

Contraceptive Innovation Index

An Adaptation of the Global
Health Innovation Index



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Executive Summary

The Contraceptive Innovation Index is intended to support ongoing discussion and decision-making around the introduction and scale up of contraceptive technologies.

This tool builds upon the United States Agency for International Development's (USAID) **Global Health Innovation Index**, with adaptations made to reflect the complexities of contraceptive markets. Using the adapted Index, stakeholders can identify which contraceptive technologies have the greatest potential for impact – both in the short and long term – using four core criteria (user demand and impact, system factors and

sustainability, supplier capacity and progression to scale). Rather than provide a go or no-go decision, the Index helps bring attention to where additional data and/or investment would be most useful prior to launching or scaling an innovation. To illustrate how to apply the Contraceptive Innovation Index, two case studies are included within this report: on the hormonal IUD in Nigeria and the Caya diaphragm in Niger. Decision-making around contraceptive introduction and scale should be informed by a context-specific understanding of the complex market into which any new method would enter. As a result, application of the Contraceptive Innovation Index is recommended within a specific geographic or market context.



Introduction

The global FP2030 partnership envisions a future with “voluntary modern contraception use by everyone who wants it, achieved through individuals’ informed choice and agency, responsive and sustainable systems providing a range of contraceptives, and a supportive policy environment.” Achieving this shared vision will require concerted action across many focus areas, including the continuous improvement of contraceptive products and the expansion of method choice.

WHY INTRODUCE NEW CONTRACEPTIVE TECHNOLOGIES?

Rights-based family planning (FP) programs make a range of contraceptive method options available to support people to voluntarily achieve their fertility intentions, meaning whether and when to have children, in a way that aligns with their varied needs and preferences over their reproductive lives. A diverse array of contraceptive method options are needed to serve everyone who has a desire to use contraception.

Contraceptive method introduction has the possibility to create health impact by increasing overall contraceptive use or changing the quality of use (e.g., fewer method failures when clients use methods that suit their preferences and lifestyles). Historically, the modern contraceptive prevalence rate (mCPR) in a country has tended

to rise when a new method choice becomes available at scale, especially in countries with few widely available contraceptive options.¹

Yet not all contraceptive product innovations are suitable for introduction in all settings. Many method introductions of the past have not gained traction, whether because of low consumer demand for the method, unaffordable pricing, inadequate introduction funding, a lack of support from health system stakeholders, or other challenges. When funding is tight and health systems are overstretched, Ministries of Health (MOH) and other decision-makers need to carefully consider the required inputs and expected outcomes of scaling a method before they move ahead.

HOW ARE CONTRACEPTIVE INTRODUCTION DECISIONS DIFFERENT?

With contraceptive product introduction, we seek to improve upon an existing array of options by expanding choice and in some cases replacing older technologies. Contraceptive introduction decisions should be informed by an understanding of the complex market of methods, suppliers, channels, prices, and payers into which the new option would enter. The health impact of method introduction depends on which market segments adopt the new method and what they would have otherwise done (e.g.,

¹ Ross, J., and Stover, J. (2013). *Use of modern contraception increases when more methods become available: analysis of evidence from 1982–2009*. *Global Health: Science & Practice*, 1(2): 203-212.

non-use of contraception, inconsistent use of another method).

While treatments to cure illness tend to be selected and prescribed by healthcare providers (with patient consent), clients themselves drive the decision to use a contraceptive method (with counseling from providers). Given this dynamic, it is critical to understand what method characteristics consumers value, how the existing range of options may fail to adequately

meet their needs, and what factors influence their contraceptive use and method choice.

The Contraceptive Innovation Index was developed to support decisions about whether to launch and/or scale new contraceptive technologies. The tool builds upon USAID's Global Health Innovation Index, with adaptations made to reflect the complexities of contraceptive markets.



Global Health Innovation Index

The Global Health Innovation Index, developed by USAID’s Center for Innovation and Impact (CII), was designed to offer a strategic approach to helping identify promising, ready-to-launch innovations. Looking across USAID’s global health innovation portfolio, spanning technologies to prevent hypothermia in low birthweight babies to a device that can manage and monitor IV infusion rates without expensive and difficult-to-use infusion pumps and beyond, the Index assesses the innovations’ potential global health impact and readiness to scale.

To measure the potential for scale and impact, the Index evaluates innovations according to four core criteria: (1) health impact, (2) demand and sustainability, (3) organizational and/or partner capacity, and (4) progression to scale. (See Figure 1). Across the criteria, innovations are scored with a color scale of red, yellow, and green, to indicate the strength and quality of evidence available.

