

ASSESSING THE COMPLETE MARKET FOR FAMILY PLANNING FROM THE CONSUMER'S PERSPECTIVE

STUDY PROTOCOL

Study Site

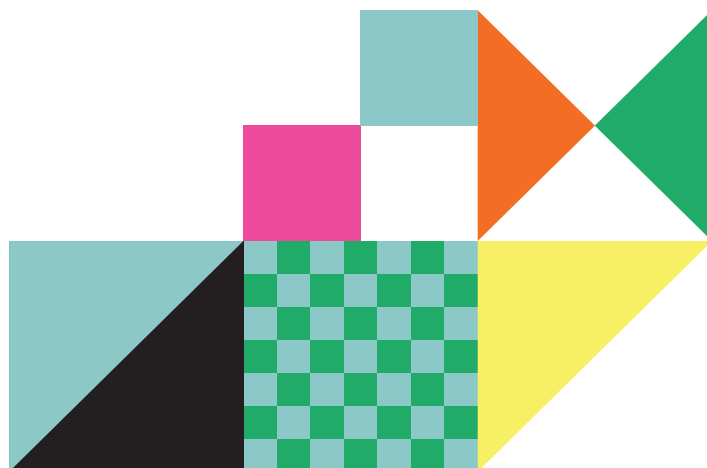
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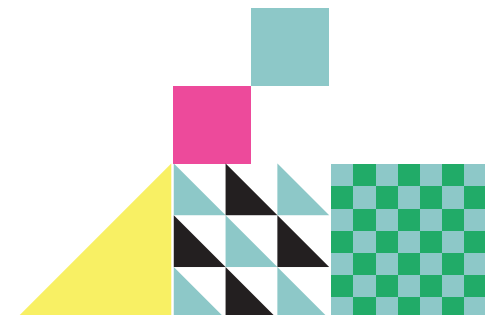


CM4FP
FP Consumer-Market Insights
by PSI



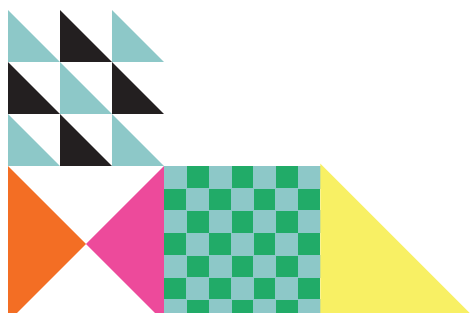
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ACRONYMS

CM4FP	Consumer's Market for Family Planning
CYP	Couple years of protection
DHS	Demographic and Health Surveys
FP	Family planning
IUD	Intrauterine device
LARC	Long-acting reversible contraceptive
mCPR	Modern contraceptive prevalence rate
PI	Principal investigator
PMA Agile	Performance Monitoring and Accountability Agile
PMA2020	Performance Monitoring and Accountability 2020
PSI	Population Services International
PSK	Population Services Kenya
SDPs	Service delivery points
SFH	Society for Family Health, Nigeria
USD	United States dollar



ABSTRACT

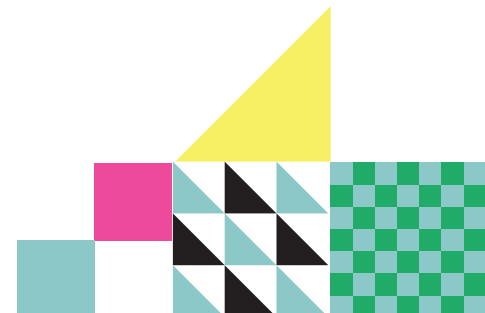
The consumer's market for family planning: Assessing the complete market for family planning from the consumer's perspective

Background: Even though substantial resources have been allocated to resolving various supply-side barriers to FP use in the recent decades, comprehensive data on the FP market from the consumer perspective is lacking. Prevalent survey approaches have failed to answer important questions related to how the supply-side and the consumer perception of the FP market interact, and where and why consumers access FP commodities. This means that multi-level FP actors do not have the necessary data for informing evidence-based decisions on resource allocation and intervention strategies to adequately meet consumers' needs.

Objectives: The Consumer's Market for Family Planning (CM4FP) is a pilot study which aims to address these data gaps by producing high quality contraceptive market data that is matched to consumer data to provide a robust picture of the "complete market" for family planning as it is and as it appears to consumers. The study will be carried out in select areas within three priority countries including Kenya.

Study design: this study will test an innovative survey approach for measuring contraceptive commodities, availability, and market dynamics and their localized impact on FP uptake and use. This involves: 1) a longitudinal survey of all outlets offering FP commodities in select geographies and 2) a repeated cross-sectional survey of women of reproductive age living in the same localized areas as the surveyed outlets. The outlet survey will involve a full audit of all FP products available at all outlets plus interviews with providers to understand volumes of sales, product stock-outs, prices, and different aspects of service readiness. In addition to collecting data on knowledge and perceptions of contraceptive availability and accessibility, the household survey will provide an opportunity for women to identify which outlets they obtain their FP methods and services from, through linkage with the outlet survey data. Data for both surveys will be collected and analyzed concurrently on a quarterly basis.

Study duration: July 2018 to October 2021



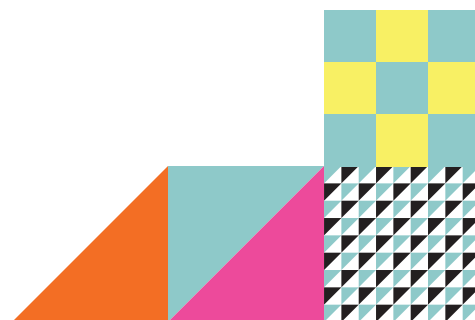
1.0 BACKGROUND

Family planning (FP) is known to be an effective and cost-effective tool for reducing the burden of both maternal and infant morbidity, improving newborn health outcomes, and bringing about socioeconomic gains for a society at large through reductions in fertility and population growth.^{1,2,3} Globally, the use of family planning among women has taken off in the recent decades. In 2017, an estimated 715 million women of reproductive age who are married or are in-union (i.e., 58% of women in this population) were using a modern method of contraception, which represents an increase of 22% since 2000.⁴

Despite the positive trend, the uptake of FP among the populations that would benefit the most from it remains too low. The Guttmacher Institute estimates that nearly 214 million women living in developing countries across the globe want to prevent or delay pregnancy but are not using a modern method of contraception.⁵ This unmet need for FP, as it is called, is greatest in Africa, where more than 46 million women who are married or are in union would like to prevent or delay childbirth but are not using a modern method of contraception.⁶ This signals the presence of multiple barriers to uptake that may include limited access to methods, lack of awareness about family planning methods and/or their benefits, concerns about side effects, and other issues such as cultural norms against use. In Kenya, for instance, where approximately 43% of all pregnancies are reported to be unintended,⁷ the proportion of reproductive age women who have an unmet need for family planning is 17% for women who are currently married or in-union⁸ and 26% for those who are sexually active and unmarried.⁹ This means that roughly 1.3 million women in the country are not using contraception but say they would like to avoid pregnancy. Millions of other women in Kenya lack awareness of the potential benefits of contraception, are misinformed about the full range of modern methods available, or were left unsatisfied with their previous experiences of using contraception.¹⁰

In recognition of the needs of women and girls living in Kenya and beyond, Family Planning 2020 was launched as a major international initiative at the 2012 London Summit on Family Planning, with the goal of “expanding access to family planning information, services, and supplies to an additional 120 million women and girls in 69 of the world’s poorest countries by 2020.”¹¹ During this meeting, various stakeholders including national governments, civil society organizations and donors committed US\$2.6 billion worth of resources toward this goal, with the intention of using the resources to tackle the key issues that face family planning use such as supply chain and service delivery barriers, insufficient demand among women, and shortage of innovations in contraceptive technologies. Kenya made a commitment at this Summit to protect individuals’ rights to good-quality reproductive health care, including family planning information, services, and supplies. To match this commitment, Kenya’s budgetary allocation for family planning grew from US\$2.5 million in 2005–2006 to US\$6.6 million in 2012–2013.¹²

Since the launch of FP2020 in 2012, an additional 38.8 million women have begun using a modern method of contraception globally¹³ and Kenya has come to realize a tremendous growth in its modern contraceptive prevalence rate (mCPR), surpassing its FP2020 target of 58 percent by 2018 to reach its current mCPR of 61%, and subsequently setting new family planning targets of 66% mCPR by 2030 and 70% by 2050.¹⁴ While this progress represents an important gain that is above historic trends, both globally and in Kenya, much more work remains to be done in order to realize the ultimate goal of adding 120 million new users by 2020 globally. In Kenya, specifically, the main challenge that remains is closing the gap in regional disparities, which show some counties reporting a CPR as low as 2% and



others reporting theirs to be as high as 76%. Similar disparities exist in unmet need. These gaps have been attributed to inadequate service provision, poor access to family planning commodities, and lack of support for contraceptive security because of overdependence on donor funding.¹⁵ These gaps suggests the need for new approaches that can augment existing efforts to expand the coverage of family planning.

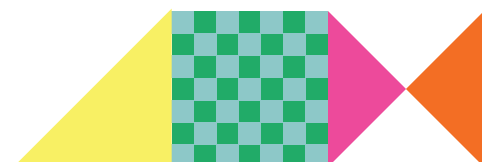
Traditionally, efforts to promote the uptake of family planning have focused on demand generation activities, supply-side activities, or a mixture of both. Demand generation interventions seek to change knowledge, attitudes, and practices around family planning, while supply-side interventions aim to increase access (including to a wider method mix), improve quality, and lower costs for family planning services. Supply side interventions currently receive a substantial share of family planning resources, and this may be warranted given that supply issues are often cited as barriers to addressing unmet need and given the evidence suggesting positive effects of such interventions on contraceptive use.¹⁶ However, the fact remains that not enough is known about how consumers experience, perceive and respond to various supply side issues. Without a comprehensive understanding of the family planning market as it appears to the consumer (rather than assumptions made from top-down extrapolations), family planning actors and decision-makers cannot adequately and cost-effectively identify or address supply-side barriers to contraceptive use.

