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measure ethnic
disparities in family
planning services in Peru**

**Study protocol and pre-trial
procedures of a crossover
randomized trial**

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Using standardized simulated patients to measure ethnic disparities in family planning services in Peru: Study protocol and pre-trial procedures of a crossover randomized trial

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ABSTRACT

Introduction

Ethnic inequalities in health outcomes, access to and utilization of health care have been well documented in Peru. Yet little evidence is available on how ethnicity affects the quality of health care services received. While qualitative studies and opinion polls have collected perceptions of ethnic discrimination in the healthcare services, to date no experimental data has been gathered to investigate whether patients' ethnic characteristics determine disparities in the quality of health services received in Peru. This study aims to evaluate whether health providers in Peru might be contributing to ethnic health disparities in the provision of family planning services, by comparing providers' adherence to national family planning guidelines.

Methods and analysis

This study is designed as a crossover randomized controlled trial. A sample of 351 out of the 408 public health establishments in Metropolitan Lima, Peru will be randomly assigned to receive unannounced simulated patients (SPs) enacting indigenous and then mestizo profiles (sequence 1) or mestizo and then indigenous profiles (sequence 2). Ethnic profiles will have distinctive cultural attributes such as clothing, styling of hair, make-up, accessories, posture and patterns of movement and speech. The primary outcome of the study is the proportion of tasks performed by providers, as established by Peruvian clinical guidelines for family planning consultations. Pre-trial procedures have been implemented including qualitative validation of profiles and script, recruitment and training of SPs, and a pilot study. The trial will comprise two treatment periods with a five-week washout period, and a post-trial statistical validation of ethnic profiles.

Ethics and dissemination

The study and instruments were approved by the Institutional Ethics Committee of the Universidad Peruana Cayetano Heredia (in Lima, Peru). Dissemination plans include peer-reviewed publications and conference presentations.

Protocol Registration

This study is registered with <http://clinicaltrials.gov> (NCT01885858).

ARTICLE SUMMARY

Article focus

- A randomized crossover design that will compare ethnic profiles performed by simulated patients in order to determine whether significant ethnorracial disparities exist in the quality of family planning services.
- Detailed description of pre-trial procedures: qualitative validation of ethnic profiles, recruitment and training of simulated patients and pilot study.

Key messages

- Ethnic profiles will have distinctive cultural attributes such as clothing, styling of hair, make-up, accessories, posture and patterns of movement and speech.
- Set-up includes qualitative pre-trial and quantitative post-trial validation of ethnic profiles.
- Outcomes will be obtained from data collected through geo-referenced mobile phones, sent via the Internet and stored immediately in a database.

Strengths and limitations of the study

- First study to implement a design that circumvents drawbacks inherent from unobserved heterogeneity using a simulated patient technique with face-to-face interactions with health providers.
- We will not know whether the same health provider provided services to both ethnic profiles.

INTRODUCTION

There is evidence, mostly in the United States, indicating that ethnoracial disparities are present across a range of clinical services,¹⁻³ including family planning (FP). Studies have shown that providers of FP services make different recommendations according to patient ethnicity/race, that ethno-racial minorities are more likely to report being pressured to limit their family size, and to receive counseling about sterilization and other highly effective contraceptive methods.⁴⁻⁸ There is also a growing body of literature which suggests that even when providers report egalitarian beliefs and no intention to discriminate, it is possible to observe bias, discrimination or implicit prejudice regarding ethnicity/race.⁹⁻¹²

In Peru, years of contradictory policy approaches discouraged delivery of modern contraceptives or pressured providers to perform non-voluntary sterilizations, particularly to poor and indigenous women.^{13,14} In 2004 the Ministry of Health (MoH) began issuing clinical guidelines for FP that subscribe reproductive and sexual rights, and gender and diversity equality.¹⁵⁻¹⁸ There are nevertheless continued ethnic disparities between indigenous and non-indigenous women in unmet needs for contraceptive methods (9.4% and 6.5%, respectively), and in use of modern contraceptives (21.9% and 34.7%, respectively).¹⁹ It is still unclear whether these ethnic differences could be explained by women's cultural preferences, income, education and other demand side factors, or by healthcare system factors including availability of services and disparities in the quality of health services. More recent observational studies in Peru suggest that disparities in quality of care may play a role, finding that health providers criticize, scold, mock or mistreat indigenous women, and restrict their autonomy by 'prescribing' contraceptives.²⁰⁻²⁴ To date there is no experimental data gathered to examine whether patient's ethnic characteristics trigger differential quality of FP services in Peru.