FIGURE 1. Global Health Innovation Index Criteria

The tool uses four core criteria to evaluate the most promising innovations:

 HEALTH IMPACT	 DEMAND & SUSTAINABILITY	 ORGANIZATIONAL AND/OR PARTNER CAPACITY	 PROGRESSION TO SCALE
Core Questions:			
Does this innovation improve health outcomes relative to the status quo? Does it relate to an important driver of morbidity or mortality?	Are health workers and other stakeholders willing to use this innovation and able to do so affordably? Is there a sustainable way to pay for the innovation?	Can this organization and/or their partners reliably produce and distribute this innovation at scale?	Has this innovation cleared regulatory and technology hurdles to scale? Has it proven ability to scale successfully?



WHO ARE THE INTENDED USERS OF THE GLOBAL HEALTH INNOVATION INDEX?

The Global Health Innovation Index tool can be applied by a variety of stakeholders, including MOHs, donors, implementers, and innovators themselves. Evaluators who use the tool are encouraged to draw on an assortment of data sources and methodologies to avoid bias. Similarly, it is recommended that multiple evaluators are tasked with using the tool so that the output is based on group consensus rather than an individual perspective. Evaluators should also consider using the tool on a recurring basis to track progress over time.

Based on the results of the Index, stakeholder roles can influence whether and how an innovation continues along the path to scale. For example, MOHs may develop costed implementation plans and initiate processes to add an innovation to national guidelines and/

or training plans. Donors may fund scale-up activities or leverage their power to connect partners. Implementers can present findings to national governments for political and financial buy-in as well as provide technical assistance in adapting the innovation for the local context. Innovators may choose to iteratively improve their technologies or its evidence base to respond to weaknesses identified by the Index.

HOW SHOULD THE INDEX BE USED?

Using the Index, stakeholders can identify which innovations are ready to launch as well as where additional data or investment would be most useful before supporting or introducing a given innovation. It is important to note that the Index is not intended to be a report card for whether to launch or scale a particular health innovation. Instead, it is meant to be a helpful tool to aid ongoing discussions and decision-making around scale up with an understanding that introduction and scale often happen in overlapping stages.

Adaptation Process

To adapt the existing Global Health Innovation Index for use with contraceptive technologies, USAID's CII and Office of Population and Reproductive Health (PRH), along with the USAID-funded Expanding Effective Contraceptive Options (EECO) project, collaborated and sought input and feedback from 32 key stakeholders through a two-part virtual workshop. Workshop participants included FP experts representing national governments, donor agencies, technical assistance partners, and implementing organizations. (See Appendix 1 for the list of workshop participants.)

The workshop objectives were two-fold. In the first workshop, we aimed to gather input on the key criteria to consider when deciding whether to launch and/or scale contraceptive technologies. Participants brainstormed and examined the criteria within the existing Index,

identifying considerations that would have the greatest utility and relevance for contraceptive technologies. The authors used this input to draft the adapted Index. In the second workshop, we tested the adapted Index by applying it to real contraceptive products in specific country contexts. By conducting this "stress test" of the adapted Index, we identified areas requiring further adjustment.

Based on the results of the two workshops, USAID's CII, PRH and the EECO project revised the Index for application to contraceptive technologies. The authors then shared the Contraceptive Innovation Index document, including two method case studies, with the workshop participants and additional experts for review. (See Appendix 2 for the list of additional reviewers.)



An Analytical Tool for Assessing Contraceptive Technologies

The Contraceptive Innovation Index is a tool intended to assess contraceptive technologies and identify those with the greatest potential for impact – both in the short and long term. The Index can be used to examine method categories (e.g., hormonal IUD) or products within those categories (e.g., Bayer AG’s Mirena, Medicines360’s Avibela).

The Index has two main goals:

1. Highlight promising contraceptive innovations that have already scaled to some degree and are ready to scale further;

2. Demonstrate how the Index criteria can be applied to existing contraceptive innovations within specific country contexts.

Like the Global Health Innovation Index, the Contraceptive Innovation Index uses four core criteria to evaluate the most promising innovations. However, the four criteria have been adapted for relevance to contraception. The four core criteria and assessment questions are presented in Figure 2.

