A HealthTech Report

HealthTech V Final Report
October 1, 2011 to September 30, 2016

Cooperative Agreement AID-OAA-A-11-00051
Acknowledgment

This program is made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the HealthTech cooperative agreement AID-OAA-A-11-00051. The contents are the responsibility of PATH and do not necessarily reflect the views of USAID or the United States government.
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Achievements of PATH HealthTech V Project

- **33** High-potential technologies identified
- **104** Research/development partnerships formalized
- **14** Technologies designed with in-country user input
- **115,232** Downloads/views from PATH website related to technology
- **22** Technologies evaluated in a lab, bench, or controlled setting
- **88** Conferences where results were disseminated
- **37** Suppliers with assessed capacity to enter market with technology meeting product specifications
- **9** Technologies evaluated and introduced in the field
- **25** Published articles

**FUNDING SUMMARY: $17.3M OVER 5 YEARS**

- **REPRODUCTIVE HEALTH** $4.5M
- **HIV/AIDS** $6.8M
- **MATERNAL AND CHILD HEALTH, IMMUNIZATION, AND NUTRITION** $6M

**PATH** is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drug, diagnostics, devices, and system and service innovations—to harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity.

**Technologies for Health Program** is a 5-year collaboration between PATH and USAID to develop and introduce low cost health tools and technologies to accelerate reductions in infectious diseases as well as mortality and morbidity in maternal and child health.

For more information about this project, visit [www.path.org](http://www.path.org).

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PEER-REVIEWED JOURNAL PUBLICATIONS AUTHOR ED BY PATH STAFF

Bekinska M, Greener R, Smit J, Maphumulo B, Mphiili N, Kilbourne-Brook M, Coffey PS. A randomized crossover study evaluating the health and acceptability of the SILCS diaphragm compared to vaginal applicators for vaginal gel delivery. (submitted to Contraception)

Quaife M, Eakle R, Cabrera M, Vickerman P, Kilbourne-Brook M, Delany-Moretlwe S, Terris-Prestholt F. Heterogeneous preferences for new HIV prevention products among South African men, women, adolescent girls and female sex workers. (will be submitted to Social Science and Medicine)


PEER-REVIEWED JOURNAL ARTICLES AUTHOR ED BY PATH SUBRECIPIENTS

Mauck CK, Schwartz JL, Littlefield S, Kimble T, Brache V, Linton K, Doncel GF. A Phase I Randomized Postcoital Testing and Safety Study of the Caya Diaphragm used with 3% Nonoxynol-9 gel, ContraGel, or No Gel. (submitted to Contraception)

Schwartz JL, Littlefield S, Linton K, Thurman A, Doncel GF. A Phase I Randomized Safety Study of the Caya® Diaphragm Used with Contragel®. (will be submitted to Contraception)

Quaife M, Terris-Prestholt F, Vickerman P. A model to estimate the costs of ARV-based prevention roll-out in South Africa. (will be submitted to Cost effectiveness and Resource Allocation)


Available at: https://www.guttmacher.org/about/gpr/2015/09/multipurpose-prevention-technologies-developing-world-us-investment-critical.


RELATED PUBLICATIONS


Introduction

The purpose of the HealthTech program is to improve maternal and child health and survival by assessing field needs and developing affordable, appropriate health, nutrition, and family planning technology solutions that address those needs. Activities include needs assessments; technology design, adaptation, development, and transfer for local production; field assessments; and introduction, distribution, marketing, and licensing.

Under five continuous HealthTech cooperative agreements, PATH has investigated hundreds of technologies and evaluated dozens in the field. Approximately 20 of our technologies have been made available for regional or global use, including: vaccine vial monitors (5 billion), SoloShot™ auto-disable syringe (nearly 7 billion), Uniject™ prefilled injection system, and in particular, Sayana® Press, the HIV dipstick test, among others. PATH’s first HealthTech award was issued in 1987, and the five consecutive awards under this mechanism have totaled $90 million.

HealthTech V was a 5-year, $17 million cooperative agreement awarded to PATH by USAID (Technologies for Health Program RFA).

HealthTech V is one of four implementation research and health technology projects that comprise the USAID Health Research Program (HaRP) 1.0 portfolio. The four projects are HealthTech V, implemented by PATH; Health Research Challenge for Impact, implemented by Johns Hopkins Bloomberg School of Public Health; Accelovate, implemented by Jhpiego; and Translating Research into Action (TRAction), implemented by University Research Corporation.

Charged with identifying and advancing technology solutions for priority health issues in USAID priority countries, the HealthTech program supports both product and market development across the research-to-use continuum. PATH’s first HealthTech award was issued in 1987; it focused on upstream discovery and research and development efforts that, over the last 25 years, resulted in not only the development but also subsequent introduction and scale-up of global health cornerstones such as auto-disable syringes and vaccine vial monitors. Under HealthTech V, our focus is toward the middle or far right of the value chain. This part of the value chain is where we work on technology validation, health system fit, market dynamics, policy alignment, regulatory approvals, introduction, and scale.

HealthTech links the public and private sectors to forge collaborations that benefit both partners, resulting in increased access by people in low-resource settings to innovative technologies made with people in low-resource settings, through cost-effective distribution channels that build on existing health ecosystems. We also incentivize local and international commercialization partners to make the commitment to participate in emerging public health markets.

Over the last 5 years, the HealthTech V program has worked in a variety of health areas, including reproductive health, HIV/AIDS, maternal/newborn health, immunization, and nutrition. As shown in the infographic, we have investigated a broad landscape of technologies to identify 33 that show great promise for low-resource settings and have evaluated 22 on the bench or in the lab or other controlled setting. For example, we have conducted early proof-of-concept and feasibility studies on fast-dissolving microbicide inserts as well as microarray patches and implants for alternative delivery of antiretroviral drugs (ARVs) for long-term HIV protection. We have employed our user-centered design process to
optimize 14 technologies and assessed 37 suppliers to determine if they can meet rigorous product specifications and have the capacity to enter the market in a sustainable way. Importantly, we have evaluated and introduced 9 technologies in the field. These include evaluating noninvasive devices for point-of-care hemoglobin screening in Ghana and Rwanda, development and scale-up of OpenLMIS to support supply chain requirements in Tanzania and Zambia, and introduction and scale-up of chlorhexidine for umbilical cord care and the SILCS single-size contoured diaphragm. The following paragraphs provide some details about what we have been able to accomplish with a few other technologies.

- This video provides an overview of the technology and market development efforts of the HealthTech V project. View the video here: HealthTech V: Life-changing Health Technologies for Women and Children.

HealthTech V, in collaboration with the United Nations Commission on Life-Saving Commodities for Women and Children, developed and evaluated simple user instructions and a job aid for amoxicillin dispersible-tablet (DT) treatment of pneumonia to support implementation of revised pneumonia treatment guidelines at the national and subnational level. Our results from implementation research in Bangladesh showed that 1) providers who are trained and use these tools are more likely to adhere to World Health Organization (WHO) recommended treatment guidelines and 2) caregivers who use these tools are nearly four times more likely to adhere to the full 5-day amoxicillin DT treatment regimen than caregivers who do not.

This work indicates a clear demand for user-tested tools and resources for pneumonia and amoxicillin DT use in countries transitioning from other treatment regimens. These research results are being used in several ways. UNICEF Bangladesh has incorporated these simple user instructions and job aid into an information packet that is being distributed throughout the country. In Kenya, key decision-makers are adapting these tools to use as part of their current system of medicine dispensing. And, in Uganda, a distributor has submitted packaging that includes these user instructions to the local regulatory authority.

Another example is the Cold Chain Equipment Inventory (CCEI) software package, which was developed by HealthTech. This important technology provides a standardized set of software tools for national Expanded Program on Immunization managers to improve their management and maintenance of the complex and widely dispersed set of physical assets that make up the cold chain, including the refrigerators and freezers that keep vaccines safe and effective. This tool is now integrated into DHIS2 and was pilot-tested in collaboration with the ministries of health and UNICEF in Ghana, Laos, and Nigeria. This technology was further leveraged when WHO included cold chain equipment inventory requirements in their draft Effective Vaccine Management assessment criteria and UNICEF included the CCEI software in their cold chain equipment inventory toolkit for immunization programs and consultants, which is now posted on www.TechNet-21.org.

Birth asphyxia remains a major cause of newborn mortality worldwide. To address this, HealthTech V has supported global scale-up of basic neonatal resuscitation by:

- Assessing reprocessing practices for neonatal resuscitation equipment in Uganda and then using that information to drive an evidence-based consensus process to develop a seminal and much-needed global reference on the topic and an accompanying job aid.
- Developing a quantification tool for basic neonatal resuscitation commodities.
- Developing a procurement toolkit and using it to build procurement capacity in Ghana, Malawi, Tanzania, and Uganda.
- Evaluating a new neonatal resuscitator design against the standard of care in Seattle and India.

In Figure 1, the 15 technologies that advanced under HealthTech V are displayed along the Research-to-Use continuum used in the USAID HaRP 1.0 portfolio framework. As shown, over half of the projects are focused on catalytic activity to facilitate product adoption and/or scale-up at the country level. Next, detailed summaries of the health need, solution and potential impact, goals and outcomes of the development and introduction plan (DIP), status as of September 2016 and plans for the future/recommendations for follow-up activities for each technology are presented.

The success of HealthTech over the past 25 years highlights the critical nature of collaboration. HealthTech V itself has benefited greatly by working with 104 partners over the last 5 years (see infographic). This number includes the 25 distributors of the Caya® contoured diaphragm and the 25 members of the Chlorhexidine Working Group. HealthTech V draws upon PATH staff members with a broad range of skills and expertise including product designers, engineers, biomedical and social scientists, public health experts, clinicians, health economists, and marketing and business specialists. Clearly, it takes more than a village to move any one technology across the Research-to-Use continuum. Our experience at PATH and the results achieved under the HealthTech V project show that our unique and integrated approach to product and market development offers a compelling option for creating access to technologies to improve global health.
Pathway from Research to Field Implementation and Use

- **Strategic planning, problem identification, and priority setting**
  - Alternative Methods for the Delivery of Long-Acting HIV Antiretroviral Drugs
  - Evaluation of Hemoglobin Measurement Tools for Anemia Screening
  - Fast-Dissolving Inserts for Microbicide Delivery
  - Initiative for Multipurpose Prevention Technologies
  - Injectable Antibiotics for Newborn Sepsis Treatment
  - Paper Applicator for Microbicide Delivery

- **Applied research to create tools, approaches, and interventions**
  - Amoxicillin Dispersible Tablets
  - Global Campaign for Microbicides
  - Innovation Countdown 2030
  - Neonatal Resuscitation
  - Planning for Introduction and Scale: Synthesizing Best Practices and Lessons Learned

- **Catalytic activity to facilitate adoption of product**
  - Chlorhexidine for Umbilical Cord Care
  - Cold Chain Equipment Inventory Software
  - OpenLMIS
  - SILCS Diaphragm

- **Country-level program/policy rollout/diffusion in to regular use**
  - Strategic planning, problem identification, and priority setting
  - Applied research to create tools, approaches, and interventions
  - Catalytic activity to facilitate adoption of product
  - Country-level program/policy rollout/diffusion in to regular use
Alternative Methods for the Delivery of Long-Acting HIV Antiretroviral Drugs

Health Need Addressed
Despite significant progress in recent decades, HIV/AIDS is still the leading cause of mortality among adults from 15 to 59 years of age, and women in sub-Saharan Africa bear the disproportionate share of this disease burden. To meet the requirements of different consumer groups, there is a need for additional well-tolerated, easy-to-deliver, discreet, low-cost products for HIV pre-exposure prophylaxis (PrEP).

HIV PrEP products requiring pericoital use (gels), daily dosing (oral pills), and even vaginal rings (long-acting protection) can be effective, but have been difficult for some women to use consistently. A PrEP product with a self-administered, long-acting delivery method that is discreet and acceptable could be of particular benefit for expanding access and compliance. This project explored two alternative methods for long-acting delivery of antiretroviral drugs (ARVs) for HIV PrEP.

HealthTech V Solution and Potential Impact
Microarray patches (MAPs), also known as microneedle patches, are minimally invasive devices that painlessly penetrate the stratum corneum barrier of the skin, thus accessing the skin’s microcirculation and achieving systemic delivery by the transdermal route. They can also be used for targeted delivery into tissue to elicit immune responses or to achieve other local effects. In this project, HealthTech partnered with Queen’s University Belfast to design and evaluate novel MAPs for transdermal or vaginal delivery of rilpivirine, which could expand access and adherence through enabling self-administration and provide long-acting protection (up to three months).

