PERFORMANCE EVALUATION OF FHI 360’S ENVISION FP: TRANSFORMING CONTRACEPTION TO EXPAND ACCESS AND CHOICE

November 2019

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DISCLAIMER

The authors’ views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.
ABSTRACT
Envision Family Planning (FP) is USAID’s flagship contraceptive technology research project. Envision FP is a five-year cooperative agreement awarded to FHI 360 in August 2015 with the overall goal to broaden choice of and access to quality, affordable, and acceptable contraceptives to meet the changing needs and desires of women and girls throughout their reproductive lives.

The evaluation consisted of three key questions: 1) How has the evidence generated been used to inform the development, introduction, expansion and understanding of contraceptive technologies? 2) To what extent has Envision FP achieved each aim? 3) Recommendations for implementation priorities for the remainder of Envision FP and for future program design, and identify new priorities that should be addressed in future projects. The evaluation methodology consisted of key informant interviews with FHI 360, partners, and funders, and document reviews.

Key findings include: generation of evidence on the effectiveness of the injectable contraception depot medroxyprogesterone acetate—DMPA—at lower doses and extension of re-injection intervals; successful responses to product-related issues that arose in the field; effective coordination and leadership of the Evidence for Contraceptive Options and HIV Outcomes (ECHO) trial, which generated critical data on the risk of HIV acquisition and contraceptive methods that led to a publication in the journal The Lancet; updating evidence on drug-drug interactions between hormonal contraception and anti-retroviral therapy, and spearheading the development of a one-month microneedle contraceptive patch in partnership with Georgia Tech. FHI 360 has been successful in meeting key project goals and is praised by its partners for their valuable contribution to the field.
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MEC Medical Eligibility Criteria
MoH Ministry of Health
MPA Medroxyprogesterone acetate
MSI Marie Stopes International
NICHD National Institute of Child Health and Development
NIH National Institutes of Health
NORMAL Normal, Opportunities, Return, Methods, Absence of Menses, and Limit
OHA Office of HIV/AIDS (USAID)
P4O Planning for Outcomes
PD Pharmacodynamics
PEPFAR President’s Emergency Plan For AIDS Relief
PK Pharmacokinetics
PPIUD Postpartum intrauterine device
PrEP Pre-exposure prophylaxis
PSI Population Services International
R&D Research and Development
SC Subcutaneous
SIFPO2 Support for International Family Planning and Health Organizations 2
SPE Sayana® Press Extension
SPR Selected Practice Recommendations
SSAC Scientific and Strategic Advisory Committee
STI Sexually transmitted infection
TA Technical assistance
TB Tuberculosis
UNFPA United Nations Population Fund
UNICAMP University of Campinas
USAID United States Agency for International Development
WHO World Health Organization
Wits RHI Wits Reproductive Health and HIV Institute
EXECUTIVE SUMMARY

EVALUATION PURPOSE AND EVALUATION QUESTIONS

The purpose of this evaluation is to assess the Envision Family Planning (FP) project’s progress (successes and challenges) toward the achievement of the project’s aims. The evaluation addressed three key questions:

1. How has the evidence generated been used to inform the development, introduction, expansion, and understanding of contraceptive technologies?
2. To what extent has Envision FP achieved each aim?
3. Looking to the Future:
   a. Recommendations for improving implementation priorities for the remainder of Envision FP
   b. Recommendations for future program design, particularly reflecting on the response mechanism of Aim 2
   c. New priorities that were identified that should be addressed in the remaining year vs. addressed in future projects

PROJECT BACKGROUND

As a founding partner of Family Planning 2020 (FP2020), USAID supports the partnership’s goal to reach 120 million more women and girls in the world’s poorest countries with access to voluntary FP information and services by 2020. To this end, USAID funds a number of partnerships and projects, including Envision FP: Transforming Contraception to Expand Access and Choice. Envision FP is USAID’s flagship contraceptive technology research project awarded to FHI 360 in August 2015. The project is a core funded five-year cooperative agreement (2015-2020) with a ceiling of $39,637,858. Envision FP is centrally managed by the Bureau of Global Health, Office of Population and Reproductive Health, Research Technology and Utilization Division (GH/PRH/RTU). Envision FP is starting its fifth year (with an added year of no-cost extension) and this evaluation will inform future programming decisions.

The objectives of Envision FP are to develop, introduce, and expand understanding of contraceptive technologies and approaches to enhance choice and reduce unmet need. The research agenda aligns with three specific Annual Program Statement aims (herein referred to as “Aims”): 1) refine existing methods, 2) respond to product-related issues that arise from the field and impact provision, and 3) develop new methods to fill gaps. Envision FP focuses on key challenges and opportunities significant for users and programs. The project’s overall goal is to broaden choice of and access to quality, affordable, and acceptable contraceptives to meet the changing needs and desires of women and girls throughout their reproductive lives.

EVALUATION DESIGN, METHODS, AND LIMITATIONS

The evaluation was primarily qualitative in nature, consisting of key informant interviews (KII) and document reviews. A list of potential KIIs was provided by USAID and FHI 360 before the
start of data collection. Interviewees include FHI 360 Envision FP teams, partners, and funders (USAID and Bill & Melinda Gates Foundation or BMGF). A total of 34 individual KIIs were conducted and five group interviews with FHI 360 Envision FP teams were held. Each interview was approximately one hour in duration.

Reviewed documents include: FHI 360 workplans, semi-annual and annual reports, published papers, conference presentations, unpublished study reports, and tools developed under Envision FP (e.g., provider counseling tools). The documents were used to provide background information and triangulation with information from the interviews.

The main limitation was that interviews were not recorded or transcribed and as such, the number of direct quotes is limited. However, this limitation was mitigated because both evaluators took notes for each interview.

FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS

Key Findings: Aim 1. Refining existing methods

Key activities in Aim 1 include: (1) efficacy study of lower-dose depot medroxyprogesterone acetate subcutaneous (DMPA-SC), (2) extending the reinjection interval of SC DMPA (brand names, Depo-SubQ Provera 104®, and Sayana® Press), and (3) a Pharmacokinetics/Pharmacodynamics (PK/PD) study of DMPA 150 mg or 300 mg compared to DMPA-SC (referred to as “DMPA XT” study).

Lower dose DMPA

A partially-blinded randomized trial was conducted to assess the PK and PD of three doses of Pfizer’s current intramuscular DMPA (DMPA-IM) formulation (45 mg, 75 mg, and 105 mg) compared with the currently available SC DMPA (104 mg). The study was implemented in three trial sites: Profamilia in the Dominican Republic, El Instituto Chileno de Medicina Reproductiva (ICMER) in Chile, and University of Campinas (UNICAMP) in Brazil. At the time of this evaluation the results are embargoed and will be released mid-November 2019.

Extending duration of Sayana® Press

FHI 360’s goal was to determine whether the Sayana® Press re-injection interval could be extended from three to four months. The primary outcomes are one-year pregnancy rates, side effects and adverse outcomes, and discontinuation rates. To answer this question, FHI 360 developed a 12-month single-arm study to determine the effectiveness, safety, and acceptability of Sayana® Press given every four months. The study is also determining the appropriate grace period for re-injection. The trial is currently underway and will continue through April 2020.

Phase 1. Clinical PK/PD study of DMPA XT

FHI 360 set out to test if the currently available formulations of Pfizer’s Depo-Provera® (150 mg or 300 mg) given subcutaneously would provide protection from pregnancy for up to six months. FHI 360 implemented a partially-blinded randomized trial at two sites—Oregon Health Sciences University (United States) and Profamilia (Dominican Republic)—in order to assess the PK/PD of either 150 mg or 300 mg of DMPA-IM delivered subcutaneously through the abdomen compared with two injections at three-month intervals of Depo-subQ Provera 104® (reference).
The initial clinical study results were submitted to the U.S. Food and Drug Administration (FDA) in June 2019, and meetings are underway with two European regulators to discuss a Phase III clinical trial. FHI 360 has identified a commercial partner that may be interested in developing a generic six-month product.

**Supporting scale-up of the levonorgestrel intrauterine system (LNG-IUS)**

Leveraging funding from both USAID and BMGF (via the Learning, Evaluation, and Analysis [LEAP] Initiative), FHI 360 supports the learning agenda, introduction, and scale-up of LNG-IUS products into more countries through reducing the cost of goods sold, increasing the number of suppliers, and incentivizing manufacturers to lower their prices of products. In 2017, FHI 360 spearheaded a market research and demand forecasting study in Kenya, Zambia, and Nigeria. In 2018, longitudinal LNG-IUS acceptor and rejecter surveys, along with interviews with women and youth, were conducted in Nigeria and Zambia. In 2019, the results were used to inform an introduction strategy for LNG-IUS products into Kenya, Nigeria, and/or Zambia.

**Contraceptive Drug-Drug Interaction (DDI) Database**

As more HIV and/or Tuberculosis (TB) positive women have access to life-saving antiretroviral therapy and anti-TB drugs, there has been increasing debate about the impact of hormonal contraception on the efficacy and/or toxicity of those drugs. Under Envision FP, FHI 360 undertook a systematic review of the most recent literature and developed a “DDI Database” housed on the Contraceptive Technology Innovation Exchange. The database contains up-to-date information on contraceptive drug-drug interactions with antiretrovirals and anti-TB drugs.

**Implant removal study**

As the number of implants increases throughout sub-Saharan Africa, there have been questions on whether providers are prepared for the inevitable increase in demand for implant removal. There is little information on the quality and availability of implant removal services. With funding from USAID and BMGF, FHI 360 led a study assessing access to implant removal services in Ghana in collaboration with the Population Council, Ghana Health Service, and Marie Stopes International. The results of the study informed revisions to the implant training curriculum and a new standardized algorithm for providers to use in managing difficult removals. The results were shared with the Ministry of Health for future training and follow-up.

**Key Findings: Aim 2. Respond to product-related issues that arise from the field and impact provision**

**Open Response Activity**

The purpose of the open response activity is to rapidly respond to method-related issues that arise in the field that affect provider/user perceptions and/or the supply chain. From 2015-2019, 14 requests for, or proactive supply of, evidence was fulfilled through the open response activity. FHI 360 was able to respond to all requests that were made and which fell within the scope of the activity. A majority of requests were to inform policies or guidelines, quality assurance, and/or provide specific information on a method (e.g., mechanism of action). Respondents state unequivocally that the open response activity was a success. A key feature cited as contributing to the activity’s success is its flexibility to respond to an array of requests in real time as issues arise.
Evidence for Contraceptive Options and HIV Outcomes (ECHO) Trial

The ECHO trial was a multi-center, open label, randomized clinical trial comparing risk of HIV acquisition among women using DMPA-IM, Levonorgestrel (LNG) Implant (Jadelle®), and Copper Intrauterine Device (Cu IUD). The main trial was co-funded by USAID and BMGF. The study was implemented between 2015 and 2018 at 12 trial sites in eSwatini, Kenya, South Africa, and Zambia, enrolling 7,800 women between the ages of 16 and 35. The ECHO management committee was comprised of FHI 360, University of Washington (United States), Wits Reproductive Health and HIV Institute (Wits RHI) (South Africa), and the World Health Organization (WHO).

The ECHO trial found no substantial difference in the risk of HIV acquisition among women using DMPA-IM, a Cu IUD, or LNG implant methods. The results were published in the journal The Lancet and soon thereafter WHO changed its Medical Eligibility Criteria for progestin-only injectables for women at high risk for HIV acquisition from a Category 2 back to a Category 1. Moreover, both types of intrauterine devices were reclassified from a Category 2 to a Category 1.

Key Findings: Aim 3. Develop new methods to fill gaps

Microneedle Patch

Biodegradable microneedles are being developed as a drug and vaccine delivery platform. FHI 360 worked in conjunction with Dr. Mark Prausnitz at Georgia Tech to develop a microneedle patch for contraception.

Development of biodegradable contraceptive implants

The contraceptive implants that are currently available must be removed at the end of their efficacy duration or when the woman wants to stop using the method. The necessity of removal, by definition, imposes a burden on users. A biodegradable implant would alleviate many of these challenges. FHI 360 assisted Gesea Biosciences, Inc. in responding to FDA regulatory concerns and moving the biodegradable implant closer to a Phase 1 trial. FHI 360 supported Dr. Mark Saltzman of Yale University with bridge funding. Dr. Saltzman’s team has developed a unique set of copolymers comprised of two monomers, pentadecalactone and dioxanone. With Envision FP funding, site qualification visits for the selection of the contract laboratory to conduct the Yale PK study took place and a vendor was selected.

RECOMMENDATIONS

There was a wide range of responses to recommendations for future program design. The evaluators chose the recommendations that are the most salient and realistic given USAID’s funding profiles and strategic priorities. The evaluation team, with input from FHI 360, partners, and funders, identified the following set of key recommendations.

1. Change the duration of funding or change what to fund

It can take years to get a new product developed, through clinical trials, and ultimately registered. Given that USAID awards are for five years, several respondents wondered if USAID’s money would be better spent on later stage Research and Development, for example,
supporting clinical trials. Conversely, some respondents stated that USAID should in fact keep funding new products and advocate for longer award durations.

2. **Strengthen commercial ties, particularly with generic manufacturers**

An often-cited recommendation for FHI 360 (or any organization working in this space) and USAID is to strengthen ties with the commercial sector, particularly in manufacturing. This was cited as a way to ensure that what is developed makes it to the market. In order to strengthen those ties, an implementing organization would need the right type of expertise and network to work with manufacturers. Currently, FHI 360 does not have the manufacturing expertise that would be required. Moreover, USAID would need to provide adequate funding and resources to support stronger ties to the commercial sector.

3. **Continue the open (rapid) response in future awards**

Respondents were overwhelmingly in favor of continuing the open response and found the mechanism helpful.

4. **Form partnerships**

FHI 360 was highly praised for their stellar ability to coordinate and lead. In the future, some respondents recommended that FHI 360 broaden the network of organizations/institutions they typically work with (e.g., new clinical trial sites), and partner with a larger decision-making role and who will be present throughout the life of the project (not limited to sub-contractors/sub-awardees that perform short-term and limited scope work). Recognizing that a prime award holder will ultimately oversee the work of sub-awardees, the sentiment is that FHI 360 (or any prime) should have a set of partners that can oversee a greater share of the work from the beginning to the end of the award. Moreover, this recommendation was made to USAID for any follow-on award to include partnerships—for example, partnering with companies in the for-profit sector that can contribute both expertise and funding.

5. **Encourage innovation and new funding streams**

The nature of National Institute of Health (NIH) funding is to support basic science research, especially in support of early stage high risk projects. NIH funding would allow for more flexibility to be innovative and develop a robust pipeline of technologies. This ability to innovate would help an organization such as FHI 360 remain relevant in the contraceptive biomedical field.
I. INTRODUCTION

EVALUATION PURPOSE

The purpose of this evaluation is to assess the Envision Family Planning (FP) project’s progress (successes and challenges) toward the achievement of the project’s aims.

EVALUATION QUESTIONS

Evaluation Question 1: How has the evidence generated been used to inform the development, introduction, expansion and understanding of contraceptive technologies?

Evaluation Question 2: To what extent has Envision FP achieved each aim?

Evaluation Question 3: Looking to the Future:

a. Recommendations for improving implementation priorities for the remainder of Envision FP

b. Recommendations for future program design, particularly reflecting on the response mechanism of Aim 2

c. New priorities that were identified that should be addressed in the remaining year vs. addressed in future projects

The results from Evaluation Question 3 will be covered in the “Recommendations” section.
II. PROJECT BACKGROUND

As a founding partner of Family Planning 2020 (FP2020), USAID supports the partnership’s goal to reach 120 million more women and girls in the world’s poorest countries with access to voluntary FP information and services by 2020. To this end, USAID funds a number of partnerships and projects, including Envision FP: Transforming Contraception to Expand Access and Choice. Envision FP is USAID’s flagship contraceptive technology research project awarded to FHI 360 in August 2015. The project is a core funded five-year cooperative agreement (2015-2020) with a ceiling of $39,637,858. Envision FP is centrally managed by the Bureau of Global Health, Office of Population and Reproductive Health, Research Technology and Utilization Division (GH/PRH/RTU).

The objectives of Envision FP are to develop, introduce, and expand understanding of contraceptive technologies and approaches to enhance choice and reduce unmet need. The research agenda aligns with three specific Annual Program Statement (APS) aims (herein referred to as “Aims”): (1) refine existing methods, (2) respond to product-related issues that arise from the field and impact provision, and (3) develop new methods to fill gaps. Envision FP focuses on key challenges and opportunities significant for users and programs. The project’s overall goal is to broaden choice of and access to quality, affordable, and acceptable contraceptives to meet the changing needs and desires of women and girls throughout their reproductive lives.

**Aim 1: Refine existing contraceptive methods:** Refining existing FP methods to enhance safety, use, and/or acceptability is a cost- and time-efficient approach to improve FP technologies. The project works on method refinements for Depot medroxyprogesterone acetate or DMPA (lower dose), Sayana® Press (extended use), and postpartum intrauterine device (PPIUD) (improved applicator).

**Aim 2: Respond to product-related issues with existing contraceptive methods:** Under Aim 2, a rapid-response team of technical experts systematically responds to field-based product concerns. In addition, Envision FP technical experts conduct product-related research and systematic reviews to address knowledge gaps affecting program practice and use. Conduct research on the relative risk between three contraceptive methods and HIV acquisition (Evidence for Contraceptive Options and HIV Outcomes [ECHO] trial), and drug-drug interactions.

**Aim 3: Develop new methods to address method-related non-use or fill gaps:** The project conducts new product development research to address significant gaps in contraceptive method mix, including development of an intradermal biodegradable microneedle patch.

Envision FP is starting its fifth year of a five-year award (with an added year of no-cost extension) and this performance evaluation will inform future programming decisions. A small proportion of the portfolio included Office of HIV/AIDS (OHA) co-funding for FP/HIV integration work and the ECHO trial. This evaluation will include those activities in the review.