FIGURE 2. Contraceptive Innovation Index

<p>USER DEMAND & IMPACT</p> 	<p>What is the evidence that the product will improve health, wellbeing, and/or choice over the status quo?</p> <ul style="list-style-type: none">• Does the product address a critical gap in the contraceptive market (e.g., overcomes access barriers, offers unique features valued by end-users)?• Which market segments are likely to use it? How strong is the evidence that they want this product?• What are the risks of unintended consequences (e.g., environmental damage, effects on local suppliers)?• In the short and long term, how might this addition affect the overall market for contraception (e.g., mCPR, method mix, unintended pregnancies averted, equity)?
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SYSTEM FACTORS & SUSTAINABILITY



What is the willingness and capacity of health system actors (e.g., providers, MOH) to add the product to the current offering? In the case of self-care methods, how feasible is use in this setting?

Considering costs alongside demand and impact, what is the cost-effectiveness over time?

- What are the full costs of adding the product (e.g., product cost, provider training, demand creation, savings from de-prioritization of older product)?
- Who will pay (e.g., balance of public/private sector use) in the short and long term future? How aligned are costs with willingness and ability to pay?
- Is it feasible to achieve price sustainability given near- and long-term financing and other considerations (e.g., estimated time to supply diversification)?

SUPPLIER* CAPACITY



Is there a potential for more than one supplier in this method category?

Do product specifications align with requirements of procurer(s) and health system realities (e.g., shelf-life, storage conditions)?

- What is the supplier's capacity to adapt the product as needed (e.g., languages, duration of use, shelf-life, storage conditions)?

What is the supplier's capacity to manage production (including over- or under-estimation of demand), quality assurance, sales, marketing, and pharmacovigilance (e.g., experience with other contraceptive products)?

What is the supplier's commitment to this market, ability to manage stakeholder relationships, and openness to direct rather than centralized procurement?

What is the supplier's level of financial resourcing and stability?

Can we adequately manage risk to the supplier (e.g., advance market commitments, possible public relations impact of a challenging launch)?

*Suppliers can include innovators, licensees, and generic manufacturers

PROGRESSION TO SCALE



Have all available channels of access (e.g., public and private facilities, pharmacies and drug shops, community-based distribution) been considered?

What policies, tools, or guidelines would need to change for the innovation to deliver on its potential impact (e.g., over-the-counter sales, self-administration)?

To what extent has this innovation already scaled? Or is there a clear path to scale? For example:

- Have potential roadblocks been considered and plans made to address them?
- Has the World Health Organization (WHO) included the product/method in guidelines?
- Has the product cleared regulatory hurdles or will clear them soon (e.g., WHO Pre-Qualification (PQ) or Stringent Regulatory Authorities (SRA) approval, national registration)?
- Is the product listed in donor agencies' procurement catalogs (if relevant)?

Scoring Innovations

As with the Global Health Innovation Index, the questions in the Contraceptive Innovation Index can be used to color code, under each of the four core criteria, how ready and suited an innovation is for scale based on its stage. Green is used

to signal strong evidence, yellow for medium or mixed evidence, and red for evidence of no positive impact. Blue is used where no evidence is available. Color codes are shown in Figure 3.

FIGURE 3. Color coding of strength and availability of evidence under each of the four core criteria

Early stage:



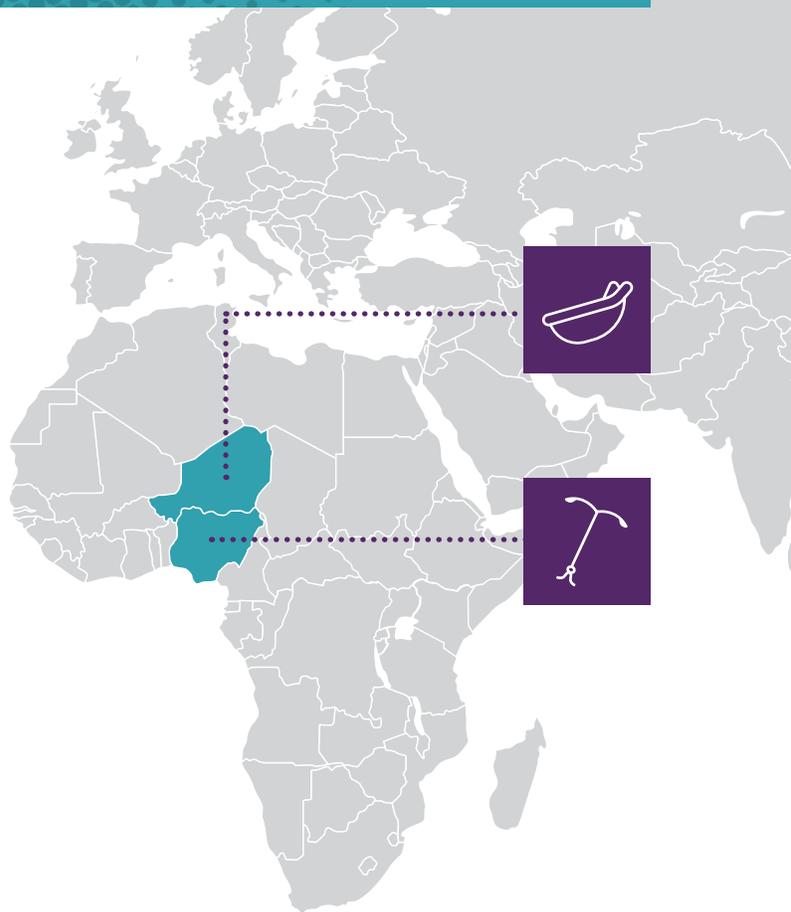
Scaling:



