

DIRECTIONS

IN GLOBAL HEALTH

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SPECIAL
ISSUE ON
**Maternal
and newborn
health**

Safeguarding the lives of mothers and babies

PATH builds on innovation to create and expand high-impact interventions

Many countries have achieved remarkable improvements in maternal and child health over the past few decades. Death rates among young children, for example, have steadily declined around the world. Some researchers have recently found evidence of a major decrease in maternal mortality since 1980.

Progress has been uneven, however. Although some countries are on track to meet Millennium Development Goals for maternal health, most are not. Also, newborn mortality rates have resisted improvement.

PATH has worked for more than 30 years to improve health for mothers and their young children, including newborns. Our goal is to scale up use of promising packages of technologies, tools, and interventions that build on innovative solutions for long-standing health problems.

This special issue of *Directions in Global Health* features PATH's work to improve maternal and newborn health. Much of this work focuses on advancing use of low-cost technologies to protect women's health, ensure safe birth, and provide a healthy start for newborns. In collaboration with others, we are making progress against some of the most intractable health challenges for mothers and babies in the poorest parts of the globe.



PATH/Julie Jacobson

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 **PATH**
A catalyst for global health

Advancing technologies to save newborns

Low-cost interventions can enhance health system performance

Project area

Technologies to improve newborn health

Location

Global

Methods

Clinical trials, health system strengthening, market research, product evaluation, public-private partnerships, technology development, technology transfer, training, vaccine development

Partners

Numerous partners include Bharat Biotech International, Boehringer Ingelheim, GlaxoSmithKline, ICDDR,B, John Snow International, Johns Hopkins University, Laerdal Medical, Merck, Murdoch Childrens Research Institute, Nepal Family Health Project, Nepal Ministry of Health, RTM International, Save the Children, Shantha Biotechnics, UK Department for International Development, UNICEF, United Nations Population Fund, US Centers for Disease Control and Prevention, World Health Organization, and Wuhan Institute of Biological Products.

Funders

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For more information

Please contact Patricia Coffey, senior program officer, at pcoffey@path.org.

THE FIRST FOUR WEEKS OF LIFE are especially risky for babies in developing countries. Breathing problems, infections, and other conditions kill more than 4 million newborns each year. Many of these deaths, however, can be prevented with simple interventions.

Much of PATH's work to safeguard the health of newborns has focused on low-cost technology solutions. Examples include affordable resuscitators to help struggling newborns breathe, simple kits for healthy outcomes during home births, and tools and techniques to prevent mother-to-child transmission of HIV. We collaborate with public- and private-sector partners to accelerate development of appropriate technologies and then work with governments, communities, and others to strengthen health systems and ensure that health workers can use the new technologies effectively.

Expanding use of low-cost neonatal resuscitators

Newborn deaths account for nearly 40 percent of all mortality among children under five years old, and most of these deaths occur in the first week of life.¹ Experts estimate that two-thirds of these babies can be saved if skilled health workers perform effective health measures at birth and during the first week of life.

To prevent death or permanent disability from breathing problems at birth—which kill nearly a million babies each year—PATH has worked to expand the availability and use of low-cost neonatal resuscitators, especially in Africa and Asia. Project



PATH/Patrick McKern

Expanded use of low-cost resuscitators promises to prevent many newborn deaths.

staff first surveyed experts in neonatal health to determine practices and preferences for these devices in developing countries. The team also inventoried available resuscitators and evaluated their performance, functionality, safety, ease of assembly, and construction, with emphasis on reusable devices that cost less than US\$30. PATH then published a guide to neonatal resuscitators, available on our website, to help developing-country program managers select the best products to meet their needs. UNICEF recently used the guide to identify manufacturers that could supply high-quality, affordable devices.

PATH has also researched markets, distribution systems, and facility use of resuscitators in Africa and India. The findings have been used to raise global awareness about the need for these devices in low-resource settings. In India, the results have informed efforts by the National Rural Health Mission to reduce newborn deaths.

