

# An adaptive experiment to improve quality in contraceptive counseling and increase the uptake of long-acting reversible contraceptive methods

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*This document is an abridged version of the study protocol submitted to the Cameroon National Ethics Committee. Readers interested in obtaining additional documentation including: the study's registration at [clinicaltrials.gov](https://clinicaltrials.gov), a technical appendix on the adaptive experimentation, the follow-up surveys questionnaires, or the contraceptive methods cue cards used during consultations, please contact Berk Özler at [bozler@worldbank.org](mailto:bozler@worldbank.org).*

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## Glossary

**A/B testing:** refers to a classical RCT with only two treatment conditions, where treatment condition A is compared to treatment condition B, using static (or fixed) random assignment probabilities and statistical hypothesis testing.

**Adaptive experimental design:** Adaptive experiments are trials which are designed to increase the efficiency with which multi-armed trials establish the best-performing arm or arms. In conventional (or static) randomized controlled trials (RCTs), the proportion of subjects allocated to each treatment arm is determined at the onset of the trial. By contrast, in adaptive trials the proportion of subjects allocated to each treatment arm is adjusted as the trial is ongoing, typically to favor better performing arms. Adaptive trials can thus declare a ‘winner’, or best performing arm, with greater confidence than a static experiment for a given sample size, or more quickly than a classical RCT, allowing resources to be saved and reallocated to achieve other research objectives.<sup>1</sup> Adaptive designs can also decrease the likelihood that subjects are allocated to inferior treatment arms for the duration of the study.

In the case of this study, the research team will analyze (de-identified) data from clients, who received FP counseling at HGOPY, monthly and will randomly assign more clients to treatments that performed better in the previous month(s) and less clients to underperforming interventions. The exact details of how the research team will conduct this analysis and reassign allocation probabilities to each intervention arm is described in the *Experiment Design* section. The result is a potential increase in the probability that each new client is assigned to the intervention best suited for her. The procedure also makes the experiment more efficient (statistically) than a classic RCT that allocates clients to each intervention with a fixed probability throughout the study period. The algorithm that produces the adaptive probabilities is called a “multi-armed bandit algorithm,” which is defined below and discussed in the *Experiment Design* section.

**Multi-armed bandit algorithm:** It is a type of algorithm to manage an adaptive experiment, where:

- a) the goal is to find the best treatment condition for the subjects, and
- b) the probabilities of random assignment to each treatment arm can be updated as the experiment progresses.

The **multi-armed** refers to the fact that there are more than two treatment conditions from which to choose. The highly developed mathematical models to run these algorithms try to manage the desire to assign each client to the best possible treatment for her while at the same time trying to learn which seemingly inferior arms may perform better in the long-run. (*Bandit comes from an analogy to a slot machine at a casino, which is sometimes referred to as a one-armed bandit.*) As the experiment progresses and the high-performing treatments get more clients assigned to them, this helps to better separate the “best” treatments from simply the “good” ones faster and maximize expected benefits to the clients.

**Contextual** multi-armed bandit algorithm refers to a MAB, where the algorithm considers the characteristics of the individual client. For example, it might be the case that treatment arm 1 is performing very well among adolescent females while treatment arm 2 is performing better among adults. Then the algorithm would update the random allocation probabilities differently for adolescents

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<sup>1</sup> Offer-Westort, Molly and Coppock, Alexander and Green, Donald P., Adaptive Experimental Design: Prospects and Applications in Political Science (February 12, 2019). Available at SSRN: <https://ssrn.com/abstract=3364402> or <http://dx.doi.org/10.2139/ssrn.3364402>

and adults, assigning more adolescents Treatment 1 and more adults to Treatment 2. In other words, the MAB algorithm considers the clients' context while adapting random assignment probabilities during the study period. This again benefits the clients (by providing them with individually-tailored treatments) and the experimenter, who can devise better policies for different sub-groups of the target population.

**Partially randomized patient preference trial** (page 8, under *literature review*): Patients who present seeking a service or a method are asked whether they would prefer to (a) simply receive the service/method they are seeking OR (b) accept to be randomized into the service/method they are seeking or another one. Those who opt into (b) are then randomized into the specified treatments. The randomized arms can be compared to each other among those who accepted randomization, while those randomly assigned to the service they were seeking vs. those who received it by preference (i.e. declined randomization) can also be compared to provide a bridge between observational and experimental samples. Please see Hubacher et al (2015, 2017) for an example of such a trial.

**Title X clinics in the U.S.** (page 9, under *literature review*): "Established in 1970, Title X provides affordable birth control and reproductive health care to people with low incomes, who couldn't otherwise afford health care services on their own. Federal Title X funding helps ensure that every person — regardless of where they live, how much money they make, their background, or whether or not they have health insurance — has access to basic, preventive reproductive health care."

## Introduction and objectives

Cameroon exhibits a high and nondecreasing level of maternal mortality (roughly 600 per 100,000 live births), partially related to its relatively high total fertility rate (roughly 4.6). Survey evidence furthermore suggests that a significant fraction of these pregnancies is unwanted or considered mistimed by the mother, especially among females aged 15-19. Despite this, the rate of utilization of family planning (FP) methods is low: e.g. only 48% of sexually active unmarried women use any form of modern contraception, or MC, and even then, it is primarily condoms. The use of LARCs (long-acting reversible contraceptives, i.e. the IUD and implant) is less than 1% according to the most recent Demographic Health Survey.

We propose to test whether the introduction of a tablet-based job-support tool for nurses conducting FP consultations, along with price discounts for contraceptive methods, can increase the uptake both SARCs (short-acting reversible contraceptives, i.e. the pill and injectable) and especially LARCs among reproductive-age females in Cameroon, including adolescents who may be unmarried and/or nulliparous, who present at HGOPY seeking family planning counseling. In addition to decreasing maternal mortality and unintended pregnancies, indirect effects for the community will include: increased welfare from reduced side effects that arise due to current one-size-fits-all FP counseling; healthier children due to improved birth spacing; and increased human capital formation both for children and for young (often school-aged) potential mothers.

The interventions are centered around the use of a newly developed *tablet-based decision-support tool*, or, simply, the “app,” which was designed for use by service providers conducting FP counseling sessions. It takes a patient-centered approach to counseling and is designed to explicitly and fully take the needs and preferences of the client regarding contraceptive methods into account, while also helping providers make the most appropriate recommendations. In this way, the job-support tool focuses on improving quality from the client’s perspective by creating an empathetic and respectful environment that fosters shared decision-making. The job-support tool was developed by a multi-disciplinary working group formed in Cameroon and comprised of nurses, doctors, and researchers from HGOPY, public health and adolescent health specialists from the Department of Family Health in the Ministry of Health (DSF/MinSanté), and public health and economics researchers focusing on adolescent health from the World Bank.

The job-support tool structures the counseling session and records the answers to a series of questions eliciting the client’s goals, fertility plans, needs, and preferences regarding contraceptive methods, while also assessing her medical eligibility for each method.<sup>2</sup> This inclusive approach is not only recognized as having utmost importance for the client to be able to make an informed decision, but is also empowering – endowing her with agency and making her feel respected. At the same time, the working group acknowledged that while clients, especially adolescents, may benefit from a shared decision-making approach, health providers may also bring their own biases into the counseling session. Therefore, to counter any potential provider bias, the job-support tool ranks contraceptive methods from most suitable

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<sup>2</sup> The working group used the latest version of the U.S. Center for Disease Control and Prevention’s recommendations on the medical eligibility criteria for contraceptive use. The software used to program the “app” uses these recommendations to automatically eliminate methods that are contra-indicated from the set of methods eligible for recommendation to the client.

to least suitable for the client. The providers are trained to use these rankings to suggest methods in order of suitability until the client decides to adopt a method (or refuse all of them).

We propose to conduct an adaptive experiment at the **Hôpital Gynéco-Obstétrique et Pédiatrique de Yaoundé** (HGOPY) in the Family Planning, Gynecology, and Maternity departments, for a duration of 12 months. All providers at HGOPY, who conduct FP counseling, will be given tablets and receive training to use the job-support tool. We propose to test alternative counseling approaches using the job-support tool to improve its efficacy – both for the clients and for the providers – and to provide random discounts for modern contraceptive methods to all clients. The treatment conditions are described under *Experiment Design* in the *Study Procedures and Methodology* section below.

## Research questions and hypotheses

- 1. “Is the quality of FP counseling important in increasing the uptake of more effective methods of family planning, such as LARCs?”** All providers at HGOPY, who provide family planning counseling (in three different wards: maternity, gynecology, and family planning), will be given tablets and receive training to use the job-support tool. We have access to aggregated monthly administrative data on outcomes prior to the intervention, such as the number of each type of modern contraceptive adopted by clients at HGOPY, so we will be able to conduct an event-study analysis to detect a change in method composition among new FP clients at HGOPY. Furthermore, within the job-support tool, we will test alternative counseling approaches by randomly assigning clients to “status quo” or “ranked recommendation” treatment conditions.<sup>3</sup> Our hypotheses are that (a) the use of the tablet-based job-support tool will increase the uptake of modern contraceptives at HGOPY; and (b) “ranked recommendations” will increase the uptake of more effective long-acting methods of contraception, especially among younger, unmarried, and nulliparous clients.
- 2. “What is the effect of FP counseling on client satisfaction and discontinuation rates?”** Of course, with any intervention that tries to improve counseling strategies, the uptake of LARCs is not the only, or even the most important outcome. The aim is to be able to reduce unintended pregnancy rates and improve related maternal and child health issues, while increasing, or at least maintaining client satisfaction. In addition, we know that many clients discontinue their chosen method within a short period of time after adoption, due to various reasons, including inconvenience and side effects. Since the tablet-based job-support tool explicitly takes the client’s preferences with respect to side effect into account, it is also possible that discontinuation rates will decline, further reducing unintended pregnancies and improving client satisfaction. So, the research team hypothesizes that (a) potential increases in the uptake of modern contraceptives in general, and long-acting methods in particular, will not be obtained at the cost of client satisfaction with the health provider and their chosen method; and (b) that discontinuation rates will decline under the “ranked recommendation” treatment condition compared with the “status quo.” A review of the literature suggests that most studies focus on the immediate method choice of the client and do not track clients longitudinally. As a result, there is limited knowledge on the relationship between the quality of FP counseling and discontinuation rates, which is an important policy question for public health. We plan to interview consenting clients recruited into our study

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<sup>3</sup> These approaches are described in detail in the Section *Interventions*.

during three rounds of follow-up phone surveys (two-week, 16-week, and 12-month surveys), which will provide important information on a number of critical short- and longer-term outcomes, such as client satisfaction; counseling quality; renewal, switching, and discontinuation rates for modern contraceptives; experiences with side effects and their management by the provider; and, ultimately, 12-month unintended pregnancy rates. Indeed, while the immediately observable outcome of modern contraceptive adoption at the clinic is a good proxy for reduced rates of unintended pregnancies within 12 months, validation of this fact within the study population would increase the credibility of study findings and improve subsequent policy advice.

