Technologies for Health: Assessing Affordability

An Interview with David L. Heymann

By Erin Schneider
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In an era when innovative technology is rapidly developing and increasingly accessible, both high- and low-income countries continue to grapple with the concept of affordability. This week, in anticipation of the 2012 Pacific Health Summit on "Affordability and Technologies for Health," NBR spoke with Professor David Heymann about the complexities of defining the concept of affordability and assessing value in a health context, and the challenges and critical considerations that should be taken into account when implementing affordable, innovative technologies, particularly in resource-poor settings.

David Heymann is Head of the Centre on Global Health Security at Chatham House, London; Chairman of the Health Protection Agency, UK, and Professor of Infectious Disease Epidemiology at the London School of Hygiene & Tropical Medicine. Previously he was Assistant Director-General for Health Security and Environment at the World Health Organization (WHO). Dr. Heymann also represented the WHO Director-General for polio eradication and was Executive Director of the WHO Communicable Diseases Cluster until 2003. He held the post of Director for the WHO Program on Emerging and other Communicable Diseases from 1995 to 1998. He was Chief of Research Activities in the WHO Global Program on AIDS until 1995. Prior to 1995, Dr. Heymann was seconded from the US Centers for Disease Control and Prevention to work on infectious disease prevention and control programs sub-Saharan Africa and Asia.

Q. The definition of "affordability" with regard to novel technologies, particularly in low-income settings, is complex and varies widely between the public, private, and nonprofit sectors, as well as between low- and high-income countries. How do you define "affordability" from the donor perspective versus the industry and country leader perspectives?

The definition of affordability of health technologies that seems most appropriate to me is the price that the market will pay. This in turn depends on the amount of money that the market has at its disposal and the level of priority that the market places on the technology. In other words, it is the potential purchaser who defines affordability. This becomes complex when one takes into consideration the diverse priorities and budgets of purchasers of technology for health. For example, international donor organizations, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria,[1] which already have a dedicated budget, are usually able to purchase health technologies at a lower price than a developing country government can negotiate because they can buy in bulk through a pooled procurement scheme. Defining affordability in general terms is difficult, and requires an understanding of both the priority placed on the technology and the funds available for its purchase.

Q. Multinational companies sometimes serve in a donor role in which they selectively subsidize the provision of innovative technologies, such as vaccines and diagnostic tools, to low- and middle-income countries to help fill domestic R&D and manufacturing capacity gaps. In what ways does this approach contribute to, or prevent, technologies from becoming more "affordable" for low- and middle-income countries?

1 The Global Fund to Fight AIDS, Tuberculosis and Malaria is a public-private partnership and major international financing institution. The Global Fund provides performance-based grants to in-country partners who implement and carry forward health interventions against its namesake diseases.

As previously mentioned, in determining affordability one must consider how much of a priority the purchaser places on the technology and the amount of funding available. If a donor purchases a high priority technology or provides funds for its purchase because they have a larger funding pool than developing countries, then developing countries have no rational option but to purchase drugs through the donor.

Most research-based pharmaceutical companies indicate that they will provide tiered pricing as a means of making technologies affordable in developing countries. This could serve to engage countries in purchasing technologies they consider a priority at a price that they deem affordable. The challenge, however, is that countries must have the skills to negotiate with the manufacturer, and the manufacturer must be willing to engage with governments, as well as with potentially higher revenue markets.

We must guard against the possibility that donors decrease the initiative of countries to participate in the purchase of priority technologies because they can't compete with the price-negotiating skills of donor agencies and also against the possibility of fluctuation in sustainability, because donor funding decreases. One responsible option that some global funding mechanisms are beginning to use is a cost-sharing initiative in which countries share the financial burden of the cost of a priority technology from the start, and through careful planning gradually assume more of the cost, thus better ensuring sustainability.

Q. What examples can you offer where the affordability of an innovative technology was not properly assessed, or where a new technology, though innovative, did NOT make investment sense for a low- or middle-income country?

One clear example of the improper assessment of the value and affordability of technology is the case of the rapid diagnostic test for malaria. Currently, many countries treat malaria presumptively—a child with fever is given a full course of anti-malarial drugs without laboratory testing. Accurate diagnosis of malaria could ensure best possible treatment, and, by minimizing the over-use of anti-malarial drugs, also slow the development of malaria parasites that have acquired resistance to treatment. Studies in some countries have shown that the recently developed rapid diagnostic tests for malaria result in a higher overall cost for treatment, even though there is more rational and decreased use of anti-malarial drugs. A clear understanding of the long-term value of a rapid diagnostic test could raise its priority despite the high upfront cost, and presumptive treatment could be replaced by best practices that will help conserve the effectiveness of anti-malaria drugs.