PATH is broadening our work in this area by assessing suction devices for clearing mucus from

newborns' airways. Additionally, PATH is an implementing partner in the Global Development Alliance: Management of Birth Asphyxia, an effort sponsored by the US Agency for International Development to promote public-private partnerships that stimulate economic growth and address health and other issues in developing countries. As part of this effort, PATH is collaborating with a manufacturing company to create global market-development plans focused on increasing the availability of high-quality, affordable resuscitators, suction devices, and training mannequins in low-resource settings.

Providing simple newborn care kits to save lives

Nearly half of all births in developing countries occur at home, often without a skilled attendant. To reduce risks for babies born outside health facilities, PATH partnered with a women's cooperative in Nepal to develop a simple clean-delivery kit and collaborated with the World Health Organization (WHO) to create a guide for developing locally produced kits. Subsequent evaluations demonstrated the PATH kit's acceptability to users and effectiveness for preventing infections among newborns and their mothers.

PATH recently began developing an enhanced newborn care kit. Contents may include soap for washing hands, clean string for tying the umbilical cord, a new razor for



Contents of an enhanced newborn care kit under development will facilitate behavior changes to reduce complications during home births.

Improving newborn care in South Africa

In South Africa, one of every three neonatal deaths is caused by breathing problems at birth. For the Maternal and Newborn Health Technology Initiative, PATH is expanding the accessibility, availability, and use of appropriate and effective neonatal resuscitators in KwaZulu Natal Province. Our integrated approach includes identifying low-cost resuscitators ideally suited for use in South Africa, conducting a participatory device evaluation with health workers to give voice to their preferences and needs, and training health workers in their use, as well as providing training in other practices to safeguard newborn health.

In another project, PATH and our partners have joined with the Eastern Cape Department of Health to reduce the impact of HIV and AIDS on babies. The project is based on an integrated approach to prevent transmission that delivers services throughout the continuum of care, from before pregnancy through the first months of the baby's life. The team is strengthening Eastern Cape Province's health systems, building the capacity of facilities and providers, increasing community demand for services, and integrating reproductive health into efforts to prevent mother-to-child transmission.

PATH / Amy MacIver



cutting the cord, a cap to keep the baby warm, and key messages in pictorial form to facilitate desired behavior changes. Once finalized and manufactured, the kit may be distributed to targeted countries and offered with related training and communications activities.

Improving umbilical cord care to prevent life-threatening infections

Infection of the umbilical stump is a common cause of death among newborns in developing countries. Research has suggested that cleaning the umbilical stump with a solution of 4 percent chlorhexidine, an antiseptic, within 24 hours of birth can markedly reduce the death rate.²

PATH is helping to develop and introduce a 4 percent chlorhexidine solution for low-resource settings,

beginning in Bangladesh. We developed product specifications and transferred them to a Bangladeshi pharmaceutical company for manufacturing high-quality chlorhexidine at a reasonable cost, then collaborated with a market research firm to evaluate the preferences of potential users and service providers for containers and applicators. PATH shared the study results with the pharmaceutical company to refine product design and market strategy.

This company is continuing to test the product's stability and is seeking regulatory approval to launch the product in the next year. PATH continues to prepare for product launch, anticipated in December 2010, by:

- Determining acceptable product pricing.

Protecting young children with vaccines

Increasing use of vaccines is a critical component of PATH's work to improve health for infants and other young children. PATH has worked, for example, to advance vaccines against rotavirus, the most common cause of severe diarrhea, which kills more than 500,000 young children each year.³ Two vaccines against rotavirus are already in use in North America and Europe. PATH has partnered with the GAVI Alliance, WHO, and US Centers for Disease Control and Prevention to conduct clinical trials to test the vaccines' safety and effectiveness among children in other parts of the world. Findings from Malawi and South Africa were a major factor in WHO's 2009 recommendation to include rotavirus vaccine in all national immunization programs. The results confirming safety and efficacy were published in *The New England Journal of Medicine* in January 2010. Results from Bangladesh, Ghana, Kenya, Mali, and Vietnam will be available for publication later in 2010.

PATH has also collaborated with emerging-country manufacturers to develop several promising new rotavirus vaccine candidates, which are key to improving affordability and ensuring a sustainable supply for widespread use. To support vaccine development, PATH has provided a "shared technology platform" for manufacturers to access needed training, methodologies, and materials. We have also provided technical support to manufacturers in India and Brazil and partnered with an Australian research institute on vaccine development.