Innovation Profiles

This Index profiles two innovations – the hormonal IUD and the Caya diaphragm – and assesses their introduction in Nigeria and Niger respectively, to illustrate how to apply the assessment tool to existing technologies. The profiled innovations have demonstrated early evidence of strong performance across the Index criteria. These examples are just two of the many contraceptive technologies that may be scaled over the coming decade.

When introducing any innovation, local context is crucial to consider. Consumer preferences and health systems vary widely from one setting to the next, which can make contraceptive technologies suitable for scale up in some markets and not in others. For this reason, the innovation profiles presented here are grounded in specific country contexts.





HORMONAL IUD IN NIGERIA

The hormonal intrauterine device (IUD) is a highly effective, long-acting, reversible contraceptive option. The small T-shaped device, about the size of a matchstick, prevents pregnancy through the daily release of a low dose of the hormone levonorgestrel. A trained provider inserts the hormonal IUD into the uterus through a simple procedure. The hormonal IUD is more than 99% effective at preventing pregnancy for 3-8 years depending on the product. It can be used by women of any reproductive age, regardless of parity or future fertility intentions.^{2,3}

In addition to contraceptive benefits, the hormonal IUD offers non-contraceptive lifestyle and health benefits that are appealing to many users. For most users, the method causes lighter or paused periods, which can reduce the need for menstrual hygiene products and the experience of menstrual cramping. The hormonal IUD is also indicated for treatment of menstrual disorders and may reduce iron-deficiency anemia.⁴ Since the hormonal IUD releases a low dose of levonorgestrel directly into the uterus, users also often experience fewer side effects relative to other hormonal methods—an important factor to consider given side effects are a primary reason for contraceptive non-use among women in Nigeria.⁵

Although the hormonal IUD was originally developed more than 30 years ago, it has remained largely out of reach in low- and middle-income countries (LMICs), due in large part to its historically high procurement cost relative to other methods as well as a lack of evidence on potential demand in these markets. The

² World Health Organization (WHO) et al. (2018). *Family Planning: A Global Handbook for Providers*.

³ Bayer. (2022). *FDA Label Update Reflects Bayer's Commitment to Providing Options for Long-acting Contraception*.

⁴ WHO et al. (2018). *Family Planning: A Global Handbook for Providers*.

⁵ Moreira, L.R., et al. (2019). *Reasons for nonuse of contraceptive methods by women with demand for contraception not satisfied: an assessment of low and middle-income countries using demographic and health surveys*. *BMC Reproductive Health* 16(148).

SCALING PROGRESS TO DATE



In 2015, an interagency working group comprised of various stakeholders, including donors, researchers, suppliers, and service delivery organizations, convened to develop a global learning agenda for the hormonal IUD. By developing and coordinating a shared learning agenda, this group – now known as the Hormonal IUD Access Group – improved harmonization among introduction activities and pilots and generated a body of data to support scaling at the country and global levels.



Pilot introductions of the hormonal IUD in Kenya, Madagascar, Nigeria, and Zambia demonstrated high levels of acceptability and continuation of the method.



In 2021, both USAID and UNFPA added the hormonal IUD to their procurement catalog, which was a key step to ensuring that Ministries of Health and donor-funded projects can procure this method on a meaningful scale moving forward.



Several countries, including Nigeria, have developed and begun to implement strategies to scale up access to the hormonal IUD.