USAID works very closely with the other major donors of contraceptive technologies, including the Bill & Melinda Gates Foundation (BMGF) and the National Institute of Child Health and Human Development (NICHD). The donors leverage support from each other to move contraceptive pipelines forward and use mechanisms such as Envision FP and inter-agency agreements to fund co-prioritized activities. This project also works in parallel with FHI 360’s BMGF-funded contraceptive technology innovation initiative to co-support research and development portfolio priorities (e.g., microneedle work).
The Envision FP strategic framework, shown at right, depicts the project aims. Project activities fall under one of three aims: 1) refine existing methods, 2) respond to product-related issues that arise from the field and impact provision, and 3) develop new methods to fill gaps. The activities and aims work together to achieve the intended impact of broad choice of and access to quality, affordable, and acceptable contraceptives to meet the changing needs and desires of women and girls throughout their reproductive lives.

Note: “Normative guidelines” (under Outcomes) refers to technical and policy guidance issued from global normative bodies, such as the World Health Organization.
III. EVALUATION METHODS AND LIMITATIONS

METHODOLOGY

Key Informant Interviews (KIIs)

A list of potential KIs was provided by USAID and FHI 360 before the start of data collection. Interviewees include FHI 360 Envision FP teams, partners, and funders (USAID and BMGF). Interviews were conducted either in-person or over the phone. With the exception of two interviews, both evaluators conducted all interviews. Each interview was approximately one hour in duration and was not recorded (notes were taken by both evaluators). A total of 34 individual KIs and five group interviews with FHI 360 Envision FP teams were conducted. A full list of interviewees can be found in Annex III.

The interview guides were semi-structured, which allowed for responses to be structured enough to meet the objectives of the evaluation but flexible in order to solicit new perspective (see Annex II for interview guides). The guides were consistently revised through an iterative process as data collection proceeded to ensure questions remained relevant and solicited the most useful information. Interview probes and requests for examples were used as a means to best capture how activities are implemented—and received—at the field level.

Document reviews

A number of documents were reviewed, including FHI 360 workplans, semi-annual and annual reports, published papers, conference presentations, unpublished study reports, and tools developed under Envision FP (e.g., provider counseling tools). The documents were used to provide background information and triangulation with information from the interviews.

Analysis

Interview notes were analyzed to identify information that could answer each evaluation question. Each evaluator independently extracted key findings and findings were then compared. Findings that were consistent between the evaluators were classified as “key results.” The best quotes—those that could adequately illustrate each key result—were extracted from the notes.

The findings from the KIs, if possible, were triangulated with information from the document reviews. Information from the documents was also used to provide background and context.

ETHICAL CONSIDERATIONS

Before each interview, the interviewer read aloud an informed consent script and requested oral consent before proceeding with the interview. The interviews stressed confidentiality of the interview and to the greatest extent possible maintained anonymity. Interview notes were stored on a password-protected cloud drive and only accessible to the evaluation team members and Global Health Program Cycle Improvement Project (GH Pro).
LIMITATIONS

The main limitation is that interviews were not recorded and transcribed, and as such, the number of direct quotes is limited. However, this limitation was mitigated because both evaluators took notes for each interview.
IV. FINDINGS

EVALUATION QUESTION 1. HOW HAS THE EVIDENCE GENERATED BEEN USED TO INFORM THE DEVELOPMENT, INTRODUCTION, EXPANSION AND UNDERSTANDING OF CONTRACEPTIVE TECHNOLOGIES?

In this section “evidence generated” is categorized into two categories: evidence generated and supplied via the open response activity and via planned activities.

A. Evidence from the Open Response Activity

The purpose of the open response activity is to rapidly respond to method-related issues that arise in the field that affect provider/user perceptions and/or the supply chain. From 2015-2019, 14 requests for—or proactive supply of—evidence was fulfilled through the open response activity (see Annex V for a full list of requests).

- FHI 360 proactively supplied evidence/information (3)
- USAID Missions, Offices/Bureaus requested evidence/information (11)

FHI 360 was able to respond to all requests that were made and fell within the scope of the activity.

A majority of requests were to inform policies or guidelines, quality assurance, and/or provide specific information on a method (e.g., mechanism of action). It is more difficult to evaluate whether the application of this evidence/information was used to successfully inform the expansion and understanding of contraception technologies. The definition of “success” is highly dependent on the desired outcome. “Success” may mean maintaining the status quo of a policy. For example, the regulatory body of a partner country was considering a policy change around a specific FP method. At the request of USAID, FHI 360 provided a review of existing scientific evidence on the issue. The evidence provided alleviated the regulatory body’s concerns and ultimately no policy change was made.

In another example, the successful outcome of generating and applying evidence was to “quell anxiety.” In three separate countries, there were concerns about counterfeit FP products in circulation. FHI 360 checked USAID-procured products to determine if stocks contained products with the counterfeit lot numbers. In two countries, FHI 360 performed quality testing on a specific set of product that were suspected to be counterfeit. FHI 360 found no evidence of counterfeiting. In other requests, “success” was defined as “galvanizing other projects.” For example, USAID requested that FHI 360 prepare a response to the meta-analysis on the interaction between hormonal contraception (HC) and HIV acquisition. This request led to a much longer response monitoring of HC-HIV, especially in relation to the ECHO trial. The end result was the creation of the Planning for Outcomes (P4O) model and a publication in the journal Global Health Science and Practice in 2019.

Respondents stated unequivocally that the open response activity was a success. A key feature cited as contributing to the activity’s success was its flexibility to respond to an array of requests in real time as issues arise.

“Love it! Extremely helpful and useful to get things responded to. It is flexible and given that you don’t know what will come up in the future, as you design the award it is an important response mechanism. We actually used the mechanism to support one of the largest clinical trials.” –USAID
FHI 360’s technical capacity to respond to requests using evidence, and by extension their credibility, were also cited as key reasons for the success of the open activity.

“FHI 360 is extremely responsive to our requests and grounds each response in science.” —USAID

“FHI does have a lot of biomedical experience and the ability to do a rapid response. Even if others could do it FHI is a trusted name.” —USAID

“It's been incredibly helpful to have FHI as a resource to turn to outside of USAID. The rapid response has been very helpful. It would be great to have it in future awards.” —USAID

Respondents were overwhelmingly in support of retaining the open response in future awards.

B. Evidence from planned activities

The inherent nature of Envision FP is the generation/collation of evidence and the application of that evidence to inform the development and improvement of contraception. To varying degrees, each major activity under Envision FP generated/collated evidence for use by FHI 360, funders, and/or partners, or provided to the global community to advance a myriad of efforts. The limited space in the evaluation report precludes adequate discussion of all evidence generated and applied as a result of Envision FP; therefore, the evaluation team selected three key activities to highlight in this section. The findings under Question Two highlight evidence generation/collation and application for each major activity.

a. ECHO Trial

The ECHO trial was a multi-center, open label, randomized clinical trial comparing risk of HIV acquisition among women using intramuscular DMPA (DMPA-IM), Levonorgestrel (LNG) Implant (Jadelle®), and Copper Intrauterine Device (Cu IUD). The main trial was co-funded by USAID and BMGF. The study was implemented between 2015 to 2018 at 12 trial sites in eSwatini, Kenya, South Africa, and Zambia, enrolling 7,800 women between the ages of 16 and 35. The ECHO management committee was comprised of FHI 360, University of Washington (United States), Wits Reproductive Health and HIV Institute (Wits RHI) (South Africa), and the World Health Organization (WHO).

The significance of the trial is not inconsequential. In the 2015 WHO Medical Eligibility Criteria for Contraceptive Use (MEC), DMPA and implants were classified as Category 1 (no restriction for use) and intrauterine devices (IUDs) (both copper and hormonal) as Category 2 (the advantages of using the method generally outweigh the theoretical or proven risks). Because concerns regarding data from observational and laboratory studies suggested that some hormonal methods, particularly DMPA-IM, may increase women’s susceptibility to HIV acquisition, in 2017 WHO changed its Medical Eligibility Criteria (MEC) for DMPA for women at high risk for HIV from a Category 1 to a Category 2. The purpose of ECHO was to inform WHO and in-country guidelines with results derived from a rigorous scientific study.

The ECHO trial found no substantial difference in the risk of HIV acquisition among women using DMPA-IM, a Cu IUD, or LNG implant methods. The results were published in the journal *The Lancet* and soon thereafter WHO changed its MEC for progestin-only injectables for women at high risk for HIV acquisition back to a Category 1. Moreover, both types of IUDs were re-classified from a Category 2 to a Category 1. The ECHO trial results also found a high incidence of HIV for women in all arms of the study even though all women received the “gold standard” of interventions aimed at lowering risk of
This finding has important implications for funders and policy-makers as it demonstrates that decreasing HIV incidence will require more than high-quality counseling, testing, and condoms.

In Kenya and eSwatini, the ministries of health (MoHs) used ECHO results to inform national guidelines. The Kenya MoH had previously considered promoting self-injectable subcutaneous DMPA (DMPA-SQ) but hesitated due to concerns about the possible increased risk of HIV acquisition. After the ECHO trial, the MoH started scale-up and promotion of self-injectable DMPA. In eSwatini, the MoH paid greater attention to the importance of sexually transmitted infection (STI) prevention and treatment as a part of FP programming. The MoH subsequently developed training courses to increase the capacity of FP providers to diagnose and treat STIs.

The type of important evidence generated as a result of ECHO went far beyond the risk of HIV acquisition as a result of contraception usage. Several interviewees stated other important data were collected about contraception, such as weight gain, bleeding changes and irregularities, STI acquisition, side effect management, and the role of high-quality FP and HIV counseling. One respondent described ECHO as a “treasure trove” of data.

ECHO trial participants had very low rates of discontinuation, which is largely attributed to high-quality counseling and FP services. Although the low rates of discontinuation are not typical in a real world setting, the study team is using the opportunity to continue to follow some ECHO participants beyond the end of the trial in order to assess method-specific and overall continuation rates, reasons for discontinuation, and implant and IUD removal outcomes.

b. Microneedle user preferences study

A microneedle user preference study (funded by NICHD through the interagency agreement between USAID and National Institutes of Health [NIH]) was conducted alongside development of the microneedle patch with the results informing patch specifications. Results from the study indicate that women preferred a patch that is discreet and did not cause any skin irritation, such as a rash. The survey also collected data on hypothetical tolerability of pain levels associated with patch application, desirable patch size, and preferred location of patch application. The study included a discrete choice experiment (DCE) survey to quantify the relative importance of various patch characteristics for potential user acceptability. In India, the DCE results showed that effect on menstrual bleeding was the single most important consideration to women (driving greater than 50 percent of user preferences), followed by duration of efficacy (six months is preferred over one or three months). The latter finding reinforced FHI 360’s decision to try to develop a product with a duration of up to six months. The importance of the menstrual attribute was so strong in the India survey that FHI 360 added a second sample of 500 women for the DCE survey in Nigeria to explore preferences in both the presence and absence of the menstrual attribute. As in India, for the DCE survey which included menstruation, this characteristic proved most important to women, followed by duration of effectiveness. For the survey without menstruation, duration was most important, followed by application pain. All the user preference information has been analyzed and is being used to inform the final attributes of the microneedle patch. The results were also shared with BMGF, who are pursuing their own microneedle patch development, and praised the findings as “very helpful” to their own work.

c. Southern Africa Method Mix Technical Assistance (TA)

FHI 360 was asked by OHA to provide TA for up to five Southern African countries (Botswana, eSwatini, Lesotho, Namibia, and South Africa) to support an analysis of existing method mix and
technical/advocacy efforts currently underway to foster method mix expansion. USAID funding for FP programming in Southern Africa is minimal (most countries in the region are "graduated countries" and do not receive FP money), yet despite a "graduated status" many of these countries have poor FP outcomes (e.g., high rates of unplanned pregnancy).

In the Southern Africa region, many countries with high HIV prevalence also have a method mix heavily skewed in favor of injectable contraception, such as DMPA. As countries awaited the results from the ECHO trial, there was concern about what may occur in countries with a high HIV burden, high rates of DMPA usage, and limited method mix. With President’s Emergency Plan For AIDS Relief (PEPFAR) funding, FHI 360 undertook an individual country assessment in Namibia (with plans for similar assessments in other countries underway) to identify gaps in method choice and to devise a plan of TA regarding how best to address those gaps.

FHI 360 was asked by the USAID/Namibia Mission to conduct a rapid assessment of national level FP policy, guidelines, and service delivery programs, with a view to developing actionable recommendations. FHI 360 used standardized data collection tools (which allows for greater comparison across settings) to assess service providers' knowledge and practices and their strengths and gaps. FHI 360 also performed a desk review of current policies and guidelines. Other in-country partners had been weighing in over the prior two years about updates to guidelines and other aspects of FP programming but the input was considered superficial and not systematic.

Findings of the rapid assessment include: limited method mix, persistent stockouts, outdated guidelines (e.g., women must "prove" they are menstruating by showing a menstrual pad before being initiated on a method), emergency contraception available only in cases of rape, and adolescents encouraged to complete childbearing before beginning contraception.

The rapid assessment led to recommendations used to inform national FP guideline revisions and development of a provider Training of Trainers curriculum. With assistance from FHI 360, the Ministry of Health and Social Services updated their National FP Guidelines and National FP Training of Trainers Curriculum. FHI 360 developed a provider training package and obtained the necessary training tools for providers, and facilitated the hiring of a regional consultant to deliver the updated National Training of Trainers. One valuable outcome of the entire activity was to greatly strengthen USAID/Namibia’s capacity in FP. This increased capacity lent greater credibility to the Mission’s capacity and improved the working relationship with the MoH.

"FHI helped us build rapport with the MoH.” —USAID

"FHI helped me (my background is infectious diseases) become more conversant in FP.”
—USAID

"This process put FP back on the map for this country.” —USAID

"FHI 360 has never had this level of impact with such a little amount of money in so little time.”
—FHI 360

EVALUATION QUESTION 2. TO WHAT EXTENT HAS ENVISION FP ACHIEVED EACH AIM?

This next section outlines major achievements for activities under each Aim. Additional sub-questions include:
a. What are the major achievements to date for each aim?

b. What areas could not be implemented in each aim and why?

c. What were the implementation/management challenges faced and how did the project address them?

d. What was the quality of research conducted, including input from the Scientific and Strategic Advisory Committee (SSAC) on clinical trial designs, decisions on patent rights and sub-partners selected?

e. Course corrections based on SSAC feedback.

f. Management and project team’s organization to maximize the work of this project.

g. Management challenges faced.

Evaluation Question 2a) What are the major achievements to date for each Aim?

Aim 1: Refine Existing Contraceptive Methods

Key activities in Aim 1 include: (1) Pharmacokinetics/Pharmacodynamics (PK/PD) study of lower-dose DMPA, (2) extending the reinjection interval of DMPA-SC (brand names, Depo-SubQ Provera 104® and Sayana® Press) and, (3) a PK/PD study of DMPA 150 mg or 300 mg compared to DMPA-SC (referred to as “DMPA XT” study).

In sub-Saharan African countries, injectable contraceptives constitute more than one-third of the modern method mix and injectables are very popular in other areas, such as Indonesia and Latin America. Current evidence suggests that DMPA dosages are likely higher than required for three-months’ worth of pregnancy protection (effectiveness). Higher doses have raised safety concerns (especially in terms of bone thinning), particularly if DMPA is used long-term. It is also known that subcutaneous (SC) delivery of DMPA has a more favorable PK profile than intramuscular (IM) delivery, suggesting that lower dosing via SC may be possible. Finally, higher dosing may result in an undesired longer return to fertility. To date, no injectable contraceptive had been tested and shown to be effective for more than three months.

FHI 360 addressed three important questions related to the effects of DMPA usage: (1) Could the dose of DMPA be lowered so as to provide women with the lowest dose possible for three months of pregnancy protection? (2) Could the reinjection interval of Sayana® Press be extended from three to four months? and (3) Could Depo-Provera (DMPA-IM) at doses of 150 mg or 300 mg, given subcutaneous, be effective for up to six months? The studies seek to address key safety concerns by ensuring that women have reduced drug exposure either by decreasing the amount of drug or extending the re-injection interval. Moreover, there are potential cost savings to women and the healthcare system as well as the possibility of enhanced continuation rates.
1. PK/PD study of lower dose DMPA

A partially-blinded randomized trial was conducted to assess the PK and PD of three doses of Pfizer’s current DMPA-IM formulation (45 mg, 75 mg, and 105 mg) injected subcutaneously1 compared with the currently available DMPA-SC (104 mg). The primary objective was to determine suppression of ovulation as a function of medroxyprogesterone acetate (MPA) levels over a six-month time period.

The study was implemented in three trial sites: Profamilia in the Dominican Republic, El Instituto Chileno de Medicina Reproductiva (ICMER) in Chile, and the University of Campinas (UNICAMP) in Brazil. At the time of this evaluation, the results are embargoed and will be released mid-November 2019.

2. Extending the reinjection interval of Sayana® Press

The Sayana® Press Extension (SPE) study is co-funded by BMGF, under two grants: the “Contraceptive Technology Innovation Initiative (CTII)” and “Advancing priority contraception leads to meet user needs.” Sayana® Press is a formulation of DMPA-SC delivered through a Uniject2 device. Currently, the Sayana® Press re-injection interval is indicated every three months. Evidence suggests that this interval could be extended from three to four months. FHI 360 reports that the implications of extending Sayana® Press duration even by one month would not only reduce drug exposure and increase convenience to women, but also decrease commodity costs for one year of pregnancy protection by 25 percent. Furthermore, based on those savings, countries could serve 33 percent more women annually.

FHI 360’s goal was to determine whether the Sayana® Press re-injection interval could be extended from three to four months. The primary outcomes are one-year pregnancy rates, side effects and adverse outcomes, and discontinuation rates. To answer this question, FHI 360 developed a 12-month single-arm study to determine the effectiveness, safety, and acceptability of Sayana® Press given every four months. The study will inform the grace period for re-injection. The study is being implemented at three sites: the Dominican Republic3 (Profamilia), Brazil (CEMICAMP), and Chile (ICMER) and has met the enrollment target of 750 women. FHI 360 has also completed KIIs with FP providers and MoH decision-makers on the acceptability of extending Sayana® Press intervals from three to four months.