Other examples of PATH's work to advance use of vaccines to protect newborns and other young children include:

- Improving coverage of vaccination against tetanus among both infants and pregnant women, who may transfer antibodies to newborns.
- Increasing use of vaccines to protect babies from hepatitis B at birth.
- Creating new vaccines against malaria, pneumococcal disease, and the main types of bacteria that cause diarrheal disease.
- Developing new formulation methods that protect vaccines from the potentially damaging effects of extreme heat or cold during storage and transport.
- Further expanding use of vaccine vial monitors, which are stickers placed on vials to monitor exposure to heat over time, showing health workers at a glance whether vaccine is spoiled.
- Through the Optimize project, contributing to development of flexible and efficient supply systems that will ensure all vaccines are delivered in good condition where and when they are needed (see the December 2009 issue of *Directions in Global Health*).

- Assessing product demand.
- Developing product introduction plans.
- Conducting workshops with key stakeholders to provide feedback on introduction plans.
- Obtaining regulatory approval for commercial product launch.

PATH is also conducting a landscape analysis to identify other countries that are well positioned to adapt the chlorhexidine product for cord care.

Rapidly delivering antibiotics to newborns in rural areas

More than a million newborns die each year from infections.¹ Although prompt treatment with antibiotics can prevent many of these deaths, getting these drugs rapidly to

newborns in developing countries can be challenging, especially in rural areas where hospitals and clinics are scarce and community health workers provide many essential services.

Penny Dawson



Prompt treatment with gentamicin in the Uniject device can save newborns from life-threatening infections.

To improve the odds for newborns with serious bacterial infections, PATH has advanced the use of gentamicin in the Uniject® device. The prefilled, easy-to-use device makes it feasible for community health workers and birth attendants to give antibiotics in community locations or homes when infections are first detected.

Because the device gives a fixed dose, PATH has supported work to determine safe and therapeutic fixed-dosing intervals for newborns in common weight ranges. PATH has partnered with an Argentine pharmaceutical firm to conduct research and development and pursue the product registration necessary to make gentamicin in Uniject commercially available.

The first field use of gentamicin in Uniject has occurred in Nepal.

PATH and our project partners recently evaluated use of the product by female community health volunteers to treat sick newborns in five villages. Results of the 2009 study suggest that volunteer health workers equipped with gentamicin in Uniject can provide effective, timely treatment for newborns with infections in areas where families are unable or unwilling to travel to health facilities.

Preventing mother-to-child transmission of HIV

Most of the more than 2 million children who have HIV acquired it from their mothers. HIV can be transmitted from mothers to their children during pregnancy, childbirth, or the postnatal period.

PATH has implemented a variety of interventions to prevent HIV transmission to newborns and infants, including counseling and testing for women, family planning, and promotion of appropriate infant feeding practices (see sidebar on page 7). We have also advanced technology solutions to reduce risk. Examples include:

- Developing a special foil pouch that enables nurses to send a single dose of nevirapine syrup home with pregnant women during antenatal care visits. The drug can then be given to newborns immediately after birth to help prevent HIV transmission.
- Providing technical assistance to scale up use of flash-heating, a low-tech pasteurization method that mothers can use to inactivate HIV in breast milk.
- Exploring use of solar energy as a heat source to inactivate HIV in breast milk and determining which environmental conditions ensure adequate temperatures for pasteurization.
- Assessing user acceptability of a prototype nipple shield to

inactivate HIV and prevent transmission during breastfeeding.

Scaling up use of technologies for greater impact

Simple interventions are available to drastically reduce the number babies who die within the first few weeks of life, and more, innovative solutions are in the works. By developing, introducing, and scaling up use of effective, low-cost technologies, PATH is helping to reduce deaths among newborns in the world's poorest and most remote settings. ■

A special foil pouch developed by PATH enables nurses to send nevirapine syrup home with pregnant women for giving to newborns to prevent HIV transmission.



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Uniject is a registered trademark of BD.