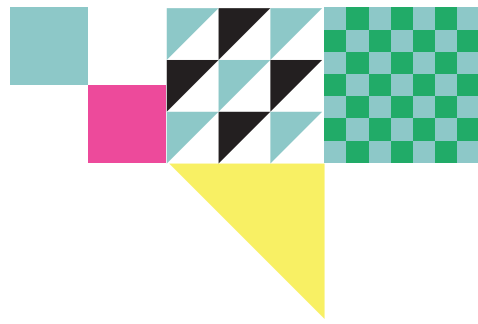
The Consumer's Market for Family Planning (CM4FP) study, funded by Bill and Melinda Gates Foundation (referred to as "the Foundation" or "the donor") as part of its recent portfolio of investments seeking to better understand the family planning market dynamics, will pilot an innovative survey approach to address this critical and persistent evidence gap in consumer data related to the total family planning market. Focused in three strategic foundation countries, Kenya, Nigeria, and Uganda, this project will build upon lessons learned from PSI and the foundation's previous partnerships under the successful FPwatch initiative, which shed light on contraceptive availability, price, and relative market share in the study countries. It will

test a new methodology for measuring contraceptive commodities, availability, and market dynamics; and their localized impact on family planning uptake and use. This protocol outlines the study that is to be carried out in Kenya, in close collaboration with PSI's local affiliate, Population Services Kenya (PSK), and with broad engagement with multi-level stakeholders within Kenya to ensure applicability and uptake of the survey methodology and data collected.

2.0 PROBLEM STATEMENT

Despite allocating substantial resources to resolving various supply-side barriers to contraceptive uptake and use, the family planning field lacks comprehensive family planning market data from the consumer's (e.g. current and potential user's) perspective. Although there has been significant progress in the collection and analysis of robust family planning data globally, prevalent survey approaches have failed to answer important questions related to how the supply-side and the consumer perception of the family planning market interact, and where and why consumers access family planning commodities. Most existing data attempting to link the family planning supply and demand markets together reflect correlations of aggregated data on supply or stock and family planning use and/or need, rather than representing measures of true access. Therefore, existing data fail to clarify how supply-side constraints at the consumer level encourage or impede contraceptive use. This missing data is critical to providing family planning decision-makers, including government ministries, health care providers, and retail outlets, the information that is needed to inform evidence-based decisions on resource allocation and intervention strategies that better meet the needs of family planning consumers. Without a comprehensive understanding of the total family planning market, family planning actors cannot adequately and cost-effectively identify or address supply-side barriers to contraceptive use. This can lead to discounting or improper measuring of the private and unregulated markets that supply the majority of contraceptive products in many countries including Kenya.





3.0 REVIEW OF THE LITERATURE: CURRENT DATA GAPS

A dearth of comprehensive data on the consumer perspective of the complete family planning market leaves many unanswered questions about the actual supply-side factors that impact family planning use. Research to date on contraceptive supply provides insight on only some pieces of this supply-side puzzle. Perhaps most notably, the Demographic and Health Surveys (DHS) and Performance Monitoring and Accountability 2020 (PMA2020) surveys collect data on Service Delivery Points (SDPs), but both take only a sample of registered facilities and exclude the pharmacies and unregistered outlets that make up a substantial portion of the market in many settings. Moreover, both DHS and PMA2020 use small samples of facilities (e.g. up to three public and three private SDPs per cluster), leading to the question of whether these sampled facilities are representative of the survey population and leaving uncertainty about the validity of this sampling approach. A recent systematic review of articles describing mechanisms for linking household and facility data noted that the majority of studies link these sources of data by geographic proximity, which make a wide range of assumptions about consumers, including around where they likely obtain their family planning methods, and thus creates questions about the validity of results. To date, there have been no head-to-head comparisons between this kind of indirect linkage and direct linkage of household and facility data in order to understand whether validity of results is truly a concern and to what extent it is.¹⁷

Additionally, the vast majority of family planning supply-side studies do not directly link supply data with corresponding data on the consumer perspective or measurements of demand-side factors. For example, while both DHS and PMA2020 ask current contraceptive users where they obtained their modern method, this cannot be directly matched with comprehensive data on the supply landscape. Therefore, existing data do not lend themselves well to ascertaining whether users are obtaining their method from a “preferred” source (based on quality

or personal preference) or from a source selected as a function of convenience, availability, or proximity. Geographic proximity to products and services, while widely cited as a barrier to contraceptive uptake, is a particularly problematic measure with the current data. This is especially the case in urban areas, where nearly all measures of proximity use either a respondent’s reporting of nearest facility/source or estimates of proximity calculated from the sampled SDPs. Previous studies have found that using this approach to measure distance to nearest facility can result in misclassification as high as 50%, often under-estimating access to services.¹⁸

At the other end of the market relationship, supply chain data that is designed to monitor contraceptive supply down to the “product on shelf” level yields limited information on consumer experiences or perspectives of availability for two main reasons: 1) the most readily available supply chain data generally only follows public sector distribution, and 2) supply chain data does not include broader measures of availability that directly impact a consumer’s ability to access a product that is technically “on the shelf” (e.g. service readiness for methods that require credentialed staff and equipment). Likewise, routine service statistics are generally only available for public sector facilities or the larger registered private sector facilities that offer family planning, excluding a large portion of the total market for contraceptives which include unregistered facilities and informal outlets.

To date, the most comprehensive supply-side data was collected through the FPwatch surveys carried out by PSI in Ethiopia, Democratic Republic of Congo, Nigeria, and India.¹⁹ These surveys, whose goal was to collect robust supply market data that can be used to inform strategic family planning decision-making for increasing contraceptive coverage and choice, selected clusters, implemented censuses of all outlets that distributed contraceptives, and carried out full audits on all family planning products (types

and brands) and stock levels in order to describe contraceptive availability, price, and relative market share. However, because these surveys were cross-sectional single-wave studies in each country and were not matched with survey data on individuals and demand-side factors in the study geographies, they did not provide data on changes over time or on the consumer perspective of supply and stock in these areas.

4.0 RESEARCH OBJECTIVES

Building on the FPwatch surveys, the CM4FP project is a pilot study, to be implemented in select geographies in Kenya, Nigeria and Uganda, which is aimed ultimately at addressing these critical data gaps in consumer perspectives on the family planning market. Its specific aim is to produce high quality contraceptive market data and data on consumers in the same localities that can be matched with each other to provide a robust picture of the “complete market” for family planning as it is, and as it appears to consumers.

The study will entail piloting a new methodological approach which involves fielding repeated surveys at all outlets offering family planning commodities in a set of localized geographies (i.e., a “ringed fence” census), to be carried out concurrently with a household survey exploring perceptions of contraceptive supply, demand, and consumer behavior among women of reproductive age in those same locations. The longitudinal outlet survey, which will be carried out quarterly over the course of one year and will include a full audit of all family planning products (types, brands, formulations and manufacturers) and stock levels, will not only shed light on the local contraceptive commodity availability but will also present a unique opportunity to examine the supply market dynamisms. Furthermore, there will be a direct linkage of this data on the supply landscape with the data from local consumers and thus giving insight to the localized impact of the supply market and its dynamism on family planning uptake and use.

As a secondary aim, CM4FP pilot data will be compared to current sampling and data collection approaches of other large-scale data collection efforts, including DHS and PMA2020, to understand the strengths and limitations of this new data collection approach in addressing the gap around the family planning supply market and interaction with the demand market.

5.0 RESEARCH QUESTIONS AND HYPOTHESES

There are three main study research questions which are exploratory in nature. They are outlined below with the respective hypotheses that will be tested.

5.0 RESEARCH QUESTION 1

DO SUPPLY-SIDE CONSTRAINTS MODIFY THE CONTRACEPTIVE BEHAVIORS OF CONSUMERS?

5.1 HYPOTHESIS 1

SUPPLY-SIDE CONSTRAINTS DIRECTLY MODIFY THE CONTRACEPTIVE BEHAVIORS OF CONSUMERS.

6.0 RESEARCH QUESTION 2

DO CONSUMERS ALWAYS GO TO THE GEOGRAPHICALLY MOST PROXIMAL SDP FOR CONTRACEPTIVE SERVICES?

6.1 HYPOTHESIS 2

CONSUMERS DO NOT ALWAYS GO TO THE GEOGRAPHICALLY MOST PROXIMAL SDP FOR CONTRACEPTIVE SERVICES.

7.0 RESEARCH QUESTION 3

DO THE CURRENT LARGE-SCALE SURVEYS (SUCH AS DHS AND PMA2020), WHICH INCLUDE A SMALL SAMPLE OF SDPS, PROVIDE REPRESENTATIVE SUPPLY-SIDE INFORMATION?

7.1 HYPOTHESIS 3

CURRENT LARGE-SCALE SURVEYS UNDER-SAMPLE SDPS, AND THEREFORE PROVIDE LESS THAN REPRESENTATIVE SUPPLY-SIDE INFORMATION.



These three hypotheses are supported by the set of learning questions outlined below. The learning questions address different aspects of the primary study objectives.

1.0

IN A SET OF LOCALIZED GEOGRAPHIES, WHAT ARE THE ASPECTS OF THE RELATIONSHIP BETWEEN CONTRACEPTIVE SUPPLY AND USE OF/DEMAND FOR FAMILY PLANNING THAT CAN BE MEASURED AND/OR LINKED?

2.0

HOW WELL DO THE MOST COMMON CURRENT SAMPLING FRAMES FOR SDPS REPRESENT THE ACTUAL SERVICE DELIVERY ENVIRONMENT IN A GIVEN LOCALITY (E.G. SURVEY CLUSTER)? MORE SPECIFICALLY, ARE THE CURRENT DHS AND PMA2020 SDP SAMPLES SUFFICIENTLY REPRESENTATIVE OR DO THEY NEED LARGER SAMPLES, NEW SAMPLING TECHNIQUES, OR DIFFERENT SAMPLING FRAMES?

