



EXPANDING EFFECTIVE CONTRACEPTIVE OPTIONS:

Introducing the Caya Diaphragm in Niger

JUNE 2020



USAID
FROM THE AMERICAN PEOPLE





Acronyms

AE	Adverse Event	MAH	Marketing Authorization Holder
ANC	Antenatal Care	MOH	Ministry of Health
CHW	Community Health Worker	OC	Oral Contraceptive
EECO	Expanding Effective Contraceptive Options	PNC	Postnatal Care
FGD	Focus Group Discussion	PSI	Population Services International
FP	Family Planning	QA	Quality Assurance
IDI	In-Depth Interview	STI	Sexually Transmitted Infection
IPC	Interpersonal Communication	TFR	Total Fertility Rate
ISO	International Organization for Standardization	WCG	WCG Cares
IUD	Intrauterine Device	WHO	World Health Organization
		USAID	United States Agency for International Development

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Introduction

UNMET NEED FOR CONTRACEPTION

In developing countries, 214 million women want to avoid pregnancy but are using no modern method of family planning (FP). Sub-Saharan Africa has the highest proportion of women with an unmet need for modern contraception in the world.ⁱ Side effects, infrequent sex, breastfeeding, and opposition to use are among the top reasons women cite for non-use of contraception globally.ⁱⁱ The introduction of new contraceptive options can address several of these reasons for non-use, giving women more choices as they seek to plan their families in a way that aligns with their needs and preferences.

EECO PROJECT

The Expanding Effective Contraceptive Options (EECO) project, funded by the United States Agency for International Development (USAID), was designed to address women's method-related reasons for non-use of FP. To this end, EECO introduces new and improved contraceptive methods with varying key benefits: some are non-hormonal, others are long-acting and reversible, and still others are discreet or used only on-demand. Many EECO products are also woman-initiated, helping to overcome provider-related barriers to access like shortages of skilled healthcare professionals and provider bias. These methods expand the range of choices available to women who wish to delay, space, or limit births, giving

women more power to fulfill their reproductive intentions in ways that suit their needs and desires at different points in their lives.

EECO TEAM

WCG Cares (WCG) leads the team, bridging the private sector and non-profit worlds, linking upstream product developers/suppliers and downstream marketing and distribution partners. WCG also leads EECO's regulatory and quality assurance efforts.

Population Services International (PSI), the social marketing and service delivery partner, works through existing healthcare and product distribution networks to market the products in EECO's portfolio.

EECO PROCESS

EECO collaborates with a variety of market players along the supply chain, from manufacturers to providers and clients, to introduce new and innovative contraceptive methods. In addition, EECO works with a diverse group of stakeholders, such as regulatory bodies, Ministries of Health (MOH), donors, and other implementing agencies, to influence the policy environment around the introduction and potential scale-up of these methods. EECO-supported product introduction takes places in five stages, some of which occur concurrently, as described in Figure 1.

I had tried other methods before Caya... which I didn't like...

I heard about the diaphragm and decided to try it.

I like that there aren't any side effects at all! And it's easy to use and easy to remove. I've been using it for a month, but I already needed a new tube of gel, so I called the agent to buy more.

I've spoken with my neighbors about this method actually. One of my neighbors asked me what I used for contraception, asking if it's one that doesn't change my bleeding. I showed her my diaphragm and told her about it. She hopes to start using Caya too.

– Caya Diaphragm user in Niger

Figure 1. **EECO PRODUCT INTRODUCTION MODEL****STAGE 1****Regulatory Assessment & Product Registration**

- Perform regulatory landscape assessment
- Engage stakeholders and meet with regulatory authorities
- Support identification of a suitable market authorization holder
- Prepare the registration package, submit and support its lifecycle upon approval

**STAGE 2****Consumer & Market Research**

- Plan and conduct market research
- Complete market segmentation analysis
- Determine pricing and branding strategies

**STAGE 3****Procurement & Quality Assurance**

- Perform manufacturer audits
- Initiate pre-shipment inspection and testing of product
- Develop and initiate pharmacovigilance systems

**STAGE 4****Marketing, Distribution & Service Delivery**

- Launch product, with marketing and communications support
- Supply stock to commercial outlets and providers
- Deploy medical detailers to train and follow-up with providers

**STAGE 5****Monitoring & Learning**

- Monitor and course-correct
- Conduct baseline and endline evaluations
- Disseminate lessons learned

Caya Diaphragm and Accompanying Caya Gel

The Caya Diaphragm is a non-hormonal, discreet, and reusable barrier method of contraception. The product comes in the form of a thin contraceptive cup that fits over the cervix to prevent sperm from entering the uterus. With support from USAID, PATH and its partners developed the Caya Diaphragm through an iterative, human-centered design process involving women, male partners, and providers from multiple countries to expand women's options for non-hormonal contraception—especially in countries where diaphragms are no longer or never were available.

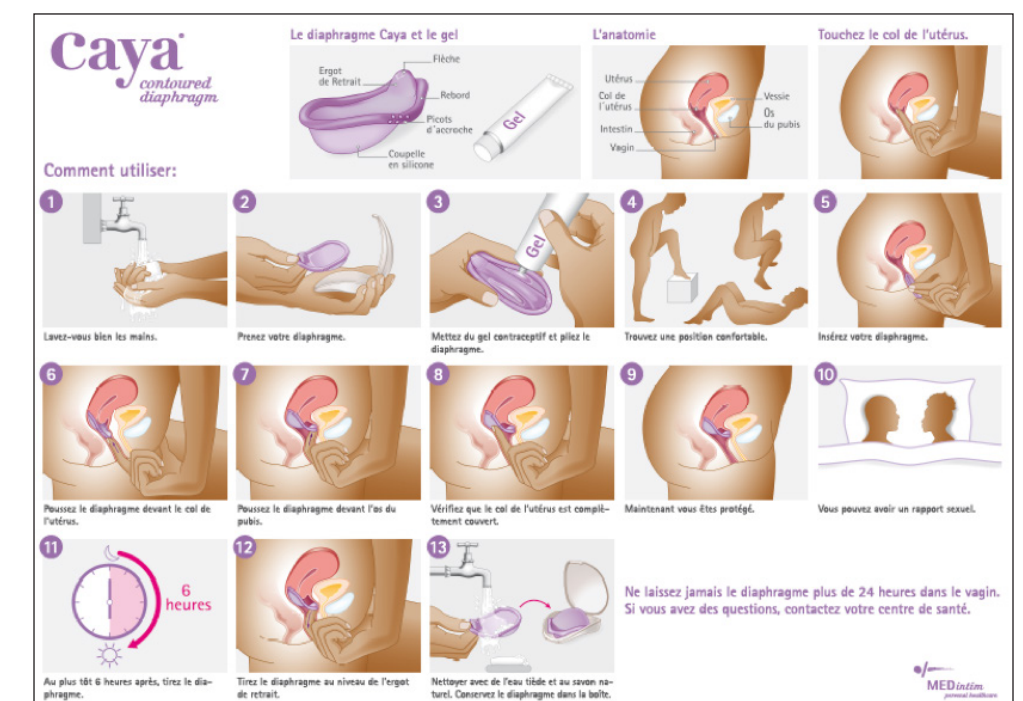
Unlike traditional diaphragms that come in multiple sizes, the Caya Diaphragm is a “one size fits most” device. This makes Caya easy to supply and provide, eliminating the need for procurement of multiple sizes of diaphragms and a provider fitting before use.