In order to evaluate whether health providers in Peru might be contributing to ethnic disparities in the provision of family planning services, we designed a field experiment combining audit studies and standardized simulated patient methodologies. Audit studies have been widely used in labor economics to isolate the impact of racial and gender discrimination on labor outputs such as wages or hiring decisions.^{25,26} Simulated patients (SPs) have been used to evaluate patient-provider interactions in a wide variety of contexts,²⁷⁻²⁹ including FP services,^{23,30,31} and pharmacy workers and clinicians.^{32,33} To isolate the impact of ethnicity on quality of FP service delivery, we will experimentally manipulate the ethnic characteristics of each SP, who will be sent to request FP services alternating two ethnic profiles: indigenous and mestizo (people of mixed Spanish and Indigenous descent). We will manipulate the SPs ethnic attributes modifying distinctive cultural markers such as clothing, hairstyle, posture and patterns of speech and movement. Both ethnic profiles will use the same scripted scenario for seeking contraceptive advice. This study aims to evaluate whether patients' ethnic characteristics trigger differential quality of FP services.

METHODS

Study design

The study is designed as a crossover randomized controlled trial. The primary outcome measure is the proportion of technical tasks established by clinical guidelines, performed by providers during a consultation. The study population consists of MoH establishments providing FP services, in Metropolitan Lima, the capital of Peru. The intervention consists of SPs visiting these health centers, randomly assigned as indigenous or mestizo clients, and seeking contraceptive advice following a standardized script. Within the first 30 minutes after the FP consultation, SPs will notify through georeferenced mobiles whether the provider performed or not the expected guideline tasks as well as the costs and time spent to get a consultation in FP. The effect of ethnicity disparities is measured as the mean difference in the proportion of technical tasks completed between the indigenous and mestizo profiles.

Study setting, participants and eligibility criteria

FP services are provided free of charge by midwives employed by the MoH - the main public health service provider in Peru, which is also responsible for ensuring that healthcare services meet quality and safety standards. As part of its regulatory function, the MoH issued between 2004 and 2008 a normative documents that set out standards for FP services in Peru. These are “Guidelines for Sexual and Reproductive Services”,¹⁵ “Technical Norms for Family Planning”,¹⁶ “Counseling Manual for Sexual and Reproductive Services”,¹⁷ and “Culturally Appropriate Counseling for Sexual and Reproductive Services”.¹⁸ Amongst other things, these guidelines establish the specific information to be provided to new and continuing contraceptive users (e.g., new users should receive complete information about all available contraceptive methods), and instruct health providers to offer FP counseling by implementing a five-step framework.^{16,17} This framework, which is widely disseminated among midwives, requires providers to (1) establish a friendly rapport with clients; (2) identify her/his needs; (3) respond to these needs; (4) verify the client’s understanding; and (5) maintain rapport and schedule a follow-up visit. These guidelines define our conceptual approach to assessing the quality of healthcare in the study.

The MoH operates a total of 408 health establishments In Metropolitan Lima via four Health Districts that administrate 14 Healthcare Networks, which, in turn, link health establishments providing different levels of care. FP services are offered at all levels of care except at 6 specialized hospitals that were excluded from the study. 13 small health posts - primary care establishments with the lowest degree of specialization-, were also excluded because they do not provide care to a sufficiently large number of patients to enable the SPs to pass through the facilities undetected. In addition we excluded the 16 health centers where we recruited midwives to assist us with pre-trial procedures (validation and training). The eligible MoH establishments participating in the study are therefore 17 non-specialized hospitals and 334 health centers. In practical terms, our sample is a census of available health centers in Metropolitan Lima.

Intervention

The intervention consists of unannounced SPs visiting FP services, altering key ethnic markers to enact mestizo and Quechua indigenous clients but otherwise following an identical standardized script. The script and the distinctive attributes that define profiles were both adjusted after a qualitative study, and further validated during training and a pilot study. Details of the validation process are described below as part of the pre-trial procedures.

