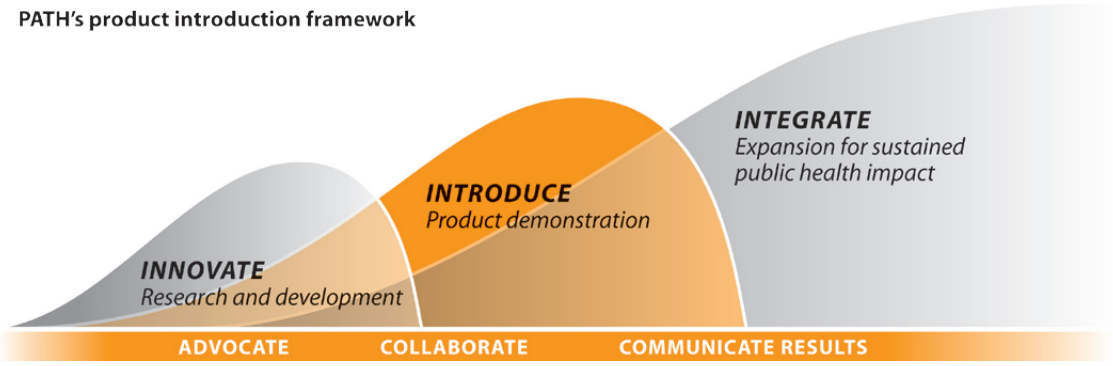
PATH's framework for product introduction

For nearly 30 years, PATH has developed, adapted, transferred, and introduced technologies that improve global health. These technologies build on the latest scientific advances to ensure effective use in diverse settings—especially urban, rural, and remote areas of developing countries.

PATH's approach is based on productive collaborations with public, private, and commercial institutions. Our collaborations have advanced more than 55 technologies—26 of which have been commercialized and 19 of which are now in use in more than 25 developing countries. These technologies are designed to alleviate some of the world's most urgent health issues, particularly in the fields of maternal and child health, reproductive health, vaccines and immunization, and emerging and epidemic diseases.

This paper focuses on PATH's product introduction activities. It also outlines the lessons learned and principles used to measure the impact of our efforts to reach underserved populations and improve global health.

PATH's product introduction framework



What is "product introduction"?

At PATH, "product introduction" refers to the integrated set of activities that prepare health systems to accept and embrace new, improved, or underutilized health technologies. Effective introduction is essential to sustaining a product's public health impact.

From the earliest stages of product research and development, PATH works to ensure broad adoption where the need is greatest. Our systems approach allows us to strategically identify and address barriers that could hinder the technology's introduction and use. Equally important, our user-oriented perspective ensures that the intervention is appropriate for the intended beneficiaries.

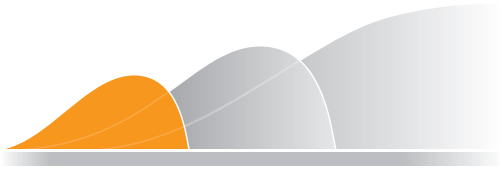
By bringing the right networks of people, knowledge, and systems together, we integrate each solution in an effective, sustainable way.

Throughout our product introduction activities, we use people's stories and evidence to advocate for health solutions; we proactively collaborate with communities, industry, governments, and other stakeholders to mobilize resources and tackle problems; and we communicate our progress and lessons learned so that others can build on these successes.

PATH

Advancing products from concept to widespread use

Product introduction is part of a broader process that encompasses product development, introduction, and integration. These phases are seldom linear or sequential. In fact, many of the activities within these phases unfold concurrently.



Product development

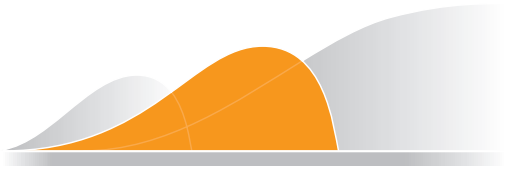
Because a community's health needs should drive any new product, we base our designs on thorough needs assessments and our institutional capability to develop appropriate solutions. We engage end-users as both product testers and co-designers, and we place the product's potential for health impact at the forefront of our plans.

