Research Protocol

Title: A randomized controlled trial of safety and effectiveness of Depo Provera intramuscular and subcutaneous administration comparing lay Lady Health Workers with clinically-trained Lady Health Visitors in Pakistan

Study #: 1035709

Study Sponsor: Pfizer Foundation

FHI 360 Project Leader: Dawn Chin-Quee

Study Site(s): Sindh, Pakistan

Principal Investigator: Dr. Sarah Saleem

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Study Summary

Title: A randomized controlled trial of safety and effectiveness of Depo Provera intramuscular and subcutaneous administration comparing lay Lady Health Workers with clinically-trained Lady Health Visitors in Pakistan

Study #: 1035709

Design: Randomized controlled trial comparing Lady Health Workers with Lady Health Visitors on quantitative measures of safety and effectiveness.

Population: Lady Health Workers and Lady Health Visitors trained to initiate intramuscular and subcutaneous Depo Provera use. DMPA clients of trained Lady Health Workers and Lady Health Visitors.

Study Duration: 12 months

Primary Objective:	To assess whether the community health worker cadre, Lady Health Workers (LHWs) in Pakistan can screen and initiate women on intramuscular and subcutaneous Depo Provera injections as safely and effectively as their clinically-trained counterparts, Lady Health Visitors (LHVs).
Primary Outcomes:	• Proportion of Lady Health Workers and Lady Health Visitors that appropriately screen women for DMPA use; • Proportion of Lady Health Worker and Lady Health Visitor clients that report discussion with their respective providers on side effects, danger signs, advantages and disadvantages of DMPA use; • Proportion of Lady Health Workers and Lady Health Visitors that demonstrate appropriate injection technique • Proportion of Lady Health Workers and Lady Health Visitors that report needle stick injuries; • Proportion of Lady Health Workers that properly maintains a client (re)injection log.
Secondary Objective:	To assess whether DMPA clients of Lady Health Workers and Lady Health Visitors are equally satisfied with their respective providers and the family planning services they provide.
Secondary Outcomes:	• Satisfaction with the method; • Satisfaction with the services received from the provider; • Reports of client ability to speak freely and ask questions of provider; • Friendly and respectful behavior toward client.
Study Sites:	Five urban sites in Karachi; five rural sites in Thatta district.

Abbreviations and Acronyms

AKU	**Aga Khan University**
CBA2I	**community-based access to injectables**
CPR	**contraceptive prevalence rate**
DMPA	**depot medroxyprogesterone acetate**
FP	**family planning**
HQ	**headquarters**
ICF	**informed consent form**
IM	**intramuscular**
IRB	**institutional review board**
LHV	**lady health visitor**
LHW	**lady health worker**
LTF	**lost-to-follow-up**
mCPR	**modern contraceptive prevalence rate**
OIRE	**Office of International Research Ethics**
PI	**principal investigator**
PNC	**Pakistan Nursing Council**
RA	**research assistant**
SAP	**statistical analysis plan**
SP	**Sayana Press®**

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I. Introduction

Task sharing of health services by higher and lower level cadres of providers has been adopted as a pragmatic response to human resource shortages in many developing countries.[1,2] Family planning service delivery has benefited enormously from this strategy by increasing access to contraception--particularly to women in rural and underserved areas.[3] Access to a wider range of methods and of providers, such as the provision of long-acting and permanent methods (LAPMs) by clinical and health officers;[4] long-acting reversible contraceptives (LARCs) by midwives, auxiliary nurses and some lay health workers;[5,6,7] and injectable contraceptives by community health workers,[8,9] are the products of task sharing. In fact, the popularity of injectables in sub Saharan Africa combined with the practicality of lay health worker provision of the method has increased modern contraceptive use in many of these countries.[10]

Task sharing is supported by the World Health Organization (WHO), formalized in its guideline document, *OptimizeMNH*[11] and reiterated in the Safe Abortion guidelines.[12] Recommendations in this key guideline document are based on and supported by evidence obtained through systematic reviews of research--including qualitative and case studies--and programmatic experience. As shown in the figure in Appendix 1, the cadre of health provider and the contraceptive method in question are organized by four categories of guidance—*recommended, recommended with targeted monitoring and evaluation* (M&E), *consider in the context of rigorous research*, and *recommend against*. The guidelines recommend provision of all methods: tubal ligation, vasectomy, intrauterine devices (IUDs), implants and injectables by associate clinicians and non-specialist doctors. However, limitations are placed on the methods that midwives, nurses, auxiliary midwives, auxiliary nurses and lay health workers may provide. For example, there are no restrictions on the provision of oral contraceptive pills and condoms (which are not shown in Appendix 1) by lay health workers, but the provision of tubal ligation, vasectomy and IUDs is recommended against; implants can be provided in the context of rigorous research; and provision of injectable contraception using standard syringes for intramuscular injections should be accompanied by targeted M&E. Currently, there are no guidelines for subcutaneous contraceptive injectables.

These recommendations are subject to revision if new evidence becomes available and meets WHO standards. WHO uses the GRADE (**G**rades of **R**ecommendation **A**ssessment, **D**evelopment and **E**valuation) approach to assess the quality of the evidence—one of the factors that contributes to the strength of the recommendation. Currently, the evidence supporting lay health worker provision of injectable contraception, while strong and bolstered by many pilot studies and programs worldwide, does not include a randomized controlled trial (RCT).[7] An RCT constitutes the highest level of evidence in the WHO research framework; thus, a trial demonstrating that lay health workers can just as safely and effectively initiate injectable contraception as clinically-trained cadres of health providers could modify the recommendation of targeted M&E for intramuscular injections.

FHI 360 and Jhpiego in collaboration with USAID, Aga Khan University (AKU) and the Government of Sindh province propose a randomized controlled trial (RCT) to provide evidence needed not only to change current policies in Pakistan forbidding initiation of DMPA by LHWs, but also for WHO to consider

modifying the recommendation for targeted M&E for lay health worker provision of intramuscular injectable contraceptives. The trial will be conducted in Pakistan with Lady Health Workers (LHWs)—the main lay health worker cadre. Given the very large number of LHWs—perhaps as much as 150,000[13]--this trial could just as importantly facilitate access to injectable contraception for thousands of Pakistani women, potentially increasing the country's modern contraceptive prevalence rate (mCPR).

The Pakistani Context

According to the latest Pakistan Demographic and Health Survey (PDHS 2012-13),[14] the contraceptive prevalence rate (CPR) for any method among currently married women is 35%; the mCPR is 26%. Female sterilization and condoms are the predominant modern methods at 9% each, with injectables at 3%, and pills and intrauterine devices (IUDs) at 2% each (no data provided on subdermal implants). The public sector, which includes LHWs, currently provides 46% of family planning methods, while the private sector provides 35%.

Knowledge of family planning methods in Pakistan is universal at 99% for women and 96% for men. For both currently-married men and currently-married women, the most commonly known methods are the pill (85% and 95%, respectively) and injectables (82% and 95%, respectively), along with awareness of condoms reported by currently-married men (89%) and female sterilization reported by currently-married women (91%). Unmet need for family planning among currently married women has fallen since the 2006-07 PDHS from 25% to 20%, but it is 22% in rural areas where met need for family planning is also predictably lower in rural (31%) than urban areas (45%).