Nutrition

Nourishment when it's needed most

PATH uses technology and education to target nutrition problems

Project names

Infant & Young Child Nutrition (IYCN) Project
Ultra Rice® technology

Location

Global

Methods

Behavior change communication, capacity-building, efficacy trials, market development, operations research, policy development, public-private partnerships, technical assistance, technology development and introduction

Partners

IYCN: CARE, The Manoff Group, and University Research Co., LLC

Ultra Rice: Adorella Alimentos Ltda, Department of Biotechnology (Government of India), Christy Friedgram Industry, Global Alliance for Improved Nutrition (GAIN), Indian Institute of Crop Processing Technology, Naandi Foundation, Swagat Food Products (P) Ltd, Unión de Arroceros S.A., University of Toronto, World Health Organization

Funders

IYCN: US Agency for International Development

Ultra Rice: Bill & Melinda Gates Foundation

For more information

IYCN: Please contact info@iycn.org.

Ultra Rice: Please contact Dipika Matthias, project director, at dmatthias@path.org.

GOOD NUTRITION IS ESSENTIAL TO THE survival of infants and young children and to their health and productivity throughout life. Children who get adequate nutrition are at less risk for health problems, go further in school, and are more economically productive as adults.¹

Infants and young children who do not receive proper nutrition face a more threatening future. Undernutrition, as *The Lancet* reported in 2008, “is the largely preventable cause of over a third—3.5 million—of all child deaths.”²

Improving nutrition in developing countries is a vital part of PATH's work. We develop technologies to increase nutrients in a staple food; strengthen the systems and policies that address nutritional concerns; and encourage healthy feeding and nutrition behaviors, especially among pregnant women, infants, and other young children.

Focus on feeding young children

Poor nutrition in early childhood increases the severity of common diseases and the risk of stunted growth and death. To prevent these effects, the PATH-led Infant and Young Child Nutrition (IYCN) Project works to improve nutrition practices for children two years of age and younger and to enhance maternal nutrition. The project emphasizes infant feeding in the context of HIV/AIDS (see sidebar on page 7). IYCN operates in Africa, Asia, and Latin America and the Caribbean.

A key part of the project's strategy is support for and promotion of

exclusive breastfeeding for infants ages six months and younger followed by continued breastfeeding with appropriate complementary feeding for children ages 6 to 24 months. Although breastmilk has all the energy, nutrients, fluids, and antibodies that an infant needs during the first six months of life, from 6 to 24 months of age, children need complementary foods to ensure that they continue to grow and thrive.³

Community actions encourage better feeding

Because infant and young child feeding takes place outside of health centers, many of IYCN's approaches are community-based. IYCN trains leaders of mothers' support groups, for example, and works to enlist support for infant and young child feeding among influential members of the family—often grandmothers, mothers-in-law, and men.

The project focuses on building the capacity of both health workers and community volunteers to educate families. Since 2008, IYCN has trained 3,630 facility- and community-based health workers in five countries on infant, young child, and maternal nutrition.

The project also finds innovative ways to reach families. After conducting research in Zambia on community attitudes and practices regarding infant and child feeding, IYCN worked with partners to develop a 13-part radio program that encourages mothers to prevent malnutrition for their children and offers practical advice for feeding.

The program, which began airing on a popular radio station in January, introduces a topic—such as the common, harmful belief that infants less than six months of age need water and watery porridge to satisfy thirst—and airs a scripted fictional segment. The program concludes with a discussion, often with listeners calling in their questions. The project team is considering adding a radio quiz show to elicit discussion among their growing audience.

Expanding the reach of Ultra Rice® technology

In communities where complementary foods available to families lack some or all of the energy and nutrients young children require, innovative products such as fortified staple foods can help prevent malnutrition. On a large scale, fortifying staple foods with the missing micronutrients—such as iron or folic acid—can be cost-effective. It also allows people to get more nutritional value from the food they already eat.

To bring fortification to vulnerable rice-consuming communities, PATH developed Ultra Rice—manufactured “grains” that provide a customizable nutritional boost to consumers. Ultra Rice grains resemble locally milled rice grains in size, shape, and color, but they

are made from rice flour, selected micronutrients, and nutrient-protecting ingredients. The mix is combined and extruded—like pasta—through a rice-shaped mold and dye cut. When blended with locally milled rice, typically at a ratio of about 1 to 200, the result is nearly identical to unfortified rice in smell, taste, and texture.