Feedback from women, their partners and healthcare providers led to several design features that make Caya easy to use (especially for new users) and comfortable for both partners. The Caya Diaphragm has a contoured nylon spring and grip

dimples which aid with insertion as well as a finger dome to help women grab the diaphragm during removal. Caya is made of silicone that is soft and durable.ⁱⁱⁱ

To use the Caya Diaphragm, women apply a small amount of gel, such as Caya Gel, to the rim of the diaphragm. The Caya Diaphragm can be inserted into the vagina any time before sex but should remain in place for six or more hours following sexual activity, the point at which most sperm cells are no longer active. Women can use the removal dome, at the tip of diaphragm, to hook the rim of the diaphragm during removal. The diaphragm can be cleaned using soap and water and reused for up to two years. Each Caya Gel tube lasts for approximately 16 uses. See Figure 2 for an instructional poster on how to use the Caya Diaphragm.

Studies have demonstrated the Caya Diaphragm to be safe, effective, and acceptable to women and their partners in North America, Latin America, sub-Saharan Africa, and southeast Asia.^{iv-vii}

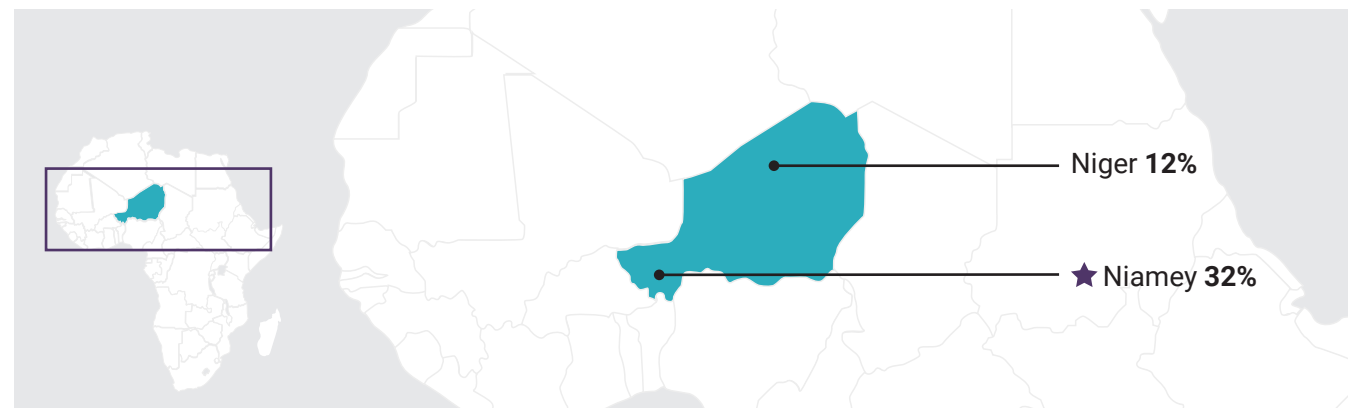
Figure 2.
**CAYA DIAPHRAGM
INSTRUCTIONAL
POSTER³**

³ Manufacturer KESSEL MEDintim GmbH developed the Caya Diaphragm instructional poster. EECO provided input during the development and pre-tested the poster with potential clients to ensure it was easily understood in Niger.

Country Context: Niger



Figure 3. **MODERN CONTRACEPTIVE PREVALENCE RATES IN NIGER***



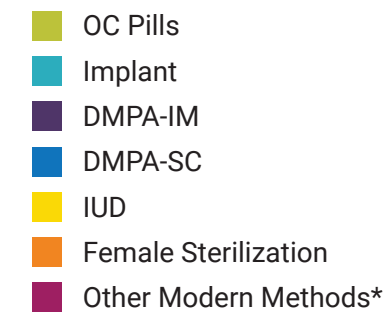
*mCPR among women in union | Source: DHS 2012 (Niger), PMA2020 (Niamey)

EECO's Caya Diaphragm pilot is based in Niamey, the capital of Niger. The country has the highest Total Fertility Rate (TFR) in the world at 7.6 births per woman, with a TFR of 5.3 births per woman in Niamey. Among women in union, modern contraceptive use is higher in Niamey (32%) than in Niger as a whole (12%), but remains low relative to other capital cities and countries around the world (Figure 3).^{viii,ix} As shown in Figure 4, oral contraceptive (OC) pills account for almost half of the modern FP use in Niamey, though this share is declining as intrauterine devices (IUDs), implants,

and injectables become more available.^x

Reasons for non-use of contraception in Niamey, as shown in Figure 5, are led by a perceived lack of risk/need and unmarried status. Figure 6 shows that, for women in Niamey, the median age of first contraceptive use is 25.1, nearly five years after the median age of first marriage (20.5 years) and after women have had an average of 2.2 children. The median age of first sex (18.6 years) precedes the median age of first marriage by more than a year.^{xi}