- 3. “How does the demand for modern contraceptives respond to reductions in prices? Are women much less likely to adopt modern contraceptives at a very small price than when they are provided for free? Is the sensitivity of clients to contraceptive prices different for adolescents vs. adults?”** We will investigate these questions by randomly offering discounts to FP clients via the job-support tool during each counseling session. All clients will receive discounts during the study period and the sizes of the discounts will range from small (20%) to medium to large, with the largest discounts providing free contraception to the clients. The details of the exact amounts of discounts that will be offered to the clients and how these offers are integrated into the tablet-based job-support tool at the end of the counseling session are described in detail in section *Interventions*. Our hypotheses regarding price discounts are that (a) adolescents – especially younger, unmarried, and nulliparous adolescents – are much more sensitive to prices of modern contraceptives than adults; and (b) there is discontinuity of demand for contraceptives at price equal to zero, meaning that individuals are much less likely to adopt a method that costs a very small amount (say, FCFA 150 or approximately € 0.25) compared with the same method being provided for free. Evidence in favor or rejecting these hypotheses would be helpful to both the private sector and the government in setting prices for family planning services and methods.

## Literature review

There is a growing literature tackling the issues of under-provision of more effective modern contraceptive methods from both developed and developing countries. The tablet-based decision-support tool that is being tested in this study aims to increase the uptake of LARCs by overcoming provider bias (by making recommendations based on the information given by the client) and empowering the young clients (by asking them to be actively involved in the decision-making process, based on their goals, needs, and preferences). In the U.S., counseling interventions, which included peer counseling, a “waiting room app” for contraceptive counseling, and motivational interviewing techniques allowing the client to articulate goals and discuss plans, showed promise in leading to higher levels of knowledge of contraceptive effectiveness, increased interest in adopting the implant, and higher rates of LARC uptake (Gilliam 2014; Wilson 2014; Tomlin et al. 2016). Use of tablet-based decision-support tools for family planning and provision of information to young people via SMS have been tried in various countries, such as Tanzania, but the evaluations of these tools are generally to assess feasibility and acceptability, rather than larger causal impact evaluations to gauge effects on take-up and fertility (Agrawal 2016; Braun et al. 2013, 2016; Vahdat et al. 2013).

The use of the tablet-based job-support tool by the provider is likely to increase the chances of long-acting methods being discussed with the clients, who might have initially presented seeking a short-acting

method. Studies that assess the acceptability of LARCs, especially implants, find many women, including young women, to be amenable to adopting them – with low discontinuation and unintended pregnancy rates (Hubacher et al. 2012). In a partially randomized patient preference trial among women arriving at a facility seeking a short-acting method, 57% chose to be in the preference cohort and 43% agreed to be randomized into receiving a short- or long-acting method. Those choosing the randomized assignment more likely to cite cost as a reason for not having tried a LARC previously. Those in the preference cohort were most likely to cite fear of pain, injury, side effects, and health risks for not wanting to try a long-acting method (Hubacher et al. 2015). The same study showed significantly higher continuation rates and lower unintended pregnancies after 12 months among the randomized LARC group than both the randomized SARC group and the preference SARC cohort (Hubacher et al. 2017). Satisfaction with randomly assigned methods was high in both randomized groups, but slightly higher in the SARC group (89% v. 77%,  $p < 0.05$ ). These three studies showed that LARCs could prove highly acceptable even among populations presenting to adopt a SARC, but it also bears acknowledging that not all women want long-acting methods and not all women will be satisfied with them.

With respect to *behavioral science*, our study will also build on and contribute to the literature as applied to decision-making in health. In particular, concerning the tablet-based decision-support tool, this includes the key role of defaults and choice architecture (Johnson et al. 2005), among others. In addition, there is a general sense that agency (being involved in decisions, rather than being told what to do) is especially important for compliance in medical contexts (Donovan 1995) – beyond the simple fact that it is also likely to produce better decisions in the first place – in the sense of matching personal preferences. There also exists a large literature in marketing, along with a small but a growing one in development economics, which suggests that a price of zero is fundamentally different than a very small, but positive price (Bates et al. 2012). However, this hypothesis has not been examined in the context of demand for modern contraceptives, which we aim to do in the proposed study.

Finally, cost is an important barrier to the adoption of contraceptives, perhaps especially for adolescents, who may not independently have the means to adopt methods that are not free or very cheap. While large changes in prices of contraceptive methods were found to have little impact on contraceptive use in Indonesia during the 1998 financial crisis (McKelvey, Thomas, and Frankenberg 2012), more recent studies indicate that women, unmarried young women in particular, may be more responsive to contraceptive prices (Lindo and Packham 2017; Rau, Sarzosa, and Urzúa 2017). In the U.S., adolescents who receive comprehensive counseling and face no cost barriers preferentially select LARC methods and continue to use them long-term (Mestad et al., 2011). In Colorado, U.S., funding provided to Title X clinics on the condition that they stock and provide free LARCs to low-income women not only caused many facilities, which had never offered these methods before, to start providing them for free, but also decreased teen birth rates substantially, with the effect being largest in the poorest counties of the state (Lindo and Packham 2017).

## Study Procedures and Methodology

### Overview

#### *Type of study*

The proposed study is an **adaptive experiment**. As described in the glossary at the beginning of this protocol, adaptive experiments are trials which are designed to increase the efficiency with which multi-



armed trials establish the best-performing arm or arms. Adaptive experiments or trials are a form of randomized controlled trials (RCT), but they differ in the following manner: in a classical (or static) RCT, the proportion of subjects allocated to each treatment arm is determined at the onset of the trial and remains fixed for the duration of the intervention period. By contrast, in adaptive trials the proportion of subjects allocated to each treatment arm is adjusted periodically throughout the trial, typically to favor better performing arms. Adaptive trials can thus declare a ‘winner’, or a best-performing arm, with greater confidence than a static experiment for a given sample size, or more quickly than a classical RCT, allowing resources to be saved and reallocated to achieve other research objectives. Adaptive designs can also decrease the likelihood that subjects are allocated to inferior treatment arms for the duration of the study.

The research team will use an algorithm to manage the adaptive experiment, called **multi-armed bandit algorithm**. The **multi-armed** refers to the fact that there are more than two treatment conditions from which to choose. The highly developed mathematical models underlying these algorithms try to balance the desire to assign each client to the best possible treatment for her while at the same time trying to learn which seemingly inferior arms may perform better in the long-run. (**Bandit** comes from an analogy to a slot machine at a casino, which is sometimes referred to as a one-armed bandit.) As the experiment progresses and the high-performing treatments get more clients assigned to them, this helps separate the “best” treatments from simply the “good” ones faster and maximize expected benefits to the clients.

Adaptive designs require multiple periods of treatment and outcome assessment. As such, they are well suited to experiments, where participants are treated, and outcomes measured in batches over time. This makes the setting at HGOPY, where clients present at multiple departments (maternity, gynecology, and family planning) everyday seeking family planning services and counseling, particularly suitable for this type of adaptive experimentation. As the hospital has a significant interest in improving the quality of and increasing the demand for its family planning services, trying alternative methods of counseling and pricing strategies with new incoming clients, analyzing these data in batches (say, every month), and adapting the strategies makes perfect sense. In such a process, interim results are assessed periodically, and in the next period subjects are assigned to treatment arms in proportion to the posterior probability that a given arm is best: the more likely an arm is to be “best,” the more subjects it receives.

While the use of adaptive trials is gradually winning acceptance in biomedical research (Chin 2016), applications are still surprisingly rare. As Villar et al. (2015, p.200) note, “Despite this apparent near-perfect fit between a real-world problem and a mathematical theory, the [multi-armed bandit problem] has yet to be applied to an actual clinical trial.” The research team is therefore employing a novel and cutting-edge method to a real-world policy question at HGOPY, which will make the trial more efficient (by making it faster) and more ethical (by assigning more clients to the treatment condition with the highest probability of success for their context).

#### *Enrollment criteria*

The target population is **childbearing-age females, i.e. females aged 15-49**.<sup>4</sup> Subjects will be enrolled into the study continuously as they visit the hospital seeking family planning services.

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<sup>4</sup> Following Sawyer et al. (2018) in *The Lancet Child & Adolescent Health*, we adopt an expanded and more inclusive definition of adolescence up to age 24 years, rather than 19.

**Inclusion criteria:** All women presenting at one of the following departments at HGOPY, who wish to receive family planning counseling are eligible for enrollment in the study:

- Family Planning,
- Gynaecology, or
- Maternity.