Iron-enriched Ultra Rice is already integrated into the rice-based meals of some 60,000 children in India through a pilot project. In 2010, PATH plans to launch similar pilot introductions in Brazil, potentially reaching 200,000 children each day during the school year. Just one serving of rice will provide a child a third of his or her recommended daily allowance of iron, thiamin, folic acid, and zinc.

Stopping malnutrition before it starts

Heading off malnutrition before it happens—through best feeding practices and fortified staple foods—has the potential to avert the underlying cause of millions of deaths among children each year. PATH will continue to advocate for prevention, educate on best feeding practices, and innovate in developing technologies to help ensure good nutrition for children. ■

PATH/Satvir Malhotra



Ultra Rice technology is helping to improve nutrition for children in India.

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Ultra Rice is a registered trademark in the United States of Bon Dente International, Inc.

To keep infants free of HIV

Because HIV can be passed from a mother to her child through breastfeeding, HIV-positive mothers have sometimes been advised to avoid breastfeeding or stop breastfeeding early. But infants in developing countries who are not breastfed are at vastly increased risk for malnutrition and serious illnesses such as diarrhea and pneumonia, regardless of the mother’s HIV status. On balance, breastfeeding is usually the safest option for babies of HIV-infected mothers.

IYCN works with partners to ensure that HIV-positive mothers get support and reliable information on infant feeding. In Kenya, for example, IYCN has collaborated with

the PATH-led AIDS, Population, and Health Integrated Assistance Program II Western project and the Society for Women and AIDS in Kenya to train more than 400 volunteer counselors to integrate nutrition support into their community HIV activities. Counselors provide individual and group support to breastfeeding mothers and have reached more than 34,000 community members with infant feeding messages, helping to increase infants’ chances of HIV-free survival.

For additional information on PATH’s work to prevent mother-to-child transmission of HIV, see page 5.

Maternal health

Tools to protect mothers' lives

Technologies for safe pregnancy and childbirth

Project area

Maternal health technologies

Location

Global

Methods

Capacity-building, research and pilot studies, technology development and introduction, technology evaluation

Partners

Key partners include BD, Gland Pharma, Global Alliance to Prevent Prematurity and Stillbirth, Global Network for Perinatal and Reproductive Health, ICDDR,B, Instituto Biológico Argentino (BIOL), Johns Hopkins University, and the University of California, San Francisco.

Funders

Bill & Melinda Gates Foundation, John D. and Catherine T. MacArthur Foundation, US Agency for International Development under the HealthTech IV program

For more information

Please contact Patricia Coffey, senior program officer, at pcoffey@path.org.

IN LOW-RESOURCE SETTINGS AROUND the world, simple tools can save a new mother's life. An estimated 342,000 women each year die during pregnancy, childbirth, or the six weeks following birth, mostly in developing countries.¹ PATH is delivering interventions that prevent maternal deaths and address birth-related complications.

Despite substantial decreases in maternal deaths over the past few decades, the burden of maternal mortality remains high, especially in countries in sub-Saharan Africa and South Asia.¹ To further reduce deaths, PATH is expanding the use of technologies and interventions that address the leading causes of maternal mortality. Our goal is to ensure women have sustainable and affordable access to these important solutions, even when they give birth outside of health facilities.

Protection from hemorrhage

Postpartum hemorrhage (PPH) is the most common cause of maternal illness and death, accounting for approximately 25 percent of maternal deaths worldwide.² Many deaths can be prevented, however, with a proven, effective intervention: active management of the third stage of labor (AMTSL). The three-component process includes the use of uterotonic drugs to reduce bleeding (oxytocin is the drug of choice), controlled cord traction, and uterine massage after the placenta has been delivered.

In the absence of full AMTSL, the WHO recommends that women receive oxytocin when giving birth

in a health facility or at home when attended by a trained health worker. Because many women in developing countries give birth in settings not equipped to handle obstetric emergencies, PATH is conducting a three-year project with two goals: to facilitate adoption of AMTSL and to build evidence for the safe use of oxytocin delivered in the Uniject[®] device.