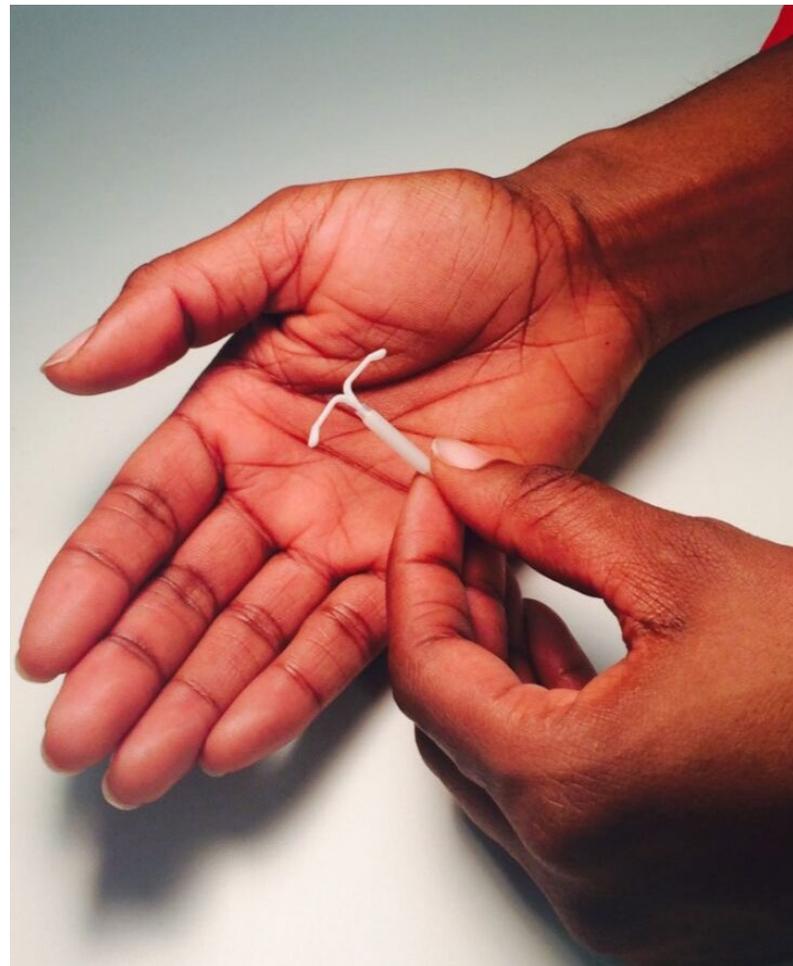


readiness of the hormonal IUD to be scaled in LMICs has recently improved thanks to public sector access pricing, a coordinated research effort, and country-level introduction planning efforts currently underway.

In 2015, an interagency working group comprised of a diverse set of stakeholders, including donors, researchers, suppliers, and service delivery organizations, convened to develop a global learning agenda for the hormonal IUD.⁶ Today called the Hormonal IUD Access Group, this group identified priority research and evaluation questions regarding the potential for uptake of the hormonal IUD in LMIC markets, and partners coordinated efforts to answer these questions through various research initiatives. This coordination and shared learning agenda improved harmonization among introduction activities and pilots and generated a body of data that catalyzed progress toward scale at the country and global levels.⁷

Pilot introduction studies in Kenya, Madagascar, Nigeria, and Zambia found that the hormonal IUD appealed to many women who would have chosen a short-acting method or no modern method at all if the hormonal IUD had not been available. Satisfaction and continuation rates were high among hormonal IUD users in all four countries.^{8,9}

This evidence and collaboration between suppliers, donors, and implementers contributed to decisions by the United Nations Population Fund (UNFPA) and USAID to add hormonal IUD products, Bayer's Mirena™ and Medicines360's Avibela™, to their procurement catalogs in 2021. This was a key step toward ensuring that Ministries of Health and donor-funded projects can procure this method on a meaningful scale.



Additionally, the public access commodity prices of the products in these catalogs are the lowest they have ever been, with one product now available for USD \$9.50, a price nearly comparable to that of contraceptive implants. Major international donors have also committed funding to helping to scale up this product in both the public and private sectors.

To guide the expansion of access to this method, Nigeria's Federal Ministry of Health (FMOH)

⁶ Rademacher, K., et al. (2018). *A Global Learning Agenda for the Levonorgestrel Intrauterine System (LNG IUS): Addressing Challenges and Opportunities to Increase Access*. *Global Health: Science & Practice*, 6(4):635-643.

⁷ Rademacher, K., et al. (2022). *What Have We Learned? Implementation of a Shared Learning Agenda and Access Strategy for the Hormonal Intrauterine Device*. *Global Health: Science & Practice*.