The trial is currently underway and will continue through April 2020. If the results support a four-month re-injection interval, FHI 360 will seek changes to the WHO Selected Practice Recommendations (SPR), label changes, and/or and updates to in-country FP guidelines.

Over the course of the trial at one of the sites, study investigators reported a number of site reactions and several instances of Uniject device malfunctions. While these reports are not inconsistent with the Sayana® Press label nor with the previous reports from the field about episodic malfunction of the Uniject device, FHI 360 revised the study Case Report Forms to collect this information at all trial sites in order to better understand the problems.

At the CEMICAMP site in Brazil, two additional sub-studies resulted from the clinical trial. One sub-study, led by a local investigator with independent funding, is evaluating changes in body composition associated with use of Sayana® Press. A second sub-study is assessing immunological changes associated with use of Sayana® Press.

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1 Drug concentrations are typically higher when injected intramuscularly so the reasoning is that a lower dose of DMPA IM given subcutaneously might have a greater effect than when given intramuscularly.
2 Single use pre-filled injection system delivered subcutaneous.
3 The study at this location is funded by BMGF.
Phase 1 Clinical PK/PD study of DMPA-XT

Depending on the formulation, injectable contraceptives are effective for one to three months. For each re-injection (of non-self administered products) a woman must visit a healthcare provider, which means that over the course of a year, a woman will require 12 or four (every three months) visits a year. A number of studies have found that method inconvenience is one reason women choose to discontinue a method prematurely. In order to decrease the inconvenience of returning for injections, FHI 360 set out to test if the currently available formulation of Pfizer’s Depo-Provera® (150 mg/mL) given subcutaneously (either one or two ml SC to give 150 mg total or 300 mg total) would provide protection from pregnancy for up to six months. The study was co-funded by BMGF, under the CTII and “Advancing priority CT leads to meet user needs” grants. USAID funds were not used for any Profamilia site activities. FHI 360 implemented a partially-blinded randomized trial at two sites—Oregon Health Sciences University (United States) and Profamilia (Dominican Republic)—in order to assess the PK/PD of one injection of either 150 mg (1 ml) or 300 (2 ml) of DMPA-IM delivered subcutaneously through the abdomen compared with two injections at three month intervals of Depo-subQ Provera104® (reference). The study evaluated progesterone levels as an indication for suppression of ovarian activity. A total of 42 women were enrolled and followed over a period of 18 months.

The initial clinical study results were submitted to the FDA in June 2019. Meetings have taken place with two European regulatory authorities (Netherlands and Sweden) to discuss a Phase III clinical trial in the European Union as a next step toward obtaining new product approval. A manuscript is currently in development for submission to an open-access journal. Finally, FHI 360 has identified a commercial partner that may be interested in developing a generic six-month product.

Aim 2: Respond to product-related issues that arise from the field and impact provision

Key activities under Aim 2 include: supporting the learning agenda and scale-up of Levonorgestrel intrauterine system (LNG-IUS) products, hormonal contraceptive-antiretroviral (ARV) drug interaction database (DDI), and the Implant Removal study.

1. Supporting scale-up of the LNG-IUS

The LNG-IUS is a highly effective reversible contraceptive method that offers a number of advantages, including the reduction of menstrual blood flow and menstrual cramps, and the possible alleviation of anemia in some populations. However, the high cost of the method has been a significant barrier to making it more widely available in low- to middle-income countries. Leveraging funding from both USAID and BMGF (via the Learning about Expanded Access and Potential [LEAP] LNG-IUS Initiative), FHI 360 seeks to increase the introduction and scale-up of LNG-IUS products into more countries through reducing the cost of goods sold, increasing the number of suppliers, and incentivizing manufacturers to lower their prices of products. Currently there are six LNG-IUS products available, although only two products have Stringent Regulatory Approval (Mirena™ and Lilleta™(also known as Abivella). Three other products are registered in individual countries or are in the process of seeking registration.
In 2015, USAID convened an LNG-IUS working group with the goal of making LNG-IUS products more affordable and more available to women in low resource settings. The size of the working group has kept growing and now includes USAID, BMGF, Population Services International (PSI), JHPIEGO, Marie Stopes International (MSI), Women’s Care Global, Pathfinder, DFID, and a number of commercial suppliers. In 2017, FHI 360 spearheaded a market research and demand forecasting study in Kenya, Nigeria, and Zambia. In 2018, longitudinal LNG-IUS acceptor and rejecter surveys, along with interviews with women and youth, were conducted in Nigeria and Zambia. In 2019, the results were used to inform an introduction strategy for LNG-IUS products into Kenya, Nigeria, and/or Zambia. The results of these studies have not been publicly released.

In 2018, FHI 360 co-published a systematic review of LNG-IUS induced amenorrhea in the *American Journal of Obstetrics and Gynecology* and in 2019, FHI 360 drafted a second systematic review on LNG-IUS bleeding and spotting. For a full list of studies, see Annex IV.

A wealth of evidence has shown that a major reason women discontinue contraception is due to normal changes in menstrual bleeding. FHI 360, in collaboration with PSI, developed the NORMAL (Normal, Opportunities, Return, Methods, Absence of Menses, and Limit) job aid for healthcare providers. The purpose of the NORMAL job aid is to assist healthcare providers to counsel their clients on normal bleeding changes due to hormonal contraception and the Cu IUD. The NORMAL job aid has been shared in a number of venues. For example, NORMAL has been added to the Namibia MoH National Family Planning Guidelines and the National Training of Trainers Package. Additionally, it was added to the Ghana Health Services’ (GHS) MoH implant removal training curriculum. PSI has included NORMAL in its counseling “Choice Book” (developed under Support for International Family Planning and Health Organizations 2 [SIFPO2]). FHI 360 helped the Bedsider/Power to Decide campaign adapt the tool for US audiences.

2. **Contraceptive DDI Database**

As more HIV and/or Tuberculosis (TB) positive women have access to life-saving antiretroviral therapy (ART) and anti-TB drugs, there has been increasing debate about the impact of hormonal contraception on the efficacy and/or toxicity of those drugs. WHO’s updated guidelines on concomitant use of HCs and ART note that women taking ARVs can use all contraceptive methods, but special consideration may be needed for women who use progestin-only contraceptives with certain ARVs. The suite of ARVs has undergone rapid changes with the number and types of drugs being developed and used as first line treatment, and drugs that fall out of favor to make way for more effective treatment. Consequently, information on drug-drug interactions can quickly become out-of-date or obsolete. Under Envision FP, FHI 360 undertook a systematic review of the most recent literature and developed a “DDI Database” housed on the Contraceptive Technology Innovation Exchange (www.ctiexchange.org). The database contains up-to-date information on contraceptive drug-drug interactions with ARVs and anti-TB drugs. FHI 360 also developed a DDI handout for providers.

Through the DDI work, FHI 360 published six journal articles (see Annex IV) and galvanized interest to develop a database for contraceptive and anti-malarial interactions.

3. **Implant Removal study**

As the number of implants increases throughout sub-Saharan Africa there have been questions on whether providers are prepared for the inevitable increase in demand for implant removal. There is little information on the quality and availability of implant removal services. With funding from BMGF and
USAID, FHI 360 led a study assessing access to implant removal services in Ghana in collaboration with the Population Council, GHS, and MSI. Respondents involved with the study stated that the results were actionable in large part because FHI 360 was “responsive to the local context” and ensured the study questions were appropriately contextualized in the Ghana setting. Furthermore, the usability of the findings was also credited to FHI 360, ensuring the GHS had a lead role in protocol development and study questions. FHI 360 was praised for good organization by one Partner: “Roles and responsibilities were well defined from the very beginning. Everyone’s efforts were well appreciated and there was a complementary arrangement between all. Each organization had different strengths so we made sure to leveraged everyone’s strength.”

The results were shared at a national dissemination meeting in Accra, Ghana in October 2018. As a result of this meeting, GHS and the Population Council (supported with a sub-award from FHI 360’s BMGF award) led to two regional dissemination meetings and a follow-up meeting to synthesize recommendations. A two-day workshop resulted in a revised implant training curriculum and a new standardized algorithm for providers to use in managing difficult removals. The workshop materials were shared with national and regional level Training of Trainers for use in subsequent provider training. One respondent noted that an additional, and important, outcome of the study was building local capacity to undertake similar studies. Subsequent to the implant removal study, Population Council and GHS adapted the study protocol to undertake a study on emergency contraception.

A second study was planned with BMGF funding in Senegal. Based on experiences with the Ghana survey, a number of revisions were made to the data collection tool in order to improve usability of the results. FHI 360 reports that “the client questionnaire was revised to better capture women’s experiences with removal, a provider survey and health facility assessment was added to help improve understanding of the potential provider and health system factors contributing to removal outcomes, GIS mapping was added to look at scenarios for improving access to difficult removals, and in order to frame the results in the broader context of method choice, the study was expanded to look at access to IUD removal services as well.”

The results of the study were shared on a Knowledge for Health (K4H) blog and a study on the costing implications of implant removal was published in June 2017. The results were also shared at two major FP conferences and shared with the MoH for future training and follow-up. A journal publication describing the study results is also in progress.

**Aim 3: Develop new methods to fill gaps**

The characteristics most important to women when choosing a method, and continuing with that method, include efficacy, ease of use, duration of use, type and severity of side effects, privacy/concealment, administration, and costs (direct and indirect). Healthcare policy-makers have their own considerations, including cost, level of training needed for providers, and staff time and equipment required to provide the method. Innovations in contraceptive methods must take both sets of desired characteristics into account. The microneedle patch and the biodegradable implant (BDI) are two such methods.

### 1. Microneedle Patch

In contrast to existing contraceptive patches, which must remain in place to be effective, the microneedle patch is applied and then removed. Additionally, the patch is small, thus providing women with a method that is discreet.
FHI 360 recruited one of the leading microneedle patch developers, Dr. Mark Prausnitz at Georgia Tech, to develop a microneedle patch for contraception.

“FHI got with the ‘Godfather of Microneedles.’” —Partner

Funding for development of the microneedle patch came from USAID and Interagency Agreement funds from the NICHD. BMGF is funding parallel research using a slightly different approach to drug release. The challenges addressed include moving from water-soluble to organic-soluble drugs, microneedle separation from the patch backing, enlargement of the patch, increasing the duration of drug release, and reducing the effect of the initial drug release burst. FHI 360 and its partners have formulated the first-ever microneedle patch that releases LNG over a period of one month. The next step is to refine the formulation to provide up to six months of pregnancy prevention. Microneedle research as a result of Envision FP has resulted in three peer-reviewed publications in high-impact journals.

FHI 360 has been working closely with BMGF to ensure “cross-pollination” of ideas and limit redundant research. For example, results on an effective mechanism to release the microneedles from the patch backing could be used in both projects, as well as for other indications. Overall, the microneedle work spurred interest among other academic research institutions—and funders—to enter the field. Development activities under these two research projects are proceeding towards de-risking the projects so as to make them attractive to a commercial partner.

2. Development of biodegradable contraceptive implants

The contraceptive implants that are currently available must be removed at the end of their efficacy duration or when the woman wants to stop using the method. The necessity of removal, by definition, imposes a burden on users. Moreover, some removals can be technically challenging, which is problematic for both the user and the provider. There is also a financial cost to implant removal, which may represent a financial burden to the healthcare system (and the user in a fee-for-service setting). A BDI would alleviate many of these challenges for many users. BMGF is funding FHI 360’s current work to develop a BDI that builds on previous grants from USAID.

The FHI 360 team was focused on two distinct approaches to BDI development. One approach has been to collaborate with Gesea Biosciences, Inc., the company that owns the technology (pH Sciences conducts the research and development [R&D]). With Envision FP funding to support FHI 360 staff time, FHI 360 assisted Gesea in responding to FDA regulatory concerns and move the BDI closer to a Phase 1 trial. Dr. Mark Saltzman of Yale University spearheads a second approach that USAID supported with bridge funding between two BMGF grants. Dr. Saltzman’s team has developed a unique set of copolymers comprised of two monomers, pentadecalactone and dioxanone. With Envision FP funding, site qualification visits for the selection of the contract laboratory to conduct the Yale PK study took place and a vendor was selected. This was the final BDI activity using Envision FP funds.

Evaluation Question 2b) Areas that could not be implemented in each aim and why

A number of activities were cancelled, had a reduction in activity levels, or closed out early due to lack of funds or human resources. See Annex VI for a table of activities and reasons for cancellation, reduction in activity levels, or closeout.
Evaluation Question 2c) Implementation/management challenges faced and how the project addressed them

Electronic regulatory reporting

FHI 360 needed to outsource activities related to electronic regulatory submissions and reporting for the FDA since they do not have the electronic submission platform in-house. However, in several cases, FHI 360 did not anticipate the level of internal staff time required to manage some of the outsourced activities (e.g., needing to write results/conclusions of a clinical study report themselves). Consequently, more staff time was required than budgeted. In the future, FHI 360 will know to budget adequate staff/time.

Maintaining rapid response

Neither FHI 360 nor USAID could state significant challenges maintaining the open response. The only challenges cited were potential challenges that may arise in any future awards.

- **Risk for budgeting:** Since requests for assistance are not known, budgets cannot be prepared in advance. There is a risk that if the response to a request requires significant staff time and/or resources, money may need to be drawn from other projects.

  “If something does come up during the open response that may require money, then you will need to pull from elsewhere in the project. It is a bit more of a burden on staffing and management.” —USAID.

- **Risk of scope creep:** FHI 360 is a trusted and credible organization. As such, there is the risk that FHI 360 will be asked to take on more work because they are reputable.

  “You run the risk of FHI becoming the ‘quality police’ of the world. If there is a problem with quality then you would need to bring in logistics and a quality team to address it. Quality assurance typically needs CSL [Commodity Service and Logistics] folks and if something happens at the country level then you ultimately need to bring in the Mission.” —USAID.

- **Risk of too much work:** FHI 360 said that the number and type of requests were well managed under the current award. However, if something significant had arisen, such as a result from a major study that would upend current family practice programming, then they may not have been able to respond.

  “If the ECHO results had been a mess, and we had many requests to respond to, then I don’t think we would have had the staff time.” —FHI.

- **Lack of feedback from the requestor:** Without a feedback mechanism FHI 360, or any organization that may implement the activity, may not know if the evidence/information supplied was useful. Without that information there is no way to know whether the quality of the response is adequate.

  “We don’t always get feedback from USAID so we don’t know if what we gave them was helpful or not.” —FHI 360

**ECHO Trial**

In South Africa, there is a limited method mix and therefore both providers and women have limited experience with IUDs and, in some settings, with implants. FHI 360’s response was to provide intense
provider and user education. There was a challenge to find enough women outside of the study interested in using the IUD and willing to participate in provider training for IUD insertions. A South African nurse with previous experience working with Wits RHI helped identify and recruit these women. There were also challenges getting foreign providers/trainers registered in-country to conduct the trainings.

**Contraceptive drug-drug interactions database**

The first database took longer than anticipated to develop and the final product was “buggy.” This led to a decision to change developers, which delayed the launch. Problems with the database were not discovered until the end; by then, time and resources had been wasted. The lesson learned was that there needs to be regular work product review. FHI 360 said that in the future they would be more intimately involved in the design and development phases (closer oversight).

**Microneedle Patch**

Georgia Tech published research on contraceptive jewelry, stating (incorrectly) that USAID had supported the study. In response, FHI 360 had discussions with Georgia Tech reminding them that USAID must approve any deviations from the scope of work and milestones. Furthermore, USAID must approve any manuscript prior to publication.

During the testing of the microneedle patch it became apparent that FHI 360 lacked sufficient depth of experience to oversee product testing to the degree required for regulatory approval. At the urging of BMGF, FHI 360 hired a Chemistry, Manufacturing, and Controls (CMC) expert who could oversee the work undertaken by contract laboratories to ensure it aligned with FDA CMC guidance. FHI 360 also increased frequency of sites visits at testing laboratories.

**Evaluation Question 2d) Quality of research conducted, including input from SSAC on clinical trial designs, decisions on patent rights, and sub-partners selected.**

In the opinion of all those interviewed about quality of research, the quality of the research has been excellent. As one Partner stated, “The quality of the research is excellent—beyond reproach.” A member of the SSAC opined that “FHI 360 has an exceptionally well-balanced team, in terms of its knowledge of basic science and the pharmaceutical industry, allowing it to generate high quality pre-clinical and clinical trial work.”

Regarding its research for Sayana® Press, FHI 360 imposed a higher standard on itself: it conducted the research under the FDA’s Investigational New Drug (IND) guidelines although Sayana® Press is not, in fact, under an IND. The ECHO trial results were published in *The Lancet*. Given that *The Lancet* is one of the most prestigious and well-known medical journals in the world, publication there is a testament to the quality of the ECHO trial research.

FHI 360 sub-partnered with the University of Michigan via Georgia Tech on the microneedle patch. The choice of the University of Michigan as a sub-partner was based on the long-standing and productive collaborative relationship that the investigators at these two universities have had and the expertise in controlled drug delivery at the University of Michigan. Selection of partners for the DMPA clinical trial sites—Brazil, Chile, and the Dominican Republic—were also chosen based on long-standing relationships. FHI 360 had previously used these sites for other studies and were familiar with the technical expertise but also had long-standing collegial relationships with the trial staff.

The issue of patent rights was raised although little was said about it other than it is an area that must be given greater consideration in the future (see Recommendations).
The quality of research is, to a large extent, a result of the technical capacity of those performing it. Although respondents were not directly questioned about FHI 360’s technical capacity, many interviewees chose to volunteer their opinions.