Figure 4. **CURRENT MODERN METHOD MIX AMONG CONTRACEPTIVE USERS IN UNION IN NIAMEY**



*Includes male condoms, LAM

Source: PMA2020

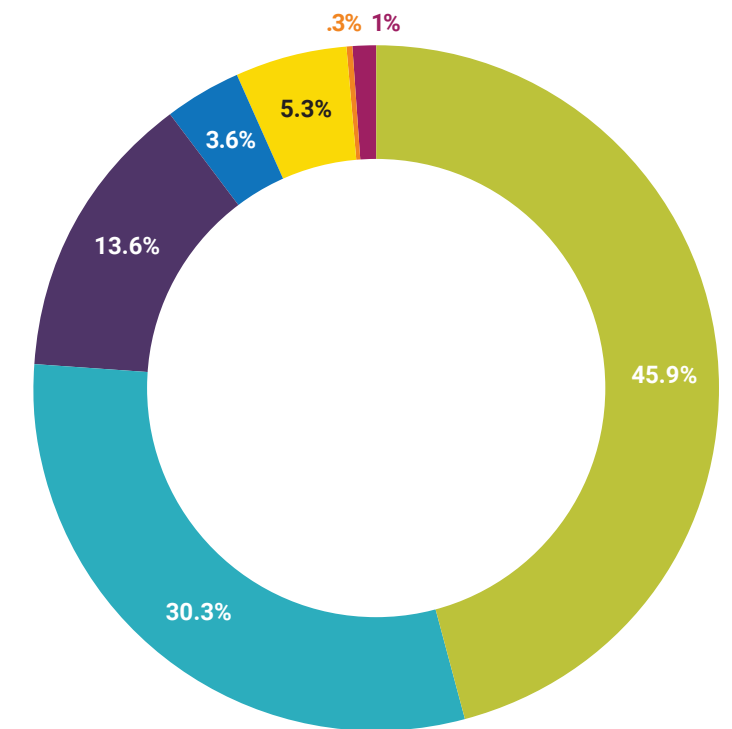


Figure 5. **REASONS FOR NON-USE OF CONTRACEPTION AMONG ALL WOMEN WITH UNMET NEED (NIAMEY)***

Side Effects or Health-related Concerns

11%

Opposition to Use

16%

Not Married

38%

Perceived Lack of Risk/Need

51%

Other**

7%

*Respondents allowed to select more than one answer.

**Other includes lack of knowledge/access

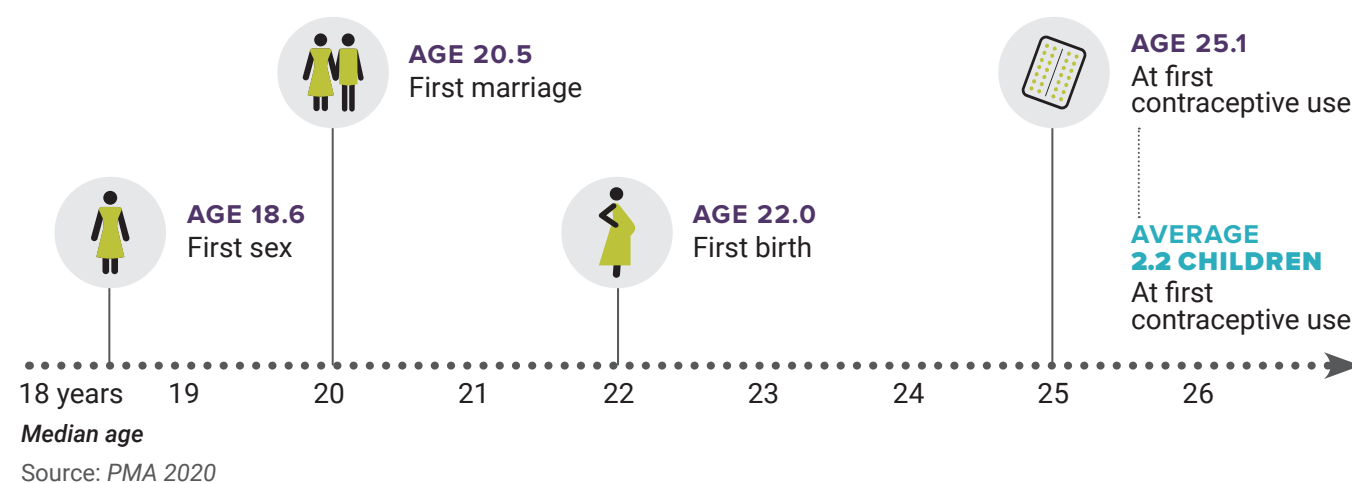
Source: PMA 2020

Opposition to use and side effects are other major contributors to non-use of FP. For some, opposition to use of FP is rooted in religion. Although Niger is officially a secular country, the vast majority of the population is Muslim. Many men and women in Niger believe that the use of modern contraceptives is in conflict with Islamic teachings.^{xiii} While many FP projects in Niger and the region work closely with religious leaders—seeking their support for use of FP in their communities and working with them to identify Koranic passages in favor of using FP—the

common perception that use of FP is in conflict with traditional religious teachings remains a barrier to voluntary uptake of modern methods of contraception.^{xiii}

The low HIV prevalence in Niger (less than 1%) was a factor in EECO's country selection for the Caya Diaphragm introduction.^{xiv} Since the Caya Diaphragm is not a dual prevention method that protects against HIV and unplanned pregnancy, EECO prioritized countries with low HIV prevalence.

Figure 6. **REPRODUCTIVE HEALTH AND CONTRACEPTIVE INDICATORS AMONG WOMEN AGED 25-49 (NIAMEY)**



I hated taking pills! They just weren't for me. I was always forgetting to take them when my husband was away, and on top of that, they made me nauseated. I eventually gave up on the pill, and during that time my husband and I used the withdrawal method. We knew there were other options, but none of them seemed right.

One day, a health worker came to our house. She told me about lots of different contraceptive methods, but the one that I thought was most interesting was the Caya Diaphragm. It was the first time I had heard about this method. She showed me how it worked and how to use it. I started using it right away.

My husband and I both really like this method. I've also told some of my friends about how you only have to use it when you have sex, and some of them are very interested.

I'm really glad to have found a method that works for me.

