districts 1, 3, 5, and 7 serve as the intervention group and sites in districts 2, 4, 6, and 8 serve as the comparison group.

Strengths

- Allows researchers to include a control group even when all participants need to receive the intervention.
- Avoids ethical issues caused in other true experiment randomized assignments as even the control group receives the intervention at a later point.
- It protects against most of the threats to validity (see footnote 1, page 4).
- Most of the extraneous attributions or counterfactual factors or confounders are balanced between the intervention and control groups.
- High interval validity.
- External influences affect both groups equally.

Limitations

- In some situations randomization might not be possible.

Caution/concerns

- As the intervention is rolled out at a later stage in the comparison group, events in the community could affect the intervention.
- Due to the longer duration of the intervention in the intervention group, some maturation effects may be observed.
- Contamination is a concern if the study units such as health facilities are in close proximity.

Data collection

For the **phased-in pretest-posttest design** quantitative data collection is done using a standardized structured questionnaire administered by trained interviewers to ensure uniformity in the order and manner in which respondents are asked questions. The questionnaire is pretested in the field several times before finalizing.

Data analysis

This study design permits analyses to determine the following:

- What is the extent of difference between the two groups, at pretest?

- Is there a change in the output and outcomes of interest in the intervention and comparison group?
- Is there more change in the intervention group compared to the comparison group?
- What is the magnitude of difference in the dependent variable between intervention and control group and is this difference statistically significant?

This design allows for a three-way analysis (i) between the two groups in phase 1; and (ii) a pretest-posttest within-group analysis in the control group before and after the intervention has been initiated; and (iii) the difference between groups at endline phase 2 to compare a mature established program with a newly initiated program.

Quasi-experimental study designs

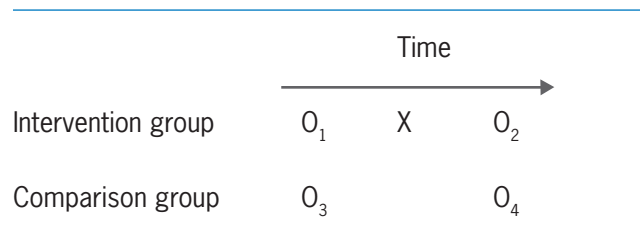
In many situations it may not be possible to meet the random assignment criteria of true experimental design due to program or cost constraints or ethical considerations. A reasonable compromise is to select a quasi-experimental design that offers a comparative evaluation while limiting threats to validity (Campbell and Stanley 1963; Fisher et al. 2002). A quasi-experimental design is similar to an experimental design except it lacks random assignment, i.e., the individuals or study units are not randomly assigned to intervention or non-intervention groups (comparison groups). It is important to note that while study units are purposively assigned to the intervention or comparison group, the individuals who participate in the evaluation are randomly selected to limit selection bias; however, selection bias can never be ruled out completely. There are several different quasi-experimental study designs, but in this section some of the more frequently used designs—namely non-equivalent group design (NEGD), separate sample pretest-posttest and phased-in pretest-posttest comparison design are described.

Non-equivalent group design

The most frequently used quasi-experimental comparison group design is the non-equivalent group design. With this design both an intervention and a comparison group are compared (Flaskerud and Nyamathi 1990; Fisher et al. 2002). A pretest is conducted for the inter-

vention group and comparison group, followed by an intervention and then the posttest for both groups. This design can also be used to test multiple interventions to assess comparison groups similar to the multiple treatment design described on page 35.

Figure 7: Non-equivalent group design



Application

The non-equivalent group design is selected when a program intervention is introduced into an area (for example one district) and the researcher wants to compare the program effects in that district against a similar, but not necessarily equivalent, neighboring district.

Strengths

- Allows researchers to include a comparison group when random assignment to control attribution or counterfactual confounders is not possible.
- May avoid ethical issues caused in some true experiment randomized assignments by withholding the intervention or treatment when it could have otherwise been provided.
- It protects against several threats to validity (see footnote 1, page 4) namely history, maturation, testing, and instrumentation due to the presence of the comparison group.
- Causality can be inferred if rival hypotheses are rendered implausible.