HealthTech also partnered with RTI International (RTI) to develop a suitable applicator system for subdermal implantation of RTI’s thin-film polymer device (TFPD), a biodegradable implant used to deliver long-acting ARVs (for protection up to three months). The TFPD is made with a flexible, polycaprolactone (PCL) membrane designed to biodegrade. The device is designed to be inserted under the skin with the aid of a trocar-like applicator, in a manner similar to existing subcutaneous contraceptive implants such as Norplant.

Goals and Outcomes of the DIP
The first goal of the DIP was to investigate the feasibility of MAP delivery of ARVs for HIV PrEP using either transdermal or vaginal patches.

Outcomes:
- Completed market research in South Africa, which found that women and health care providers see value in MAPs for delivery of HIV PrEP.
- Developed dissolving MAPs containing high concentrations of the long-acting nanoparticle formulation of rilpivirine and capable of releasing the drug in vitro—potentially achieving dose requirements in a patch of acceptable size.
- Designed and tested prototype vaginal applicators; product design was informed by parallel patch development and preliminary user assessment.
- Conducted preclinical studies evaluating pharmacokinetics of MAP delivery of rilpivirine in a small animal model.

The second goal of the DIP was to support RTI’s development of the TFPD through identification of a suitable trocar applicator system.
Outcomes:

- Developed a target product profile for subdermal insertion of RTI’s TFPD implant to help guide product development by specifying minimally acceptable and desired targets for applicator characteristics.
- Conducted a landscape review and procured samples of currently available trocar-like applicators for evaluation in a simulated tissue model, to define ideal trocar applicator design features, including the recommendation that applicators should be preloaded.
- Completed a preliminary risk analysis to identify hazards associated with packaging, use, and disposal and characterize the harm those hazards may induce (hazard severity and hazard probability), which led to initial designation of potential mitigation pathways.

Status of Technology and Results as of September 2016

Status of technology: In development for both MAP delivery of ARVs and the TFPD for long-acting HIV PrEP.

MAPs were developed and tested in both in vitro and in vivo model systems. Four, second-generation vaginal MAP applicator prototypes were developed that incorporated feedback from the market research in South Africa and technical requirements from the formulation development work. These vaginal MAP applicator prototypes were evaluated in a vaginal model to assess embedment pressure, patch area, MAP flexibility requirements, and feedback capabilities of each applicator. A single, second-generation trocar-like applicator prototype was developed to fit RTI’s current TFPD implant specifications and evaluated by users in a bench model to measure insertion forces.

Plans for the Future/Recommendations for Follow-Up Activities

- Next steps for MAP development include evaluating delivery of an alternative ARV for HIV PrEP, such as long-acting cabotegravir (with a lower risk of HIV resistance) and optimizing MAP formulation for rapid release in vivo.
- Next steps for other skin patches would be to conduct preclinical studies to enable a Phase 1 clinical trial.
- For the vaginal patch, future work would include evaluating drug migration through vaginal tissue following MAP application (using modeling as well as preclinical testing in sheep) to determine requirements for patch dose and surface contact area and assessing the feasibility of maintaining protective concentrations of ARVs throughout target tissue.
- Vaginal tissue integrity following MAP application in a large animal model should also be assessed to evaluate safety and ensure the risk of HIV infection is not increased due to compromised tissue integrity. Future goals for MAP delivery of ARVs include investigating the potential for using MAPs for HIV treatment as well.
- For the TFPD applicator, next steps include advancing designs for an applicator and packaging for the TFPD that is acceptable to users and suitable for use in low-resource settings. Applicator development activities would support preparation for Phase 0/1 trials; such activities would include conducting a human-factors evaluation and an expanded risk analysis and providing recommendations on packaging strategies and stability studies.
Health Need Addressed
Pneumonia is a leading cause of death among children less than five years of age. Estimates indicate that 936,000 children died from pneumonia in 2013, accounting for 15 percent of child deaths globally. The high burden of childhood pneumonia deaths belies the fact that pneumonia-related mortality is preventable with simple interventions and appropriate treatment. The World Health Organization (WHO) integrated community case management (iCCM) strategy recommends that children between two months and five years of age diagnosed with fast-breathing pneumonia are treated with an oral antibiotic. The recommended first-line treatment of pneumonia is oral amoxicillin dispersible tablets (DT). Despite these recommendations, only one-third of pneumonia cases receive antibiotics as part of the treatment regimen. Even when antibiotics are available, evidence indicates that only two-thirds of children completed the full course of antibiotics. Failure to complete the course of amoxicillin DT treatment as prescribed can lead to treatment failure, pneumonia relapse, and the potential for the patient to develop drug resistance.

Adherence to and completion of treatment with amoxicillin DT is dependent on understanding how and why to take the medication as prescribed. One barrier to medication adherence is low literacy, which is correlated with poor health. Caregivers of children who receive amoxicillin DT may not know how to administer the medication. Caregivers need to have a clear understanding of how to administer amoxicillin DT to children, including the dosage, frequency, and timing of treatment as well as how to prepare DT. Low-skilled health care providers working in both the public and private health care systems need better guidance on how to dispense amoxicillin DT and be able to explain to caregivers the steps for administering the drug at home. These tools must be made available to countries in a way that encourages their uptake, adaptation, and widespread use.

HealthTech V Solution and Potential Impact
HealthTech developed a prototype of a job aid and user instructions for amoxicillin DT to increase the capacity of health care providers to prescribe and dispense appropriate treatment and to increase the ability of caregivers to understand amoxicillin DT administration instructions for childhood pneumonia. The integration of these tools into health care systems has the potential to improve adherence to first-line treatment and reduce the number of deaths attributable to pneumonia in children under five.

Goals and Outcomes of the DIP
To facilitate improved adherence to amoxicillin DT treatment for childhood pneumonia through the development and evaluation of a job aid (JA) and user-friendly product presentation and to leverage progress in childhood pneumonia treatment to improve the use of amoxicillin DT for other indications such as neonatal sepsis and possibly severe acute malnutrition.

Outcomes:
- Built synergies between the design, development, and introduction of tools to support use of amoxicillin DT in the treatment of childhood pneumonia and neonatal sepsis through presentations to the child and newborn health working groups, results dissemination with targeted stakeholders, and a publication that outlines the design and development process.
- Conducted a scoping analysis in Bangladesh to understand the use of current tools and the need for adapted or revised tools to address the use of amoxicillin DT for neonatal sepsis. Findings shared with Bangladesh Ministry of Health and Family Welfare and national newborn technical working group.
- Improved, vetted, and generated widespread support for the content and design of the JA and user instructions by convening a meeting of experts in design, communication, manufacturing, and health. User instructions revised based on expert feedback and made available on forthcoming Every Breath Counts website.
• Assessed the feasibility of incorporating the user instructions into amoxicillin DT packaging at the global manufacturing level or at different points along the amoxicillin DT value chain.
  o Documented policies and procurement plans in Bangladesh, Democratic Republic of Congo, Ethiopia, and Kenya to highlight gaps in amoxicillin DT availability.
  o Identified global manufacturers of amoxicillin DT and interviewed them to understand the process of making changes to current packaging. It is feasible to change the packaging at the point of manufacturing, and manufacturers are largely willing to do so if requested to by UNICEF or other customers.
  o Identified criteria for understanding the preferred introduction points through a case study in Kenya. Introduction at the national level through the Kenya Medical Supplies Agency, using preprinted plastic envelopes, is the recommended introduction point. Results shared with Kenyan Ministry of Health, Homa Bay County health management team, and other key stakeholders at a dissemination meeting.
• Assessed the usability, feasibility of introduction, and influence on treatment adherence when the JA and user instructions are used in the treatment of childhood pneumonia at the community level through a pilot evaluation in Homa Bay County. The study findings showed that the user-friendly product presentation and the JA for treatment of childhood pneumonia among community health volunteers and caregivers are usable, feasible, and acceptable.
  o It is feasible to integrate the user-friendly product presentation and JA into the current system of care at the individual provider and health care system.
  o The caregivers and community health volunteers both liked using the tools and were able to understand and recall the meaning of JA and user instructions.
  o The JA and user-friendly product presentation influenced adherence to the treatment regimen of amoxicillin DT by reminding the caregivers when and how to deliver amoxicillin DT. Nearly all of the caregivers completed delivery of the five-day treatment regimen.

Status of Technology and Results as of September 2016
Status of technology: Introduced; available in print.

The Kenya case study and evaluation determined that the tools are feasible to introduce, to use, and positively influence adherence behaviors. In Homa Bay County, we recommend that the sub-county management team and the health facility in-charge should ensure availability of amoxicillin DT with user instructions and job aids at the health facility and community level. The county health management team should consider similar tools to be used not only by community health volunteers and not only for amoxicillin DT but also for other conditions that are managed at the community level including malaria and diarrheal conditions.

The tools and the evidence generated around how and why to use them has been disseminated and made available through the Every Breath Counts campaign. Results have been shared with the global working group and with key decision-makers in Bangladesh and Kenya. The tools have been incorporated into materials distributed by UNICEF Bangladesh. The results from this work will be compiled with the results from additional pilot evaluations in Bangladesh, Bolivia, Democratic Republic of the Congo, Niger, Solomon Islands, and Zimbabwe at a UNICEF-supported meeting in October 2016. At that point, UNICEF and UNICEF Supply Division will determine how they will support further long-term studies of the impact of the tools and channels for country adaptation and procurement.

Plans for the Future/Recommendations for Follow-Up Activities
Recommendations for introduction in other countries include:
  • Understand local procedures for medication dispensation and adapt accordingly.
• Work within existing supply chain logistics to increase feasibility.
• Adapt training materials to sensitize health care workers and minimize confusion.
• Procurement agencies need to provide incentives and actively request that manufacturers and distributors provide user-friendly instructions.
• For pediatric medications with multiple indications, consider a disease-agnostic approach to user instructions to reduce potential for health care workers and caregivers to confuse regimens.
• Evaluate the need for more user-friendly instructions for pediatric medications beyond amoxicillin DT.

Next steps:
• Continue to work with countries to update treatment guidelines and essential medicine lists.
• Emphasize the importance of user-friendly instructions when providing recommendations for amoxicillin DT.
• If the manufacturer route is preferred, provide technical assistance to countries to write tenders and procurement requirements that require user-friendly packaging and instructions.
• Continue to build evidence on the impact of user-friendly instructions on treatment compliance and other health outcomes.
Chlorhexidine for Umbilical Cord Care

Health Need Addressed
Severe infection is one of the top three causes of newborn deaths worldwide, causing about 15% of all neonatal deaths across the globe, but in developing countries, infections can account for more than half of all neonatal deaths. A baby’s newly cut umbilical cord can be an entry point for bacteria, which can lead to infection—and potentially life-threatening sepsis.

HealthTech V Solution and Potential Impact
Community-based randomized trials in rural areas in Bangladesh, Nepal, and Pakistan have shown that applying 7.1% chlorhexidine digluconate (delivering 4% chlorhexidine) to the umbilical cord stump prevents infection and saves newborn lives. These trials and concurrent research demonstrated that 7.1% chlorhexidine digluconate for umbilical cord care is an efficacious, acceptable, feasible, and cost-effective newborn care intervention.

Appropriate chlorhexidine application reduces the risk of death before 28 days by up to 23% and eliminates two-thirds to three-quarters of serious umbilical infections. Recent modeling suggests that between 2015 and 2030, chlorhexidine could save over 1 million newborns in home birth settings alone (assuming average peak coverage of 55%). It can be delivered through existing health services, antenatal and obstetric care, other essential newborn care activities, and through retail outlets, including pharmacies, public facility- and community-based providers, and community health workers.

Goals and Outcomes of the DIP
The goal of this DIP was to coordinate and support efforts to accelerate introduction and global scale-up of chlorhexidine for umbilical cord care to at least ten countries by the year 2016.

Outcomes:
- Chlorhexidine for umbilical cord care has reached the implementation stage in 11 countries.
- Chlorhexidine for umbilical cord care has reached the pilot/policy alignment stage in an additional 14 countries.
- Inclusion of chlorhexidine in the WHO Essential Medicines List for Children, the Lives Saved Tool (LiST), the Maternal and Neonatal Directed Assessment of Technology (MANDATE) website, and the Demographic and Health Surveys newborn module.
- Convened and acted as the Secretariat of the Chlorhexidine Working Group (CWG).
- Developed materials to support chlorhexidine introduction and scale-up including:
  - Consensus building.
  - Building evidence for implementation.
  - Aligning policies and guidelines.
  - Demand generation and training.
  - Manufacturing and distribution.
  - Monitoring and evaluation.
  - Maintained the CWG resource page on the Healthy Newborn Network website.

Status of Technology and Results as of September 2016
Status of technology: Field implementation.