— Caya Diaphragm user in Niger



STAGE 1 Regulatory Assessment & Product Registration

The objective of the first stage of EECO's Product Introduction Model is to work with the manufacturer to register the product in the country where EECO will introduce it. In almost all cases, registration of contraceptive products is a prerequisite for sustainable access. For a primer on product registration, see the EECO guide *Introducing New Contraceptive Options: Product Registration Basics for Global Health Program Managers*.^{xv}

REGULATORY LANDSCAPE ASSESSMENT

WCG conducted a regulatory landscape assessment to determine the most efficient pathway for registration of the Caya Diaphragm and Caya Gel in Niger. This assessment was comprised of two parts: a desktop review of available resources and a series of in-country interviews. During the desktop review, WCG identified and reviewed online guidance and regulations from Niger's MOH and relevant stakeholders, as well as global standards from the World Health Organization (WHO) and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Using these resources, WCG developed a questionnaire for in-country interviews to confirm the regulatory requirements and process. Interviews were conducted with a variety of stakeholders including Niger's MOH and relevant organizations and associations.

SELECTION OF MARKETING AUTHORIZATION HOLDER

As part of the regulatory landscape assessment,

WCG evaluates potential candidates to serve as the marketing authorization holder (MAH) for the product in line with country-specific regulations. For example, some countries stipulate that the MAH must be a local entity whereas others allow the MAH to be a foreign manufacturer or distributor. The MAH is tasked with post-approval surveillance, including documenting end-user complaints, reporting adverse events (AEs) to the regulatory authority, and reporting any AEs or quality issues to the manufacturer.

In Niger, the MAH must be a locally based manufacturer or distributor. WCG vetted and recommended EECO partner PSI's local network member, PSI Niger, to be the MAH based on the organization's experience distributing reproductive health products. KESSEL MEDintim GmbH, the manufacturer of the Caya Diaphragm and the global distributor for Caya Gel, officially appointed PSI Niger as the MAH as part of the registration application.

REGISTRATION IN NIGER

WCG's Regulatory Team submitted the registration application package to Niger's MOH in August 2017. Given its product classification as a medical device, and that the Caya Diaphragm and Caya Gel had been approved by multiple Stringent Regulatory Authorities⁴ by 2014, the registration timeline in Niger was expedited. In February 2018, the MOH granted marketing authorization approval of the Caya Diaphragm and Caya Gel. This registration was granted to PSI Niger for a period of five years.

⁴ The Caya Diaphragm and Caya Gel achieved CE certification as a Class II b medical device in 2013 and approvals from Canada and Australia in 2014. The Caya Diaphragm received market clearance via a 510(k) submission in the United States in 2014. As of 2019, Caya Diaphragm/Caya Gel are registered and marketed in nearly 40 countries. See more here: <https://www.caya.eu/caya-development/>.



STAGE 2

Consumer & Market Research

To better understand the needs and preferences of potential consumers, EECO carries out consumer and market research in focus countries. Drawing upon formative research, EECO can better design marketing and service delivery strategies to reach the product's intended beneficiaries.

FORMATIVE RESEARCH

In September 2017, EECO held a series of focus group discussions (FGDs) and in-depth interviews (IDIs) with a variety of stakeholders, including women of reproductive age, men aged 20-50 with at least one child, and healthcare providers, including facility-based family planning providers and pharmacy staff. FGDs and IDIs were completed in two Nigerien urban centers: Niamey (10 FGDs, 7 IDIs) and Dosso (4 FGDs, 3 IDIs). The formative research study protocol was approved by PSI's Research and Ethics Board as well as the local Institutional Review Board.

The study found that in the Nigerien context, the decision to adopt FP almost always involves consultation with the woman's male partner. Male partners are often supportive of FP for birth spacing, but once the decision to use FP is made by the couple, women tend to have latitude in the choice of method and typically consult family members and friends for advice on which method to use.

Since diaphragms have not been included in FP programs in recent decades, the method was largely unknown in Niger before this pilot introduction (though some potential users recognized it from WHO-produced posters in public and private clinics and a few providers had learned about diaphragms during pre-service training). After viewing a demonstration on how to use the Caya Diaphragm and Caya Gel using a pelvic model, participants provided their feedback. Women said the primary benefit of the method was that it is non-hormonal, thus alleviating fears about side

effects and concerns about future fertility. Women also appreciated that it could be used on-demand rather than continuously. Furthermore, women were interested in the Caya Gel as a way to address vaginal dryness while also facilitating insertion of the diaphragm.

However, participants also voiced concerns around how to insert the diaphragm correctly, the time it would take to do so, and what the implications would be for effectiveness if the diaphragm were inserted incorrectly or moved out of place. Participants worried about the requirement for the diaphragm to stay in place for six hours post-sex, and whether this may interfere with women's prayer times and the hygienic consequences of leaving it in too long. Similarly, participants worried about properly storing the gel and cleaning the diaphragm. They noted that cleaning instructions (requiring easily accessible and low-cost materials) should be provided. Participants were also disappointed that the diaphragm does not protect against HIV or sexually transmitted infections (STIs). Male participants in particular were concerned that the diaphragm could be a physical barrier to intimacy, which they reported to be a deterrent to the use of condoms.

To market the product, participants suggested community sensitization through talks at health centers and door-to-door visits, as well as the use of mass media. Female participants also highlighted the importance of hearing from satisfied users to raise awareness and encourage use of a new, unfamiliar contraceptive product. With respect to pricing, all participants suggested keeping the price of the diaphragm and gel low so that the method is accessible to women and consistent with free and low-cost contraceptive options available in the public and private sectors, respectively.



STAGE 3

Procurement & Quality Assurance

EECO introduces products that are new and have not yet been added to USAID's standard procurement system. As agreed with USAID, EECO ensures that these products undergo independent quality assurance steps that mirror those of USAID's broader procurement system to verify product safety and performance. Products are tested in accordance with international product standards developed by a consortium such as the International Organization for Standardization (ISO). ISO is an independent, non-governmental organization that brings together subject-matter experts to share knowledge and develop voluntary, consensus-based international standards for product quality assurance.