The National Program for Family Planning and Primary Health Care, also known as the Lady Health Worker Program, was established to provide rural communities and slum areas with essential primary health care services, including maternal, newborn and child health care; family planning services; and integration of other vertical health promotion programs, such as polio vaccinations. The most common LHW services received by women were child vaccinations (20%), treatments for minor ailments (7%), contraceptive supplies (7%), and information on maternal and child health (4%).[11] In recent years, the workload of LHWs has increased enormously. For that reason, one of Pakistan's FP2020 goals is to re-focus priority on family planning services, which would also enable the government to meet its goal of increasing the CPR to 55% by 2020 and an mCPR of 36.5%.[15,16] Additionally, provinces have set their own goals, such as Sindh Province with a target of 45% CPR for 2020.

LHWs receive 18 months of didactic and practicum training--many more months than CHWs in other countries who are authorized to initiate clients on DMPA (e.g., Afghanistan, Nepal, Madagascar, Uganda, Kenya). LHVs receive two years of training, and upon completion, are issued a diploma by the Pakistan Nursing Council (PNC). In terms of clinical competency, they are just below the level of midwife, which requires a third year of training. Lady Health Visitors work primarily in health facilities, but like LHWs, they also provide services in the community. Lady Health Visitors often supervise LHWs; unlike this lay cadre, they can provide injectables with no restrictions or need for monitoring or supervision.

There are two other types of clinically-trained health care providers assigned to health facilities who are essentially equivalent to LHVs: Family Welfare Counselors (FWCs) and Family Welfare Workers (FWWs)

who provide all FP methods except for tubal ligations. Henceforth, these providers will be subsumed under and referred to as LHVs for the purpose of simplicity.

There is no national policy or strategy for community-based access to injectable contraception (CBA2I) in Pakistan. However, the PNC curriculum for LHWs includes training for administration of follow-up doses of intramuscular (IM) injectable contraception in the community, and they are allowed to do so without monitoring or supervision. Thus, the key and missing element for LHWs is evidence that they can screen and counsel first-time users of Depo Provera (DMPA) as proficiently as LHVs. Some LHWs have already demonstrated proficiency in injection technique for DMPA IM and many also provide vaccinations in their communities, which is the basis for allowing LHWs to resupply DMPA injections (M. Villanueva & F. Midhet, personal communication, December 19, 2016).

National advocacy efforts to develop a strategy for CBA2I are ongoing and there is widespread support amongst the government, implementing partners, and donors. In 2014, a policy roundtable meeting on "Increasing Access to Family Planning through Task Sharing" was hosted by Marie Stopes and led by the Population Welfare Department. The focus of the meeting was to discuss options for addressing the high unmet need for FP and to develop policy recommendations and a way forward, including updating pre- and in-service curricula and training. There have also been policy level discussions at the community level in the Punjab and Sindh provinces on task sharing the administration of the first dose of Depo Provera IM. There is agreement among stakeholders that a comparative study is valuable and timely, particularly for assurance on feasibility. Thus, the study is seen as essential to taking action. With evidence, support can be focused on preparations for uptake in new areas and with new partners (for example, BMGF is launching a new program where task shifting injectables might be added to their approach).

The Government of Sindh province has expressed interest in moving forward with this CBA2I action following positive results from targeted research. There is also interest in introducing Pfizer's subcutaneous form of Depo Provera, Sayana Press® (SP) in Pakistan, which could simplify administration of injectable contraceptives—whether by LHWs or self-administration. As such, an SP arm will be included in the trial, which will be facilitated by relevant training of LHWs and LHVs by Jhpiego and stocks provided by a special USAID procurement, as the registration process for SP is ongoing. A successful RCT comparing the performance of LHWs and LHVs on first-dose initiation of Depo Provera IM (DMPA IM) and (SP) would facilitate efforts to expand CBA2I in Pakistan, and in turn improve access to family planning services for a potentially large number of underserved women.

II. Objectives and Outcomes

The overall goal of the trial is to provide high-level evidence that lay or community health workers can safely and effectively screen and initiate women who choose to use injectable contraceptives. The primary objective is:

To assess whether the community health worker cadre, Lady Health Workers (LHWs) in Pakistan can screen and initiate women on intramuscular and subcutaneous Depo Provera injections as safely and effectively as their clinically-trained counterparts, Lady Health Visitors (LHVs).

Although LHWs are already allowed to provide follow-up doses in the community, this RCT will focus on the comparison of safety and effectiveness of screening, counseling and first-time administration of DMPA IM and SP. Rather than focusing on determining whether services are better provided by one of the two health worker cadres, we want to determine if LHWs can perform just as well as the more experienced LHVs. Therefore, the trial will be powered specifically to detect non-inferiority (i.e., no difference) within a tolerance margin in the performance of LHWs compared to LHVs with regard to screening--the procedure that determines a woman's eligibility to receive DMPA. We consider the assessment of the screening for DMPA use as the primary outcome of interest for addressing the primary objective. However, in addition to screening, metrics for counseling and administration of DMPA will constitute the endpoints for the primary objective described below:

- Proportion of Lady Health Workers and Lady Health Visitors that appropriately screen women for DMPA use;
- Proportion of Lady Health Worker and Lady Health Visitor clients that report discussion with their respective providers on side effects, danger signs, advantages and disadvantages of DMPA use;
- Proportion of Lady Health Workers and Lady Health Visitors that demonstrate appropriate injection technique
- Proportion of Lady Health Workers and Lady Health Visitors that report needle stick injuries;
- Proportion of Lady Health Workers that properly maintains a client (re)injection log.

Details on analysis of these endpoints will be provided in a separate data analysis plan.

The secondary objective is:

To assess whether DMPA clients of Lady Health Workers and Lady Health Visitors are equally satisfied with their respective providers and the family planning services they provide.

The endpoints will be measures of satisfaction and quality reported by clients of LHWs and LHVs, such as:

- Satisfaction with the method and its delivery (IM and SP);
- Satisfaction with the services received from the provider;
- Reports of client ability to speak freely and ask questions of provider;
- Reports of friendly and respectful behavior toward client.

III. Methodology

Overview

This will be a randomized controlled trial conducted in Sindh Province, Pakistan, using quantitative methods. Third-party, independent data collectors will be trained to perform onsite observations of screening and counseling of first-time DMPA clients performed by LHWs and LHVs in health facilities. Another health facility provider--blinded to the LHW or LHV who provided the initial screening--will verify client eligibility to use DMPA through their own client interview. If the independent screener deems the client eligible to receive DMPA, then the same provider who earlier screened and counseled her on the method will administer the injectable to her. Clients will also be randomized to receive DMPA IM or SP to prevent selection biases between these groups. However, comparisons between these injection techniques will only be considered exploratory, focusing instead on acceptability of and satisfaction with the method as reported by clients.

Survey interviews with participating LHWs and LHVs will be conducted four to six months after trial initiation to obtain their feedback on providing DMPA IM and SP and attitudes towards LHW-initiation of injectables.

The study is limited to participating LHWs, LHVs and to their clients who voluntarily and independently accept DMPA as their contraceptive method before study recruitment is initiated.