Limitations

- Does not control for extraneous variables that may influence findings, as the two groups may not be completely similar due to lack of random assignment, therefore any difference observed in the dependent variable could be due to these other factors.

- Susceptible to the threat to internal validity related to sample selection, i.e., the bias that may result while selecting the comparison group (see Campbell and Stanley 1963).

Caution/concerns

This method is resource-intensive as it involves two geographical areas.

Data collection

For NEGD, quantitative data is most often collected through a structured interview administered by a trained interviewer using a standardized questionnaire to ensure that all respondents are asked exactly the same set of questions in the same order. The questionnaire is pre-tested in the field several times before finalizing.

Data analysis

This study design permits analyses to determine the following:

- What is the extent of difference between the two groups, at pretest?
- Is there a change in the output and outcomes of interest in the intervention and comparison groups?
- Is there a difference in the dependent variable between the intervention and comparison group?
- Is there more change in the intervention group compared to the comparison group?
- What are the major differences between the two groups that might explain differences at posttest?
- What is the magnitude of difference in the dependent variable between the intervention and comparison group and is this difference statistically significant?

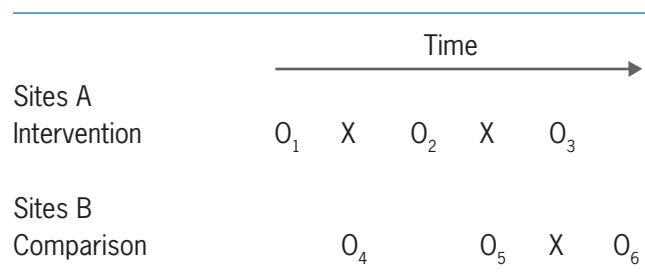
The **non-equivalent group design** allows for an inference to be drawn with regard to the direction and extent of effect of the intervention tested. Descriptive statistics such as frequency distribution, percentages, means, and standard deviations can be calculated at pretest for all socio-demographic covariates. Baseline equivalence of the two groups can be determined by examining bivariate relationships using chi-square tests for categorical variables and t-tests for continuous variables.

Techniques such as generalized estimating equations (GEE) can be used to analyze the effect of time and intervention on the outcomes of interest (see footnote 4, page 35).

Phased-in pretest-posttest control design

This design is a variation of the non-equivalent group design, the difference being that the intervention is initiated later in the comparison group. This design involves doing a baseline pretest with randomly selected individuals from the study population in the intervention and comparison groups. This is particularly suitable in settings where new programs are initiated in a phased manner in different geographic locations; this is seen most commonly in the roll out of national health programs across districts or provinces. The sites where the intervention is rolled out first serve as the intervention group and sites where the intervention is yet to roll out serve as the comparison group. A pretest is conducted at both sites prior to the roll out of the program in the comparison groups. Subsequently, an intervention is introduced and then a posttest is done with randomly selected individuals from the same study population. There is a pretest measure of the outcome prior to the start of the intervention, that provides a benchmark against which the posttest measure can be compared.

Figure 8: Phased-in pretest-posttest design



X: intervention
O: observation or data collection

Application

This design is often used where the researcher cannot randomize or segregate subgroups for receiving the intervention.

Illustrative example:

An information campaign to change community attitudes toward HIV and AIDS is being initiated in province A this year and is to be initiated in province B after 6 months. Sites in Province A serve as the intervention group and sites in Province B serve as the comparison group.

Strengths

- Allows researchers to include a comparison group when random assignment to control attribution or counterfactual confounders is not possible
- May avoid ethical issues caused in some True Experiment randomized assignments by interfering with the implementation of the program design such as changing the geographic rolling out of intervention or treatment in an efficient manner.
- It protects against threats to validity (see footnote 1, page 4) testing and instrumentation are controlled due to the presence of a comparison group.
- Causality can be inferred if rival hypotheses are rendered implausible.