PATH, as the Secretariat of the global Chlorhexidine Working Group successfully led the group to identify and coordinate programmatic opportunities for chlorhexidine integration into global and regional platforms and built regional supplier bases for manufacturing and distribution as well as provided support to global manufacturers and suppliers, such as GSK and UNICEF Supply Division. This effort has resulted in four regional manufacturers who are currently producing quality assured
chlorhexidine for umbilical cord care, one global supplier, and one global manufacturer. Further, there are two regional suppliers who have received technical assistance from our partners and can begin manufacture of chlorhexidine should the market demand further supply needs. We also provided leadership and technical support for both supply and demand initiatives in support of the UN Commission on Life-Saving Commodities for Women and Children’s chlorhexidine implementation work plan and have continued to build on the knowledge and implementation base to scale the chlorhexidine product worldwide. As a direct result of these efforts, chlorhexidine implementation has progressed from 1 country in 2011 to 11 countries in 2016, and a further 14 countries are in the pilot/policy alignment stage.

Plans for the Future/Recommendations for Follow-Up Activities
The Chlorhexidine Working Group will be able to continue its work under a different funding mechanism for at least the next year. The group has identified needs in several areas and hopes to address the following:

- Maintenance of global-level technical resources.
- Enhanced advocacy activities and implementation research to support policy development and implementation with selected countries.
- Technical assistance to support development of national introduction and scale-up strategies.
- Conduct sustainability workshops with countries who have reached the stage of aligning their national policies/guidelines and engaging in program introduction.
Cold Chain Equipment Inventories

Health Need Addressed
Access to accurate cold chain equipment (CCE) inventory data can support decision-making by staff working at all levels of an immunization program. This data helps quantify the available cold chain capacity at vaccine stores or service delivery points and also supports estimates of CCE requirements, both for today’s vaccine volumes and for those forecasted five to seven years in the future.

With access to accurate equipment inventory data, planners can identify cold chain capacity gaps, decide when to rehabilitate existing equipment and when to procure new equipment, and investigate how vaccine supply chain design changes can potentially impact quality, efficiency, and coverage goals. It is important to recognize how quickly CCE information changes; equipment that was working last month may no longer work, or facilities that did not have access to grid-electricity last year may have access to grid-electricity today. Because of the dynamic nature of vaccine supply chains, immunization programs need not only to collect accurate CCE inventory data, but also to strengthen routine mechanisms to maintain the accuracy of the data, ideally by ensuring that the data is continuously used and improved to support a strong routine immunization program.

HealthTech V Solution and Potential Impact
The Cold Chain Equipment Manager (CCEM) software tool was deployed in 13 countries, with the most recent deployment in Uzbekistan in 2016 (made possible with financial support from the World Health Organization [WHO] and technical support from Georgia’s national immunization program). CCEM continues to evolve with immunization program input. In September 2016, Uganda’s immunization program finalized new functionality in CCEM to help track repair and spare part information. This functionality supplemented new CCEM reports and better navigation, which were added based on input from the national immunization program in Cambodia. With CCE inventories about to become a requirement in the new WHO/UNICEF Effective Vaccine Management (EVM) assessment framework, there is likely to be an increase in the number of CCEM deployments starting in 2017.

Under HealthTech, CCEM functionality was added to the widely used, open-source, web-based DHIS2 software platform, with the vision that CCE inventories could become more easily updated and used in near “real-time” by district medical or health officers when deployed as part of national health information systems. The CCE inventory add-on to DHIS2 was piloted by the Laos national immunization program, with the support of UNICEF, to improve communication with health center staff on cold chain temperature excursions and vaccine stock levels using the SMS functionality already integrated into DHIS2. UNICEF and WHO are currently working with the University of Oslo to scale this tool as part of the national rollout of DHIS2 currently underway. Although interest in the DHIS2 CCE inventory application was also expressed by the national immunization teams in the Democratic Republic of the Congo, Ghana, Kenya, and Nigeria, PATH was unable to align these immunization programs with the internal and external technical partners and funding needed to help them deploy the CCE inventory application in DHIS2. However, with CCE inventories about to become a requirement in the new WHO/UNICEF EVM assessment framework and with increasing interest in data analytics and dashboards, both of which are supported by DHIS2, it is possible that interested immunization programs soon may be able to access the support needed to deploy web-based tools like the CCE inventory add-on to DHIS2.

Goals and Outcomes of the DIP
The goal of the DIP for CCE inventories was to make collecting, updating, and using CCE inventory data a common and sustainable practice among Expanded Programme on Immunization (EPI) teams and their
partners through the development and introduction of an appropriate inventory system that makes evidence-based equipment planning and management easier at all levels of the vaccine supply chain.

Outcomes:
- DHIS2 developers released the CCE inventory extension as part of the core DHIS2 software, thereby enabling the application to be sustainably managed by global, regional, and national DHIS2 technical teams.
- CCEM applications informed a global CCE inventory data standard and a generic set of data collection forms and guidelines released in December 2015 by UNICEF on the TechNet21.org website.
- CCE inventories were added as a national and subnational requirement in the WHO/UNICEF EVM assessment framework.
- CCEM was deployed in Ghana (pilot), Malawi, Nigeria (pilot), Pakistan, and nine other countries.
- Lessons learned from CCEM deployment are included in the draft *How to collect a cold chain equipment inventory* document released by UNICEF in January 2016.

**Status of Technology and Results as of September 2016**
Status of technology: Introduced; available online.

Two software tools to support CCE inventories were designed, developed, validated, introduced, and made available online under HealthTech. These CCEM tools are available online or by contacting the DHIS2 global development team at dhis2.org (the CCE inventory add-on to DHIS2).

**Plans for the Future/Recommendations for Follow-Up Activities**
Advocate globally and at the USAID mission level for better support to national immunization programs seeking to use data to monitor and manage CCE at all levels of the immunization supply chain and help interested immunization programs gather the internal and external investments needed to meet the technical, training, and overall change management requirements for introduction and long-term use of both CCEM and the DHIS2 CCE inventory add-on.
Evaluation of Hemoglobin Measurement Tools for Anemia Screening

Health Need Addressed
Anemia continues to be one of the most serious global health problems, with far-reaching consequences for human health as well as social and economic development. The World Health Organization (WHO) estimates one in four people are affected by anemia worldwide. Anemia particularly affects pregnant women and young children. In Africa, all-cause anemia rates are estimated to be very high at 57.1 percent and 67.6 percent for pregnant women and children under five years, respectively. Rates of iron-deficiency anemia in Africa are estimated at 20.3 percent and 20.2 percent for pregnant women and children under five years, respectively. Iron deficiency is the most widespread form of malnutrition in the world; in children, it has been associated with impaired growth, cognitive performance, motor development, coordination, and language development. In pregnant women, iron-deficiency anemia contributes to 20 percent of all maternal deaths and places women at risk for poor pregnancy outcomes, including increased risk of mortality and morbidity, preterm births, and low-birthweight babies.

Because of the prevalence and public health impact of anemia, there is consensus that anemia should be prevented, detected, and treated. One important aspect of any anemia control program is effective screening to improve survival among vulnerable women and children and to avoid secondary problems due to iron-deficiency anemia. Hemoglobin estimation should be an integral part of maternal newborn and child health programs. Access to rapid, safe, and accurate point-of-care methods of hemoglobin assessment is an important component of the care package. Innovations in hemoglobin estimation using noninvasive devices provide promising and more acceptable options to patients and providers.

HealthTech V Solution and Potential Impact
Under HealthTech V, a landscape of noninvasive technologies was carried out, and the Pronto® noninvasive Hb estimation device manufactured by Masimo Corporation (Irvine, CA) was identified as the most advanced technology. It is a handheld device that uses a finger probe to give an immediate readout of Hb in g/dl. The device also provides oxygen saturation (SpO₂) levels and a pulse rate, which could allow use of the device for other applications within the facilities. The device is portable and requires no additional consumables.

The Pronto device has been tested and validated and is in use in high-income countries, but it had not been validated in developing-country settings where different population characteristics, user variability, and environment often play a role in the accuracy of point-of-care devices. With HealthTech support, PATH evaluated the Pronto device in Ghana in an ANC clinic among pregnant women and in Rwanda in a pediatric clinic among children between the ages of 6 and 59 months to assess accuracy, performance, and potential impact. We hypothesized that a noninvasive point-of-care device that is simple to use, accurate, and affordable would improve clinical practice by (1) expanding access to screening among high-risk populations by less formally trained cadres of workers, (2) providing immediate quantifiable measurements to guide and support early treatment and monitoring, especially among pregnant and postpartum women and among children, and (3) facilitate population surveillance and monitoring efforts. More recently, a number of potential applications for SpO₂ are emerging—pneumonia, sepsis screening, preeclampsia/eclampsia—which would increase the impact and value proposition of the noninvasive device.
Goals and Outcomes of the DIP

The goal of the DIP was to evaluate the accuracy of the Pronto noninvasive Hb estimation device and compare it to the standard reference method. The study was conducted among pregnant women attending an antenatal clinic in Kintampo, Ghana, and among children ages 6 to 59 months attending a pediatric clinic at the CHUK referral hospital in Kigali, Rwanda. A secondary goal included testing the accuracy of the HemoCue® point-of-care device as another measure that will be compared to the gold standard. In our second site in Rwanda, the study evaluated two methods of blood sampling by the HemoCue® 201+ because recently the accuracy of the HemoCue has been called into question and alternate methods of blood sampling required investigation. The accuracy of both blood sampling methods by the HemoCue 201+ were compared to the reference standard method. The key outcomes were as follows:

Outcomes in Ghana:
- The study was completed and data was collected from 240 healthy pregnant women between the ages of 18 and 40 from Kintampo Municipal Hospital ANC clinic. Of these women, 221 (98%) had a complete Hb measure from the Pronto and the HemoCue® 201+. Results were calculated for the difference between the Pronto and HemoCue 201+ compared to the reference standard for each participant.
- The proportion of women with an Hb as measured by the noninvasive method falling within +/- 1.0 g/dl as measured by the reference hematology analyzed was calculated. The proportion of women falling within those limits when tested with the HemoCue against the standard reference was also calculated as a secondary endpoint.
- The results of this study show that the noninvasive Hb devices tested were biased upward, giving a higher Hb measurement than the reference and were not accurate compared to the reference standard. The Pronto had an average bias of 2.06 g/dl. By contrast, the HemoCue had an average bias of 0.67 g/dl. The implications of missing the mothers at highest risk because of low Hb is significant. One hypothesis is that the calibration of the device was based largely on a healthy population of nonpregnant women.
- Study findings were shared with Masimo. The calibration and other technical modifications that were potential sources for the bias were investigated by the engineering team at Masimo.
- A follow-on calibration study was conducted in Ghana by the Masimo engineers to collect raw waveform data using a Pronto. The raw data was used to make adjustments to device algorithms and calibration curves and improve the accuracy of the devices.
- Recommendations for technical and user-based approaches to optimize the device for antenatal care use were presented and discussed at a meeting with the PATH and Ghana principal investigators and the Masimo team.

Outcomes in Rwanda:
- The study was completed; a total of 112 children over 3 kg in weight and between the ages of 6 to 59 months were enrolled in the study and tested with the Pronto noninvasive device.
- The first arm of the study showed that the Pronto overestimated the anemia prevalence in comparison to the reference standard (42 percent vs 37 percent respectively) and had a sensitivity of 66 percent and a specificity of 70 percent.
- Study results were shared with Masimo at the completion of the study analysis. The number of cases where a reading was not possible (20 cases) was shared.
- The second arm of the study was completed and enrolled 132 children to be tested using the HemoCue point-of-care device. About half (66 children) were tested using the blood wicking method and half (66 children) were tested using the gravity blood sampling method.
- Study results showed that between the wicking and gravity blood sampling methods (77 percent and 91 percent, respectively) the gravity method was more accurate.
- The sensitivity and the specificity for the wicking method at 11 g/dl was better than that of the gravity method at 11.5 g/dl.
• The gravity method performed better overall than wicking but implementation of that method under normal conditions in low-resource settings would limit its use. Increased training in proper wicking methods was recommended.
• Study results including feedback on user experience and device performance were shared with Masimo.

Overall, in both studies providers and patients expressed a strong interest in the technology. Key advantages mentioned were the ease of use, the size and portability of the device, the acceptability to patients due to the noninvasive testing, the additional indicators that the device provides, and the minimal training requirements. However, accuracy would need to be improved to equal other point-of-care devices.

**Status of Technology and Results as of September 2016**

Status of technology: In development.

The Pronto technology continues to be refined and optimized by the manufacturer. Validation of the device should be expanded to other countries, using larger sample sizes, incorporating learnings from the two studies in Ghana and Rwanda. At the start of the project, the device came equipped with several sensors ranging in size (large, medium, and small). The ability of the device to get an accurate read depends on proper sizing of the finger and a good sensor fit. In 2015, a next generation of Pronto sensor, the DCI®-mini device, meant for use with children weighing between 3 and 30 kg, was released. As of June 2016, Masimo announced that the next generation device has been released and that the DCI®-mini has now been approved as a universal sensor that works on all patients over 3 kg, making the device more versatile and more affordable by negating the need to buy different sensor sizes.

