Postpregnancy Family Planning Choices in Public and Private Sectors in Kenya and Indonesia (PPFP Choices)

Study Protocol

Jhpiego

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JHSPH IRB Research Plan for New Data Collection

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Study Title: Postpregnancy Family Planning Choices in the Public and Private Sectors in Kenya and Indonesia
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I. Aims of the Study: Describe the aims/objectives of the research and/or the project's research questions or hypotheses.

The primary goal of PPFP Choices is to generate actionable evidence that can be used to improve programmatic activities to address post-pregnancy family planning in the public and private-for-profit sectors, and the ultimate intent of this investment is to advance and scale up post-pregnancy FP. The primary research question is:

Research Question
What are the key determinants at service delivery, provider and client levels that influence the uptake of post-pregnancy family planning in the public and private health care sectors in Indonesia and Kenya?

Secondary study questions evaluate: the program's impact on postpregnancy family planning uptake; the feasibility and acceptability of introducing programmatic elements and new methods of postpregnancy family planning; and the potential for scaling up successful programmatic elements and interventions. A detailed list of secondary study questions can be found in **Appendix I**.

II. Background and Rationale: Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.

Family planning (FP) is important throughout an individual's and couple's reproductive life, and particularly during the time immediately following pregnancy. The provision of family planning following pregnancy is a life-saving intervention that not only prevents unintended pregnancies, but also improves postnatal outcomes for mothers and infants and perinatal outcomes in subsequent pregnancies [1][2]. The WHO recommends spacing pregnancies by 2 years or more following the delivery of a newborn, and at least six months following spontaneous or induced abortion [1][2]. However, these recommendations are not always followed.

Prospective estimates find that 63% of Kenyan women and 27% of Indonesian women in their first year postpartum have an unmet need for FP [3][4]. Data from Kenya demonstrates a great need for PPFP services as 23% of births occur at intervals of less than 24 months, while only 19% of postpartum women begin using a family planning method during the first 6 months postpartum and 36% between 6-12 months postpartum [3]. In Indonesia, while the contraceptive prevalence rate among married women of reproductive age is 58%, despite these methods' higher effectiveness and the merits of a broader method mix, long-term methods such as implants, intrauterine devices (IUDs) and sterilization account for only 10.6 percent of contraceptives used [4]. Both IUD and implant use has fallen from 17% to 4% and 6% to 3% respectively from 1994 to 2012 [6][7].

Fertility typically returns within two to three weeks after spontaneous or induced abortion, and as noted earlier, the WHO recommends a six month delay before subsequent conception. While USAID endorses post-abortion family planning (PAFP) as one of the proven high impact practices (HIPs) for FP, a Jhpiego assessment of facilities in both Kenya and Indonesia found that postabortion family planning counseling does not typically receive adequate attention of providers at health facilities in either country and is often not completed. In Kenya especially, more than half of postabortion clients expressed interest in using contraception, but only 1 in 4 left the facility with a contraceptive [8].

Jhpiego, with funding from the Bill and Melinda Gates Foundation, and in collaboration with the governments of Indonesia and Kenya, is implementing a program which aims to work within existing public and private health facilities to strengthen the quality of post-pregnancy family Planning (PPFP), which focuses on the prevention of unintended pregnancies through the first 12 months following childbirth and the first 6 months following spontaneous or induced

abortion. The program will strengthen and assess the effectiveness of PPFP counseling and services, and expand method choice for women during antenatal, early labor, and post-pregnancy pre-discharge periods.

This protocol outlines the evaluation of the program's postpregnancy family planning intervention with a comparison group to measure the outcomes of the intervention package in both countries and generate evidence to inform and accelerate national and global policy change and program implementation. Indonesia and Kenya are the two settings from which we will generate actionable evidence for realistic programmatic efforts - implementation research - to address PPFP in the public and private sectors by gaining an understanding of PPFP barriers and facilitators.

III. Study Design:

A. Provide an overview of your study design and methods. The study design must relate to your stated aims/objectives. Details will be requested later. If your study also involves analysis of existing data, please complete Section XI, "Secondary Data Analysis of Existing Data" in the last part of this research plan. If your study ONLY involves analysis of existing data, please use the research plan template for secondary data analysis (JHSPH IRB Research Plan for Secondary Data Analysis of Existing Data/Specimens).

This study will employ a quasi-experimental design with an intervention and control group. The intervention package will be implemented in phases: the comparison group will eventually receive the intervention package after the final study assessment. A mixed method approach will be used; both quantitative and qualitative data will be collected at multiple timepoints, as is described in Study Procedures Section C 5. The implementation study is planned to encompass a period of 36 months as depicted by the timeline in **Appendix II**.

Following the implementation of the intervention in the "intervention group" (in this case, the "intervention group" and "control groups" consist of health facilities within certain districts/counties borders), both qualitative and quantitative data will be collected in public and private facility settings to explore individual, community and institutional supply- and demand-side factors influencing PPFP uptake. In Kenya, the entry point will be at antenatal care (ANC) while in Indonesia, it will be at delivery. Enrolled post-pregnancy clients will be followed up prospectively. **Table 1** displays the time points during a participants' pregnancy experience for the quantitative data collection tools and **table 2** shows all study data elements to be collected.

Table 1: Quantitative Questionnaires by Country

	ANC (>28 weeks gestation)	Immediate Postpartum (within 72 hours in Indonesia, within 48 hours in Kenya prior to discharge)	6-Months Postpartum	Immediate Postabortion (within 72 hours in Indonesia, within 48 hours in Kenya, prior to discharge)	6-Months Postabortion
Kenya Questionnaire	Postpartum Interview 0 (Kenya)	1) Postpartum Interview 1_ Kenya Pre-Supplement 2) Postpartum Interview 1	Postpartum Interview 2	PAC Interview 1	PAC Interview 2
Indonesia Questionnaire	*nil*	1) Postpartum Interview 1_ Indonesia Pre-Supplement 2) Postpartum Interview 1 3) Postpartum Interview 1_ Indonesia Post-Supplement	Postpartum Interview 2	PAC Interview 1	PAC Interview 2

Shading in green indicates tool used only in Kenya, while orange shading indicates a tool used in Indonesia only. Tools without shading will be used in both countries.

Table 2: Data collection strategies for the different study populations at intervention and control sites

Strategy	Sample	Goal	Study Timepoint	Client Timepoint
Key Informant Interviews (KIIs)	From Each Country: 1. (1) National Ministry of Health/ 2. (2) County/District Level Ministry of Health and Policy Makers 2. (2-3) Community influencers 3. (3) Public Facility providers and administrators 4. (3) Private Facility providers and administrators	Identify social, cultural, contextual, economic and age- and gender-related factors impacting community perceptions of and barriers to accessing and utilizing FP services	Baseline (Study month 4-6), endline (Study month 28-30)	
Client interview	Postpartum and Postabortion Women who gave birth or accessed postabortion services at a study facility during the project period	Understand relationships between client satisfaction and attitudes, PPFP knowledge and FP intentions, use and continuation		Kenya Postpartum: ANC, Immediately postpartum, 6 months postpartum Kenya Postabortion: Immediately postabortion, 6 months postabortion Indonesia Postpartum and Postabortion: Immediately post-pregnancy, 6 months post-pregnancy
Focus Group Discussions (FGDs)	From Each County/District: Women 6 to 12 months postpartum 1. (2) groups of 8 adult public facility acceptors 2. (2) groups of 8 adolescent public facility acceptors 3. (2) groups of 8 adult private facility acceptors 4. (2) groups of 8 adolescent private facility acceptors 5. (2) groups of 8 public non-acceptors 6. (2) groups of 8 private non-acceptors Total = 96 participants per arm per country per year	Identify social, cultural, contextual, economic and age- and gender-related factors affecting women's perceptions of, access to and use of FP	Year two	Postpartum Clients: 6-12 months postpartum
In-Depth Interviews	Postabortion women who had planned to receive a FP method did not receive a FP method during the immediate postabortion period	Identify social, cultural, contextual, economic and age- and gender-related reasons women did not receive an immediate postabortion family planning method		Postabortion clients: 6-month follow-up
Facility Audit	Facilities, facility in-charges	Identify facility-level supply-side barriers to accessing and utilizing PPFP	Year one (baseline), year two (midline), year three (endline)	

B. Provide a sample size and a justification as to how you arrived at that number. If you use screening procedures to arrive at a final sample a table may be helpful.

Health facilities selected for study implementation, from where participants will be recruited, will have met the following criteria:

- Site where provider(s) trained in LARC methods exist (or in Kenya: where we can train them);
- Facility birth rate at least 50 deliveries per month;
- Programmatically feasible (distance, etc.);
- The health facility is within or serves the study region;
- The facility is legally registered and current in its registration;
- Either public, or private for-profit (Indigenous owned, tax paying) facilities

This study will collect data from individuals recruited at selected facilities through both qualitative and quantitative methods. An overview of the total sample to be included is outlined in table 3.

Table 3: Sample size of recruited study participants

	Kenya Public Facilities	**Kenya Private Facilities**	**Kenya Ministry of Health and Policy Makers**	**Kenya Community Influencers**	**Indonesia Public Facilities**	**Indonesia Private Facilities**	**Indonesia Ministry of Health and Policy Makers**	**Indonesia Community Influencers**	**Total sample**
Key Informant Interview	3	3	3	3	3	3	3	3	**24**
	Kenya Public Facilities Intervention	**Kenya Public Facilities Control**	**Kenya Private Facilities Intervention**	**Kenya Private Facilities Control**	**Indonesia Public Facilities Intervention**	**Indonesia Public Facilities Control**	**Indonesia Private Facilities Intervention**	**Indonesia Private Facilities Control**	**Total sample**
Postpartum Client Interview	1803	1803	451	451	1715	1715	429	429	8796
Postabortion Client Interview	174		69		161		82		486
TOTAL SAMPLE SIZE									**9282**
Focus Group Discussions	48	48	48	48	48	48	48	48	384
Postabortion In-Depth Interviews	6	6	2	2	6	6	2	2	32
Total FGD and Postabortion Qualitative Interviews (Participants from Postpartum and Postabortion Client Interviews)									416
TOTAL SAMPLE SIZE									**9282**

More detail about the sample sizes for each method is outlined in the following section, categorized by data collection method or population of interest.

Qualitative Interviews (Focus Group Discussions, Initial Key Informant Interviews, In-Depth Interviews):
In each country, 12 initial Key Informant Interviews (KIIs) will be conducted at baseline and again at the end of the study.

In each county/district, 12 FGDs will be conducted with participants 6 to 12 months postpartum. Two FGDs will take place for each of the following groups:

- 2 FGDs of 8 adult public facility acceptors
- 2 FDGs of 8 adolescent public facility acceptors
- 2 FDGs of 8 adult private facility acceptors
- 2 FDGs of 8 adolescent private facility acceptors
- 2 FDGs of 8 public non-acceptors
- 2 FDGs of 8 private non-acceptors

Each FGD will be comprised of eight participants as a group size of six to twelve has been advocated for logistical purposes as well as to ensure the breadth of responses required [9][10][11][13][14].