⁸ Sitrin, D., et al. (2021). *Expanding Contraceptive Method Choice With a Hormonal Intrauterine System: Results From Mixed Methods Studies in Kenya and Zambia*. *Global Health: Science & Practice*, 9(1):89-106.

⁹ Danna, K., et al. (2022). *Introducing the hormonal Intrauterine Device in Madagascar, Nigeria, and Zambia: results from a pilot study*. *BMC Reproductive Health*, 19(4).



developed and adopted The National Hormonal IUD Strategic Introduction and Scale-Up Plan in 2021. The plan focuses on coordination, capacity building, procurement and supply chain management, demand creation and communication, and monitoring and supervision. Mirena and Avibela both have SRA approval and are registered in Nigeria. The FMOH carried out national quantification exercises and placed their first procurement order of the hormonal IUD in 2021 via the UNFPA procurement mechanism for public sector distribution. In-country partners

who have been working to increase access to this method in Nigeria are aligned with this strategy and are leveraging new and existing funding opportunities to support its objectives. Nongovernmental organizations have accessed funding to carry out components of the national scale-up plan, including activities to train master trainers nationwide, train providers at tertiary facilities, develop pre-service and national training curricula, and improve data management and monitoring systems.



Avibela is one of the three hormonal IUD products registered for use in Nigeria.

Photo: Medicines360



FIGURE 4. Contraceptive Innovation Index Snapshot: Hormonal IUD in Nigeria

A snapshot assessment against the 4 core Index criteria:

 USER DEMAND & IMPACT	 SYSTEM FACTORS & SUSTAINABILITY
Proven positive evidence	Proven positive evidence
<p>The hormonal IUD has been found to have broad appeal across demographic health segments in Nigeria, including new FP users, those who have previously only ever used short-acting methods, and those who discontinued use of other methods.</p> <p>Hormonal IUD use has been shown to lead to high rates of continuation and satisfaction in pilot countries, including Nigeria.</p> <p>The hormonal IUD offers both highly effective contraception and non-contraceptive benefits, with evidence suggesting that many users find these benefits appealing. Specifically, research has shown that most users who experienced reduced bleeding report that it has had a positive impact on their lives.</p> <p>Based on consumer research and pilot studies showing an interest in the hormonal IUD by non-users of contraception, it appears that scale up might contribute to growth in Nigeria’s mCPR. However, further evidence will be needed to understand effects on mCPR.</p>	<p>The FMOH developed and adopted a national plan for an incremental and phased approach to scale up the method nationwide in 2021.</p> <p>Reception of the hormonal IUD among providers has been very positive, with providers in both the public and private sectors enthusiastic about participating in trainings to be able to offer the method.</p> <p>Though the public sector commodity price remains the highest among available methods in Nigeria, cost-effectiveness analyses based on data from Nigeria has showed that over a 10-year period, the hormonal IUD is more cost-effective (i.e., lower incremental cost per unintended pregnancy avoided) compared to implants from both a health systems and societal perspective.¹⁰</p> <p>Partners are developing cost-effective approaches to scale up, including digital (e-learning), virtual (live), and on the job training approaches. Preliminary results from research evaluating these training approaches show that they have promising potential to train competent providers affordably and efficiently.</p>

¹⁰ LEAP. (2021). *Cost-effectiveness of including the hormonal IUD in the contraceptive method mix in Nigeria and Zambia: Summary of results.*



SUPPLIER CAPACITY

Proven positive evidence

Multiple suppliers offer this product and have demonstrated a commitment to LMIC markets including Nigeria. Global demand has not surpassed production capacity, although attention to capacity limits needs to continue as demand grows.

Packaging for branded products is adapted to meet specific country requirements.

Suppliers' strong relationships with donors and implementing partners through the Hormonal IUD Access Group have enabled a collaborative environment whereby potential risks to the suppliers can be identified and managed.

Two suppliers have committed to public sector access pricing. One of these suppliers, Bayer, is a very large and stable company with history of supplying other contraceptives to USAID and UNFPA. Another supplier, Medicines360, a non-profit pharmaceutical company with a mission to increase access to women's health medicines, currently offers the lowest-priced SRA-approved hormonal IUD.



PROGRESSION TO SCALE

Proven positive evidence

Three hormonal IUD products—Mirena, Avibela, and Eloira—have already been approved by the national regulatory authority in Nigeria.