Ethnic profiles

The final attributes used to distinguish indigenous and mestizo profiles were culturally appropriate clothing, styling of hair, make-up, accessories, posture, and patterns of movement and speech (figures 1-2). The indigenous profile will wear long braids, no make-up, a *lliclla* (a traditional woven cloth that covers the back and shoulders), a woven cardigan and loose pants, and her patterns of speech will be slower and her posture and movement more rigid than the mestizo profile. The mestizo profile will wear a ponytail or loose hair, use light make-up, and wear a vest made of polar fleece, tight pants and culturally salient accessories. Her patterns of speech will be faster and her posture and movement less rigid than the indigenous profile. In order to manipulate ethnicity, while holding all other aspects of the patient constant (such as attitudes and physical attractiveness), the study protocol establishes that every SP alternates ethnic profiles. This means that the same SP will sometimes seek FP services enacting an indigenous profile while other times she will do so enacting a mestizo profile (see profiles performed by the same individual in Figures 1 and 2).

Figure 1. Indigenous profile



Figure 2. Mestizo profile



Script

On the basis of the work by León *et al.*,³⁴ a script was developed for a new user of FP services, interested in the possibility of using pills as her contraception method. The script consists of a standard opening sentence for the first contact at the health establishment (“I want to be seen by FP services, where do I need to go?”), and information that is to be provided only if asked by health personnel at service points (such as admissions, the cash desk and triage) and during FP consultation. The script gives the SP information regarding the profile she is performing, including demographics, personal history and health/obstetric history. Scripts do not vary by ethnic profile, except information about place of birth and length of time living in Lima. SPs will retain their original names and birth dates (information registered on their National Identity Card that could be verified by providers), and will present themselves with old-looking photocopies of their ID (to cover photographs). The SPs’ addresses will be fictitious; they will scout around in the neighborhood of the health establishment for local addresses (see Box 1).

Box 1. Simulated Patient Script (Indigenous and Mestizo)

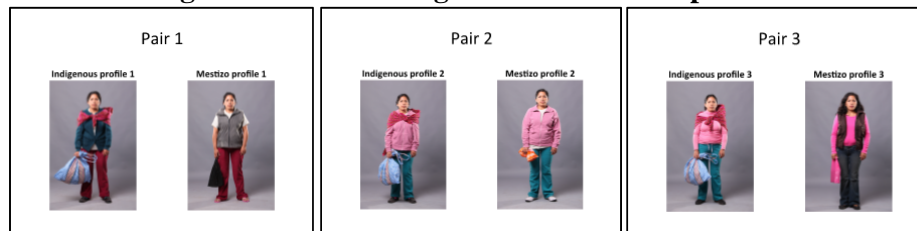
Name [real]. Age [real]. Migrant from the Andes [born in the countryside if indigenous or the city if mestizo]; has moved to Lima [one month ago if indigenous; 5 years ago if mestizo]. She studied until the second year of high school. She is a housewife. She has been cohabiting in a monogamous relationship with [real name] for [one year longer than her oldest child]. She has [2 if younger and 3 if older than 30 years old] children (the last and penultimate children are 2 and 5 respectively). She is healthy (natural deliveries at 9 months, without complications, without abortions, all children born alive, without unexplainable bleeding, without diagnosed cancer, all deliveries having taken place at public institutions). She, her siblings and parents are in good health (no history of hypertension, diabetes or any other illness or disease). There is no family violence. They decided to migrate to Lima for economic reasons and in order to provide a future for their children. Her husband has been travelling for the last 6 months and will arrive back home shortly. She does not want to have any more children for now, nor does her husband. She does not trust natural family planning methods. Before she was using the withdrawal method and condoms from time to time but her husband does not like using condoms, does not always use one and only puts one on towards the end. She knows nothing or very little about other methods. She does not want the injection. She is scared of inserting something into her uterus. She chooses pills if given the option. She will reject a pelvic examination (due to embarrassment or because she is menstruating). She will reject a breast examination (due to embarrassment). She wants to be given the pills. Her period returned 5 months ago (when she stopped breastfeeding). She is on the second day of her period and it is heavy. She had a smear test at the beginning of the year (she does not know the results, she cannot afford another).