Study setting and site selection

Sindh Province, Pakistan was selected for this trial, because the Government of Sindh expressed interest in expanding community-based injectable provision. On a national scale, the Ministry of National Health Services, Regulation and Coordination is also receptive to CBA2I. Currently, LHWs in 17 of Sindh's 23 districts have been trained to provide follow-up injections of DMPA IM. A subset of LHWs who are actively providing services in these 17 districts will be selected to participate in the trial, which will ensure that experienced and competent lay health workers are trained to initiate clients on DMPA IM or SP.

As family planning is widely-accepted–including with both religious and community leaders--opposition to the study is expected to be little to none. As such, community engagement will primarily include reaching out to existing structures such as active community-level health committees to inform them of and enlist support for the study. The relevant community health committees will be provided with information about the study and potential outcomes. In keeping with their role in the community, the committees will be encouraged and supported to cascade the announcement and ongoing sharing of information about the study launch, progress, and opportunities to participate. Community health committees will also be consulted to align launching the study with other messaging and events in the community which may impact awareness and interest in the study and availability of LHW provision of DMPA. If needed, deeper engagement with community health committees will be considered to boost

awareness of the study and services available to qualified FP clients. This can be accomplished through monthly Community Support Group meetings designed to raise awareness about various maternal, new born, child health (MNCH) and family planning topics that LHWs discuss with women's groups in their catchment areas.

In this trial, health facilities (and their associated catchment areas) will be selected to allow for representation of rural and urban districts. Other criteria including moderate to high client volume, as well as practical considerations such as the implementation of fieldwork and randomization of LHWs or LHVs to provide DMPA services will be considered.

Ten (10) health facilities will be selected from two districts in Sindh: Karachi and Thatta. Within those districts, health facilities in urban areas of Karachi and rural areas of Thatta will be approached to participate in the trial. The health facilities will be selected based on 1) the number of DMPA acceptors; 2) availability of both LHVs and LHWs; and 3) logistical factors. Table 1 provides a proposed sample of study sites with DMPA client volume from the most recent month of available data. Final selection of districts and health facilities within them will be determined in collaboration with in-country partners, AKU and Jhpiego as more information on the distribution of LHWs and LHVs and client volume in Sindh becomes available. The sample, including the number of districts or the number of health facilities and their distribution may be adjusted based on this information. For example, we may add another rural district if sufficient numbers cannot be found that meet criteria for LHW experience, current status (i.e., active, not active) or the health facility's ability or willingness to participate in the trial. Alternatively, more sites may be added within the same districts if client volume or health provider interest in trial participation is low.

Table 1. Proposed health facilities and most recent DMPA client volume data

Facility name	District (location)	Client volume in most recent month available of new and continuing injectable clients*
RHS-A Center, SG Hospital Saudabad	Karachi (urban)	30
FWC, SG Hospital Korangi 5	Karachi (urban)	125
FWC-Shah Faisal Colony No. 1, KMS MCH Center	Karachi (urban)	82
FWC Korangi 33-C, BHU Korangi 33-C	Karachi (urban)	73
RHS-A Center, SG Hospital Ibrahim Hyderi	Karachi (urban)	67
RHS-A Center, DHQ Hospital Makli	Thatta (rural)	32
RSH-A Center, THQ Hospital Mirpur Sakro	Thatta (rural)	19
Rural Health Center, Jherruk	Thatta (rural)	0[1]
RHS-A Center, THQ Hospital Sujawal	Thatta (rural)	38
RHS-A Center, THQ Hospital Mirpur Bathoro	Thatta (rural)	16

*Data received 2/20/2017

[1] It is anticipated that this proposed study site will have sufficient clients during the data collection period.

Target groups

The three target groups in this RCT are LHWs, LHVs and DMPA clients. All women in these target groups will be at least 18 years of age.

Lady Health Workers

Selections will be based on LHW affiliation to the 10 health facilities in Sindh chosen to take part in the trial. Jhpiego will make the final selection of LHWs to be trained and to participate in the trial, which will be based on the following criteria:

- Already trained to provide follow-up DMPA IM injections in their community;
- Currently providing services in their community
- Willingness and ability to participate in the trial

Jhpiego will develop relevant materials and tools to carry out the training of LHWs to screen and counsel first-time DMPA users—both IM and SP acceptors. LHWs will also be trained, or if already experienced in this area, given a refresher on maintaining DMPA client records and re-injection logs—adapting existing Pakistani forms if necessary. Jhpiego's training materials will be reviewed with the study team to ensure that the content is aligned with study objectives and procedures.

Lady Health Visitors

LHVs assigned to health facilities that correspond to the catchment areas of these LHWs, and who may in the normal course of their duties serve as their supervisors, will be eligible.

Study logistics, resources and need will determine if LHVs should be included in trainings for DMPA IM, but they will be required to attend trainings on SP, as that method will be new to both health cadres. It is particularly important that LHVs be trained on SP along with LHWs, not only to ensure consistency in training and knowledge for both cadres, but also to enable LHVs' supervisory obligations to their charges providing SP. Jhpiego will certify that once trained, LHWs and LHVs are proficient in screening, counseling and administration of both forms of DMPA prior to interacting with DMPA clients.

Screening and counseling on the use of either type of DMPA has been simplified by WHO's decision to employ the same medical eligibility requirements for both IM and SP formulations and to harmonize recommendations for the re-injection schedule and grace period (i.e., 2 weeks before the re-injection date or as late as 4 weeks after). Therefore, the only difference in service delivery will be the injection technique for DMPA IM and SP, as all other elements of method provision remain the same.

LHWs and LHVs selected to participate in the trial should not be the "cream of the crop". To reflect the real-world context outside a trial setting, any provider who successfully completes Jhpiego's training should be eligible to participate in the trial. Consent will be sought from LHWs and LHVs to observe their interactions with DMPA clients, including the provision of services, as well as to be interviewed by study staff.

DMPA acceptors

Family planning clients provide the basis for assessment of LHW and LHV service provision. Thus, the eligibility criteria for family planning clients of LHWs and LHVs are:

- Women who select DMPA as their contraceptive method for the first-time or after more than a six-month hiatus from the method;
- Women of reproductive age (18 to 49) who can legally consent to receive reproductive health services and participate in research studies in the Pakistani context;
- Women who consent to provision of DMPA services from LHWs or LHVs trained for the RCT;
- Women who provide consent to be observed and interviewed by independent data collectors during the trial.

Sample size

We require a minimum of 342 DMPA clients randomized to receive care from either the LHV or an LHW (1:1 allocation) for 90% power and 5% significance level to test the non-inferiority hypothesis that LHWs can screen potential DMPA clients for method initiation just as adequately as LHVs with a non-inferiority margin of 7.5%, assuming that both LHVs and LHWs perform at a 95% success rate. In Pakistan, there is usually at least one LHV assigned to a health facility and many more LHWs affiliated with and under the supervision of resident LHVs. Therefore, we will use a 3 to 1 ratio of LHWs to LHVs at each health facility in the trial. The three LHWs will be placed on rotation to cover a three-month enrollment and data collection period in the health facility. Rotations among the three LHWs will be based on their individual availability and schedules; not on their perceived competencies or the preference of facility staff.