National guidelines in Nigeria have already been adapted to include the hormonal IUD. Inclusion of the method in the National Essential Medicines List is part of the strategic plan.

In Nigeria, funding has been secured for initial phases of scale-up, including training master trainers, training providers at tertiary facilities, developing pre-service and national training curricula, and improving data management and monitoring systems. Funds will be needed for future stages as well.

SRA-approved and WHO PQ products included in catalogs, available for USAID and UNFPA (for the FMOH) procurement on a large scale.



CAYA DIAPHRAGM IN NIGER

Diaphragms are a centuries-old barrier method of contraception. A user inserts the soft and flexible cup into her vagina before sex, where it sits just under the cervix and physically blocks sperm from passing into the uterus. Although diaphragms were commonly used in the United States and Europe in the early 20th century, the method has never been widely available in West African countries like Niger.

With funding from USAID, PATH and partners developed the Caya® contoured diaphragm (originally called SILCS) through human-centered design to address limitations of traditional diaphragms. For example, Caya includes grip dimples along the rim and a removal dome to make the product easier than older diaphragms to handle, insert, and remove. Caya also comes in a single size that fits most users, simplifying production, procurement, and distribution. Importantly, women can initiate use of Caya without a fitting from a provider, which was necessary for previous diaphragms. Caya diaphragms are labeled for use with a contraceptive gel such as Caya® gel (also sold as ContraGel®), which contains lactic acid and cellulose, or a spermicide.



SCALING PROGRESS TO DATE

With support from USAID, PATH and partners developed the Caya diaphragm through an iterative, human-centered design process to address the limitations of traditional diaphragms. The redesigned Caya diaphragm is “one-size-fits-most” and reusable for up to two years.

A pilot introduction of Caya in Niger demonstrated that women and their partners appreciated that the method is non-hormonal, causes no side effects for most users, works on demand, and is reusable.

Additionally, the pilot introduction in Niger showed that both community health workers and facility-based providers could successfully offer the method to interested clients.

The Caya diaphragm, and accompanying Caya gel, are not yet available through USAID or UNFPA procurement catalogs. Some challenges related to the storage conditions and shelf-life of the Caya Gel remain.



A pilot introduction in urban and peri-urban Niamey, Niger, found that for a subset of women and girls, Caya met their specific desires for contraception. Community health workers and facility-based providers in the public and private sectors added the Caya diaphragm to their offering of voluntary contraceptive methods with few challenges. Research with Caya adopters, men in the community, and providers in Niger identified several product features that appealed to women and couples: the product is non-hormonal, causes no side effects for most users, works on demand, and is reusable for up to two years. Diaphragms are not visible while inserted and were used by some women in Niger without their male partner's knowledge. As a method used only at the time of sex, Caya particularly appealed to women who have infrequent sex. Most Caya adopters in Niger continued to use the method six months after adoption. The top reasons for discontinuation by six months were the desire for pregnancy and concerns about method effectiveness.¹¹

The Caya diaphragm and Caya gel, both owned by the German manufacturer Medintim,

are not yet available through the USAID and UNFPA procurement catalogs. Medintim supplied USAID's pilot project in Niger with prices of \$5.66 USD per Caya diaphragm and \$3.76 USD per tube of Caya gel in 2021. Each 60mL Caya gel tube is intended to last for about 15 acts of intercourse.

Although the Caya diaphragm itself is a simple device that could be procured and distributed with little difficulty, Caya gel and other contraceptive gel options pose more challenges: Caya gel has a 24-month shelf life and must be stored under 25° C / 77° F. To respond to these concerns, Medintim is currently exploring a reformulation that would extend the shelf life, expand the storage conditions to additional climactic zones, and consider packaging in single-use sachets. Alternatives to Caya gel contain nonoxynol-9, which is problematic because these spermicides may increase HIV risk.¹² However, a postcoital testing study found that the Caya diaphragm alone functions almost as well as when used with ContraGel (Caya Gel) or a spermicide.¹³ More evidence may be needed to support a label change that would allow use of Caya diaphragms with no gel.



¹¹ Jackson, A., et al. (2022). *A new contraceptive diaphragm in Niamey, Niger: a mixed methods study on acceptability, use, and programmatic considerations*. *Global Health: Science & Practice*, 10(2):e2100532.

¹² Van Damme, L., et al. (2002). *Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-1 transmission in female sex workers: a randomised controlled trial*. *The Lancet*, 360(9338):971-7.