Prepackaged injections of oxytocin

The easy-to-use, autodisable Uniject injection device developed by PATH can be prefilled with a dose of oxytocin, allowing semiskilled midwives and other birth attendants to correctly administer the drug with limited training and increased safety. The device can also be packaged with another PATH technology, a time-temperature indicator that helps ensure that oxytocin has not been damaged by exposure to heat. The Uniject device is already widely used for delivering vaccines in low-resource and remote settings.

With our partners, PATH is carrying out rigorous evaluation and research to maximize the safe use of oxytocin and answer key questions about its delivery with the Uniject device. In 2007, PATH evaluated the use of oxytocin in Uniject among semiskilled midwifery assistants in Mali. Results informed the government's decision to allow all midwifery assistants to administer oxytocin and greatly expanded the availability of the drug to new

mothers. A 2009 pilot study in Guatemala also found oxytocin in Uniject highly acceptable and easy to use. Other pilot projects are planned for Ghana, Honduras, India, Nicaragua, and South Africa.

To ensure production and adequate supply, PATH is working with two oxytocin manufacturers—BIOL of Argentina and Gland Pharma of India—to package and sell the drug in the Uniject device at an affordable price. BIOL has made oxytocin in Uniject commercially available in Argentina and Guatemala and is actively seeking regulatory approval in other countries in Latin America and the Caribbean. Gland Pharma has obtained regulatory approval in India and is completing stability studies this year before seeking registration in other countries. Together, BIOL and Gland Pharma could produce around 2 million units per year.

A garment for lifesaving support

PPH requires immediate treatment to control bleeding, prevent or reverse shock, and stabilize the patient for safe transport to a hospital. Recent studies have indicated that a nonpneumatic

antishock garment can be used to apply pressure to a woman's lower body at the first signs of PPH to control blood loss and improve clinical outcomes. The reusable, wetsuit-like garment can be tightened with Velcro straps around the legs, pelvis, and abdomen to force blood to a woman's key organs, keeping her alive until she receives treatment at an emergency obstetric care facility. PATH is currently assessing several options to make the one-size-fits-all garment more affordable for developing countries while maintaining a high level of quality. We are also exploring global access strategies to ensure the garment is available to women in low-resource settings.

Other safe, low-cost tools that PATH is assessing for management of PPH include a balloon tamponade and intrauterine clotting agents.

Tools to address infection

Maternal sepsis, or severe infection after childbirth, is another important cause of pregnancy-related deaths and remains prevalent in developing countries, accounting for 15 percent of total maternal mortality.³ The condition is particularly common when women

give birth at home without the help of a trained health worker.

In addition to developing low-cost clean delivery kits to reduce the risk of infection (see page 3), PATH is examining the potential for affordable tools to diagnose common infections and other illnesses among pregnant women and new mothers. We are conducting a landscape analysis in three countries in Africa and Asia to identify common bacterial infections, determine available diagnostic tests, and understand the opportunities and challenges for uptake of potential new diagnostic tools. The findings will help inform future investment in maternal infection diagnostics. PATH is also investigating the need for an antenatal screening tool to measure pregnant women's hemoglobin levels and check for malaria, HIV, syphilis, and iron deficiency by using a single sample for a point-of-care test.

Sustained protection for mothers

PATH continues to expand its work to address maternal mortality, especially in light of Millennium Development Goals to reduce the maternal death rate. As technologies and interventions become more affordable and reach further into clinics and communities, more women will have a chance at lifesaving protection. ■

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Uniject is a registered trademark of BD.

Suellen Miller



The nonpneumatic antishock garment applies pressure to a woman's lower body to help control postpartum hemorrhage.

Reproductive health

Expanding women's options for family planning

Increased options and use mean better health for women and their babies

Project names

Depo-subQ provera 104™ in the Uniject® device, SILCS Diaphragm, Woman's Condom

Location

Global

Methods

Product development and introduction, user-centered design

Partners

Multiple partners include BD; California Family Health Council; Contraceptive Research and Development Program (CONRAD), Eastern Virginia Medical School; Instituto Nacional de Salud Publica; Khon Kaen University; Pfizer; Profamilia; Shanghai Dahua Medical Apparatus Co.; University of Pennsylvania; University of Washington; and University of the Witwatersrand.