This next generation Pronto has been modified to incorporate additional motion tolerance, which will be a significant improvement, especially when testing children. Other improvements include a 40 percent reduction in time to display results and greater accuracy at the lower levels of Hb for the 6 to 11 g/dl ranges to match the performance of comparable point-of-care invasive devices such as the HemoCue.

**Plans for the Future/Recommendations for Follow-Up Activities**

In July 2016, a HealthTech expert consultation meeting entitled “Hemoglobin testing methods: research and program implications” gathered about 20 experts in Washington, DC. Research on current Hb testing with HemoCue and with the noninvasive devices showed that both methods had limitations. Future direction and expert feedback suggest that the noninvasive methods should continue to be tested and optimized as the most promising long-term approach to Hb estimation. One key recommendation from the consultation meeting was for the research community to attempt to standardize research methodologies so that studies evaluating various Hb estimation devices and techniques can be compared. A second recommendation was to continue with an emphasis on training, quality control, and supervision as an integral part of any anemia-control program, regardless of the device used. The noninvasive device is simple to use but does require a specific technique to ensure accurate, reliable results. The studies carried out under HealthTech are the only ones done on the noninvasive device in low- and middle-income countries among vulnerable populations. Additional studies in low-resource countries will be necessary to better understand how these devices will be used, how well they will perform under normal conditions, and the feasibility of introduction in the field. The sample sizes for both studies were small and therefore conclusions are not easily generalizable. Larger studies among pregnant women (controlling for gestational age) and children (spanning a wide range of age groups) are needed. Tradeoffs in cost and convenience versus accuracy must be carefully weighed and taken into account when making a decision about the most appropriate tools for Hb measurement. Further assessment of the value of additional indicators provided by the Pronto device could aid programs in their choice of methods.
Fast-Dissolving Inserts for Microbicide Delivery

Health Need Addressed
With respect to women and the HIV epidemic, the US Centers for Disease Control and Prevention report trends indicate that women account for 23 percent of new infections in the United States and 50 percent of all new infections globally. Microbicides offer a women-initiated HIV prevention method, which would form a useful addition to the existing prevention interventions. There is a need for novel prevention approaches that allow women to independently control their HIV acquisition risk. Although potent anti-HIV activity is an essential attribute of a microbicide candidate, other attributes are equally important. For example, a candidate must be first formulated in a dosage form that is safe, acceptable, and effective. A successful microbicide would provide women with an affordable and feasible option for HIV prevention that is self-initiated and self-managed.

HealthTech V Solution and Potential Impact
The earliest microbicide candidates developed have been formulated as coitally dependent (used around the time of sex) gels and creams. All microbicide candidates tested in Phase 3 clinical trials, so far, have been gel products with nonspecific or moderately specific mechanisms of action.

Tablets are the most commonly used dosage form outside the microbicide field due to their inexpensive manufacturing costs, ease of dosing, potential for high drug loading, and stability compared to aqueous-based dosage forms like liquids and gels. They also offer the potential for an inexpensive, discreet, portable product that has no environmental waste. Some of the issues reported in literature around vaginal tablets are slow disintegration time, residue, and discomfort due to texture. One of the essential factors to be considered during development of vaginal solid dosage form is to ensure the tablet adequately disintegrates in available fluid to avoid unwanted particulate discharge. In this work, the freeze-drying process produced fast-dissolving inserts (FDIs) that are highly porous and therefore disintegrates rapidly and completely in minimal fluid volume. This is seen as a huge advantage for vaginal delivery, where the resting fluid volumes are reportedly under 0.5 ml, an amount that poses a challenge for disintegration of conventional vaginal tablets. The inserts are compact with good handling properties, allowing for discreet self-administration by the user.

Goals and Outcomes of the DIP
The goal of the DIP was to determine feasibility to develop a self-administered FDI dosage form for microbicide delivery. The key outcomes are listed below.

Outcomes:
- Developed heat-stable FDI for anti-HIV inhibitor Griffithsin (GRFT).
- The GRFT-FDI were found to be robust with good handling properties for blister or bulk packaging.
- The FDIs containing broadly neutralizing antibodies (bnAbs) disintegrate completely in limited fluid volume in the macaque vaginal region while maintaining therapeutic levels of bnAbs based on enzyme-linked immunosorbent gp120 binding assay.

Status of Technology and Results as of September 2016
Status of technology: In development.

As of September 2016, all activities under this project have been completed as per the proposed timelines. In collaboration with Population Council, we have developed an FDI formulation containing Griffithsin as a topical dosage form. The GRFT-FDI disintegrates in minimal volume (less than 0.5 ml) of simulated vaginal fluid and is robust with good handling properties based on friability and hardness evaluation. The results from a three-month stability evaluation at 40°C/75% relative humidity (RH) show that Griffithsin content is maintained in the range 90% to 110% for the lead FDI formulation. The antiviral activity data
from testing against human papillomavirus and herpes simplex virus show that GRFT maintains its activity in this dosage form even after storage at 40°C/75% RH at the end of three months. Under this project, in collaboration with The Scripps Research Institute, we tested FDIs containing bnAbs for retention of activity in a macaque model. The results from the bnAb retention study in macaques show that the bnAbs are retained in macaque vaginal cavity for more than four hours while maintaining gp120 binding activity and HIV-neutralization activity in in vitro assay.

**Plans for the Future/Recommendations for Follow-Up Activities**
We plan to continue the advancement of microbicide FDIs for Griffithsin through collaboration with the Population Council. Under this collaboration, we will conduct an efficacy study in macaques, optimize the GFRT-FDI formulation for improved long-term stability, and prepare for manufacturing process scale-up at a contract manufacturer facility to support toxicology studies.
Global Campaign for Microbicides

Health Need Addressed
The Global Campaign for Microbicides (GCM) sought to advance HIV prevention options and women’s role in research.

GCM was initiated at a time when nearly half of all HIV infections occurred in women and women-initiated prevention options were limited. GCM worked to raise awareness of these challenges and the need for HIV prevention options that could address the specific needs of women, as well as the need to include women as active participants in all product development/research stages. GCM primarily targeted women in sub-Saharan Africa who were at the greatest risk of HIV.

HealthTech V Solution and Potential Impact
An advocacy and mobilization effort was designed to address this health issue. The effort brought together key stakeholders—African women and communities, government officials, policymakers and health stakeholders, researchers and scientists, and global advocates and activists—in an effort to raise awareness about microbicide development and introduction, generate champions to call for policy action on microbicides, and identify the needs of women relative to HIV prevention clinical research.

Goals and Outcomes of the DIP
The GCM was dedicated to advancing the introduction and successful implementation of proven microbicides for preventing HIV acquisition in women. GCM intended to meet this goal through a combination of political mobilization, education, and community engagement activities.

Outcomes:
- GCM piloted multiple community engagement/gender analysis activities in different target communities to help inform microbicide implementation strategies that would support end users, employing different techniques such as storytelling, connecting with African water cooler communities, engaging through professional associations, facilitating discussions in a science cafe format, and working with community parliaments. Eight dialogues were conducted in Kenya, nine dialogues conducted in South Africa, and six dialogues conducted in Zambia. Through these engagements, individuals were identified and cultivated to serve as microbicide champions in their communities.
- Following GCM’s engagement with policymakers on microbicide research and development, two policies that support broader scale-up were put in place in South Africa and Kenya.
- GCM co-convened the USAID Microbicide Access Working Group. Following feedback from participants, the meeting structure, participants, and format were evolved; at GCM’s termination, convening of the working group was transitioned to USAID and the Population Council.
- GCM participated in the Microbicides 2012 Conference; at this event GCM helped develop and foster relationships with potential partners to identify opportunities for integrated health partnerships for microbicide implementation.
- GCM participated in the AIDS2012 Conference, including co-hosting with AVAC a Meet the Experts session to join scientists and advocates and build greater collaboration between research and advocacy efforts for microbicide implementation.

In 2012, in consultation with key stakeholders including USAID, PATH made the decision to close GCM. Project assets were made available through PATH’s website and were shared and distributed to partners (for instance, AVAC took up management of GCM’s Microbicides e-course).
Status of Technology and Results as of September 2016
The project was closed in September of 2012 and all assets and results disseminated to partners.

Plans for the Future/Recommendations for Follow-Up Activities
There are no additional plans for this project.
Health Need Addressed
Women worldwide confront two frequently concurrent sexual and reproductive health (SRH) risks: unintended pregnancy and sexually transmitted infections (STIs), particularly HIV. Global statistics reflect this burden: each year, there are 85 million unintended pregnancies around the world; every day, 1 million people contract an STI; and every 60 seconds, a young woman is infected with HIV. While condoms are extremely effective prevention methods when used correctly and consistently, they require planning and negotiation with partners, neither of which is guaranteed. Women need more comprehensive options that suit the diverse circumstances of their lives.

Multipurpose prevention technologies (MPTs) are an innovative class of products that deliver varied combinations of HIV prevention, other STI prevention, and contraception and will improve the SRH of women and girls with the highest unmet need around the world. The vision for MPTs is an array of accessible products that are woman-initiated, efficient, and easy to use.

HealthTech V Solution and Potential Impact
The Initiative for Multipurpose Prevention Technologies (IMPT) is a product-neutral collaboration that advances the development of MPTs to address the interlinked risks of HIV, other STIs, and unintended pregnancy. We believe that the availability of desirable methods that deliver an array of prevention combinations will improve the lives of women and their families worldwide. Comprising members from across disciplines and more than 15 countries, the IMPT is the central body that researchers, product developers, funders, policymakers, and advocates rely on for objective technical guidance and strategic planning related to MPTs. By facilitating interdisciplinary partnerships, the IMPT enables experts from across the family planning, HIV, and STI fields to strategize around the unique technological, market access, and regulatory challenges presented by developing combined prevention technologies, thus refining the pathway to impactful MPT development. Since the launch of the Initiative in 2009, CAMI Health has served as the Secretariat and neutral convener of the IMPT, providing central leadership and coordination to the MPT field. Throughout this report, CAMI Health’s work will be referred to as ‘IMPT Secretariat.’

In addition to their immediate health effects, HIV, other STIs, and unintended pregnancy negatively impact the quality of life and productivity of women around the world. Prudent investments in MPTs could lead to an array of health and social benefits for women and their families, including:

- Reduced rates of unintended pregnancy, HIV, and other STIs, which will, in turn, reduce rates of infertility and cancers caused by untreated STIs, reduce rates of maternal mortality, and lead to an overall improvement in women’s health.
- Improved educational attainment for girls by raising age at first birth and increasing number of years in school.
- Improved economic attainment by allowing women to plan pregnancies and avoid infections that lead to lost work days.
- Improved child health by facilitating effective birth spacing, reducing mother-to-child HIV transmission, and decreasing the number of high-risk pregnancies and births.

Overall, MPTs have the potential to address many of the world’s health priorities identified in the Sustainable Development Goals (SDGs), including good health and well-being (SDG 3), gender equality (SDG 5), quality education (SDG 4), decent work and economic growth (SDG 8), and no poverty (SDG 1).
**Goals and Outcomes of the DIP**

The goal of this DIP is to advance development and access to multipurpose prevention technologies (MPTs) that will simultaneously prevent pregnancy and/or sexually transmitted infections and/or reproductive tract infections.

