Vaccine innovation done differently

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Over the past 15 years there has been a change in perceptions of what constitutes vaccine innovation to meet developing country needs. This change could reduce the global burden of infectious diseases and contribute to the ultimate achievement of many of the Millennium Development Goals.

Until recently the vaccine needs of developing countries were met through a process best described as "trickle down". Major vaccine companies developed commercially attractive vaccines for markets in industrialized countries. These vaccines were then sequentially adapted and adopted into developing countries if local officials had funding and some belief of their usefulness. This usually occurred with great delays – often decades – as prices fell slowly.[1] Historically, the term "vaccine innovation" was used to describe just the product development phase of this process, undertaken mostly by large pharmaceutical companies in industrialized countries. This model of vaccine innovation is illustrated in various reports from the Institute of Medicine of the United States National Academy of Sciences from the 1980s and 1990s.[2,3] New products developed specifically for first use in developing countries or licensed by non-commercial entities were rare.

In recent years, the following disease-specific, not-for-profit product development partnerships and the International Vaccine Institute have changed this picture: the International AIDS Vaccine Initiative (established in 1996), Aeras Global TB Vaccine Initiative (established in 1997 in its first form), the Malaria Vaccine Initiative (established in 1999), the European Malaria Vaccine Initiative, (established in 1998), the Human Hookworm Vaccine Initiative (established in 2000), the Meningitis Vaccine Project (established in 2001) and Global Solutions for Infectious Diseases (established in 2004). The International Vaccine Institute was established in 1998 by the United Nations Development Programme as an offshoot of the former multi-agency Children's Vaccine Initiative. Its headquarters are in Seoul in the Republic of Korea and it is currently working in approximately 30 developing countries. It manages product development partnerships to develop vaccines against cholera, dengue fever and typhoid fever, along with efforts on other diseases.

For these initiatives and institution, the stimulus for innovation is the public health need in poor populations in developing countries. Product development is accompanied by studies to better define the burden of specific diseases in the developing world and early testing of new products in real-world, resource-poor settings. Early consultation and collaboration with policy-makers in developing countries help to identify and generate the information (including cost-effectiveness) they need to set policies for rational use of new vaccines.[4] High prices and lack of such information – historically gathered retrospectively after a new vaccine was licensed in Europe or the United States of America – have often contributed to the delay in uptake of new vaccines in poorer countries.

Vaccine design, development and delivery are considered together from the outset, with disease control – not simply product licensing – as the goal. Affordability is addressed through development of low-cost production methods in parallel with clinical licensing trials. Such trials are conducted first in developing countries where the diseases occur.

In less than 10 years, the Meningitis Vaccine Project, funded at approximately US$ 78 million by the Bill & Melinda Gates Foundation, has resulted in a vaccine against meningitis A for use in the low-income countries of the so-called "meningitis belt" in sub-Saharan Africa. This vaccine has just received a "seal of approval" on its safety, effectiveness and quality, i.e. World Health Organization pre-qualification for purchase by United Nations agencies.[5] Throughout its development process, affordability was regularly discussed between the potential users, the manufacturer, the Serum Institute of India, and the Meningitis Vaccine Project. Initial introduction in 2010 in Burkina Faso, Mali and the Niger is being financed by the GAVI Alliance, the Michael & Susan Dell Foundation and respective governments. Follow-on funding for other meningitis belt countries will require commitments from individual governments and other organizations.

There has long been a need for a vaccine with prolonged effectiveness against cholera, suitable for developing country use beyond existing vaccines that offer partial and short-term protection to travellers. In a collaboration funded by the Bill & Melinda Gates Foundation and the governments of Sweden and the Republic of Korea, and also involving India and Viet Nam, the International Vaccine Institute has developed such a new vaccine and is in the process of applying for prequalification by the World Health Organization.[6]

Vaccine innovation is thus shifting from the narrow realm of product development and is increasingly being done by new, not-for-profit initiatives and institutions that creatively engage the public and private sectors to accomplish their goals. ■

References

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