¹³ Mauck, C.K., et al. (2017). *A phase I randomized postcoital testing and safety study of the Caya diaphragm used with 3% Nonoxynol-9 gel, ContraGel or no gel*. *Contraception*, 96(2):124-130.



FIGURE 5. Contraceptive Innovation Index Snapshot: Caya diaphragm in Niger

A snapshot assessment against the 4 core Index criteria:

 USER DEMAND & IMPACT	 SYSTEM FACTORS & SUSTAINABILITY
Medium quality early evidence	Medium quality early evidence
<p>Caya users appreciate this on-demand, self-use, and non-hormonal FP option. The method fills a gap for users looking for this combination of method benefits.</p> <p>In many contexts, there is potential for Caya to be entirely self-care; users might learn about, obtain and initiate use of the method entirely outside of health facilities.</p> <p>Women who are intermittently sexually active appear to be a key market segment interested in this method.</p> <p>Dissatisfied oral contraceptive pill (OCP) users may also be a key market; many Caya adopters in Niger were lapsed OCP users who had discontinued use due to method dissatisfaction.</p> <p>Counseling on transmission of HIV and sexually transmitted infections (STIs) will remain critically important. Although Caya is a barrier method, it does not prevent HIV or other STIs.</p> <p>While demand for Caya is evident in Niamey, further research is needed to understand potential demand in rural areas of Niger. The current requirement to use Caya diaphragms with a gel, which needs to be resupplied more frequently and has narrower storage conditions, may limit the potential of the method in rural Niger.</p>	<p>Following a pilot introduction in Niamey, Niger, the MOH expressed interest in expanding method availability to more remote areas to better understand acceptability and feasibility in these settings.</p> <p>Many providers were initially skeptical that this vaginally inserted method would appeal to clients. After gaining experience offering the method to clients, providers reported higher acceptability of Caya than anticipated.</p> <p>The pilot introduction established that community health workers and facility-based providers alike can offer the method successfully. By expanding the range of options offered at the community level, Caya may reduce strain on facility-based providers.</p> <p>Reusable for up to two years, Caya's one-time cost is defrayed over time, in stark contrast to other short-acting or on-demand methods that must be replaced after each cycle/use. However, the requirement to pair diaphragms with a gel adds to cost and complexity.</p> <p>Training on Caya could be easily folded into existing, national FP trainings or refreshers. The method can be included in broader FP awareness-raising efforts.</p> <p>In the pilot study in Niger, most Caya adopters accessed the diaphragm and gel for free. Subsidization is necessary in Niger given constraints on clients' ability to pay.</p>



SUPPLIER CAPACITY

Medium quality early evidence

Due to Caya's one-size-fits-most design, procurement and stock management is far simpler and more manageable than for traditional diaphragms. As a medical device, instead of an active drug, it is a highly stable commodity with a 5-year shelf-life. However, Caya gel's shelf-life and storage conditions present challenges.

Caya is available in nearly 40 countries, and instructions for use and packaging are available in many languages. For introductions in Niger, Caya's manufacturer adapted packaging as needed.

Small orders of Caya for new markets require several months of lead time.

While there is only one supplier of single-size diaphragms, this supplier is highly committed to serving LMICs such as Niger. The manufacturer, Medintim, donated pelvic models, product samples, communication materials, and technical assistance for the pilot introduction in Niger.



PROGRESSION TO SCALE

Medium quality early evidence

While distribution of Caya through the public sector, the private sector, and community-based distribution has been piloted, pharmacy-based distribution has not yet been attempted in Niger.

The product has 510(k) authorization from the US Food and Drug Administration and CE Mark in the European Union. Furthermore, both Caya diaphragms and Caya gel are registered in Niger.

Given challenges with contraceptive gel options, it is worth exploring further the possibility of offering Caya diaphragms with no gel.

While this innovation is included in the WHO FP handbook (under its former name, SILCS), the method has not been made widely available in many LMICs. Next steps to scale include making the method easier to procure through common mechanisms, such as the USAID and UNFPA catalog.

Conclusion

The introduction and scaling of contraceptive technologies has the potential to expand the range of methods available to women and better meet their contraceptive needs and preferences.

By making new methods available and accessible, overall contraceptive use may be increased or improved. However, not all

contraceptive technologies are ready for introduction and scale in all settings. To determine where introduction and scaling are poised to be most impactful, Ministries of Health, donors and other stakeholders need tools to evaluate their potential. The Contraceptive Innovation Index outlines a practical, easy-to-use process to support decision-making around the introduction and scale up of contraceptive technologies rooted in local contexts and realities.



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