EECO partners with FHI 360 Product Quality and Compliance, an ISO 17025-accredited⁵ laboratory partner, to verify compliance with product specification requirements. FHI 360 conducts pre-acceptance testing of all Caya Diaphragm and Caya Gel lots, with WCG providing final review and release of acceptable products.⁶ For both the Caya Diaphragm and Caya Gel, EECO completed the technical transfer of test methods, which:

- allows product evaluation by Third Party Laboratory (FHI 360) prior to procurement;
- ensures that Pre-Acceptance Testing is in alignment with Manufacturer Testing;
- establishes foundation for testing and procurement if products are added to the USAID Catalog in the future.

EECO developed a shared Quality Agreement with KESSEL MEDintim GmbH, PSI and WCG to outline the roles and responsibilities of the various partners

to ensure quality of the Caya Diaphragm and Caya Gel. KESSEL maintains documentation of Good Manufacturing Practices required by regulatory authorities as part of its Caya quality file. PSI is required to report any product related AEs or quality issues to KESSEL. In addition, WCG conducts regular quality assurance (QA) audits of the Caya Diaphragm and Caya Gel manufacturers, both of which have passed with no major issues identified.

To determine the size of the initial procurement of Caya Diaphragm and Caya Gel units for Niger, EECO weighed several factors, including procurement lead time; time for QA testing, shipping, and processing through Customs; product shelf-life; and, the operating environment given diaphragms would be a new contraceptive product category in a country with relatively low contraceptive use. Ultimately, EECO decided to launch the pilot in Niger in June 2019 with a modest procurement of 800 Caya Diaphragms and 800 Caya Gel units. To meet the gel resupply needs of continuing users, EECO ordered an additional 500 Caya Gel units, which arrived in Niger in March 2020. Based on sales and distributions trends, EECO ordered an additional 750 Caya Diaphragms, expected to arrive in mid-2020, to keep pace with current demand. A third order of Caya Gel is also planned for 2020.

While the timeline from the initiation of a purchase order to receipt of product in country spanned roughly five months for the initial procurement, this timeframe has shortened for subsequent orders thanks to finalization of product packaging and completion of the technical transfer of test methods.

⁵ ISO/IEC 17025 enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world.

⁶ As part of the USAID-funded HealthTech V program, PATH and KESSEL developed QA test equipment and test protocols for the Caya Diaphragm. PATH and KESSEL provided equipment, technical assistance and training to FHI 360 to build their capacity for diaphragm QA testing.



STAGE 4

Marketing, Distribution & Service Delivery

Based on the findings of the consumer and market research, EECO develops a marketing, distribution, and service delivery strategy unique to the product and pilot setting.

MARKETING

EECO introduced the Caya Diaphragm in Niger using the brand name and packaging developed by KESSEL, which formative research showed to be both attractive and acceptable to potential users. For the ongoing pilot, the primary communication strategies are interpersonal communication (IPC),

carried out by community health workers (CHWs) employed by PSI Niger, and counseling with a facility-based provider, typically a nurse-midwife. New clients can obtain the Caya Diaphragm plus one Caya Gel, packaged together as a kit, directly from CHWs and providers. Resupplies of the Caya Gel are also available directly through CHWs and providers. The pilot introduction in Niger does not involve pharmacies, although this channel may play a role in future efforts to scale up access.

EECO emphasizes four key benefits when offering the Caya Diaphragm:



Non-hormonal

The Caya Diaphragm does not cause changes in menstrual bleeding patterns or other side effects that are frequently cited as reasons for not using hormonal contraceptive methods.



On-demand

The Caya Diaphragm can be inserted moments before sex for use during sex and does not require action when women do not need protection. PSI Niger anticipates that this message appeals to a large segment of women whose partners migrate or travel for work and are often away from home.



Self-use

Users can decide to start, stop, and re-start using the Caya Diaphragm at any time without needing to see a provider. Users only need initial counseling and access to the product, which is convenient and gives the client more control.



Discreet

Since the Caya Diaphragm is reusable for up to two years, clients can use it privately during that time with no need to resupply the method as they would with condoms, OC pills, or injectables. Resupplies of Caya Gel are needed, however.

DISTRIBUTION & SERVICE DELIVERY

In June 2019, EECO conducted a four-day training for four MOH trainers, seven public sector providers, three private sector providers from PSI's social franchise, and five CHWs employed by PSI. The training included a review of the Informed Choice policy, as well as a refresher on good counseling practices and the technical aspects of all FP methods. More extensive training on the technical aspects of the Caya Diaphragm and Caya Gel, in addition to the relevant counseling messages and key details around provision of the method, were also covered. KESSEL also participated in the training, providing technical assistance as well as an educational training poster for use by providers and CHWs during counseling (see Figure 2). Distribution

and sales of the Caya Diaphragm and Caya Gel began immediately after the training through public health centers, private social franchise clinics, and CHWs.

While developing the training curriculum, EECO took concerns raised during formative research into account. As such, CHWs and providers practiced using everyday language to walk clients through insertion/removal of the Caya Diaphragm, instructions for proper storage and cleaning, and counseling around keeping the diaphragm inserted for six hours after intercourse while still being able to fully perform cleansing rituals before prayer time. So far, the EECO team has not seen any of these initial, theoretical concerns voiced during the formative research to have surfaced during the pilot.

I think the most important part of my job is communicating to women the different benefits of all methods, while also dispelling any rumors they may have heard about them. My role is also to help a woman find a solution to her contraceptive needs.

– CHW

Providers in the Public and Private Sectors:

When a client visits an EECO-trained provider for FP, she receives a counseling session that covers all methods, including the Caya Diaphragm. Providers demonstrate how it is used on a pelvic model, similar to how they would demonstrate condom usage, and offer the method alongside other FP methods available to Nigerien women. If clients opt for the Caya Diaphragm, they can access it on the spot. Providers request the client's name and contact information to share with CHWs. If

the client consents, the CHW follows up with her to respond to any questions or concerns and provide support to use the method correctly. Women can also buy resupplies of the Caya Gel from CHWs, who can meet clients at their homes, a health center, or in the community.

Community Health Workers:

PSI Niger employs four female CHWs and one male CHW to provide comprehensive counseling on all FP methods available in Niger, including the

Caya Diaphragm.