In order to meet the desired sample size from LHWs and LHVs, we will select 10 health facilities that provide the most DMPA in Karachi and Thatta districts. These facilities will be distributed between rural and urban areas. For logistical reasons, we plan to obtain the full target sample size of 342 DMPA initiators from the urban health facilities to ensure that adequate analyses can be done with this group. We will recruit additional participants from rural facilities to help assess possible differences in performance between LHVs and LHWs in rural and urban areas. Although, we don't expect these differences to exist, the additional sample size will help us to assess whether differences may be likely to exist. If we can be comfortable that providers in rural and urban areas perform in similar manner, the overall sample size for the analysis may be pooled for an increase in power. Please note, however, that the additional sample size from rural areas will not be adequate for separate analyses by location or to assess rural and urban differences statistically. Rural facilities will likely provide a much lower number of DMPA acceptors in the three-month data collection period, but they will each be selected for their ability to enroll at least 20 new acceptors in that period of time. We will then expect to enroll approximately 100 DMPA acceptors from the rural facilities in the recruitment period for an overall total sample size of approximately 442 for this study.

Given the relationship between LHWs and LHVs within clinics, we plan to account for the correlations of participant outcomes within providers and providers within clinics in the analysis. We expect that some of these correlations would lead to decreases in power, others to lead to increases in power for within

clinic comparisons. Power calculations were not adjusted for these potential correlations as the net effect on power may be offset with each other.

Please note that the screening outcome is not affected by the injection technique used, so power calculations focus on the overall comparison between LHV and LHW on the primary outcome. Furthermore, comparisons regarding injection techniques will be considered exploratory.

Study procedures

Data collection instruments

FHI 360 Headquarters (HQ) staff will develop two survey questionnaires and three observation checklists for screening and counseling first-time DMPA acceptors. One questionnaire—an exit interview-- will be administered to DMPA clients, and the other, to LHWs and LHVs four to six months after initiation of the trial. Interviews with LHWs will be conducted during one of their routine visits to the health facility for resupply and supervision. LHWs will also be asked to present their family planning records at that time to determine if they properly maintain their injection and re-injection log books. Questions specific to LHWs and to LHVs will be arranged in separate sections of the instrument with appropriate skip patterns.

Three observation checklists will be developed for screening and counseling DMPA users. Independent observers will document screening and counseling procedures employed by LHWs and LHVs on one checklist, while the other two checklists will document injection technique separately for DMPA IM and SP.

Questionnaires

The questionnaire items in the client exit interview instrument will focus on the following domains:

- Sociodemographic characteristics
- Experiences using contraceptive methods
- Factors in her decision to use DMPA
- Interaction with and information provided by LHW/LHV about DMPA
- Satisfaction with her choice of DMPA as a contraceptive method (IM or SP)
- Satisfaction with LHW/LHV

Questionnaire items in the LHW/LHV interview instrument will focus on:

- Sociodemographic characteristics
- Knowledge of DMPA use and provision
- General experiences and satisfaction with providing DMPA services
- Reports of needlestick injuries
- Observations of LHW (re)-injection logs

Observation checklists

The first checklist will adapt the 15 screening items from FHI 360's "Checklist for Screening Clients Who Want to Initiate DMPA" (Figure 2). It includes pregnancy checklist items that determine client eligibility for DMPA use in the absence of pregnancy tests. The pregnancy checklist has been endorsed by WHO, is a proven proxy for pregnancy tests[17,18] and is indispensable in non-clinical settings. In addition, items that capture the presence or absence of counseling on DMPA use will be incorporated as a second part of this checklist instrument, such as:

- Discussion of advantages and disadvantages of DMPA use
- Danger signs of DMPA use
- Side effects and management of DMPA

The remaining two checklists will separately assess LHW and LHV injection technique for DMPA IM and SP. The content of the checklists will be adapted from instruments developed for previous task sharing studies of injectable contraception and from PATH's Sayana Press® training materials.

All three checklists will be modified to capture the information from the point of view of the observer. That is, RAs will be asked to: 1) record if the LHW/LHV uses a physical checklist during screening and counseling; 2) make note of the questions asked and the responses given for the items on the checklists; and 3) document LHW's/LHV's decision(s) in light of client responses.

<u>Pilot testing and recruitment procedures</u>

Before the trial is initiated, we will pilot test not only the client exit interview instrument, but also procedures associated with recruitment, consent, randomization, blinded assessment and verification of DMPA eligibility by the independent, clinically-trained staff member. The client interview instrument will be pilot tested to ensure that 1) the items are understandable to DMPA clients, 2) they elicit the intended information, and 3) research assistants (RAs) acquire real-world practice in administering the interviews. Recent and continuing DMPA clients who may be known to Jhpiego's LHW and LHV trainees will be identified and asked to assist with pilot testing the instruments.

Pilot testing study procedures will familiarize RAs and health facility staff with the order and logic of randomization and blinding to reduce the occurrence of procedural errors that may compromise the quality and reliability of the findings.

The provider interview instrument will also be pilot tested to ensure that the intended information is gathered and that RAs acquire practice in its administration.

Since pilot testing is solely for providing practice to research staff and to improve the comprehensibility of our materials, data collection instruments will be destroyed by AKU after the necessary information has been obtained.

Observation checklists have already been vetted through use in previous studies. However, RAs will be thoroughly trained by AKU staff to accurately record their observations of screening, counseling and injection technique in a standardized manner. AKU staff will receive guidance and in-person technical

assistance from the FHI 360 Project Leader on data quality, management and human subjects research ethics before the training of data collectors is performed in Pakistan.

After the instruments have been pilot tested and vetted, AKU research staff will identify women who: 1) meet age, marital status and new DMPA user criteria, 2) independently present at the study site or are accompanied by an LHW, and 3) express a desire to use injectable contraception. AKU research staff will approach women at each study site, inviting those who self-identify as potential DMPA clients and meet eligibility criteria to participate in the trial. In low volume health facilities, all women will be approached; in a high-volume facility, such as a hospital, we will approach women based on a random number generator (e.g., every nth woman) to meet the desired sample size at each study site.

This study involves the provision of Sayana Press®, the subcutaneous form of DMPA that would not otherwise be available outside the study context, but only women who voluntarily and independently accept injectable contraception **before** study recruitment and enrolment will be asked to participate in this trial.

The trained RA posted at each study site will confirm eligibility to participate in the study and obtain consent. The RA will explain to potential participants that participation in the study involves being randomized to receive services from an LHV or an LHW and either DMPA IM or SP; being observed during service delivery at the facility; and being interviewed right after completing her visit at the facility. Thus, the RA will obtain consent for the following:

- Willingness to be randomized to provider and DMPA type
- Observation of screening and counseling for DMPA (identical procedure for IM and SP);
- Observation of first-time administration of either DMPA IM or SP (disparate procedures for the two);
- Exit interview right after she receives very first dose of DMPA and before she leaves the health facility.