3.0

HOW ACCURATELY DO CONSUMERS AND POTENTIAL CONSUMERS KNOW THE CONTRACEPTIVE MARKET? DO CONSUMER PERCEPTIONS (E.G. OF COMMODITY AVAILABILITY, GEOGRAPHIC DISTANCE TO NEAREST OUTLET, PRICING, ETC.) MATCH OR DEVIATE FROM THE “TRUE SUPPLY” DATA COLLECTED FROM THE SDP/ OUTLET CENSUS?

4.0

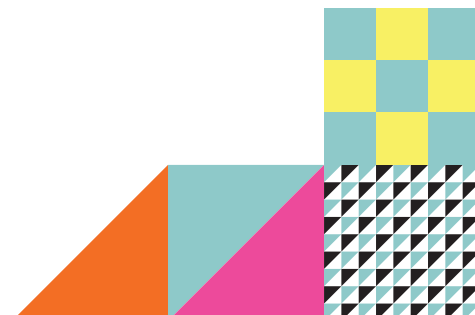
WHAT PROPORTION OF CONTRACEPTIVE USERS OBTAIN THEIR FAMILY PLANNING METHODS OR SERVICES AT THE NEAREST SDP (E.G. THE OUTLET CLOSEST TO THEIR PLACE OF RESIDENCE, AS CAPTURED IN HOUSEHOLD SURVEYS)? IS “CLOSEST SDP” AS MEASURED IN MOST SURVEYS (EITHER AS REPORTED BY RESPONDENTS OR DISTANCE TO CLOSEST KNOWN FACILITY) A VALID MEASURE?

5.0

HOW DYNAMIC IS THE FAMILY PLANNING COMMODITY MARKET OVER A 12-MONTH PERIOD? IS IT SUFFICIENTLY DYNAMIC (E.G. ENOUGH CHANGES IN STOCKS, METHOD CHOICE, AND AVAILABILITY) TO WARRANT QUARTERLY TRACKING FOR A MEASURE OF “TRUE SUPPLY” OR WOULD COLLECTING OUTLET DATA WITH LESS FREQUENCY SUFFICE? OR IS COMMODITY TRACKING ON A LESS FREQUENT BASIS (E.G. ANNUALLY OR BI-ANNUALLY) SUFFICIENT?

6.0

TO WHAT EXTENT DO COMMODITY STOCK/STOCKOUTS HAVE AN IMPACT ON CONTRACEPTIVE USE WITHIN A LOCALITY? HOW DO CONSUMERS BEHAVE IF THEIR METHOD OF CHOICE IS STOCKED OUT AT A PARTICULAR OUTLET? DOES LENGTH OF STOCKOUT MATTER? DO STOCKOUTS ONLY HAVE A MEASURABLE IMPACT IF THERE IS ANY STOCKOUT OR ONLY ABOVE/BELOW A PARTICULAR THRESHOLD? FOR EXAMPLE, DOES A STOCKOUT OF INJECTABLES AT A PARTICULAR OUTLET TYPE HAVE LITTLE/ NO IMPACT SO LONG AS MOST OF THE SAME OUTLET TYPES DO HAVE STOCK? IF SO, AT WHAT POINT DOES A LOCALIZED STOCKOUT HAVE A DISCERNIBLE ASSOCIATION WITH USE/DISCONTINUATION AND WHEN DOES IT NOT? AND IS THERE DIFFERENTIAL IMPACT OF STOCKOUT ON CONSUMER BEHAVIOR BASED ON CONTRACEPTIVE METHODS?



6.0 STUDY DESIGN

6.1 OVERVIEW OF DESIGN

The CM4FP study is composed of two quantitative surveys, to be carried out concurrently within each selected study region.

A longitudinal survey of all outlets offering family planning methods and/or services within each selected survey area. This is referred to as a “ringed fence census”. This survey will be carried out in four rounds over a period of one year, so data will be collected and analyzed quarterly. This survey is mainly aimed at identifying all outlets that carry contraceptives and all contraceptives currently on the market (including product type, brand names, formulations, and manufacturers) in the defined geographical areas. Identification of all outlets that carry contraceptives will be done through an outlet census screening and mapping. This activity, which will produce maps that reflect family planning service delivery points and other outlets with the potential to sell or distribute modern methods of contraception, will be conducted in Round 1. It will then be repeated in Round 4 in order to identify any changes in the supply market in terms of new outlets that may have emerged. The identification of all contraceptives that are currently in the market will be accomplished through product audits that will be completed at each eligible outlet at every survey round.

A repeated cross-sectional survey of women living in households that are randomly sampled from within the outlet survey ring fence. This survey will also be carried out in four rounds over a period of one year, so data will be collected and analyzed quarterly, in tandem with the outlet survey. Unlike the outlet survey, this household survey is not longitudinal. A new random sample of women will be drawn and interviewed at each round. This survey is focused on capturing information about women’s family planning use history, experiences and perceptions of receiving family planning services and products from outlets, choice of outlets that women frequent to obtain

such products and services and factors driving this choice, and their level of knowledge of the supply market in general.

See Figure 1 below for an overview of the data collection timeline which shows the ordering of activities.



Fig 1: timeline showing repeated survey waves through a 12month period of fieldwork

6.2 GEOGRAPHICAL AREAS OF FOCUS

The study will take place in a few selected geographies in Kenya, namely, Nairobi, Nakuru, Kilifi and Migori. Given that this study is a methodological pilot looking to answer research questions that are largely broad and exploratory in nature, there is no intention for these selected areas of focus to produce data that are representative at the national, regional, or County levels. Rather, the areas will allow for a deep-dive through comprehensive data collection exploring the local supply and demand interaction.

Through close collaboration between PSI, PS Kenya, and the donor, these areas were selected purposefully to be suggestive of trends in geographies that meet specific strategic purposes. Selection was driven partly by considerations of the donor's priority areas.

An important focus of this study, and main consideration for the selection of geographies, is to understand the family planning market in the urban landscape. Urban settings are of special interest for this study given that the outlet census approach provides an advantage of capturing the breadth of private facilities and outlets, which tend to be more heavily concentrated in urban areas. In the typical sampling approach that many studies take, these private facilities and outlets would be left out. The varying sizes of urban areas are also of strategic interest. The study seeks to do a deep dive of a major urban area (which Nairobi represents), an urban area of medium size (which Nakuru represents), and a smaller urban area (which Kilifi represents). Smaller urban areas are of particular interest given how little we know about the family planning market in these settings and the fact that they make up the largest proportion of the "urban" population throughout sub-Saharan Africa. This study also aims to generate some insights for peri-urban and/or rural area given the dearth of FP data that exists for these areas. Therefore, one peri-urban area was selected (Migori).

Migori county also serves the purpose of exploring the research question which aims to understand how well current surveys capture the actual service delivery environment in a given locality. Performance

Monitoring and Accountability Agile (PMA Agile), is an ongoing study, funded by the same donor, which collects quarterly family planning supply data from a sample of facilities in various geographies including Migori. By choosing an overlapping geography, we would be able to better understand the strengths and limitations of the PMA Agile sampling approach compared to the CM4FP census approach.

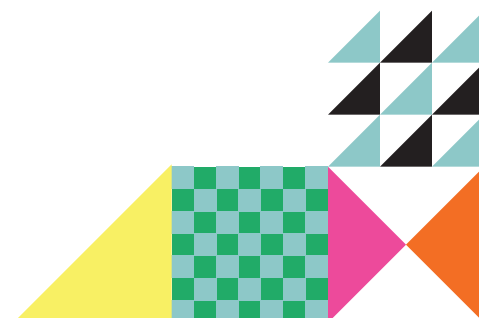
6.3 OUTLET SURVEY METHODS

STUDY POPULATION

The outlet survey is a study of all facilities and outlets that provide modern family planning commodities or services. In Kenya, this includes public health facilities, private facilities (for profit and not-for-profit), pharmacies, dispensaries, and drug stores. In addition to these static outlet types, mobile community health workers (CHWs) who work within the community to provide FP products and services to community members in their homes and in community locations, will be included in the outlet survey. The study will include both outlets that are registered and ones that are unregistered, though it will not seek to obtain information about registration status.

SAMPLE SIZE AND SAMPLING PROCEDURES

Given that this study is an exploratory pilot that takes on a census approach, there is no statistically predetermined number of outlets and CHWs that is sought based on a given level of precision. Using the census approach means that all outlets and CHWs in each selected area make up the sample size. Given this and given the limitations of budget and the high frequency of data collection within a short timeframe, a further selection of sub-geographies within the selected areas will be made in order to ensure that the study is manageable within resources while providing the intended deep-dive into localized family planning markets. Based on the available data collection



budget, a maximum number of outlets (including CHWs) across all 4 geographies has been determined to be 600 (150 per geography, on average). With this number as a guide, and using existent data on outlet densities within and across these geographies in addition to information about socio-demographic characteristics, a determination was made about the specific regions within Nairobi, Nakuru and Migori Counties, and within Kilifi that will be selected for the study. The final selections are made up of contiguous Administrative Wards within which a census will be conducted for the outlet survey.

TABLE 1. KENYA COUNTIES SELECTED FOR THE SURVEY

COUNTY
Nairobi
Nakuru
Kilifi
Migori

INCLUSION CRITERIA

Outlets with the potential to provide modern family planning methods and/or services will be screened, meaning that eligibility to participate in the survey will be assessed. Participation in the survey involves being part of a product audit and provider interview. Outlets will be invited to participate in the study if they have modern contraceptive methods or services available, with availability defined as having at least one modern method, beyond condoms, in stock at the time of the survey or within the past three months; or offering contraceptive services, beyond counseling, such as intrauterine device or implant insertions and removal. Modern family planning methods and services which are used in this eligibility determination are: male and female condoms, oral contraceptive pills, emergency contraceptive pills, contraceptive injections, contraceptive implants, hormonal and copper-based intrauterine devices (IUDs), male sterilizations, and female sterilizations. If an outlet has at least one of these method (besides

condoms) or services available on the day of screening or in the prior three months, then it is eligible to participate in the survey. Outlets which have only condoms available now and in the prior three months are excluded because condom availability is almost ubiquitous and the study is intended to survey only outlets which make up the broader family planning supply market.