**Outcomes:**

- Coordinated and convened the IMPT Network of Experts (NoE), which has been key in facilitating interdisciplinary collaboration among stakeholders. The NoE has convened quarterly for virtual updates and has grown to include over 150 active members from across SRH fields.
- Facilitated IMPT Working Groups, including the Scientific Agenda Working Group the Communications and Advocacy Working Group, and the IMPT Steering Committee. These groups were convened regularly to provide strategic and technical oversight to the work of the IMPT.
- Supported IMPT In-Country Task Forces in Kenya, South Africa, India, China, and Australasia, with the aim of laying the groundwork for MPT introduction.
- Organized and hosted over 20 in-person and virtual technical and strategy convenings with key stakeholders.
- Launched the IMPT Supporting Agency Collaboration Committee (SACC) in FY13, with the aim of facilitating information sharing and collaboration between supporting agencies. The SACC has been convened biannually to strategize around MPT funding gaps.
- Maintained the IMPT and MPTs101 websites, including a searchable database of hundreds of MPT-relevant articles, outreach materials, presentations, fact sheets, and other resources.
- Surveyed the field for relevant literature and distributing it through monthly article e-blasts. To date, 29 issues of “MPTs: Articles from the Field” have been distributed to a growing listserv of over 1,200 stakeholders.
- Developed and distributed newsletters with the latest MPT-related news. To date, eight newsletters have been sent to the IMPT listserv.
- Organized live webinars to keep stakeholders up-to-date on the latest developments in MPT research. The IMPT has hosted seven technical webinars on issues ranging from MPT manufacturing challenges, to MPT acceptability, to the latest research on non-HIV STI MPTs.
- Conducted a field-wide priority issues identification survey in FY14, in which five priority issues were identified, including 1) gaps in knowledge with regard to MPT market access and other related end-user considerations, 2) strategies and challenges for inclusion of hormonal contraceptives (HC) in MPTs, 3) MPT trial design issues, 4) MPTs for non-HIV STIs, and 5) MPT modeling efforts (e.g., cost-effectiveness, demand forecasting).
- Developed technical tools and resources including the MPT Product Development Database, which has been updated on a biannual basis., MPT dosage-form specific Target Product Profiles (TPPs), the MPT MAF, a resource to inform product development and investment decision-making that is focused specifically on market access components of MPT development, with the aim of ensuring that MPTs in development are not only efficacious in clinical trials but also desired, acceptable, and accessible to women and adolescent girls once introduced and commercially available ) a MPT Product Prioritization and Gap Analysis, aimed at informing IMPT efforts to support strategic focus on MPT priority product development strategies among funders and product development organizations, and the MPTs 101 slide deck, developed to assist stakeholders in integrating MPTs into their presentations.
• Authored 7 MPT-relevant articles in peer-reviewed publications. In addition, the IMPT Secretariat organized and co-edited a special supplement on MPTs in *BJOG: An International Journal of Obstetrics and Gynaecology*.
• Developed 8 articles and op-eds for strategic media outlets, including *Health Affairs*, the *Guardian*, and the *San Francisco Chronicle*.
• Presented MPTs at over 30 priority meetings and conferences.
• Developed relevant MPT outreach materials, including fact sheets, slide decks, informational postcards, and infographics.

**Status of Technology and Results as of September 2016**

Status of technology: In development.

The IMPT has advanced the MPT field through an iterative and collaborative research strategy that harnesses the expertise of a global network of product developers, researchers, advocates, funders, and health care providers. As the product-neutral coordinating body of the field, the IMPT has served as a forum for interdisciplinary collaboration and as a source of objective guidance for its 1,200 stakeholders. The IMPT is not a product developer, but rather a platform for collaboration and information-sharing among stakeholders. Overall, the IMPT’s strategic coordination and advocacy has bolstered the MPT development pipeline, which now consists of nearly two dozen products in various stages of development, including close to a dozen in clinical trials. The IMPT’s efforts have generated interest and support for MPT development, with global investments in the field increasing by 39% since 2013.

**Plans for the Future/Recommendations for Follow-Up Activities**

Building on support provided by HealthTech V and leveraging the support of the Bill & Melinda Gates Foundation, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institutes of Health – Office of AIDS Research (NIH-OAR), and the Mary Wohlford Foundation, the IMPT Secretariat was recently awarded a sole-source, $4.49 million award to continue its efforts to advance MPTs from FY16 through FY20. The overall goal of this new award is to support the IMPT Secretariat in its role as the product-neutral coordinator of the MPT field, specifically aiming to facilitate collaboration among MPT stakeholders; advance a common research and development (R&D) agenda for the MPT field, including developing objective tools and guidance for MPT development; and optimize collaboration among supporting agencies to support efficient investment decisions. Ultimately, the IMPT Secretariat seeks to facilitate the creation of a strategic roadmap to support the successful development and introduction of MPTs.
Injectable Antibiotics for Newborn Sepsis Treatment

Health Need Addressed
Neonatal sepsis is a leading cause of neonatal mortality, particularly in low-resource settings. Treatment guidelines for neonatal sepsis recommend inpatient courses of intravenous or intramuscular antibiotics, but many infants do not receive such treatment because they lack access to facility-based care. Recently issued World Health Organization (WHO) guidelines for managing neonatal sepsis expand treatment to the outpatient setting by administration of intramuscular gentamycin and oral amoxicillin when referral is not possible or accepted. Delivery of antibiotic treatment in an outpatient setting will expand access to lifesaving medications for neonatal sepsis and potentially reduce the rate of infant mortality due to infection in the first days of life. However, current presentations require that providers be trained in dose calculation based on infant weight and have access to safe injection supplies and sharps disposal. Moreover, countries who implement these new guidelines need support in planning for the supply of all related commodities and training in lower levels of care.

HealthTech V Solution and Potential Impact
HealthTech V focused on supporting the Injectable Antibiotics Technical Resource Team in preparation for the implementation of the new WHO guidelines by contributing analyses that would lead to informed global recommendations. Additionally, foreseeing the need to increase quality of care through less invasive and affordable platforms to administer gentamycin, HealthTech explored the feasibility of innovating in that space. HealthTech reviewed delivery options for gentamycin, monitored gaps relating to new delivery systems and formulations of gentamycin, and advanced promising gentamycin formulations. The potential impact of these activities is increased availability, accessibility, and correct use of antibiotics for the outpatient treatment of neonatal sepsis and, in the long run, decreased neonatal mortality.

Goals and Outcomes of the DIP
The goal of this DIP was to contribute to efforts to accelerate availability, accessibility, and correct use of injectable antibiotics for newborn sepsis treatment in key countries by the year 2016. HealthTech supported the Injectable Antibiotics Technical Resource Team in preparing for the implementation of the WHO guidelines for outpatient treatment of neonatal sepsis.

Outcomes:
1. Completed and disseminated the landscape report titled Gentamicin for Treatment of Neonatal Sepsis: A Landscape of Formulation, Packaging, and Delivery Alternatives. Input was gathered on this report from experts who recommended exploring the feasibility of one short-term solution (customized marked syringe) and two long-term solutions (reformulation of gentamycin for administration via transdermal and rectal routes) for delivery of gentamycin.
2. Completed and disseminated the presentation titled Outpatient Treatment of Neonatal Sepsis: Analysis of Options for Related Commodities. In this document, HealthTech presents the results of the analysis of existing presentations and delivery options for gentamycin and amoxicillin in the outpatient treatment of neonatal sepsis, considering recommended dosages, cost, market availability, and other supply chain factors.
3. Completed and disseminated the brief titled Viability of Customized, Marked Syringes for Gentamicin Delivery: Considering Demand and Supply Factors for the Outpatient Treatment of Neonatal Sepsis. This brief concludes that even when technically and financially feasible, a customized marked syringe has other training and logistics implications that might make its implementation more complex than pursuing a widely available 1-ml syringe.
4. Completed a technical feasibility study of reformulating gentamicin for rectal and oral administration. The conclusion of this work based on in vitro analysis suggests that it is feasible to improve the absorption and potential uptake of gentamicin through rectal administration.

5. A non-HealthTech funded project at PATH has developed a target product profile for a microarray patch for gentamicin delivery and conducted technical development of such a patch.

6. Through a non-HealthTech funded project, completed scoping analysis to understand progress regarding the adoption and implementation of neonatal sepsis treatment guidelines and define the need for new or revised tools in Bangladesh. Results were shared with the Bangladesh Ministry of Health and other stakeholders in a meeting through a presentation titled *Tools to Support the Outpatient Treatment of Neonatal Sepsis: A Consultation with Implementing Partners in Bangladesh.*

7. Completed the brief titled *Lessons Learned from the Implementation Strategies of Global Health Interventions,* in which lessons learned from the implementation strategies of the Chlorhexidine Working Group and GAVI that could be applied to the implementation of new WHO guidelines for outpatient treatment of neonatal sepsis are documented.

**Status of Technology and Results as of September 2016**

Status of technology: In development.

1. Rectal gentamicin. It is technically feasible on a lab scale to reformulate gentamicin for rectal administration. Status: Research/design.


**Plans for the Future/Recommendations for Follow-Up Activities**

1. The evidence gathered during the technical feasibility study for rectal gentamicin can be used to inform the next stage of feasibility work through a potential Saving Lives at Birth seed grant. This is a promising formulation that could, in the long run, increase safe use and acceptability of gentamicin.

2. The analyses conducted by HealthTech are useful resources of current information that can enhance the development of the WHO implementation guidelines for the outpatient treatment of neonatal sepsis.

3. An effective global partnership for implementation of the new WHO guidelines that can provide technical assistance to adopter countries may lead to wider implementation of the new antibiotic regimens.
Innovation Countdown 2030

Health Need Addressed
The United Nations (UN) Millennium Development Goals (MDGs) showed us what we can accomplish by coming together around a common set of health targets. The MDGs galvanized attention, resources, and accountability around ending preventable maternal and child deaths and helped accelerate progress. Embarking into the era of the UN Sustainable Development Goals (SDGs), we sought to build on the progress catalyzed by the MDGs by being more intentional about our approach and prioritizing innovations with the greatest potential to save lives.

Through the Innovation Countdown 2030 (IC2030) initiative, PATH engaged a cross-sector set of thought leaders to identify, evaluate, and showcase innovations that can reduce maternal deaths and end preventable deaths of newborns and young children; ensure universal access to reproductive health supplies and services; end the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases and combat other infectious diseases; and reduce the toll of diabetes, cancer, and respiratory and cardiovascular disease.

HealthTech V Solution and Potential Impact
Technical and social innovations have been pivotal to global health by improving the efficacy, access, and cost of interventions. The decline in child mortality from 12.6 million in 1990 to 6.6 million in 2011 was largely due to innovations in vaccines, drugs, diagnostics, health devices, and digital health tools. Looking back to 2000, most of these tools were already known, had established proof of principle, or were even at an early stage of introduction. IC2030 is designed to proactively spur the development and introduction of innovation by:

- Raising awareness across the global health community and mobilizing action around the innovations with greatest potential.
- Engaging political, technical, and financial leaders who have played a longstanding role in supporting global health innovation or who are new to this area, including social investors, new foundations, entrepreneurs, and technology companies.
- Energizing and mobilizing decision-makers and thought leaders with a call to act through regulatory, investment, or development pathways.
- Creating a common framework through which to prospectively identify and assess innovations and the big issues that will accelerate development and scale-up for impact.

PATH gathered more than 500 innovative ideas submitted by people in nearly 50 countries across five platforms: devices; diagnostics; drugs and therapeutics; systems and services, including digital health; and vaccines. We tapped more than 60 independent health experts to evaluate and rank those innovations to select the final set featured in the report, taking into account their potential for impact based on affordability, accessibility, effectiveness, and other key factors. We also developed a health and cost impact modeling process to quantify the impact of select maternal, newborn, and child health innovations, providing a framework to assess innovations in other health areas in the future.

Goals and Outcomes of the DIP
The goal of this DIP was to engage and influence both traditional and nontraditional innovators and funders around high-potential innovations to accelerate progress toward the SDG targets. Crowdsourcing innovations has contributed to broadening the channel for nontraditional innovators to share their ideas. Using an independent expert platform to down-select innovations to the 30 highlighted in the report was a valuable process that engaged dozens of experts and focused their attention on the ambitious
SDG health targets. The validated modeling of social return (health impact) is providing valuable and comparable data on the selected innovations. Importantly, the information was packaged in a compelling and accessible way, helping to ensure it was read by a broad array of stakeholders outside the health expert community.

Outcomes:
- The inaugural report has been downloaded over 12,000 times and the online pipeline visualization tool has nearly 7,000 views.
- Digital coverage includes over 1,485 #IC2030 tweets that were delivered 9.4 million times and reached over 3.96 million Twitter users, which includes partner promotion of PATH’s infographics and videos. On Facebook: 24,000 views of PATH’s IC2030 videos were delivered to 66,000 people.
- The report, the dialogue it generated at the Financing for Development Conference, and the website have resulted in high media coverage that stresses the importance of innovation to accelerate progress toward the global goals. Select media coverage to date includes Tech/Business Insider, Devex, The Guardian, Huffington Post, NPR, Stanford Social Innovation Review, Smithsonian.com, and Voice of America.
- Groups including the World Bank, Philips, GlaxoSmithKline, UBS, and others have conveyed the value of IC2030 outputs, including that the report is being used in various high-level discussions to spur dialogue around the importance of social return and thus is influencing decision-making. The curated list of innovations and the social return data are also being used by innovators and investors (for example, the Global Health Investment Fund) to inform their investment decisions. There is a strong interest in our vetted methodology, especially the health impact modeling. For example, Becton Dickinson’s Executive Team, which includes the CEO of the company, invited PATH to present its vetted methodology at a teleconference in September 2016 and has incorporated PATH’s qualitative assessment framework into an internal tool of their own. We continue to receive requests for information about the impact methodology, the highlighted innovations, and possible areas for future collaboration.

Status of Technology and Results as of September 2016
Status of technology: Introduced; available in print and online.