Pre-trial procedures

Qualitative validation of ethnic profiles and script

A qualitative validation study was implemented to select the choice of distinctive indigenous and mestizo attributes described above, and to validate the script. First, a week of fieldwork research was carried out in healthcare facilities in Lima to document demographic characteristics and appearances of indigenous and mestizo women attending FP services. Second, based on these observations, three pairs of tentative indigenous and mestizo profiles were constructed by manipulating clothing, hairstyle and personal upkeep. Care was taken to ensure that each indigenous/mestizo pair would have equivalent socio-economic characteristics. Third, these pairs of profiles were enacted by four individuals and we registered photographically all of them. The individuals were recruited according to their physical traits and age (in order to ensure accurate representations of typical FP clients observed in the health centers), as well as for their capacity to enact both ethnic profiles with minimum production (see in Figure 3 the pairs of ethnic profiles enacted by one individual). This photographic register was used for a qualitative validation exercise

Figure 3. Pairs of indigenous and mestizo profiles



The validation exercise with a purposive sample of 12 MoH midwives was conducted in two steps. First, free-listing techniques were used to elicit spontaneous perceived attributes of indigenous and mestizo women attending FP services. Next, midwives were presented with the repertoire of photographic portraits in series of four, and were asked to rank and sort them according to several factors such as indigeneity, socio-economic status, level of education, and degree of verisimilitude, while also explaining the criteria they used to perform the tasks. The exercise was recorded in audio and video, and a conventional content analysis was performed.³⁵

Results confirmed both the script and the chosen appearance attributes, but also highlighted two challenges for recruiting the SPs and constructing the ethnic profiles: (1) SP with strong indigenous phenotypes had to be avoided since it was difficult for them to pass a mestizo women and (2) specific attitudes and behaviors perceived as key attributes to distinguish mestizo from indigenous women had to be included, for example, indigenous women were seen as more passive and shy, less talkative, less assertive, and with a marked accent.

To avoid jeopardizing the validity and realism of the SP portrayal, we decided to further manipulate two attributes to convey different degrees of assertiveness and

shyness: the rigidity in body posture and the speed in patterns of speech and movement. Regarding the accent, since it is a difficult attribute to enact convincingly and could not be learned within the time frame of the project, we decided to recruit SPs with a provincial Andean accent. Thus the final ethnic profiles included culturally appropriate clothing, hairstyle, make-up, accessories, but also distinctive posture and patterns of movement and speech (see Table 1).

Table 1. Attributes manipulated in the study

Attribute	Indigenous profile	Mestizo profile
Clothing	<i>Manta</i> or <i>lliclla</i> , a traditional woven cloth that covers the back and shoulders	No <i>manta</i> or <i>lliclla</i>
	Woven cardigan	Vest made of polar fleece
	Looser clothing	Tighter clothing
Styling of hair and accessories	Long braids (wigs) and hair covering ears	Loose hair or a pony tail
	Culturally salient earrings	Culturally salient earrings and/ or headbands or clips
	Synthetic colorful bag	Cotton white bag
Make-up	No make-up	Light make-up
Posture	More rigid	Less rigid
Patterns of speech and movement	Slower	Faster

Recruitment, selection and training of SPs and supervisors

We recruited SPs in Lima and three other Andean cities by various means: sending letters to professional associations and universities, and publishing announcements in social networks, job listings websites and other relevant interest lists. 132 biographical sketches were received from which 96 applicants were invited to an information session and 69 were interviewed. 17 women with the desirable phenotype, accent, cognitive and interpersonal skills were invited to participate in the training program.³⁶ Finally 12 women, aged between 25 and 35 years old, with higher education degrees (most of them midwives), with Andean phenotypical features but without extreme traits (as defined by midwives in the qualitative validation), with a ‘provincial’ accent and with no permanent make-up, facial surgery or short hairstyles were trained as SPs. A two-week training program was implemented for the SPs. During the training we were assisted by an experienced actor and by 3 midwives who were recruited to act as supervisors and had previously received a two-day workshop training on research ethics, project procedures, data collection and monitoring procedures.

The SPs' training was implemented in four phases. First, SPs internalized the roles at a cognitive level by understanding and memorizing the script. Second, they worked on the characterization and interpretation of the ethnic profiles engaging in role-play and simulations. The complexity of the rehearsal was increased sequentially by adding the clothing, hairstyle, verbal language, non-verbal language and personal upkeep. When all SPs showed confidence and realism interpreting the indigenous profile, they practiced the mestizo profile. The validated ethnic profiles were further adjusted during training in order to accommodate for the particular phenotypes and personalities of the SPs. Care was also taken to avoid educated and/or professional jargon that would sow doubts about the scripted level of education. All SPs dyed their hair to match the black braid wigs, and were not allowed to use creams, shave or further modify their appearance.