Additionally, 16 in-depth interviews per country will be conducted with postabortion clients who did not receive any modern FP method at the immediate postabortion period. We anticipate that a sample size of 16 will allow for data saturation.

Our sampling strategy for qualitative interviews will help to achieve saturation of themes for our domain of interest, and will also provide a sufficient amount of data to compare across regions and countries.

Client Interviews:
All postpartum and postabortion participants will complete an interviewer-administered survey at each study visit. In calculating our sample sizes for this study, we make the following assumptions:

Table 4: Sample Size Calculations, Postpartum

	Sample Size, assuming 30% attrition, 10% refusal	Design Effect (2.5) and Cluster Size Adjusted Sample Size Per Arm	Sample size per arm (80% Public, 20% Private)	Total per Country (2 arms)
Kenya Public	721	2254	1803	4508
Kenya Private			451	
Indonesia Public	686	2144	1715	4288
Indonesia Private			429	

Table 5: Sample Size Calculations, Postabortion

Study Arm	Base sample size of post-abortion clients (per arm – assuming 50% uptake and 40% continuation at 6-months)	Attrition Adjusted Sample Size per arm (estimating 20% attrition)
Kenya Intervention	194	243
Indonesia Intervention	194	243
	Total	**486**

Separate sample sizes have been calculated for Indonesia and Kenya. Estimates aim to measure a difference in the six-month postpartum acceptance of long-acting reversible and permanent methods (LARC+PMs) by postpartum women seeking services at comparison and intervention facilities. Sample size calculations for both countries are based on a 95% two-sided confidence interval with 80% power. The sample size was calculated in two stages. First, we calculated the sample size for simple random sampling. Next, the sample size was adjusted to take into account a design effect of 2.5 in order to adjust for within-cluster correlation and non-response.

In Indonesia, we used an analysis of PPFP utilization from the 2012 Demographic and Health Survey (DHS) and conversations with the My Choice project team (My Choice is a Bill and Melinda Gates Foundation-supported project currently strengthening family planning services at facilities in Indonesia) to estimate a baseline LARC+PM use of approximately 10% at six months postpartum. In Kenya, we analyzed FP method use among a subset of 3,857 women with a child under one year interviewed during the 2014 Kenya DHS to estimate a LARC+PM use rate of 6% at six months postpartum. Sample sizes were calculated to measure a change from 10% to 15% in Indonesia and from 6% to 10% in Kenya at intervention facilities over the course of the study. We have further estimated a need for 20% of the sample to be recruited from private facilities in order to effectively measure changes in both types of facilities. An overview of the sample size for each country is shown in Table 4. This table displays the required number of post-pregnancy women to be recruited per arm to measure the change in LARC+PM use post-pregnancy from 10% to 15% in Indonesia and from 6% to 10% in Kenya at the end of the study.

The population of women who will experience postabortion care was calculated differently. Since the current proportion of these women who take up an FP method after PAC has not been reliably determined in the two countries, we have assumed an estimate of 50% (assumption of 50% provides us a high sample size). After six months, we estimate that 40% of them will still be using the method, and thus we need a sample size of 243 women in the intervention group only, per country. This group will be recruited at baseline, and will include an adjustment of 20% to account for loss to follow-up. This sample size is adequate to detect a 10 percentage point change within a 95% two-sided confidence interval at 80% power. The research question for PAC clients is: what percentage of PAC clients who want to use a method of family planning are using a method six months after the premature end of pregnancy? With this question, we hypothesize that 80% who want a method will get a method.

Health Facility Assessments: Prior to Implementation of the study, in order to reach adequate sample size, 18 facilities in Kenya (9 intervention and 9 control, which are each split into 5 public and 4 private-for-profit in each arm) and 8 facilities in Indonesia (4 intervention and 4 control, which are each split into 3 public and 1 private-for-profit in each arm) will be purposefully selected in collaboration with respective Ministries of Health.

IV. Participants:

Describe the study participants and the population from which they will be drawn. Specify the inclusion and exclusion criteria. If you plan to include children, note their ages and whether you will include children in foster care. Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.

Participants will be selected based on their relationship to intervention and control facilities where the PPFP Choices project is being introduced.

Participants in this study fall into two distinct categories: 1) Key Informants, and 2) female clients who participate in Client Interviews, Focus Group Discussions, and In-Depth Interviews.

Some study tools will collect data from individuals under the age of 18 (adolescents). In Kenya, these individuals will be treated as adults in accordance with the research ethics guidelines laid out by the Kenya Medical Research Institute's (KEMRI) Ethics Review Committee (ERC) and National AIDS and STI Control Programme (NASCOP), which allows pregnant adolescents to provide their own consent for participating in research [15]. In Indonesia, adolescents who are aged 17 or older are considered to be legal adults, and married adolescents are considered to be emancipated minors [16]. For purposes of obtaining consent, in Indonesia we will only be enrolling adolescents who are aged 15-16 if they are married. We will be able to enroll any (married and unmarried) pregnant adolescents aged 17 and older in Indonesia, while in Kenya, will be able to enroll any (married and unmarried) pregnant adolescents.

Selection of study participants will vary depending on the category of respondents as described below:

Key Informants: Participants will be purposefully selected to represent key groups of interest that understand the individual, community and institutional factors affecting PPFP within the region. They include representatives from the Ministries of Health and other policy makers, community influencers, and public and private facility health care providers and health facility administrators. Potential respondents include:

- National and County/District level Ministry of Health representatives and other political and local leaders, such as local council leaders and Parish chiefs with knowledge of local culture
- Religious and community leaders and other community influencers who routinely disseminate messages to community members
- Hospital administrators/Decision makers and providers from public facilities in the selected communities
- Hospital administrators/Decision makers and providers from private facilities in the selected communities

Female Clients: Women aged 15-49 years who are either pregnant with a gestational age of 28 weeks or greater (in Kenya) or in the immediate post-pregnancy phase (within 72 hours in Indonesia, within 48 hours in Kenya, prior to leaving the health facility – in Indonesia), are eligible to be included in this study. Kenyan postpartum clients will be approached at an ANC visit (if this is not their first ANC visit and if they are of a gestational age greater than 28 weeks), while all postpartum and postabortion clients in Indonesia will be approached in the immediate post-pregnancy stage (within 72 hours in Indonesia, within 48 hours in Kenya, prior to leaving the health facility) and will be enrolled in the study if they meet the eligibility criteria below.

Client questionnaires: For Kenyan ANC/Postpartum women, we will administer a client questionnaire at ANC, in the immediate postpartum stage, and again 6 months postpartum. In Indonesian Postpartum women, we will administer the client questionnaires at the immediate postpartum stage and 6-months postpartum. For both Kenyan and Indonesian postabortion clients, we will administer a questionnaires in the immediate postabortion period and 6 months postabortion.

Focus Group Participants: Participants will be adolescent and adult women 6 to 12 months postpartum.

In-Depth Interview Participants: Participants will be adolescent and adult women who did not receive a method in the immediate postabortion period.

A. Inclusion Criteria:

1. **Key Informants Inclusion Criteria:**
    1. Currently living/working in a study region

2. At least 18 years old
3. Understands the local language or English
4. In an authoritative, political, or programmatic position that could influence issues affecting access to postpregnancy family planning
5. Provides voluntary informed consent
6. Agrees to the audio taping of the discussion

2. **Female Clients Inclusion Criteria:**

Client questionnaires Inclusion Criteria:

a) Kenyan postpartum participant (Enrollment starts at ANC):
   1. At least 28 weeks pregnant
   2. Plans to deliver at the study facility
   3. Aged 15-49 years at enrollment[1]
   4. Provides voluntary informed consent
   5. Not planning to relocate in the next 12 months

b) Indonesian postpartum participant (Enrollment starts at L&D):
   1. In the immediate postpartum period (within 72 hours, prior to leaving the health facility),
   2. Reported having attended ANC within her 3rd trimester (28-weeks pregnant and later),
   3. Aged 15-49 years at time of enrollment (Indonesian adolescents aged 15-16 must be married for purposes of the study consent)
   4. Provides voluntary informed consent
   5. Not planning to relocate in the next 12 months

c) Kenyan and Indonesian postabortion participants:
   1. A female in the immediate post-pregnancy treatment phase (within 72 hours in Indonesia, within 48 hours in Kenya, prior to leaving the health facility for treatment of incomplete abortion)
   2. Aged 15-49 years at time of enrollment (Indonesian adolescents aged 15-16 must be married for purposes of the study consent)
   3. Provides voluntary informed consent
   4. Not planning to relocate in the next 6 months

Focus Group Participants Inclusion Criteria:

1. Previously enrolled in study as a postpartum participant (see criteria 2a and b above)
2. Understands the local language
3. Aged 15 – 49 years old at time of enrollment (Indonesian adolescents aged 15-16 must be married for purposes of the study consent)
4. 6 to 12 month postpartum
5. Provides voluntary informed consent
6. Agrees to the audio taping of the discussion

[1] Indonesian adolescents who are married, as well as Indonesian adolescents who are 17 years old and older are considered legal adults. Pregnant adolescents in Kenya are considered legal adults

In-Depth Interviews Inclusion Criteria:

1. Previously enrolled in study as a postabortion participant (see criteria 2c above)
2. Understands the local language
3. Aged 15 – 49 years old (Indonesian adolescents aged 15-16 must be married for purposes of the study consent)
4. Provides voluntary informed consent
5. Agrees to the audio taping of the discussion

B. **Exclusion Criteria:**

The exclusion criteria for ALL study participants is

1. Refusal to provide consent to be included in the study
2. Post-delivery baby or mother being treated for trauma or in an intensive care unit

NOTE: If you are recruiting participants or receiving, accessing, or using data from a U.S. health care provider, HIPAA review is likely to be required. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. Check "yes" to the HIPAA question in the PHIRST application.

V. Study Procedures:

In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of JHSPH clear. If the JHSPH will serve as **data coordinating center**, indicate in the sections below which procedures JHSPH will not be performing. Additional information regarding data coordinating centers is requested in a later section. If your study will develop in phases, address each item below by phase.

A. Recruitment Process:

1. Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and what their qualifications are.

The study team will liaise with the local ministries of health to obtain permission to conduct the study at these facilities. As is practice in Kenya and Indonesia, the local ministries of health will issue letters to the participating facilities advising those in charge that the study will be taking place. Once the letters have been sent, the study team will coordinate with the facilities to place Research Assistants (RAs) on-site. RAs are study staff with some understanding of the community, research experience, ethics training, post-high school diploma, and ability to communicate in the local language.

Key Informants: These participants will be selected purposefully by study management on the basis of their potential to influence family planning, familiarity with the culture and community and their ability to articulate in detail, the challenges operating at different levels of the system. The KIIs will be done at the initiation of the study in part to inform the intervention, and at the end of the study.

As we expect KIIs to include community leaders, policymakers and community influencers, PPFP Choices study management familiar with the participants' roles in the community will identify, consent and interview the participants. For senior level officers, the PI or a senior level study staff member will complete the consenting and interviewing process. Providers and facility leadership will be identified by Facility In-Charges and recruited, consented and interviewed by RAs or higher-level study staff.