Caution/concerns

- As the intervention is rolled out at a later stage in the comparison group, events in the community could affect the intervention.
- Due to the longer duration of the intervention in the intervention group, some maturation effects may be observed.

Limitations

- Does not control for extraneous variables that may influence findings, as the two groups may not be completely similar due to lack of random assignment, therefore any difference observed in the dependent variable could be due these other factors.
- As the intervention is not randomly assigned selection bias cannot be ruled out (see Campbell and Stanley 1963).

Data collection

For the **Phased-in pretest-posttest design**, standardized structured survey instruments administered by

trained interviewers are employed to collect quantitative data. This technique ensures that all respondents are asked questions in a uniform order and manner. The questionnaire is pretested in the field several times before finalizing.

Data analysis

This study design permits analyses to determine the following:

- What is the extent of difference between the two groups, at pretest?
- Is there a change in the output and outcomes of interest in the intervention and comparison groups?
- Is there more change in the intervention group compared to the comparison group?
- What are the major differences between the two groups that might explain differences at posttest?

This design allows for a three-way analysis (i) between the two groups in phase 1; and (ii) a pretest-posttest within-group analysis in the comparison group before and after the intervention has been initiated; and (iii) the difference between groups at endline phase 2 to compare a mature established program with newly initiated program.

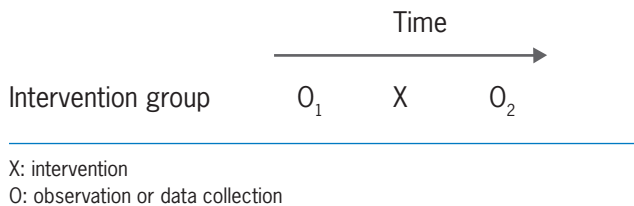
Non-experimental study designs

True experimental and quasi-experimental study designs include control or comparison groups to compare the study intervention(s) with. However, in many settings it may not be possible to include a control group; for instance when researchers would like to assess the impact of a HIV prevention program that is to be rolled out simultaneously across all districts. In such settings, there are several non-experimental designs that can be used by HIV/AIDS researchers. These study designs lack a control group making them less robust research designs, but nevertheless an important methodology for impact assessment and monitoring change over time. In this section we describe the most commonly used design, namely pretest-posttest single group design.

Pretest-posttest single group design

This design is also known as the observational cohort study design where a group of study participants is followed over time; there is no control group. An initial measurement is taken at baseline (pretest) and is followed by the introduction of the intervention. Subsequently, after the intervention period or after a specified period of time, a second set of measurement observations are made (posttest). A comparison of the two measurements allows the researchers to determine the level of change in the outcome of interest.

Figure 9: Pretest-posttest single group design



Application

The pretest-posttest single group design is suitable when the purpose of the study is to measure change but not demonstrating attribution. It is a common design used for evaluating the immediate effects of a training activity (change in knowledge and skills between pretest and posttest).

Illustrative example:

In situations when the investigator wants to see the improvement in knowledge of sex workers about HIV/AIDS after the introduction of HIV prevention intervention in the community.

Strengths

- Less expensive than experimental designs.
- Easy to conduct.
- The findings are useful to indicate whether the intervention is making a difference.

Limitations

- The design does not have a control or comparison group therefore effectiveness of the intervention cannot be assessed and can only be stated as a contribution based on a good theory of change.
- Threats to validity include history, maturation, testing, and instrumentation (see footnote 1, page 4).

Data collection

For the **pretest-posttest single group design**, quantitative data collection is done by trained interviewers who use a standardized questionnaire such that there is uniformity in the order of and manner in which questions are asked. The questionnaire is pretested in the field several times before finalizing.

