February 2019

This report was prepared independently by Judy M. Manning, PhD., and produced at the request of the United States Agency for International Development.
FINAL REPORT:

2018 CONTRACEPTIVE RESEARCH & DEVELOPMENT
KEY STAKEHOLDER REVIEW

Executive Summary

February 2019

USAID Contract No. AID-OAA-C-14-00067; Assignment 637

DISCLAIMER

The author’s views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.
ACKNOWLEDGMENTS

This work would not have been possible without the sustained support of USAID’s staff in the Research, Technology and Utilization Division of the Office of Population and Reproductive Health, who provided information and input throughout the process as well as arranging for in-depth discussions with key stakeholders worldwide. Sincere thanks to each informant for their candid and thoughtful responses to the online survey and during the phone interview. The author also appreciates the always-helpful staff of GH Pro, who provided guidance and administrative support throughout this activity.
ACRONYMS

CT  Contraceptive
GH Pro  Global Health Program Cycle Improvement Project
LMICs  Low and middle income countries
PPP  Public-Private Partnership
PRH  Office of Population and Reproductive Health (GH / USAID)
RH  Reproductive health
R&D  Research and Development
RTU  Research, Technology and Utilization Division (PRH / GH / USAID)
ROI  Return on investment
SD  Service delivery
USAID  United States Agency for International Development
EXECUTIVE SUMMARY

I. INTRODUCTION AND BACKGROUND

As the world’s largest family planning bilateral donor, the United States Agency for International Development (USAID) is committed to helping low- and middle-income countries (LMICs) meet the voluntary family planning and health needs of their people. When USAID launched its voluntary family planning program in 1965, fewer than 10 percent of women in the developing world (excluding China) were using a modern contraceptive (CT) method. Today, in the 31 countries where USAID focuses its support, modern CT prevalence has increased to 30 percent. Throughout its history, USAID has played a significant role in the research and development (R&D) of new and improved CT methods. In fact, USAID has been involved, directly or indirectly, in the R&D of nearly every CT method available today.

In 2006, USAID implemented a review of its CT R&D portfolio that included input from 50 stakeholders representing United States and foreign government agencies, private foundations, private sector entities, independent consultants, and implementing partners. One of the main recommendations emerging from that review was for USAID to continue supporting the development of new and improved CT technologies, and simultaneously ensure that these new products, as well as existing products, are accessible and available to individuals in developing countries. At the time of the 2006 review, USAID’s CT R&D portfolio included a number of methods and technologies that are still being supported today, such as the Population Council’s 12-month Contraceptive Vaginal Ring, and three Program for Appropriate Technology in Health (PATH) products: Depo in Uniject, SILCS Diaphragm, and Women’s Condom. Since 2006, these four CT R&D investments have seen significant advancement along the continuum of research-to-use. As these technologies shift to scale and move out of the USAID CT R&D support space, it is an opportune time for USAID to reevaluate its CT R&D priorities, and develop a core strategy for its investments over the next 10 years. Hence the purpose of this activity: to assist the Agency with reexamining its role and comparative advantages in the CT R&D field by soliciting the candid thoughts, perspectives, and recommendations of key stakeholders representing donors, implementing partners in CT R&D and service delivery, the pharmaceutical industry, and regulatory agencies.

II. EVALUATION PROCESS & METHODS

In August 2018, USAID staff in the Research, Technology and Utilization (RTU) Division of the Office of Population and Reproductive Health (PRH) developed a scope of work for the key stakeholder review, and utilized the Global Health Program Cycle Improvement Project (GH Pro) contract to engage the author as the Lead Consultant. USAID staff crafted an initial list of key stakeholders to contact, as well as a draft set of core questions for the stakeholders. Input was solicited using two methods: online survey and in-depth phone interview, and similar sets of questions were finalized for each survey method. On October 15, 2018, USAID staff sent a broadcast email to key stakeholders to announce the review process, and provided a link to the survey on SurveyMonkey (www.surveymonkey.com), which remained live until November 2, 2018. Additional key stakeholders to be interviewed were identified through the online survey, and vetted with USAID staff as to whom to contact. In-depth phone interviews with 34 key stakeholders were conducted between October 29 and November 21, 2018.
III. FINDINGS

Forty-four individuals responded to most of the questions in the online survey. The distribution of their self-identified primary role in CT R&D was 36 percent Donor, 32 percent R&D Partner, 20 percent Service Delivery (SD), 7 percent Regulatory, and 5 percent Pharmaceutical. Respondents who self-identified as SD (N=9) were automatically directed within the online survey to a specific subset of four additional questions, while all other respondents (N=35) were directed to another subset of nine additional questions.