With regard to providers, all LHVs will be interviewed, but only LHWs who provide DMPA services to at least nine new DMPA clients will be interviewed by RAs. With a 3:1 ratio of LHWs to LHVs, LHWs placed on rotation during the data collection period with approximately 34 clients being randomly assigned to LHWs per facility[a], it is possible that not all three LHWs participating in the trial will interact with at least nine DMPA clients. The threshold of nine DMPA clients served will ensure that LHWs interviewed obtain sufficient experience to share their perspectives on providing DMPA to new users. In order to interview some LHWs from rural sites, the quota will be lowered to include those who provided services to at least four new DMPA clients.

Randomization procedures

A randomization manager from FHI 360, who is not otherwise involved in the study, will prepare a computerized randomization list using permuted blocks before the start of the study. These envelopes

[a] A total of 342 DMPA acceptors will be distributed among the 5 health facilities in urban Karachi district. On average, about 68 acceptors will be recruited per facility of which half will be assigned to LHWs.

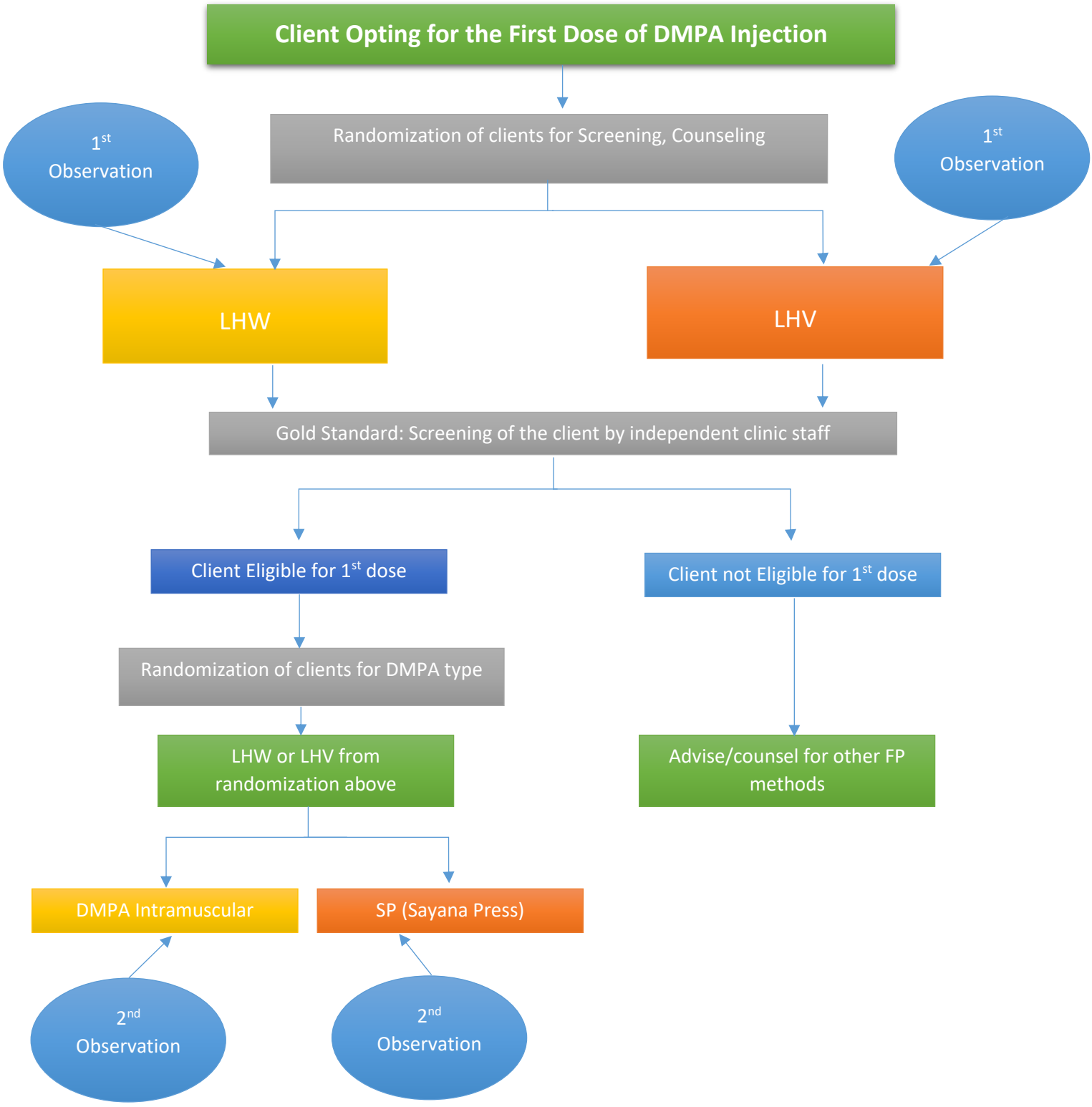
will be given to the local PI at AKU who will distribute the envelopes to RAs assigned to study health facilities. These RAs will open the randomization envelopes and inform LHWs or LHVs when they have been selected to provide DMPA services (screening, counseling) and which form of DMPA (IM or SP) they will provide after the independent third party verifies the client's eligibility for DMPA use.

Women will be randomized in a 1:1 ratio to proceed with DMPA screening by an LHV or LHW. After the independent staff member confirms the client's eligibility to use DMPA, an identical randomization procedure will be performed to randomize women to receive either DMPA IM or SP. The master randomization list will be maintained at FHI 360 and will not be available to study staff.

Randomization groups will be concealed in sequentially numbered, sealed opaque envelopes (SNOSE). We will instruct study staff never to open an envelope until the participant has given consent to participate in the study, is found to be eligible for the study, and is present for DMPA screening and the subsequent administration of the injectable. These envelopes will be provided to AKU in advance of trial implementation. The opened randomization envelopes will be retained as source documents and will be kept under secure and restricted access to protect the confidentiality of the participants.

This is an open-label study – neither study staff nor participants will be blinded to study treatment arms after the point of randomization. Nonetheless, strict policies will be in place to preserve randomization integrity. Randomization documentation will be stored in a secure location. Data recording, assessment of the primary and secondary study outcomes, and other assessments, such as DMPA eligibility assessment by independent facility staff, will be blinded to treatment arm where possible. The FHI 360 lead statistician and data analysts will perform a blinded review of the data to make final statistical decisions that could affect the comparison of the primary and secondary outcomes before fully unblinding the data for final analyses. Details of the analysis processes will be described in the detailed analysis plan.

Screening, counseling and DMPA administration will all be performed by the same LHW or LHV randomized to provide services to that client. The receipt of DMPA IM or SP is being randomized to avoid an imbalance of DMPA type that could occur if clients are given the choice between the two delivery systems. Similarly, provider bias/preference for one form or the other of DMPA could result in the same. The following graphic describes the procedures, including randomization, to be adopted in this trial.


Client Opting for the First Dose of DMPA Injection
1st Observation
Randomization of clients for Screening, Counseling
1st Observation
LHW
LHV
Gold Standard: Screening of the client by independent clinic staff
Client Eligible for 1st dose
Client not Eligible for 1st dose
Randomization of clients for DMPA type
LHW or LHV from randomization above
Advise/counsel for other FP methods
DMPA Intramuscular
SP (Sayana Press)
2nd Observation
2nd Observation

Data collection procedures

Observation of screening and counseling

After the DMPA client has provided informed consent and been randomized to see an LHW or an LHV, the RA posted at the study site will observe the screening and counseling interaction between the LHW/LHV and client. The RA will request that the interaction be conducted in accordance with the health facility's privacy policy and with the normal procedure for client-provider interaction. As such, we are currently unable to specify a range of time in which these observations will be performed.