Clients at HGOPY, seeking to receive FP counselling, are a diverse set of women. Some people can present at the Family Planning unit seeking to receive information, adopt a new method, renew their current method, switch to another method, manage side effects of their current method, or discontinue their current method. All such clients are eligible for enrolment in the study. Some other clients may be in the maternity ward, receiving ante-natal services and may wish to plan for post-partum adoption of a method. Others may be in the same department, post-partum, and wish to receive counselling to choose a method. Yet, other women may be clients at the gynaecology unit, seeking to adopt a birth control method before their discharge. Such clients are also eligible for enrolment in the study.

As detailed in the section that describes the content and the functioning of the job-support tool, the health provider using the tablet (a) welcomes the client; (b) tells her the purpose of the session; (c) puts her at ease by explaining that the session is completely private and confidential; and (d) describes her the new measures the hospital is taking to improve quality of service (such as the use of the tablet, improved counselling techniques, and provision of discounts for family planning methods and services). Once the health provider is satisfied that the client has understood all this information, the job-support tool directs her to ask the client: “Are you ready to go on with counselling?” All clients who respond “Yes” to this question will be considered enrolled in the study.

**Exclusion criteria:** Other than age and sex, there are no exclusion criteria. Females outside of the age range 15-49 can receive the same service with the provider using the tablet-based job-support tool, but they will not be enrolled as subjects in the proposed study. In such cases, the job-support tool will default to the “status quo” counseling strategy but will still offer random discounts for modern contraceptive methods – should the client choose to adopt one.

#### *Duration of study and sample size*

The study is intended to be conducted for a **duration of 12 months**, starting in mid-2019, during which we expect to recruit approximately 2,400 subjects – based on the administrative data available from HGOPY on the number of family planning consultations per month from January 2017 to the start of the study. The study period may be slightly shorter or longer depending on the number of participants recruited into the study, but the number subjects enrolled into the study will not exceed 3,000. The maximum sample size has been determined using simulations of the adaptive experiment, based on the number of past clients receiving FP counseling at HGOPY and their method mix. The simulations are necessary because the standard power calculations that can be used for classical RCTs do not apply for this adaptive experiment.

#### *Experiment design*

##### *The tablet-based job-support tool*

Before describing the design of the experiment, the unit of intervention, and the details of each intervention, it is necessary to describe the tablet-based job-support tool that will be used by all health

providers from HGOPY, who are involved in this study. This is because the tablet-based job-support tool serves multiple functions:

- ***A job-aid for the health provider***, which makes the process of family planning counselling more streamlined, efficient, and less prone to human error.
- ***Electronic health records for the hospital***: the data that are collected on the tablet are uploaded to the hospital's server, which can then become part of the patient's electronic health records and facilitate the scheduling of future appointments and sending clients reminders.
- ***A rich source of administrative data for research***: the data collected during the counseling session, which is described in detail below, are, by and large, the same data that health providers informally collect during FP counseling sessions around the world, but because these data are not collected systematically or recorded, they are not available for important public health research. These data, after careful de-identification by medical personnel bound by doctor-patient confidentiality, can become part of an unusually rich administrative dataset on family planning services, which can be made available to biomedical, public health, and social science researchers, who have proper ethical clearance for the retrospective studies they wish to conduct using these previously unavailable administrative data.

#### *Why was a tablet-based job-support tool developed?*

Counseling clients adequately on contraceptive method choice and use is critical to ensuring that individuals' needs are respected and met (Holt, Dehlendorf, and Langer 2017). While there is justifiably a focus on increasing the update of long-acting contraceptive methods to reduce unintended and mistimed pregnancies, concerns have been raised over potentially negative consequences of this focus on respect for the clients' autonomy and decision-making. In this context, a new framework for contraceptive counseling seems appropriate, which improves individual welfare and public health while providing the client with a needs assessment, decision-making support, and provision of important information surrounding contraceptives and sexually transmitted infections in an environment that ensures privacy, confidentiality, non-discrimination, respect, empathy, and trust.

Counseling clients on family planning and contraceptive methods is not straightforward. There are more than 10 methods that can be considered by a client. Each modern method, especially hormonal ones, can cause various side effects, which can vary from person to person. The clients' contexts, such as how long she would like to wait before getting pregnant, her birth history, her previous experience with some of the methods, her preferences for side effects, are relevant as to what methods will be most suitable for her. Finally, depending on her birth history, breastfeeding status, medical history, blood pressure, and medicines she is taking at the time of the visit, some methods may be contra-indicated for the client.

An experienced family planning counselor, whether it is a medical doctor or a nurse – is trained to consider all these issues during a family planning counseling session. Since all of this information is difficult to consider and impart from memory, health providers often have job-aids, such as the medical eligibility criteria wheel or the quick reference chart of the WHO, the Balanced Counseling Strategy Plus Toolkit of the Population Council, checklists to be reasonably sure that the client is not pregnant, cue cards describing each contraceptive method, etc. These job aids are often available in counseling room in the form of posters and booklets in print form.

Referring to these job aids during the counseling session is necessary, but often takes time and leaves room for provider error. A tablet-based job-support tool, into which all this information has been carefully programmed and extensively tested by health providers, is the perfect substitute for these charts, posters, toolkits, and reference books. By eliminating the need to refer to different documents, the tablet-based application streamlines the counseling session and saves valuable time. More importantly, it also automatically eliminates methods that are contra-indicated by the client's context, such as her breastfeeding status, medical history, or current medications. This reduces the possibility of provider error. Finally, a tablet-based counseling application saves all the data from the counseling session with the client, making her return visits more efficient as these data become part of her medical records.

Examples of similar smartphone-based job-support tools exist elsewhere. For example, in Nigeria, an initiative by the International Committee of the Red Cross, Swiss Tropical and Public Health Institute, and the Adamawa State Primary Health Care Agency developed a smartphone-based tool, called the Algorithm for the Management of Childhood Illnesses is an electronic upgraded version of the more commonly used IMCI (Integrated Management of Childhood Illnesses), which improves both preventive efforts and curative care for children under 5.<sup>5</sup>

Hence, the tablet-based job-support tool, which will be used by family planning counselors at HGOPY, was designed by a group of doctors, nurses, public health specialists, and researchers to:

- make counseling sessions more streamlined and efficient,
- reduce provider errors,
- elicit client preferences, goals, and needs, which can be incorporated into the algorithm for decision-making support, and
- to reduce potential provider bias, particularly against adolescents and nulliparous clients.

The tool has been extensively tested by Ob-Gyns, medical doctors, nurses, and other health providers conducting family planning counseling, and their feedback has been incorporated to improve the framework adopted by the tool. The tool does not require additional training for the providers charged with using it, because the tool is simply guiding and streamlining the counseling they would have already provided the client without the tablet. To incorporate the job-support tool into their day-to-day work in family planning counseling, the providers simply need some basic training on using tablets, get used to the various features and study protocols, and practice with the tablet so that the tablet becomes a natural and useful part of the counseling process.

#### *What does tablet-based job-support tool do?*

The structure of the counselling session as guided by the job-support tool is not fundamentally different than the standard practice –worldwide and at HGOPY. In other words, the tool does not require any new knowledge or training on part of the provider. It simply is a job-aid that allows her to conduct the counseling session more efficiently. The principles of counseling remain the same and the provider simply needs to familiarize herself with the tablet and the flow of the guided session to be able to take advantage of this tool in counseling clients.

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<sup>5</sup> <https://www.icrc.org/en/document/nigeria-smartphone-technology-help-tackle-child-mortality-conflict-areas>

The main innovation that the tool brings to counseling sessions is the introduction of a ranked recommendation to the client in the “Method Choice” phase of the session, which comes towards the end. The algorithm employed by the tool takes all the answers by the client up to that point into consideration and ranks methods from most suitable to least suitable for the client. The provider is then instructed to ask the client whether she would like to discuss the method that is most suitable for her. We describe this small but important innovation, in more detail below.

The process of family planning counselling using the job-support tool consists of three main sections, followed by a concluding section:

### **I. Introduction:**

1. Welcome the client, explain the purpose of the session (talk about her life and goals, healthy families, pregnancy spacing, safe sex, and contraceptive methods), and clarify that the session is private and confidential.
2. Collect basic demographic information (age, marital status, education, primary activity, religion, and neighbourhood)
3. Discuss client’s plans for having children in the future, how long she would like to wait before getting pregnant, how many more children she would like to have, and healthy birth spacing
4. Cover her birth history and establish her breastfeeding status
5. Conduct a pregnancy check

### **II. Consultation and needs assessment:**

6. Discuss current method of birth control used by the client, if any. Discuss her experience with the method, how long she has been using it, and assess whether she would like to continue or switch
7. Discuss any methods that she might be worried about. Any methods she has in mind that she is curious about.
8. Clarify any questions or misconceptions the client might have about any contraceptive methods
9. Ask her about her preferences regarding side effects concerning:
  - a. Increased bleeding and cramping,
  - b. Decreased bleeding, spotting, and amenorrhea, and
  - c. Weight gain
10. Obtain her medical history to avoid the adoption of contra-indicated methods. Take blood pressure and measure the height and weight of the client.

### **III. Method choice and follow-up:**

11. Depending on the intervention condition, either ask the client to choose the modern method she would like to discuss first OR ask her whether she would like to discuss the method that is recommended by the tool as being the most suitable for her needs. Regardless of the intervention condition (please see more below in the next section on intervention details), the tool excludes methods that are contra-indicated from the list of methods presented to the client. When the client makes her choice as to which method she would like to discuss, the provider presents neutral, evidence-based, and understandable information on the effectiveness and the side effects of that method. The provider does so with the help of printed and laminated cue cards,

each of which contain the necessary information for a different method. The cue cards used at HGOPY are available from the authors upon request.