Thirty-four key stakeholders were interviewed by phone. The distribution of their self-identified primary role(s) in CT R&D was 48 percent R&D Partner, 20 percent SD, 17 percent Donor, 9 percent Regulatory, and 6 percent Pharmaceutical. Twenty-five of the interviewees self-identified as one of the five primary roles, while the remaining nine interviewees self-identified as two or more primary roles. (It is worth noting that only one person self-identified as Regulatory only, and none of the interviewees self-identified as Pharmaceutical only.) All interviewees were asked the same eight general questions; those who self-identified as SD only (N=3) were asked one additional question, while all other respondents (N=31) were asked an additional four questions.

RESPONSE TRENDS TO QUESTIONS IN COMMON TO BOTH SURVEY METHODS.

It is important to note that the trends across responses to questions in both the online survey and phone interview were generally consistent, and did not differ significantly by survey method or by self-identified primary role. Seven key questions (in addition to the primary role question) were common to both survey methods, and the following general response trends to those questions reflect this overall consistency in response.

What do you see as the current and future needs of women in LMICs with regard to CT and reproductive health (RH) R&D?

General response: Strong consensus on equity in access to existing methods, especially existing or refined methods that enable minimal interaction with the healthcare system (e.g., provision via over-the-counter, direct-to-consumer, community-based distribution and/or community health worker or self-administered). Highly effective non-hormonal, long-acting, and discreet use methods would help to fill key gaps.

What do you see as the role of industry and other private-sector stakeholders in meeting the reproductive healthcare needs of women in LMICs?

General response: Strong consensus that big pharma is just not interested in family planning markets in LMICs. Therefore, USAID has to make the case to smaller pharma and private sector regarding potential return on investment (ROI), including providing incentives through public-private partnerships (PPPs), assistance with regulatory approval and product registration in-country, price tiering, and volume guarantees, etc.
How should USAID prioritize its CT R&D funding (across later-stage product introduction; refining existing methods; and participating in the global coordination of the CT R&D pipeline) if annual levels:

A: Stay at $10 million annually

General response: Consistent consensus that some combination of priorities is needed, but also that $10M/year is limited; later-stage product introduction is viewed as part of USAID’s core mandate, but should transition from R&D support to SD support after initial pilots; refining existing methods is important, but needs to be prioritized regarding greatest potential impact; USAID participation in the global coordination of the CT R&D pipeline is central to its leadership role.

B: Decrease to $5 million annually

General response: No clear consensus, other than that $5M/year is not enough to do much of anything in CT R&D other than coordination, and that product introduction should be supported by SD and country programs.

C: Increase to $15 million annually

General response: General consensus to double down on the core priorities; some consensus to expand support for R&D on multipurpose prevention technologies, direct-to-consumer products, and CTs with other health benefits.

What is USAID’s comparative advantage in CT R&D relative to other donors?

General response: Strong consensus on USAID’s expertise regarding CT needs in LMICs, and its long-term support for the full continuum of R&D through product introduction and scale-up. USAID’s focus on translational CT R&D (i.e., refining existing methods to make them more acceptable, affordable, and easier to provide and/or use) was seen as unique among donors, and critical to helping women in LMICs achieve equity in access to CT methods. Uniform response that no other donor has USAID’s depth and breadth in the field.

How could USAID better leverage support for CT R&D from other donors?

General response: Consistent consensus that USAID should use its global leadership to bring together other government agencies, foundations, industry, development groups, etc., to discuss a common agenda that focuses more broadly on the positive outcomes to be gained by providing women in LMICs with equity in their CT method mix (and which may attract new donors to the field), and the importance of CT R&D within that agenda.

How could USAID be more strategic in its support for CT R&D?