If a suitable solution exists but is underutilized, PATH works to bring the solution to new markets. If promising solutions do not exist, we develop new designs or adapt existing products.

Our work is informed by both quantitative and qualitative research that focuses on local realities. Through an iterative process, we test and retest prototypes against clear performance criteria—such as functionality, durability, and ease of use—in different field environments. We consult with end-users, buyers, communities, and other stakeholders, and we perform validation studies to help determine the product's potential effectiveness.

Early in the process, PATH identifies the partners—from industry, the global health community, and governments—that will be critical to success. To demonstrate the product's value to these groups, we rigorously define market opportunities and potential demand. We then conduct due diligence and engage with qualified collaborators—building capacity and transferring technologies as needed—to produce technologies that, in the absence of PATH involvement, would not be a private-sector priority.

Carefully crafted products and partnerships are essential to success, but the products must also pass significant regulatory hurdles before they can be widely introduced. PATH and its partners take targeted steps—such as creating regulatory dossiers—to help secure approval by the US Food and Drug Administration or other national regulatory bodies. We also strive to obtain endorsements from the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), and other agencies that are critical to country-level uptake.



Product introduction

Once a product has been developed, the introduction phase places it in developing-country markets on a limited scale. Yet much must be done to advance the product to broader acceptance and use. PATH and its partners advocate, collaborate, and communicate with vital stakeholders at each turn.

Strategic planning

Successful introduction begins with the strategic selection of countries and populations. PATH begins all of its introduction efforts by working with stakeholders to develop international, regional, country, and sector-specific introduction strategies. "Early adopter" populations or countries are crucial; their example can stimulate uptake by mid- to late-adopters and influence policymakers. Often, targeted collaboration with a country's government and private sector can establish the groundwork for global endorsement of a new product or intervention.

Demonstration projects also build the evidence base for broader adoption—on either the national or global level. Since many new technologies involve broad system changes, demonstrating how the system—rather than just the technology—works is essential. We therefore monitor and evaluate key process indicators closely.

Market development

PATH works with manufacturers and potential buyers to define the market opportunity and help position products in different market segments. Tracking sales and market dynamics, we work

with manufacturers to introduce the product to stakeholders, grow the market, and drive down prices. We also provide country decision-makers with synthesized information they can use when deciding whether to adopt a new product or service.

Together, PATH and its partners harness the efficiencies of the private sector, reaching poor and underserved populations with vital health interventions. In exchange for ensuring a product's public-sector availability, accessibility, and affordability in developing countries, the private sector has few—if any—restrictions on the development of private-sector and developed-country markets.

Distribution channels can be equally critical to a product's market entry. PATH works with private-sector partners and other stakeholders to determine the most effective public, private, and nongovernmental distribution channels for reaching underserved populations and achieving maximum public health impact.

Supply and financing

To ensure a reliable product supply, PATH finds partners that have the capacity and commitment to produce products at prices that are affordable for the developing world. We provide manufacturers with technical assistance to help them meet international standards.

PATH also creates linkages between public-sector buyers, sellers, and, if appropriate, donors to ensure access to and financing for specific product and program costs. This planning must begin as a product is being readied for market. In addition, we work to influence public-sector logistics and procurement—for example, by working with governments to place a new health intervention on public-sector–approved buying lists.

Service delivery

Our experience has shown that simply training providers is not enough to change their practices. For this reason, we orient stakeholders to the new product and enlist their help in implementing coordinated introduction activities. We help staff responsible for policy, administration, procurement, and health education understand the benefits of the new product, so they can support the introduction on an ongoing basis.

To enable health workers to use a new technology, PATH employs adult-learning approaches and develops tools to help trainers assess training needs and effectiveness. To improve service quality, we use supportive supervision and sustained on-the-job training. We also develop training and reference materials, encourage manufacturers to include clear instructions with the product packaging, and distribute training materials through a variety of outlets. To measure the impact of these new health interventions, we update health information forms and systems, which allows for more effective surveillance.