12. Answer client's questions and concerns about the method being discussed. Listen to the client carefully and counsel her individually, based on her needs assessment.
13. Ask the client whether she would like to adopt the method or discuss another method. Discuss next preferred method, and so on, until the client decides to adopt or leave with no method.
14. Adoption of chosen method, as appropriate, along with documentation of consent for adopting a modern method, such as the pill, injectable, implant, or IUD.
15. Provide information on method use and follow-up mechanisms for switching or discontinuing selected method.

#### **IV. Conclusion:**

16. Discuss the importance of dual protection from sexually transmitted diseases and provide the client with a package of condoms.
17. Schedule the next appointment, as appropriate.
18. Provide the client information about the study and seek her informed consent to participate in the study.

It is important to reemphasize that the process of counselling a client for modern contraceptives with the help of the tablet-based job-support tool is very similar to what the provider would have done in the absence of the tablet. The main difference is in the "method choice and follow-up" section, where we introduce a small but important paradigm shift with respect to shared decision-making. In the established approach to counselling, the client is given information about all the methods and asked to choose which method she would prefer to discuss: this is encapsulated in the "status quo" intervention condition, discussed in more detail in the "Interventions" section. We want to test whether it is more beneficial to the client for the provider to make a recommendation, based on the ranking of methods provided by the tablet using the information provided by the client earlier in the session: this is the "ranked recommendation" intervention.

#### *How does the tablet-based job-support tool rank modern contraceptive methods for each client?*

The tablet-based job-support tool has a built-in algorithm that considers all medical eligibility criteria to eliminate contra-indicated methods. It also takes client preferences regarding how long to wait before becoming pregnant and the importance of various side effects into account, which allows the tool to produce method rankings. Finally, the tool eliminates any methods the client does not want to consider and elevates any method she has in mind.

#### *Method rankings*

The algorithm uses three key criteria to rank the suitability of contraceptive methods for a client:

1. How long she would like to wait before becoming pregnant, and
2. How strongly she feels about avoiding the following three categories of side effects:
  - a. Increased bleeding and cramping,
  - b. Decreased bleeding, spotting, and amenorrhea, and
  - c. Weight gain
3. Typical use effectiveness of each method

Based on the client's answers to these questions, the algorithm creates a score for each method. In the "ranked recommendation" intervention condition, the highest ranked method (that is not eliminated by the algorithm due to contraindications or client wishes – please see below) is suggested to the client first, followed by the next highest ranked method, and so on until the client decides.

For example, if the client feels strongly about minimizing the chances of all three categories of side effects and would like to wait more than one year before getting pregnant, the ranking of methods (from most suitable to least suitable) is as follows: IUD, pill, (lactational amenorrhea method or LAM), implant, and the injectable. The LAM method is included in the rankings if a client has (i) given birth in the past six months; (ii) is fully breastfeeding; and (iii) has not menstruated since birth; and excluded otherwise. Please note that in this example, the pill, which is a short-acting method with a typical use effectiveness much lower than the implant and the injectable, is ranked above both methods because of the client's preferences regarding side effects. The algorithm uses evidence on the average side effects of each method from the existing peer-reviewed literature. Similarly, the typical use effectiveness data used by the algorithm comes from peer-reviewed literature.

In contrast, consider a client who wishes to have no more children and does not care about any of the side effects. The method rankings for such an individual is: IUD, implant, injectable=(LAM), and the pill. The reader will now notice that because the client is interested in avoiding pregnancies altogether and is not concerned with side effects, long-acting methods are ranked higher, while the pill, which has the mildest expected side effects, is ranked at the bottom. Please also note that the algorithm sometimes produces identical scores for two or more methods that result in a tie in the rankings. In such cases, the client is told that two (or more) methods are equally suitable for her and the tablet uses an internal random number generator to decide the ordering of the tied methods for discussion.

#### *Medical eligibility and contra-indications*

We use the U.S. Centers for Disease Control and Prevention's recommendations for "U.S. Medical Eligibility Criteria for Contraceptive Use, 2016" to determine methods that are contraindicated for various conditions the clients may have. The main considerations are the following:

- Recent delivery of a baby
- Breastfeeding
- Unexplained vaginal bleeding
- Current blood pressure/history of hypertension
- Older age (>35), smoking, diabetes
- Medications such as TB drugs or barbiturates

A large number of medical eligibility rules relating to the conditions above are programmed into the algorithm and when a condition is satisfied, the method is ruled out and excluded from rankings. When this happens, the job-support tool displays a message at the top of the method choice section that certain methods are being excluded due to medical eligibility criteria, so that the provider can explain the client why she is not being given the option to discuss that method.

For example, the IUD can be administered within 48 hours after delivery, but after that it is recommended that the client wait to adopt the IUD four weeks after the delivery. Therefore, if the client is being counselled between 48 hours and 27 days after delivery, the tool would exclude the IUD from the rankings.

Of course, the client could choose to come back after four weeks to adopt the method should she wish to do so.

Alternatively, the combined oral contraceptive (COC) pill is not recommended for clients who have systolic blood pressure over 140 or diastolic blood pressure over 90. Such clients are told that they cannot adopt the COC but can adopt the progestin only pill (POP) if they wish. There are many other eligibility rules, which are too numerous to be included in this proposal.

#### *Elevation of methods according to the client's wishes*

Conversely, in some cases, a client may have arrived at the facility almost certain of the method that she would like to adopt. For example, a client may have a friend or relative who is very satisfied with a certain method. Or, the client may have experience with a method in the past, say before her last pregnancy, and would like to return to using that method. To ascertain such cases, the provider asks the client in the "Consultation and needs assessment" phase, whether she has any method in mind. If she specifies a method and indicates that she would not like to discuss any other methods, the specified method is moved to the top of the rankings.

#### *Interventions*

This study consists of two primary independent interventions:

##### **1. Randomly varying the prices individual clients face by offering discounts**

As described in the *Research questions and hypotheses* section, this study seeks to answer several questions regarding clients' demand for modern contraceptives and its sensitivity to changes in prices. Therefore, as part of the experiment, all clients who receive a FP consultation by a provider in one of HGOPY's participating services will be offered randomly varying discounts, or randomly varying prices, for each type of modern contraceptive methods. The discounts offered to each client will be randomly calculated by the tablet with the help of an inbuilt random number generator and the corresponding prices will be displayed after the client has chosen to adopt her preferred method. The prices for all methods at the same time will be displayed on the tablet for the client and the provider to see. More information on the random allocation of prices is provided in the *Data analysis* section.

The decision to incorporate prices only at the end of the consultation, after clients have made their initial method choice, was made after careful deliberation with the healthcare providers at HGOPY based on established best-practices and ethical norms.

For the intervention and the analysis, the four modern methods offered at HGOPY are grouped into two categories: **LARCs** – i.e. the IUD and Implant – and **SARCs** – the pill, injectable, and LAM. Of course, LAM is free to use so it can be ignored in the discussion of the price intervention. Based on this distinction, clients will be randomly offered two independent sets of prices, one for the two LARCS and another for the two SARCS. Each combination of a set of LARCS prices and a set of SARCS prices constitutes a treatment, or experiment arm. The experiment comprises five LARCS price categories {High, Mid, Low, Very Low, and Free}, and two SARCS price categories {High and Free}, implying a total of **ten** possible price combinations, or ten experiment arms. Table 1 describes the prices offered for each modern method offered at HGOPY and how they compare to the current prices (or pre-experiment prices). It is relevant to note that all prices offered for LARCs, even the highest, consists of discounted prices relative to the current prices offered at HGOPY.



Table 1: Prices offered during the experiment.

| Type | Method     | Pre-experiment prices | Experiment prices |       |       |          |      |
|------|------------|-----------------------|-------------------|-------|-------|----------|------|
|      |            |                       | High              | Mid   | Low   | Very low | Free |
| LARC | IUD        | 5,000                 | 4,000             | 2,000 | 1,000 | 150      | 0    |
|      | Implant    | 5,250                 | 4,000             | 2,000 | 1,000 | 150      | 0    |
| SARC | Pill       | 500                   | 500               | -     | -     | -        | 0    |
|      | Injectable | 1,250                 | 1,250             | -     | -     | -        | 0    |

These two independent price sets imply a 5x2 factorial experimental design, detailed in Table 2. With equal probability of assignment this means that each client has a 10 percent probability of being assigned to either one of the ten different price combinations shown in Table 2.

Table 2: Initial probability of assignment per each price set.

|                                      |      | Price of LARCs (IUD and implant) |          |     |     |      | Total |
|--------------------------------------|------|----------------------------------|----------|-----|-----|------|-------|
|                                      |      | Free                             | Very low | Low | Mid | High |       |
| Price of SARCs (pill and injectable) | Free | 10%                              | 10%      | 10% | 10% | 10%  | 50%   |
|                                      | High | 10%                              | 10%      | 10% | 10% | 10%  | 50%   |
| Total:                               |      | 20%                              | 20%      | 20% | 20% | 20%  | 100%  |

## 2. Randomly varying whether the app makes a “ranked recommendation” vs. the “status quo”

Here, we would like to test, as closely as possible, the proposed paradigm shift in FP counseling – i.e. going from discussing all modern methods and letting the client state the method she would like to discuss first, to having the job-support tool recommending which method to discuss first based on the information elicited from the client during the session. This intervention occurs during the “method choice” section towards the end of the consultation once clients are ready to discuss specific methods and potentially choose to adopt one. The “method choice” happens after the providers have discussed the clients’ past experiences with contraception and have elicited their fertility goals, their preferences towards side effects, their desires to exclude or favour specific modern methods, and their medical eligibility – i.e. the elements necessary to make an informed choice for a contraceptive method to adopt. Keeping in mind that all clients receive a consultation using the app, the two different paradigms are compared by randomly varying the protocol providers are asked to follow when assisting clients during this “method choice” phase and is reflected through the instructions and options displayed in the job-support tool.

