



HOW STANDARDS CAN IMPROVE **PUBLIC HEALTH**

In 2011, 6.9 million children died before their fifth birthday. That same year, 287,000 women died during pregnancy or childbirth and there were 390,000 new HIV infections in children. Infectious, life-threatening diseases like pneumonia, diarrhea, and malaria are further exacerbated by endemic malnutrition and poor access to health services.

Government, donors, and private industry have long recognized the development benefits of investing in global health. Children who are healthy avoid permanent disability and spend more time in school. Their parents miss fewer days of work, earn more wages, and have fewer, healthier children.

But making the right investments in health also requires investing in regulatory frameworks, including standards. With quality and testing standards in place, consumers and patients are assured safe, quality, effective care and therapeutic

interventions. Internationally recognized product code management standards enable product recalls and help in detecting and removing counterfeit and substandard medical products from the market. Adopting and implementing

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techniques for manufacturing and other practices that conform to consensus international standards enables manufacturers in developing countries to produce higher quality products that can help assure safety as well as compete in local and international markets.

Health regulation, based on standards developed by consensus and approved by a recognized body, can encourage innovation and knowledge sharing and can strip health systems of excess costs and inefficiencies. Alternatively, when regulation is not based on consensus standards, or national standards are adopted that either restrict competition or are not based on sound science, at-risk communities can be denied access to the most effective and innovative health solutions.



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THE POTENTIAL OF STANDARDS FOR DEVELOPING COUNTRIES

CASE STUDY: CONTROLLING SARS IN CHINA

In China, one of the many challenges associated with control of Severe Acute Respiratory Syndrome (SARS) was assuring sufficient respiratory protection to prevent spread of the disease among healthcare providers. Traditionally, a gauze mask was worn for respiratory isolation of healthcare workers and family members from infected individuals. But because traditional flat masks do not seal against the face, they can allow particles access.

In response to the growing number of SARS cases, the Peoples' Republic of China State Standardization Bureau and State Drug Administration (SDA) sought to create a new respirator standard since China's masks and respirators were previously unregulated. The problem before the SDA was how to quickly establish a scientifically based respirator standard including test methodology in a field of study requiring highly specialized instrumentation and technical expertise.

With a short time frame to respond to the public health crisis, the SDA referred to the N95 filtration efficiency standard and testing standards previously recommended by the U.S. Centers for Disease Control (CDC) and the World Health Organization (WHO), and collaborated with the 3M medical division, which provided access to laboratories. CDC and WHO guidance, along with partnering with industry, enabled the SDA to develop and publish a standard for healthcare respirators sold in China to help contain the spread of SARS. *Source: 3M*

Adoption of effective consensus standards can play a key role in helping developing countries address public health priorities.

IMPROVING THE EFFICACY OF HEALTH SOLUTIONS

Broadening access to medicines and other health products is a critical public health intervention undertaken by governments and donors. But unless health products reflect sound science and engineering, they can leave communities vulnerable. Unfortunately, many developing countries are flooded with sub-standard, products, such as medicines that do not meet appropriate ingredient and composition specifications—and which can be ineffective and often dangerous to patients. Substandard products are more prevalent in developing country markets than in developed ones; negligence, human error, insufficient human and financial resources, or counterfeiting are all contributing factors.

Governments can adopt consensus standards to help ensure that health products perform to expectations and effectively address the needs of at-risk populations. Since consensus standards incorporate advances in science and technology as well as the past experience of stakeholders, they reflect the latest expertise and can help ensure that the most innovative and effective processes and products are deployed to meet health needs.



BUILDING A NATIONAL HEALTHCARE INDUSTRY

As many larger developing countries seek to develop home-grown healthcare industries, a key challenge is regulating those industries to ensure products are manufactured in sanitary conditions to prevent contamination and appropriate testing procedures are applied to guarantee drug quality and efficacy. In some countries with emerging healthcare industries, regulators may not be equipped to develop appropriate regulations that ensure products are consistently produced, and are appropriate for their intended use. In these cases, regulators can rely on international standards such as the WHO Good Manufacturing Practices to ensure quality and safety standards govern the entire lifecycle of production and distribution. Adoption of these standards can also help to boost exports to international markets, where adherence to Good Manufacturing Practice is often essential to market access.

LOWERING HEALTHCARE COSTS

Regulators in developing countries often unknowingly increase healthcare costs and delay the introduction of new treatments because of how they adopt standards. While international standards that represent the latest advances in science, technology, and innovation frequently exist, some governments opt to develop their own national standards. Sometimes these national standards can be redundant, placing onerous requirements on manufacturers or service providers, delaying the introduction of new products, and ultimately raising costs for patients. In other cases, the national standard may diverge from the consensus international standard, creating other complications—a higher standard imposes

needless costs and a lower standard may reduce efficacy and curb export opportunities. Adopting consensus international standards rather than imposing redundant or ineffective national standards can often reduce costs for healthcare systems and accelerate the introduction of life-saving health solutions.





OPPORTUNITIES TO ENGAGE

International consensus standards are a critical tool for regulators seeking to improve public health outcomes. Donors can play a key role in working with developing country partners to ensure that standards are effectively integrated into programs to achieve their public health goals. Potential interventions include:

- Enhancing the quality of healthcare products and improving patient safety by working with governments to adopt regulations based on consensus standards that address health product quality and efficacy requirements.
- Creating a competitive healthcare industry by promoting the adoption of international standards across the entire product lifecycle, from production to distribution, in countries with growing healthcare sectors that wish to access international markets.
- Increasing access to safe healthcare technologies by ensuring national standards do not discriminate against products from specific countries or producers and do not increase costs or delay the introduction of innovative healthcare products.

CASE STUDY:

MALARIA PREVENTION WITH INSECTICIDE-TREATED MOSQUITO NETS

Malaria causes about 261 million illnesses and an estimated 655,000 deaths each year. Research shows that use of insecticide-treated mosquito nets reduces malarial infections among children under five and pregnant women by up to 50 percent.

In 2005, the World Health Organization convened a technical meeting to address standards issues associated with the large-scale procurement of mosquito nets by institutional buyers, NGOs and national control programs. Simple and practical guidelines were needed to help inexperienced buyers, especially in national malaria control programs, to address the issue of quality during procurement and subsequently to maintain adequate quality control. The meeting brought together: manufacturers of insecticides and mosquito nets; specialists from textile quality testing laboratories and major procurement agencies; scientists with expertise in chemistry and malaria vector control; and experts from UNHCR, UNICEF and WHO. Participants reached consensus and issued guidance on standards relating to mesh count, bursting strength of netting materials, fire safety, and insecticide uptake, enabling more cost-effective procurements of bed nets and improving malaria prevention efforts. *Source: World Health Organization*

For more information on USAID assistance related to standards please visit standardsalliance.ansi.org or contact us at SA@usaid.gov