Once identified, the study managers will contact the potential key informants and introduce the study using the prepared recruitment script. If they are interested in participating, a date and time for the interview will be finalized. KIIs will be conducted at both baseline and endline of the study period.

Client Interviews, Focus Group Discussions, and Postabortion In-Depth Interviews:

Client Interviews: After receiving permission from the facility to implement the study there, RAs will be placed at each facility to recruit and interview clients. Initial recruitment will be done by ANC, maternity ward and postabortion care providers using the provided recruitment scripts. The study design as related to patient recruitment will differ slightly between Kenya and Indonesia for the following reason: During an assessment completed in April of 2016, we determined that while the majority of Kenyan ANC patients attend the same facility for their antenatal care (ANC) visits and their Labor and Delivery (L&D) visits, Indonesian patients are less likely to do so [8]. In order to reduce higher than optimal loss to follow-up between an ANC and L&D, we will be recruiting postpartum women in Indonesia at their delivery visit. However, as we will not be comparing Kenyan outcomes to Indonesian outcomes, we will recruit Kenyan pregnant women at their ANC visits for the postpartum aspect of the study. Recruitment of postabortion women will take place prior to discharge after receipt of treatment for a miscarriage or incomplete abortion at study facilities in both countries.

After being identified by providers through use of standardized screening tool, a document for providers that presents the study eligibility criteria and the study introduction script, providers trained in use of the study introduction script will explain the study and ask clients if they are interested in participating in the study. If they are, the providers will direct the RAs to the clients. If the client is not in a private room, the RAs will then bring the clients to a private location. When they are in a private area, the RAs will provide more detailed information about the study through use of a recruitment script. RAs will determine clients' study eligibility, using the RA's screening tool which screens for the inclusion criteria discussed above, and will ensure that clients provide full informed consent to participate. Upon meeting these criteria and providing informed consent, clients will begin the process for study enrolment. The first step in study enrolment is the provision of the participant's contact information. If the participant refuses to provide any contact information, her basic demographic information will be recorded but she will not continue with study enrolment. If she does provide her contact information, she will be enrolled in the study. If the participant does not meet study eligibility criteria or is not willing to provide informed consent, she will be thanked for her time and the interview will stop.

Focus Group Discussions: During the initial consent process, RAs will also ask clients if they are willing to take part in a focus group when they are between 6 and 12 months postpartum: RAs will ask if they are comfortable talking in a group where they may not know any other group members and the discussion will be audio taped. If a client accepts, the RA will check a box on the front of her consent form indicating her willingness to participate in a FGD. When the time for FGDs is approaching, the RAs will contact women between 6 and 12 months postpartum who previously agreed to participate and invite them to the FGDs. They will continue contacting eligible women who meet the criteria for each FGD (1. adult acceptors in public facilities, 2. adult acceptors in private facilities, 3. adolescent acceptors in public facilities, 4. adolescent acceptors in private facilities, 5. adult non-acceptors in public facilities, 6. adult non-acceptors in private facilities) at random from the list of those who previously agreed to participate until they have the required sample size.

In-Depth Interviews: During the initial consent process, RAs will also ask clients if they are willing to take part in an In-Depth Interviews (IDI). Several questions in the postabortion questionnaires will be used to help identify clients who represent key postabortion client groups. Once the second questionnaire is completed, RAs will remind selected women of the option of participating in IDIs and confirm their willingness to participate. If they agree, RAs will commence with the IDI.

2. Address any privacy issues associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks.

The recruitment scripts and consent forms will be used to introduce the study to enroll participants in a consistent manner. They will include a Study Information Section- containing basic information on the intervention study- for all cadres of study participants. They will specify the topics, the activities and the reporting procedures included in the intervention study, and will be shared during recruitment.

For those recruited for FGDs, an invitation note which specifies the time and venue of the discussion group/interview may be provided.

Prior to KIIs, client interviews, FDGs and IDIs, an informed consent script will be used to obtain consent from eligible individuals selected for the study.

There are no privacy concerns associated with the recruitment process of participants in this study. Once the participant has indicated an interest in joining the study, they will be taken to a private location to finalize the consent process and conduct the KII, client interview, FDG or IDI. All interviews will be conducted in a quiet and private place of the participant's choosing and FGDs will be taken to a designated private space at the facility or community location to respect the privacy of participants, and maintain confidentiality of information provided.

B. **Consent Process**:

1. Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening.

   a. Who will obtain informed consent, and their qualifications:

Written consent will be obtained from key informants by a Senior Study Staff member, while written consent will be obtained from the clients by Research Assistants. All members of the research team will be trained in how to obtain informed consent for the study in English as well as in the local language using an approved script that includes all the elements for informed consent.

   b. How, where, and when the consent discussion(s) will occur:

For Key Informant Interviews, A senior study staff member or the PI will sit down with each KII participant at the time and place identified by the participant. They will review the Key Informant Consent and the Study Staff member will answer any questions the participant may have before beginning the interview. The Key Informant's consent will be written.

For Client Interviews, Focus Group Discussions, and In-Depth Interviews:

Client Interviews: RAs will sit down in a private space with each eligible client who is willing to participate in the study and will go over the translated Client Consent Script. After discussing all the elements of the Consent Script, the assessor will answer any of the client's questions. The client's consent will be **written using participant initials or signature**. The consent form will be translated into the appropriate local language based on the study site. The RA will ask the client to provide her consent.

Focus Group Discussions and In-Depth Interviews: Only those who stated consent for follow-up during their original ANC or postpartum client interview recruitment or their original postabortion client interview recruitment may be contacted for participation in the FGDs and IDIs. For those who agree to participate in the **FGDs or IDIs**, research assistants will obtain consent in the following manner: Consent will be obtained by reading translated consent forms verbatim to the participant in the language of their choice. The consent process will be conducted in person prior to each FGD or IDI in a quiet and private place. Potential participants will be informed about the study, its purpose, and the methods for obtaining data. They will also be informed about confidentiality of their contributions, how their personal information will not be connected to this FGD or IDI, how data will be protected, voluntary participation, and their rights

as participants. They will be informed that they can refuse to answer any question during the interview and can stop the interview at any time without consequence. The clients' consent will be **written using participant initials or signature**.

c. The process you will use to determine whether a potential participant meets eligibility criteria:

For Key Informant Interviews, the bulk of the eligibility criteria (a through d in the KII eligibility criteria listed above) will be determined by study staff prior to approaching the KII participant to request an interview. Prior to setting a time and place for the interview, the study staff will ask the KII participant if they would be willing to participate and to be audiotaped during the discussion (e and f above). The staff member will again ask these questions prior to beginning the informed consent process immediately before the Interview.

For all clients, Providers trained in screening clients for recruitment will identify clients who meet demographic and pregnancy related eligibility criteria and refer them to RAs. RAs will confirm eligibility of referred clients, including demographic and pregnancy related factors as well as willingness to participate, before proceeding with the questionnaire, FGD or IDI.

d. Whether you will obtain a signature from the participant or will use an oral consent process:

We will be **written consent** with all clients and KIIs.

Whether you will obtain a legally authorized representative's signature for adults lacking capacity: **N/A**

e. If children are included in the study, if and how you will obtain assent from them:

All enrolled participants will be legally considered adults either because they have reached the age of maturity for their country or because local legislation allows for the classification of pregnant and/or married women as adults.

If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision) :

All enrolled participants will be consented as adults using the recruitment and consent materials outlined in the sections above.

f. If you are seeking a waiver of informed consent or assent, the justification for this request:

N/A

Whether you will include a witness to the consent process and why: **N/A**

If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials: **N/A**

2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

Country	Consent Document(s) (Adult Consent, Parental Permission, Youth Assent, etc.)	Languages
Indonesia	Adult Consent	Bahasa
Kenya	Adult Consent	English, Swahili

C. **Study Implementation**:

1. Describe the procedures that participants will undergo. If complex, insert a table below to help the reviewer navigate.

Key Informant interviews: KIIs will take place at 2 timepoints in the study: baseline and endline. The interviews will be conducted using the semi-structured guide led by a senior study staff member or the PI in a quiet private place. They are expected to last about 90 minutes. KIIs will be conducted in the language of choice of the respondent as data collection tools will be translated into the local dialects specific to the region of study. The interview will be audio recorded and during the interview, the participants will not be addressed by their names. Unique study codes will be assigned to each participant on the interview forms and participant names will not be recorded. At the end of the interview, the data will be analyzed and a summary report will be prepared. The participants may be reimbursed for travel costs/time.

Client Interviews, Focus Group Discussions, and In-Depth Interviews

Client Interviews: Clients opting to participate in this study will be contacted two to three times for the interviewer-administered survey

As displayed in **Table 1** and **Figure 1**, the point of recruitment or entry into the study will differ by country and type of client.

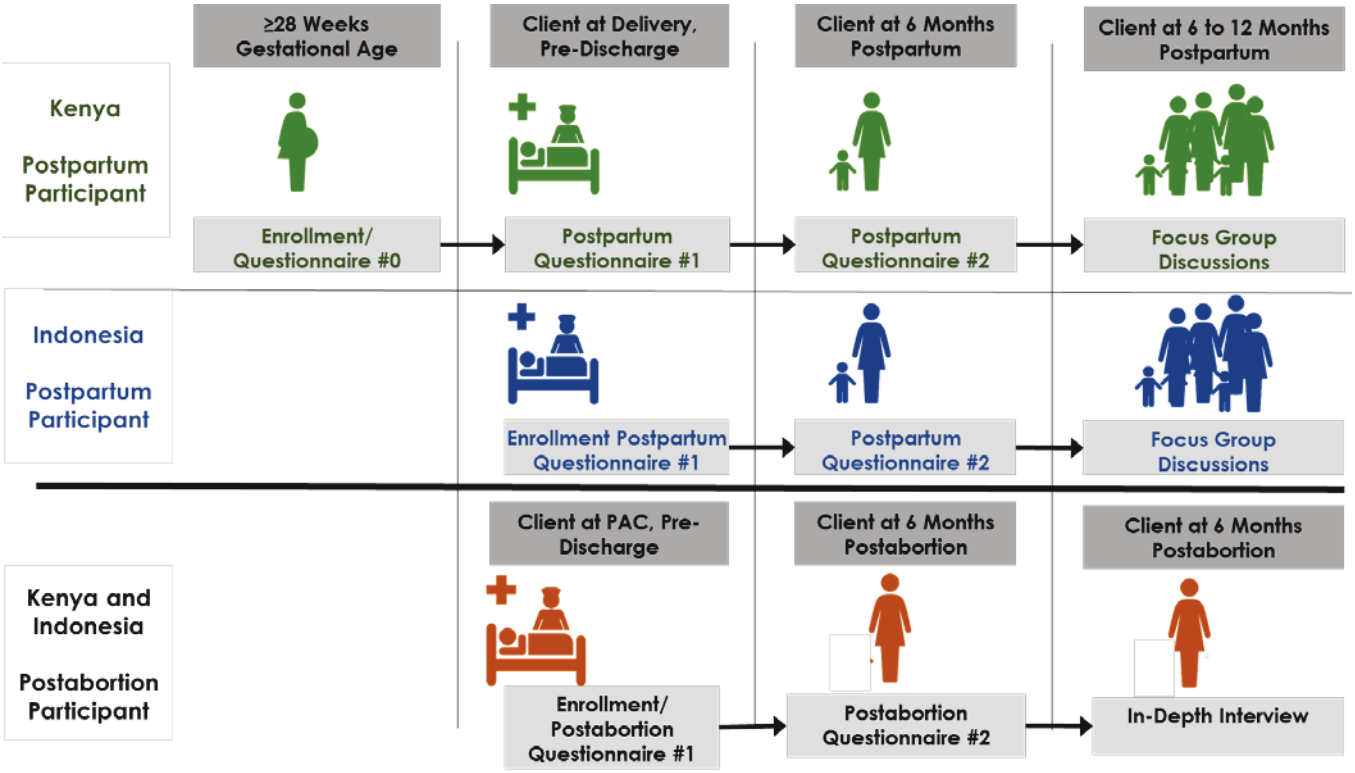


Figure 1: Client Participation timepoints

For Postpartum Women

ANC: In Kenya, the first contact for pregnant/postpartum participants, will take place at the participant's ANC visit. At this time, a 30 minute questionnaire will be administered which includes sociodemographic information, assessment of the quality of the client provider knowledge attitudes and beliefs regarding PPFP, and barriers and facilitators of intended PPFP use. The interviewer will also ask to see their ANC card and Mother Child Booklets and note

any pertinent medical or gynecological history that might be relevant to the study – this includes chronic diseases like hypertension, diabetes, HIV and tuberculosis.