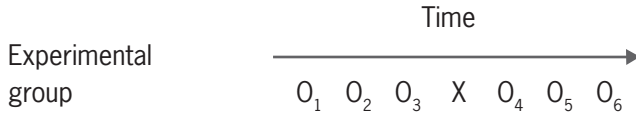
Data analysis

This study design permits analyses to determine the following:

- Is there change over time in the outcomes of interest? For example, has correct knowledge about HIV/AIDS increased between pretest and posttest?
- What is the magnitude of the change observed between pretest and posttest and is that change statistically significant?

The **time series design** is an extension of the pretest-posttest single group design that has been used in different OR studies; often as the only feasible alternative when a control group is not possible. This design is frequently used in HIV/AIDS research for estimating the outcome measures using a representative sample of the study population. The time series design is similar to the non-experimental pretest-posttest design except that it has the advantage of repeated measurement observations before and after the program intervention X and has the advantage of eliminating some of the threats to internal validity. At each time point individuals are randomly selected from the same study population.

Figure 10: Time series design



While it is a stronger design compared to the pretest-posttest single group design the strengths and limitations are similar in terms of not having attribution of results.

A1.3 Qualitative methods

Although quantitative methods provide data and effect estimates for a problem in a community that can be generalized to other settings, these studies provide responses to structured questions designed by researchers. Qualitative methods, on the other hand, provide detailed and in-depth information examining the ‘how’ and ‘why’ of a situation or problem. They provide supplementary and explanatory data to augment the findings from quantitative surveys. This section describes the three qualitative methods frequently used in operations research studies, namely in-depth interviews, focus-group discussions, and direct observation.

In-depth interviews

In-depth interviewing methods seek detailed open-ended responses on areas of research inquiry. Unlike the structured interview, the in-depth interview, also known as semi-structured interview, permits greater depth and seeks detailed responses. The interviewee is often purposively selected. The interviewer uses an outline or a set of general questions that serve as a guide to gather the required information from the respondents. Detailed information on behaviors or other topics of interest can be further explored through probing.

Application

In-depth interviews can be used to explore in greater detail results obtained from quantitative studies, thus

providing supplementary information; or to clarify concepts and generate hypothesis to be further examined by quantitative studies.

Illustrative example: They are frequently used in exploratory studies that seek to clarify concepts. For example, sex workers are highly mobile, and violence has been identified as one of the main factors associated with mobility. It is important to understand whether violence led to mobility or mobility leads to violence so that interventions can be designed accordingly.

Strengths

Detailed information can be obtained through this approach, which is a chief drawback of the structured interview.

Limitations

- In-depth interviews require highly skilled and experienced interviewers.
- The analysis is complex and time consuming; it can be done manually or with special software such as Atlas.ti or NUD*IST NVivo.
- The sample is rarely randomized and therefore the results cannot be generalized to other geographic area or other populations.

Focus-group discussion

Focus group discussions (FGDs) bring together a number of respondents to discuss a particular topic. FGDs yield detailed qualitative information from a large number of respondents in a single interview session. The interviewer follows procedures similar to those used in in-depth unstructured interviews and examines topics listed in a discussion guide; areas of inquiry and interest are probed to better understand the context and bring out details. The questions are asked in an interactive group setting, where participants talk to each other during discussion. Participants are usually sampled purposively to reflect heterogeneity among the target group, for example sex workers.

Strengths

- Reduces the amount of time and number of persons required for conducting an in-depth interview.
- Is more economical compared to undertaking in-depth interviews with several participants.

Limitations

- Not easy to conduct, a highly skilled and trained facilitator is required to guide the group.
- The discussion can be influenced by one or two dominant people.
- May not be as effective as in-depth interviews when it comes to sensitive issues that participant may not want to discuss in public.
- Analysis is complex and time-consuming.

Direct observations of operations

This approach generates quantitative or qualitative data; used for small-scale exploratory studies. Individuals perform their day-to-day activities in their environment without being disturbed and they are observed by the researcher who records both subjective and objective information. This activity is undertaken most often to assess quality of services.