Advocacy

A range of factors—including individual opinions and behavior, corporate activities, and public policy—can affect a product's uptake. PATH therefore works on a variety of levels to advocate for promising health solutions.

To influence global, regional, and national policies and standards, we strive to demonstrate the value of a technology or intervention, particularly by providing evidence for policy decisions. Our staff may also participate in committees and help draft standards. Since policy change and endorsements can entail lengthy processes, such policy work must begin early—for example, at the same time the product is initially validated.

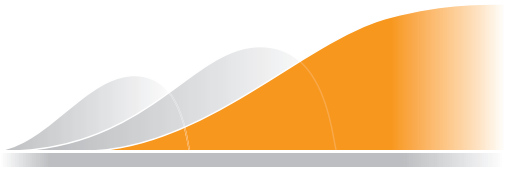
PATH may also use social mobilization and communication approaches to encourage uptake. Behavior change communication can help increase awareness of a new technology, transform public perceptions and attitudes, and encourage individuals to adopt healthier behaviors. These activities also help civil society engage with their policymakers—and help advocates share evidence through channels that mobilize key audiences and resources.

Research

Essential to all of these efforts is clear evidence of the product's value and potential impact. PATH conducts a range of research activities to provide this evidence. Operations research, for example, can identify the appropriate role of a technology within a health system. Cost- and cost-effectiveness analyses can provide critical insights into priorities, resource allocations, service design,

and introduction costs, particularly when health interventions compete for limited resources.

PATH also monitors product and program effectiveness—including health outcomes, adverse events, and sales—to determine results. In turn, we widely disseminate results and lessons learned to advance thinking in global health.



Product integration

Extending a product's reach beyond the initial product introduction is critical to achieving widespread and sustained use. PATH catalyzes the expansion process by working with countries to articulate demand, increase access, measure impact, and build on the lessons learned during introduction.

Because national and international leadership is critical to expanding availability, PATH fosters and supports leadership by other institutions and creates self-sustaining systems. We work with stakeholders to plan for product expansion that will meet the needs of broader populations. We also expand training activities to include pre-service and on-the-job-training of providers and managers, and we may help revise health-consumer information and work to incorporate the product into national procurement lists. Throughout these activities, we present our findings to local, national, and global stakeholders to help guide country decisions about adopting specific products.

The keys to success

In PATH's experience, several factors contribute to the successful introduction of health technologies and interventions in low-resource settings:

- **Advance solutions that address critical public health gaps and leverage the highest impact.** Our focus on finding the best solutions for people and their communities—rather than being tied to particular products, technologies, or approaches—is critical to our success.
- **Ensure that solutions are appropriate and culturally relevant.** To advance solutions that truly respond to users' needs, we work closely with end-users at every phase. In addition, our longstanding in-country presence, relationships with governments, and collaborator networks enable us to obtain the input we need to ensure that health products are well-suited to the primary users and locations.
- **Create public-private partnerships to solve neglected health problems and sustain impact.** PATH acts as a bridging agent between the public and commercial sectors. Our work with more than 100 private-sector partners has created linkages between developing countries' public health needs and realities and industrialized-world manufacturers' capabilities. It has also enabled us to build the capacity of local manufacturers in developing countries.
- **Employ an integrated approach.** PATH implements its work through multidisciplinary teams representing disciplines from epidemiology to engineering to business development. By working across a portfolio of programs, we leverage talent, infrastructure services, and experience. Our approach also allows new projects to draw on critical skills to get up and running quickly.
- **Strive for measurable results.** PATH conducts quantitative measures and qualitative assessments to assess impact and ensure efficient use of resources. Systematic monitoring allows us to make timely and well-informed programming decisions.

By focusing on all aspects of the product life cycle—development, introduction, and integration—PATH helps ensure that promising health technologies have a sustained impact on the health of people around the world.

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