EECO has prepared CHWs to offer the Caya Diaphragm in multiple settings. In partnership with public health centers, CHWs provide FP counseling sessions to groups of women who gather in health center waiting areas to visit a provider to obtain FP, immunize their children, or attend antenatal (ANC)/postnatal (PNC) care visits. While these clients can opt to wait to visit the FP nurse to access the Caya Diaphragm for free, many prefer to buy immediately

from the CHW, saving time for both the provider and client. From there, CHWs offer to exchange contact information with clients so that they can provide follow-up support and answers to any questions or concerns that may emerge, as well as provide replacement units of Caya Gel.

Early in the pilot in Niger, CHWs went door-to-door to offer FP counseling. In Niamey, it is common for visitors to come directly to the door, and women are generally very receptive to this type of visitor.

Bonjour. My name is Aminata. I'm a nurse-midwife at a public sector health facility in Niamey.

My clients are numerous and sometimes they wait hours to meet with me. When I meet with a client, I offer her the full range of FP methods available in Niger and if she chooses Caya, I give it to her for free as all FP methods are free in the public health system. Caya is a wonderful addition to the method mix; a woman may continue to use Caya for up to two years!

When a woman chooses Caya as her FP method, it saves her time. She no longer has to visit me every month, as she might if she were using pills. Working with the new CHWs also helps us serve more women. They can introduce women to the full range of FP methods and can even directly offer Caya if a client requests that method. The introduction of Caya, and the support of the CHWs has had many benefits. Among them is that they allow me more time to concentrate on serving clients that require my specific skill level.

Salut! I'm Maimouna and work as a CHW with the EECO project.

I speak to women in the community and around health centers, teaching them about their full range of contraceptive options. This now includes Caya!

A lot of women appreciate being visited in the privacy of their homes, where they are comfortable asking questions about FP. I'm able to meet their preference for privacy, while also referring them to health centers for their desired method, or selling Caya on the spot for 500CFA (\$0.80 USD) if that's the option they decide to use.

Hello, I'm Ramatou, a nurse-midwife in a private clinic.

We are a small clinic but are proud of the FP and maternal health care services we provide. Here at our clinic, we now offer Caya as one of the options women can choose if they need FP.

Caya is a new method for Niger. We purchase each unit through PSI for 300CFA (about \$0.50 USD). This is the private sector, so FP methods are not free. Our clinic has chosen to sell Caya to clients for 500CFA. We have the discretion to sell it for more or less than that, but so far 500CFA has been a marketable price.



While many women appreciated the direct in-home visit, this method of IPC was very time-intensive. To improve the efficiency of the model, EECO shifted CHW outreach to community areas where women gather. However, CHWs continue to make home visits to clients who have already selected the Caya

Diaphragm as their FP method of choice and have voiced the desire for follow-up support to address questions or concerns, provide resupplies of Caya Gel, or meet their friends who are interested in the Caya Diaphragm. Word of mouth from satisfied users has led to potential clients seeking out the

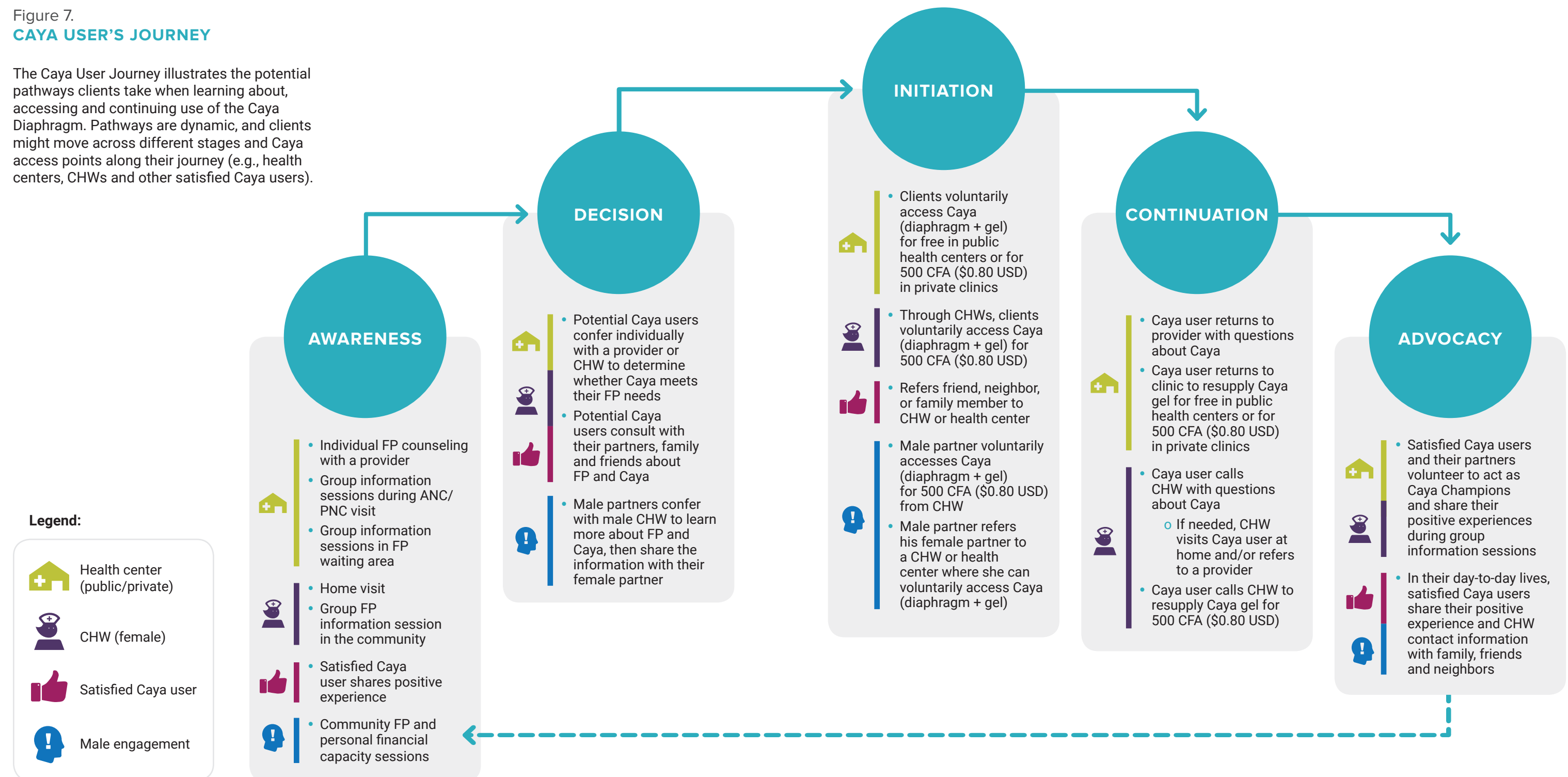
Caya Diaphragm from FP providers, who offer balanced counseling on the range of FP methods and provide clients the method of their choice.