“I’m highly impressed with their technical capacity. If I have any questions I reach out to Laneta and Greg…Vera…and they are quick to help.” —USAID

“Their technical acumen is impressive. They are also used to working in development and know how things work in a cooperative agreement. They are a good partner.” —USAID

“They’ve done a really good job. They are on time, flexible when they need to be, and work collaboratively with other departments in USAID.” —USAID

“FHI was able to find the right person to do the work. I’m not sure if my team could have done what we wanted without having access the FHI’s experts and networks. In this respect FHI was very useful because they had such great depth of experience but also had a big network to pull from if they didn’t have the expertise in house. One probably couldn’t get this from a smaller organization.” —USAID

“Laneta is great about integrating what is learned across the portfolio.” —Partner

“Overall, I’m always impressed with what comes out of Envision.” —USAID

“They are excellent. I’ve worked with a lot of technical advisers and a lot of people who assist the Ministry. FHI 360 always brings in two skills: interpersonal and professional capacity. FHI 360 was very familiar with the setting, respectful, and recognized the challenges…even when identifying the challenges they packaged them in a respectful manner. Their expertise was phenomenal. I learned a lot from them. Their support was really, really impactful.” —USAID

“Few successors are being trained to fill the ranks to conduct contraceptive product development. The field of contraceptive development needs long-term succession planning. How can we sustain the workforce with people with experience and commitment? FHI has the potential to be a good training ground for the next generation in the workforce. FHI also has the important social component.” —SSAC member

“Our technical expertise for contraception counseling and safety was excellent and they continue to be excellent at that. They also provided statistical support which was exceptional.” —Partner

Indirectly, interpersonal relationships impact the quality of work produced. Again, interviewees were not directly questioned about FHI 360’s interpersonal relationships, but they offered many comments on this issue.

“We are both physicians and speak the same language. If we have disagreements about the protocol then I feel free to speak with her.” —Partner

“Good personal relationship with Vera and Laneta make it very easy to work with FHI…. The personal relationship is an ‘open door,’ which facilitates everything.” —Partner

“Good personal relationships are very important. Trust and honesty between colleagues. We don’t hide our pitfalls and we can work through challenges together.” —USAID
“The role of interpersonal relationships is very important. The number of people in the contraception biomedical field is small and everyone knows each other. Meetings are well run and cordial and that it makes a huge difference.” —USAID

“FHI has been the partner for so long with USAID on FP/HIV that I have worked with the same people on other activities. We are able to bridge across other projects.” —USAID

**Evaluation Question 2e) Course corrections based on SSAC feedback**

Respondents with knowledge of SSAC reported that FHI 360 were “very receptive to SSAC feedback.” One respondent stated, “FHI 360 does take the advice of SSAC to heart. If it doesn’t do exactly what SSAC recommends, it finds a path that is acceptable.” Other examples include:

“It can be difficult to hear ‘cut bait’ (terminate planned research)—but they did it based on SSAC input.” —SSAC member

“FHI seemed to welcome SSAC input—especially advice within the regulatory arena.” —SSAC member

**Evaluation Question 2f) Management and project team’s organization to maximize the work of this project**

The Envision FP project spans a broad range of activities and oversees a large number of partners, subcontractors/awardees, and vendors. FHI 360 Envision FP staff work on teams, which facilitates greater sharing and problem-solving. It was clear to the evaluators that Envision FP senior leadership is involved to a degree—to be helpful but not stuck “down in the weeds.” The leader of each team is highly experienced and demonstrated great depth of knowledge in their particular area of expertise and an understanding of the greater global landscape.

Respondents overwhelmingly praised FHI 360’s capacity to manage and lead:

“FHI is very open to collaboration. They need the pharmaceutical industry and universities. Collaboration is baked into their DNA.” —SSAC member

“I give FHI gold stars for its project management—especially given the number and diversity of subcontractors it works with. It’s not easy. It can be a three-ring circus.” —SSAC member

“The team that manages FHI is stellar.” —USAID

“Patient, flexible, and responsive.” —USAID

“FHI creates minimal management burden for USAID.” —USAID

“FHI is reliable, honest, great. Unfailingly collaborative and cooperative.” —USAID

Overall the assessment of FHI 360’s management performance was very positive.

**Evaluation Question 2g) Management challenges faced**

The most significant management challenges faced were in conjunction with microneedles and was addressed previously.

Evaluation Question 3 is addressed in the next section.
V. RECOMMENDATIONS

EVALUATION QUESTION 3. LOOKING TO THE FUTURE

The final evaluation question was focused on recommendations for implementation priorities for the remainder of Envision FP, recommendations for future program design and activities, and new priorities for future awards. The evaluation team, with input from FHI 360, partners, and funders, identified the following set of key recommendations.

Evaluation Question 3a) Recommendations for improving implementation priorities for the remainder of Envision FP

- **DMPA low dose**: Finish publication of studies.
- **Extending long-acting reversible contraception**: Based on evidence from long-term studies, continue to advocate and raise awareness for WHO to update SPR in 2021 to extend the acknowledged efficacy of etonogestrel (ENG) implants and LNG IUS at least two years beyond their labeled durations of use.
- **LNG-IUS products**: FHI 360 continues as a neutral party in the LNG-IUS Working Group with the goal of introducing LNG-IUS into a couple of countries. Continue to work with LNG-IUS commercial parties, provide country-level support work (unofficial task force) in Zambia and Nigeria, and pursue information on demand creation.
- **ECHO trial**: Continue data analyses, including priority secondary analyses, the continuation study, and additional publications.
- **Microneedle patch**: Complete in vivo animal dosing studies, select a hormonal candidate, determine microneedle formulation characteristics, and prepare for human studies.

Evaluation Question 3b) Recommendations for future program design, particularly reflecting on the response mechanism of Aim 2

There was a wide range of responses to recommendations for future program design. The evaluators chose the recommendations that are the most salient and realistic given USAID’s funding profiles and strategic priorities.

**Change the duration of funding or change what to fund**

It can take years to get a new product developed, go through clinical trials, and ultimately registered. Given that USAID awards are for five years, a few respondents wondered if USAID’s money would be better spent on later stage R&D, for example supporting clinical trials:

“The current award is primarily focused on modification of existing products followed by responding to questions from the field. Then, lastly, product innovation. This is probably the way to go for USAID [focus on existing products and responses to questions] given how they fund. For example, incremental funding is good for clinical trials since clinical trials proceed in an incremental approach. An incremental approach may not be the best for developing new products, but it’s good for running clinical trials.”

—Partner.
Conversely, some respondents stated that USAID should in fact keep funding new products and advocate for longer award durations:

“Sometimes longer timelines are needed (longer than five years), such as those for the microneedle and those that require a lot of regulatory procedures. For example, if something is funded for a year or five years that may not be long enough time. It can take time to form partnerships and then get registration approval. For example, they may have wanted to test something in the field—in an African country—and within that country it could take a very long time to get through the regulatory process. Or some time to get the staff capacity up to speed.” —SSAC member

“We can no longer fund long-term awards, such as a 10-year award. It is difficult to get anything longer than a two-year extension. You need more than five years to conduct some of these trials and for product development.” —USAID

Get projects started on solid financial ground

Once a project is awarded, the awardee is given funds for the fiscal year (or whatever time remains in the fiscal year) and not a full calendar year. For a project that has big start-up costs, such as R&D, this can be a significant hindrance, especially for smaller organizations/companies.

“One lesson learned is the importance of having money available up-front to get the project started. Sometimes the awardee doesn’t get a full calendar year of money at the start but only a fiscal year. We need to reassess that approach.” —USAID

Funding by project phase

Two respondents highlighted that USAID has previously provided funding by project phase rather than a fiscal year. This also has important implications for smaller organizations that may not have the resources on scale with FHI 360. For example, funding an entire phase of clinical trial instead of by fiscal year would ensure the activity has adequate funding (and no gaps in funding).

“Given the amount of leveraging to move contraception tech along then maybe we need to ask ‘Who would fund at certain phases?’ The more USAID can collectively do that addresses risks, the better to the implementer.” —USAID

Strengthen commercial ties particularly with generic manufacturers

An often-cited recommendation for FHI 360 (or any organization working in this space) and USAID is to strengthen ties with the commercial sector, particularly in manufacturing. This was cited as a way to ensure that what is developed makes it to the market. In order to strengthen those ties, an implementing organization would need the right type of expertise and network to work with manufacturers. Currently, FHI 360 does not have the manufacturing expertise that would be required. Moreover, USAID would need to provide adequate funding and resources to support stronger ties to the commercial sector.

“USAID needs to balance resources vs. impact. If they want to continue to develop products then perhaps they should focus on funding pre-clinical trials and de-risking for private companies. But first you need to make sure that private companies are interested. FHI needs to strengthen commercial ties if they want to continue in that space so they would need to bring someone in to help them work with the manufacturing sector.” —Partner
“Perhaps USAID should invest more money in strengthening commercialization ties, such as through CTII. Perhaps consider investment into a commercialization ‘arm’ or consultancy to get product to the market.” —Partner

“We need to look more closely at generic manufacturers, private sector, women and men users. We also need more market research to show that investment in a particular method is grounded in evidence.” —USAID

“There is a need to go after generic manufacturers especially in developing countries, keep pursuing microneedle work, and develop contraception for individuals who have intermittent sex.” —USAID

Form partnerships

FHI 360 was highly praised for their stellar ability to coordinate and lead. In the future, some respondents recommended that FHI 360 broaden the network of organizations/institutions they typically work with (e.g., new clinical trial sites), partners who have a larger decision-making role and who will be present throughout the life of the project (not limited to sub-contractors/sub-awardees that perform short-term and limited scope work). Recognizing that a prime award holder will ultimately oversee the work sub-awardees, the sentiment is that FHI 360 (or any prime) should have a set of partners that can oversee a greater share of the work from the beginning to the end of the award. Moreover, the recommendation was made to USAID for any follow-on award to include partnerships, for example, partnering with companies in the for-profit sector that can contribute both expertise and funding. FHI 360, in fact, did not have an implementing partner but rather a network of sub-contractors/awardees. In the future, some respondents recommended that FHI 360 work with organizations/companies in a more shared decision-making partnership and that USAID structure any follow-on award to include a partnership. The recommendation to form real partnerships is important not only for the sharing of ideas and drawing on expertise, but also from a capacity building and sustainability standpoint:

“FHI tends to ‘play in their own sandbox’ and in the future they will need to bring in partners early on and get them involved. They should build partner capacity throughout the award. When FHI uses labs they tend to be in the US but they should be using labs in developing countries and building those partnerships [relationships]. You also can’t have all clinical trial sites in the same countries, for example, in South Africa. They need to broaden those partnerships out as well. [Finally] since FHI will eventually need to seek WHO Prequalification they need to identify interested [manufacturing] partners early in the award. I’m not referring to sub-agreement partners but a real partner.”

Continue the open (rapid) response in future awards

Respondents were overwhelmingly in favor of continuing the open response and found the mechanism helpful.

Evaluation Question 3c) New priorities that were identified that should be addressed in the remaining year vs. addressed in future projects

DMPA-SC Extension

Continue to have discussions with the manufacturer(s) about using FHI 360’s evidence base to re-label the product for four-month duration. Continue to advocate and promote revisions to the WHO SPR to reflect new evidence on the reinjection interval. Continue to provide feedback to the manufacturer, as appropriate, related to problems with the Uniject devise identified in FHI 360 research.
Preparation for Phase 3 trials (identify manufacturing partner, develop regulatory strategy, dossier, protocol, conduct site selection). The aim is for a Phase 3 trial for European Union approval by 2023 and then national approvals and WHO prequalification.

**Continue to work to try to close the gap between FP and HIV**

The ECHO trial helped shrink the gap between HIV and FP programming but a few respondents worried that there is a risk that the gap will widen again post-ECHO. ECHO demonstrated that although contraception does not increase HIV acquisition, good HIV counseling, testing, and prevention (e.g., condoms) does not decrease it either. What has been proven to bring down HIV transmission is pre-exposure prophylaxis (PrEP) and ART.

"USAID’s own data has shown that if you can put PrEP and treatment into FP women will take it up. If USAID wants to continue down that path then they need to acknowledge that women need HIV services integrated into FP services. They should implement service delivery integration from the get-go or not at all." —Partner

The Envision FP project was not designed for service delivery of integrated programming; this priority is outside the scope of the project. Nevertheless, it should be an important priority for USAID.

**Promote the health benefits of contraceptive methods**

There are a number of calls about the importance of promoting the health benefits of contraception. A number of respondents in this evaluation also made it clear that more must be done to promote the health benefits: e.g., anemia reduction, treatment of endometriosis, etc.

**Support the advancement of self-administered methods**

The WHO defines self-care as “the ability of individuals, families and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a healthcare provider.” In recent years, increasing attention has been paid to the need to advance the goal of developing new methods (e.g., microneedle patch) that can be used by women with little to no interaction with the healthcare system. A number of respondents encourage USAID to pursue these types of methods.

"Self-care—what methods can women use with less interaction with the healthcare system? The microneedle patch can hold some promise with that." —USAID

**Conduct more research on method-related side effects**

All hormonal methods, regardless of delivery method, induce some types of side effects, bleeding changes being notable among them. A handful of respondents made clear that women would not adopt a new method if it results in the same negative side effects. More research about side effects is warranted to better understand frequency and severity, individual risk factors, correlation between compliance with method use and severity, efficacy of various strategies for management, etc. Likewise, more attention regarding counseling about and management of side effects is needed within service delivery programs.
Encourage innovation and new funding streams

The nature of NIH funding is to support basic science research, especially in support of early stage high-risk projects. NIH funding would allow for more flexibility to be innovative and develop a robust pipeline of technologies. This ability to innovate would help an organization such as FHI 360 remain relevant in the contraceptive biomedical field.

“Organizationally, FHI 360 could be more innovative in order to compete and remain relevant. FHI could benefit from an NIH award that would support them to be very innovative. I would like to see them go after money like that.” —USAID
ANNEX I. SCOPE OF WORK

Global Health Program Cycle Improvement Project (GH Pro)
Contract No. AID-OAA-C-14-00067

EVALUATION OR ANALYTIC ACTIVITY STATEMENT OF WORK (SOW)
Date of Submission: 10-23-18
Last update: 7-22-19

Refer to the USAID How-To Note: Evaluation SOW and the Evaluation SOW: Good Practice Examples when developing your SOW.

I. TITLE: Performance Evaluation of FHI360’s Envision FP Project

II. Requester / Client

☐ USAID/Washington

Office/Division: _____ PRH / _____ RTU

III. Funding Account Source(s): (Click on box(es) to indicate source of payment for this assignment)

☐ 3.1.1 HIV         ☐ 3.1.4 PIOET
☐ 3.1.2 TB          ☐ 3.1.5 Other public health threats
☐ 3.1.3 Malaria     ☐ 3.1.6 MCH
☐ 3.1.7 FP/RH       ☐ 3.1.8 WSSH
☐ 3.1.9 Nutrition   ☐ 3.2.0 Other (specify):

IV. Cost Estimate: Note: GH Pro will provide a cost estimate based on this SOW

V. Performance Period

Expected Start Date (on or about): August 5, 2019
Anticipated End Date (on or about): December 6, 2019
VI. Location(s) of Assignment: (Indicate where work will be performed)

Consultant’s home office; GH Pro and USAID CP-3 Arlington VA, Durham NC FHI360 office

Type of Analytic Activity (Check the box to indicate the type of analytic activity)

EVALUATION:

☐ Performance Evaluation (Check timing of data collection)
  ☐ Midterm ☐ Endline ☐ Other (specify): Near endline, year 4 of 5-year award

Performance evaluations encompass a broad range of evaluation methods. They often incorporate before–after comparisons but generally lack a rigorously defined counterfactual. Performance evaluations may address descriptive, normative, and/or cause-and-effect questions. They may focus on what a particular project or program has achieved (at any point during or after implementation); how it was implemented; how it was perceived and valued; and other questions that are pertinent to design, management, and operational decision making.

☐ Impact Evaluation (Check timing(s) of data collection)
  ☐ Baseline ☐ Midterm ☐ Endline ☐ Other (specify):

Impact evaluations measure the change in a development outcome that is attributable to a defined intervention. They are based on models of cause and effect and require a credible and rigorously defined counterfactual to control for factors other than the intervention that might account for the observed change. Impact evaluations in which comparisons are made between beneficiaries that are randomly assigned to either a treatment or a control group provide the strongest evidence of a relationship between the intervention under study and the outcome measured.

OTHER ANALYTIC ACTIVITIES

☐ Assessment

Assessments are designed to examine country and/or sector context to inform project design, or as an informal review of projects.

☐ Costing and/or Economic Analysis

Costing and Economic Analysis can identify, measure, value and cost intervention or program. It can be an assessment or evaluation, with or without a comparative intervention/program.

☐ Other Analytic Activity (Specify)

PEPFAR EVALUATIONS (PEPFAR Evaluation Standards of Practice 2014)

Note: If PEPFA-funded, check the box for type of evaluation

☐ Process Evaluation (Check timing of data collection)
  ☐ Midterm ☐ Endline ☐ Other (specify): 

Process Evaluation focuses on program or intervention implementation, including, but not limited to access to services, whether services reach the intended population, how services are delivered, client satisfaction and perceptions about needs and services, management practices. In addition, a process evaluation might provide an understanding of cultural, socio-political, legal, and economic context that affect implementation of the program or intervention. For example: Are activities delivered as intended, and are the right participants being reached? (PEPFAR Evaluation Standards of Practice 2014)

☐ Outcome Evaluation

Outcome Evaluation determines if and by how much, intervention activities or services achieved their intended outcomes. It focuses on outputs and outcomes (including unintended effects) to judge program effectiveness, but may also assess program process to understand how outcomes are produced. It is possible to use statistical techniques in some instances when control or comparison groups are not available (e.g., for the evaluation of a national program). Example of question asked: To what extent are desired changes occurring due to the program, and who is benefiting? (PEPFAR Evaluation Standards of Practice 2014)
### Impact Evaluation (Check timing(s) of data collection)

- [ ] Baseline  
- [ ] Midterm  
- [ ] Endline  
- Other (specify): 

Impact evaluations measure the change in an outcome that is attributable to a defined intervention by comparing actual impact to what would have happened in the absence of the intervention (the counterfactual scenario). IEs are based on models of cause and effect and require a rigorously defined counterfactual to control for factors other than the intervention that might account for the observed change. There are a range of accepted approaches to applying a counterfactual analysis, though IEs in which comparisons are made between beneficiaries that are randomly assigned to either an intervention or a control group provide the strongest evidence of a relationship between the intervention under study and the outcome measured to demonstrate impact.