After the providers elicit the clients’ medical eligibility, the app randomly assigns each client to one of two regimes with the help of the random number generator inbuilt into the tablet software. Each experiment arm will initially be assigned to clients with equal probability:

- i. **Status quo:** In this regime, the job-support tool displays all available modern contraceptive methods that have not been ruled out by the client or contraindicated due to medical eligibility (contraindicated methods will be indicated as such as well as the reason for contraindication). The available modern methods are presented as unranked (i.e. as if each method is equally suitable

for the client) and the providers will provide basic information on all available methods (in order of the methods displayed, *which is also randomized*). The basic information covers what the method is, how it is used and its duration (capsule placed under the skin in the arm for 3-5 years or pill taken daily, etc.), and its typical use effectiveness. This quick description is expected to take about 30-60 seconds for each method. The provider will then ask the client to indicate which method they would like to discuss first. The provider will use the relevant cue card (available from the authors upon request) to discuss the method in question in more detail to inform the client of all the relevant information the client needs to know before adoption. After going through this information, the client can choose to either adopt this method or discuss another method (of her choice). This process is repeated until a decision is made.

- ii. **Ranked recommendation:** In this regime, the tablet will first display the method that is deemed most suitable for the client given her preferences, as described in section *The tablet-based job-support tool*, and ask her if she would like to hear about it. If the client answers ‘no,’ then the next highest ranked recommendation is displayed, and the provider asks the client if she would like to discuss this method, the process is repeated until the client decides to discuss one of the recommended methods (the app displays non-modern methods if the client does not want to discuss any one of the modern methods). If the client answers ‘yes,’ that she would like to hear about a modern method, then the procedure is the same as in the “status quo” regime, whereby the provider uses the appropriate cue card to explain to the client everything she needs to know about the method in question. The client can then decide whether to adopt this method or discuss the next method recommended by the app. Again, this process is repeated until a decision is made.

#### *Random assignment procedures and adaptive experimentation*

The tablet is programmed to assign clients to a treatment arm for each one of the two interventions with the help of a random number generator that is embedded in the tablet.<sup>6</sup> Clients are assigned one set of prices – i.e. one of the ten possible price combinations – and one recommendation style – i.e. “ranked recommendation” vs “status quo.”<sup>7</sup> Initially, the probability distribution of each treatment arm will be equal, meaning that, on average, an equal number of new clients will be assigned to each treatment arm.

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<sup>6</sup> For example, to assign a client into the status quo method choice vs. the ranked recommendation regime, the tablet will make use of a 12-digit random number that is automatically generated each time a new counselling session is started. Using a simple formula, we scale up the first four digits of this number to create a new number between 1 and 5,000. We then use that number to select a row in a table that has been pre-loaded onto the tablet, which contains 5,000 random draws from a standard normal distribution with mean equal to zero and standard deviation equal to one. For example, if the number we created is 1234, then we select the 1234<sup>th</sup> row of the pre-loaded table. This row is assigned to the status quo method choice regime while the next row (i.e. the 1235<sup>th</sup> row, which is an independent draw) is assigned to the ranked recommendation regime. Whichever number in those two rows is bigger is then selected for the client. For example, if the 1234<sup>th</sup> row contains 0.13687 and the 1235<sup>th</sup> row contains 0.00035, then row 1234 is chosen and the client is assigned to the status quo method choice regime.

<sup>7</sup> Clients are assigned to one set of treatments which is maintained throughout the experiment duration, meaning that clients return to the hospital for follow-up visits and receive a new consultation they will be allocated to the same treatment arms.

This is typical of classical (i.e. static and not adaptive) RCTs conducted in medicine and other social sciences, otherwise known as “A/B testing.”

However, as mentioned in the “*Research Questions*” sub-section above, this experiment is an **adaptive RCT**, whereby the assignment probabilities will be adjusted as the experiment is ongoing. Throughout the study period, the research team will continuously analyze the anonymized client data (*please see the section below, titled “Data management”*) in monthly batches to evaluate which interventions are more successful and which ones are less promising. We will then use machine learning techniques to adjust the probabilities that clients are assigned to each one of the various treatment arms to more efficiently establish which are the best performing arms.

The difference between a conventional RCT and an adaptive RCT is essentially the following: In conventional, or static, experiments the proportion of subjects allocated to each treatment arm is generally determined at the onset of the trial. The probabilities will typically be based on ex-ante power calculations, which determine the sample size required to estimate an effect of a given size. Clients are then assigned to treatment arms with probabilities that are pre-specified and fixed throughout the study period. In contrast, an adaptive trial will typically begin like a conventional RCT, but after a pre-specified period of data collection it will allow these probabilities to evolve over time to achieve balance between two distinct goals: (i) to maximize learning, which requires assigning enough subjects to every treatment arm so as to estimate its relative success with enough accuracy, and (ii) to maximize patient welfare, which requires assigning subjects to the treatment arms that show the most promise. As the researcher learns more about how people respond, they will increase the chances that a person will be assigned to a treatment that will be beneficial to them. Adaptive trials can thus declare a ‘winner’, or best performing arm, with greater confidence than a static experiment for a given sample size or experiment duration. In addition to the benefits to the experiment participants just discussed, adaptive experimental designs can also aid in the ex-post analysis because more observations are collected from the most beneficial treatments, and there will be more statistical power to test hypotheses about those arms specifically since less observations will be effectively wasted on non-performing arms.

To determine the probabilistic allocation of clients to each treatment arm, this study will employ an algorithm known as the “multi-armed bandit algorithm.” In particular, this study will employ a “**contextual** multi-armed bandit algorithm,” which further varies the assignment probabilities based on the client’s characteristics, or “context.” Therefore, the implication is that *Contextual* bandit algorithms go even further than general adaptive trials towards improving efficiency and maximizing the welfare of clients during the experiment, because not only will the algorithms favor arms that are performing better overall, they will also favor certain arms specifically for those clients who have been found to respond well to those arms.

Since our interventions are likely to have different effects for different types of clients, our algorithms can take the clients’ contexts into account and increase the probability that they get assigned to the intervention that is, on expectation, most beneficial for them. For example, if younger women, who may have fewer financial resources available to them, are found to respond particularly strongly to the offer of free contraceptives, then the algorithm will learn this over time and allocated more young women to the intervention arms where contraceptive are provided for free. An added advantage of these algorithms is that they do not require pre-specifying these contexts before the experiment begins, since the

algorithms are built to retain the flexibility to incorporate various contexts after they have become apparent once the first few batches of data have been analyzed.

#### *Data collection and the adaptive process*

This section describes in more detail the process of data collection and analysis, including how the probabilities of assignment are updated while the trial is ongoing. For a more technical treatment we refer the reader to the *Technical Appendix*, available from the authors upon request.

As explained in the previous section, data will be analyzed in monthly batches. In the first batch – i.e. the initial phase of the experiment, before any adaptive experimentation will be taking place – the experiment will proceed in the same manner as in a conventional RCT. Clients who receive a family planning consultation are randomly assigned a set of prices and a recommendation style uniformly at random. The tablet-based job-support tool records the clients' answers to the providers' questions as they go through the consultation, including basic demographics and the method chosen by the client, if any. This data is automatically uploaded to a password-protected secure server – accessible only to assigned hospital staff bound by medical secrecy (see the next section *Data management* for a comprehensive discussion of data confidentiality and data management issues). The tablets are also password protected, and once the data from the consultations is uploaded to the server it disappears from the tablets, adding another level of security.

After one month, the adaptive phase of the experiment will begin. At this point we will allow the assignment probabilities to change based on weighing the predicted benefit to the clients against the cost of providing subsidies (or discounts). From the perspective of the healthcare providers and the clients, the adaptive phase of the experiment will be no different than the initial phase of the experiment. The random assignments into each treatment arm is done by the tablets' software, the probabilities for which will be remotely updated by research team once each batch is analyzed. Therefore, the providers and the clients will not notice anything different about the consultation.

*There are five main steps to updating the probabilities of assignment:*

**Step 1 – calculating the probabilities of adoption:** At the end of the each monthly batch, the research team will train a statistical model to estimate the likelihood of a client selecting each contraceptive method given their basic demographics (e.g. age, level of education, birth history, current employment, marital status, etc.), the set of prices they were offered, and the recommendation style they received during the consultation. This will be done by fitting a multinomial logistic model to regress the choice of contraceptive method on the client characteristics and a set of binary variables indicating to which treatment arms they were assigned. Based on this statistical model, we can calculate the predicted probabilities of a client adopting each contraceptive method, for every possible combination of the observed set of characteristics that can be exhibited by clients – we will henceforth refer to a client's set of characteristics, e.g. her age, her maternal history, her marital status, etc., as this client's *context*.

These probabilities are used to compute two values for every combination of a context and a set of treatments: the expected cost and the probability of unintended pregnancy.

**Step 2 – calculating the expected cost of each intervention:** The expected cost of each price intervention, or subsidy profile, is obtained by multiplying the value of the subsidy offered for each method by the predicted probability that a client exhibiting a certain context adopts this method given the subsidy profile

(Figure 1). This estimate tells us what we would expect, on average, to spend on subsidies for a client exhibiting a certain context if we were to offer her this specific set of subsidies.