In this study, CHW is being used as an umbrella term to include all available varieties of mobile health workers or volunteers who have the official role of working within the community to provide health services to people. This includes people with the job titles, “Community Health Extension Worker” and “Community Health Volunteer”. To be considered for inclusion, these CHWs need not have a formal linkage to existent static health facilities, to government, or to NGOs (including faith-based organizations, FBOs) that operate in the area, whether public or private, though it is expected that most will have such linkage. CHWs who provide FP services informally (i.e., CHWs who are not officially qualified as CHWs and those who have the proper qualification as CHWs but independently provide services to women in the community without any formal registration) in the communities of interest will be included in the study in order to meet the study’s goal of capturing the complete FP supply market as it is and as it appears to consumers. If the initial rounds of the survey reveal that most women do not access FP methods through CHWs (as may be expected in this largely urban-based study), and where we have confidence that CHW activity is reflected largely in the data captured from static facilities (which is expected), a decision will be made to exclude CHWs from the remaining follow-up Rounds of the study.

Furthermore, similar to static outlets, inclusion in the study will be limited to CHWs who have modern contraceptive methods or services available, with availability defined as the CHW offering at least one modern method, beyond condoms, at the time of the survey or within the past three months; or offering FP services such as contraceptive injections, intrauterine device insertions or removals, or implant insertions or removals. This refers to products and services that the CHW is able to provide himself or herself and

not those which are available at the static facility to which the CHW is tied. By current policy, the only FP service that CHWs in Kenya are allowed to provide is injections. They are not allowed to provide implant and IUD insertions and removals officially. However, there may be cases where CHWs provide these more advanced services against policy or in the context of ongoing research or service delivery pilots, and we intend to capture these cases in our survey as they are part of the FP supply market picture.

EXCLUSION CRITERIA

The following types of outlets will be excluded from the survey: those that serve the military and do not serve the general public; outlets such as bars, hotels or brothels where condoms are typically available, but other modern family planning methods are not available; outlets which are eligible to participate but do not provide informed consent to participate.

To minimize double counting, CHWs who only work within static outlets will be excluded, as the facility where they work will be considered for inclusion in the outlet survey. CHWs who are eligible to participate but that do not provide informed consent will also be excluded. By default, CHWs that are tied to facilities which refuse to participate in the outlet survey, and therefore from whom CHW contact information cannot be obtained, will automatically be excluded from the survey. The exception to this latter exclusion criteria is where community key informants, local health authorities, or local NGO partners separately identify some of these CHWs who will then be included in the survey upon consenting (please see section 7.2 for further details on how CHWs will be identified and recruited into the study).

6.4 HOUSEHOLD SURVEY METHODS

STUDY POPULATION

The household surveys will include women who live within the localized regions where the outlet survey will be conducted. Inclusion and exclusion criteria are outlined in the table below. The survey will include both women who have ever used family planning and those who have never used family planning. There will be a special focus on those who have used

family planning in the past 12 months regardless of current use status, as we are seeking to learn about women’s experiences of recent encounter with the family planning supply market. Thus, contraceptive use is not part of the eligibility criteria. While non-users are not the primary focal population for the objectives of this study, insights into their general knowledge of the supply market warrant exploration as these non-users may become users in the future.

TABLE 2. HOUSEHOLD SURVEY ELIGIBILITY CRITERIA

INCLUSION	EXCLUSION
<ul style="list-style-type: none"> • Woman • Ages 18-49 • An identified member of a household in the selected geography 	<ul style="list-style-type: none"> • Man • Under the age of 18 or over the age of 49 • Not an identified member of a household in the selected geography • Eligible women who do not give consent

SAMPLE SIZE

As in the outlet survey, budget considerations must be taken into account when determining the sample size for the household survey. Our intended sample size of “users” of modern contraception is 800 in total for all geographies (200 per geography). This target number (including those for the outlet survey) were not statistically defined, as the study is exploratory and carries no objective around attaining representativeness at any geographic level. But rather, the sample size is optimized to allow for meaningful exploration of how consumers interact with the localized family planning supply markets within the allocated study budget.

In this study, users are defined as women who have used any modern method of contraception at some point in the past 12 months (looking back from the day of their interview) while non-users are defined as women who have not used any contraceptive method (whether modern or traditional) in the past

12 months. The 12-month timeline has been applied to these definitions because we are seeking to learn about women’s encounter with the family planning market at any point in the past 12 months (a timeframe within which recall of past events can be considered reliable), even if they are not currently using family planning. This User sample size will be distributed across the four geographies evenly, allowing for 200 users per geography. The number of women that enumerators will need to approach in order to reach this number of Users will be based on the actual mCPR in each lower level geography that is targeted for the household survey. Table 1 below outlines estimates of the number of eligible women to be approached in each geography, based on the County-level mCPR from the 2014 Kenya Demographic and Health Survey (DHS). The table also presents the estimated number of non-users that would be reached while trying to reach the target number of users, given these mCPR rates. In total, about 2,221 women will need to be interviewed in order to attain the desired sample size of 800 users of family planning across the four study geographies in each study Round.

It is important to note that it is the number of eligible women approached for interview that will be fixed (indirectly by fixing the number of households), not the number of users to be reached. This means that the target sample size of Users (200) is not a minimum.

The number of users actually reached may differ in accordance with the true mCPR that exists at the lower geographic levels, in addition to the attained survey response rates. If the true prevalence of contraceptive use for each study geography is lower than that reflected in the DHS, then the number of users interviewed would be lower and the number of non-users would be higher. A maximum target number of non-users has been set to 50 per County per round, due to desire to minimize burden on non-users who are of secondary interest in this study and also to minimize associated costs. In order to implement this, a module has been added at the beginning of the tool to allow for early screening of FP use status. Once 50 non-users have been interviewed in each County, all subsequent selected women who are deemed to be non-users upon screening will be screened out (i.e., they will not complete a full interview). However, if the screening tool turns out not to be sensitive enough in discriminating between users and non-users (e.g, if we find that some of the initial 50 non-users are later deemed to be users as they progress through the interview), then this screen-out procedure will be stopped in order to avoid erroneously screening out non-users and thus jeopardizing the user sample size. Notably, no sample limit has been set for those women who have only used a traditional method of contraception in the last 12 months.

TABLE 3. HOUSEHOLD SURVEY SAMPLE SIZES PER SURVEY ROUND

GEOGRAPHY	INTENDED SAMPLE SIZE OF MODERN CONTRACEPTIVE USERS*	ESTIMATED MCPR ¹	ESTIMATED TOTAL NUMBER OF ELIGIBLE WOMEN TO BE APPROACHED TO REACH INTENDED SAMPLE SIZE OF USERS*	INTENDED SAMPLE SIZE OF NON-USERS
Nairobi	200	44%	455	50
Nakuru	200	38.4%	521	50
Kilifi	200	26.6%	752	50
Migori	200	40.6%	493	50
Total	800	N/A	2,221	200

*Users defined as those who have used FP in the last 12 months. Given that mCPR represents current users and we are including former users who used in the past 12 months in our sample and count of users, we expect to reach our target number of users before fully interviewing the number of women shown here, provided that non-response rates are not higher than expected.

¹ Modern contraceptive prevalence rate for women aged 18-49 years. Source: Demographic and Health Survey, Kenya 2014

SAMPLING PROCEDURES

Because the study intends to examine the interaction between the supply market and consumer behavior, an effort will be made to capture women who access family planning products and services from outlets within the outlet survey ring fence (i.e., the “outer ring”) rather than those located outside this fence. In order to achieve this, the sample of households will be drawn from within a boundary (called the “inner ring”) that lies precisely in the middle of the outer ring rather than covering the full boundary of the outlet survey, to minimize the chances that women participating in the household survey have visited outlets located outside of the outer ring (see figure 2 below).



Figure 2: Depiction of household survey boundary (“inner ring”) within the outlet census boundary (“outer ring”)

It is expected that the size of the inner ring selected will vary across study sites based on variations in household density and spread in those areas. Generally, the inner ring will be expected to be a small area made up of a collection of contiguous census enumeration areas, usually located across several villages but not necessarily covering entire villages. Unlike the outlet census where the outer ring covers entire Wards, the inner ring will not necessarily follow boundaries of any administrative boundary such as villages.

The most important factor for determining the size and location of the inner ring is the target number of households to be approached. With the target number of users as a starting point, and taking into account the expected rate of modern contraceptive use for each study region, along with other demographic factors such as average household size and the female population aged 18-49 (based on the latest DHS data), the number of households that needed to be sampled in each study region per study round was calculated. The biggest assumption that underlies these calculations is that the regional-level DHS mCPR used in these calculations holds at the lower Ward geographic level within which the study takes place and that it has remained largely constant since the last DHS survey. Though more recent surveys indicate some increase in mCPR across countries at the national level (and therefore possibly at the regional levels), there is the possibility that wide variations exist at lower geographic levels and that the true mCPR is higher or lower for the specific Wards where this study is being conducted in each country. Table 4 shows the results of these calculations.



TABLE 4. HOUSEHOLD SAMPLE SIZE ESTIMATION PER STUDY ROUND

COUNTY	TARGET NUMBER OF MODERN FP USERS	ESTIMATED TOTAL NUMBER OF ELIGIBLE WOMEN TO BE APPROACHED TO REACH INTENDED SAMPLE SIZE OF USERS	NUMBER OF ELIGIBLE WOMEN EXPECTED TO BE IN EACH HOUSEHOLD, ON AVERAGE*	NUMBER OF HOUSEHOLDS TO VISIT IN ORDER TO REACH 200 FP USERS IN EACH ROUND+
Nairobi	200	455	0.71	637
Nakuru	200	521	0.71	729
Kilifi	200	752	0.71	1053
Migori	200	493	0.96	514
Total	800	2,221	N/A	2948

* This is based on 2014 DHS-derived averages of 3.5 people on average per urban household (4.7 for rural area, which has been applied for Migori), 51% of Kenya population being female, and roughly 40% of females being aged 18-49 years.