### Economic Evaluation (PEPFAR)

Economic evaluations identify, measure, values and compares the costs and outcomes of alternative interventions. Economic evaluation is a systematic and transparent framework for assessing efficiency focusing on the economic costs and outcomes of alternative programs or interventions. This framework is based on a comparative analysis of both the costs (resources consumed) and outcomes (health, clinical, economic) of programs or interventions. Main types of economic evaluation are cost-minimization analysis (CMA), cost-effectiveness analysis (CEA), cost-benefit analysis (CBA) and cost-utility analysis (CUA). Example of question asked: What is the cost-effectiveness of this intervention in improving patient outcomes as compared to other treatment models?

### VII. BACKGROUND

If an evaluation, Project/Program being evaluated:

<table>
<thead>
<tr>
<th>Project/Activity Title</th>
<th>Envision FP: Transforming Contraception to Expand Access and Choice</th>
</tr>
</thead>
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<td>Award Number</td>
<td>AID-OAA-A-15-00045</td>
</tr>
<tr>
<td>Award Dates</td>
<td>8/17/15 to 8/16/20</td>
</tr>
<tr>
<td>Project/Activity Funding</td>
<td>$39,637,858 ceiling</td>
</tr>
<tr>
<td>Implementing Organization(s)</td>
<td>FHI360</td>
</tr>
<tr>
<td>Project/Activity AOR</td>
<td>Tabitha Sripipatana</td>
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</table>

Background of project программ/intervention:

The objective of Envision FP is to develop, introduce, and expand understanding of contraceptive technologies and approaches to enhance choice and reduce unmet need. The research agenda aligns with three specific APS aims: 1) refine existing methods; 2) respond to product-related issues that arise from the field and impact provision; and 3) develop new methods to fill gaps. Envision FP focuses on key challenges and opportunities significant for users and programs. The project’s overall goal is to broaden choice of and access to quality, affordable, and acceptable contraceptives to meet the changing needs and desires of women and girls throughout their reproductive lives.

AIM 1: Refine existing contraceptive methods: Refining existing FP methods to enhance safety, use, and/or acceptability is a cost- and time efficient approach to improve FP technologies. The project works on method refinements for DMPA (lower dose), Sayana Press® (extended use), and post-partum IUDs (improved applicator).

AIM 2: Respond to product-related issues with existing contraceptive methods: Under Aim 2, a rapid-response team of technical experts systematically responds to field-based product concerns. In addition, Envision FP technical experts conduct product-related research and systematic reviews to address knowledge gaps affecting program practice and use. Research on relative risk between three contraceptive methods and HIV acquisition (ECHO trial), drug-drug interaction guidance falls under Aim 2.

AIM 3: Develop new methods to address method-related nonuse or fill gaps: The project conducts new
product development research to address significant gaps in the contraceptive method mix, including development of an intradermal biodegradable microneedle patch.

Envision FP is starting its 4th year of a 5-year award and a performance evaluation will inform future programming decisions. Project all core funded. A small proportion of the portfolio included Office of HIV/AIDS co-funds for FP/HIV integration work and the ECHO trial. This evaluation will include those activities in the review.

USAID works very closely with the other major donors of contraceptive technologies, including the Bill and Melinda Gates Foundation (BMGF) and the National Institute of Child Health and Human Development (NICHD). The donors leverage support from each other to move contraceptive pipelines forward and use mechanisms, such as Envision FP and inter-agency agreements to fund co-prioritized activities. This project also works in parallel with the BMGF funded contraceptive technology award to fill gaps in research and development portfolios (ex microneedle work).

Strategic or Results Framework for the project/program/intervention (paste framework below)

If project/program does not have a Strategic/Results Framework, describe the theory of change of the project/program/intervention.

The Envision FP strategic framework, shown at right, depicts the project aims. Project activities fall under one of three aims: 1) refine existing methods; 2) respond to product-related issues that arise from the field and impact provision; and 3) develop new methods to fill gaps. The activities and aims work together to achieve the intended impact of broad choice of and access to quality, affordable, and acceptable contraceptives to meet the changing needs and desires of women and girls throughout their reproductive lives.
**VIII. SCOPE OF WORK**

A. **Purpose:** Why is this evaluation or analysis being conducted (purpose of analytic activity)? Provide the specific reason for this activity, linking it to future decisions to be made by USAID leadership, partner governments, and/or other key stakeholders.

This primary purpose of this performance evaluation is to assess the Envision FP project’s progress (both successes and challenges) towards achievement of each of the project’s aims. The findings of this performance evaluation will be used by the GH/PRH office, particularly its RTU division, to inform decisions about future programming in biomedical research.

B. **Audience:** Who is the intended audience for this analysis? Who will use the results? If listing multiple audiences, indicate which are most important.

What is the geographic coverage and/or the target groups for the project or program that is the subject of analysis?

Project’s geographic scope is global. Specific countries were sites for studies; however, the outcomes of those studies are intended for a global impact. There are very few instances of specific country technical assistance (Philippines), covering responses to Aim 2 and will be included in this evaluation.

*Normative guidelines refers to technical and policy guidance issued from global normative bodies, such as the World Health Organization*
USAID/GH/PRH, particularly the RTU division, is the primary audience for the findings of this performance evaluation. Evaluation findings may also be useful for research and development donors and Implementing Partners including NICHD, BMGF and FHI360 and their sub-partners. There will be two audiences for the evaluation reports. All confidential proprietary information will be included in a report that goes directly to the Envision FP USAID management team. The general evaluation report will be more broadly shared with stakeholders mentioned above.

C. Applications and use: How will the findings be used? What future decisions will be made based on these findings?

The evaluation findings will be used directly by GH/PRH, particularly the RTU division, to inform decisions about future biomedical research programming.

D. Evaluation/Analytic Questions & Matrix:

a) Questions should be: a) aligned with the evaluation/analytic purpose and the expected use of findings; b) clearly defined to produce needed evidence and results; and c) answerable given the time and budget constraints. Include any disaggregation (e.g., sex, geographic locale, age, etc.), they must be incorporated into the evaluation/analytic questions. **USAID policy suggests 3 to 5 evaluation/analytic questions.**

b) List the recommended methods that will be used to collect data to be used to answer each question.

c) State the application or use of the data elements towards answering the evaluation questions; for example, i) ratings of quality of services, ii) magnitude of a problem, iii) number of events/occurrences, iv) gender differentiation, v) etc.

<table>
<thead>
<tr>
<th>Performance Evaluation Question</th>
<th>Suggested methods for answering this question</th>
<th>Sampling Frame</th>
</tr>
</thead>
<tbody>
<tr>
<td>How has the evidence generated been used to inform the development, introduction, expansion and understanding of contraceptive technologies? <strong>Areas for consideration:</strong> a) Importance of an open response activity (under Aim 2) related to responding to immediate needs b) Successes/Achievements and challenges managing an open activity that allows for responding to unknown needs and still allows for budget and staff planning</td>
<td>Document and data review Key informant interviews</td>
<td>Final list to be determined by the evaluation team based on availability, relevance, and coverage of information.</td>
</tr>
<tr>
<td>Performance Evaluation Question</td>
<td>Suggested methods for answering this question</td>
<td>Sampling Frame</td>
</tr>
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<td>---------------------------------</td>
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</tbody>
</table>
| 2. To what extent has Envision FP achieved each aim?  
*Areas for consideration:*  
a) Major achievements to date for each aim  
b) Areas that could not be implemented in each aim and why (for example, what priority work was not launched due to funding uncertainties or other reasons)  
c) Implementation/management challenges faced and how the project address them  
d) Quality of research conducted, including input from SSAC on clinical trial designs, decisions on patent rights and sub-partners selected.  
e) Course corrections based on SSAC feedback | Document and data review  
Key informant interviews | Final list to be determined by the evaluation team based on availability, relevance, and coverage of information. Quality questions will require input from Scientific and Strategic Advisory Committee (SSAC) members and may require NDA from evaluation lead. The quality analysis will be included in the USAID only report with the management recommendations. |
| 3. Looking to the Future:  
a. Management and project team’s organization to maximize the work of this project  
b. Management challenges faced  
c. Recommendations for improving implementation priorities for the remainder of Envision FP  
d. Recommendations for future program design, particularly reflecting on the response mechanism of Aim 2  
e. New priorities that were identified that should be addressed in the remaining year vs. addressed in future projects | Document and data review  
Key informant interviews | Envision FP management. Final list to be determined by the evaluation team based on availability, relevance, and coverage of information. Recommendations to be included in internal USAID only report. |

E. **Methods:** Check and describe the recommended methods for this analytic activity. Selection of methods should be aligned with the evaluation/analytic questions and fit within the time and resources allotted for this analytic activity. Also, include the sample or sampling frame in the description of each method selected.
Once the evaluation team has developed the data collection tools (questionnaires, interview guides, etc.) based on the agreed upon evaluation questions and approaches, they will present them to GH Pro Technical Advisor and the AOR for review and approval prior to their application, in order to verify their appropriateness. All tools should include an informed consent statement. These tools will be used in all data collection situations, in order to ensure consistency and comparability of data.

The evaluation team is expected to travel to FHI360’s office in Durham NC and USAID’s GH office (CP-3) in Arlington VA. The team and USAID will determine how best to cover visits to these two offices. The evaluation team is expected to interview project staff, sub-partner staff, other donors (NICHD, BMGF), and the members of the Scientific and Strategic Advisory Committee (SSAC).

In addition to these key informant interviews, the evaluation team will also conduct document reviews as described below.

### Document and Data Review (list of documents and data recommended for review)

This desk review will be used to provide background information on the project/program for this evaluation. Documents and data to be reviewed include:

- Cooperative agreement
- M&E Plan
- Annual work plans
- Semi-annual reports
- Management review reports
- Project Technical Advisory Group (SSAC) reports ( Requires Non-Disclosure Agreement – only team lead will have access and will send outcomes of this review in a separate report for USAID only)
- Key project deliverables, including activity reports and presentations
- Interviews with experts, project managers and sub-partners
- Other key project documents, including research protocols and peer review feedback

### Key Informant Interviews (list categories of key informants, and purpose of inquiry)

- USAID staff to obtain an overview of the technical and operational perception of the project, discuss challenges and successes.
  - Envision FP management team (Tabitha Sripipatana, Mihira Karra, Kevin Peine, Abdulmumin Saad, Erika Houghtaling)
  - FP/HIV Team: Jennifer Mason, Nithya Mani
  - PRH Front office: Ellen Starbird, Kendra Phillips
  - Other key PRH/Agency staff: Shelley Snyder, Philippine Mission, Ghana Mission
- Scientific and Strategic Advisory Committee members to obtain their expert opinion on the quality of the research undertaken, discuss challenges and successes, discuss remaining priorities.
- Contraceptive Technology Donor Group to obtain an overview of the technical outcomes of the project, and their perspectives on utilizing/co-funding for this project. Diana Blythe, Kirsten Vogelsong, Dan Johnston
- FHI 360 Envision FP Staff to obtain detailed technical and operational information about the project’s progress and discuss challenges and successes: Laneta Dorflinger, Gregory Kopf, Amanda Troxler
- ECHO Trial staff to obtain detailed technical and operational information about the project’s progress and discuss challenges and successes specific to the ECHO trial: Julia Welch, Tim Mastro,
consider ECHO sub-partners
- Research Leads to obtain detailed technical and operational information about specific research activities: Vera Halpern, Jennifer Deese, Markus Steiner, Elena Lebetkin, Kate Rademacher, Rebecca Callahan, Kavita Nanda, Derek Owen, Irina Yacobson,
- Sub recipients partner staff to obtain detailed technical and operational information about specific activities undertaken by the partner and to provide detailed feedback on working with FHI360 as prime: WHO, Georgia Tech, CEMICAMP, ICMER, Profamilia, University of Washington; and others as needed.

Focus Group Discussions (list categories of groups, and purpose of inquiry)

Group Interviews (list categories of groups, and purpose of inquiry)
Key informants may be interviewed in small groups of similar respondents, as long as all participants feel free to express their own opinions.

IX. HUMAN SUBJECT PROTECTION
The Analytic Team must develop protocols to insure privacy and confidentiality prior to any data collection. Primary data collection must include a consent process that contains the purpose of the evaluation, the risk and benefits to the respondents and community, the right to refuse to answer any question, and the right to refuse participation in the evaluation at any time without consequences. Only adults can consent as part of this evaluation. Minors cannot be respondents to any interview or survey, and cannot participate in a focus group discussion without going through an IRB. The only time minors can be observed as part of this evaluation is as part of a large community-wide public event, when they are part of family and community in the public setting. During the process of this evaluation, if data are abstracted from existing documents that include unique identifiers, data can only be abstracted without this identifying information.

An Informed Consent statement included in all data collection interactions must contain:
- Introduction of facilitator/note-taker
- Purpose of the evaluation/assessment
- Purpose of interview/discussion/survey
- Statement that all information provided is confidential and information provided will not be connected to the individual
- Right to refuse to answer questions or participate in interview/discussion/survey
- Request consent prior to initiating data collection (i.e., interview/discussion/survey)

X. ANALYTIC PLAN
Describe how the quantitative and qualitative data will be analyzed. Include method or type of analyses, statistical tests, and what data it to be triangulated (if appropriate). For example, a thematic analysis of qualitative interview data, or a descriptive analysis of quantitative survey data.

As the team reviews the documents available and interview lists and develops the data collection tools, they will ensure that they will in fact have the data they need to adequately respond to the evaluation questions. Once all data is collected, several days will be spent on carefully compiling, reviewing and identifying key findings prior to making a presentation of preliminary findings to USAID. All analyses will be geared to answer the evaluation questions. Additionally, the evaluation will review both qualitative and quantitative data related to the project/program’s achievements against its objectives and/or targets.
Thematic review of qualitative data will be performed, connecting the data to the evaluation questions, seeking relationships, context, interpretation, nuances and homogeneity and outliers to better explain what is happening and the perception of those involved. The Evaluation Report will describe analytic methods employed in this evaluation.

XI. ACTIVITIES
List the expected activities, such as Team Planning Meeting (TPM), briefings, verification workshop with IPs and stakeholders, etc. Activities and Deliverables may overlap. Give as much detail as possible.

Background reading – Several documents are available for review for this analytic activity. These include Envision FP proposal, annual work plans, M&E plans, and progress reports. This desk review will provide background information for the Evaluation Team, and will also be used as data input and evidence for the evaluation.

Team Planning Meeting (TPM) – A two-day team planning meeting (TPM) will be held at the initiation of this assignment and before the data collection begins. The TPM will:
- Review and clarify any questions on the evaluation SOW
- Clarify team members’ roles and responsibilities
- Establish a team atmosphere, share individual working styles, and agree on procedures for resolving differences of opinion
- Review and finalize evaluation questions
- Review and finalize the assignment timeline
- Develop data collection methods, instruments, tools and guidelines
- Review and clarify any logistical and administrative procedures for the assignment
- Develop a data collection plan
- Draft the evaluation work plan for USAID’s approval
- Develop a preliminary draft outline of the team’s report
- Assign drafting/writing responsibilities for the final report

Briefing and Debriefing Meetings – Throughout the evaluation the Team Lead will provide briefings to USAID. The In-Brief and Debrief are likely to include the all Evaluation Team experts but will be determined in consultation with the AOR Team. These briefings are:
- Evaluation launch, a call/meeting among the USAID, GH Pro and the Team Lead to initiate the evaluation activity and review expectations. USAID will review the purpose, expectations, and agenda of the assignment. GH Pro will introduce the Team Lead and review the initial schedule and review other management issues.
- In-brief with USAID, as part of the TPM. At the beginning of the TPM, the Evaluation Team will meet with USAID to discuss expectations, review evaluation questions, and intended plans. The Team will also raise questions that they may have about the project/program and SOW resulting from their background document review. The time and place for this in-brief will be determined between the Team Lead and USAID prior to the TPM.
- Work plan and methodology review briefing. At the end of the TPM, the Evaluation Team will meet with USAID to present an outline of the methods/protocols, timeline and data collection tools. Also, the format and content of the Evaluation report will be discussed.
- In-brief with Envision to review the evaluation plans and timeline, and for the project to give an overview of the project to the Evaluation Team. This is likely to be a virtual web-conferenced meeting. Follow-up phone calls and in-person meetings will be discussed at this time, as well.
- The Team Lead (TL) will brief the USAID weekly to discuss progress on the evaluation. As preliminary findings arise, the TL will share these during the routine briefing, and in an email.
• A debrief with USAID Envision Management team will be held at the end of the evaluation to present preliminary findings to USAID. During this meeting a summary of the data will be presented, along with high level findings and draft recommendations. For the debrief, the Evaluation Team will prepare a PowerPoint Presentation of the key findings, issues, and recommendations. The evaluation team shall incorporate comments received from USAID during the debrief in the evaluation report. (Note: preliminary findings are not final and as more data sources are developed and analyzed these finding may change.)

• A final debrief with USAID/PRH will be held at the end of the evaluation following the debrief with the USAID Envision Management Team, and likely after the first draft of the report has been submitted. During this meeting a summary of the evaluation results will be presented, along with high level findings and draft recommendations. For the USAID/PRH final debrief, the Evaluation Team will prepare a PowerPoint Presentation of the key findings, issues, and recommendations. The evaluation team shall incorporate comments received from USAID during the debrief in the evaluation report.

• IP and Stakeholders’ debrief/workshop will be held with the Envision project staff and other stakeholders identified by USAID. This will occur following the USAID debrief, and will not include any information that may be procurement deemed sensitive or not suitable by USAID. This may be done as a webinar or in-person, and will be determined during the TPM.

Evaluation Report – The Evaluation Team under the leadership of the Team Lead will develop a report with findings and recommendations (see Analytic Report below). Report writing and submission will include the following steps:

1. For the external viewing report, Team Lead will submit draft evaluation report to GH Pro for review and formatting
2. GH Pro will submit the draft report to USAID
3. USAID will review the draft report in a timely manner, and send their comments and edits back to GH Pro
4. GH Pro will share USAID’s comments and edits with the Team Lead, who will then do final edits, as needed, and resubmit to GH Pro
5. GH Pro will review and reformat the final Evaluation/Analytic Report, as needed, and resubmit to USAID for approval.
6. Once Evaluation Report is approved, GH Pro will re-format it for 508 compliance and post it to the DEC.