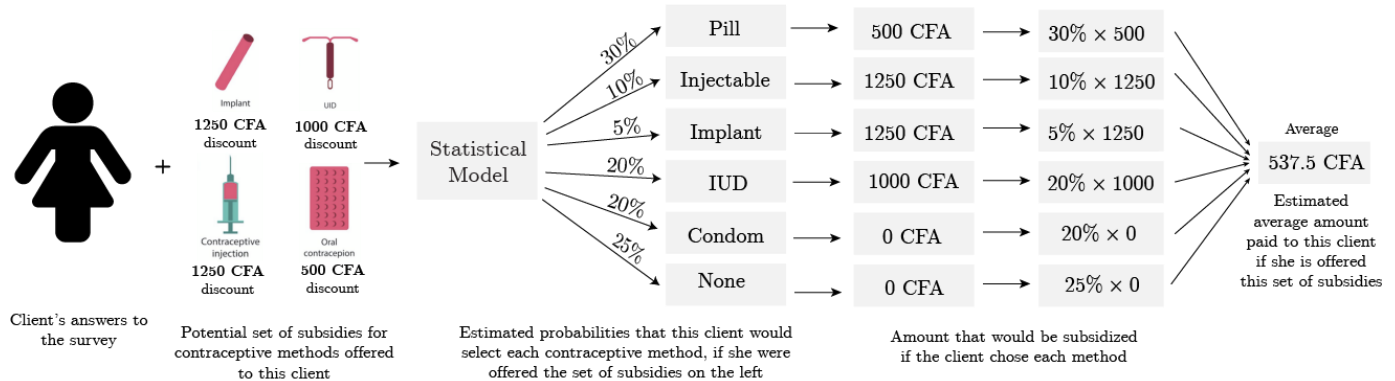


Figure 1 - Use our statistical model to predict the client's choice of contraceptive, and how much we would need to disburse depending on that choice

**Step 3 – calculating the probability of an unintended pregnancy:** The probability of an unintended pregnancy is obtained by multiplying the likelihood of a client with a certain context adopting each method, given that they are offered this specific set of subsidies, by the 12-month typical use failure rate for each contraceptive method (Figure 2). The typical use failure rate is based on the latest and best peer-reviewed evidence available (Trussel 2011).

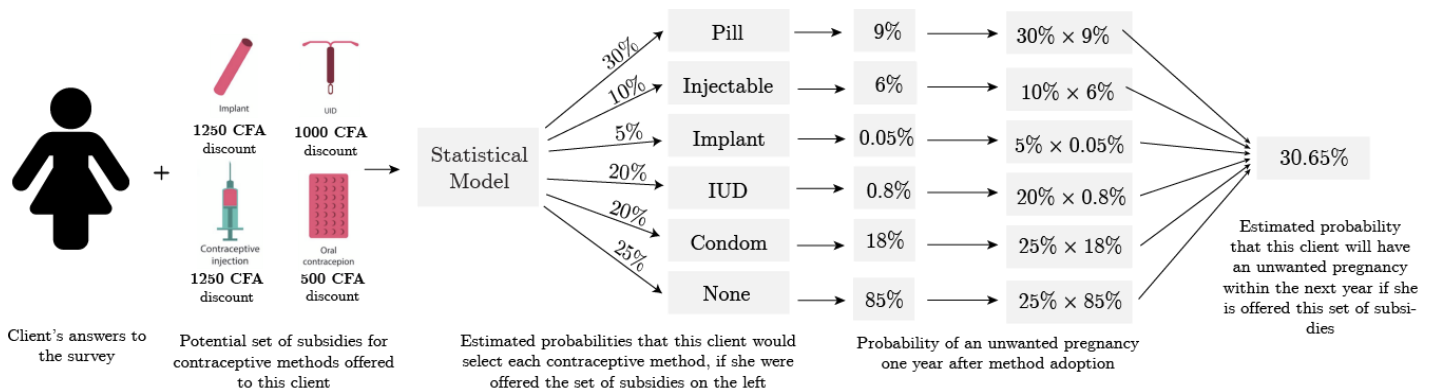


Figure 2 - Use our statistical model to predict the client's choice of contraceptive, and how likely she would be to suffer an unintended pregnancy one year after the contraceptive adoption.

**Step 4 – calculating value of each intervention for each context:** Once we have computed the expected cost of the subsidy profile (Figure 1) and the probability of an unintended pregnancy (Figure 2) for each intervention-context combination, we can combine these two values into what we will call the expected *intervention benefit*. The *intervention benefit* effectively assigns a numerical value to each intervention, i.e. treatment arms, summarizing the benefit of this intervention for clients exhibiting a certain context. The value of the intervention is obtained by weighing the cost of the intervention – i.e. the expected cost of the subsidy package – relative to the benefit of the intervention to the client – the probability of avoiding an unintended pregnancy.

Then, steps 1 – 4 are repeated for a large number of bootstrap samples drawn from the main dataset collected in all previous batches thus far, i.e. a large number of randomly selected subsamples of the main

sample. The *intervention benefit* for each intervention-context combination will therefore have a distribution with a mean and a variance.

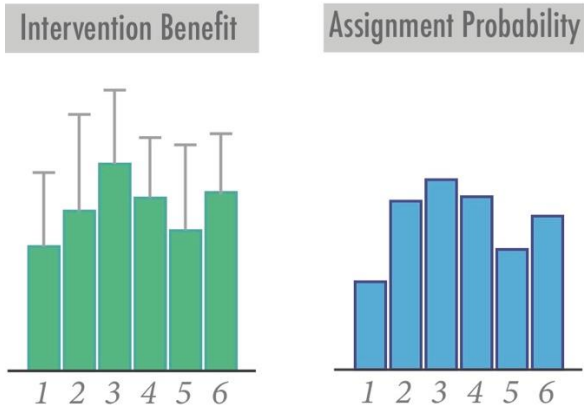
**Finally, Step 5 – assigning the clients to an intervention given their context:** After having calculated the value of each intervention for each client context, we will be using a method called *Thompson Sampling* to generate new probabilities of assignment. *Thompson sampling* effectively tilts the assignment probabilities towards better performing arms by assigning clients to intervention arms in *proportion to the probability that an intervention arm has the highest benefit* for the subject's context. For example, if a certain intervention arm has a 70 percent chance of being the best arm for a client, then there will be a 70 percent chance that this client will be assigned to this intervention arm. In practice, Thompson Sampling will be implemented by: (i) using the tablet's internal random number generator to draw a random value for each one of the treatment arms from their context-specific distributions of intervention benefits, and (ii) assigning the client to the treatment arm with the highest drawn random value.

*What is the rationale for Thompson Sampling?*

If we were only looking to maximize the benefit of the intervention and *exploit* the benefits of the better performing arms, we would be tempted to assign all subsequent clients to the interventions with the highest predicted benefit. However, this would be naïve for the simple reason that at this stage in the experiment we may not be able to ascertain with enough confidence that any one intervention that has been performing very well in the previous batches will continue to do so in future batches. Hence, we run the risk of making a mistake by assigning too many subjects to the wrong intervention. Case 1 shown in Figure 3 below highlights such a situation, where although arm 3 may have the highest average benefit, all the arms have a high variance and large confidence intervals. In this case, we may want to assign slightly more clients to arm 3 because it looks promising, but we should also keep assigning clients to the other treatment arms to *explore* their potential benefits. This will allow us to optimize the benefits to the clients of the various interventions while also allowing learning.

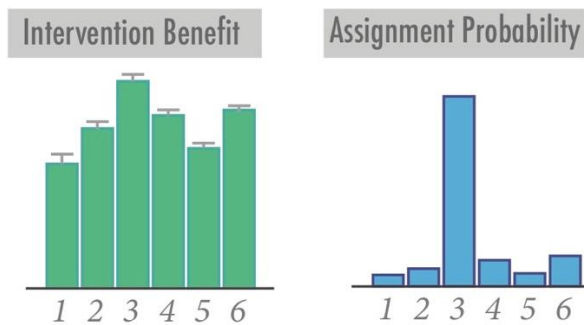
In contrast, towards the end of the experiment, once we have collected enough data so that the variances of the predicted benefits of each intervention are low, we can more confidently assign clients to the most beneficial arm, as is shown in Case 2 of Figure 3 for intervention arm 3. It is important to note that although the mean levels of the expected intervention benefits may not have changed, the assignment probabilities are now very different. This is because our level of confidence regarding relative expected intervention benefits has greatly improved over time – from Case 1 to Case 2. This is evident from the figure by the tighter confidence intervals depicted in Case 2. Therefore, we can assign a much higher share of clients to this intervention arm because we have a significantly lower risk of being wrong about our predictions, and thus maximizing the expected benefit to the clients.

### Case 1: High uncertainty



In the beginning of experiment, the statistical model used to predict the benefit of each intervention is estimated only using a small amount of data, so there is still high uncertainty surrounding its predictions. In this illustrative example, arm 3 has the highest probability of being the most beneficial arm, so the client is assigned to it with highest probability. However, the runners-up may still be selected quite often.

### Case 2: Low uncertainty



Towards the end of the experiment, the statistical model used to predict the benefit of each intervention is estimated using a lot of data, so the uncertainty surrounding its predictions is much lower. In this illustrative example, we are very certain that arm 3 has the highest probability of being the most beneficial arm, so the client is assigned to it with overwhelming probability.

Figure 3 - Illustration of the Thompson Sampling method used to determine intervention probabilities.