Reimagining Global Health, the IC2030 inaugural report, was designed to raise the awareness of the global health community and financiers about the importance of innovations generally, and 30 curated technologies specifically, to accelerate progress toward the ambitious UN SDGs’ health targets. The IC2030 report featured 30 high-impact innovations selected by independent global experts, health impact modeling results, and commentaries by 10 health, technology, and business leaders around the world. The report was officially launched July 13, 2015, at a standing-room-only side event at the UN Financing for Development meeting in Addis Ababa, Ethiopia. The event was co-hosted by PATH, the Bill & Melinda Gates Foundation, the Government of Norway, the UN Foundation, and Grand Challenges Canada. It engaged a cross-sector audience of 70 people in a discussion around the key issues highlighted in the report—including how we can keep health innovations cost-effective and how we can ensure investment is made in the innovations with the most potential impact.

Plans for the Future/Recommendations for Follow-Up Activities
Going forward, the IC2030 and report/website can contribute to keeping the innovation agenda a priority and broadening the engagement of new stakeholders with rigorous data and fresh and interesting material
from innovators and thought leaders around the world. We believe that IC2030 can be a mechanism to stimulate and support country-level dialogues on the innovation pipeline and national priorities, giving country leaders an opportunity to share their insights. It also highlighted additional activities that would address important needs. For example, the impact modeling is highly valuable, and investment is needed to scale the methodology to enable more innovations to be assessed. It also needs to be made user-friendly so that other partners can use the model to estimate social returns that are comparable.

Following are ideas to leverage both the IC2030 process and deliverables:

1. Increase the visibility of the importance of innovations and research and development investment with traditional and new health stakeholders through annual reports, fresh content on the ic2030 website, and targeted engagement of partners.
2. Develop investment cases with select innovation stakeholders and circulate to a network of investors through Every Woman Every Child, UN Foundation, and other IC2030 channels to stimulate dialogue on where to focus further funding. Explore strategies to mitigate risk—for example, through open innovation platforms to source ideas and accelerate scale-up (e.g., lower-cost ways to scale manufacturing, logistics, and supply chain constraints).
3. Develop real-time case studies about select innovations, highlighting progress and obstacles over the coming years. Disseminate findings in future IC2030 reports.
4. Scale IC2030 health impact modeling approach, which evaluates cost and lives saved as compared to the current standard of care, to inform investment decisions. Widely distribute findings at conferences and international convenings.
5. Develop and apply down-selection and health-impact modeling methodologies to evaluate cross-cutting innovations.
6. Expand the data visualization tool with more innovations through continued collaboration with Tableau.
Neonatal Resuscitation

Health Need Addressed
Birth asphyxia is a leading cause of neonatal mortality, particularly in low-resource settings. Many of these deaths can be easily prevented with basic resuscitation by a competent skilled birth attendant. To address this, the Helping Babies Breathe (HBB) program has been training skilled birth attendants in developing countries in basic resuscitation and equipping them with resuscitation equipment. However, challenges in country implementation and sustainability remain, including retention of resuscitation skills by less-experienced users, procurement of resuscitation equipment by countries, and poor maintenance of such equipment in the field, among others.

HealthTech V Solution and Potential Impact
Through HealthTech V, PATH focused on supporting the Neonatal Resuscitation Working Group (NRWG) and addressing use, maintenance, and procurement challenges of neonatal resuscitation equipment. HealthTech V participated in user evaluations of simplified resuscitator designs with health providers in low-resource settings, addressed maintenance challenges, monitored gaps in new designs of neonatal resuscitators, and developed global neonatal resuscitation planning tools and guidelines to address issues of quality and procurement. The potential impact of these activities is improving neonatal resuscitation coverage and quality and, in the long run, reducing neonatal mortality in resource-limited settings.

Goals and Outcomes of the DIP
The goal of this DIP was to conduct an independent, third-party evaluation of new designs of neonatal resuscitators and/or component pieces (e.g., face/device interface) to reduce neonatal mortality by improving newborn resuscitation.

Outcomes:
1. Completed and disseminated a series of seven purchasing guides (weight scales, birthing and cesarean section simulators, continuous positive airway pressure, fetal monitors, portable ultrasound, rechargeable lighting, and thermoregulation devices) to be disseminated directly to the Survive and Thrive Global Development Alliance (GDA) and elsewhere.
2. Completed and disseminated the landscape report titled Neonatal Airway Interface Devices: A Landscape Review. Gathered input on the report; some experts recommended further innovation for resuscitation and continuous positive airway pressure (CPAP) interfaces.
3. Completed and disseminated the Reprocessing Guidelines for Basic Neonatal Resuscitation Equipment in Resource-Limited Settings, its associated job aid, and training materials developed to introduce these guidelines.
5. Conducted pilot introduction of reprocessing guidelines in Uganda through training workshops.
6. Distributed printed copies of the reprocessing guidelines and job aid to Uganda.
Status of Technology and Results as of September 2016
Status of technology: Introduced; available in print and online.

The following resources were developed or updated under HealthTech V: weight scales purchasing guide; Reprocessing Guidelines for Basic Neonatal Resuscitation Equipment in Resource-Limited Settings, the associated job aid, training materials, and French and Spanish translations of the guidelines and the job aid; and the Quantification Tool for Basic Neonatal Resuscitation Commodities: Version 2. These resources are all available online (links provided in the previous section). The reprocessing guidelines were introduced in Uganda and the Uganda Ministry of Health has plans for scale-up. Global HBB stakeholders will discuss how best to continue dissemination of the reprocessing guidelines.

Plans for the Future/Recommendations for Follow-Up Activities
Recommendations for follow-up activities (not currently funded):
1. Collaborate with developer of the neonatal laryngeal mask airway to explore its potential to improve neonatal resuscitation delivery.
2. Research/design a prototype of an innovative interface for CPAP administration in newborns.
3. Develop strategies for continued dissemination of reprocessing guidelines and incorporation into HBB curricula.
4. Continue providing technical assistance to countries to effectively implement reprocessing guidelines.
5. Do a post-introduction evaluation of reprocessing practices in facilities in Uganda.
6. Develop strategies to strengthen infection prevention and control practices during maternal and newborn care in facilities in low-resource settings.
7. Continue providing technical assistance to countries in procurement of neonatal resuscitation equipment to increase availability of quality-assured equipment.

Plans for the future:
8. With funding from Save the Children, PATH will publish a manuscript to disseminate the results of the user evaluation of simplified resuscitators conducted in India.
**OpenLMIS**

**Health Need Addressed**
A country’s logistics system should ensure that adequate quantity and quality of vaccines, essential medicines, medical devices, and supplies are always available to meet patient demand. In order to achieve this, logistics systems must be able to support:

1. Capturing accurate routine administration, dispensing, and consumption data.
2. Real-time, end-to-end logistics management from point of origin to service delivery point.
3. Demand forecasting, capacity planning, and modeling based on consumption.

Unfortunately, the historical paper processes used in certain developing countries are burdensome on the health worker and are not responsive enough to prevent stockouts of essential medicines.

**HealthTech V Solution and Potential Impact**
Through improved reporting and data use, the efficiency of the supply chain should improve so that medicines are available where and when they are needed. USAID pass-through funding to HealthTech V filled a critical gap for this work in Year 2 until other USAID and donor programs carried this work forward.

**Goals and Outcomes of the DIP**
The goal of this DIP was to extend capabilities of an open-source, scalable, and sustainable electronic logistics management information system (OpenLMIS) for requisitions, order processing, and system administration to address supply chain issues such as poor data for supply chain decision-making, poor quantification and forecasting of commodities, poor distribution channels and storage, and poor stock inventory management.

**Status of Technology and Results as of September 2016**
Status of technology: Field implementation.

No additional investments were made to OpenLMIS through HealthTech V after 2013. However, the system has currently been implemented across five countries (Tanzania, Zambia, Mozambique, Benin, and Cote d’Ivoire) with funding from USAID and others. In addition, the Bill & Melinda Gates Foundation is funding a re-architecture of the software and the development community to improve the long-term sustainability that HealthTech helped to catalyze. PATH continues to be engaged through integration of GS1 standard barcode functionality to improve automated track and trace of health commodities.

**Plans for the Future/Recommendations for Follow-Up Activities**
Country-specific functionality funded by the United States Agency for International Development (USAID) for Cote d’Ivoire, Tanzania, and Zambia are at risk of being deprecated during the re-architecture efforts. Ongoing governance and investment by USAID will be needed to ensure the customizations are upgraded and integrated into the new versions to be released in 2017.
Paper Applicator for Microbicide Delivery

Health Need Addressed
HIV/AIDS is the leading infectious cause of adult mortality worldwide. Women, especially those in developing countries, bear the disproportionate burden of the epidemic. In Africa today, women are 1.3 times more likely than men to be infected with HIV, and young women aged 15 to 24 are 2.5 times more likely to be infected than young men. It was estimated that at the end of 2003, 5.3 million adults and children in South Africa and 5.1 million adults and children in India were living with HIV.

Microbicides could provide urgently needed options for women seeking protection from HIV and other sexually transmitted infections. With numerous microbicide products in preclinical or clinical trials, most research has focused on the safety and effectiveness of candidate products, with much less research targeted on devices for delivering these products. Prefilled, plastic, single-use applicators are being used to deliver microbicide gels in the majority of clinical trials. However, prior research has indicated that acceptable, low-cost, user-filled applicators are an important alternative for microbicide introduction in developing countries.

HealthTech V Solution and Potential Impact
A user-filled paper applicator that is low cost, easily disposed of, and acceptable to women could be an important option for microbicide gel delivery in low-resource settings. This delivery mechanism, if proven to be safe, effective, and acceptable for delivery of microbicide gels, could contribute to reducing a women’s risk of becoming infected with HIV.

Goals and Outcomes of the DIP
The goal of this DIP was to evaluate whether a user-filled, paper applicator was a safe, acceptable, and appropriate delivery mechanism for tenofovir (TFV) gel and would be available for introduction and use with TFV, or other microbicide gels, in low-resource settings.

Outcomes:
- Facilitated discussions between ProPreven (a joint venture set up for the manufacturing and distribution of TFV gel), Tekpak (manufacturer of paper applicator), and CONRAD (regulatory sponsor for TFV gel) to inform microbicide commercialization strategies in South Africa and elsewhere.
- In support of microbicide commercialization efforts, conducted a manufacturer scan in China, India, and South Africa to identify companies that could potentially manufacture low-cost gel applicators. The scan identified nine companies in China, India, and South Africa that met manufacturing and commercialization criteria and recommended them for future in-depth assessment.
- Developed lab tests to support bench testing with the Tekpak paper applicator and TFV gel to assess optimal time for filling paper applicators prior to use and various cleaning methods for re-use. These results were intended to support microbicide introduction efforts with TFV gel with paper applicators. However, due to the results of the FACTS 001 trial, it was jointly determined with CONRAD that this activity would no longer move forward; thus, these activities did not occur.
- In collaboration with CONRAD and CAPRISA (Center for the AIDS Programme of Research in South Africa) PATH supported the development of a study to assess the acceptability of the paper applicator for TFV delivery among women in South Africa. The study was intended to inform future introduction and commercialization efforts with TFV gel. However, due to the results of the FACTS 001 trial, a phase 3 trial which tested whether a TFV gel could prevent HIV and herpes infections in women and which did not show reduction in HIV infections, it was agreed by all study partners that the study development be ceased. This occurred prior to study initiation; thus, no research activities took place.
Status of Technology and Results as of September 2016

Status of technology: In development.

Results from the manufacturer scan were shared with the donor to support future delivery and commercialization efforts for microbicide gels in low-resource settings. Other non-HealthTech funded activities in support of development of fast-dissolving tablets for microbicide delivery are ongoing.

Plans for the Future/Recommendations for Follow-Up Activities

Much of the work completed by HealthTech V surrounding low-cost microbicide delivery over the last five years focused on the delivery of TFV gel, as this was the leading gel candidate in the microbicide pipeline and was expected to be the first microbicide product approved for HIV prevention. In collaboration with CONRAD and other partners, HealthTech V sought to complement the field’s efforts by focusing on issues related to drug delivery in low-resource settings and how to ensure safe, acceptable, low-cost methods were made available for TFV delivery.

While the results from the FACTS 001 trial led to the cessation of activities to advance TFV gel for the prevention of HIV, it is anticipated that our work on gel delivery can be applied to alternative microbicide gels in the future, as needed.
Planning for Introduction and Scale: Synthesizing Best Practices and Lessons Learned

Health Need Addressed
Despite the existence of hundreds of technologies to improve global health, too few are available to save lives in the developing world, where morbidity and mortality burdens are greatest. An antiseptic that costs less than 10 cents could be used to reduce neonatal infection across South Asia. An injection that costs just 60 cents could halve a premature infant’s risk of respiratory distress. A set of pills costing less than one dollar could reduce maternal death from postpartum hemorrhage. All of these technologies exist, yet none reaches more than a fraction of the mothers and babies whose lives they could save. Those technologies that do eventually make it to those hardest-to-reach populations often take far too long to get there. An opportunity lies in synthesizing best practices across this product introduction continuum to help better define the optimal product introduction approach and enable practitioners to accelerate the introduction and uptake of lifesaving global health innovations.