Third, SPs could alternate ethnic profiles and rehearse all aspects of the script by simulating itineraries across service points at fictitious health establishments and by interacting with four invited midwives who work as providers in MoH FP services (these centers were excluded from the sample before randomization). After every simulated consultation the invited providers gave feedback to the SPs and suggested changes to the script to make the SP presentation more realistic.

Lastly, SPs were trained to recall the clinical encounter and to complete a checklist of tasks expected to be performed by the provider. After completing the checklist, answers were contrasted, disagreements discussed, and agreement reached after the trainer's judgment. During this process the checklist and the operational definitions of guideline tasks were adjusted. Video recordings of the simulated sessions with the external midwives were used to improve the consistency of SPs reports. Pilot testing began when SPs reached more than 95% accuracy of reporting guideline tasks, as measured by agreement with trainer's judgment. Of the 12 individuals initially recruited, 10 performed the required standards and were included in the team for the study.

Pilot testing

A one-day pilot test was conducted outside Metropolitan Lima. Every SP visited at least two health centers, alternating ethnic profiles. All steps in the protocol for data collection and monitoring were tested. The pilot testing constituted the final validation of the ethnic profiles, the script and the protocols for data collection and monitoring.

Randomization, masking, and blinding

Health centers will be assigned to a sequence of ethnic profiles with a 1:1 allocation using a computer generated randomization schedule and permuted blocks of four, either to receive the indigenous and then the mestizo profile (sequence 1) or the mestizo and then the indigenous profile (sequence 2) in two periods. At least a five-week 'wash-out' period will be included between the two periods of visits by SPs to mask the study.

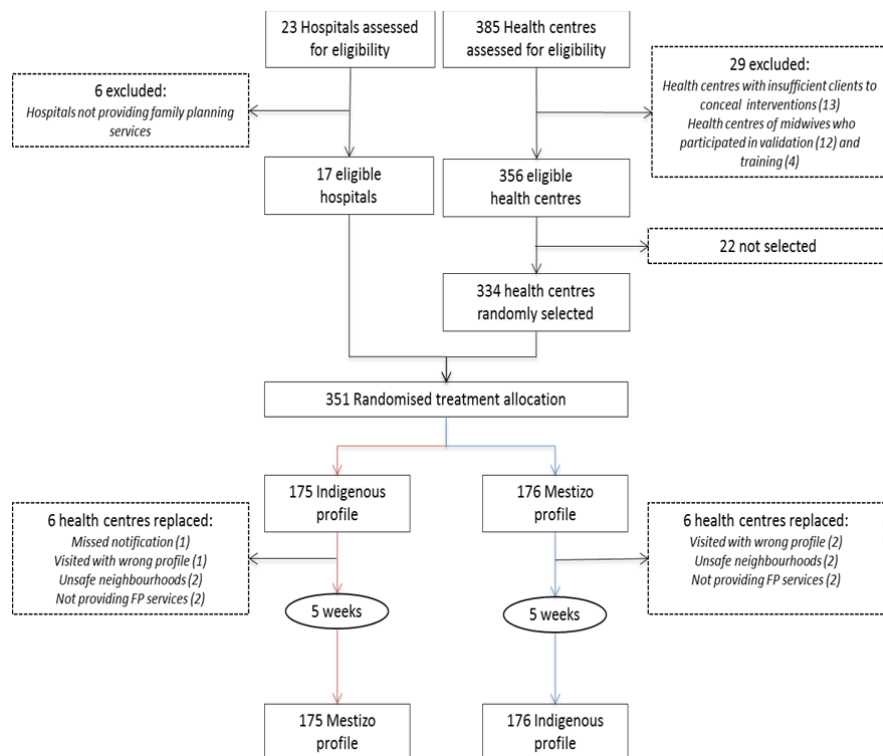
The order of visits to health establishments will be selected through a probability multi-stage sampling. In the first stage the health centers in the sample will be divided into three areas according to geographic proximity. In the second stage, the order of visits will be randomized within each of the 13 Healthcare Networks in Metropolitan Lima. The SPs will be split into three teams and each team will be assigned to one of the three areas with an ordered list of health establishments. The teams will change the areas they worked in from week six onwards. Turns will be allocated systematically – groups of two establishments will be assigned sequentially to the SPs in the same team.