A1.4 Sampling strategies

Key affected populations such as female sex workers are marginalized groups that are not easy to reach due to the nature of their work. Hence, studies with these populations require special sampling approaches. Sampling is the method of selecting a subset of individuals from the study population. This is particularly significant as inferences drawn from these samples are applied or generalized to other situations or populations. Operations research projects depend on data that have been obtained from samples; therefore, selecting an appropriate sample is a critical component of OR. The nature of the operations research study and the type of data required determine the sampling methodology. Simple random sampling requires listing of the larger population out of which the study sample is to be

selected; based on the sample size study participants are then selected randomly from this list. In the case of marginalized or hidden populations such as female sex workers, listing of the larger population is not available. Table 9 describes some of the frequently used sampling methods in operations research with regard to studies with marginalized populations

A1.5 Statistical techniques

One of the most important parts of OR is the data analysis plan. The researcher must know which analysis s/he plans to perform in the design phase of the study. It is critical to decide in advance about the analytical approaches that are most appropriate for the study objectives. This section describes a range of statistical tests that are widely used in OR.

Chi-square test: This is the test of statistical significance used for categorical data. This test is used to find the association between two categorical variable. For example, to check for association between the place of solicitation of clients by sex workers and their condom use behavior.

Fisher's exact test: This test of significance is recommended for categorical data when a chi-square test cannot be used, i.e., when the sample size is small, when the overall total of the table is less than 20 or when one of the cell counts is less than 5. For example, 60 women were enrolled in a randomized control trial to assess the effectiveness of a behavior change intervention in increasing the use of female condoms. In the follow-up interview 10 of the 30 women in the intervention group reported using female condoms, whereas only 4 in the control group reported female condom use. In this example, if a two-by-two table was constructed, one of the cell counts is less than 5, therefore Fisher's exact test is to be used.

Student's t-test: This test is used to assess the statistical significance of the difference between two population means in a study based on data obtained from independent observations. For example, it may be used in an HIV/AIDS prevention intervention where we want to assess if the participants who received a week-long course reduced their number of sexual partners, compared to those who did not receive the course.