The Evaluation Report excludes any procurement-sensitive and other sensitive but unclassified (SBU) information such as proprietary information on product development.

Short Report – The Evaluation Team will also develop a short USAID business and procurement sensitive report. This information will be submitted in a separate short report (no more than 5 pages) to USAID separate from the Evaluation Report, and does not need to go through a GH PRO for review.

Data Submission – All quantitative data will be submitted to GH Pro in a machine-readable format (CSV or XML). The datasets created as part of this evaluation must be accompanied by a data dictionary that includes a codebook and any other information needed for others to use these data. It is essential that the datasets are stripped of all identifying information, as the data will be public once posted on USAID Development Data Library (DDL). A quantitative dataset is not likely for this evaluation.

Where feasible, qualitative data that do not contain identifying information should also be submitted to GH Pro. No information that has been obtained from SBU sources, including business confidential information will be submitted to GH PRO.
DELIVERABLES AND PRODUCTS

Select all deliverables and products required on this analytic activity. For those not listed, add rows as needed or enter them under “Other” in the table below. Provide timelines and deliverable deadlines for each.

<table>
<thead>
<tr>
<th>Deliverable / Product</th>
<th>Timelines &amp; Deadlines (estimated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Launch briefing</td>
<td>August 15, 2019</td>
</tr>
<tr>
<td>In-brief with USAID</td>
<td>August 19, 2019</td>
</tr>
<tr>
<td>Workplan and methodology review briefing</td>
<td>August 23, 2019</td>
</tr>
<tr>
<td>Workplan (must include evaluation questions, methods/protocol, timeline, data analysis plan, and data collection tools)</td>
<td>August 23, 2019 (COB)</td>
</tr>
<tr>
<td>In-brief with Envision project (virtual)</td>
<td>August 25, 2019</td>
</tr>
<tr>
<td>Routine briefings</td>
<td>Weekly</td>
</tr>
<tr>
<td>Debrief with USAID Envision Management Team with Power Point presentation</td>
<td>September 30, 2019</td>
</tr>
<tr>
<td>Findings review workshop with Envision and stakeholders with Power Point presentation</td>
<td>October 1, 2019</td>
</tr>
<tr>
<td>Debrief with USAID/PRH with Power Point presentation</td>
<td>November 6, 2019</td>
</tr>
<tr>
<td>Short Report submitted</td>
<td>October 15, 2019</td>
</tr>
<tr>
<td>Draft Evaluation report</td>
<td>Submit to GH Pro: October 9, 2019</td>
</tr>
<tr>
<td></td>
<td>GH Pro submits to USAID: October 17, 2019</td>
</tr>
<tr>
<td>Final report</td>
<td>Submit to GH Pro: October 31, 2019</td>
</tr>
<tr>
<td></td>
<td>GH Pro submits to USAID: November 5, 2019</td>
</tr>
<tr>
<td>Raw data (cleaned datasets in CSV or XML with codesheet)</td>
<td>October 31, 2019</td>
</tr>
<tr>
<td>Report Posted to the DEC</td>
<td>December 6, 2019</td>
</tr>
</tbody>
</table>

Estimated USAID review time

Average number of business days USAID will need to review deliverables requiring USAID review and/or approval? ______ 5 _________ Business days

XII. TEAM COMPOSITION, SKILLS AND LEVEL OF EFFORT (LOE)

Evaluation/Analytic team: When planning this analytic activity, consider:

- Key staff should have methodological and/or technical expertise, regional or country experience, language skills, team lead experience and management skills, etc.
- Team leaders for evaluations/analytics must be an external expert with appropriate skills and experience.
- Additional team members can include research assistants, enumerators, translators, logisticians, etc.
- Teams should include a collective mix of appropriate methodological and subject matter expertise.
• Evaluations require an Evaluation Specialist, who should have evaluation methodological expertise needed for this activity. Similarly, other analytic activities should have a specialist with methodological expertise.

• Note that all team members will be required to provide a signed statement attesting that they have no conflict of interest, or describing the conflict of interest if applicable.

Team Qualifications: Please list technical areas of expertise required for this activity

At least one of the consultants should have clinical trial coordination experience.

Team Lead: This person will be selected from among the key staff, and will meet the requirements of both this and the other position. The team lead should have significant experience conducting project evaluations/analytics.

Roles & Responsibilities: The team leader will be responsible for (1) providing team leadership; (2) managing the team’s activities, (3) ensuring that all deliverables are met in a timely manner, (4) serving as a liaison between the USAID and the evaluation/analytic team, and (5) leading briefings and presentations.

Qualifications:

• Minimum of 10 years of experience in public health, which includes experience in management and implementation of biomedical research and health

• Demonstrated experience leading health sector project/program evaluation/analytics, utilizing both quantitative and qualitative methods

• Excellent skills in planning, facilitation, and consensus building

• Excellent interpersonal skills

• Excellent organizational skills and ability to keep to a timeline

• Excellent writing skills, with extensive report writing experience

• Experience working in the developing country contexts is desirable

• Familiarity with USAID

• Familiarity with USAID policies and practices
  – Evaluation policy
  – Results frameworks
  – Performance monitoring plans
**Key Staff 1 Title: Evaluation Specialist**

**Roles & Responsibilities:** Serve as a member of the evaluation team, providing quality assurance on evaluation issues, including methods, development of data collection instruments, protocols for data collection, data management and data analysis. S/He will oversee the training of all engaged in data collection, insuring highest level of reliability and validity of data being collected. S/He is the lead analyst, responsible for all data analysis, and will coordinate the analysis of all data, assuring all quantitative and qualitative data analyses are done to meet the needs for this evaluation. S/He will participate in all aspects of the evaluation, from planning, data collection, data analysis to report writing.

**Qualifications:**

- Experience in design and implementation of evaluations
- Strong knowledge, skills, and experience in qualitative and quantitative evaluation tools
- Experience implementing and coordinating other to implements surveys, key informant interviews, focus groups, observations and other evaluation methods that assure reliability and validity of the data.
- Experience in data management
- Able to analyze quantitative, which will be primarily descriptive statistics
- Able to analyze qualitative data
- Experience using analytic software
- Demonstrated experience using qualitative evaluation methodologies, and triangulating with quantitative data
- Able to review, interpret and reanalyze as needed existing data pertinent to the evaluation
- Strong data interpretation and presentation skills
- An advanced degree in public health, evaluation or research or related field
- Proficient in English
- Good writing skills, including extensive report writing experience
- Familiarity with USAID health programs/projects, primary health care or health systems strengthening preferred
- Familiarity with USAID and PEPFAR M&E policies and practices
  - Evaluation policies
  - Results frameworks
  - Performance monitoring plans

**Key Staff 2 Title: Contraceptive Technology Expert**

**Roles & Responsibilities:** As the technical expert on the team, s/he will serve as a member of the evaluation team, providing expertise in FP/RH and contraceptive technologies. S/He will participate in planning and briefing meetings, data collection, data analysis, development of evaluation presentations, and writing of the Evaluation Report.

**Qualifications:**

- At least 10 years’ experience with FP/RH projects; USAID project implementation experience preferred
- Knowledgeable about contraceptive technologies
• Experience conducting evaluation, assessments and/or related research, preferably under USAID.
• Excellent interpersonal skills, including experience successfully interacting with host government officials, civil society partners, and other stakeholders
• Proficient in English
• Good writing skills, including experience writing evaluation and/or assessment reports
• Experience in conducting USAID evaluations of health programs/activities

Other Staff Titles with Roles & Responsibilities (include number of individuals needed):

| US-based Program Assistant | to work part time with the Evaluation Team to arrange interviews, meetings and logistics, and other support duties as needed by the Evaluation Team. S/He will assist the Evaluation Team to arrange interviews, meetings and logistics, and other support duties as needed by the Evaluation Team. S/He will conduct programmatic administrative and support tasks as assigned, and ensure the processes moves forward smoothly. Additionally, s/he will manage the uploading of the e-survey to the website (if part of the final methodology), and will routinely monitor it for response rates, as well as download the data as needed. [This position may be filled by a GH Pro Program Assistant, if feasible.] |

Will USAID participate as an active team member or designate other key stakeholders to as an active team member? This will require full time commitment during the evaluation or analytic activity.

☐ Yes – If yes, specify who:
☐ Significant Involvement anticipated – If yes, specify who: USAID/PRH may add a USAID technical staff to assist with this assignment.
☐ No

Staffing Level of Effort (LOE) Matrix:

This optional LOE Matrix will help you estimate the LOE needed to implement this analytic activity. If you are unsure, GH Pro can assist you to complete this table.

a) For each column, replace the label "Position Title" with the actual position title of staff needed for this analytic activity.

b) Immediately below each staff title enter the anticipated number of people for each titled position.

c) Enter Row labels for each activity, task and deliverable needed to implement this analytic activity.

d) Then enter the LOE (estimated number of days) for each activity/task/deliverable corresponding to each titled position.

e) At the bottom of the table total the LOE days for each consultant title in the 'Sub-Total' cell, then multiply the subtotals in each column by the number of individuals that will hold this title.
## Level of Effort in days for each Evaluation/Analytic Team member

<table>
<thead>
<tr>
<th>Activity / Deliverable</th>
<th>Evaluation/Analytic Team</th>
<th>TL &amp; Research &amp; Eval Spec</th>
<th>Contraceptive Technologies Spec</th>
<th>Research/Eval Assist</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Launch Briefing</td>
<td></td>
<td>0.5</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>2 Desk review</td>
<td></td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>3 Travel to/from DC and Durham, NC</td>
<td></td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>4 In-brief with USAID</td>
<td></td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>5 Team Planning Meeting</td>
<td></td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>6 Workplan and methodology review briefing with USAID</td>
<td></td>
<td>0.5</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>7 In-brief with project/IP</td>
<td></td>
<td>0.5</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>8 Prep / Logistics for Interviews</td>
<td></td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>9 Data collection</td>
<td></td>
<td>17</td>
<td>17</td>
<td>2</td>
</tr>
<tr>
<td>10 Data analysis</td>
<td></td>
<td>6</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>11 Debrief with USAID Envision Management Team with prep</td>
<td></td>
<td>1</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>12 IP and Stakeholder debrief workshop with prep</td>
<td></td>
<td>0.5</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>13 Draft report Eval report &amp; short report</td>
<td></td>
<td>8</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>14 GH Pro Report QC Review &amp; Formatting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 Submission of draft reports (eval &amp; short) to USAID</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 USAID Report Reviews</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17 Revise reports (eval &amp; short) per USAID feedback</td>
<td></td>
<td>5</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Debrief with USAID/PRH with prep</td>
<td></td>
<td>0.5</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>18 GH Pro reviews/edits reports</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 USAID approves report</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 Final copy editing and formatting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 508 Compliance editing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 Upload Eval Report(s) to the DEC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total LOE</strong></td>
<td></td>
<td><strong>54</strong></td>
<td><strong>52</strong></td>
<td><strong>6</strong></td>
</tr>
</tbody>
</table>

- **6-day workweek permitted, if needed**: □ Yes □ No
- **Travel to/from work locations is permitted on weekends**: □ Yes □ No
**Travel anticipated:** List international and local travel anticipated by what team members.

Durham NC and to Washington, DC/Arlington VA

### XIII. LOGISTICS

**Visa Requirements**

List any specific Visa requirements or considerations for entry to countries that will be visited by consultant(s):

N/A

List recommended/required type of Visa for entry into counties where consultant(s) will work:

<table>
<thead>
<tr>
<th>Name of Country</th>
<th>Type of Visa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐ Tourist</td>
</tr>
</tbody>
</table>

**Clearances & Other Requirements**

**Note:** Most Evaluation/Analytic Teams arrange their own work space, often in their hotels. However, if Facility Access is preferred GH Pro can request it.

*GH Pro does not provide Security Clearances, but can request Facility Access.* Please note that Facility Access (FA) requests processed by USAID/GH (Washington, DC) can take 4-6 months to be granted. If you are in a Mission and the RSO can grant a temporary FA, this can expedite the process. If FA is granted through Washington, DC, the consultant must pick up his/her FA badge in person in Washington, DC, regardless of where the consultant resides or will work.

If Electronic Country Clearance (eCC) is required, the consultant is also required to complete the **High Threat Security Overseas Seminar (HTSOS).** HTSOS is an interactive e-Learning (online) course designed to provide participants with threat and situational awareness training against criminal and terrorist attacks while working in high threat regions. There is a small fee required to register for this course. [Note: The course is not required for employees who have taken FACT training within the past five years or have taken HTSOS within the same calendar year.]

If eCC is required, and the consultant is expected to work in country more than 45 consecutive days, the consultant must complete the one week **Foreign Affairs Counter Threat (FACT) course** offered by FSI in West Virginia. This course provides participants with the knowledge and skills to better prepare themselves for living and working in critical and high threat overseas environments. Registration for this course is complicated by high demand (must register approximately 3-4 months in advance). Additionally, there will be the cost for one week’s lodging and M&E to take this course.

Check all that the consultant will need to perform this assignment, including USAID Facility Access, GH Pro workspace and travel (other than to and from post).

☐ USAID Facility Access (FA)

Specify who will require Facility Access: ____________________________________________
Electronic County Clearance (ECC) (International travelers only)

High Threat Security Overseas Seminar (HTSOS) (required with ECC)

Foreign Affairs Counter Threat (FACT) (for consultants working on country more than 45 consecutive days)

GH Pro workspace

Specify who will require workspace at GH Pro: ____________________________

Travel - other than posting (specify): Durham NC, and Washington, DC

Other (specify): ____________________________

XIV. GH PRO ROLES AND RESPONSIBILITIES
GH Pro will coordinate and manage the evaluation/analytic team and provide quality assurance oversight, including:

- Review SOW and recommend revisions as needed
- Provide technical assistance on methodology, as needed
- Develop budget for analytic activity
- Recruit and hire the evaluation/analytic team, with USAID POC approval
- Arrange international travel and lodging for international consultants
- Request for country clearance and/or facility access (if needed)
- Review methods, work plan, analytic instruments, reports and other deliverables as part of the quality assurance oversight
- Report production - If the report is public, then coordination of draft and finalization steps, editing/formatting, 508ing required in addition to and submission to the DEC and posting on GH Pro website. If the report is internal, then copy editing/formatting for internal distribution.

XV. USAID ROLES AND RESPONSIBILITIES
Below is the standard list of USAID’s roles and responsibilities. Add other roles and responsibilities as appropriate.

<table>
<thead>
<tr>
<th>USAID Roles and Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>USAID will provide overall technical leadership and direction for the analytic team throughout the assignment and will provide assistance with the following tasks:</td>
</tr>
</tbody>
</table>

**Before Field Work**

- **SOW.**
  - Develop SOW.
  - Peer Review SOW
  - Respond to queries about the SOW and/or the assignment at large.
- **Consultant Conflict of Interest (COI).** To avoid conflicts of interest or the appearance of a COI, review previous employers listed on the CV’s for proposed consultants and provide additional
information regarding potential COI with the project contractors evaluated/assessed and information regarding their affiliates.

- **Documents.** Identify and prioritize background materials for the consultants and provide them to GH Pro, preferably in electronic form, at least one week prior to the inception of the assignment.
- **Local Consultants.** Assist with identification of potential local consultants, including contact information.
- **Site Visit Preparations.** Provide a list of site visit locations, key contacts, and suggested length of visit for use in planning in-country travel and accurate estimation of country travel line items costs.
- **Lodgings and Travel.** Provide guidance on recommended secure hotels and methods of in-country travel (i.e., car rental companies and other means of transportation).

**During Field Work**

- **Mission Point of Contact.** Throughout the in-country work, ensure constant availability of the Point of Contact person and provide technical leadership and direction for the team’s work.
- **Meeting Space.** Provide guidance on the team’s selection of a meeting space for interviews and/or focus group discussions (i.e. USAID space if available, or other known office/hotel meeting space).
- **Meeting Arrangements.** Assist the team in arranging and coordinating meetings with stakeholders.
- **Facilitate Contact with Implementing Partners.** Introduce the analytic team to implementing partners and other stakeholders, and where applicable and appropriate prepare and send out an introduction letter for team’s arrival and/or anticipated meetings.

**After Field Work**

- **Timely Reviews.** Provide timely review of draft/final reports and approval of deliverables.

### XVI. ANALYTIC REPORT

Provide any desired guidance or specifications for Final Report. (See *How-To Note: Preparing Evaluation Reports*).

The **Evaluation Final Report** must follow USAID’s Criteria to Ensure the Quality of the Evaluation Report (found in Appendix I of the USAID Evaluation Policy).

- a. The report must not exceed 20 pages (excluding executive summary, table of contents, acronym list and annexes).
- b. The structure of the report should follow the Evaluation Report template, including branding found [here](#) or [here](#).
- c. Draft reports must be provided electronically, in English, to GH Pro who will then submit it to USAID.
- d. For additional Guidance, please see the Evaluation Reports to the How-To Note on preparing Evaluation Draft Reports found [here](#).

**Reporting Guidelines:** The draft report should be a comprehensive analytical evidence-based evaluation/analytic report. It should detail and describe results, effects, constraints, and lessons learned, and provide recommendations and identify key questions for future consideration. The report shall follow USAID branding procedures. **The report will be edited/formatted and made 508 compliant as required by USAID for public reports and will be posted to the USAID/DEC.**
The findings from the evaluation/analytic will be presented in two draft reports at a full briefing with USAID and at a follow-up meeting with key stakeholders. The report should use the following format for the general evaluation:

- Executive Summary: concisely state the most salient findings, conclusions, and recommendations (not more than 4 pages);
- Table of Contents (1 page);
- Acronyms
- Evaluation/Analytic Purpose and Evaluation/Analytic Questions (1-2 pages)
- Project [or Program] Background (1-3 pages)
- Evaluation/Analytic Methods and Limitations (1-3 pages)
- Findings (organized by Evaluation/Analytic Questions)
- Conclusions
- Recommendations
- Annexes
  - Annex I: Evaluation/Analytic Statement of Work
  - Annex II: Evaluation/Analytic Methods and Limitations
  - Annex III: Data Collection Instruments
  - Annex IV: Sources of Information
    - List of Persons Interviews
    - Bibliography of Documents Reviewed
    - Databases
    - [etc]
  - Annex V: Disclosure of Any Conflicts of Interest
  - Annex VI: Statement of Differences (if applicable)

A separate short report with any information obtained under an NDA, any proprietary information or any information that is procurement sensitive will be sent directly from the evaluation team lead to the Envision FP AOR, Tabitha Sripipatana.