The Caya User Journey (Figure 7, below) describes the different pathways of potential clients in Niger.

The Caya User Journey begins with the ways that potential clients might learn about and decide to use the method. The figure then shows how EECO enables women to initiate and continue use of the method, if desired, and how some women share their experience with others.

Figure 7.
CAYA USER'S JOURNEY

The Caya User Journey illustrates the potential pathways clients take when learning about, accessing and continuing use of the Caya Diaphragm. Pathways are dynamic, and clients might move across different stages and Caya access points along their journey (e.g., health centers, CHWs and other satisfied Caya users).



SERVICE STATISTICS

PSI Niger reached 13,658 women and 628 men through FP communication sessions with individuals and groups through March 2020. See Table 1 (below) for sales and distribution of the Caya Diaphragm and Caya Gel by channel from the start of the pilot in June 2019 through March 2020.

Anecdotally, the EECO team hears that women like the Caya Gel but we have not seen as many gel resupplies as expected. Based on early insights from our operational research, it seems this is due

to infrequent sex rather than non-use of the Caya Gel. This finding suggests that the Caya Diaphragm may help to meet the needs of women who cite infrequent sex as a reason for non-use of other FP methods.

Figure 8 shows how many initial diaphragm and gel kits have been sold or given freely to clients by channel and quarter. Relative to facility-based providers, CHWs played a much larger role in providing the method to clients in the first quarter. Over time, the public sector has become the primary source of supply for the Caya Diaphragm in Niger.

Table 1.
CAYA DIAPHRAGM & CAYA GEL SALES & DISTRIBUTION BY CHANNEL
From June 2019 to March 2020

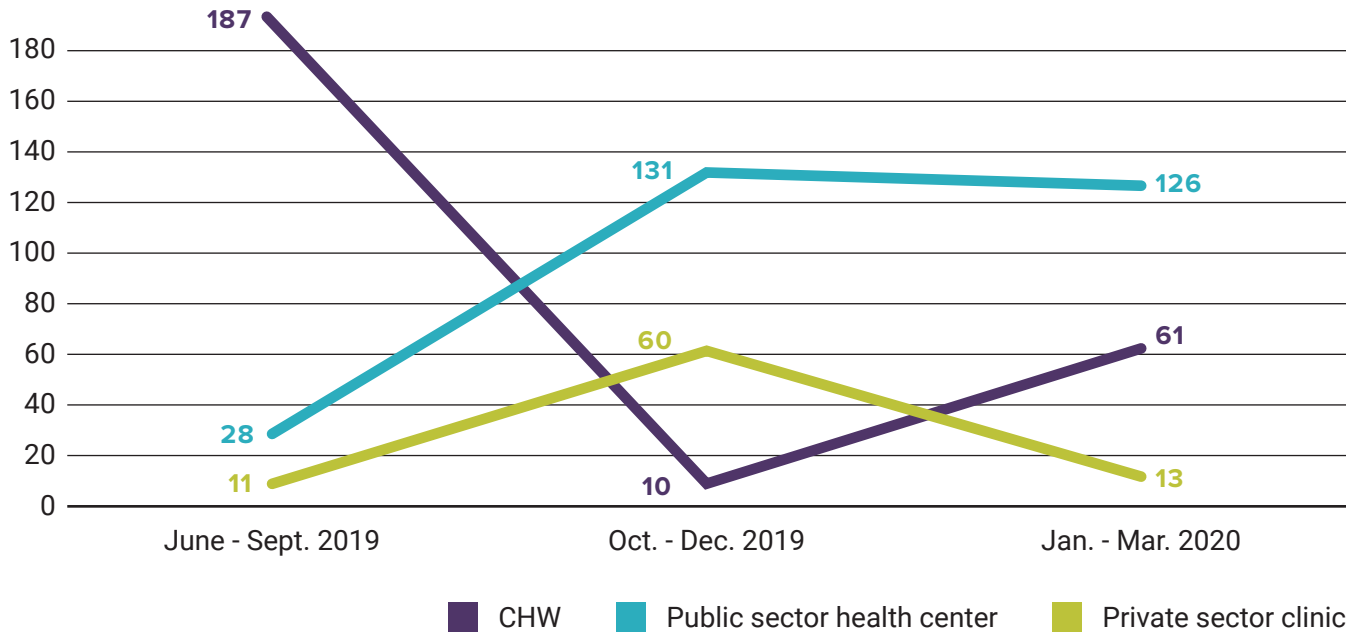
Sold/distributed via:	Caya Diaphragm + Caya Gel	Caya Gel Resupplies
Public Health Centers	285	26
CHWs	258	19
Private Clinics	84	12
► Total Clients	627	57

The first time I used it, yes, it was a little difficult – the insertion was difficult. I didn’t understand which way to put it in, and I put it in upside-down or backwards or something, and it ended up being a little hard to get out.

But I called Hadiza, [a PSI Niger CHW] and she came back with the model to show me the correct way to insert it. Since then I have had no problems.

– Caya Diaphragm user

Figure 8.
CAYA DIAPHRAGM & GEL KITS: DISTRIBUTION BY CHANNEL AND QUARTER



Program Quality Improvement

To assure the quality of comprehensive FP counseling by CHWs and providers, including about the Caya Diaphragm, EECO has initiated several ongoing quality improvement mechanisms. CHWs meet with a supervisor weekly to discuss any concerns with counseling tools and/or communication strategies. Supervisors also periodically visit CHWs and providers and use a counseling checklist on the Caya Diaphragm to ensure all essential information conveyed to women is accurate and allows for full and informed choice.