Due to the nature of the intervention there will be no concealment of treatment groups. The investigator who generates the allocation sequence will not be involved with the enrolment and implementation of the study. Both the data manager and the data analysts will be blinded while the data bank is open. Field supervisors and SPs will be aware of the profile that has to be performed a week in advance.

Sample considerations

The sample consists of 351 health establishments in total: all 17 non-specialized hospitals and a random selection of 334 out of the 356 eligible health centers (see flow chart of the trial in Figure 4). The impact of the SP's ethnic profile will be estimated as the average difference in outcomes between the indigenous and mestizo profile visits in each centre. We estimated a power over 99% to detect 10% differences in the primary outcome across health establishments, using a significance level of 95%, and a standard deviation of 40.

Figure 4. Flow chart of the trial



Primary outcome

The composite primary outcome measure of the study is defined as the proportion of guideline technical tasks performed by providers. We selected 23 quality measurement tasks derived from the Technical Norms for Family Planning¹⁶ and the five-step framework for FP counseling.¹⁷ These tasks relate specifically to 4 competences: i. to identify client's needs (7 tasks); ii. to respond to client's needs by offering an appropriate range of contraceptive methods and explaining the characteristics of method of choice (12 tasks); iii. to verify client's understanding of characteristics of method of choice (2 tasks); and iv. to maintain rapport and schedule a follow-up visit (2 tasks) (see Table 2).

Table 2. Guideline tasks for measuring providers' technical performance during SP visit

Technical guideline competences	Description of tasks
To identify client's needs considering her preferences and risk factors	<p>The midwife...</p> <ul style="list-style-type: none"> • asks for SP's age. • asks SP's number of children • asks SP's desire to have more children. • asks about the contraceptive methods SP has used or is using. • asks how SP uses or used the method. • asks about the opinion of SP's partner on the use of contraceptive methods. • asks the date of SP's last menstruation/suspected pregnancy.
To respond to client's needs by offering the appropriate range of contraceptive options, and explaining characteristics of the method of choice (pill)	<p>The midwife...</p> <ul style="list-style-type: none"> • offers condoms without insisting. • offers vaginal tablets without insisting. • offers the pill without insisting. • offers the injection without insisting. • offers the intrauterine device without insisting. • offers sterilization without insisting. • asks to choose a method. • explains at least one contraindication of the pill. • explains at least one action mechanism of the pill • explains at least one instruction for using the pill. • explains at least one side effect of the pill. • provides the method of choice (pills) when available at the health establishment.
To verify client's understanding of characteristics of method of choice (pill)	<p>The midwife...</p> <ul style="list-style-type: none"> • asks if the information was understood • verifies whether the information was understood correctly.
To maintain rapport and schedule a follow-up visit	<p>The midwife...</p> <ul style="list-style-type: none"> • invites SP to come back if she has doubts or questions • establishes a follow-up appointment for a month later.

Secondary outcomes

1. Proportion of guideline socio-emotional tasks performed by providers, measured by 16 tasks related to one competence of the five-step framework for FP counseling described as establishing a friendly rapport with clients (see Table 2).
2. Length of FP consultation, defined by time in minutes from entering the consultation until leaving the consultation.
3. Length of visit to the health center, defined by time in minutes from entering the health center until leaving the center.
4. Number of attempted visits, defined as the number of re-visits required to complete the family planning consultation.
5. Length of re-visits, defined as the total number of days from the first visit to the effective one.
6. Cost of appointment, defined by the total amount of money that is paid for a FP appointment.

Table 3. Guideline tasks for measuring providers' socio-emotional performance during SP visit

Socio-emotional guideline competence	Description of tasks
To establish a friendly rapport with clients	<p>The midwife...</p> <ul style="list-style-type: none"> • is tired during consultation. • is upset. • is rushed. • greets SP respectfully. • says her/his name when she introduces her/himself. • asks SP the reason of her visit. • gives full attention, showing interest and keeping eye contact with SP. • treats SP with respect. • refers to SP as Ms/Madam. • criticizes or scolds SP. • uses understandable language. • presents the information very quickly and it is not easy to understand everything. • presents information using IEC material. • gives SP enough time to explain her personal situation. • ensures visual privacy in the office. • ensures auditive privacy in the office.