The RA will first record observations using the first part of the checklist devoted to screening for client eligibility. If the LHW/LHV deems the client eligible for DMPA, then the RA will record whether or not the LHW/LHV proceeded to deliver key counseling elements of DMPA use to the client. All data will be recorded via pen and paper to be later entered into an electronic database.

After the client has been counseled, the clinic staff assigned at that study site to provide support to the trial will verify that the client is indeed eligible to receive DMPA. The staff member will serve as the independent gold standard for LHW and LHV performance. If s/he confirms that the client is eligible for DMPA use, the client will then receive DMPA subcutaneously or via an intramuscular injection from the same LHW or LHV who earlier screened and counseled her. If the staff member determines that the woman is not eligible for DMPA use, she will be offered another method and released from participation in the trial. The LHV/LHW who incorrectly deemed the client eligible for DMPA will not be penalized and the event will be treated and utilized as a learning experience.

Client exit interview

After receipt of her first dose of DMPA, the RA will conduct a brief interview with the client before she leaves the health facility, at a designated area in or within 500 feet of the site that provides audio privacy. The interview is expected to take between 10 and 15 minutes.

LHW/LHV interview

About four to six months after trial initiation, some participating LHWs and all LHVs will be asked for their permission (via informed consent) to be interviewed by an RA. By that time, they would have all provided initial and follow-up injections to their DMPA clients and should be able to describe their experiences. LHVs and LHWs will be interviewed at their assigned study sites.

As part of the interview process for LHWs only, the RA will be ask in advance of the meeting to bring their DMPA client materials with them. The RA will examine DMPA client records to verify that injection and re-injection dates are being recorded appropriately. Thus, as one of the objectives of the study, we will ascertain whether or not LHWs diligently record the dates of service for DMPA clients, how many are first-time or repeat DMPA clients, and if re-injection dates were scheduled for all of them. For LHWs who do not bring their logbook with them to the interview, a second and final session will be scheduled to capture that information. No additional attempts will be made gather that information from the LHW and the data will be considered missing for that LHW.

IV. Data management and analysis plan

Coordination of activities

FHI 360 will contract with AKU to implement the trial in Sindh province. AKU will assign (or hire) and train personnel to observe and record the interactions between DMPA clients and LHWs/LHVs and to conduct the interviews as indicated. AKU personnel will also participate in the pilot testing of data collection instruments and recommend modifications if necessary before the trial is initiated. AKU will also ensure that the importance of randomization is stressed to health facility staff and strictly observed at all study sites.

FHI 360 and AKU will work together to obtain institutional review board (IRB) approval from their respective organizations, the Protection of Human Subjects Committee (PHSC) and the Aga Khan University Ethics Review Committee. AKU will also facilitate IRB approval from Pakistan's National Bioethics Committee. In conjunction with Jhpiego, AKU will develop and maintain relations throughout the trial with management and staff at study sites. Nurturing a relationship with health facility staff will help with tracking the intervention process and gaining input and insights for scale-up, which are described in the *Research Utilization* section below.

Data management

FHI 360 and AKU will use software compatible for data entry, management and analysis across the organizations. AKU will create database shells and capture interview and observation data via paper and pen instrumentation. Each participant will be assigned a unique identifier that will facilitate data entry and management, as well as ensure confidentiality.

FHI 360 will review database structures and documentation and verify the accuracy and completeness of the database shells for interviews and observations before AKU begins data entry. AKU will use a system of double data entry and frequency checks to minimize data entry errors for all interview instruments. A study coordinator at AKU will oversee day-to-day management of the trial, including cleaning and verification of data on an ongoing basis. The study coordinator will also communicate regularly with the project leader at FHI 360 to provide updates and resolve any challenges that may arise during the course of the trial. Clean databases will be sent to FHI 360 for verification and analysis according to the timeline for those deliverables.

During all phases of data collection, entry, cleaning and verification, access to hard copy and electronic data will only be granted to research staff at AKU and FHI 360. Any hard copies of interviews, observation checklists and other materials containing study data will be stored in a locked file cabinet at AKU. Informed consent forms will be stored in a separate locked drawer or cabinet. Electronic data will be stored in password-protected files. Only staff working on the study will have access to the cabinets and electronic files. Upon completion of the trial, all stored materials will be destroyed at AKU. However, no records will be destroyed without permission from the FHI 360 project leader.

Data Monitoring

Since AKU will conduct ongoing data entry and management, data monitoring will also be continuous. FHI 360's project leader will work closely with AKU to oversee the scope of the work. Management of the trial by AKU will include day-to-day supervision of RAs, including quality checks for completeness and accuracy of interview and observation checklist data shortly after they have been completed. Staff from AKU will be responsible for identifying, documenting, mitigating and reporting protocol violations as well as serious adverse events related to the provision of DMPA.

Data analysis

We plan to compare a series of indicators of the performance of LHWs compared to LHVs in the provision of injectable contraception services. Our primary outcome is related to the screening process. We will test the non-inferiority hypothesis that LHWs can screen potential DMPA clients for method initiation just as adequately as LHVs with a non-inferiority margin of 7.5%. Given the relationship between LHWs and LHVs within clinics, we plan to use a generalized mixed model using a logit link to account for the correlations of participant outcomes within providers and providers within clinics. Random effects will be included for clinics and providers within clinic. The non-inferiority test will be conducted at a 5% significance level. A similar approach will be used to compare other performance outcomes. No covariate adjustments are planned for the primary analyses. However, these may be included for exploratory analyses. If any, these will be specified in the detailed analysis plan prior to data analysis. Other comparisons between groups will be primarily descriptive to explore the differences in the provision of DMPA services by each cadre of provider. Similarly, comparisons between injection techniques will be primarily descriptive and exploratory.

V. Research utilization and dissemination activities

A detailed Research Utilization (RU) Plan, including plans for scale-up and proposed RU activity timeline, will be jointly developed and agreed upon with partners after approvals have been obtained for this study. FHI 360 will coordinate with Jhpiego to identify the major elements of the RU Plan (Findings products; End users; Dissemination partners; Communication; Evaluation; Work plan) and responsible party.

This study methodically incorporates the research utilization principles and activities needed to support the application of evidence to policies and programs and increase the return on investments in research. Findings from this study will inform policy dialogue across provinces and at the federal level and, if findings prove positive, help position the practice of LHW-provision of DMPA for future scale-up. However, the study results cannot make an impact unless decision-makers understand and use that evidence to inform policy and program design. For that to occur, research findings must be properly communicated — at relevant moments, to particular audiences, and in ways that potential users can comprehend.[19]

Deliberate and strategic research utilization activities will be carried out for each of three phases of the research utilization process: (1) research conceptualization stage (already realized with input from WHO), which includes "beginning with the end in mind", stakeholder analysis and consultation, including potential future implementers, and planning for later analysis of scale up costs; (2) implementation stage, which prioritizes continuous stakeholder engagement and intervention process documentation; and (3) dissemination and utilization stage, including stakeholder workshop, research summaries, reports and manuscripts, and development of a scale-up strategy, as appropriate.