Additionally, EECO developed a mystery client survey that was completed between October-November 2019. The goals of the survey were to confirm the availability of the Caya Diaphragm

at participating public health centers and private clinics; gather information about the quality of FP counseling offered by CHWs and providers; and identify areas for program improvement. The mystery clients, actors trained to pose as potential clients, visited each of the EECO-trained CHWs and providers (public and private). The mystery client survey revealed some gaps in counseling, including clients not given the opportunity to practice insertion and removal of the Caya Diaphragm on a pelvic model and providers not counseling clients on dual protection for prevention of both pregnancy and STIs. These and other findings of the mystery client survey were shared with the CHWs and providers, who received continued, on-the-job retraining as well as a dedicated group refresher training session in February 2020.



STAGE 5 Monitoring & Learning

OPERATIONAL RESEARCH

As part of EECO's pilot introduction of the Caya Diaphragm, data collection for a mixed methods operational research study began in January 2020. The results and insights gathered from this study will inform the recommendations made to Niger's MOH as well as other countries considering adding the Caya Diaphragm to their national FP method mix. The objectives of the study are to identify the socio-demographic profiles of women who choose this method; identify how users are learning about the product and what barriers to access might exist; understand the client experience on the counseling and use of the Caya Diaphragm; gather information on how users are storing and cleaning the product;

understand the role of male partners in choice and use of the Caya Diaphragm; and determine the discontinuation rate after 6 months. Qualitative data will be collected through IDIs with study participants (25 female users, 15 men who have learned about the method through FP counseling sessions, and 15 providers). Quantitative data from 150 women will be collected through routine data collection.

KEY INSIGHTS

In Niger, EECO has already faced and addressed several challenges. The programmatic learning below may be relevant to future introductions of the Caya Diaphragm in other countries as well as potential scale-up in Niger:



Acceptability:

The theoretical concerns voiced during the formative research that this method might be unacceptable in the Nigerien context seem not to have borne out in practice. In this small pilot introduction, hundreds of women have voluntarily sought out Caya Diaphragms and chosen this method over the range of other FP methods available from the same providers. The method appears to fill a gap in the market by appealing to women who prefer non-hormonal methods of contraception, want a user-controlled method, and/or have infrequent sex. EECO's messaging has carefully positioned the Caya Diaphragm by highlighting these benefits while providing balanced information about the range of FP options and dispelling myths about hormonal contraception. More information about acceptability will come from the ongoing operational research study.



Male Engagement:

PSI Niger employs a male CHW whose role is to engage men in FP discussions, sensitizing local male populations to modern FP options including the Caya Diaphragm. Initially, this CHW began his conversations with *fadas*, male social groups that routinely congregate in the same place, by immediately launching into an FP sensitization session. He quickly determined that men were not very engaged in the discussion. With the support of the EECO team in Niger, he instead began opening discussions by talking about family finances, typically a man's domain in Nigerien households. The CHW uses this opening to discuss the idea that having many children is expensive, and that a way to space or have fewer children (and keep the family finances under control) is through the use of modern contraception, including the Caya Diaphragm. The CHW then encourages husbands to engage their wives in conversations about FP and modern contraception use. PSI has implemented this strategy with success through another USAID FP project in West Africa, Transform/PHARE.⁷



Community Buy-In:

Buy-in from key opinion leaders is important for the success of any public health initiative. Thus, incorporated into the duties of the male CHW is ongoing advocacy with local community leaders. He alerts *chefs de quartier* and other local opinion leaders that CHWs will be holding IPC sessions and offering voluntary FP in their communities. In return for keeping them apprised of CHW activities, local leaders identify what large gatherings of men and women exist in their neighborhoods so that CHWs can coordinate their FP counseling sessions with them.



Ongoing Support for Users:

Using a new, self-use method of contraception can be confusing, especially for women unaccustomed to other vaginally inserted products (e.g., tampons, menstrual cups, vaginal rings). Each CHW and facility offering Caya has an anatomical model used to demonstrate how to insert and remove the diaphragm. Practice on the model at the time of counseling, after the client has voluntarily chosen Caya as her method of FP, is an important part of women's successful and voluntary continued use of the diaphragm. Equally important is ensuring new clients are aware of the follow-up support available to them. As part of their counseling, CHWs make it clear that they remain available to respond to follow-up questions or concerns about the Caya Diaphragm. Upon request, CHWs visit users' homes to provide additional practice on insertion and removal of the diaphragm. A good support system for correct use is an important factor in voluntary, continued use of the method.



Caya Champions:

Some early adopters of the Caya Diaphragm have been highly satisfied with the method and eager to share their satisfaction with others in their communities. CHWs have begun engaging these women as "Caya Champions" to share their stories with neighbors who have shown interest in the Caya Diaphragm. Hearing from Caya Champions can encourage potential users to learn more about the method and provide them with a link to CHWs and providers for balanced counseling and access.



Shifting Trends in Distribution Channel:

In the first three months of the pilot, the majority of Caya sales were through CHWs. However, six months into the pilot, the trend flipped when free distribution through public health centers more than quadrupled. EECO speculates that over time, CHWs' interpersonal communication and word-of-mouth in the community contributed to awareness of Caya Diaphragm as another method available for free through the public sector, the dominant source of FP in Niger, where all methods have been provided free of charge since 2006.

I like the diaphragm because I can insert it and remove it myself, and if my husband isn't around, I don't have to use it or worry about contraception at all.

— Caya Diaphragm user

⁷ Transform/PHARE was a USAID-funded project using innovative marketing, advertising, human-centered design and behavioral economics to increase demand for FP products and services. Transform/PHARE was implemented in several countries in Francophone West Africa.

Next Steps

EECO will continue pilot introduction activities in Niger and complete a mixed methods study with Caya users, men, and providers. When the results of EECO's research become available, they will be shared with local, regional, and global stakeholders to inform decision-making about whether, where, and how to introduce and scale up access to the method. Depending on the outcomes of the pilot, EECO will engage with the MOH and other partners to discuss potential pathways to scale for the Caya Diaphragm in Niger. Results will also inform the

recommendations made to other countries interested in the Caya Diaphragm and Caya Gel about how to successfully introduce the products into their own national method mix.

In 2020, EECO will launch a new pilot introduction of the Caya Diaphragm and Caya Gel in neighboring Benin. The introduction in Benin will leverage the lessons learned from utilizing the EECO product introduction model in Niger, while also adapting the introduction strategy to best fit within the Benin health system.



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