

Country Guidance for Quantification of Early Orders for Hormonal IUD Introduction

Background

The hormonal intrauterine device (IUD) is a long-acting reversible contraceptive. Despite notable hormonal IUD uptake in high-income markets, access to hormonal IUDs has historically been limited in low- and middle-income countries (LMICs). In 2015, a working group was established to coordinate efforts of pilots across several countries, which generated rich insights into method uptake, as well as user perceptions of, demand for and experiences with hormonal IUDs. There was demonstrated consumer interest in the method, but the hormonal IUD was not available on UNFPA and USAID catalogs (in part due to unaffordable pricing). Additionally, the global SRH community had not aligned on a coordinated, comprehensive market-shaping strategy. In 2019, the members of the working group, collectively known as the Hormonal IUD Access Group, developed a holistic theory of change and market-shaping strategy that targets key needs across the supply and demand sides of the market to increase hormonal IUD access in LMICs and expand method choice for women and girls.

Since 2019, the Access Group has been executing its agreed upon market-shaping strategy and has made significant strides towards increasing access to hormonal IUDs in LMICs. In 2021, USAID and UNFPA added the hormonal IUD to their catalogs, introducing two quality-assured products at the affordable price points.

As countries introduce hormonal IUD into their contraception method mix, it is important for them to develop robust assumptions for the quantification process as they prepare for health worker trainings, and the introduction and scale-up of this new product. Although guidance exists on forecasting for new and underused methods [1], it does not provide sufficient detail on the specifics of forecasting and supply planning for the hormonal IUD. The Hormonal IUD Access Group offers this document specific to hormonal IUD to help FP program managers, technical working groups and supply chain/logistics managers confront the challenges in estimating and planning for commodity needs as programs introduce and integrate provision of hormonal IUD. This document provides guidance on forecasting approaches for hormonal IUD during introduction and early scale-up and includes examples of key evidence from countries that have begun introductions, to assist others in determining reasonable assumptions.

What is the hormonal IUD?

The hormonal IUD is a highly effective, long-acting reversible contraceptive. It is highly effective (approximately 99%)[2] at preventing pregnancy and has proven non-contraceptive benefits, including treatment for heavy menstrual bleeding and potential prevention of iron-deficiency anemia. There are two stringent-regulatory authority (SRA) approved hormonal IUDs available for procurement on UNFPA and USAID product catalogues in LMICs and several non-SRA approved devices.

[1] IRH-GU, JSI, & PSI. (2012). A forecasting guide for new & underutilized methods of family planning: What to do when there is no trend data? Reproductive Health Supplies Coalition. <https://tinyurl.com/2012ForecastGuide>

[2] WHO. (2021). WHO statement on levonorgestrel-releasing intrauterine device nomenclature. World Health Organization Division of Sexual and Reproductive Health and Research. <https://tinyurl.com/2021WHONomenclature>

Products Available for Procurement on UNFPA and USAID Product Catalogues for LMICs

Product	Supplier	Quality-Assured Status	Duration of Protection	Inserter
Avibela	Medicines360	SRA	Up to 6 years*	Two-Handed
Mirena	Bayer	SRA	Up to 8 years*	One-Handed