Funders

Bill & Melinda Gates Foundation, The Lemelson Foundation, US Agency for International Development (through CONRAD and the HealthTech IV program), and others

For more information

Depo-subQ in Uniject: Please contact Sara Tiffit, project director, at stiffit@path.org.

Woman's Condom: Please contact Patricia Coffey, senior program officer, at pcoffey@path.org.

SILCS diaphragm: Please contact Maggie Kilbourne-Brook, program officer, at mkilbou@path.org.

FAMILY PLANNING LESSENS THE RISK of sickness and death for women. It reduces maternal mortality, for example, by reducing the number of pregnancies, the number of abortions, and the proportion of births at high risk.¹ The result is not only improved survival for women but also better health for children. In developing countries, a young child whose mother dies has up to a tenfold greater risk of death than one whose mother survives.²

PATH works to improve the availability and accessibility of family planning products and services around the world. Technologies we have advanced include the contraceptive depo-subQ provera 104™ in the Uniject® prefilled injection device, the Woman's Condom, and the SILCS diaphragm.

Increasing access to injectable contraceptives

Injectable contraceptives such as Depo-Provera® are increasingly popular with women around the world. One injection every three months provides a safe, effective, reversible, and discreet method to prevent pregnancy. Many women, however, cannot routinely get to clinics that offer this form of contraception.

Depo-subQ provera 104 (also known as depo-subQ) is a new subcutaneous formulation of the drug. Depo-subQ will soon be available in the Uniject device developed by PATH.

Depo-subQ in Uniject may help to increase women's access to injectable

contraceptives. Because the Uniject device is so easy to use, lower-level health workers will be better able to give injections in convenient community locations or in clients' homes. Availability of depo-subQ in Uniject may make it easier to give injectable contraceptives safely and effectively outside of clinics and strengthen clinics' injection services.

Depo-subQ in Uniject is expected to be available for use in developing countries in late 2011 or early 2012. In anticipation, PATH is collaborating with partners in Kenya, Malawi, Rwanda, Senegal, and Pakistan to plan early introduction in those nations. To provide information for global introduction, we are completing analyses of the product's logistics and supply chain benefits and developing demand scenarios. PATH is also coordinating inputs from collaborators that are contributing to the eventual global rollout of the product to countries identified as high priorities by the US Agency for International Development. To facilitate more widespread country introduction, PATH is disseminating information on all planning activities, models, and strategies to those interested in incorporating depo-subQ in Uniject into their family planning programs.

Redesigning the female condom

Although a female condom has been on the market for more than a decade, issues with acceptability, performance, and cost have limited its use. To address these challenges, PATH has developed the Woman's Condom. PATH worked with user



The Uniject device with injectable contraceptives, the Woman's Condom, and the SILCS diaphragm will increase women's contraceptive options.

groups in four countries—Mexico, South Africa, Thailand, and the United States—to develop and verify the design of the Woman's Condom.

PATH is now focusing on trials required for regulatory approval in China and the United States. In China, where PATH is working with a manufacturing partner, a study is under way to assess the product's performance and acceptability. PATH will assist our partner in submitting an application for approval to the Chinese State Food and Drug Administration in late 2010. Approval could come as soon as early 2011, with introduction in China following soon thereafter.

In the United States, a contraceptive effectiveness study required for market approval is under way. Ultimately, PATH will work to obtain regulatory approval of the product in China as well as the United States and Europe, thereby making it available for international procurement and introduction in HIV/AIDS and sexual and reproductive health programs.

Developing a diaphragm for use in low-resource settings

Diaphragms are an inexpensive, reliable, and reusable option for contraception. But they are often unavailable in low-resource settings, in large part because they come in several sizes and require a trained provider to fit them. To address the problem, PATH designed the

single-size SILCS diaphragm with a contoured rim that allows it to fit most women without requiring a pelvic exam.