An example of a technology that is valuable but does not make direct government investment sense for low-income countries is the meningitis A vaccine in Africa, because it is already being provided cheaply by donor organizations. Meningitis A causes epidemics each year in the sub-Saharan meningitis belt that runs across central Africa. Industry had developed a highly effective quadrivalent conjugate meningitis vaccine that was primarily marketed to industrialized countries, but was not affordable for emerging markets in Africa where meningitis A epidemics occur. Consequently, PATH and the World Health Organization, with funding from the Bill & Melinda Gates Foundation, transferred the technology for production of a conjugate meningitis A vaccine to a company in India, the Serum Institute, that guaranteed a price of less than US$0.50 per dose.

All countries in the meningitis belt, including those that could afford to purchase this vaccine, are now waiting for GAVI[2] to provide the vaccine for the vaccination campaigns that will confer immunity to persons under the age of 20 years of age, after which routine use of the vaccine in young children will begin. GAVI will phase in its campaigns during the coming years provided pledged funding continues. The effect of this, however, is that the promise of GAVI-funded meningitis vaccines has de-incentivized countries that have not yet benefited from a GAVI-provided vaccine but that have budgets to purchase them, from according meningitis a high priority that would allow them to purchase the vaccine in order to conduct vaccination campaigns earlier.

Q. Recently, Asian economies, such as China and India, have placed increased emphasis on the importance of technologies for health. As such, they are in the process of building and strengthening domestic innovation, R&D, and manufacturing capacity. Additionally, innovation in many Asian countries tends to feature tools and processes that are lower cost than those emerging from multinational companies in the West. What impact, if any, might the increase of technology leaders in Asia have on the broader affordability of novel technologies for both the developing and developed worlds?

Research and development, innovation, and production of medical technologies in developing countries are collectively

2 The GAVI Alliance is a public-private partnership dedicated to increasing access to vaccines in developing countries.

one solution for providing technology to developing countries at a lower cost. It will be important to see how the regulatory framework in Asia and other parts of the developing world evolves as more and more of those countries move in this direction. The current regulatory framework in these areas is based on a Western risk assessment model of zero or very low tolerance of major side effects. As leaders in Asia continue to develop their own frameworks for technology, we may find that risk assessment in developing countries is handled differently. For example, in view of the high incidence and mortality of infectious diseases, the question would be whether the regulatory framework should take those risks into account.

Think, for example, of the rotavirus vaccine, which was removed from the market in 1999 due to intussusception[3] in children in the United States and industrialized countries[4]. In some developing countries, where mortality rates from rotavirus disease are high, intussusception might be considered a minor risk compared to the risk of death from rotavirus infection. If a different regulatory framework had been used to license the rotavirus vaccine in these countries, the vaccine would perhaps not have been removed from the market there.

Regulatory frameworks based on different risk assessments would raise ethical concerns, and could result in technologies licensed and used in developing countries that might not be licensed in industrialized countries. International standards for prequalification of producers of drugs and vaccines based on an industrialized regulatory framework would also be in jeopardy. While these are some of the possible consequences, it is clear that research and development, innovation, and production in developing countries are a real solution for supplying technology to developing countries at a lower cost, no matter what regulatory framework is used.

Q. What do you view as the primary challenges to developing and implementing financially affordable technologies in developing countries?

In the long term, developing countries must identify and support inherent talent—educated either within the country or abroad. They must also create an environment favorable both to medical research and development, and the companies that produce and market the resulting technologies. This is a different model from that of an industrialized country manufacturer, which sets up a manufacturing facility in a developing country in order to decrease production costs. If this long-term vision could be achieved, the current flow of highly educated scientists from developing to industrialized countries would possibly reverse, and new markets could be created in developing countries where the purchase of highly prioritized technologies becomes more feasible within the existing available funding base.

3 Intussusception is a condition in which a portion of the intestine enfolds itself within an adjacent part of the intestine, obstructing blood flow and also the passage of food and fluids.

4 In 2006, the rotavirus vaccine was shown to be safe and effective in children, and in 2009, the WHO recommended that the rotavirus vaccine be included in all national immunization programs.