Immediate Postpartum: The **first contact for Indonesian postpartum clients** and the **second contact for the Kenyan Postpartum client** will be during the immediate postpartum period, within 72 hours of delivery in Indonesia, within 48 hours of delivery in Kenya. The questionnaire in both countries will be administered to determine whether or not the client received a modern FP method after delivery, how the participant feels about the FP services offered to them during labor and delivery, the participant's knowledge, attitudes and beliefs about PPFP, and reasons for choosing the FP method they chose or for not accepting a FP method at that time. The Kenyan visit will take about 30 minutes while the Indonesian visit will take about 45 minutes. In Indonesian, supplementary questions will be used to collect similar information to what was collected during ANC in Kenya. These questions will identify sociodemographic information and assess the client's perceptions of the quality of the provider interaction at ANC. The interviewer will also ask to see their ANC card and Mother Child Booklets and note any pertinent medical or gynecological history that might be relevant to the study.

6 Months Postpartum: The **final contact** for all postpartum participants (contact #3 for Kenya and contact #2 for Indonesia) will be made 6 months postpartum. The 30 minute questionnaire will be administered to understand participants' experience and satisfaction with their PPFP method choice whether or not they did accept an immediate postpartum FP method, any complications encountered, likelihood of discontinuation of the method and if they would refer PPFP methods to others. Prior to the interview, RAs will contact participants to set the interview time and location and to ensure the participant is still able to participate in the final interview.

Focus Group Discussions: Trained qualitative researchers will conduct the FGDs in a quiet and private place. Each FGD will take approximately 90 minutes to complete and will be conducted in the language participants are most comfortable with. The FGD will be audio recorded and during the FGD, the acceptors will not be addressed by their names, rather they will be called as 'Sister' (or in local languages). Each respondent is required to participate in only one FGD/KII throughout the study.

FGDs will occur only at one timepoint during the study: during year 2 of the study, with participants who have participated in client interviews and are between 6 and 12 months postpartum.

For Postabortion Women

Immediate Postabortion: At the **first contact for Kenyan and Indonesian postabortion participants,** the client will be recruited in the immediate postabortion period (within 72 hours in Indonesia, within 48 hours in Kenya postabortion). At this time, a 30 minute questionnaire will be administered which includes sociodemographic information, assessment of the quality of the client provider knowledge attitudes and beliefs regarding PAFP, their postabortion care experiences, knowledge, attitudes and beliefs about FP methods, and reasons for choosing the method they chose or, if they choose not to accept a method, why they made that choice.

6 Months Postabortion: The **final contact** for postabortion participants will be made 6 months postpregnancy. The 30 minute questionnaire will be administered to understand participants' experience and satisfaction with their PPFP method choice whether or not they did accept an immediate postpregnancy FP method, any complications encountered, likelihood of discontinuation of the method and if they would refer PPFP methods to others.

In-Depth Interviews: Immediately following the six-month postabortion contact, RAs will also recruit postabortion participants for In-Depth Interviews**.** Women will have been considered for IDIs if they did not receive a modern FP method in the immediate postabortion period. The IDIs will be used to gather more complete information about barriers to receiving immediate postabortion FP in this sub-set of the population.

Loss to follow-up will be minimized by coordinating with the study facilities. The cover page of each survey instrument will consist of a contact sheet to help us locate individuals for the follow-up interview. Each client will be assigned a

unique study ID number on recruitment at ANC and only that ID number will be used during subsequent data collection points during the study. This ID number will also be linked to the facility and provider and will be used as participants' identification in the study. The sheet of contact information (including participant name, address and phone number) will be separate from the survey and kept separately locked in the program office in each country where only the PI or a designee will have access.

Facility Audits: facility data will be collected by RAs and analyzed by study staff at three periods throughout the study; baseline, midline and endline. This includes a review of facility records, assessing staffing numbers and reported training/abilities, reviewing commodity availability, etc.

2. Describe the number and type of study visits and/or contacts between the study team and the participant, how long they will last, and where/how they will take place.

All interviews will be conducted in a quiet and private place. The Key Informant Interviews for MOH officials/policymakers, Community influencers and facility management and providers will all take place in a location of the interviewee's choosing.

All client interviews, focus group discussions, and In-Depth Interviews are expected to take place at the health facilities. If, for purposes of the client's comfort or availability, the health facility is not a feasible location, then interviews, focus group discussions, or In-Depth Interviews may take place at another quiet and private location agreed upon on by the participant and interviewer. Table 7 summarizes the schedule of data collection for the different categories of respondents.

Table 6: Schedule of data collection by category of respondents

Participant Data Collection	Purpose		Version of tool by category of respondent	Time Points	Duration of data collection
Key Informant interviews	Determine contexts related to facilitators and barriers to ANC and post-pregnancy women accessing PPFP counseling and service provision	1	Ministry of Health/Policymakers	2 times (beginning of study [approx. month 4–6], end of study [approx. month 30–36])	90 minutes per session
		2	Community Influencers	2 times (beginning of study [approx. month 4–6], end of study [approx. month 30–36])	90 minutes per session
		3	Public facilities (providers and management)	2 times (beginning of study [approx. month 4–6], end of study [approx. month 30–36])	90 minutes per session
		4	Private facilities (providers and management)	2 times (formative assessment, end of study [month 30–36])	90 minutes per session
Client Interviews	Understand relationships between client satisfaction, attitudes related to social contexts and services provided, PPFP knowledge and FP intentions, use and continuation	1	ANC Interview (#0) (Kenya only)	ANC (> 28 weeks gestational age)	30 to 45 minutes
		2	Immediate Pre-discharge Interviews (#1)	Immediately following pregnancy (within 48 hours)	30 to 45 minutes
		3	Six-month Interviews (#2)	6 months post-pregnancy	30 to 45 minutes
	To gain qualitative data to identify social,	1	Public Facility Acceptors (adult)	(midpoint of study) When client is 6 to 12 months post-pregnancy	90 minutes

Focus group discussions	cultural, contextual, and service-, age- and gender-related factors affecting women's perceptions of, access to and use of FP	2	Private Facility Acceptors (adult)	(midpoint of study) When client is 6 to 12 months post-pregnancy	90 minutes
		3	Public Facility Acceptors (adolescent)	(midpoint of study) When client is 6 to 12 months post-pregnancy	90 minutes
		4	Private Facility Acceptors (adolescent)	(midpoint of study) When client is 6 to 12 months post-pregnancy	90 minutes
		5	Public Facility Non-Acceptors	(midpoint of study) When client is 6 to 12 months post-pregnancy	90 minutes
		6	Private Facility Non-Acceptors	(midpoint of study) When client is 6 to 12 months post-pregnancy	90 minutes
In-Depth Interviews (IDIs)	Gain qualitative data to identify the social, cultural, contextual, economic and service-, age- and gender-related reasons women did not receive an immediate post-abortion family planning method	1	Postabortion non-acceptor In-Depth Interviews	6 months postabortion	90 minutes

3. Describe the expected duration of the study from the perspective of the individual participant and duration overall.

The Key Informant Interviews for MOH officials/policymakers, community influencers and facility management and providers will take place at the beginning of the study period (prior to implementation of the intervention) and at the end of the study period (immediately following completion of data collection).

The duration of the study from the perspective of the Kenyan postpartum clients will be from a minimum of 7 months to a maximum of 13 months, while duration of the study from the perspective of the Indonesian postpartum clients will be from a minimum of 6 months to a maximum of 12 months postpartum. All Kenyan clients will be interviewed at ANC (28 weeks gestation and later), immediately postpartum, and 6 months following. All Indonesian clients will be interviewed at their immediate postpartum period and 6 months following. Some postpartum clients between 6 and 12 months postpartum in both countries will be asked to take part in a focus group discussion.

The duration of the study from the perspective of all postabortion clients will be 6 months. Clients will be interviewed at the immediate postabortion period and again 6 months later. Some of the postabortion clients will take part in an IDI, which will also take place 6 months following the postabortion period. The time spent actually collecting data varies by the tool used; table 7 summarizes the data collection time burden for the study participants – last column.

4. Provide a brief data analysis plan and a description of variables to be derived.

Key Informant interviews, Focus Group Discussions and In-Depth Interviews: *Data analysis*: Key informant interviews, Focus Group Discussions and In-Depth Interviews will all be analyzed using Grounded Theory methods. Initial KII, FGD and IDI responses will be translated, transcribed, coded, and analyzed using software to facilitate data management. Quality of translation will be checked for each (KIIs, FGDs and IDIs) through back translation of a randomly-selected subset of 6 interviews. Using analytical software, coding will be used to conceptually name the data and reduce it to manageable units of information that cover broad and general categories. *A priori* codes will be developed based on the concepts of interest in this research (perception of risk, benefits and beliefs, etc.) and the study aims. As additional KIIs, FGDs and IDIs are conducted, these *a priori* codes will be complemented by additional codes that reflect themes and concepts that emerge from the data. Codebooks will be developed for the different concepts to facilitate consistency in the coding process. The coded data will be organized into a hierarchy of themes which are then meaningfully linked to each other to show patterns, relationships and explanations. In conjunction with the coding process, memos will be used

to develop conceptual categories and themes and to track emerging insights and interpretations [11]. Qualitative research software such as QSR NVivo or ATLAS.ti will be used to analyze the data.