Note: The above was written by the Center for Accelerating Innovation and Impact staff as part of their Best Practices in Planning for Introduction and Scale concept note shared with PATH in October 2013.

HealthTech V Solution and Potential Impact
PATH through HealthTech collected and synthesized examples of best practices and lessons learned and also designed and produced (in a ready-to-print format) the Center for Accelerating Innovation and Impact’s (CII) guide for planning introduction and scale-up, which CII then disseminated within USAID and to the broader global health community. HealthTech collaborated closely with CII staff throughout the project.

Target users of the guide for introduction and scale-up include USAID itself (for internal training and education) as well as broader nongovernmental organizations, stakeholders, and collaborating partner participants in the global health field. The ultimate beneficiaries will be developing-country citizens—through more efficient, effective introduction and scale-up of health innovations.

Goals and Outcomes of the DIP
Support for USAID’s CII in achieving its goal of developing and disseminating a comprehensive guide for effective planning for introduction and scale-up of global health innovations.

Outcomes:
- HealthTech delivered the ready-to-print final document to USAID CII at the end of 2014 and participated in USAID CII’s formal launch of the document in February 2015.
- Based on feedback HealthTech has received from USAID CII, the guide has been received very positively both within USAID and in the broader global health community.

Status of Technology and Results as of September 2016
Status of technology: Introduced; available in print and online.

HealthTech V completed this work in late 2014. The Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations final document was published and launched in February 2015 and broadly disseminated by USAID CII and many other organizations.
Plants for the Future/Recommendations for Follow-Up Activities
There is no specific follow-up regarding this project, but PATH staff continue to use the publication and tools and USAID CII continues to involve various PATH staff in providing input as they develop additional tools to support the innovation and scale-up of global health technologies.
SILCS Diaphragm, a Nonhormonal Barrier Method for Contraception and Dual Protection

Health Need Addressed
More than 220 million women worldwide have an unmet need for family planning. This unmet need leads to approximately 80 million unintended pregnancies annually, which has lifelong consequences for women, families, and communities, particularly in low-resource settings where the need is greatest. The global demand for family planning is expected to grow 40 percent by the year 2050. Guttmacher Institute analyses suggest that nearly 25 percent of women with an unmet need for family planning are not using contraceptives because of concern about side effects, because they have sex infrequently and want a method that offers protection just when they need it, or because they need a method to use while breastfeeding. Access to a nonhormonal barrier method could help meet the needs for some of these women.

Contraceptive diaphragms provide safe, reliable, and inexpensive contraception for women who cannot or do not want to use hormonal methods or an intrauterine device (IUD) or whose partner will not use condoms, but diaphragms have been deprioritized by family planning programs. This is due to challenges with supply and provision, as well as provider bias toward provider-dependent and hormonal methods, which have the potential to be longer lasting and more effective.

The SILCS diaphragm was developed through a user-centered process to be easy to use—especially for new users. Its contoured spring allows a single-size device to fit most women. The single-size design simplifies supply and provision; no pelvic exam is needed to determine the diaphragm size. The SILCS diaphragm expands women’s options for user-initiated contraception. Its greatest health impact may be in regions with low contraceptive use and high unmet need for birth spacing methods. It also can serve as a back-up method for women when clinics experience stockouts. PATH licensed the SILCS technology to Kessel medintim GmbH, which markets it under the name Caya® contoured diaphragm. As of 2016, the Caya diaphragm is marketed in more than 25 developed and middle-income countries. Early introduction experience is being used to generate awareness and build confidence for developing-country introductions.

HealthTech V Solution and Potential Impact
Project activities focused on advancing the commercialization of SILCS over five years by validating a contraceptive gel for use with the diaphragm in developing countries (Contragel® or a microbicide/contraceptive gel); conducting developing-country market assessments, cost-effectiveness/health impact assessments, and demonstration studies to assess the value proposition for SILCS as both a barrier contraceptive and as a microbicide delivery system for dual protection; and then building strategies for market introduction, developing regulatory submissions, and scaling up production to bring SILCS to key developing-country markets.

Goals and Outcomes of the DIP
The goal of this DIP was to advance the commercialization of the SILCS diaphragm (SILCS) by creating supply and building demand, conducting developing-country assessments to build the value proposition for SILCS introduction, pursuing regulatory approvals, and building evidence for appropriate gels to be coupled with the device.
Outcomes:

• Caya diaphragm registrations in Europe and United States have been achieved. These approvals by stringent regulatory authorities are facilitating approvals in other countries, and they allow “fast track” approval in developing countries such as Nigeria and Uganda.
• Women’s access to nonhormonal contraception has been improved through market introduction of the Caya diaphragm in 28 countries since 2013.
• Caya production was optimized and scaled up to achieve low-cost products appropriate for developing-country markets.
• Early market introduction experience in developed and middle-income countries has generated awareness and interest by family planning providers and consumers in developing countries; the Caya diaphragm is reinvigorating interest in diaphragms globally.
• International and national nongovernmental organizations, social marketing organizations, and country-level partners are now engaged in considering/planning for Caya introduction in developing countries based on results from health systems assessments, market research, and cost-effectiveness health impact modeling showing there is a role for the Caya diaphragm in low-resource settings.
• Caya desirability as a contraceptive for women seeking an alternative to hormonal contraception or who cannot use an IUD or condoms is confirmed.
• Caya introduction is breaking down myths about who is interested in using a nonhormonal barrier method. Consumer data from three years of Caya introduction show that Caya is used by women across a range of ages and partnership status. The percent of young women (18 to 25 years old) and women previously not using a contraceptive method has increased across the three years of market introduction as knowledge spreads about this new method. Data from SILCS studies show that women (and their partners) in low-resource settings find SILCS acceptable and find ways to wash and store this reusable device.
• CayaGel/Contragegel has been validated through clinical studies for safety, acceptability, and effectiveness. CayaGel provides an alternative for women who cannot or do not want to use N-9 contraceptive gel, and it opens the way for Caya diaphragm + CayaGel introduction in countries where no diaphragm has been available for decades.
• Clinical evidence has been generated demonstrating the acceptability and barrier effectiveness of the SILCS diaphragm used with no gel. SILCS + no gel performed nearly as well as SILCS + Contragegel or SILCS + N-9 gel in the postcoital study of barrier effectiveness. This lends additional support for the strategy of women using SILCS even where no contraceptive gel is available, or when cost of resupply of the contraceptive gel is a barrier.
• Feasibility, acceptability, and cost-effectiveness of SILCS as a barrier contraceptive has been confirmed in developing countries through health systems assessments, market research, and economic modeling, providing a rationale to support future introduction where providing a nonhormonal barrier could improve women’s contraceptive options.
• The value proposition and consumer preference for SILCS + microbicide gel as a multipurpose prevention technology (MPT) has been confirmed by key target audiences, especially in South Africa, through health systems assessment, market research, and the SILCS gel delivery study, as well as discreet choice experiment (DCE) data.
• Caya diaphragm supply and distribution has been ensured through the selection of Kessel medintim GmbH as the commercialization partner. Kessel established manufacturing, optimized production, and achieved the low cost required for developing-country markets. The Kessel team determined that Caya is the most important product in their portfolio at this time and have committed resources to develop partnerships for developing-country introduction. As of 2016, Kessel is working with Nigeria, Uganda, and India, where local partners and strategies for marketing have been identified.
Status of Technology and Results as of September 2016
Status of technology: Introduced; commercially available.

The Caya diaphragm and CayaGel have been marketed in 28 developed and middle-income countries as of 2016. Preparation is underway for market launch in Nigeria in late 2016/early 2017.

Plans for the Future/Recommendations for Follow-Up Activities
Kessel medintim GmbH and their distribution partners will continue marketing and distribution of the Caya contoured diaphragm in developed and middle-income countries; Kessel is building partnerships to bring the Caya diaphragm to low-resource countries. Kessel is prioritizing countries where the European/US approvals for the Caya diaphragm and European approval for CayaGel facilitate registration, local stakeholders are supportive of introduction, and women have a high unmet need for family planning. Registrations in Malawi and Zambia are complete, but plans for introduction were stalled by the Expanding Effective Contraceptive Options project. Registration in Nigeria and Uganda are underway. Product launch in Nigeria is scheduled for late 2016/early 2017. In India, Kessel has signed a memorandum of understanding with the Indian nonprofit organization HLLFPT to train providers and seek funding to pilot-test Caya introduction through family planning clinics across multiple states.

Recommendations/future actions:

SILC/Caya as a contraceptive
• USAID should consider procurement of CayaGel for use with the Caya diaphragm in countries where USAID or its partners are considering Caya introduction. The safety and barrier effectiveness data of Caya diaphragm used with CayaGel from the CONRAD studies, combined with decades of good consumer use experience in Europe, demonstrate CayaGel is safe, effective, and acceptable when used with a diaphragm.
• USAID, Kessel, and other partners involved in Caya introduction should seek opportunities for an introduction study to assess consumer uptake, acceptability, and satisfaction with the Caya diaphragm when used with gel compared to Caya used without gel. Although clinical studies show this is a feasible strategy, it is important to understand from a consumers’ perspective the relative pros and cons of this, and also to build education and messaging for providers before advocating that Kessel introduce Caya diaphragm in this manner.
• USAID, Kessel, and other partners involved in Caya introduction should seek opportunities for an introduction study to assess consumer uptake, acceptability, and continuation using Caya based on different service-delivery strategies and also to assess levels of interaction with the health system and family planning providers to develop appropriate strategies for Caya introduction.

SILCS/Caya as a multipurpose prevention technology
• USAID, Kessel, and other partners should continue to build evidence of the safety, effectiveness, and acceptability of using Caya with a microbicide gel as a multipurpose prevention technology by incorporating Caya as a delivery system into clinical studies for microbicides being developed, such as PC1005 or tenofovir gel or others. Data from the SILCS market research, the SILCS Gel Delivery Study, the health systems assessment, and the cost-effectiveness model all suggest that SILCS + microbicide gel as an MPT is perceived as highly desirable for some audiences in South Africa. Women are much more interested in SILCS + microbicide than SILCS as a contraceptive or a microbicide for HIV protection alone. The discrete choice experience data in South Africa suggested that SILCS + microbicide gel was preferred over other HIV prevention strategies (such as pre-exposure prophylaxis [PrEP], vaginal ring, injectable antiretroviral drugs [ARVs], and condoms) by young women and those not in a partnered relationship, specifically because it
provides protection from both unintended pregnancy and HIV and other sexually transmitted infections.

- Kessel, Queen’s University Belfast, and others should continue to seek funding to further test and develop SILCS as a controlled-release delivery system for ARVs. This has shown proof-of-concept, as well as drug delivery in bench testing with dapivirine for up to one year. Given the growing evidence that Caya diaphragm is a desirable method for some women, the concept of Caya as a sustained-release delivery system that could also protect from HIV deserves consideration.
**Predevelopment Activities**

Predevelopment activities support the identification and feasibility of health technologies for LMICs without incurring the significant investments or commitments that advanced projects require. Funding for HealthTech V predevelopment activities has had a catalytic effect by exploring and nurturing promising technologies. Also, predevelopment activities support early proof of concept and feasibility, which provides confidence and evidence to donors as well as private companies and foundations that in turn can support more extensive product development. This leverage can advance promising technologies from the research phase of the development pipeline to widespread and sustained use. Funding for predevelopment activities was allocated in Years 2 and 3 of the HealthTech V project only, greatly reducing the capacity of the PATH team to respond to unanticipated and promising innovation. This type of flexible yet modest investment is critical to support the identification and early-stage investigation of the potential of innovation for health system fit and market sustainability in LMICs.