The evaluation methodology and report will be compliant with the USAID Evaluation Policy and Checklist for Assessing USAID Evaluation Reports.

短报告 – 此短报告或备忘录将包括USAID业务和采购敏感信息，但《评价报告》必须排除任何潜在的采购敏感信息。根据需要，任何采购敏感信息或其他敏感但未分类（SBU）信息将提交给USIAD单独的备忘录，与《评价报告》分开。例如，Q3中包含的采购敏感信息。

The Evaluation Report must also exclude FHI360 business sensitive information, including research results not yet published. If this information is needed to address Q3, it should be discussed with USAID first, and if they approve, it can be included in the Short Report.

所有数据工具、数据集（如果适用）、演示文稿、会议记录和报告将提交电子方式至GH Pro Program Manager。所有数据集将提交给GH Pro Pro Program Manager。所有数据集将以开放、可读格式（CSV或XML）提交。这些数据集不得包含任何标识或敏感信息。
datasets must also be accompanied by a data dictionary that includes a codebook and any other
information needed for others to use these data. Qualitative data included in this submission should not
contain identifying or confidential information. Category of respondent is acceptable, but names,
addresses and other confidential information that can easily lead to identifying the respondent should
not be included in any quantitative or qualitative data submitted.

**XVII. USAID CONTACTS**

<table>
<thead>
<tr>
<th>Primary Contact</th>
<th>Alternate Contact 1</th>
<th>Alternate Contact 2</th>
<th>Alternate Contact 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Tabitha Sripipatana</td>
<td>Erika Houghtaling</td>
<td>Kevin Peine</td>
<td>Abdulmumin Saad</td>
</tr>
<tr>
<td>Title: Deputy Division Chief</td>
<td>Program Analyst</td>
<td>Technical Advisor</td>
<td>Senior Epidemiologist</td>
</tr>
<tr>
<td>USAID Office: GH/PRH/RTU</td>
<td>GH/PRH/RTU</td>
<td>GH/PRH/RTU</td>
<td>GH/PRH/RTU</td>
</tr>
<tr>
<td>Email: <a href="mailto:tsripipatana@usaid.gov">tsripipatana@usaid.gov</a></td>
<td><a href="mailto:ehoughtaling@usaid.gov">ehoughtaling@usaid.gov</a></td>
<td><a href="mailto:Kpeine@usaid.gov">Kpeine@usaid.gov</a></td>
<td><a href="mailto:absaad@usaid.gov">absaad@usaid.gov</a></td>
</tr>
<tr>
<td>Telephone: 571-551-7054</td>
<td>571-551-7341</td>
<td>571-551-7042</td>
<td>571-551-7325</td>
</tr>
<tr>
<td>Cell Phone:</td>
<td>571-215-2600</td>
<td>571-228-3667</td>
<td>571-242-1580</td>
</tr>
</tbody>
</table>

List other contacts who will be supporting the Requesting Team with technical support, such as reviewing SOW and Report (such as USAID/W GH Pro management team staff)

<table>
<thead>
<tr>
<th>Technical Support Contact 1</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Name: Amani Selim</td>
<td></td>
</tr>
<tr>
<td>Title: Evaluation technical advisor.</td>
<td></td>
</tr>
<tr>
<td>USAID Office/Mission: PRH</td>
<td></td>
</tr>
<tr>
<td>Email: <a href="mailto:aselim@usaid.gov">aselim@usaid.gov</a></td>
<td></td>
</tr>
<tr>
<td>Telephone: 571-551-7528</td>
<td></td>
</tr>
<tr>
<td>Cell Phone: 571-721-9577</td>
<td></td>
</tr>
</tbody>
</table>

**XVIII. OTHER REFERENCE MATERIALS**

Documents and materials needed and/or useful for consultant assignment, that are not listed above

Once the consultant is selected, materials will be provided on an as-needed basis.
ANNEX II. DATA COLLECTION TOOLS

FHI Interview Guide

Introduction: The Office of Population and Reproductive Health in USAID’s Bureau of Global Health has asked for a near endline evaluation of Envision FP to assess the project’s progress (both successes and challenges) towards achievement of each of the project’s aims. The findings of this performance evaluation will be used by the Global Health/PRH, particularly its Research, Technology, and Utilization (RTU) division, to inform decisions about future programming in biomedical research.

Through this interview, we would like to ask you about your experience with and assessment of Envision FP’s work. Your participation in this evaluation is voluntary. You may refuse to answer any question in the interview or stop the interview at any time. And, of course, your answers are confidential. Do we have your permission to begin?

Team being interviewed if applicable: __________________________________

Name(s): ___________________________________________________________

Question 1: Use of evidence

3. Please describe your role(s) at FHI as it relates to Envision. Duration?

4. Use of evidence (any evidence)

   a) Please describe the decisions you made (or anticipate making) based on evidence generated by FHI (see list below) for programming, funding, and policy-making, priority setting.

   b) Based on your knowledge, who (e.g. MoH, Missions, regulatory agencies, Gates, donors) used evidence generated by FHI and how?

Aim 1: Lower SQ dose DMPA, extended interval Sayana Press, PPIUD, DMPA XT

Aim 2: P40, NORMAL counseling tool, ECHO study, DDI, Hormonal contraceptives and ARV/TB, Lower dose DMPA, Extending LARCs (LNG-IUS), Scale up of LNG-IUS, User preference study for microneedle patch

Aim 3: Microneedle patch, biodegradable implants

5. “Open response” under Aim 2

   a) Please list any requests your team responded to under the “open response” activity? And how was the data/evidence used? What would likely have happened if FHI had not been able to generate/find the evidence to respond to requests through the “open response” activity?

   b) How did your team process and prioritize requests for data/evidence under the “open response” activity? Do you have any suggestions for a better way to process and prioritize requests?

   c) What is your opinion of having “open response activity”? What do you believe worked well and what could be improved?

   d) Additional lessons learned for the future – if any?
e) **Senior mgmt.**: What were FHI’s successes and challenges managing an “open response activity” - in terms of budget, staffing levels, and types of personnel (e.g. consultants)? Do you have suggestions that might make the process easier/better?

**Question 2: Achievement of aims**

6. What do you consider the major achievements under Envision [or of your team]?
   
   a) What factors contributed to your ability to reach these achievements? (e.g. good subs, management, money, flexibility, appropriate staff, etc.)
   
   b) What are some factors that impeded your ability to reach your achievements? (e.g. budget, resources, policy, etc.)

7. Are there any activities that you/your team could not implement, or fully implement, and why?

8. What have been some of the implementation and management challenges under Envision or within your team? How have these challenges affected your work/outcomes? How have they been addressed?

9. Quality of FHI research:
   
   a) What is your perception of the quality of research generated/disseminated by FHI/your team? Examples?
   
   b) How could the quality of research/dissemination of the research be improved?
   
   c) If applicable: What are examples of SSAC feedback (including pre-clinical, clinical trial design, patent rights, and sub-partner selection)? What is the quality, utility, timeliness and general usefulness of SSAC feedback?
      
      o How could SSAC feedback or feedback processes be improved?

**Question 3: Looking to the future**

10. Looking to the future, how could FHI’s management and organization be changed to better achieve the objectives of a comparable project?

11. How – if at all - could USAID’s management be improved to better support implementation of a comparable project?

12. In hindsight, are there ways that you might have designed the project differently?

13. Do you have recommendations regarding priorities for the remainder of Envision?

14. Do you have recommendations regarding priorities for a future award?
SSAC Interview Guide

Introduction: The Office of Population and Reproductive Health in USAID’s Bureau of Global Health has asked for a near endline evaluation of Envision FP to assess the project’s progress (both successes and challenges) towards achievement of each of the project’s aims. The findings of this performance evaluation will be used by the Global Health/PRH, particularly its Research, Technology, and Utilization (RTU) division, to inform decisions about future programming in biomedical research.

Through this interview, we would like to ask you about your experience with and assessment of Envision FP’s work. Your participation in this evaluation is voluntary. You may refuse to answer any question in the interview or stop the interview at any time. And, of course, your answers are confidential. Do we have your permission to begin?

15. Quality of FHI research:
   a) With which areas of FHI’s research are you familiar?
   b) What is your assessment of the quality of research generated?
   c) What did they do well?
   d) How (if at all) could they have done better?
   e) What are examples of SSAC feedback (including clinical trial design, patent rights, and sub-partner selection)? Did FHI respond adequately to SSAC’s feedback?
USAID Interview Guide

Introduction: The Office of Population and Reproductive Health in USAID’s Bureau of Global Health has asked for a near endline evaluation of Envision FP to assess the project’s progress (both successes and challenges) towards achievement of each of the project’s aims. The findings of this performance evaluation will be used by the Global Health/PRH, particularly its Research, Technology, and Utilization (RTU) division, to inform decisions about future programming in biomedical research.

Through this interview, we would like to ask you about your experience with and assessment of Envision FP’s work. Your participation in this evaluation is voluntary. You may refuse to answer any question in the interview or stop the interview at any time. And, of course, your answers are confidential. Do we have your permission to begin?

Question 1: Use of evidence

16. Please describe your role at USAID as it relates to Envision. Duration?

17. Use of evidence
   a) Please describe the decisions you/USAID made (or anticipate making) based on evidence generated by FHI (see list below) for programming, funding, and policy-making, priority setting.
   b) Was there evidence that you didn’t use, and if so why?

18. “Open response” under Aim 2
   a) Were FHI’s responses to “open response activity” requests adequate? How – if at all – could their response have been better? Quality? Timeliness? Prioritization?
   b) Did you identify any missed opportunities for addressing problems in the field using the “open response activity”?
   c) What were FHI’s successes/achievements and challenges - in terms of management - given FHI’s budget and staff planning? Do you have suggestions that might make the process easier/better?
   d) Did the “open response activity” of AIM 2 live up to your expectations? Why or why not?
   e) Looking to the future, do you feel it is important to include an “open response activity” mechanism? Why or why not?
   f) How could USAID have better helped FHI be more responsive under this activity?
   g) Lessons learned for the future?

Question 2: Achievement of aims

Aim 1: Lower SQ dose DMPA, extended interval Sayana Press, PPIUD, DMPA XT

Aim 2: P40, NORMAL counseling tool, ECHO study, DDI, Hormonal contraceptives and ARV/TB, Lower dose DMPA, Extending LARCs (LNG-IUS), Scale up of LNG-IUS, User preference study for microneedle patch

Aim 3: Microneedle patch, biodegradable implants

19. What do you feel are the key achievements under Envision?
20. How did the accomplishments of Envision help advance your office’s current mandate?

21. Are there areas within any of the aims where you feel that FHI under-performed or under-delivered? Please describe.

22. What do you feel have been the important implementation and management challenges and how well do you feel FHI addressed them?

23. What are your perceptions of the quality of research conducted by FHI and the policy and/or program implications?

**Question 3: Looking to the future**

24. Looking to the future, how would you change the design, management, and organization of a comparable project?

25. How could USAID’s management and organization be improved to support a comparable project?  
   Probe: budget allocation

26. What should be the priorities for the remainder of Envision?

27. What are some key activities follow-on award or similar future award? *Change
## ANNEX III. LIST OF KEY INFORMANT INTERVIEWEES

<table>
<thead>
<tr>
<th>Name</th>
<th>Job Title</th>
<th>Organization &amp; Location</th>
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<tbody>
<tr>
<td><strong>USAID</strong></td>
<td></td>
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</tr>
<tr>
<td>Tabitha Sripipatana</td>
<td>Deputy Division Chief GH/PRH/RTU (AOR Envision FP)</td>
<td>USAID, Envision FP Mgmt Team</td>
</tr>
<tr>
<td>Mihira Karra</td>
<td>Division Chief GH/PRH/RTU</td>
<td>USAID, Envision FP Mgmt Team</td>
</tr>
<tr>
<td>Kevin Peine</td>
<td>Biomedical Research Advisor GH/PRH/RTU</td>
<td>USAID, Envision FP Mgmt Team</td>
</tr>
<tr>
<td>Abdulmumin Saad</td>
<td>Senior Epidemiologist and RH Advisor GH/PRH/RTU</td>
<td>USAID, Envision FP Mgmt Team</td>
</tr>
<tr>
<td>Erika Houghtaling</td>
<td>Social Science Advisor GH/PRH/RTU</td>
<td>USAID, Envision FP Mgmt Team</td>
</tr>
<tr>
<td>Jennifer Mason</td>
<td>Senior Advisor for FP/HIV Integration GH/PRH/SDI</td>
<td>USAID, PRH</td>
</tr>
<tr>
<td>Ellen Starbird</td>
<td>Office Director GH/PRH</td>
<td>USAID, PRH Front Office</td>
</tr>
<tr>
<td>Elaine Menotti</td>
<td>Senior Technical Advisor GH/PRH/SDI</td>
<td>USAID, PRH</td>
</tr>
<tr>
<td>Shelley Snyder</td>
<td>Technical Advisor (PRB/PACE Project) GH/PRH/PEC</td>
<td>USAID, PRH</td>
</tr>
<tr>
<td>Nithya Mani</td>
<td>Division Chief (Acting), Priority Populations, Integration and Rights Division GH/OHA</td>
<td>USAID, OHA</td>
</tr>
<tr>
<td>Yolanda Oliveros</td>
<td>Development Assistance Specialist Office of Health</td>
<td>Philippine Mission</td>
</tr>
<tr>
<td>Helena Mungunda</td>
<td>TB/HIV Specialist</td>
<td>Namibia Mission</td>
</tr>
<tr>
<td>Amy Lin</td>
<td>Senior Market Advisor</td>
<td>USAID/Center for Innovation and Impact (CII)</td>
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<tr>
<td><strong>SSAC</strong></td>
<td></td>
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<tr>
<td>Jerry Strauss</td>
<td>SSAC Chair</td>
<td>Virginia Commonwealth University</td>
</tr>
<tr>
<td>Jenni Smit</td>
<td>SSAC member</td>
<td>Univ of Witswaterand, MatCH Research Unit</td>
</tr>
<tr>
<td>Lisa Rarick</td>
<td>SSAC member</td>
<td>Regulatory consultant</td>
</tr>
<tr>
<td>Name</td>
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<td>BMGF</td>
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<tr>
<td>Kirsten Vogelsong</td>
<td>Program Officer for main BMGF CTII project</td>
<td>Contraceptive Technology Donor Group</td>
</tr>
<tr>
<td>Trisha Wood</td>
<td>Program officer for BMGF LEAP project</td>
<td>Bill &amp; Melinda Gates Foundation</td>
</tr>
<tr>
<td>Sandra Laney</td>
<td>Program officer for LEAP project (interim)</td>
<td>Bill &amp; Melinda Gates Foundation</td>
</tr>
<tr>
<td>Maryjane Lacoste</td>
<td>Program officer for BMGF Implant Removal</td>
<td>Bill &amp; Melinda Gates Foundation</td>
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<tr>
<td>FHI 360</td>
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<tr>
<td>Laneta Dorflinger</td>
<td>Envision FP Project Director</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Gregory Kopf</td>
<td>Envision FP Deputy Director</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Amanda Troxler</td>
<td>Envision FP Activities Manager</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Tim Mastro</td>
<td>ECHO management committee member ECHO FHI 360 Principal Investigator</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Vera Halpern</td>
<td>Research Lead-lower dose DMPA &amp; DMPA XT</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Jennifer Deese</td>
<td>Research Lead-Sayana Press Extension</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Markus Steiner</td>
<td>Research Lead - Product Introduction and Post Marketing &amp; Extending Duration of LARCs</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Elena Lebetkin</td>
<td>Research Lead-Open Response Risk Mitigation &amp; SA Technical Assistance &amp; HIV/FP integration</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Kate Rademacher</td>
<td>Project Lead-Supporting Scale up of LNG-IUS</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Rebecca Callahan</td>
<td>Research Lead-Access to Implant Removal, Microneedle patch user preference, and ECHO continuation</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Name</td>
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<tr>
<td>Kavita Nanda</td>
<td>Research Lead-DDI</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Derek Owen</td>
<td>Research Lead-BDI</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Irina Yacobson</td>
<td>Technical Lead-TA for FP/HIV integration, SA Technical Assistance ECHO Training/Clinical Support Specialist</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Julie Welch</td>
<td>ECHO Project Director</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Lucy Wilson</td>
<td>Contractor (Former Envision FP M&amp;E Lead)</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Holly Burke</td>
<td>Research Lead - Sayana Press Key Informant Interviews</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Neha Mehta</td>
<td>Associate Director, Regulatory</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Amelia Mackenzie</td>
<td>Project Manager for NORMAL under LNG-IUS scale-up and supporting M&amp;E</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Anja Lendvay</td>
<td>Project Manager - Lower Dose DMPA and DMPA XT</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Chris Harmon</td>
<td>Scientist - DDI Database</td>
<td>FHI 360</td>
</tr>
<tr>
<td>Jennifer Ayres</td>
<td>Technical Advisor - Microneedles</td>
<td>FHI 360</td>
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<tr>
<td>Stephanie Horn</td>
<td>Project Manager - Sayana Press Extension</td>
<td>FHI 360</td>
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<td>WHO</td>
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<tr>
<td>Mary Lyn Gaffield</td>
<td>WHO CIRE (pass-through) Technical Lead</td>
<td>WHO</td>
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<tr>
<td>Craig Lissner</td>
<td>WHO CIRE (pass-through) Financial Lead</td>
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<tr>
<td>James Kiare</td>
<td>ECHO management committee member</td>
<td>WHO</td>
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<tr>
<td>Study Investigators</td>
<td></td>
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<tr>
<td>Mark Prausnitz</td>
<td>Microneedle Principal Investigator</td>
<td>Georgia Tech</td>
</tr>
<tr>
<td>Luis Bahamondes</td>
<td>Trial site Principal Investigator (Brazil)</td>
<td>CEMICAMP</td>
</tr>
<tr>
<td>Valerie Tagwira</td>
<td>ECHO trial trainer</td>
<td>Consultant</td>
</tr>
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<tr>
<td>Jared Baeten</td>
<td>ECHO management committee member</td>
<td>University of Washington</td>
</tr>
<tr>
<td></td>
<td>ECHO UW Principal Investigator</td>
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</tr>
<tr>
<td>Angela Boateng</td>
<td>Partner on Implant Removal study</td>
<td>Ghana Health Services</td>
</tr>
<tr>
<td>Emmanuel Kuffour</td>
<td>Partner on Implant Removal study</td>
<td>Population Council / Ghana</td>
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<tr>
<td>PSI</td>
<td></td>
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<tr>
<td>Ashley Jackson</td>
<td>EECO project, Deputy Director - related to LNG-IUS</td>
<td>PSI</td>
</tr>
<tr>
<td>Pierre Moon</td>
<td>SIFPO-2/PSI project, Director - related to LNG-IUS</td>
<td>PSI</td>
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</table>
ANNEX IV. LIST OF PUBLICATIONS