Client Interviews: *Data Analysis*: After data have been thoroughly cleaned, the study team will report on all outcomes included in the study tools as well as the service statistics collected as part of this study (see Section XI). The team will calculate the proportion of pregnant/postpartum women who choose a FP method during antenatal care (ANC) or early labor, and, of those, what proportion received the FP method in the immediate postpregnancy period (prior to discharge). Regression models may be used to explore differences in acceptance of PPFP between the intervention and control facilities, different demographic groups, or to compare acceptance among clients receiving varying levels of care (as determined through facility and performance assessments). Select data from the client interviews will be combined with key facility level indicators for a multilevel analysis of the factors affecting intention to use and receipt of PPFP.

Facility Audits*: Data Analysis*: Mapping of facilities will be visually analyzed to provide further understanding of structural issues that may influence perceptions and key behaviors. We will also utilize multi-level data analysis to explore the feasibility of IPPI using STATA. Select data from the client interviews will be combined with key facility level indicators for a multilevel analysis of the factors affecting intention to use and receipt of immediate post-pregnancy family planning methods.

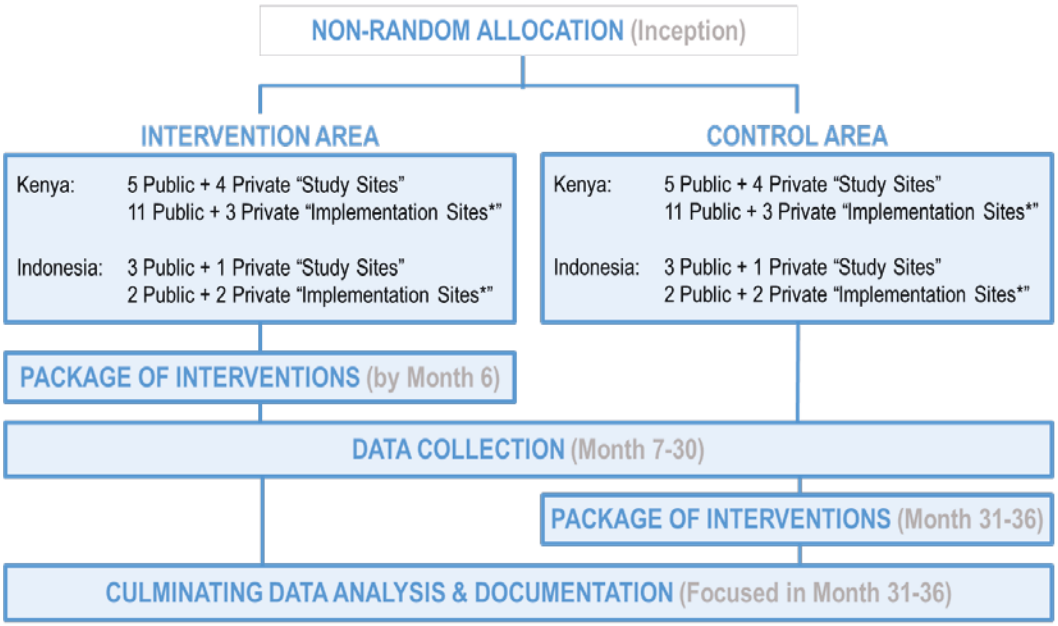
Furthermore, triangulation across methods will help to ensure quality of study findings and offer opportunities for deeper insights into the study concepts [12]. Observations will also be collated with qualitative analysis results and used to strengthen themes identified through key informant data. In addition, a team approach to data analysis will be employed where different researchers provide feedback on emerging interpretations and analysis and check developing categories and concepts back against the original data. In this way, an "audit trail" will be used to help ensure trustworthiness of findings and gather input from multiple investigators [12]

5. Answer the following **if they are relevant to your study design**:

   A. If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.

The study will employ a quasi-experimental mixed-method design; both quantitative and qualitative data will be collected at multiple time points. In coordination with the MOH, we will first identify an "intervention area" and a "control area" at County-level in Kenya and an "intervention area" and a "control area" at District-level in Indonesia. Within the "intervention areas," we will identify intervention facility sites (six in Kenya and four in Indonesia) and match them with an equal number of control facility sites from the "control areas," based on a list of predetermined criteria (e.g., service statistics and client demographics).

All facilities in the "intervention area" will receive all facility level training and support interventions at the beginning of and throughout the study data collection period, while all facilities in the "control area" will be afforded the benefits of the interventions in a phased manner; in the last 6 months of the study timeline, after data collection activities are completed. This is demonstrated in the following graphic:



*Note: exact number of implementation sites TBD

B. If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about who will collect the specimen, the volume (ml) and frequency of collection, how the specimen will be used, stored, identified, and disposed of when the study is over. If specimens will be collected for use in future research (beyond this study), complete the "Biospecimen Repository" section below.
N/A

C. If genetic/genomic analyses are planned, address whether the data will be contributed to a GWAS or other large dataset. Address returning unanticipated incidental genetic findings to study participants.
N/A

D. If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number.
N/A

E. If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA certified in the U.S.). Explain the failure rate and under what circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants.
N/A

F. If your study involves medical, pharmaceutical or other therapeutic intervention, provide the following information:

a. Will the study staff be blind to participant intervention status?

N/A

b. Will participants receive standard care or have current therapy stopped?

N/A

c. Will you use a placebo or non-treatment group, and is that justifiable?

N/A

d. Explain when you may remove a participant from the study.

N/A

e. What happens to participants on study intervention when the study ends?

N/A

f. Describe the process for referring participants to care outside the study, if needed.

N/A

VI. Data Security and Confidentiality Protections:

A. Personally Identifiable Information (PII):

Please identify the Personally Identifiable Information (PII) that you may be collecting and using at any of the following stages of your study: ***Recruitment***, ***Consent,*** *and* ***Study Implementation***.

Name, signature, initials, or other identifiable code	☒
Geographic identifier: address, GPS location, etc.	☒
Dates: birth, death, clinical service, discharge, etc.	☒
Contact information: phone numbers, email address, etc.	☒
ID: Social Security Number, driver's license number, etc.	☐
Health record identifiers: medical record, insurance plan number, etc.	☐
Account numbers	☐
Device identifiers: e.g., implants	☐
Internet identifiers: IP address, social media accounts	☐
Biometric identifiers, including finger and voice prints	☐
Audio recordings	☒
Video or full face photographic images	☐
Genomic/genetic data	☐
Any other unique identifying number, characteristic, or code (note: this does not mean the unique code assigned by the investigator to code the data)	☐
Other: Click here to enter text.	☐

B. Recruitment:

Will you collect identifiers for the purpose of contacting potential participants? Yes ☐ No ☒

If **yes**, will you retain the identifiers after the recruitment contact has been made? Yes ☐ No ☒

C. Data Collection:

In what form will you collect and store PII? When you respond, think of PII collected for recruitment, consent, and other study purposes.

1. **Hard Copy/Paper:** Yes ☒ No ☐

   If yes, please answer the following:

   a. How will the data be kept secure during transfer from study collection site to storage site?

Depending on the setting, we will be using a combination of paper and tablets. Consent may be collected via paper consent forms with either a signature, initial or the participant's mark in the signature line next to the participant's printed name. While all efforts will be made to ensure that all other study data is collected in a REDCap tablet based system, interviews may be collected on paper tools if issues arise with the REDCap tablet based data collection system. All paper-based forms will be transferred in a secured box or briefcase to the regional study offices by the data collection officer daily.

   b. Will the data be secured in a locked cabinet or room? Yes ☒ No ☐

   c. Are the data collection forms and study data stored without personal identifiers and separate from the study IDs/code? Yes ☒ No ☐

   d. How long after study completion will you keep the hard copy/paper forms?

The paper forms will be destroyed five years following completion of study activities.

2. **Electronic:** Yes ☒ No ☐

   If yes, please answer the following:

   a. Will the data be collected/stored on a portable device (laptop, mobile phone, tablet, PDA) protected by encryption? Yes ☒ No ☐

   b. Will the data be stored on a secure server or in the Cloud/Web?

      Secure Server ☐ Cloud/ Web ☒

   c. Will it be encrypted? Yes ☒ No ☐

   d. Will you be backing up your data? Yes ☒ No ☐

3. **Audiotape:** Yes ☒ No ☐

   If yes, please answer the following:

   a. Will you store the audiotape securely in a locked cabinet/room until transcription is complete? Yes ☒ No ☐

   b. Will the audiotape be destroyed after transcription? Yes ☒ No ☐

      If no, why not?

4. **Photograph/Video:** Yes ☐ No ☒

   If yes, please answer the following:

   a. Will the photographs/videos be stored securely in a locked cabinet or room? Yes ☐ No ☐

   b. Will the photograph/video be destroyed? Yes ☐ No ☐

      If yes, when?

D. PII De-Identification of Data Used for this Study:

When will you destroy the PII and/or the code linking the PII with the study ID?

All paper-based and electronic study forms will be destroyed five years following completion of the study.
Audio recordings of Key Informant Interviews, Focus Group Discussions and In-Depth Interviews will be transcribed and destroyed immediately upon transcription. The transcriptions will not have identifiers.

E. Data Storage and Analysis:

One of the keys to protecting PII is the proper use of tools to share and conduct your analysis. JH and JHSPH offers several options for you to consider. Please select the system that you plan to use to protect your study data by clicking the box. Consult JHSPH IT for assistance if needed.

☐ **JH Virtual Desktop**: IT@JH provides (for a monthly fee) a virtual Windows desktop.

☐ **JHSPH SharePoint and File Shares**: These systems provide a managed and secure platform for your research project. They also provide a built-in encrypted backup solution.

☒ **JHSPH RedCAP or HPCC**: These are departmentally managed applications.

☐ **JHBox**: Johns Hopkins Box (JHBox) is a secure cloud-based file sharing and file storage service.

☐ **Independent Departmental Servers and Systems**: These servers are typically managed by departmental or research team IT staff.

☐ **Other**: Please provide details regarding any other systems being utilized.

F. Other Data Security Measures:

In addition to the details regarding data collection, please review the following questions. This additional information will be utilized to assist in the development of a comprehensive Data Security plan. This would include the systems used to analyze the data, data security contacts and additional requirements.

1. Do you have a designated person on your research team who is the technical contact for a Data Security plan? Yes ☐ No ☒
   If yes, please provide a contact name:

2. Does your sponsor have other specific data security requirements for the study data? Yes ☒ No ☐

   If possible, please explain:

The Bill and Melinda Gates Foundation has a presumption in favor of disclosure with respect to information concerning our activities subject to operational and practical considerations and absent the following circumstances:

- Security and safety: disclosure poses a risk of physical harm to persons or property.
- Personal information: disclosure intrudes on personal privacy or breaches confidentiality.
- Legally privileged and commercially sensitive information: disclosure violates legal commitments, such as non-disclosure agreements and confidentiality agreements, or would result in substantial harm to our grantees, partners or suppliers.
- Timing of publication: disclosure upsets a dynamic process in ways that pose substantial risk to achieving the outcomes sought by our grantees and partners.
- Premature documents: document is too early in development to publish.
- Deliberations: Information related to our own internal deliberations and communications and deliberations and/or negotiations with third parties.