+ This number will be quadrupled to accommodate the four rounds of the survey and adjusted up by 10% in order to account for expected non-response. (Note that these numbers have been arrived at based on unrounded values in the previous two columns.)

HOUSEHOLD MAPPING PROCEDURES FOR SAMPLING FRAME DEVELOPMENT

With the above household sample sizes as a starting point, household mapping will be undertaken in order to enumerate all of the residential structures and households within the inner area. This enumeration activity will yield a household sampling frame from which households will be randomly selected for interview in each survey round. Mapping will be conducted systematically along study-defined enumeration areas (EAs) within the inner ring. The number of EAs to be selected will be determined directly by the population sizes of the EAs, and because EA population sizes will not be known ahead of time, we will conduct household mapping in a progressive manner such that we keep a daily count of households identified and then stop mapping once the target number of households has been reached, but ensuring that the last EA is mapped fully. The small size and defined boundaries of EAs will allow for the flexibility needed for this progressive enumeration approach.

The EAs to be used for this activity are those established from the 2009 Kenya census and whose maps and boundary shapefiles will be obtained from the Kenya National Bureau of Statistics (KNBS) for this activity. KNBS will be consulted in order to determine how best to use these official Census EA boundaries and maps for this exercise. Where these official EA maps are not accessible, the study team will create new unofficial EAs using QGIS and Google mapping resources as a desk activity.

During household mapping, a navigation app called Maplets (described further in section 7.2) will be used to navigate the boundaries of each EA, ensuring that households are assigned to the correct EA. An ID will be assigned to each identified household and written on the outside of the structure. A sketch map of each EA will be hand-drawn, depicting the boundaries of the EA, structures within it and the IDs assigned to them, along with important details such as roads, landmarks, etc. GPS coordinates and a description of each structure will also be collected. These household

details will be entered into a standard form and, along with the sketch map, will serve to facilitate interviewers in successfully locating randomly selected households later for interview. This activity will result in a sampling frame which consists of all households in the inner ring with assigned unique IDs nested within EA IDs..

After household mapping is completed and the sampling frame is finalized, a sample of households, representing exactly a quarter of mapped households, will be drawn by the PSI research team for the first survey round. In each subsequent round, another random sample of 25% of the frame will be drawn. This sampling will be done without replacement in order to avoid visiting any household multiple times across study rounds and to maximize the opportunity to learn about experiences of the FP market for users of Long Acting Reversible Contraceptives (LARCs) who are expected to have less frequent interaction with the market than short-term method users. Sampling without replacement in this context, therefore, means that the household survey would approximate a census of the inner ring by the fourth round of the survey (i.e., all mapped households will be visited by the fourth round).

In this study, a household will be defined as a non-business structure in which at least one person regularly eats and sleeps, regardless of ownership. In cases where the structure acts as a compound, each group of people that regularly eat together will be considered their own household. In cases where the structure is an apartment complex, each individual unit within the complex will be treated as a household.

7.0 DATA COLLECTION PROCEDURES

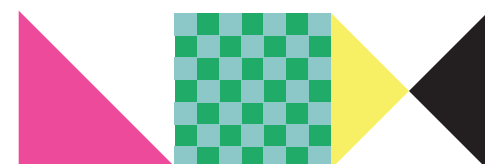
7.1 OVERVIEW

A local research agency recruited and managed by PS Kenya will oversee implementation of data collection. They will recruit survey enumerators and supervisors for the study and will participate in training and monitoring them throughout data collection. A total of 4 teams, one per geography, will be deployed for the fieldwork. Each team will be

comprised of 1 Team Supervisor, 1 Team Quality Controller and 6-7 Interviewers. The Quality Controllers will be recruited and managed directly by PS Kenya, to assure independence in monitoring of data quality. The same teams will complete both the outlet and household surveys in each region. A 10-day outlet survey training and a 7-day household survey training will be held for all fieldworker candidates with an additional day of separate training (for each survey) for Quality Controllers. The training will cover topics related to the survey procedures, instruments, and protection of human subjects. Assessments of fieldworker performance will include classroom assessments and a field exercise. Fieldworkers who do not demonstrate competency in survey procedures, instruments and protection of human subjects will not be employed on the study.

Interviewers have the primary responsibility of conducting screening, consent and interview procedures according to the study protocol. Team Supervisors are primarily responsible for coordinating activities of the team, meeting with local authorities to gain access and permissions, providing interviewers with instructions and oversight and reviewing the work of all interviewers. Team Quality Controllers are primarily responsible for ensuring adherence to the study protocol field procedures, reviewing data extracts to identify issues which may point to need for retraining enumerators, and completing backcheck interviews with a subset of interviewed outlets and households to verify information that was captured by the interviewers.

All data collection will be conducted using electronic data collection devices (tablets) containing electronic versions of the questionnaires programmed into SurveyCTO, a mobile data collection platform. This means of collecting data will allow for better data completeness and overall quality, for ease of data quality monitoring, and for timeliness of data processing and analysis. It will also facilitate the collection of geo-coordinates data, which are key for linking data from our two surveys and answering the research question regarding the proximity of outlets that consumers choose to go to.



Household interviews will be conducted in the local language of the respondent or in English, whichever the respondent desires. This will be facilitated by recruiting enumerators locally from the Counties participating in this study. All household study tools will be fully translated into the relevant local languages spoken in the study geographies (i.e., Swahili, Luo, Kikuyu, and Mijikenda). Outlet survey tools will not be translated due to the fact that respondents are expected to be largely English speakers and, therefore, enumerators will be trained to translate key concepts on the spot whenever required, with standardization of their translation ensured through training.

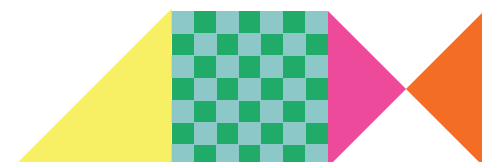
GPS coordinates will be collected automatically at the time and point of each interview for both the outlet and household survey. These coordinates will be used for quality assurance purposes and will also be included in the final dataset as they will be needed to calculate distances from women's households to the identified facilities that they have visited in the past. While GPS coordinates will be collected during the household mapping activity, this is mainly for the purpose of quality assurance (specifically, to help fieldworkers in finding randomly selected households for interview). The GPS coordinates collected during the household survey should be the same as the one collected during mapping, but where there are discrepancies, review of both will be undertaken to determine which to export into the final dataset. Methods for ensuring confidentiality of these data are described later in this protocol.

All study tools and procedures will be pilot tested well in advance of fieldwork, specifically immediately after training of the data collection teams, to ensure validity and reliability. The pilots will occur in a very small, defined geography in or near Nairobi, outside of any locations selected for this study. All members of the data collection teams will be required to participate and develop skills in all aspects of data collection procedures for both the outlet and household surveys, including following the appropriate informed consent procedures outlined for the study. For the outlet survey, this includes consenting the outlet owner or person in charge first to gain permission prior to consenting any staff; screening all outlets and CHWs

for eligibility, and completing a product audit for all eligible outlets. For the household survey, this includes mapping and listing of households and interviewing women. Each enumerator will complete at least two interviews for each survey type during this pilot. After the pilot study, the data gathered will be reviewed by the study team to help in determining where changes are needed in both the study procedures and tools. After this review, the data will be stored until the end of each quarter. All pilot data will be excluded from the final dataset and will not be shared beyond the study team. During the consent procedures for this pilot study, respondents will be informed that none of the data collected will be shared outside of the research team. A separate version of each informed consent form has been developed for this purpose. No consent will be required for the household mapping activity as that activity does not entail speaking with household residents and no sensitive information is being sought when fieldworkers do speak to someone.

FIELD MONITORING AND QUALITY ASSURANCE PROCEDURES

Daily monitoring forms will be used by all interviewers to document their progress and issues encountered. These will then serve as source for the daily summary-level reporting required of supervisors. At the end of each study round, each supervisor will complete a Ward Trip Report, summarizing all key issues encountered in the Wards that they surveyed which have the potential to affect study results. These may include road access issues, weather challenges, community activities, community pushback, team challenges, etc. The backcheck interviews completed by QCs are completed with a subset of sampled outlets and households (approximately 5%) in order to verify information that was captured by the interviewers. During a backcheck visit, QCs may collect additional data (or conduct a full interview) where the interviewer previously submitted an incomplete or missing interview. A backcheck questionnaire, which is a condensed version of each study tool, will be used by QCs for their backcheck visits, during which they will also use a specific monitoring form to document their backcheck findings. As with regular interviews, backcheck interviews are uploaded to



the SurveyCTO server and then the PSI DC team processes these together with the original interview during data cleaning.

7.2 OUTLET DATA COLLECTION

Within each of the selected clusters, interviewers will visit all outlets that have the potential to provide any type of family planning. A number of methods will be employed to ensure that all outlets with potential to provide family planning services are visited in a given sample area:

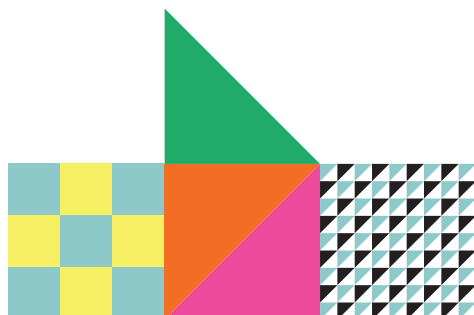
- Prior to departing for the field, survey teams will obtain official boundary maps from KNBS for selected Wards.
- Once in the field, supervisors will also approach the local administrative head for permission and to seek access to hand-picked local guides who will help the team navigate the survey area, providing necessary local knowledge and context to ensure census completeness according to current boundaries as well as safety and security
- As a measure of standardization and to prevent potential issues due to varying local perceptions of where local boundaries lie, a single set of official georeferenced boundaries will be selected to serve as a fixed reference for the local guides and enumerators in each study site. The latest and most complete administrative boundary references will be obtained as shapefiles and plotted in QGIS, a GIS application, for various map-generation activities. Where printable maps or shapefiles of official boundaries are not available or cannot be obtained from the census office, such resources from other studies may be adapted for this study.
- As an additional measure to ensure that survey teams cover the entire survey areas and adhere strictly to the identified boundaries of these areas, a software application called Maplets will be used on all data collection devices in the first survey round. This will work by exporting the boundaries

of our survey Wards into the tool to allow each data collector to view these boundaries overlaid on Google-generated base maps (which include roads and major landmarks) on her device, along with her own position on the same map as she progresses through the survey area, all in real time and while offline. In the fourth round of the survey when a full census is repeated and new outlets are identified and interviewed alongside previously surveyed outlets, to enhance data collectors' ability to readily identify outlets which are new to the market since the original survey round, these digital maps will have an additional feature of showing the location of the outlets which were surveyed in previous rounds.