On a quarterly basis, the study partners (MOH, Jhpiego, AKU, and FHI 360, and local community representatives) will convene standing meetings and review implementation progress and study data and guide the project throughout its implementation. The intervention process will be documented throughout implementation in order to help interpret findings later and to inform potential future expansion of the program. Local community representatives will also participate in the meetings. Key influencers and decision makers at this level include the Department of Health Provincial Chief Minister, LHW Program Managers, and Community Health Committees. This degree of ownership by stakeholders in the intervention and their participation in its development will help position it for future scale-up and replication, if research results are positive.

Sustainability and capacity building will be considered at all times during preparation and implementation phases of the study. Existing local materials (e.g., training curricula and M&E tools) will be adapted wherever feasible.

At the conclusion of the study, results will be disseminated locally at a stakeholder workshop. Stakeholders will be invited to discuss the research findings and the implications for policy and practice. They may also be encouraged to participate in the development of a program scale-up strategy, if appropriate.

The findings of this RCT are uniquely poised to contribute to a larger global body of evidence around task sharing best practices. Efforts to disseminate study data and lessons learned more widely after the conclusion of the project may include technical and program briefs, articles submitted for publication in peer-reviewed journals, and conference presentations.

VI. Protection of human subjects

Ethics review and certification

FHI 360's Office of International Research Ethics (OIRE) and Aga Khan University's ethics review committee will initially review and approve all study materials. Pilot testing of data collection forms may occasion changes in the content, flow and number of questionnaire items. However, we anticipate that these changes would not be at variance with the topics approved in the initial review of study materials. Any changes made to the data collection forms that are beyond the topics described in the protocol will be resubmitted for review and approval prior to use. Copies of final versions of all the data collection instruments used in the field will be submitted to OIRE to be housed as part of the research record.

Data collectors will receive training in the ethical conduct of research, which will be overseen by AKU staff using FHI 360's Research Ethics Training Curriculum. Interviewers will be particularly sensitized to the importance of properly obtaining consent and ensuring and maintaining confidentiality of the study participants.

Informed consent process

LHWs and LHVs affiliated with selected study sites and trained by Jhpiego on the use of DMPA IM and SP will be asked to participate voluntarily in the trial. RAs will describe the study, their roles and responsibilities during the trial and provide them with a copy of the informed consent form, which will describe the risks and benefits of participation. All LHWs and LHVs will be asked to provide written consent. They will be told that their interactions with DMPA acceptors will be observed and recorded (using pen and paper) and that they will be interviewed about their experiences screening, counseling and administering DMPA to clients. LHWs and LHVs will be told that they will not be penalized if checklist observations reveal shortcomings in their performance. Instead, it will be recommended that they review the case with a qualified facility staff member for remediation. Once they agree to participate in the trial, they can stop their participation at any time. During the interview process, they can refuse to answer particular questions or can stop the interview at any time. They will be interviewed in a location that affords audio privacy and their responses will be kept confidential. The data from interviews and observations will be reported in the aggregate to prevent the identification of individual LHW and LHV performance. They will also be told that their names will not appear in any reports.

As in the case of LHWs and LHVs, all participating DMPA acceptors will be adult women of reproductive age (18 to 49), almost always married, who can legally consent to participate in research studies. Moreover, it is practically unheard of that unmarried women seek family planning or reproductive health services. Nevertheless, we do not anticipate that any married study participants-LHW, LHV, or DMPA client, will be younger than 18 years of age.

RAs will read informed consent forms to potential participants in the local language; women will be provided with a copy of the form so they may also read the consent documents themselves individually. All participants will be asked to provide written consent before data collectors proceed with observations of client-provider interaction, and subsequently, the client exit interview. RAs will sign the consent form to document that informed consent has been obtained.

The informed consent form for DMPA acceptors will describe the risks and benefits of participating in the study. There is very low risk associated with participation, both because of the nature of the study (observations of client-provider interactions in health facilities, interview assessing service quality and satisfaction), because all participants will be informed that their responses will be kept in confidence and that they have the right to decline to be interviewed without fear that their refusal might affect the level or quality of services they receive at the facility. They will also be told that during the interview, they have the right to discontinue at any time or refuse to answer individual questions.

A copy of the consent forms for both providers (LHWs, LHVs) and DMPA clients, with the name and contact information of the representative of AKU as well as the local IRB contact, will be offered to every participant.

Risks and benefits

The purpose of this research is to determine if the initiation of DMPA services can be safely shifted to the lay cadre, LHWs in Pakistan so that family planning services can become more accessible to women in rural and underserved areas. Sayana Press® will be used for the first time in Pakistan as a result of this trial, but the product has been vetted and approved for contraceptive use by the World Health Organization. This subcutaneous form of DMPA is currently available in many countries where providers, including community health workers administer the method to clients and where clients themselves self-inject. As such, there are a few anticipated risks for participants enrolled in this study, because all instances of SP administration will be performed by trained LHWs and LHVs.

Some LHWs/LHVs or DMPA clients may feel uncomfortable or embarrassed when asked questions about their personal experiences using FP methods. Participants will be told they do not have to answer any questions and they can stop participation at any time. Study staff will make every attempt to ensure a comfortable and secure environment in which to interact with participants. While staff will make every effort to protect individual participant's privacy during data collection and confidentiality of the data collected, it is possible that participant's involvement in interviews and observations could become known to others or others could learn something about the participants. There will be no identifying information on data collection instruments and datasets will be cleaned of potentially identifying information. The study team will take all measures to protect the identity of study participants and the confidentiality of their data.

There is no direct benefit to participants for taking part in this research. However, the information they facilitate through observations or provide in interviews may be used to inform and improve FP services for women in Pakistan.

Compensation

As stipulated by government rules, LHWs (and as applicable, LHVs) will be provided with a daily allowance during the trial to reflect their execution of additional tasks. LHWs will also receive a transportation allowance for travel to study health facilities. No compensation will be offered to DMPA clients.