Over a decade of development, PATH evaluated more than 200 prototype designs to refine performance and features. Women's opinions and evaluations were consistently at the center of the process. Product developers were not only working toward a one-size-fits-most device but also making sure to address women's requests for a more comfortable, easier-to-use product.

Giving women more family planning tools to delay motherhood, space births, prevent unintended pregnancies, and avoid sexually transmitted infections will help to save lives of mothers and babies around the world.

Multiple studies—in the Dominican Republic, Mexico, South Africa, Thailand, and the United States—have indicated that the SILCS diaphragm is easy to use, comfortable, and acceptable for experience for both women and their partners. Additional studies have found that

its effectiveness is similar to that of a traditional diaphragm.

By late 2010 PATH expects results from a pivotal study that will provide the data required for approval to market the device as a contraceptive in the United States. PATH and our partners plan to submit an application for approval to the US Food and Drug Administration by early 2011.

Planning to thrive

Technologies developed by PATH hold promise to give women three new user-centered options for protecting their own health and planning their families. By giving women the tools they need to delay motherhood, space births, prevent unintended pregnancies, and avoid sexually transmitted infections, these family planning methods have the potential to reduce health risks for women and children around the world. ■

Depo-subQ provera 104 is a trademark of Pfizer. Uniject is a registered trademark of BD.

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Announcements and events

Technologies coalition issues recommendations

The Global Health Technologies Coalition has called for increased public financing, enhanced regulatory systems, and expanded incentives and financing mechanisms for health technologies in its first annual policy report. The coalition's recommendations, released in April, seek to ensure that the United States maximizes its investment in global health and continues as a leader in research and development. PATH serves as the secretariat of the coalition. To read the complete report, *Innovation in Action: Policies to Accelerate Development and Delivery of Global Health Tools*, visit www.ghtcoalition.org.

Meningitis vaccine nears introduction

MenAfriVac™, the meningococcal A conjugate vaccine developed by the Meningitis Vaccine Project (MVP), has received regulatory marketing authorization, clearing the way for large-scale vaccination campaigns in Africa's meningitis belt. The vaccine is expected to receive WHO prequalification later this year and be ready for introduction in Burkina Faso in late 2010. MVP—a partnership between PATH and the

WHO—has collaborated with the Serum Institute of India to ensure vaccine affordability.

New policy to control diarrheal disease in Kenya

On March 31, the Kenyan government and partners, including PATH, sponsored an event to launch the country's new diarrheal disease control policy. The Nairobi gathering brought together policymakers and the health community to recognize the policy and redouble the nation's commitment to preventing diarrheal disease. The new policy highlights both traditional and new interventions—including oral rehydration salts, breastfeeding, zinc treatment, improved hygiene, and vaccines against rotavirus, the leading cause of severe diarrhea.

Join us at Women Deliver

PATH is helping to organize a symposium on reproductive health technologies at the Women Deliver conference, to be held June 7–9 in Washington, DC. The symposium will commemorate the 50th anniversary of the introduction of the birth control pill. Please join us at Women Deliver to learn more about PATH's innovative products and methods.

New online resource for defeating diarrheal disease

 www.defeatDD.org



PATH has launched a new website—along with an associated newsletter, blog, and Twitter feed—to inform and inspire action to reduce the global toll of diarrheal disease. The website provides key documents and links to information on simple, lifesaving interventions with potential to dramatically reduce the incidence of disease. Visit the “Take Action” section to learn more about how you can help.

PATH is an international nonprofit organization that creates sustainable, culturally relevant solutions that enable communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, we help provide appropriate health technologies and vital strategies that change the way people think and act. Our work improves global health and well-being. For more information, please visit www.path.org.

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EDITORIAL TEAM: John Ballenot, Emeline Cokelet Meneken, Kathleen Donnelly

DESIGNER: Patrick McKern

OTHER CONTRIBUTORS: Patricia Coffey, Chris Crudder, Christine Demmelmaier, Rebecca Fertziger, Kiersten Israel-Ballard, Maggie Kilbourne-Brook, Paul LaBarre, Dipika Matthias, Joanie Robertson, Matt Steele, Catharine Taylor, Amy Wales