Table 9: Sampling methodologies

Type of sampling	Features	Advantages	Disadvantages
Simple random sampling	<p>This technique is usually reserved for use with relatively small populations with an easy-to-use sampling frame.</p> <p>A list of the entire population is prepared and a sample is selected randomly. Systematic random sampling is a modification of simple random sampling, where a sampling interval is fixed (n) and every nth individual is selected from the population listing – this is particularly useful when the sampling frame consists of very long lists.</p> <p>Simple random sampling may be applicable to selection of health providers at a facility.</p> <p>Systematic random sampling may be used to select households or health facilities from a municipal or government list.</p> <p>Random selection of individuals can be done using an application of a lottery system.</p>	<p>Easy to use</p> <p>This forms a representative sample.</p>	<p>Requires listing of the entire population which may not always be possible.</p>
Stratified random sampling	<p>Stratified random sampling is a technique used to ensure that all relevant strata of the population are represented in the sample, for example, rural and urban.</p> <p>Stratification can be used in conjunction with random sampling.</p> <p>One can draw a proportionate (sample distribution is similar to the population distribution) or disproportionate stratified sample.</p>	<p>Easy to use.</p> <p>Can be combined with simple or systematic random sampling to generate a representative sample.</p>	<p>Modification required when strata are very different from each other.</p>
Conventional cluster sampling	<p>This is a commonly used probability sampling technique.</p> <p>Samples are selected in two or more stages.</p> <p>A cluster is a group of sampling units (not individuals); clusters are defined by location.</p> <p>A fixed number of individuals are selected from predetermined clusters.</p> <p>Sample sizes are calculated based on probability of selection, effect size, and confidence intervals.</p> <p>This may be applied to selection female sex workers from brothels (clusters).</p>	<p>Selection probability can be calculated.</p> <p>Used when a complete list of all individuals is not available.</p> <p>Used when the population to be studied is complex.</p>	<p>Requires large sample size for reliable estimates of population characteristics.</p> <p>Increases sampling error.</p>
Time location cluster sampling	<p>Is a modified cluster sampling technique.</p> <p>Clusters are defined by both location and time.</p> <p>Venues where subgroups (for example, sex workers) can be reached are listed with time of work.</p> <p>A random sample of venues and times is selected. A fixed number of participants are selected from these locations.</p> <p>Sample sizes are calculated based on probability of selection, effect size and confidence intervals.</p> <p>Suitable for a survey with FSWs.</p>	<p>Selection probability can be calculated.</p> <p>Efficient for hard to reach populations.</p> <p>No need for a complete list of individuals.</p>	<p>Need complete mapping of venue-day-time.</p> <p>May be biased toward those who attend venues more often and omits those who do not attend often.</p>
Respondent driven sampling (Snowball Sampling)	<p>This is also called modified chain referral sampling.</p> <p>Initial seeds are selected purposively to obtain a diverse group of participants who can reach out to a variety of networks (FSWs).</p> <p>Initial seeds recruit respondents from their network, who in turn recruit further respondents from their network, leading to a chain of respondents.</p> <p>Participants are allowed to recruit a limited number of respondents to prevent oversampling of respondents with similar characteristics.</p> <p>Participants receive an incentive (payment) for their own interview and the interview of their contacts.</p>	<p>Selection probabilities can be calculated, as coupons are used for recruitment.</p> <p>Allows recruitment of participants from deep within networks.</p> <p>Can generate a representative population sample to generate population based estimates for behaviors.</p>	<p>Locates hidden population.</p>
Purposive sampling	<p>Individuals are deliberately selected to provide specific information about a population.</p> <p>This technique is mostly used for qualitative research.</p> <p>Participant selection is based on characteristics of interest requiring further inquiry.</p>	<p>A convenience sample.</p>	<p>Sampling probabilities cannot be calculated.</p> <p>Selection of individuals is subjective.</p>
Facility sampling	<p>Individuals visiting a facility are sampled for interview.</p> <p>Used mostly for facility managers, provider interviews, exit interviews with clients, and direct observation.</p>	<p>Easy to reach individuals who visit health facilities.</p>	<p>Those who visit the facility are not representative of the population.</p>

Man-Whitney U test: This test is an alternative to the student t-test. For example, a study comparing the CD4 counts of nine HIV-positive people who consume alcohol with nine HIV-positive people who did not consume alcohol.

Paired t-test: This is a statistical test that is performed to determine if there is a difference between outcome measurements made before and after an intervention.

Wilcoxon Signed Rank test: This test is an alternative to the paired t-test when the sample size is small. For example, a trial may test the effectiveness of drug A on improving sleep time among 10 AIDS patients. For each patient a sleep time is measured on one night with drug A and on another night with a placebo and results are compared.

Analysis of Variance (ANOVA) test: This test is used to compare means of several groups. The method is used to assess how much of the overall variation in the data is attributable to differences between the group means, and by comparing the amount attributable to the difference between individuals in the group. For example, comparing peer educators' performance when they receive one, two, or three days of training. **Repeated Measures Analysis of Variance (RMANOVA)** is used when there are more than two measurements on the same subject.

Pearson's Correlation or Spearman's Rank Correlation test: In a descriptive study, researchers may want to assess the relationship between two quantitative variables. Correlation quantifies the linear relationship between two continuous variables, for example, age at positive HIV test and CD4 count.

Linear regression: Regression analysis is useful in ascertaining the form of relationship between variables. Through this technique, the value of the dependent or outcome variable can be predicted corresponding to a given value of the independent or intervention exposure variable, for example, assessing the effect of the dosage of Drug A on blood pressure levels of AIDS patients.

Logistic regression: This technique is used to measure the relationship between categorical outcome or dependent variables such as dead/alive, consistent condom user or not, HIV positive or negative and an independent variable, for example, to assess the effect

of exposure to HIV prevention intervention on consistent condom use (yes/no) among female sex workers. **Nominal logistic regression** technique is used when the nominal dependent variable has three or more categories, for example, to measure the relationship between place of residence and the site where people go for voluntary counseling and testing (more than two options). **Ordered logistic regression** technique is used when multiple categories of dependent variable is ordered, for example, to assess the effect of intervention among female sex workers on condom use behavior with occasional clients: every time, most of the time, sometimes, never.