Rapid response and proactive risk mitigation for contraceptive programs


- Planning for Outcomes interactive tool


- Method Choice Framework

- Quality and Performance Guidance for Selection of Pregnancy Tests for Procurement

Access to Implant Removal Study


Contraceptive drug-drug interactions (DDIs)


- Contraceptive Drug Interactions Database

Supporting scale-up of the levonorgestrel intrauterine system (LNG IUS)


• NORMAL Counseling Tool for Menstrual Bleeding Changes (English, French, Spanish, Portuguese)

• LNG-IUS Dashboard: Perspectives of LNG-IUS Users Across Introduction Programs


**Contraceptive microneedle patch**


**The Evidence for Contraceptive Options and HIV Outcomes (ECHO) Study**


<table>
<thead>
<tr>
<th>Request</th>
<th>Requestor/date</th>
<th>Brief summary of response</th>
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<tbody>
<tr>
<td><strong>2015</strong></td>
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<tr>
<td>WHO issued a Medical Product Alert for Postinor-2 in Uganda. The Uganda National Drug Authority seized counterfeit product in August 2015. USAID requested a check of lot number of USAID products to see if they matched the counterfeit lot numbers.</td>
<td>USAID</td>
<td>FHI 360's Product Quality Compliance (PQC) lab checked the lot numbers of the USAID-procured product. USAID-procured product did not have counterfeit lot numbers. Response completed in early December 2015</td>
</tr>
<tr>
<td>Colleague in Zimbabwe reached out via email to Dr. Kavita Nanda for assistance responding to a statement issued by the Zimbabwe Registrar General stating that hormonal contraceptives are a danger to women and should be banned. He also stated that Jadelle was banned in the United States (where it is used in animals) and should therefore not be used in Zimbabwe.</td>
<td>Dr. Nanda’s colleague in Zimbabwe</td>
<td>Provided information that Jadelle was not banned in the United States. It is actually approved by the FDA. However, the manufacturer decided not to market it for financial reasons and the manufacturer was no longer producing pharmaceuticals in the area of women’s health. The issue was resolved in-country.</td>
</tr>
<tr>
<td>Forecasting extent of need for clinical services to remove contraceptive implants at end of their efficacy lifecycle (3-5 years).</td>
<td>FHI 360 proposed</td>
<td>Modeling of anticipated need and annual costs (labor and supplies) was completed for six African countries with high implant use—Ethiopia, Kenya, Nigeria, Senegal, Tanzania, and Zambia. Results published in GHSP in 2017.</td>
</tr>
<tr>
<td><strong>2016</strong></td>
<td></td>
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</tr>
<tr>
<td>USAID notified FHI 360 of a new meta-analysis on hormonal contraception (HC)-HIV set to be released in July where they anticipated a response might be needed depending on findings.</td>
<td>USAID</td>
<td>This request led to a much longer response monitoring the issue of HC-HIV especially around the ECHO trial. The end result was the Planning for Outcomes model and publication in GHSP in 2019.</td>
</tr>
<tr>
<td>Request</td>
<td>Requestor/date</td>
<td>Brief summary of response</td>
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<tr>
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</tr>
<tr>
<td>USAID requested information on the contraception NET-EN for a procurement discussion with commodity and service delivery colleagues.</td>
<td>USAID</td>
<td>Dr. Nanda prepared a PowerPoint slide deck with information and was given to USAID.</td>
</tr>
<tr>
<td>Quality assurance of pregnancy test to increase access to FP.</td>
<td>FHI 360 proposed</td>
<td>Developed recommendations on standards and specifications for procurement of pregnancy tests and disseminate to global audience. Available <a href="#">here</a>. Worked with FHI 360's PQC group to develop detailed work instructions for laboratory testing to evaluate the quality of pregnancy tests pre- or post-shipment. This Envision FP-funded part of the activity was completed in May 2017. The work instructions are currently being validated under an award led by PQC.</td>
</tr>
<tr>
<td>Quality of FP commodities (OC, EC) in Ghana and Burkina Faso.</td>
<td>FHI 360 proposed</td>
<td>Testing of oral and emergency contraceptive pills purchased from pharmacies in Ghana and Burkina Faso for quality and possible counterfeit product was conducted through May 2017 by FHI 360's PQC Lab. There were no counterfeit findings.</td>
</tr>
<tr>
<td>2017 A regulatory body of a partner country was considering a policy change around a specific method of family planning, USAID asked FHI to compile a review of all existing evidence on the issue.</td>
<td>USAID</td>
<td>The team prepared a document for the Mission that summarized key points on the mechanism of action for a specific method. The evidence that was provided alleviated the regulatory body's concerns and ultimately, no policy change was made.</td>
</tr>
<tr>
<td>USAID requested FHI 360 to work on a portfolio of activities in order to prepare for the ECHO trial results: a) finalizing the original P4O model b) developing an expanded dynamic model c) conducting a review of previous HIV risk assessment tools d) exploring any previous trials where risks were found to outweigh benefits of a drug or product, and e) potentially providing TA to local investigators to prepare manuscripts</td>
<td>USAID</td>
<td>a. Model was finalized. See Planning for Outcomes above. b. Decided in discussions with USAID not to conduct dynamic model. c. The final brief was completed in March 2019. d. A review was conducted and no relevant trials were found. e. USAID decided not to fund this activity as paper writing was to be funded out of ECHO trial funds.</td>
</tr>
<tr>
<td>Request</td>
<td>Requestor/date</td>
<td>Brief summary of response</td>
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<tr>
<td>on secondary data from ECHO.</td>
<td><strong>USAID</strong></td>
<td>The team provided scientific input to specific sections to the Global Handbook on FP.</td>
</tr>
<tr>
<td>Scientific input on FP Handbook requested.</td>
<td><strong>USAID</strong></td>
<td>USAID requested a technical review of the PRB/PACE digital update of contraceptive evidence. The team reviewed the document and send back with comments within a week.</td>
</tr>
<tr>
<td><strong>2018</strong></td>
<td></td>
<td>USAID informed FHI 360 that there was some discussion in Tanzania about bone density and DMPA use in youth and restricting the method. USAID requested we provide information on bone density and DMPA. The team developed a one-page summary brief on the evidence on bone mineral density and DMPA. Completed in February 2019.</td>
</tr>
<tr>
<td>USAID requested the development of a method choice framework.</td>
<td><strong>USAID</strong></td>
<td>USAID requested the development of a method choice framework. The framework was completed in April 2019. Available <a href="#">here</a>.</td>
</tr>
<tr>
<td><strong>2019</strong></td>
<td></td>
<td>USAID requested updated information on IUD safety for adolescents (nulliparous women). The team conducted a literature review and located 5 new papers that were sent to USAID in March 2019.</td>
</tr>
</tbody>
</table>
## ANNEX VI. LIST OF CANCELLED, REDUCED LEVEL OF ACTIVITY, AND CLOSED ACTIVITIES

<table>
<thead>
<tr>
<th>Activity Name</th>
<th>Funding Source</th>
<th>Initially approved</th>
<th>Current Status</th>
<th>Explanation of status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transforming postpartum IUD (PPIUD) insertion</strong></td>
<td>Core/PRH</td>
<td>Year 1 Workplan</td>
<td>Reduced level of activity</td>
<td>The PPIUD was expected to receive UNFPA / WHO PQ early in project, but it has not yet received it. This has limited opportunities for further introduction and evaluation. With limited funding, FHI 360 continues to provide TA to Pregna on the WHO PQ process and completed the supply chain assessment in Year 2.</td>
</tr>
<tr>
<td><strong>Extending duration of LARC methods</strong></td>
<td>Core/PRH</td>
<td>Year 1 Workplan</td>
<td>Reduced level of activity</td>
<td>Initial plans to work on synthesizing new data and advocacy for policy change on implants turned out to be unnecessary given that WHO conducted a synthesis of evidence as part of their Selected Practice Recommendations update process. The WHO has decided to keep the recommended 3-year duration and will not update the SPR at this time. Data from the clinical study of Sino-implant (II) and Jadelle were used to conduct a comparative analysis to better inform the relative durations of effectiveness of the methods and the amount of LNG daily released that is associated with a high degree of contraceptive efficacy. A manuscript is drafted and in review. Funding for this was originally planned for Envision FP, but was ultimately supported through a BMGF grant.</td>
</tr>
<tr>
<td><strong>DDI technical leadership</strong></td>
<td>Core/PRH</td>
<td>Year 1 Workplan</td>
<td>Reduced level of activity</td>
<td>This activity has supported development and dissemination of systematic reviews, but the technical assistance to other USAID-funded studies that was initially requested has only been called upon in a limited manner.</td>
</tr>
<tr>
<td><strong>Drug interactions between Implanon (ENG implants) and efavirenz (EFV)-containing antiretroviral therapy</strong></td>
<td>Core/PRH &amp; Core/OHA</td>
<td>Year 1 Workplan</td>
<td>Cancelled</td>
<td>USAID cancelled this activity in Year 2.</td>
</tr>
<tr>
<td>Activity</td>
<td>Sponsor</td>
<td>Year</td>
<td>Status</td>
<td>Description</td>
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<tr>
<td>Development of biodegradable contraceptive implants</td>
<td>Core/PRH</td>
<td>Year 4</td>
<td>Closed</td>
<td>During Envision FP Year 4, USAID approved short-term bridge funding for this activity while FHI 360’s Gates Foundation-funded work was being transitioned between two grants. This work continues to be implemented by FHI 360 with Gates Foundation funding.</td>
</tr>
<tr>
<td>Non-surgical permanent contraception</td>
<td>Core/PRH</td>
<td>Year 1</td>
<td>Cancelled</td>
<td>Due to a lack of adequate funding, this activity was cancelled in Year 2. OHSU continues to pursue this work with direct Gates Foundation funding.</td>
</tr>
<tr>
<td>Female non-surgical contraception by focus ultrasound</td>
<td>Core/PRH</td>
<td>Year 4</td>
<td>Cancelled</td>
<td>USAID cancelled this activity in Year 4. There is no further work on this concept.</td>
</tr>
<tr>
<td>Cochrane Review Initiative</td>
<td>IAA-NICHD &amp; Core/PRH</td>
<td>Year 1</td>
<td>Closed</td>
<td>Closed in Year 3</td>
</tr>
<tr>
<td>Activities at CONRAD/EVMS (Pass-through)</td>
<td>IAA-NICHD</td>
<td>Year 1</td>
<td>Closed</td>
<td>Funding via FHI 360 ended and this activity closed in Year 2. FHI 360 has not continued to track activities undertaken by CONRAD with other funding.</td>
</tr>
<tr>
<td>Support for Initiative for Multipurpose Prevention Technologies (IMPT)</td>
<td>IAA-NICHD</td>
<td>Year 1</td>
<td>Closed</td>
<td>Funding via FHI 360 ended and this activity closed in Year 2. FHI 360 has not continued to track activities undertaken by IMPT with other funding.</td>
</tr>
</tbody>
</table>
ANNEX VII. DISCLOSURE OF ANY CONFLICT OF INTEREST

GLOBAL HEALTH PROGRAM CYCLE IMPROVEMENT PROJECT

USAID NON-DISCLOSURE AND CONFLICTS AGREEMENT

USAID Non-Disclosure and Conflicts Agreement, Global Health Program Cycle Improvement Project

As used in this Agreement, Sensitive Data is marked or unmarked, oral, written or in any other form, "sensitive but unclassified information," procurement sensitive and source selection information, and information such as medical, personnel, financial, investigatory, visa, law enforcement, or other information which, if released, could result in harm or unfair treatment to an individual or group, or could have a negative impact upon foreign policy or relations, or USAID’s mission.

Intending to be legally bound, I hereby accept the obligations contained in this Agreement in consideration of my being granted access to Sensitive Data, and specifically I understand and acknowledge that:

1. I have been given access to USAID Sensitive Data to facilitate the performance of duties assigned to me for compensation, monetary or otherwise. By being granted access to such Sensitive Data, special confidence and trust has been placed in me by the United States Government, and as such it is my responsibility to safeguard Sensitive Data disclosed to me, and to refrain from disclosing Sensitive Data to persons not requiring access for performance of official USAID duties.

2. Before disclosing Sensitive Data, I must determine the recipient’s “need to know” or “need to access” Sensitive Data for USAID purposes.

3. I agree to abide in all respects by 41, U.S.C. 2101 - 2107, The Procurement Integrity Act, and specifically agree not to disclose source selection information or contractor bid proposal information to any person or entity not authorized by agency regulations to receive such information.

4. I have reviewed my employment (past, present and under consideration) and financial interests, as well as those of my household family members, and certify that, to the best of my knowledge and belief, I have no actual or potential conflict of interest that could diminish my capacity to perform my assigned duties in an impartial and objective manner.

5. Any breach of this Agreement may result in the termination of my access to Sensitive Data, which, if such termination effectively negates my ability to perform my assigned duties, may lead to the termination of my employment or other relationships with the Departments or Agencies that granted my access.

6. I will not use Sensitive Data, while working at USAID or thereafter, for personal gain or detrimentally to USAID, or disclose or make available all or any part of the Sensitive Data to any person, firm, corporation, association, or any other entity for any reason or purpose whatsoever, directly or indirectly, except as may be required for the benefit USAID.

7. Misuse of government Sensitive Data could constitute a violation, or violations, of United States criminal law, and Federally-affiliated workers (including some contract employees) who violate privacy safeguards may be subject to disciplinary actions, a fine of up to $5,000, or both. In particular, U.S. criminal law (18 USC § 1905) protects confidential information from unauthorized disclosure by government employees. There is also an exemption from the Freedom of Information Act (FOIA) protecting such information from disclosure to the public. Finally, the ethical standards that bind each government employee also prohibit unauthorized disclosure (5 CFR 2635.703).

8. All Sensitive Data to which I have access or may obtain access by signing this Agreement is now and will remain the property of, or under the control of, the United States Government. I agree that I must return all Sensitive Data which has or may come into my possession (a) upon demand by an authorized representative of the United States Government; (b) upon the conclusion of my employment or other relationship with the Department or Agency that last granted me access to
GLOBAL HEALTH PROGRAM CYCLE IMPROVEMENT PROJECT

Sensitive Data; or (c) upon the conclusion of my employment or other relationship that requires access to Sensitive Data.

9. Notwithstanding the foregoing, I shall not be restricted from disclosing or using Sensitive Data that: (i) is or becomes generally available to the public other than as a result of an unauthorized disclosure by me; (ii) becomes available to me in a manner that is not in contravention of applicable law; or (iii) is required to be disclosed by law, court order, or other legal process.

ACCEPTANCE
The undersigned accepts the terms and conditions of this Agreement.

Signature: ___________________________ Date: ___________________________

June 12 2019

Name: Katia Peterson  Title: Consultant
Sensitive Data; or (c) upon the conclusion of my employment or other relationship that requires access to Sensitive Data.

9. Notwithstanding the foregoing, I shall not be restricted from disclosing or using Sensitive Data that:
   (i) is or becomes generally available to the public other than as a result of an unauthorized disclosure by me; (ii) becomes available to me in a manner that is not in contravention of applicable law; or (iii) is required to be disclosed by law, court order, or other legal process.

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**ACCEPTANCE**
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<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
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<tbody>
<tr>
<td>Kelly O'Hanley</td>
<td>7-5-19</td>
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<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Kelly O'Hanley</td>
<td>MD, MPH</td>
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</tbody>
</table>
ANNEX VIII. SUMMARY BIOS OF EVALUATION TEAM

Katia Peterson PhD, MPH, evaluation team lead, has more than 15 years’ experience designing and implementing research and evaluation studies of health systems strengthening interventions. Her core competencies include mixed method process, outcome and performance evaluations, programmatic and policy reviews, literature and systematic reviews, qualitative and quantitative data analysis, and knowledge translation for evidence-informed decision-making. She has experience working with USAID, WHO, international and local NGOs, and ministries of health. She is an adjunct faculty member at the School of Public Health at The George Washington University, Washington DC. Her role on the evaluation was to provide overall managerial and technical leadership. In collaboration with other team members, she developed the evaluation work plan, data collection tools and analysis framework.

Kelly O’Hanley, MD, MPH, contraceptive security expert, has had public health experience in 37 countries, primarily in reproductive, maternal, and neonatal health. She has evaluated numerous health programs and has provided technical assistance to improve the quality of services and trained health care providers. She authored technical documents, including service guidelines, protocols, and training manuals. She served as the Maternal and Child Health expert for an executive course for senior personnel from ministries of health, WHO, from multiple counties organized by Harvard University. Dr. O’Hanley has provided surgical-medical consulting services to Exoxemis Inc. to execute a worldwide pivotal Phase 3 clinical trial of a novel antiseptic for surgical wound prevention. Her role on the evaluation was to help develop the evaluation work plan, data collection tools, and analysis framework; interview key informants; and help draft PowerPoint presentations for USAID and FHI 360 as well as this evaluation report.
For more information, please visit
http://ghpro.dexisonline.com/reports-publications