ICA Foundation supports LNG IUS access in low- and middle-income countries

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INTRODUCTION
The Population Council began developing Mirena® in the late 1970s\(^1\) with the aim of creating a contraceptive device combining the beneficial features of both hormonal contraceptives and intrauterine devices. Mirena®, approved by the Food and Drug Administration in 2000 and added to the World Health Organization’s Essential Medicines list in 2015, provides up to six years of safe, effective, and continuous contraception for women.

Mirena®, produced in Finland by Bayer, is distributed in the private market and is available in more than 120 countries. “LNG IUS” is the version of the product distributed in the public sector outside the United States. However, Mirena® and other branded long-acting reversible contraceptive (LARC) products remain prohibitively expensive\(^2\) for many users. Service delivery and demand constraints have also hindered large-scale public sector introductions of the method.

The Council remains committed to continuing to improve access to the LNG IUS and other reproductive health products serving women and men in LMICs.

In 2004, the Population Council and Bayer AG joined forces to establish the ICA Foundation, a public-private partnership, as a creative way of enhancing access to this innovative product. The Foundation, through its network of partners across multiple countries, has been engaged in serving women’s needs for expanded long-acting reversible contraceptive options. The Council holds two ex-officio board seats on the Foundation and three positions on the Secretariat that manages the Foundation’s affairs.
RESEARCH SUMMARY

The Council’s development of the LNG IUS/Mirena® with Bayer Oy (formerly Leiras Oy) sought to improve available intrauterine devices with the aim of decreasing menstrual bleeding and preventing anemia with the addition of a progestin (levonorgestrel, hence the generic name). The commercially marketed Mirena® was approved by the FDA for contraception in 2000 and later for the treatment of heavy menstrual bleeding. The LNG IUS is available on a not-for-profit basis through donations by the ICA Foundation to service delivery organizations working in low-resource settings.

The LNG IUS has numerous benefits: up to six years of protection, a pregnancy rate of less than 1 percent in the first year of use, a strong safety record comparable to sterilization, rapid return to fertility after removal, the ability to lighten menstrual bleeding and cramping, and the potential reduction in iron-deficiency anemia. Clinical data is available for over 13,000 women-years of product use, demonstrating high efficacy and acceptance.

RESEARCH USE AND IMPACT

The Council plays a unique role by employing a “bench to bedside” approach, investing in contraceptive development from early laboratory research to product introduction. To expand contraceptive options and provide access to the LNG IUS across varied settings, the Population Council and Bayer AG, through the ICA Foundation, have provided the unbranded LNG IUS on a not-for-profit basis for over 15 years.

To date, the ICA Foundation has donated over 150,000 LNG IUS devices to organizations in 37 LMICs, helping to prevent thousands of unintended pregnancies, unsafe abortions, and maternal deaths. These donations support the work of governments and local not-for-profit organizations, hospitals, and global partners that share the Council’s commitment to improving access to quality family planning services and expanding modern contraceptive options.

Across multiple contexts, ICA Foundation donations have responded to growing demand for modern contraception, expanded access to LARCs, and laid the groundwork for LNG IUS introduction in multiple LMICs. In several countries, such as Kenya, Nigeria, and Zambia, donated LNG IUS units have supported demonstration projects that provided a foundation for broader access to the method, institutionalization within national health systems, opportunities for regional replication and encouraging new manufacturing options.

The ICA Foundation has responded to growing demand for LARCs by supporting efforts to expand access to the LNG IUS through the public sector in multiple countries. In Kenya, recent LNG IUS donations contributed to a Jhpiego-coordinated initiative to build capacity for increasing access to modern contraception, including LARCs, through public-sector facilities in Kisumu and Migori counties. In partnership with the Ministry of Health, the LNG IUS was added to the modern contraceptive options offered at select high-volume facilities. Through these collaborative efforts, the LNG IUS is now included in Kenya’s national family planning training curriculum and health information systems. In addition, efforts are underway to transition management of commodity donations from Jhpiego to the Government of Kenya.

Modest donations of LNG IUS product have been catalytic in setting the stage for sustained efforts to increase access to the method within existing health systems by energizing service delivery organizations, harnessing the reach of professional associations, and creating linkages between public and private stakeholders. In Nigeria, LNG IUS donations have supported the efforts of Rotary and several local partners promoting provider skills-building activities; community outreach involving men and religious leaders; and increased availability of modern contraceptives, including LARCs, across multiple states. The ICA Foundation, in collaboration with these partners and others, has also contributed to recent efforts by Nigeria’s Federal Ministry of Health to sustain and expand access to hormonal IUS through a national plan for coordinated and phased introduction within the country’s health system.
LOOKING FORWARD

The ICA Foundation will continue to support increased LNG IUS availability in LMICs through its donation program. Beyond sustained country-level donations, the Foundation also continues to shape global markets, demonstrating the demand for long-acting methods, fostering competition, ensuring a more reliable and greater volume of supply, and stimulating more favorable pricing. In addition, USAID and UNFPA are in the process of adding the hormonal IUS to their procurement catalogs so that interested international buyers can procure the product.

For more information, please visit the ICA Foundation.

KEY RESOURCES

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<th>ICA Foundation Country-Level Impacts</th>
<th>Kenya Learning Brief: Incorporating the Hormonal Intrauterine System into the Contraceptive Method Mix in the Public Health Sector in Kenya</th>
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<td>Zambia Learning Brief: Incorporating the Hormonal Intrauterine System into the Contraceptive Method Mix in the Public Health Sector in Zambia</td>
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<td>Brazil Journal Article: The Benefits and Limitations of Donating New Contraceptive Technology: The case of the International Contraceptive Access (ICA) Foundation and the LNG IUS Program in Brazil</td>
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<td>Journal Article: A Global Learning Agenda for the Levonorgestrel Intrauterine System (LNG IUS): Addressing Challenges and Opportunities to Increase Access</td>
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NOTES

1 Advancing long-acting reversible contraception. popcouncil.org/news/advancing-long-acting-reversible-contraception
2 A global learning agenda for the Levonorgestrel Intrauterine System (LNG IUS): Addressing challenges and opportunities to increase access. DOI: 10.9745/GHSP-D-18-00383
3 The hormonal intrauterine system (IUS). iusportal.org/about
4 Contraceptive development. popcouncil.org/research/contraceptive-development
5 ICA Foundation projects. ica-foundation.org/projects/about-the-projects/
6 ICA Foundation impact. ica-foundation.org/ica-foundation/our-impact/

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