<table>
<thead>
<tr>
<th>HealthTech V Predevelopment Activities</th>
<th>Project Name</th>
<th>Description</th>
<th>Status and Next Steps</th>
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<tbody>
<tr>
<td></td>
<td>Diagnostic for preeclampsia and eclampsia</td>
<td>The project goal is to focus on identifying the current best methods and technologies for screening pregnant women early in their pregnancies to determine who might be at risk for preeclampsia, thus reducing the mortality and morbidity of this condition.</td>
<td>In Y2 we found that there was no expert consensus regarding the ideal biomarker and test method for preeclampsia screening. Large pharmaceutical companies are working on test development using angiogenic factors. We determined that it was prudent to wait for further developments and results in clinical research and in the commercial sector. Since then, the report on predevelopment activities has been used as a foundation for subsequent thinking and PATH submitted and received an award from Saving Lives At Birth in 2014 to develop a low-cost, point-of-care screening and diagnosis of preeclampsia/eclampsia through urine-based biomarkers.</td>
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<td></td>
<td>Local manufacture of the noninvasve hemoglobin measurement device</td>
<td>The purpose of this work was to support time in Kenya for a commercialization officer to meet with manufacturers to understand local manufacturing capacity with regard to manufacture of a low-cost noninvasive hemoglobin measurement device using the Masimo Corporation’s original equipment manufacturer technology.</td>
<td>This project was concluded in Y2 and helped create the foundation of a project funded through other sources which lead to a technology transfer to a local manufacturer in South Africa.</td>
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|                                        | Magnesium sulfate dilution bottle | PATH adapted the concept of a dilution bottle to simplify the process of magnesium sulfate (MgSO₄) administration. The dilution bottle contains a 50% MgSO₄ solution and is pre-marked | The concept of both the MgSO₄ and water for injection dilution bottles was evaluated in Ethiopia and Uganda in January 2015. The results of this concept evaluation were analyzed, and the report was disseminated in May 2015. Our field evaluation of the dilution bottle concept furthermore revealed that health care professionals
with a fill line. This MgSO₄ dilution bottle can facilitate the safe calculation of required doses by obviating the need to remember complex equations for dilution, thus minimizing the chance that the wrong dilution might be administered. The bottle could also reduce the burden associated with procurement and inventory control since only one type of dilution bottle must be procured and stocked for the treatment of preeclampsia and eclampsia. The aim of the project was to evaluate technical feasibility and commercial viability of such a MgSO₄ dilution bottle to ascertain how we should best proceed with this concept.

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**Magnesium sulfate job aid**

PATH, in collaboration with the University of Washington, developed a mobile application for magnesium sulfate (MgSO₄) administration, which includes a dosing calculator and detailed checklist based on the World Health Organization’s protocol. This application is a job aid designed specifically to address the challenges with correctly calculating MgSO₄ dosage.

In December 2013, PATH conducted a small-scale, design-stage user evaluation in Kenya in collaboration with the APHIAplus Western program. The application was validated by health care providers in Kenya; health workers felt it was an easy-to-use valuable tool and, overall, were enthusiastic about the use of mobile devices. With predevelopment funding, HealthTech updated the content of the MgSO₄ application, incorporating the feedback received from users in Kenya. A final prototype was developed and the project was included as a Saving Lives at Birth 2014 finalist but not an awardee. PATH has leveraged funding from Health Enabled through the UNCoLSC to finish the application and make it available widely through download at no cost from the Google Play Store.

**mPneumonia pilot**

PATH collaborated with the University of Washington to develop an innovative cell-phone–based application to improve frontline health workers’ ability to manage childhood pneumonia. Our mPneumonia application integrates a digital version of Integrated Management of Childhood Illnesses protocol and applications for assessing respiratory rate and oxygen saturation into a user-friendly diagnostic.

Predevelopment funding supplemented a larger effort that was funded by the United Nations Commission on Life-Saving Commodities. Ghana was selected as the country setting and Kintampo Health Research Center as the implementing partner. We created an initial version of the mPneumonia application for field testing (Phase 1) conducted in Ghana in March 2014. Based on usability testing among end users conducted in Phase 1, refinements were made and an improved iteration of the mPneumonia application was produced for the pilot study (Phase 2). The results of the design-stage qualitative pilot study provided...
and management algorithm for childhood pneumonia and other childhood illnesses. Through field testing and a small pilot study in Africa, the team assessed the feasibility, acceptability, and usability of the mPneumonia application.

<p>| Opinion paper: Uterine balloon tamponade | HealthTech used predevelopment funding to research and write a paper on the use of uterine balloon tamponades for treatment of postpartum hemorrhage (PPH) that will be submitted for publication in a peer-reviewed journal. The paper will focus on identifying key research questions and gaps in evidence that need to be addressed to inform introduction and scale-up of the technology within maternal health programs. Working closely with the knowledge services team at PATH, keywords and search terms were identified, and a literature search was initiated. Editors at two journals were contacted to assess interest level in an opinion piece on the uterine balloon tamponade. We received positive feedback and were encouraged to proceed if we had some evidence-based data to support our arguments in favor of use of uterine balloon tamponade for severe PPH. There was not a great deal of interest in an opinion piece or a literature review. The PATH team used the work completed with predevelopment funding as the basis for a paper modeling impact of the uterine balloon tamponade on lives saved. The paper has been submitted for publication to <em>BMC Pregnancy and Childbirth</em>. |
| Participation in best practice pneumonia demonstration projects roundtable | HealthTech supported participation in a roundtable discussion on Best Practice Pneumonia Demonstration Projects in New York in April 2013. The roundtable is an initiative of the Pneumonia and Diarrhea Working Group chaired by United Nations Children’s Fund and the Clinton Health Access Initiative and is in support of the United Nations Secretary-General’s <em>Every Woman, Every Child</em> movement. A HealthTech V staff member attended the pneumonia roundtable and successfully represented PATH with a presentation on pneumonia innovations and a panel discussion. She also presented on pneumonia diagnostics on behalf of Debbie Burgess from the Bill &amp; Melinda Gates Foundation. |
| Participation in an expert consultation meeting: Consultation on UBT research | In July 2014, two maternal health experts from PATH attended a meeting in New York, NY, organized by Gynuity Health Projects and Massachusetts General Hospital. The meeting convened experts on management of PPH and research design to discuss appropriate research strategies for evaluating the effectiveness and safety of using a uterine balloon Feedback from the experts on product design and key requirements was sought. Most experts stressed the need to keep the device simple and low cost. Since the meeting’s main agenda was to discuss research needs to build a strong evidence base for the technology, it was suggested we consider assessing “new” PATH devices against the Bakri balloon and the standard of care, when it becomes available. |</p>
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<th>Study</th>
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<td>Tamponade (UBT) in the management of cases of PPH.</td>
<td>While the UBT has proven to be successful in pilot studies, this was an opportunity to explore strategies to evaluate the impact of the device before this method is rolled out on a larger scale.</td>
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<td>Sickle cell disease literature review and technology landscape</td>
<td>HealthTech supported a literature review of disease prevention, diagnosis, management, and treatment of sickle cell disease in newborns and produced a landscape of technologies associated with the continuum of care. These results will be used to identify technology innovation ideas for potential future development.</td>
<td>The literature review was completed and submitted to USAID on May 15, 2014. This background paper became the basis of subsequent funding requests related to development of technologies across the continuum of care in sickle cell disease diagnosis and management. As a first step and with non-USAID funding, PATH is currently conducting early stage development work around a point of care diagnostic for sickle cell disease in newborns.</td>
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<td>Upright resuscitator video analysis</td>
<td>This study was undertaken to determine if the ventilation technique used during simulated neonatal resuscitation with the conventional and upright resuscitator could be correlated with lung function results, such as the tidal volume and peak inspiratory pressure. These criteria, if identified, may be useful in training programs. The objectives of this effort were to (1) review the key components in the method of providing bag and mask ventilation that are likely to influence ventilation and correlate these with key lung function parameters, such as tidal volume and peak inspiratory pressure; and (2) identify components, if any, that may be useful in training programs to promote adequate ventilation without producing excessive tidal volumes and peak inspiratory pressures.</td>
<td>A manuscript was submitted to Respiratory Care in September 2016.</td>
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Lessons Learned

The HealthTech V project offers many lessons to those interested in product development, introduction, and scale. Notably, we brought the expertise learned by developing products for the low-resource setting over the last 30 years to the collaborative creation of the USAID Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations. The case examples in this guide were hand-picked by HealthTech V staff to highlight critical bottlenecks and solutions to product development and scale.

The HealthTech V project was remarkable in its focus on the far right end of the research-to-use continuum. Based on this experience, we offer a number of lessons learned that will be important for donors and program implementers to keep in mind while looking forward to implementation research, introduction, and scale-up of innovation. Some lessons learned over the last 5 years include:

1. We concur with the aforementioned guide’s focus on the need for a full-time person (or uptake coordinator or product manager) to nurture the product along the research-to-use continuum. This role must coordinate all relevant stakeholders, translate information back and forth between the global and country level, and inspire and manage country-level expectations and actions. A critical lesson is that ministry of health (MOH) interest and readiness must be cultivated alongside nongovernmental implementing partners so that country-level activities do not occur in advance of when the MOH is ready for them. As the product moves from the introduction to scale-up phase, the MOH should take more significant roles and stronger leadership. The uptake coordinator therefore must closely work with the MOH and support their leadership role to accelerate the introduction/scale-up of the product.

2. It is more likely for the uptake coordinator role to be assumed by a party from a neutral organization so that they are able to engender collaboration from other relevant stakeholders including other implementing organizations. The person and organization in this role must be trusted by all relevant stakeholders including the MOH.

3. Ministries of health need tools to identify technology gaps and to evaluate existing technologies and products to fill those gaps.

4. Policy and strategy development do not occur in a linear order. Sometimes countries move forward with a strategy prior to changing policy and/or having clear consensus on their plan. This can create delays to the overall introduction and scale-up process (for example, if a country or international agency purchases a product that does not actually meet the needs because the national strategy is still in flux).

5. Decentralized health systems require additional resources in terms of time and money to develop strategy and coordinate rollout. Diffusion of information from the national to subnational level, acquisition of buy-in at the subnational level, and sustainable programing at the country level takes years. These efforts need to start as soon as possible and not wait for the strategy to be developed fully. Ideally, to avoid time lags between strategy development at the national level and implementation at the subnational level, key stakeholders at the subnational level should be involved in the strategy development.

6. Implementation research is important to adjust program reality to expectation. Therefore, implementation research should be carefully designed to answer policy and programmatic questions. Any information collected during implementation research must be clearly specified with the aim of informing national strategy development.

7. Countries do not necessarily have the process and knowledge to effectively use results of implementation research for policymaking or programming. Involving the MOH in generating research questions, informing them of interim results, and disseminating results and discussing their
implications with the MOH will enable implementation research results to be effectively translated into policymaking and sustainable programming.

8. Implementation research does not always occur prior to policy alignment. Likewise, implementation research may not always occur under a strict research protocol but rather as a phased implementation effort with a rigorous monitoring and evaluation system.

9. Uninterrupted availability of good quality products is a critical component of sustainable programming. Medical products do not always require approval from stringent regulatory authorities in developed countries. Assessing the characteristics of and risks associated with medical products is important to determine feasible and credible ways to assure quality in addition to national-level regulatory authority. Requiring the most stringent international regulatory standard regardless of the product characteristics and risks may inadvertently hinder the product introduction.

10. It is critical to identify when and how product failure could occur and actions that could be taken; use this information to develop a risk mitigation plan.

11. Practical post-market surveillance strategies must be determined in advance of new product introduction. Although this falls under the responsibilities of national regulatory authorities, there might be a role for nonprofit organizations to play until national regulatory authorities in low- and middle-income countries develop their own capacity and capability in this regard.

12. Assess national planning capacity to translate donor-funded pilot efforts into national scale-up. Donors must select the right partner and fund the right process to work with government to develop a country-led sustainable implementation effort.

13. Securing government budget or donor funding for product introduction and scale-up requires a multisectoral approach. It is useful to involve multiple departments within the MOH, other government agencies, and donor agencies in discussion as early as possible.

14. Prepare for years of donation for new and underutilized commodities. The procurement budgets of many countries are severely constrained such that existing commodities are not always available when and where needed. Adding new (even if low cost) products and significantly increasing the quantities recommended of existing products may not be feasible within the existing budgets of countries for a number of years regardless of the affordability and impact.

15. For the global community, an information repository is helpful, but this may not prove to be helpful at the country level unless knowledge transfer/exchange between the global and country levels is well planned.

16. Understanding how to incentivize manufacturers to use their private-sector channels for product distribution and demand generation can be helpful in improving access. However, use of private-sector channels requires careful consideration. Not all counties will have active, sustainable private-sector channels and not all products are suitable for private-sector distribution. In addition, if the in-country regulatory system is too weak to provide effective oversight to the private-sector channels, using these channels may have unintended adverse consequences such as distribution of unregistered or suboptimal quality products.

17. Market research data can highlight consumer behavior, cultural practices, and gaps in access to key interventions/products, but MOH staff are often unfamiliar with market research firms and processes and may not know how to best utilize these data.
The HealthTech V project has proven to be a successful vehicle for the development, introduction and scale-up of health technologies. The project has been able to leverage modest project funding to identify and complete key activities to drive product introduction and scale-up. Our dedication to increasing holistic market access to appropriate technologies is evidenced by the high-quality deliverables submitted consistently by the HealthTech V project.
The Many Faces of HealthTech V