*Labelled duration of use for these products may vary by country registration

Other Hormonal IUD Products Available in the Global Market

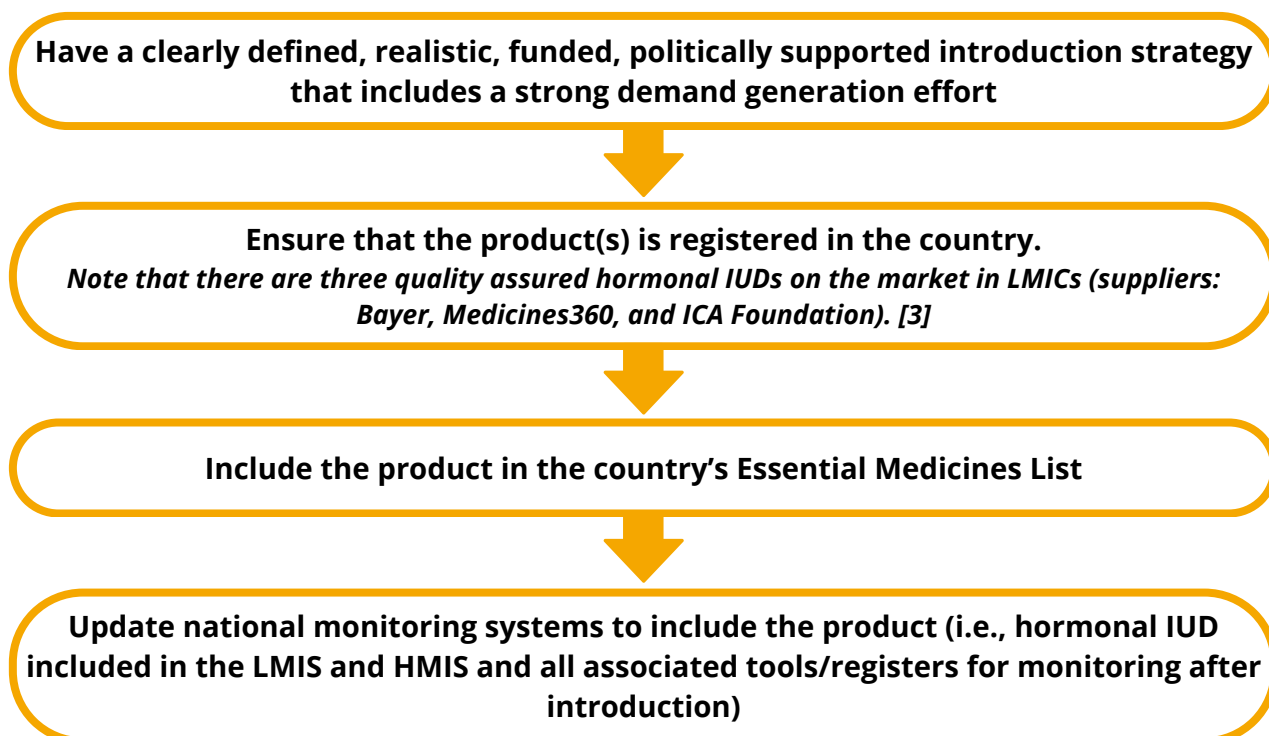
Product	Supplier	Quality-Assured Status	Duration of Protection
LNG IUS	ICA Foundation	SRA	Up to 5 years*
Eloira	Pregna	Not SRA, not WHO-PQ; approved in several countries	Up to 5 years*
Emily	HLL Lifecare	Not SRA, not WHO-PQ; approved in several countries	Up to 5 years*
Erinna	Meril Life	Not SRA, not WHO-PQ; approved in India	Up to 5 years*
Fiona	Meril Life	Not SRA, not WHO-PQ; approved in India	Up to 5 years*

*Labelled duration of use for these products may vary by country registration

It is advisable for countries to plan to procure more than one brand of product to maintain supply security and to mitigate for potential product constraints in the global market. Because the insertion process may vary for different products, a country that is procuring a mix of brands of the hormonal IUD must include the appropriate training plans in alignment with the product mix during rollout. The country's quantification team should determine the proportions of multiple product procurement depending on market availability, funding capacity, and the individual country context and preference.

Key preparation steps prior to developing a hormonal IUD quantification

There are several steps that should be taken prior to developing a quantification. Further information on these steps can be found in the [HIP Strategic Planning Guide](#) and the [Hormonal IUD Introduction Planning Guide](#), but are outlined here:



The quantification team should plan to develop the forecast and supply plan early, checking with procurers and/or suppliers on current lead times, to ensure that commodities can arrive before training and capacity-building activities begin. To do this, quantification teams should have a clear understanding of the introduction plans, including the purpose, scope, funding realities and timeframe. It is important for a quantification team to have access to and gather quality data prior to, during and after product introduction. Finally, the hormonal IUD should be included in the national quantification for all FP products as it will be incorporated into the overall method mix.

Deciding which forecasting method(s) to use for early hormonal IUD quantification

There are three main forecasting methods applicable for hormonal IUD introduction: these are service capacity, demographic, and consumption forecasts and each have advantages and drawbacks. In some ways, the “gold standard” forecast is a consumption forecast, since consumption data are based on real-world experience. However, since the hormonal IUD is a new product, most countries will not have historical service or consumption data, or the available data may not be predictive of the future given programmatic introduction and integration plans. As such, **it is recommended that quantification teams adopt a blended approach and combine and or compare different forecasting methods as they determine best estimates in the context of their country's needs.** All countries should be able to prepare at least a services capacity forecast and a demographic forecast, if historical services or consumption data are not available or not of good quality.