Multilevel modeling: This is an advanced method. This technique allows study of the simultaneous effect of individual- and aggregate-level variables, and their respective interactions, upon a response variable at the individual level. Multilevel modeling is appropriate for research designs where the data for participants are organized at more than one level; for example, to check for an association between income and the number of clients after considering the place of solicitation as the aggregate-level variable.

Generalized estimating equation: This technique is used to estimate the effect of an intervention on the outcome of interest after incorporating the effect of time trend. Through this technique one can determine if the magnitude of change in the outcome of interest is statistically significant, for example, to identify if therapy given to HIV-positive persons increases their CD4 counts at three time points.

Propensity score matching: This is a technique used when there is no true control. Propensity score matching is a technique to correct the estimation of the effect of intervention controlling for the existence of confounders by creating a counterfactual control group. It is based on the idea that when the intervention group and the control group are as similar as possible, the confounding is reduced. For example, to measure the effect of community mobilization on voluntary HIV testing, it is not ethical to randomly assign community mobilization; therefore observational studies are required and propensity score matching technique is used to create a counterfactual control group.

B. GLOSSARY AND ACRONYMS

Bias: Any systematic error in an epidemiologic study that results in an incorrect estimate of the association between exposure and risk of disease.

Selection bias: The bias that occurs when the identification of individual subjects for inclusion in the study on the basis of either exposure or outcome status depends in some way on the other axis of interest.

Confounders: Extraneous factors are associated with both the outcome and the exposure of interest.

External validity: The extent to which the study results can be generalized to other settings or groups which have not themselves been studied.

Internal validity: The extent to which the measurements are true and accurate and one can answer with confidence that the intervention made or did not make a difference in a particular geographic setting with a particular population group at a particular time in history.

Information bias: The bias that springs from systematic differences in the way data on exposure or outcome are obtained from various study groups.

Integration: Different kinds of SRH and HIV services or operational programmes that can be joined together to ensure and perhaps maximize collective outcomes. This would include referrals from one service to another, for example. It is based on the need to offer comprehensive and integrated service. For example, in the context of tailoring SRH and HIV integration for concentrated epidemics, integration of SRH services can include both delivery of specific SRH services within HIV programs for KAPs or referrals to SRH services.

Linkages: The bi-directional synergies in policy, programmes, services, and advocacy between SRH and HIV. It refers to a broader human rights based approach, of which service integration is a subset.

Sample: The subset of the population that one examines in order to generalize about the total population.

Sampling frame: The list of the population from which the sampling units are drawn.

Sampling units: The elements into which a population is divided.

Study population: Group of individuals about which the study data have been collected.

Target population: The collection of individuals from which one has sampled and about which one wishes to make statistical inferences.

Acronyms

APRO	Asia–Pacific Regional Office
ART	Antiretroviral therapy
CORT	Country OR Team
DACO	District AIDS Control Officials
DID	Difference-in-difference
FGDs	Focus group discussions
FP	Family planning
FSW	Female sex worker
GEE	Generalized estimating equation
IDIs	In-depth interviews
IDU	Injecting drug user
IEC	Information, education, and communication
GBV	Gender-based violence
KAPs	Key affected populations
KIIs	Key informant interviews
M & E	Monitoring and evaluation
MCH	Maternal and child health
MSM	Men who have sex with men
NEGD	Non-equivalent group design
OR	Operations research
PEP	Post exposure prophylaxis
PI	Principal investigator
PLHIV	People living with HIV
PMTCT	Preventing mother-to-child transmission
PWID	People who inject drugs
RORT	Regional OR Team
RSC	Regional steering committee
SDPs	Service delivery points
SOPs	Standard operating procedures
SRH	Sexual and reproductive health
STI	Sexually transmitted infection



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