Figure 4 below, depicting a completely hypothetical scenario and constructed only for illustration purposes, shows the link between the expected cost, the expected probability of an unintended pregnancy, and the probability of assignment for each subsidy package.

|             |             |            |             | Expected cost of subsidy | Expected probability of unwanted pregnancy | Probability of assignment |
|-------------|-------------|------------|-------------|--------------------------|--|---------------------------|
| 1000        | 1250        | 0          | 0           | 1090                     | 62%  | 4.2%                      |
| 1000        | 1250        | 500        | 1250        | 1700                     | 25%  | 16%                       |
| <b>3000</b> | <b>3250</b> | <b>0</b>   | <b>0</b>    | <b>1320</b>              | <b>15%</b>                                 | <b>38.7%</b>              |
| 3000        | 3250        | 500        | 1250        | 3570                     | 3%   | 7.45%                     |
| 4000        | 4250        | 0          | 0           | 2500                     | 20%  | 9.28%                     |
| 4000        | 4250        | 500        | 1250        | 3570                     | 5%   | 6.74%                     |
| 4850        | 5100        | 0          | 0           | 4650                     | 5%   | 2.3%                      |
| <b>4850</b> | <b>5100</b> | <b>500</b> | <b>1250</b> | <b>3700</b>              | <b>37%</b>                                 | <b>1.2%</b>               |
| 5000        | 5250        | 0          | 0           | 3250                     | 5%   | 9.3%                      |
| 5000        | 5250        | 500        | 1250        | 3925                     | 5%   | 4.7%                      |

This subsidy profile in green is relatively inexpensive (1320 CFA), and the client is expected to choose a method that will induce a low probability of unwanted pregnancy (3%). Therefore, this set of subsidies will be assigned with higher probability.

This subsidy profile in pink is relatively expensive (3700 CFA), and we predict the client will choose a methods that induces high probability of pregnancy (37%). Therefore, this set of subsidies will be assigned with lower probability.

Figure 4 - Using the quantities computed in Figures 1 and 2 for each set of subsidies, our algorithm will modify the probability of assignment to each treatment favoring treatments that are more inexpensive and beneficial to the client.

### *Post-experiment analyses*

Once the experiment is over, we will perform two kinds of statistical analyses using the collected data. First, we will test the following set of **hypotheses** about the primary and secondary outcomes

- Hypotheses about intervention effects:
  - Are women more likely to adopt a modern contraceptive as the subsidy towards that contraceptive increases? Moreover, is the magnitude of this effect different for:
    - Teenagers vs adults?
    - Clients who were already using a modern contraceptive vs otherwise?
  - Are women more likely to adopt a modern contraceptive depending on the recommendation method (i.e. status quo vs ranked recommendation)?
  - How do the other secondary outcomes change as a function of the intervention?
    - For example, are clients more likely to be satisfied with their choice of contraceptive method under the “ranked recommendation” condition than the “status quo”?
- Hypotheses about the demand function:
  - Are short-acting and long-acting contraceptives complements or substitutes, i.e. what is the sign of the cross-price elasticity?
  - Are women more likely to adopt a contraceptive if they pay exactly zero vs a small positive price, i.e. does the demand for long-acting contraceptives exhibit a discontinuity at zero?
- The “business as usual” counterfactual policy vs. the “best-performing intervention arm”

The “status quo” recommendation style combined with high prices for both LARCs and SARCs is the closest to “business as usual” at HGOPY when it comes to family planning services before the study. By collecting a sufficiently large sample in this group and comparing it with the “best-performing arm,” averaged over all contexts, we can conduct classical hypothesis testing. This analysis would allow us to answer the question: “Can we reject the null hypothesis that the impact of the best-performing arm on any primary or secondary outcomes is equal to that of “business as usual.”

### *Outcomes of interest*

The **primary outcomes** in this study are:

1. The client adopted a LARC or not, and
2. The client adopted a modern contraceptive method (LARC or SARC) or not.

In the short-run, these primary outcomes are proxies for use of a reliable contraceptive method in the longer-run and, hence, for avoiding mistimed or unwanted pregnancies. The data to construct the primary outcomes for the proposed study will be obtained from the tablets, as the characteristics, goals, preferences, and the choices of each client will be recorded by the job-support tool during the counseling sessions.

We will then also collect data on those longer-term outcomes through follow-up surveys with assenting/consenting clients.



The **secondary outcomes** in this study are:

3. Client satisfaction with the counseling session,
4. A checklist to assess the quality of the counseling session,
5. Side effects of methods and their management,
6. Renewal, switching, and discontinuation rates of methods,
7. Client satisfaction with adopted method, and
8. 12-month unintended pregnancy rates.

These secondary outcomes will be assessed using data from three rounds of follow-up surveys with assenting/consenting clients. Some outcomes, such as client satisfaction with and the quality of the counseling session will be assessed using a two-week follow-up phone survey. Others, such as side effects, discontinuation rates, and satisfaction with adopted methods, will be assessed using a 16-week follow-up. Finally, unintended pregnancy rates will be assessed 12 months after the initial counseling session.

#### *Data management*

The study requires two distinct types of data. To construct the primary outcomes, analyze them in monthly batches within the context of the adaptive experiment, and tailoring interventions to individual clients' contexts, we need access to the data collected by the tablets during each counseling session. To collect secondary outcomes, to gauge the longer-term (12-month) impacts of our interventions, we propose to conduct short follow-up phone surveys with clients, who provided assent/consent to participate in our study. Below, we outline our proposed method of data access and management separately for primary and secondary outcomes.

#### *Data access and management for **primary outcomes***

The data necessary to construct the primary outcomes, analyze them in monthly batches, and adapt random allocation probabilities to each intervention arm based on clients' contexts, can be found in the electronic health records of each individual client from their family planning counseling session. These records not only have the outcome indicators, i.e. what method the client adopted, if any, but also all the contextual variables needed by the adaptive experiment, such as age, marital status, birth history, previous method, future fertility plans, preferences for methods and side effects, etc. More importantly, while these records contain personally identifiable information (PII), **the research team does not need PII** to conduct analysis of the primary outcomes.

A summary of these data, which include the client's name, age, marital status, date of visit, previous contraceptive method, current selected method, next appointment date, and a phone number are recorded in HGOPY's family planning register at the end of each visit. Then, at the end of each day, these data are entered into desktop computers by the providers and become a part of the hospital's administrative health records (EHR). The use of the tablet-based job-support tool simply makes this dataset larger and more detailed, allowing the hospital to have more information on the client's birth history, preferences for methods and side effects, etc. It also eliminates the need for the double entry, as the data from the tablets can become part of HGOPY's EHR using a simple software, after the data are synced from the tablets to a secure hospital server (please see more on the server below).

Ordinarily, the primacy of respect for patient autonomy is uncontroversial: patients, of course, have the right to decide whether and which procedures they wish to undergo, what methods they wish to adopt. However, a strong argument can be made for the use of information that is already stored by the hospital

when (a) that information, properly anonymized, can have significant public health and/or biomedical value; and (b) when the only risk to the client is a breach of privacy; and (c) that risk is minimal.

Throughout this protocol, we have made the case for the value of the proposed research – both directly for the clients (please see the section below, titled *Benefits and Risks to the Client*, under *Ethical Considerations*) and indirectly for the community and for global knowledge generation. This type of research cannot be conducted using publicly available or pre-existing data, as we are interested in the effect of alternative approaches to family planning counseling with the use of a tablet-based job-support tool. While our research does require sensitive data (client’s choice of contraceptive method), the risks of harms arising from privacy breaches are minimal. As our research is focused on studying the effect of slightly different counseling approaches and reduction of prices for contraceptives on method choice, there are no other risks than privacy breaches. Our study is not a clinical trial, where a new drug or a medical product is being trialed and there are other harms that need to be considered. The clients presenting at HGOPY already get counseled and adopt all methods under consideration in our study. The expected outcome is simply a change in the method mix among the target population.

Increasingly, a case is being made by researchers and public health officials that access to de-identified, minimally risky EHR data should be made available to researchers without the need to seek consent from each patient. For example, researchers, who were interested in evaluating the effect of access to free health insurance in the state of Oregon, U.S.A., were given access to anonymized EHR data by the state’s office of health policy and research, who conducted the matching of the data and the de-identification on-site using its own authorized personnel, and then gave the researchers access to anonymized data (Finkelstein et al. 2011). Porsdam Mann, Savulescu, and Sahakian (2016) argues that when the only expected risk to the individual is a breach of privacy and the likelihood of that breach is minimal, obtaining waivers to access EHR without individual consent should be granted.

We argue that the likelihood of a privacy breach is minimal in our context for two reasons. First, the sensitive data are already kept in two locations: in physical family planning registers and in the hospital’s own administrative records. The additional probability of a breach of privacy because of this study is very small. In fact, the study may reduce this risk by eliminating the need for double entry of sensitive PII data; requiring dedicated and more secure servers for these data; and encouraging better data handling practices by hospital staff. Access to the job-support tool on each tablet requires a pre-assigned user ID and password. Each provider will be instructed to transmit data to the dedicated and secure server daily. Transmitted data will be deleted from the tablet once transmission is successful.

Second, the data management protocol envisioned for this study has the providers regularly upload the data for each family planning counseling session they conduct from the tablets to a dedicated server – accessible only by one medical personnel employed at HGOPY, who is bound by doctor-patient confidentiality. The server will be dedicated only for the purposes of the study; will be password protected and encrypted; only accessible to the server administrator bound by doctor-patient confidentiality, and off-limits to the study team.<sup>8</sup> We further elaborate on the exact data management protocols to be undertaken by the server administrator in the next sub-section below.

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<sup>8</sup> The dedicated server is hosted by Amazon Web Services (AWS) and is compliant with various assurance and certification programs, including the Health Insurance Portability and Accountability Act (HIPAA) of the USA, the EU Data Protection Directive, Privacy Acts of Australia and New Zealand, among others. Therefore, it is compliant with

**Therefore, to construct and analyze primary outcomes during the study period, the study team is requesting access to de-identified electronic counseling records for each client from the tablet-based app. For access to these data, in keeping with the arguments made above, the study team requests from the Committee the “waiving of consent from clients for review of their electronic health records from the family planning counseling session.”**

In making this request, we note that the act of seeking informed consent at the start of a family planning counseling session (especially with adolescent females and young women, who may already be apprehensive about participating in such counseling sessions) may create an undue burden (emotionally and in terms of time spent) on both the client and the nurse counselor and may alter the very nature and outcome of these sessions. The waiver of consent to access de-identified EHR data from the counseling sessions will allow our study to interfere as little as possible with the day-to-day business of family planning counseling at HGOPY, while respecting the clients and maintaining their privacy and confidentiality.