3. Please add any other information that you believe is relevant to data security.

G. Certificate of Confidentiality:

Will the study data stored in the **United States** be protected by a Certificate of Confidentiality?
No

If yes, explain who will apply for and maintain the Certificate. N/A
(http://grants.nih.gov/grants/policy/coc/appl_extramural.htm)

H. Will you use clinical data of 500 records or more from Johns Hopkins Hospital and its affiliates?
Yes ☐ No ☒

If yes, please complete the JHM Data Security Checklist available on the JHSPH IRB website: www.jhsph.edu/irb and upload a copy of the checklist to the "Miscellaneous" section.

VII. Risks of the Study:

A. Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. These risks should be described in the consent documents.

Clients: The main risk to participants is loss of confidentiality. There is also a minor risk that some questions may make participants uncomfortable. Participants will be told during the consent process that they may skip any questions that they do not wish to answer and they may stop the interview at any time without any consequences.

Providers and Facility Managers: The risk to service providers for participating in this study is minimal and relates to any potential damage to their professional reputation if it is discovered that a service provider is not performing his/her job correctly.

Policy Makers and Community Influencers: There are no anticipated risks to community influencers for participating in the study. However, some individuals may feel uncomfortable answering questions about family planning and/or reproductive health.

B. Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an "anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?

We do not anticipate adverse events to occur as a result of participation in the study.

C. Describe steps to be taken to minimize risks. Include a description of your efforts to arrange for care or referral for participants who may need it.

Clients: Every effort will be made to protect the identity and confidentiality of participants and contact information will always be kept in a secure location separate from other study materials. Research Assistants will make it clear that participants may refuse to answer questions and may stop the interview at any time.

Providers and Facility Managers: The study team will make efforts to ensure that confidential information and any records linking individuals to their responses are protected. Provider responses and results of the quality assessments will be presented at an aggregate level and individual results will not be shared with facilities or with stakeholders. While data from the provider quality assessments may be used to assess overall facility quality, information identifying specific facilities will not be included in analysis or dissemination. Data collected from KIIs will be held in a secure location and identifiers will not be collected.

Policy Makers and Community Influencers: As with other participant groups, the identities of participating community influencers will be confidential. Data collected from KIIs will be held in a secure location and identifiers will not be collected.

D. Describe the research burden for participants, including time, inconvenience, out of pocket costs, etc.

For all participants, the primary burden is time: 90 minutes per FGD (up to one per participant) and KIIs (up to one per participant) and approximately 30-45 minutes per interview (up to three per participant). However, especially for FGD and KII participants, there are potential inconveniences and out-of-pockets expenses tied to returning to the pre-identified interview/FGD location.

E. Describe how participant privacy will be protected during data collection if sensitive questions are included in interviews.

Clients: All data collection from clients will be conducted in private locations agreed upon by the interviewer and the participant. FGDs will take place in a pre-arranged private location. If the participant is accompanied to the location, the person accompanying them will not be permitted into the FGD location while discussions are ongoing. Client Interviews will ideally take place at a private location in the facility, designated by facility staff in collaboration with the study team. Anyone accompanying the client for the ANC visit from which she is recruited will be asked to wait outside the interview location during the interview. If a client would like to participate but is unable to sit with the data collector at the facility, the interviewer and client will agree on a time and private place to meet to conduct the interview. KIIs will ideally take place immediately following the 6-month postabortion interview, also ideally in a private location at the facility, but will be held at a designated time-place if needed.

Providers and Facility Managers: Interviews will be conducted in a private location agreed upon by the participant and the interviewer. If the location is in the facility, extra efforts will be taken to ensure that the location has audio and visual privacy in order to assure the provider of the confidentiality of responses.

Policy Makers and Community Influencers: We do not anticipate questions asked during KIIs with Community Influencers to be sensitive. However, steps will still be taken to ensure privacy during interviews, which will be conducted in a private location agreed upon by the participant and the interviewer.

VIII. Direct Personal and Social Benefits:

A. Describe any potential direct benefits the study offers to participants ("payment" for participation is not a direct personal benefit).

Providers and clients will not directly benefit from participating in this assessment. Clients will not be offered any money or gift for participating in the study.

Describe potential societal benefits likely to derive from the research, including value of knowledge learned.

Potential benefits we anticipate include the fact that the results of this study will generate crucial learning about implementing quality immediate postpregnancy FP counseling and service in low-resource settings, to be applied widely now that revised MEC are in place.

IX. Payment:

A. Describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain.

Participants will not receive any payment or compensation for participating in the study. No payment will be made to any health facility, nor will any provider or administrator receive any payment. However, travel costs may be reimbursed for FGD and KII participants without a receipt for up to $10 USD. If the amount is greater than $10, a receipt will be requested.

B. Include the possible total remuneration and any consequences for not completing all phases of the research.

As travel costs will be reimbursed for all FGD, IDI and KII participants without a receipt for up to $10 USD, the total travel reimbursement is up to $20 (two KIIs) per KII participant and $10 (one per FGD or IDI participant). If the amount is greater than $10, a receipt will be requested.

X. Study Management:

A. Oversight Plan:

1. Describe how the study will be managed.

The study will be managed by the PI (Elaine Charurat) and co-investigators on this study. Additionally, in-country PIs will be Eunice Omanga for Kenya and Siti Nurul Qomariyah for Indonesia.

2. What are the qualifications of study personnel managing the project?

Ms. Charurat, MBA, MHS is the Project Director for the Postpregnancy Family Planning Choices project at Jhpiego and has over 10 years of research experience in international settings. She will provide overall oversight in the implementation of all aspects of the study in both Kenya and Indonesia.

Co-investigators include Paul Nyachae from Jhpiego/Kenya who will be the Kenya Team Leader managing the study implementation in Kenya and Siti Qomariyah from Jhpiego/Indonesia who will be the Indonesia Team Leader managing the study implementation in Indonesia. Both of these co-investigators have previous experience managing research studies in their countries and have programmatic knowledge and management skills to lead the study implementation according to this protocol.

Table 7: Roles Investigators

Name of Investigator	Position/ Role	Specific responsibility
Elaine Charurat, Jhpiego	Principal Investigator	Overall study implementation oversight in Kenya and Indonesia
Eunice Omanga, Jhpiego Kenya	Senior MER Advisor, Kenya	Lead-in country Investigator
Siti Nurul Qomariyah, Jhpiego Indonesia	Senior MER Advisor, Indonesia	Lead-in country Investigator
Ricky Lu, Jhpiego	FR/RH Director;	Clinical Oversight
Sara Kennedy, Jhpiego	Global Study Manager	Study contact at JHSPH IRB; communication with IRB along with PI, Support oversight of study implementation and management
Anne Schuster, Jhpiego	IRB Support, Research Advisor	MER support including data management and reporting
Mark Kabue, Jhpiego	Senior MER advisor	MER support including data management and reporting
Megan Christofield, Jhpiego	Family Planning Technical Advisor	Technical oversight during implementation in both countries
Lindsay Breithaupt, Jhpiego	Technical Program Coordinator, Global	Technical oversight during implementation in both countries
Nuriye Hodoglugil, Jhpiego	Senior Clinical FP Advisor	Clinical advisor
Paul Nyachae, Jhpiego Kenya	Project Lead	Overall technical oversight during implementation in Kenya
Emmah Kariuki, Jhpiego Kenya	Technical Officer	Implementation and data collection coordination - Kenya
Michael Muthamia, Jhpiego Kenya	Technical Officer	Implementation and data collection coordination - Kenya
Andang Syamsuri, Jhpiego Indonesia	Study Manager, Indonesia	Implementation support - Indonesia
Holly Blanchard, Jhpiego Indonesia	Clinical Training/QA Advisor	Implementation and data collection coordination - Indonesia
Fransisca Maria Lambe, Jhpiego Indonesia	Program Officer	Implementation and data collection coordination - Indonesia
Irfan Riswan, Jhpiego Indonesia	Program Officer	Implementation and data collection coordination - Indonesia
Biran Affandi	Professor of Obstetrics & Gynecology, University of Indonesia	Technical and Implementation Consultant - Indonesia

3. How will personnel involved with the data collection and analysis be trained in human subjects research protections? (Use the JHSPH Ethics Field Training Guide available on the JHSPH IRB website: www.jhsph.edu/irb.)

The data collectors and supervisors will undergo a week-long training workshop in research ethics for fieldwork and research protocol including study methods, procedures and tools. This training will be provided by the Co-Is and PI. A training workshop for the local research team (including but not limited to project managers, data collectors, team leaders, local co-investigators, quality control officers, translators, transcribers, database developers, data entry clerks) will be conducted in local offices prior to data collection. Training content will include information on research ethics in the field, rights of human subjects during research, research methodology and protocol, sampling procedures, informed consent, data collection tools, interviewing techniques, and data management, security, and quality. The JHSPH IRB

Training will also include opportunities for practice using the study methods and the forms and tools in English as well as their local versions. Training on processes and logistics for field management, supervision, communication and documentation will be provided by the local contractor.

Team Leaders/Field Supervisors will be required to report to the head of their country office on a daily basis. The local office will maintain contact with the Jhpiego/headquarters and will provide research updates every 2 to 3 days while data collection is on-going. The local office will maintain contact with the PI on a weekly basis throughout the contract period for the local contractor.

4. If the PI will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team.

The PI, Ms. Charurat, or the Global Study Manager, Ms. Kennedy, plan to travel from Jhpiego/headquarters to local offices for the preparation of data collection, training of assessors, and the supervision of the initial data collection. They worked with the other members of the team to develop the protocol and tools. Locally, the co-investigators (and other staff members in the Jhpiego/local office) will manage all aspects of the data collection and entry.

The PI or the Global Study Manager will also visit the data collection sites to support start-up of data collection and ensure that correct procedures are being followed with fidelity to the research protocol. All study investigators schedule weekly calls with the project manager for the local contractor to discuss study progress and any issues that require problem solving. Additional conference calls will be held on an ad hoc basis to ensure that the protocol is followed and proper records are kept. They will also address questions or concerns that arise during the fieldwork and data entry process.

B. **Recordkeeping:**
Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation. For assistance, contact housecall@jhu.edu.

All study staff will be instructed of the study protocol and the need to adhere to it. A Field Manual and Standard Operating Procedures will be developed that outline, among other guidelines, processes for recording and storing data. Algorithms will be created for research assistants and data managers to ensure that data is collected and stored in line with the protocol. All data collected will be linked to the corresponding data collector and manager in order to track records.

Data will be collected electronically with tablets and the data tools will have quality assurance measures designed into the platform such as skip patterns and illogical responses.

The PI and research team will monitor all IRB correspondence and study documentation during their team meetings/ conference calls.

C. **Safety Monitoring:**

1. Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role? N/A

2. If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following:

   a. The DSMB membership, affiliation and expertise. N/A

   b. The charge or charter to the DSMB. N/A

c. Plans for providing DSMB reports to the IRB. N/A

4. Describe plans for interim analysis and stopping rules, if any. N/A

D. **Reporting Unanticipated Problems/Adverse Events (AE's) to the IRB (*all studies must complete this section*)**:

Describe your plan for reporting to the IRB and (if applicable) to the sponsor. Include your plan for government-mandated reporting of abuse or illegal activity.