- Interviewers will obtain a list of all registered facilities and pharmacies in the selected areas from national and sub-national health authorities.
- Interviewers will conduct a census of all outlets with a potential of stocking, selling and distributing family planning methods. This will entail walking/traveling throughout the entire sampled areas and enumerating all health facilities, pharmacies, and drug shops. Based on findings from FPwatch, it is expected that a large majority of general retail outlets such as supermarkets will not be eligible for this study. This will be confirmed during the pilot study and in which case this outlet category will be excluded.
- Once an outlet and CHW has been audited and the provider interviewed, they will be asked about other outlets in the area that may typically or occasionally stock family planning commodities or provide services

The following methods will be used to enlist, identify and reach eligible CHWs operating within the same boundaries where the static outlets are located:

- Prior to fieldwork, Interviewers will obtain a list of all mobile CHWs (of various types) attached to public health facilities in sampled areas from local government ministries. Names and contact information for these CHWs will be obtained, where possible.



- During the survey of static facilities, information about mobile CHWs who are tied to each facility (i.e., those who receive support, supplies or supervision) will be collected using a standard form. This includes names and telephone numbers, where possible, for making contact with them.
- Through PS Kenya's local knowledge and/or through key informants, local NGOs and FBOs that have CHWs will be identified and then these NGOs will be approached for lists of their CHWs and their contact information, if possible.
- Local key informants, who will be Community Health Volunteers (CHVs) that usually work with PS Kenya as cluster guides, will be enlisted to identify the CHWs that they are aware of who work in the community. These key informants, who have an established relationship with PS Kenya through collaboration on previous studies and programs, will be employed on a daily basis during the survey period, and will be paid an appropriate daily wage. Names and telephone numbers of target CHWs, where available, will be collected from these CHVs.
- While the intention is to include all eligible CHWs operating within the enumeration areas, some will inevitably be missed if some static outlets decline to provide contact information for the CHWs (and this automatically includes the outlets that decline participation in the outlet survey) and if the local key informants are not able to identify, locate or provide contact information for some of the CHWs that they are aware of.
- All of the lists that are built from the various sources listed above will be reconciled prior to initiating contact with target CHWs.
- After lists have been reconciled and a final list created for each enumeration area, enumerators will make contact with CHWs using the contact information provided. This will include making phone calls, where phone numbers have been made available, and visiting a specific site such as a community center where a CHW is known to provide services to the community. Where a phone number

is not available, enumerators will accompany the key informants on a search to find the target CHWs (it is expected that the key informants will know where in the community to find some CHWs). When a CHW is found, the enumerator (and not the key informant) will approach the CHW to introduce himself or herself, introduce the study, and begin the informed consent procedure. It is important for enumerators to contact the target CHWs directly (or to approach them first, in the case of in-person-contact), in order to minimize the chances that undue influence is exerted on the target CHWs through the presence of the key informants who are paid for their involvement in the study and with whom the target CHWs are likely to be familiar. As an added layer of protection, the key informants will be informed not to speak with the target CHWs about participation in the study at any point before the study team makes contact with the target CHWs.

- Once an enumerator has made contact with each target CHW, a time and location will be agreed for an interview to take place, and the CHW will be instructed to bring all FP methods that he or she usually offer to clients at the time of the interview, in order to allow for a product audit to be completed. Where a first contact is made in person and the CHW has all of his or her available methods in hand, then the interview can be completed on the spot after consent is received, if the CHW chooses. To minimize risk of CHW identification in the study, all interviews will be conducted at the facility to which each CHW is tied or at a central public place in the community where the CHW chooses. Interviews will not be conducted at the homes of CHWs.

A structured questionnaire will be used for all outlet interviews. It is expected that the questionnaire content will vary slightly across rounds based on learnings and gaps from previous rounds. A separate CHW version of the outlet questionnaires will be used for all CHWs.



In the first round, a series of screening questions embedded within the tool will be administered to all respondents to screen for initial survey eligibility. Outlets and CHWs meeting the eligibility criteria will be invited to participate in the survey and will be interviewed in all subsequent rounds while those deemed ineligible at baseline will only be screened again in the fourth round.

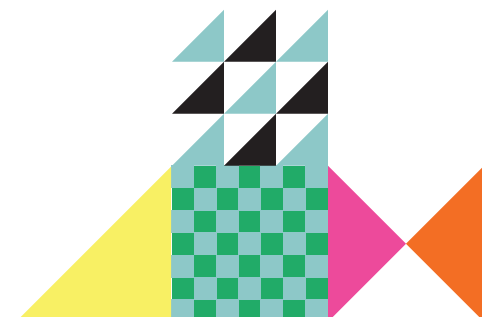
For all rounds, informed consent procedures will be followed prior to start of data collection. For static outlets, consent will firstly be obtained from the outlet owner, or in cases where there is no owner (such as a government facility) or where the owner is not available, from the person in charge such as a manager, before proceeding. There may be multiple respondents from each outlet because of the technical nature of some of the interview questions, and in this case, any and every staff member who is interviewed during the course of the visit will also be consented. Reconsent will also be obtained from each respondent who is interviewed for subsequent visits in rounds 2-4 of the survey, but another owner/person-in-charge consent will not be required.

If consent is received for an outlet or CHW, an audit of all modern family planning commodities and services will be conducted using the audit sheets in the questionnaire. The audit will capture information for each contraceptive method in stock at the outlet on the day of the survey, including brand name, price, any recent stockouts, cost and volume of procedures, and readiness to provide contraceptive services. Readiness for provider-dependent contraceptive services will be assessed for those outlets and CHWs which provide contraceptive services including injections, insertion of implants or IUDs, and provision of sterilization procedures. Readiness for service delivery will focus on three aspects: availability of the contraceptive commodity on-site at the time of the survey; availability of a credentialed provider; and availability of a minimum set of equipment needed for the service. For static outlets, a senior provider responsible for providing select family planning services will then be interviewed to capture these service readiness data.

For those outlets and CHWs that have the potential to provide commodities and/or services but do not currently, a limited set of information including methods which are stocked out, will be collected during the audit and these outlets and CHWs will be revisited during each subsequent round of data collection to track whether they come into service through the course of the project implementation period. At baseline, background information for these outlets and CHWs will also be collected. The data collection tool has been structured so that basic information about these outlets and CHWs can be obtained.

As part of data collection, the name and location of each static facility, alternative facility names that may be more recognizable in the community, and photograph of the exterior of each outlet, will be collected. For CHWs, only the CHW's real name and other names that he or she is known by will be collected but not photographs, in order to protect the privacy of the CHW. In lieu of a picture, the interviewer will write down a physical description of the CHW. These details will be used when designing and programming the household survey tool, to pre-populate questions about where (or from whom) respondents most recently accessed a contraceptive service or product.

The length of each static outlet interview will be determined mainly by whether a product audit is being completed and the number of products to be audited. On average, the round 1 interview will take about 20 minutes without a product audit, while the duration for those involving a product audit will range from 35 minutes to 60 minutes in total. The same amount of time will be expected for the fourth round, when the procedures and tools from round 1 will be used again. For the second and third rounds, each interview is expected to take about 15 minutes without a product audit, while the duration for those involving a product audit will range from 25 minutes to 50 minutes in total.



Once listing is completed for a household, the electronic survey platform, SurveyCTO, will randomly select only one eligible woman from the household to be included in the survey, if one is available. This woman could be a user or non-user of family planning. After an eligible household member has been selected from the listing exercise, the enumerator will ask to speak with the potential respondent, indicating that she is seeking to learn about her views and experiences regarding healthcare in her community. Once the potential respondent agrees to proceed, the enumerator will read the informed consent form to the woman, providing a description of the study and inviting the woman to participate. The interview will only proceed after the woman has provided oral consent and once the enumerator reads and provides a copy of the consent form. If she provides consent, then she will be interviewed on the spot if she is willing. If she is unavailable, then the enumerators will make a note to return another time. Up to three additional visits will be made to the household in order to interview the woman before she is excluded. The informed consent form will be translated into the local language(s) of each geography prior to data collection. Once a woman has consented to participation, the enumerator will continue with the survey in the language preferred by the respondent.

A structured household questionnaire will be used for all interviews, with some variation in content across rounds. Before the 50 non-users quota has been reached, each interview, regardless of the respondent's FP use history, will cover questions about the household; the woman herself including her birth history, fertility preferences, knowledge of family planning methods, and family planning use history. Women who have used FP in the last 12 months will be asked to identify which outlet or CHW, of those that were included in the outlet survey, she

has visited. FP users will also be asked questions to elicit factors affecting outlet choice, knowledge of the supply market, and reaction to supply-side issues. After the 50 non-user quota has been reached, then any subsequent non-user will only be screened for her FP use status.

The full length of the interview will vary depending on respondent's FP use history and how long it takes to attempt to match the outlets visited by the respondent, but on average is expected to take 30-45 minutes to complete for respondents who have used FP in the last 12 months and 15 minutes for those who have not (with even less time expected for those non-users being screened out once the 50 quota is reached). Each respondent will be given a small gift amounting to approximately US \$2 as an in-kind acknowledgement of her time. The gift will be a mobile air time card.