The EHR data include the treatment status of each client, access to which would allow us to evaluate treatment effects on primary outcomes for every client counseled during the study period. Furthermore, having access to de-identified client-level background characteristics – such as age, education, marital status, parity, religion, as well as preferences and history regarding contraceptive methods – will not only allow the implementation of the proposed adaptive experiment, but also enable the research team to investigate the mechanisms underlying the potential program impacts.

#### *Data access and management for **secondary outcomes***

To collect data on secondary outcomes, which were listed above, the research team needs to conduct follow-up interviews with clients. As such data are not part of existing records at HGOPY and need to be collected via follow-up client interviews, **they will only be collected from clients who provide their assent or consent to participate in our study.** Below, we briefly describe the nature of the follow-up surveys and the procedure for obtaining consent.

Three follow-up interviews, each of which are expected to take 15 minutes or less to conduct by phone, are planned at two weeks, 16 weeks, and 52 weeks after the initial visit – when the client is counseled for the first time by a provider at HGOPY using the “app.” The short follow-up interviews will include questions about client satisfaction with the counseling session; side effects of the chosen methods; renewal, switching, or discontinuation of the chosen methods; and 12-month pregnancy status. The follow-up interviews will be conducted by a local survey firm using phone numbers provided by the client specifically for this purpose. The data for secondary outcomes obtained through the phone survey will be hosted on another server, with the same safety standards as the server hosting the administrative EHR data.

As the evaluation of treatment effects on secondary outcomes requires knowledge of treatment status, as well as background characteristics and primary outcomes, all of which were collected as part of the electronic counseling records using the “app,” the follow-up surveys will be linked with the electronic health records for analysis using the unique study identifier assigned to each client.

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the highest standards of security to protect the privacy and confidentiality of clients and will only be accessed by a person authorized by the HGOPY administration through a username and password.

We will seek informed consent from all first-time clients at the end of their counseling session to participate in the follow-up study. Seeking informed consent at the end of the counseling session ensures that our study does not interfere with the counseling session between the provider and the client or influence the client's actions and decisions regarding the adoption of a contraceptive method in any way.

The tablets will be programmed to prompt the provider at the end of the counseling session to invite the client to participate in the follow-up study by reading them a notice of information, go over the informed consent form for the client that is embedded into the tablet, and obtain their digital signature if they agree to participate in the study. Physical copies of the notice of information and informed consent forms will also be given to the client. The English and French versions of these client-level forms, as well as the draft questionnaires for each follow-up interview are available from the authors upon request.

The target population of our study is females aged 15-49, who present at HGOPY seeking family planning counseling. This means that a small percentage of the clients seeking family planning services will be under the age of 18. While some of these clients will be married and, hence, emancipated, others will be minors. For the purposes of our study, we will refer to a client as "a "minor adolescent" if she is between the ages of 15-17 and is unmarried. The consent protocols described in the paragraph above will apply to anyone who is **not** a "minor adolescent, whose consent we will simply seek to participate in our study.

For a "minor adolescent," we will seek her assent to participate in our study following the same protocol described above. Assent forms for minor adolescents are available from the authors upon request. In addition, we will explain to her that since she is legally a minor, we would like to seek her parents' or guardians' permission for her participation in our study. Notices of information and consent (available from the authors upon request) will describe the follow-up surveys within the context of an adolescent health survey. If the parents/guardians are at HGOPY with the "minor adolescent" client, then their verbal consent will be sought in person. If they are not present at the hospital, then the provider will ask the "minor adolescent" to provide a contact number for the parents/guardians to obtain their verbal consent by phone. For "minor adolescents" wishing to adopt a contraceptive method, HGOPY requires parental consent before providing such clients with a method. For these clients, the provider will seek to obtain parental consent to adopt a method and to participate in the study at the same time. For all other "minor adolescents", the local survey firm will be in charge of obtaining consent from their parents/guardians by phone before any follow-up interview with them can take place.

The server administrator, who will serve as the liaison between the research team and the hospital, will be responsible to **de-identify the electronic health records from the family planning counseling session** for non-assenting/consenting clients – by removing any PII (name, surname, and telephone number) from each such record, and share the client-level data with the research team on a weekly basis. For these clients, we will only have de-identified EHR data. For everyone else, we will have follow-up survey and EHR data, which will be linked using the unique study identifier assigned to each client.

The procedures described above imply the following:

- The research team will receive all data, including PII, for
  - consenting clients, who agreed to participate in the follow-up study, and
  - "minor adolescents," who assented to participate in the follow-up study and whose parents/guardians provided consent

- The research team will only have access to de-identified EHR data, anonymized for research purposes, for non-consenting clients who have declined to participate in the follow-up study.
- The server administrator at HGOPI, who will be chosen from medical personnel bound by doctor-patient confidentiality, will de-identify the data according to the consent status of the client.
- There will be no need for de-identification of data at the server hosting the follow-up survey data, as everyone interviewed will have provided consent or assent.

## Ethical considerations and confidentiality

### Benefits and risks to the clients

#### *Direct benefits to study participants*

All clients presenting at HGOPI seeking to receive family planning counseling during the study period will enjoy the following benefits:

- Receive counseling from providers working within a revised quality in contraceptive counseling framework with the help of the tablet-based job-support tool,
- Free pregnancy tests, removal of LARCs, and provision of condoms throughout the study period,
- Discounted prices for all modern contraceptive methods,
- Free treatment for the rare but serious side effects mainly associated with combined oral contraceptives, such as blood clots, deep vein thrombosis, or pulmonary embolism.

#### *Indirect benefits to future clients at HGOPI and elsewhere in Cameroon*

Once we understand the effects of the discounted and free FP services on client behavior, satisfaction, and outcomes, it will be up to HGOPI and the responsible health officials in Cameroon to incorporate the study findings into policies to improve RMNCAH. In addition to decreasing maternal mortality and unintended pregnancies, potential indirect effects for the community include:

- increased welfare from reduced side effects that arise due to current one-size-fits-all FP counseling,
- healthier children due to improved birth spacing, and
- increased human capital formation both for children and for young (often school-aged) potential mothers.

#### *Global knowledge generation*

The study aims to make a number of contributions to global knowledge in family planning:

- The use of a tablet-based job-support tool in family planning,
- The importance of designing family planning counselling to empower clients to make choices that are more informed and better suited for the needs and preferences,
- The importance of reduced prices (or free provision) for modern contraceptives,
- Employment of adaptive experimentation techniques to learn about the effectiveness of interventions tailored to each client's context, and
- Follow-up interviews with clients to assess rates and reasons for method continuation, switching, or discontinuation.

### *Risks to study participants*

As mentioned above, since our research is focused on studying the effect of slightly different counseling approaches and reduction of prices for contraceptives on method choice, there are no other risks than privacy breaches. Our study is not a clinical trial, where a new drug or a medical product is being trialed, where there are other harms that need to be considered. The clients presenting at HGOPY – with or without our study – already get counseled and adopt all contraceptive methods under consideration in our study. The expected outcome is simply a change in the method mix among the target population.<sup>9</sup>

With regards to the risk of a breach of privacy, we argue that the likelihood of this is minimal in our context for two reasons. First, the sensitive data are already kept in two locations at HGOPY: in physical family planning registers and in the hospital's own administrative records. The additional probability of a breach of privacy because of this study is very small. In fact, the study may reduce this risk by eliminating the need for double entry of sensitive PII data; requiring dedicated and more secure servers for these data; and encouraging better data handling practices by hospital staff. Access to the job-support tool on each tablet requires a pre-assigned user ID and password. Each provider will be instructed to transmit data to the dedicated and secure server daily. Transmitted data will be deleted from the tablet once transmission is successful.

Second, the data management protocol envisioned for this study has the providers regularly upload the data for each family planning counseling session they conduct from the tablets to a dedicated server – accessible only by one medical personnel employed at HGOPY, who is bound by doctor-patient confidentiality. The server will be dedicated only for the purposes of the study; will be password protected and encrypted; only accessible to the server administrator bound by doctor-patient confidentiality, and off-limits to the study team.<sup>10</sup> The server administrator from HGOPY, who will serve as the liaison between the research team and the hospital, will be responsible to *de-identify* the data by removing any PII (name, surname, and telephone number) for each client who has withheld consent (or assent), and share the data with the research team on a weekly basis.

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<sup>9</sup> It is true that using combined oral contraceptives (COC) as a birth control method can very slightly elevate the risk of developing blood clots, even though this risk remains below the risks caused by pregnancy or during the first 12 weeks after giving birth. According to the U.S. Food and Drug Administration, out of every 10,000 women taking COC, 3 to 9 of them will develop a blood clot, compared with 1 to 5 women who are not pregnant and do not use COC. Furthermore, not all blood clots result in a pulmonary embolism. Therefore, the chances of clients in the study developing a blood clot are extremely small: of the maximum number of 3,000 subjects, only some of them will adopt the COC, meaning that we can expect less than 1 to 3 individuals to develop a blood clot and an even lower chance of someone experiencing deep vein thrombosis or pulmonary embolism. However, if any study participant using the COC presents at HGOPY with one of these severe side effects, the study protocols require HGOPY to provide treatment for the condition free of charge and the hospital will be reimbursed by HEREG under the terms of the performance-based financing contract.

<sup>10</sup> The dedicated server is hosted by Amazon Web Services (AWS) and is compliant with various assurance and certification programs, including the Health Insurance Portability and Accountability Act (HIPAA) of the USA, the EU Data Protection Directive, Privacy Acts of Australia and New Zealand, among others. Therefore, it is compliant with the highest standards of security to protect the privacy and confidentiality of clients and will only be accessed by a person authorized by the HGOPY administration through a username and password.

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