General response: Consensus that USAID is already strategic, with a clear link between R&D and SD in LMICs; make the SD end goal central to CT R&D programs, and the focus point of coordination with other donors; include industry partners early on in the R&D process, and engage with USAID country programs, procurement teams, implementation science teams, and product introduction teams as the product nears regulatory approval; stay focused on the top CT R&D priorities that have the greatest potential for uptake and impact in LMICs.
What other recommendations should USAID consider regarding its role in CT & RH R&D?

**General response:** Strong consensus / plea to stay involved, given decades of leadership focused on women's needs in LMICs; attract new donors by making USAID's history in the field much better known, and broadening the perspective of CT R&D as underscoring equity in access writ large; emphasize USAID's unique support for translational R&D to refine existing methods, and bridging the gap between regulatory approval and pilot introduction of new methods; collaborate with other funding agencies supporting CT R&D of particular interest and relevance to USAID, and carve out a role that is appropriate to USAID's mission.

**IV. CONCLUSIONS AND RECOMMENDATIONS**

**CONCLUSIONS**

It is clear from the many responses received during the 2018 review process that USAID should continue its involvement in CT R&D, especially given its history of success and unique focus on the needs of women in LMICs. This sentiment reinforces a similar and strongly-held view resulting from the 2006 CT R&D review. Interestingly, and unlike the 2006 review, the responses received throughout the 2018 review process were surprisingly consistent across the self-identified primary roles in the CT R&D field: Donor, R&D Partner, SD Partner, Pharmaceutical, and Regulatory. This consistency in responses may reflect a more focused approach to CT R&D by those dedicated stakeholders still remaining in the field, despite its continuing contraction over the last 12 years. Although the 2018 review had some limitations (i.e., time constraints, incomplete scan across all possible CT R&D entities, potential inherent biases of the lead consultant, etc.), the general consensus in responses to nearly every question validates the outcomes of this process; thus, the results are worthy of serious consideration by USAID as they chart the future course of their CT R&D portfolio. The clearest outcome from this review process is the consistent advice provided by so many respondents: *focus on the CT R&D that would have the greatest potential to help meet the needs of women in LMICs.*

**FIVE RECOMMENDATIONS**

1. **Make it clear to all that USAID’s core strategy is its expertise and focus on the contraceptive needs of women in priority LMICs.** This core strategy needs to inform:
   - In-house coordination across the product development-to-introduction continuum: from R&D through regulatory approval and procurement to pilot introduction and scale-up.
   - Support to external partners through cooperative agreements, contracts, and grants.
   - External coordination with other CT R&D and RH donors and organizations.

2. **Create a road map for USAID family planning:** In the broad array of what's necessary for meeting the CT needs of women in priority LMICs, focus on those key leverage points where USAID could make a difference, and coordinate with other stakeholders on the rest. Embrace the perspective that a successful transition process from product R&D to introduction and uptake by necessity involves many stakeholders — and that there is room for all at the drawing board.
2. Make tough funding decisions as to which products — new, existing or refined — have the greatest potential to provide women in LMICs with a range of CT methods that meet their changing needs over time, and that involve limited interaction with an overburdened healthcare system. Analyze likely ROI scenarios for the potential increase in access or use to be gained through the introduction of a new product, refinement of an existing product or its delivery system, or addition / expansion of an existing product into the lower level healthcare cadres.

3. Make it clear within PRH as to where CT R&D funding ends and other funding begins in the transition from late stage product approval to in-country registration, introduction, and scale-up — and the critical role of implementation science in that process. Establish product-specific cross- Divisional teams within PRH that support an integrated (and fully funded) development-to-introduction strategy.

4. Engage the private sector early on in the product development-to-introduction strategy process, and make the case for ROI in LMICs through in-depth country data on market potential and PPPs that include leveraged funding or other financial incentives.

5. Plan for the long haul, even though funding is annual.

- Ensure that key technical positions within RTU and PRH exist — and are filled — in order to provide essential in-house expertise, and balance the reliance on the expertise of external partners.
- Develop five-year+ funding plans for each in-house product development-to-introduction strategy, including “what if” scenarios to prepare for and accommodate fluctuations in annual funding.
- Engage the commitment of other donors by understanding their respective agendas, and advocating as to how coordination with USAID fulfills one or more of their key objectives.