We do not anticipate that this study will result in AEs. However, if any unanticipated adverse event or problems occur, the interviewer will immediately report it to the Local Co-Investigator, and will provide a written statement describing the incident. The local investigator will report it to the study PI and the study PI will report it to the JHSPH IRB and the local IRBs, named below:

NOTE: The IRB does not require submission for all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**.

E. **Other IRBs/Ethics Review Boards:**

If other IRBs will review the research, provide the name and contact information for each IRB/ethics review board and its Federal Wide Assurance, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances).

Indonesia
National Institute of Health Research and Development
Address: Jl. Percetakan Negara No. 29 Jakarta 10560. Po Box 1226
Phone : +62 21 426 1088

Kenya
KEMRI Scientific Ethics Review Committee
P.O Box 54840-00200, Nairobi;
Telephone numbers: 020-2722541, 0722205901, 0733400003;
Email address: ERCadmin@kemri.org

F. **Collaborations with non-JHSPH Institutions:**

For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

Insert Name of Institutions in Partner column(s); add additional columns if necessary.

	JHSPH	Partner 1	Partner 2
Jhpiego	X		
University of Indonesia		X	

For the following, indicate "P" for "Primary", "S" for "Secondary" (as appropriate to role and level of responsibility.) Add additional items if useful.

1.	Human subjects research ethics training for data collectors	P	S	
2.	Day to day management and supervision of data collection	P	S	
3.	Reporting unanticipated problems to the JHSPH IRB/Sponsor	P	S	
4.	Hiring/supervising people obtaining informed consent and/or collecting data	P		
5.	Execution of plan for data security/protection of participant data confidentiality, as described in the Data Security and Confidentiality Protections section above .	P	S	
6.	Biospecimen processing, storage, management, access, and/or making decisions about future use	N/A	N/A	

XI. Jhpiego Dissemination Plans

A. ☒ **Check the box if you intend to disseminate findings from this study broadly.** Broadly means sharing findings through posters, abstracts at conferences and publications in journals, beyond immediate stakeholders such as MOH and sponsors.

1. Provide a brief description of your dissemination plan (include if you plan to have a writing workshop). Are the prospective forums (national and international conferences)?

Our planned documentation and dissemination will be mapped to our study objectives, ensuring that all relevant technical findings are presented through global fora in a timely manner. Channels for this dissemination include: the PPFP Global Movement community; our network of field presence (including through the large-scale, USAID-funded, Jhpiego-led MCSP, which supports PPFP in 22 countries and is globally recognized for establishing PPFP as a critical component along the continuum of care for reproductive health); the recently launched FP2020's FP platform, which Jhpiego co-designed; the donor community; professional associations; and other implementing partners. We will use these platforms to present field implementation highlights of our interventions. From commencement of the study throughout implementation at relevant time points, and following a writing workshop at the conclusion of data collection, we will globally disseminate learnings through the provision of country spotlights, media and other resources. Key knowledge outputs, including reports of findings and technical materials, will additionally be shared on an ongoing basis with the global community through research articles, including in peer-reviewed journals offering timely publication opportunities such as "field action reports" that capture ongoing learnings for rapid dissemination. Knowledge will also be shared through monographs and conferences.

a. For journal publication (list all possible journals of interest)

- Contraception
- Reproductive Health
- Studies in Family Planning
- International Family Planning Perspectives
- Reproductive Health Matters.
- Studies in Family Planning
- BMC Public Health
- Global Health: Science and Practice Journal

b. For posters, presentations and abstracts (list all potential conferences and events)

- International Conference on Family Planning
- FIGO
- ICM
- ICN

B. ☒ Check the box if you will be working in advocacy with government throughout the project

a. ☐ You will be disseminating findings to government for policy change?

XII. Please complete the attached worksheet of your Logic Model and submit to Jhpiego IRBhelp with your completed research protocol. *This is for Jhpiego internal review only.*

COMPLETE THE FOLLOWING SECTIONS WHEN RELEVANT TO YOUR STUDY:

XIII. Secondary Data Analysis of Existing Data:

A. **Study Design:**

1. Describe your study design and methods. The study design must relate to your stated aims/objectives.

In addition to the methods described above, the study will monitor immediate postpregnancy family planning clients and participating providers and facilities through analysis of routine program and facility records. These records are outlined below.

FP Facility Register	Facility clients	Determine overall facility PPFP acceptance, PPFP method mix and adverse events	Monthly service statistic record review	Descriptive statistics
Supportive Supervision Records	Kenya: Intervention Site Providers Indonesia: All providers	Measure service quality against PPFP performance standards	Intervention Area: Kenya: 3 and 12 months post-training Indonesia: Beginning of the study, Year 2, Year 3 Control Area: Kenya and Indonesia: month 30	Descriptive, chi-sq, ANOVA (depending on sample size)

Family Planning Facility Registers: Information about immediate PPFP clients will be documented in a Family Planning register at the intervention and control health facility where they receive care – part of the health system. This information will be used to track overall PPFP service statistics, assist with validating responses from the Client Interviews, and help the study team ensure that the Client Interview sample continues to be representative of the overall client population (especially regarding adolescent enrollment).

Supportive Supervision Records: The project will employ Jhpiego staff and a ministry of health representative or consultant to provide Supportive Supervision to intervention facility providers trained in implant service provision and counseling at project facilities. Supportive Supervision is a proven method for improving the quality of services offered by trained providers through guiding, helping, and encouraging staff to continue using the skills they learn through training. Regular Supportive Supervision visits will be conducted to each facility. During these visits, supervisors use a Supportive Supervision Checklist to monitor the quality of services provided. Quality will be measured against a set of performance standards developed at the national level with stakeholders from each country. The study team will use

Supportive Supervision Records to track whether or not services are improving at project facilities. Data will be linked to facilities to assess overall facility quality and help determine the impact of the intervention.

2. Provide an estimated sample size and an explanation for that number.

Family Planning Facility Registers: We estimate that roughly 15% of women who deliver at intervention facilities and 10% of women who deliver at control facilities will accept a method of postpartum family planning and that on average 30 women per month will deliver in each of the 62 project facilities over the course of the project. Therefore, we anticipate facilities will collect information about approximately 3,906 postpartum FP acceptor clients during the 30 months of the study. Furthermore, we estimate that approximately 50% of women receiving postabortion care at both intervention and control facilities will accept a method of postabortion family planning and that on average 12 women per month will receive PAC at the project facilities over the course of the project. Therefore, we anticipate facilities will collect information about approximately 4,680 postabortion FP acceptor clients during the 30 months of the study. Based on these estimates, we expect to collect de-identified service statistics for approximately **8,586 postpregnancy FP acceptor clients**.

Supportive Supervision Records: Supportive Supervision will be provided to relevant health care providers at all participating facilities as part of the project's main activities. We anticipate that this will include around 5 providers per facility, for 200 providers in Kenya and 100 providers in Indonesia from both intervention and control facilities. This leads to supportive supervision records for review for around **300 total providers**.

3. Provide a brief data analysis plan and a description of variables to be derived.

Family Planning Facility Registers: Using FP Facility Register data, the study team will assess trends in service delivery at participating facilities including the total number of ANC clients, the total number of Labor and Delivery clients, total number of postabortion clients, the total number of postpartum family planning acceptors broken into the type of family planning method accepted. Additionally, the study and project teams will monitor facility records for reports of adverse events related to PPFP acceptance.

Supportive Supervision Records: Supportive Supervision Records will primarily be used to measure changes in service provision quality according to data collected during the Supportive Supervision. Overall changes in the number/percent of standards met will be calculated through difference in difference analysis. Facility aggregate provider performance information may also be calculated into assessment of facility readiness and overall facility quality.

B. **Participants:**

1. Describe the subjects who provided the original data and the population from which they were drawn.

Family Planning Facility Registers: Information about family planning service provision will be collected from all project facilities. All information recorded through facility records will be included in the sample. The sample will likely include the same women contacted during the client interviews. However, it may also include data on those who were otherwise ineligible for recruitment.

Supportive Supervision Records: Providers trained in PPFP counseling and method service provision as well as leadership and management working at study intervention facilities will be monitored using supportive supervision. All trained providers receiving supportive supervision will be included. It is probable that providers receiving supportive supervision will also participate in the structured interview.

2. If you are receiving, accessing, or using data from a U.S. health care provider, the need for HIPAA review is likely. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. If either of these conditions is met, check "yes" to the HIPAA question in the PHIRST application. N/A

3. If you plan to analyze human specimens or genetic/genomic data, provide details about the source of those specimens and whether they were collected using an informed consent document. If yes, explain whether your proposed use is "consistent with" the scope of the original consent, if it potentially introduces new analyses beyond the scope of the original consent, and/or if it introduces new sensitive topics (HIV/STDs, mental health, addiction) or cultural/community issues that may be controversial. N/A

4. Explain whether (and how) you plan to return results to the participants either individually or as a group.

Results will not be returned to the participants. However, project staff will use Supportive Supervision records to monitor provider performance and make adjustments to individual and/or group trainings and other follow-up activities as needed.

XVI. Data Coordinating Center:

Complete if JHSPH serves as the Data Coordinating Center.

A. How will the study procedures be developed?

The planned study procedures, including Study SOPs and the study Data Collector's manual, have been developed by the Jhpiego Baltimore Family Planning Team in concordance with the study teams in Kenya and Indonesia. The study teams in Kenya and Indonesia, as well as the study team in Baltimore, include research and technical experts, whose inputs and reviews ensure that they procedures are culturally, ethically, and technically appropriate.

B. How will the study documents that require IRB approval at each local site be developed? Will there be some sort of steering or equivalent committee that will provide central review and approval of study documents, or will template consent forms, recruitment materials, data collection forms, etc. be developed by and provided to the local sites by the coordinating center without external review?

All study documents, including all study tools, consent forms and recruitment materials are developed by the Jhpiego Baltimore Family Planning Team in concordance with the study teams in Kenya and Indonesia. While the Baltimore study manager oversees the process of study tool review, each study tool has been edited by key study research and technical staff in Baltimore, Kenya, and Indonesia to ensure research, technical and cultural relevance.

C. Will each local clinical site have its own IRB with an FWA? State whether the coordinating center will collect IRB approvals and renewals from the clinical centers; if not, explain why.

The study will gain approval from the Kenya Medical Research Institute (KEMRI) IRB in Kenya and the Kementerian Kesehatan (KemKes [Ministry of Health]) IRB in Indonesia. Local and JHSPH ethics approvals will be shared, along with letters of support from local ministries of health, with each local PI.

D. How will the coordinating center provide each local site with the most recent version of the protocol and other study documents? What will be the process for requesting that these updates be approved by local clinical center IRBs?