Protection of privacy and confidentiality

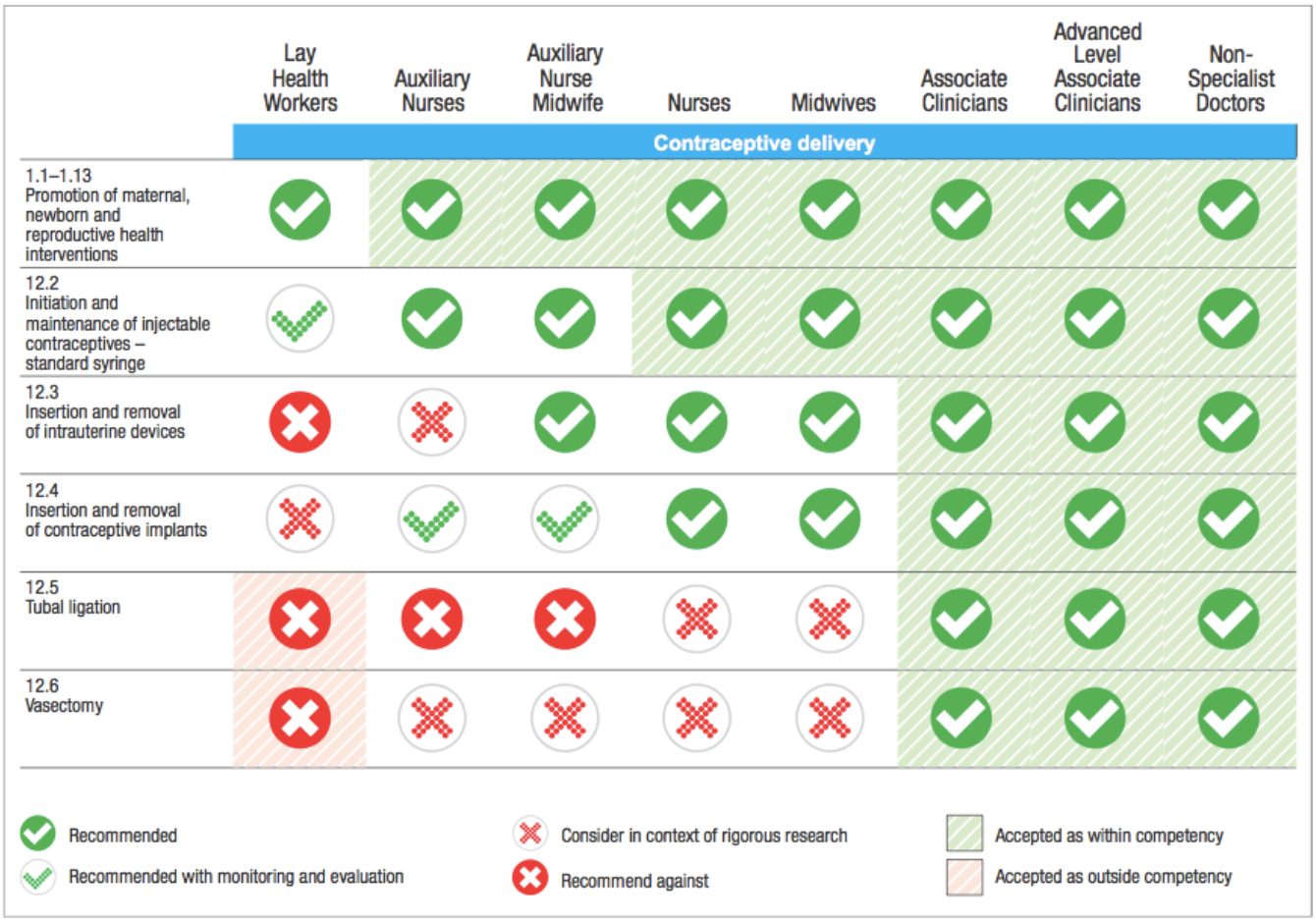
All interviews will be conducted in a private area in or within 500 feet of the health facility where the conversation will not be overheard. To ensure confidentiality, all participants will be assigned unique ID numbers. Names will not appear on any of the data collection instruments. Findings will be reported in the aggregate for both LHWs/LHVs and DMPA clients—limiting identification of individual participants. All study materials will be secured in dedicated locked cabinets/drawers or stored on password-protected computers with access granted only to research staff for data management and analysis.

For observations, if problems emerge during client interactions, a qualified facility staff member will be asked to intercede, take corrective measures and provide supportive supervision to the LHW/LHV as a

learning experience. The LHW/LHV will not be penalized, and the data captured by the observer, pre-intercession, will be entered in the study record and kept confidential.

VII. Appendix

Figure 1: WHO guidance on task sharing of family planning service delivery



Source: WHO recommendations Optimizing health worker roles to improve access to key maternal and newborn
www.optimizemnh.org

Figure 2: Graphic presentation of observation checklist for screening

Observation Checklist to Evaluate Providers Who Screen Clients for Initial DMPA Use

Type of provider being observed: ___ 1. Lady Health Worker ___ 2. Lady Health Visitor

___ 3. Other (specify): _____

Please record the response given to the provider by the client for the following items. If the provider does not ask the question, please draw a line through the item.

NO	1. Have you ever been told you have breast cancer?	YES
NO	2. Do you have or have you ever had problems with your heart or blood vessels?	YES
NO	3. Do you have a serious liver disease or jaundice (yellow skin or eyes)?	YES
NO	4. Have you ever been told you have diabetes (high sugar in your blood)?	YES
NO	5. Have you ever been told you have high blood pressure?	YES
NO	6. Do you have bleeding between menstrual periods, which is unusual for you, or bleeding after intercourse (sex)?	YES
NO	7. Do you have two or more conditions that could increase your chances of a heart attack or stroke, such as smoking, obesity, high blood pressure, or diabetes?	YES
NO	8. Are you currently breastfeeding a baby less than 6 weeks old?	YES

If the client answered **NO** to **all of questions 1–8,** did the provider tell her she is a good candidate for DMPA?
___ Yes ___ No

Did provider proceed to questions 9–14?
___ Yes ___ No

If the client answered **YES to question 1**, did the provider tell her that she is not a good candidate for DMPA? ___ Yes ___ No

Did the provider counsel her about other available methods or refer?
___ Yes ___ No

If the client answered **YES to any of questions 2 – 7,** did the provider tell her that DMPA cannot be initiated without further evaluation?
___ Yes ___ No

Did the provider then evaluate or refer her as appropriate?
___ Yes ___ No

Did the provider give her condoms to use in the meantime?
___ Yes ___ No

If the client answered **YES to question 8,** did the provider instruct her to return for DMPA as soon as possible after the baby is six weeks old?
___ Yes ___ No

Please record the response given to the provider by the client to the items below. If the provider does not ask the question, please draw a line through that item.

NO	9. Did your last menstrual period start within the past 7 days?	YES
NO	10. Have you abstained from sexual intercourse since your last menstrual period or delivery?	YES
NO	11. Have you been using a reliable contraceptive method consistently and correctly since your last menstrual period or delivery?	YES
NO	12. Have you had a baby in the last 4 weeks?	YES
NO	13. Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then?	YES
NO	14. Have you had a miscarriage or abortion in the last 7 days?	YES

Please record the action taken by the provider based on the client's responses:

Figure 3: Timeline of trial activities

Study Tasks	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
In-house review of study materials	X											
IRB (PHSC, AKU) review of study materials	X	X										
Local IRB(s) review of study materials		X	X									
SOW finalized with AKU			X									
Study prep in field (local approvals, community engagement)			X	X								
Orient trained LHVs, select trained LHWs for rotation at study sites;				X								
Train RAs; conduct pilot tests				X								
Pilot-test trial procedures at study sites				X								
Recruit DMPA clients; conduct observations, exit interviews				X	X							
Conduct interviews with LHVs and select LHWs								X	X			
Perform ongoing data entry, management and cleaning				X	X	X	X	X	X	X		
Analyze and interpret data								X	X	X		
Write-up trial results										X	X	
Disseminate trial results (in-country seminar, research brief, publications)											X	X

Endnotes

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