Given the aim of understanding where precisely women go for their FP methods and services, as part of this survey, outlet information collected in the outlet survey, such as picture of the outlet and name and description of the outlet or providers (including CHWs), will be linked to the household survey ahead of time, to allow for direct identification of outlets and CHWs frequented by the sample of women. During the interview, to begin the process of better linking supply and demand data, women will be asked to identify what outlet(s) or CHWs they have visited. The survey tool will allow for starting with free-response recollection of the outlet name (including alternate or informal names) followed by staff names and then outlet location. If the information provided matches with that of an outlet in the pre-populated list, the woman will then be asked to confirm through a picture of the outlet taken during the outlet survey.



8.0 PROTECTION OF HUMAN SUBJECTS AND ETHICAL CONSIDERATIONS

In order to help ensure that participants in this study are protected from risk, prior to any field piloting and data collection, all study procedures and tools will be reviewed and approved by the PSI Research Ethics Board (REB), the Kenya Ethics and Scientific Review Committee of the African Medical and Research Foundation (AMREF), and the local ethics board for each of the four Counties included in the study.

8.1 POTENTIAL RISKS

In Kenya, contraception is generally readily available, used (the national mCPR is 53.2%) and discussed with a fair degree of openness. Contraception is provided and used in Kenya with relatively little stigma attached. More stigma exists for unmarried women who are sexually active; but even still, this remains quite low, particularly in comparison with other countries in the region.

Potential risks to respondents include:

- **Breach of Confidentiality:** The most significant risk is a breach of confidentiality. In this study, a breach of confidentiality could occur if private and sensitive information from the survey is linked to an individual research respondent and this information is obtained by person(s) outside of the research project. For outlets, a related risk is the potential for recriminations for outlets that report illegal activities such as the distribution of commodities or services that are not permitted by national laws and regulations.

During the study, the following directly identifying information will be collected:

- 1. From outlets:** outlet name, type, name and age of owner and/or of other employees who complete the survey, address and telephone numbers of outlet, and photo of the outlet

- 2. From CHWs:** names (including alternate names that each CHW is known by), physical description of the CHW, contact information (for making contact), and name of outlet to which the CHW is tied

- 3. From women:** name, age, household address, and description of household structure

- 4. From both outlets and households:** GPS coordinates

- **Psychological Discomfort/Stress:** Another source of risk is psychological discomfort or stress associated with the data collection process for the women respondents as some of the questions are sensitive in nature.

- **Inconvenience Resulting from Participation in the Study:** Women respondents will be recruited at their home, at a time which may be an inconvenient time for some people, and/or some people may feel that the survey takes too long to administer. Respondents to the outlet survey will be recruited at their place of work and it may be an inconvenient time for some people to respond to the survey.

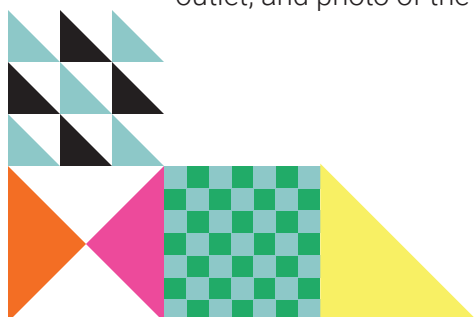
8.2 STRATEGIES TO ADDRESS RISKS

Steps will be taken to protect participants against potential risks posed by their participation in this research. All data and other information will be maintained confidentially to the greatest extent possible. The following steps will be taken to protect against risks.

PROTECTING PARTICIPANTS AGAINST BREACHES OF CONFIDENTIALITY

1. Identification on data sources.

During data collection, all data will be uploaded to a secured SurveyCTO server and will contain identifiers including names and addresses of respondents. These data will be accessible only by the study PI, Co-PIs, data analysts, and other members of the PS Kenya research team (including the research manager and members of the local agency managing data



collection, all of whom will be involved in monitoring the quality of data during data collection). Only the PI, Research Manager, and data analysts will have access to edit and download the data, while all others will have view-only access. At the end of the study, once all data have been downloaded from this server, all data will be deleted from the server by the lead data analyst or PI only.

All outlets will be assigned a sequential ID number during data collection and this will be used as the ID variable for analysis. Once outlet data are downloaded from the SurveyCTO server, all identifiers including outlet names, respondent names, addresses and phone numbers will be removed from the final datasets. No document linking the ID and these identifiers will exist. Because the study questions require geo-spatial analysis (See Research Question 2 and Learning question 4), GPS coordinates of outlets will be used to calculate distance and time matrices that will permit relational analysis between outlets and households but all GPS coordinate data, and geographic data below county/ state/ study site level will be removed from the outlet and household datasets that are publicly available. GPS and other geographic data in the datasets will only be accessible to essential research staff including the principal investigator (PI), co-PIs (those listed on this protocol), and the PSI data analysts.

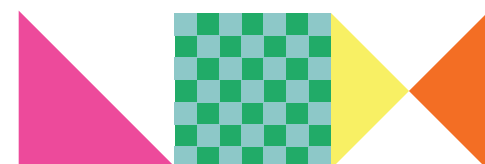
Similarly, all CHWs will be assigned a sequential ID number during data collection and this will be used as the ID variable for analysis. Once CHW data are downloaded from the SurveyCTO server, all names, physical descriptions and contact information will be removed from the final datasets. No document linking the ID and these identifiers will exist. The name of the outlet to which CHWs are tied will be replaced with the appropriate outlet ID number.

Similarly, once household datasets have been downloaded from the SurveyCTO server, all women will be assigned a sequential ID number during data cleaning. Names, addresses and description of their homes will be removed from the final datasets. No document linking the ID and these identifiers will exist. GPS coordinates for all households will be

retained in the PSI-internal datasets because it is a variable needed to answer the research questions requiring geospatial analyses and will be used to create distance and time matrices that will be made publicly available. All data that includes this household identifying information will be accessible only to essential research staff including the principal investigator (PI), co-PIs (those listed on this protocol), and the PSI data analysts. Data will be kept and used only on secured, password-protected computers. The dataset containing this household GPS data will be kept for one year beyond the end of the study (the study end date is currently October 31, 2021), to enable PSI to conduct further data analysis that will inform programming activities and retain the ability to generate additional public distance and time metrics. Confidentiality of these data will be maintained by restricting access only to the PI and data analysts and using the data only on password-protected computers. Furthermore, these datasets will be used only when the raw GPS coordinates are required. The study PI will be responsible for managing the dataset, controlling access to it, and deleting it.

The dataset stemming from the household mapping exercise will be used for data collection purposes only. Namely, for randomly selecting households and use of GPS coordinates for locating sampled households for interview. The data will be stored and accessed only by the PSI data analysts who will conduct random selection of households for each survey round. These sampling data will not be released to anyone outside of the PSI research team and will be deleted at the end of the study. Sketch maps which were drawn during the household mapping activity and which aided data collectors in locating households for interviews were scanned and stored securely electronically and the original paper copies were destroyed after scanning. These scans will be deleted at the end of the study.

When the study comes to an end, a fully de-identified dataset that contains distance and time matrices between outlets and households will be created. No GPS coordinates will be retained in the final datasets that are to be made publicly available.



The de-identified household dataset will be stored indefinitely, along with a copy of the outlet and CHW datasets. As was done in FPwatch, the datasets will be kept and managed by the PSI Strategy and Insights department after the end of this study. No GPS data will be available for outlets or households, even on special request.

All study data will be shared directly with the donor via a secure file-sharing system.

To further minimize risk of identification, oral consent will be used, and therefore respondents will not sign their names on the consenting documents.

2. Staff ethical training. All research staff including the interviewers and supervisors will be trained in human subjects' protection, especially the importance of protecting privacy and confidentiality. Training for interviewers will focus on ethical and technical aspects of data collection process to ensure proper behavior of interviewers, strict adherence to ethical procedures, and high quality of data.
3. Participants' rights. Research participants will be informed of all risks and protections in the oral consent script. Participants will also be informed of their right to withdraw from the study and to not answer any questions they do not feel comfortable answering. Respondents will be provided contact information for a PSI employee who will be available to answer any questions about the study.
4. Data reporting. All data based on this research will be reported in aggregate form. No individual respondents will be identified.
5. Place of data collection. Interviews will be conducted in quiet and private spaces of respondents' homes or in as quiet of a space of the outlet as possible.
6. Data collection and management supervision. Field supervisors will be deployed to monitor data collection to ensure that appropriate sampling and interview methodologies are being applied. Supervisors will ensure that questions are being asked appropriately and comfort level and privacy of respondent is maintained.

PROTECTING PARTICIPANTS AGAINST PSYCHOLOGICAL DISCOMFORT/STRESS

If the respondent expresses discomfort or stress during the interview, the enumerator will remind the respondent she does not have to answer questions which make her uncomfortable and will give the respondent time to recover before proceeding with data collection.

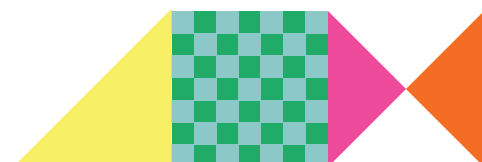
Field supervisors will monitor data collection to ensure that appropriate interview methodologies are being applied.

PROTECTING PARTICIPANTS AGAINST INCONVENIENCE

Data collection will take place in a quiet and private space of the women respondent's house. If the time is inconvenient for her, she has right to ask the enumerator to come back at a more appropriate time. Data collection for the outlet survey will take place in as quiet of a space at the outlet as possible and if the time is inconvenient, the respondent has the right to ask the enumerator to come back at a more appropriate time.