[3] Hormonal IUD Access Group. (2020). The Method. Hormonal IUD Access Portal. <https://www.hormonaliod.org/about>

Comparison of Three Forecasting Methods [4]

Service Capacity Forecast	Demographic Forecast	Consumption Forecast
<i>Key data and assumptions</i>	<i>Key data and assumptions</i>	<i>Key data and assumptions</i>
<ul style="list-style-type: none"> • Actual or planned numbers of trained service providers • Level of the system at which hormonal IUD will be provided • Estimated capacity of available providers to offer the service (e.g., potential insertions per provider per month) • Timing of product introduction 	<ul style="list-style-type: none"> • Total population • Annual population growth rate • % of total population that is women • % of total population that is women of reproductive age (WRA) • % of WRA that are sexually active • Modern contraceptive prevalence rate (mCPR) • Method mix (proportion of CPR attributable to each method of contraception) • Product mix (proportion of method mix attributable to each method) • Product mix (proportion of method mix attributable to each product/brand) • Source mix (proportion of method or product by service delivery source, e.g., public, social marketing, etc.) • Couple-year protection factor to convert numbers of users to quantities of product 	<ul style="list-style-type: none"> • Consumption data on hormonal IUDs from HMIS or LMIS (ideally dispensed-to-user data; alternatively, data from lowest level possible) • Product mix assumption(s) • Stock-out rate assumption(s) • Timing of product introduction • Estimates of growth in hormonal IUD use due to new product introduction
<i>Benefits</i>	<i>Benefits</i>	<i>Benefits</i>
Ideal for products that haven't yet been introduced	Draws from quality data sources that are readily available	Data is based on actual consumption which will typically be more accurate than an estimate
<i>Challenges</i>	<i>Challenges</i>	<i>Challenges</i>

[4] IRH-GU, JSI, & PSI. (2012). <https://tinyurl.com/2012ForecastGuide>

Gaps in available data often exist, requiring additional assumptions	Assumptions on the hormonal IUD proportion of the FP method mix may not be accurate	Gaps in available data often exist, requiring additional assumptions
Diminishes in relevance as a new product becomes integrated into the system	Likely to generate an over-estimation of demand for new products	Existing consumption may be limited to pilots and may not be representative of national consumption trends

All hormonal IUD forecast types require information from the method introduction, including, but not limited to:

- the program’s goals for introducing the new method (i.e., demand generation efforts, number of health facilities, number of health workers to be trained, timelines for roll out and scale-up, etc.)
- the types or cadres of providers who will offer the method and at what levels of the health system
- the number of providers to be trained and timing of trainings
- the geographic coverage for introduction and potential expansion

After the forecasting data have been collected, they should be organized by type—either consumption, service capacity, or demographic. When data are missing or are of questionable quality (unreliable, outdated, or incomplete), the quantification team will need to formulate assumptions on current program performance. Once the team has assessed the data quality for their forecasting method(s), they should choose the forecasting method for which they have the best data, or they can attempt several methods for comparison (some teams will want to choose after seeing the results of multiple forecasting methods and other teams will decide to use an average of the methods for a final quantification estimate). For more information on how to complete a consumption, service capacity or demographic forecast, the Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement is an excellent resource [5].

Building assumptions: Considerations for estimating hormonal IUD impact on the FP method mix [6]

One assumption that can be especially challenging when estimating for a new method is how the introduction of that new method will impact the existing FP method mix. Below are some key factors based on existing evidence from hormonal IUD introduction activities in LMICs that should be considered when developing assumptions for the product’s interaction with the existing method mix in a country.

[5] JSI. (2017). Quantification of health commodities. John Snow, Inc. <https://tinyurl.com/2017JSIQuant>

[6] FHI 360, SFH Zambia, & PSI. (2020). LEAP Initiative: A mixed-method, longitudinal study of the user population in Zambia [Slide show]. Hormonal IUD Access Portal. <https://tinyurl.com/2020LEAPZambia>