Data collection and management

The data to be collected on quality of care (technical and socio-emotional tasks), cost of consultation and length in time of visit or consultation will be reported from a mobile phone (*Nokia E5 or E63* model) on specially developed questionnaires using using Magpi (formerly EpiSurveyor).³⁷

The fieldwork will be organized in three teams each led by one supervisor who will give the SP a weekly roster of establishments to be visited, with precise information on routes and the ethnic profile to be presented in every visit. Every morning, the supervisor will meet with the SPs to organize the daily work, and to verify the correct characterization of the ethnic profile by taking a picture of every SP. Afterwards every SP will report the time of arrival to the environs of the health establishment and will georeference her location. The notification of time will be repeated in six other occasions: upon arrival at the entrance of the health establishment, upon confirming whether the FP appointment was booked or not for that day, upon entrance at the FP waiting room, upon entrance at the FP consultation, upon exit of the FP consultation, and finally after having reported the checklist. The checklist includes costs and specific and discrete guideline tasks performed or discussed by providers, and will be filled out within the first 30 minutes after having left the health center. Note that by using a checklist with items requiring yes-no responses, similar to the ones used by Leon *et al.*³⁸ and García *et al.*,^{33,39} it is expected that problems associated with reliability and SP's subjective judgment will be minimized.³⁰

Supervisors will conduct an exit-interview with every SPs, asking the SPs to narrate the itinerary followed across service points at the health establishment and the information exchanged with the midwife encountered. Exit interviews will enable the supervisor to confirm that data has been entered correctly onto the checklist, to assess the SP judgment of the provider's performance, to detect potential departures from the script, and also to give SP the appropriate feedback. When an inconsistency is detected, it will be corrected using printed supervision forms. The exit-interview will be audio taped and the supervisor will also send a daily notification through her mobile confirming each supervision visit and whether the checklist was reported according to protocol. The supervision forms, accompanied with photographs, audiotapes and all material collected by the SP during the visit (such as payment bills, pills and prescriptions, etc.) will be handed over by the supervisor to the data manager on a daily basis. The use of Magpi together with the mobile telephones will enable information to be registered, sent via Internet and stored immediately in a database.

For quality control, the design of the questionnaire using Magpi enables the inclusion of conditional questions. The information sent to the database will be downloaded daily and tested weekly to ensure that the codes have been entered correctly and that responses to the questions are consistent. The database administrator will correct data entry errors weekly against the information collected on supervision forms as well as the materials submitted by the fieldwork supervisors. The database administrator will also present a weekly report of inconsistencies and incorrect data entries to the research team. These inconsistencies will be corrected by checking with the fieldwork supervisor and/or the SP responsible. The data will then be stored using the STATA statistical software.

SPs and the supervisors will be required to send information on a daily basis. In order to send information SPs and supervisors will be supplied with a username

and a password by the database administrator. The information sent via the cellular telephones will be stored on a secure server on the web and only the database administrator will have access to it. A backup of the database will be saved every day. The research team will meet weekly with the supervisors and the data manager to assess the progress of the fieldwork and the performance of the SPs.

Data analysis plan

- Primary estimated effects are evaluated using a Student t test and computed as the mean of the differences of outcomes:

$$\alpha_j = 1/N \sum_{j=1}^N y_j(\text{indigenous}_i) - y_j(\text{mestizo}_k) \text{ for health center } j \text{ and simulated patients } i \text{ and } k, \text{ where } i \neq k.$$

The quality index is constructed by the sum of the affirmative responses for receiving service j as a proportion of the total:

$$\text{Index} = \sum_{j=1}^T D_j / T \text{ where } D_j \text{ is an indicator variable that takes value 1 when the response is affirmative for receiving service } j, \text{ and 0 otherwise.}$$

- Secondary estimated effects are computed using lineal regression analysis controlling by midwives characteristics (gender, age, and ethnicity), health center fixed effects (to control for time-invariant health center characteristics), SP fixed effects (to capture unobserved patient-specific heterogeneity) and time fixed effects (to control for the day of the week and time of the day that the SP makes the clinical visit).

Post-trial validation

We plan to validate the ethnic profiles performed by the SPs after having collected the data for the main outcome. This exercise will confirm if the MoH midwives perceive a statistically significant difference between the indigenous and mestizo profiles used in the study and if these profiles are amongst the most common patient types visiting MoH FP services in Metropolitan Lima.