8.3 INFORMED CONSENT

All eligible participants will be asked to provide informed consent. The consent form will be translated into local languages and read aloud in the language of preference to the participant. The consent forms describe the study, the expectations for participation, and makes it clear that participation is voluntary and that declining to participate will have no negative effect on their employment or access to or quality of healthcare. Each participant will then be given an opportunity to ask questions. If s/he agrees to participate, the enumerator will acknowledge consent through a digital signature confirmation in the SurveyCTO programmed tool and the date will be automatically recorded. This process will acknowledge that the form was read in its entirety and that the respondent agreed to participate. All participants will be given a copy of the consent form.



8.4 BENEFITS

There are no direct benefits, either for those interviewed as part of the outlet survey or those interviewed as part of the household survey, to participating in this study but the results of the study will inform future data collection efforts around key family planning indicators that could lead to improvements in healthcare.

8.5 PARTICIPATION COMPENSATION

OUTLETS AND CHWS

Each outlet or CHW which participates in the study will be given a small gift during two rounds of the survey- the first and the second, in acknowledgement of the time spent providing data. Each gift will have a value of approximately US \$2.50 for a total of US \$5.00. The gift will be an item which can be used in the facility such as a notebook and pen or an apron (for outlets) or an umbrella for CHWs.

WOMEN

Each household survey respondent will be given a small gift amounting to approximately US\$2 as compensation for her time. The gift will be a mobile air time card rather than cash.

9.0 DATA PROCESSING AND ANALYSIS

SurveyCTO allows for real-time data upload, following the completion of an interview, to a central server provided a WiFi or mobile data connection is available. This in turn allows for real-time data quality assurance throughout the data collection process, which will allow for course corrections if necessary, particularly during the first round. The research team will establish routine data quality checks that will facilitate timely feedback to enumerators as needed. SurveyCTO also allows for the pre-programming of certain data quality checks within the tool itself, including the non-acceptance of invalid or inconsistent responses, to minimize data entry error.

All data will be stored on the SurveyCTO server which is password protected and only accessible to designated members of the research team, namely the PI, PSI analysts, and PS Kenya research manager. All data

downloaded for analysis will be stored on password protected computers and will be limited to the PI, the co-PIs, the PSI research team's data analysts, and the PS Kenya Research Manager who will play a key role in data quality monitoring and cleaning. Data will be deleted from the SurveyCTO server, by the study PI or lead data analyst only, at the end of each study quarter, once the quarter's report has been submitted to the donor.

Data cleaning will be done by the PSI research team, following defined procedures. Data cleaning and processing is likely to take longer for the first round of data collection and will speed up over subsequent rounds, particularly once brand names of products are pre-programmed for subsequent rounds and data cleaning codes are refined. PSI aims to preliminarily clean and process the data within six weeks following the end of data collection for rounds 2-4 and within 10 weeks for the first round. Final data cleaning and processing will be conducted after the last round of data collection.

Data analyses, also to be done by the PSI research team, will occur after data are cleaned and processed following every round of data collection. An analysis plan that seeks to answer the study research questions and main objectives will be developed ahead of the inception of data analysis, to make sure that data analysis is thorough and consistent across analysts. Descriptive statistics will first be calculated within each collected dataset, including audits and consumer surveys. Longitudinal data analysis method will be used to analyze the four rounds of outlet survey, to help shed light on the dynamism of the contraceptive market in the selected areas, especially contraceptive availability and stock history. Supply-side and demand-side data will then be linked via a geographic variable and analyses will seek to uncover, among other things, whether consumers' perceptions of FP supply in their area is similar or dissimilar to the reality of the supply-side data. Analyses will also seek to understand where current contraceptive users travel to receive FP commodities and/or services and whether this reflects the traditional notion that women travel to the geographically closest facility. Finally, the approach of CM4FP will be compared to current SDP

sampling approaches and household survey data from PMA2020 and DHS through comparison of a number of key indicators, selected jointly by the donor and PSI. None of these analyses will be carried out in aggregate across all four study geographies given that the study does not seek to achieve national or regional representativeness.

One aim of the outlet survey data analysis would be to produce standard family planning market indicators, including the ones listed below. These indicators could be presented for each outlet type and/or managing authority (e.g., public vs. private).

- The proportion of outlets that had any modern family planning methods in stock at the time of the survey visit, by outlet type.
- The proportion of outlets that had each individual family planning method of selected methods (condoms, oral contraceptives, emergency contraceptives, injectable contraceptives, contraceptive implants, IUDs) in stock at the time of the survey visit, by outlet type.
- The proportion of outlets that had three or more modern family planning methods in stock at the time of the survey visit, by outlet type.
- Family planning market composition: the distribution of outlet types among outlets with at least one and three or more modern family planning methods in stock on the day of the survey.
- Median cost of one couple year protection (CYP),²⁰ by method.
- Median cost of CYP from the most popular modern family planning method relative to the minimum daily wage of an unskilled government worker.
- The total volume of each modern family planning method sold or distributed in the last month, by outlet type, within each specific geography.

For the household survey, the following is an illustrative, and not exhaustive, list of descriptive statistics that will be calculated at each round:

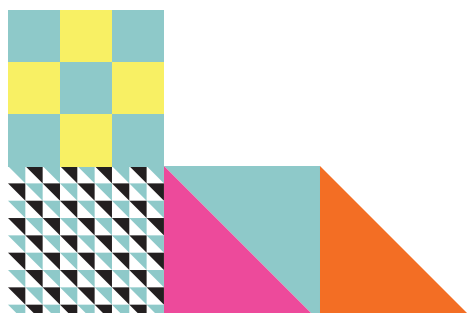
1. Proportion of women who obtained their most recent/last method from an outlet not geographically most proximal
2. Main reasons for choosing a non-geographically proximal outlet
3. Percent of women who have heard about a commodity stockout from people in their family or community
4. Percent of women who don't know whether methods are stocked out of outlets in their community
5. Percent of women who are able to provide correct price that an outlet charges for methods

All data analyses will be completed using Stata (© StataCorp, College Station, TX). Sampling weights will be applied in the analysis of the household survey data for each study region, to account for variations in probability of selection, and standard error estimation will account for clustering.

10.0 DISSEMINATION STRATEGY

Dissemination of study findings is planned at the national, regional and international levels. A national dissemination meeting will be planned following the completion of data collection and analysis and will include participants from the Ministry of Health and other relevant family planning researchers and implementors. Additional dissemination efforts will focus on peer-reviewed publications, regional and international conferences, such as the International Conference on Family Planning, and a presentation to the donor.

Additionally, all data will be made publicly available, in accordance with the donor, at a time dictated by the finalization of all planned analyses. These datasets will be made available only upon request and will not include any of the identifiable information listed in the previous section.



11.0 STUDY LIMITATIONS AND RISKS

11.1 LIMITATIONS OF THE STUDY DESIGN

The study design and methodology carry some disadvantages which may limit the study findings and their application. Most notably, the study is not intended to produce data or findings that are representative at the regional or national levels. Rather, its main aim, as a pilot study, is to understand the FP market in the specific areas within which the study is carried out. However, the study may provide some general indication of how the FP supply and demand markets interact in varying types or sizes of urban settings. It may also provide transferable lessons about the methodological validity of the census approach for understanding the supply market when compared to the sampling approach; and about the mechanics of linking outlet and consumer data.

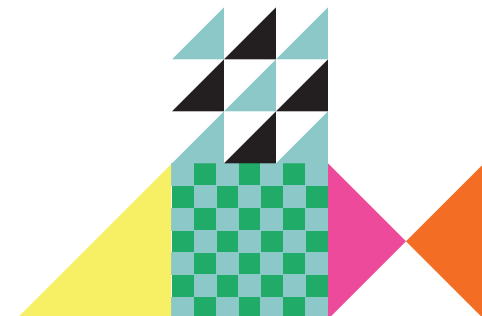
Recall issues may come into play, given that women are being asked to recall their experiences from up to 12 months prior. Where they do occur, this will affect the reliability of the data. However, given that an important goal of the study is to understand how much women know and don't know or remember and don't remember about their FP-seeking experiences, it is important that true experiences of difficulty recalling information be recorded fully. Respondents will be informed at the beginning of an interview that a "don't know" response is perfectly acceptable in order to prevent them from providing spurious answers. This will also help to mitigate any discomfort they may experience in not being able to answer questions with certainty. Enumerators will be trained to ascertain and record a "don't know" or "not sure" response and to avoid asking leading questions throughout the questionnaire. Social desirability bias may also be a concern for this study given the need to rely on self-reported data for a topic that is very sensitive (i.e., family planning). To mitigate this risk, all household interviewers will be women.

The four rounds of data collection implemented quarterly may present a burden for outlet respondents, especially those which stock many FP products and brands. The concern with this burden is twofold: firstly, it may increase the non-response or attrition rate in subsequent rounds. Secondly, it may cause respondents to provide data that are not valid (e.g., junk data in order to finish an interview more quickly). Both of these issues would affect the validity and reliability of the data. To mitigate this, Respondents will be informed that they can stop the interview at any time. They will also be presented a gift for their time.

Given the study design, the household survey will not allow for sampling from all households within the outlet study area. This may thus introduce sampling bias which would cause the household survey data to not be representative of the full study area.

Given that the household survey is not designed to follow the same respondent over the four survey rounds, the study is limited in its ability to shed light on individual-level changes in FP behavior and any correlation between these changes in behavior and changes in the FP supply market. The 3-month window between survey rounds would only allow for changes to be observed for users of short-term FP methods such as pills and injections. This may not be a huge source of concern, however, given that the majority of FP users in Kenya are short-term method users.

Lastly, due to the need to limit the length of the household survey questionnaire, the survey may not capture the full breadth of patterns of FP use and outlet choices.



11.2 MAJOR ASSUMPTIONS OF THE STUDY

The study carries the following assumptions:

1. The DHS-sourced County-level mCPR data used to calculate target household survey sample sizes holds true at the local level where the study will be carried out. (Note: If the mCPR turns out to be much lower, then a much larger sample of women need to be screened for eligibility)
2. Boundary maps will be available (and will be made available by relevant authorities), along with population data, for use in selecting local survey areas. Also, these maps will be reliable and useful for quality control when in the field.

12.0 REFERENCES

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