Quantification Assumption/Consideration	Potential Impact on Forecast
<p>Strong demand generation activities inclusive of hormonal IUD and completed in conjunction with introduction and scale-up for hormonal IUD are essential for the uptake of the new method.</p>	<p>If country has plans for demand generation activities inclusive of hormonal IUD, and think these plans will be funded, the technical working group may consider increasing estimated insertions, which would increase the overall need for commodities.</p>
<p>Studies show that 68% of users who choose to use hormonal IUD will either be new contraceptive users (7%) or users who are transitioning from short-acting hormonal methods including oral pills and injectables (61%). [7]</p>	<p>When considering how hormonal IUD will interact with the existing method mix, the quantification team should consider that consumption will more closely align with the trends for short-acting hormonal methods over copper IUD consumption. Although the hormonal IUD uptake trends will vary among countries depending on the country's context, veering away from the assumption that consumption for hormonal IUD will match or take market share of the copper IUD consumption will likely lead to an increased need in the quantification for hormonal IUD consumption.</p>
<p>Users seeking hormonal IUD are not typically the same users who seek copper IUD. Hormonal IUD and copper IUD have some attributes in common—including similar insertion and removal techniques— but their side effect profiles and bleeding patterns are notably different, and thus, experiences with the 2 methods may differ among both providers and clients. [8]</p>	
<p>According to a longitudinal study on user preferences in Zambia continuation rates for the hormonal IUD (95%) were higher than those for compared copper IUD (89%) and implants (83%). [7] A similar study on hormonal IUD introduction showed that continuation rates for hormonal IUD were similarly high in Madagascar (84%) and Nigeria (90%). [9]</p>	<p>High estimated rates of continuation for hormonal IUD could mean lead to less need for short-acting methods over time.</p>

The proportions of the method mix with the incorporation of hormonal IUD will vary from country to country. Assumptions for changes in the method mix should consider the procurement and funding capacity and country-specific context including user preferences for existing contraceptive methods. Once a forecast is established, compare the forecasted consumption with the existing method mix to determine viability. If using multiple forecasting methods, compare them and determine best estimate.

Supply plan and procuring

Once the quantification team has gained consensus on the estimated need for the hormonal IUD, they can use the forecast to inform the supply plan and proceed with ordering the methods.

[7] FHI 360, SFH Zambia, & PSI. (2020). <https://tinyurl.com/2020LEAPZambia>

[8] Rademacher, KH., et al. (2022). What have we learned? Implementation of a shared learning agenda and access strategy for the hormonal intrauterine device. *Global Health, Science and Practice*, 10(5). <https://doi.org/10.9745/ghsp-d-21-00789>

[9] Danna, K., et al. (2022). Introducing the hormonal Intrauterine Device in Madagascar, Nigeria, and Zambia: results from a pilot study. *Reproductive Health*, 19(1). <https://doi.org/10.1186/s12978-021-01300-x>

Country choice and preference should drive procurement decisions. Supply diversification – ordering multiple products/brands of the same method – is important to consider when working to maintain supply security. Having at least a small stock of both products for training is recommended, so that health workers are comfortable with provision of both products. Procurement plans should take into account the supplier lead times and the shelf life for products as these may vary by product and will be essential for comprehensive supply planning. Procurement of hormonal IUDs is possible through direct procurement or through USAID or UNFPA. The UNFPA Supplies Partnership included hormonal IUD in its New & Lesser-Used Product fund, which allows country governments to procure new methods with funding above their UNFPA Supplies country funding envelope for commodities.

Monitoring

Once the first order has been made, the quantification team should begin to monitor actual consumption trends regularly in comparison to original estimations of need. This is especially important in early stages of introduction when needs are often shifting and unstable. The quantification team must adjust the supply plan as needed, and transition to using actual consumption data for future forecasting when possible. Quantification team must make estimates on how consumption of hormonal IUD will grow over time after health facilities begin to provide the service and uptake grows among consumers.

Country examples

Countries will determine a best estimates of hormonal IUD needs based on their own context. The following are brief examples on how countries have made early estimates of hormonal IUD need for introduction and scale up in their countries so far:

Kenya

Uganda

Forecasting method used

Service capacity forecast

Forecasting method used

Consumption forecast

Country context

Used a service-level capacity forecast based on quantity of product needed for training and scale up plans

Country context

Product was introduced to a large regional health facility for research purposes. The consumption rate from that facility was used as a baseline for quantification estimates

Key data and assumptions

Established timeline for introduction over 5 years, targets for number of health workers to be trained, number of health facilities for introduction, and geographic targets for forecast

Health worker training benchmark of 5 successful hormonal IUD insertions, and 7 hormonal IUD insertions after training for certification

Assumption of 1 hormonal IUD insertion per health worker per month

Key data and assumptions

Established timeline for introduction over 5 years and estimated it would grow by 10% each year as facilities come online

Hormonal IUD was introduced to a large regional health facility for purposes of a research study – assumption about other health facilities’ consumption made using consumption data from this health facility

3-month reflection period built into annual forecast for necessary analysis and forecast adjustments.