We will recruit a representative sample of the population of midwives who provide FP services in MoH establishments in Metropolitan Lima (N=1200).⁴⁰⁻⁴³ With 90 percent of power to detect differences between ethnic profiles of 0.25%, the established goal is to recruit 311 midwives. They will be selected as they fill proportional quotas per Health District; midwives who do not work in establishments included in the study sample will be excluded.

The sample of midwives of each Health Districts will be divided in two groups at random and will answer a questionnaire consisting of two sections. The first section will show a repertoire of full-body photographs of our 10 SPs characterizing either the indigenous or mestizo profiles. Each midwife will observe only one SP under one profile, with the ethnic assignment determined at random. To assess ethnicity, we will request midwives to evaluate each of these photographs using a score-based

procedure that captures the intensity of an individual's observable characteristics of indigenesness.⁴⁴ Every photograph will receive one score on an ordinal scale ranging from zero to 10, with 0 being nothing indigenous and 10 completely indigenous.

The second section will show midwives a repertoire of 8 full-body photographs of 2 of our SPs (the ones with the lightest and darkest skin color), and six other ethnic profiles that will represent the ethnic diversity in Metropolitan Lima, including extreme indigenous and white profiles. Based on fieldwork observations, these six ethnic profiles will be constructed and individuals will be recruited according to their phenotype and age to produce a photographic register. We will ask midwives to assess the ethnicity of this set of photographic profiles using the ordinal scale described before and also to evaluate how often they provide FP services to clients resembling these profiles.

ETHICS AND DISSEMINATION

The research protocol and instruments were approved by the Institutional Research Ethics Committee (IRB) of the Universidad Peruana Cayetano Heredia in Lima, Peru. The IRB approved a waiver of consent for the midwives who will interact with the SPs, given that the study involves no more than minimal risk to the subjects, does not adversely affect the rights and welfare of the subjects, and could not practically be carried out without the waiver.⁴⁵ To guarantee the anonymity of the health service providers and data confidentiality, the instruments used in the study will not identify the individual providers. The study databases will contain no personal data, only codes that will be kept on computers protected with passwords. A clause pertaining to confidentiality and data protection will also be included in the contracts of the fieldwork personnel (both SPs and supervisors). The study proposal was presented to relevant authorities of the MoH, and an agreement was reached to make a formal and public presentation of the results once the study is completed.

DISCUSSION

Ensuring that contraceptive information and services are of good quality and non-discriminatory is internationally recognized as contributing to achieve maternal health and other Millennium Development Goals by reducing the unmet need for contraceptive methods and by increasing the use of modern contraception.⁴⁶⁻⁴⁸ This protocol describes the rationale and design of a crossover randomized controlled trial that combines audit and simulated patient methodologies to evaluate whether health providers in Peru might be contributing to ethnic health disparities in the provision of family planning services. Because each individual SP will be sent to request FP services alternating between both indigenous and mestizo profiles, the study design circumvents potential drawbacks inherent from unobserved heterogeneity among pairs. Conventional audit studies have evaluated ethnic or racial disparities in the quality of services provision, assigning auditors or SPs to pairs (e.g., one of each ethnicity), and matching them in equivalent characteristics.^{7,31} However, not knowing whether all SPs characteristics that had been matched vary by the variable of interest (such as ethnicity), differences in treatment might be explained by unobserved idiosyncratic characteristics (for example, physical attractiveness, sympathy,

interviewing ability) rather than by bias, prejudice or stereotypes of providers.^{25,49,50} This limitation has been addressed before by randomizing ethnicity within each quality pair in studies that used photographs and surnames sent in résumés as ethnic/racial proxies,^{25,51} and in Implicit Association Tests (IAT),² but to our knowledge this is the first time it is implemented using a SP technique that assesses face-to face interactions with health providers. We expect that our findings will provide objective data upon which to clarify whether observed disparities between indigenous and mestizo women in contraceptive use are explained specifically by service provider-related factors.

CONTRIBUTORS

All listed authors provided substantial contributions to the conception and design of the study to the trial, and critically reviewed the manuscript for important intellectual content and approved the final version. MEP drafted the manuscript.

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COMPETING INTERESTS

None declared.

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