The Baltimore-based coordinating center keeps the most up-to-date versions of all study tools and the study protocol in a dropbox folder shared by the Kenya and Indonesia based PIs and researchers. The study manager monitors the

dropbox folder to ensure the integrity of the forms and keeps back-up copies of the tools in the event anything happens to the tools in the dropbox. All up-to-date quantitative data collection tools will similarly be stored in the REDCap system which will be used to physically collect the data. Any changes to the study tools must be made in accordance with the PPFP Choices "Study Tool Alteration and Data Steward Management" SOP, which states that all suggested edits to tools will only be made by the Data Steward, who is the Baltimore-based study manager, or her chosen deputy, after conversation with the study staff member who suggests the edit and, when necessary, a secondary reviewer (member of study staff) and the PI.
Any alterations to the study tools or protocol that would require IRB approval will be immediately sent to the relevant IRBs as an amendment. These will be sent to the Kenya and Indonesia IRBs by the in-country PI, and to the JHSPH IRB by the PPFP Choices PI or study manager. The study team will await approval from all necessary IRBs prior to enacting the proposed amendments.

E. What is the plan for collecting data, managing the data, and protecting the data at the coordinating center?

All quantitative data will be collected through the secure web application, REDCap, and transmitted via a secured network to the central database which, for Jhpiego, is located in the Jhpiego Nairobi office. All equipment used to enter or access study data will be password protected and will have security software installed. In addition, each REDCap user will be required to log-in using their personal ID to enter or access the data. Only the database administrators will have the permission to download the data from the central database. When data is exported for statistical analysis, it will be de-identified and kept in a password protected directory accessible to the statistician and the data managers.
All qualitative data obtained during FGDs, KIIs, and IDIs will be collected via audiotapes at the interview. The audiotapes will be transcribed and the transcriptions will be stored in a password protected database with security software installed. While the audiotapes are being transcribed, they will be stored in a locked cabinet. As soon as the transcription is completed and saved, the audio files will be destroyed. When data is exported for statistical analysis, it will be de-identified and kept in a password protected directory accessible to the statistician and the data managers.

F. What is the process for reporting and evaluating protocol events and deviations from the local sites? Who has overall responsibility for overseeing subject safety: the investigators at the recruitment site, the Coordinating Center, the Steering Committee, or a Data and Safety Monitoring Board (DSMB)? Is there a DSMB that will evaluate these reports and provide summaries of safety information to all the reviewing IRBs, including the coordinating center IRB? Please note that if there is a DSMB for the overall study, then the coordinating center PI does not have to report to the coordinating center IRB each individual adverse event/problem event that is submitted by the local site PIs.

If any unanticipated adverse event or protocol deviations occur, the data collector or study staff will immediately report it to the Local PI, and will provide a written statement describing the incident. The local PI will report it to the study PI and the study PI will report it to the JHSPH IRB and the local KEMRI and/or KemKes IRBs in accordance with Jhpiego's IRB policy and SOP for Reporting of Adverse Events and Serious Adverse Events for Jhpiego Studies. Overall responsibility for overseeing subject safety lies with the Coordinating Center, which will regularly monitor study progress and will be in regular communication with the in-country staff

G. Some FDA regulated studies have different AE reporting criteria than that required by the IRB (IRB Policy No. 103.06). How will you reconcile the different requirements, and who is responsible for this reconciliation?

n/a

H. Who is responsible for compliance with the study protocol and procedures and how will the compliance of the local sites be monitored and reviewed? How will issues with compliance be remedied?

Overall responsibility for compliance with the study protocol and procedures lies with the PI and the Study Manager. Compliance of the local sites will be the responsibility of the local PIs who will report to the Study PI. Compliance will be monitored from the Baltimore location through biweekly calls between the Baltimore Study staff, occasional site visits, and through monitoring of data quality. Compliance will be monitored by the Kenya and Indonesia PIs through the weekly communication with and monthly reports from the data collection teams, regular site visits, and regular data monitoring, quality assurance and verification.

REFERENCES

[1] World Health Organization. (2012). Family planning: a health and development issue, a key intervention for the survival of women and children. Retrieved on October 10 2013, from WHO: http://www.who.int/reproductivehealth/publications/family_planning/rhr_12_23/en/index.html
[2] World Health Organization. (2005). Report of a WHO Technical Consultation on Birth Spacing http://www.who.int/maternal_child_adolescent/documents/birth_spacing.pdf
[3] Moore, Z. (2013). Family Planning Needs During the Extended Postpartum Period in Kenya. USAID
[4] FP2020. (2015). *Indonesia.* Retrieved September 19, 2015, from FP2020: http://www.familyplanning2020.org/entities/59
[5] Indonesia Demographic Health Survey, 2012
[6] Guttmacher Institute, Abortion and Unintended pregnancy in Kenya. (https://www.guttmacher.org/sites/default/files/report_pdf/ib_unsafeabortionkenya.pdf).
[7] Guttmacher Institute. Abortion in Indonesia (https://www.guttmacher.org/sites/default/files/report_pdf/ib_abortion_indonesia_0.pdf).
[8] Jhpiego Family Planning Team, Postpartum and Postabortion Family Planning Assessment in Kenya and Indonesia, April 2016
[9] Cresswell J, Klassen A, Clark V, & Smith K. (2010). Best practices for mixed methods research in health sciences. Retrieved on December 15, 2015 from: https://obssr-archive.od.nih.gov/mixed_methods_research/pdf/Best_Practices_for_Mixed_Methods_Research.pdf
[10] Wilkinson, D., & Birmingham, P. (2003). *Using research instruments: A guide for researchers*. Psychology Press.
[11] Crabtree, B. F., & Miller, W. L. (Eds.). (1999). *Doing qualitative research*. Sage Publications.
[14] Patton, M. Q. (2005). *Qualitative research*. John Wiley & Sons, Ltd.
[15] Maxwell, J. A. (2005). Qualitative research design (Vol. 41). *Applied social research methods series*.
[16] Republic of Kenya National AIDS and STI Control Program. (2013) Kenya AIDS Indicator Survey 2012.
Guidelines for Conducting Adolescents Sexual and Reproductive Health Research in Kenya, May 2015
[17] Law no. 8 year 2012 about Legislation Election, Chapter IV Voting Rights, Article 19; sentence (1); Regulation of Minister of Health No. 290 year 2008 – Medical Consent, Chapter I General Term, Article 1; sentence (1) and (7)); Peraturan Menteri Kesehatan Republik Indonesia, 2008

APPENDIX I. Secondary Study Questions

Study Theme	Question
Overarching Question	What are the key determinants at service delivery, provider and client levels that influence the uptake of post-pregnancy family planning in the public and private health care sectors in Indonesia and Kenya?
Programmatic Effort	• What programmatic inputs increase a woman's likelihood of accepting an FP method immediately postpartum or postabortion? • What are the costs associated with implementing such interventions? • What are the costs and programmatic efforts needed to scale up and sustain these interventions? • What are the barriers and facilitators for young women's accessing post-pregnancy FP services? • What are effective programmatic approaches to engaging the private sector to provide a full range of post-pregnancy family planning methods?
Feasibility	• What proportion of post-pregnancy women receive an FP method, according to standard, prior to discharge, among those who opted for an FP method, by age, type of client, timing and method? • To what extent was the health care system able to offer a full range of post-pregnancy FP methods within existing service delivery platforms? (Areas to be examined will include infection prevention, resources, practices, knowledge and skills, commodity supply chain management, labor and delivery staffing, workflow, etc.) • To what extent were the health care facilities offering appropriate and quality post-pregnancy FP counseling at all relevant time points (antenatal care, early labor, prior to discharge, follow-up visits)? • To what extent were providers able to provide, with technical quality, FP counseling and services within the immediate post-pregnancy period? • What are internal and external inputs that incentivize or disincentivize private sector facilities in the provision of post-pregnancy FP services?
Acceptability	• What proportion of women post-pregnancy choose a FP method after FP counseling? What proportion receive the method in the immediate post-pregnancy period prior to pre-discharge? • What proportion of women received a different FP method in the immediate post-pregnancy period than the one they opted for prior to delivery or uterine evacuation? What were the determining factors in this difference? • To what extent do providers and women understand the benefits of FP in the immediate post-pregnancy period? • To what extent do providers accept the need to provide post-pregnancy FP counseling and service provision? • What was the continuation rate (within six months post-pregnancy) and reasons for discontinuation for those no longer using the method? • What proportion of women using the lactational amenorrhea method (LAM) transition to another contraceptive method by six months postpartum? To what methods?
Safety	• What were the rates of minor, moderate and major adverse events? • Were women experiencing adverse events treated to standard?
Scalability	• When scaling up post-pregnancy interventions, what are the key players and what are the key factors? What works and what doesn't? Are these different between public and private sector? • What contributes to the success of implementing and scaling up of post-pregnancy FP in the private sector?
A set of questions on private sector including behavioral economics may also be included based on the interventions/defined intervention package described in Objective 2.	

APPENDIX II. Timeline of Study Activities

Month 0-3: Completion of Study Tools and IRB	1. Completion of Protocol 2. Completion of the following tools: a. Client Interview questionnaires b. Focus Group Discussion and In-Depth Interview guides c. Key Informant Interview guides d. Facility Assessment guide e. Data Abstraction guides f. Data Collector's Field Guide 3. Completion of the following trainings/capacity building tools a. Trainings on FP Counseling and full method mix service provision b. Leadership and Management training and support materials c. Supportive Supervision guides 4. Formation of Technical Advisory Groups 5. Private Sector Formative Assessments 6. Submission of IRB materials
Months 4-6: Site and Study Preparation	1. Kenya Intervention and Intervention Implementation Site Preparation: a. Trainings on FP Counseling and full method mix service provision for post-pregnancy FP for public and private facilities b. Leadership and Management support training and intervention for public and private facilities c. Private sector business planning 2. Indonesia Intervention and Intervention Implementation Site Preparation: a. Supportive Supervision on FP Counseling and full method mix service provision for post-pregnancy FP for public and private facilities b. Leadership and Management support training and intervention for public and private facilities c. Private sector business planning 3. Study Preparation: a. Key Informant Interviews i. Ministry of Health and Policy Makers ii. Community Influencers iii. Public Facility providers and management iv. Private Facility providers and management b. First facility assessment (baseline) c. Study Tools testing d. Training materials testing and revisions
Months 6-30: Study Recruitment and follow-up	1. Recruitment at Intervention and Control sites a. Client interviews b. Postpartum Client Focus Group Discussions c. Postabortion Client In-Depth Interviews d. Last recruitment by month 24 2. Intervention continuation activities a. Midline and End-line Facility Assessments b. Routine Data Abstraction c. Supportive Supervision/Quality Assurance with Refresher Trainings as needed 3. Regular Technical Advisory Group and Private Sector Associations meetings 4. End-line Key Informant Interviews

	5. Study analysis activities
Months 31-36: Phase II Implementation, Analysis, Global Dissemination	1. Control Sites and Control Implementation Sites Trainings e. Kenya: i. Trainings on FP Counseling and full method mix service provision for post-pregnancy FP for public and private facilities ii. Leadership and Management support training and intervention for public and private facilities iii. Private sector business planning f. Indonesia: i. Trainings on FP Counseling and full method mix service provision for post-pregnancy FP for public and private facilities ii. Leadership and Management support training and intervention for public and private facilities iii. Private sector business planning 4. Completion of all Analysis 5. Dissemination of Results