

## Introduction of new vaccines; public health and policy decisions

André Meheus and Fred van der Veen

NESI (Network for Education and Support in Immunisation), University of Antwerp, Belgium

Introduction of new vaccines and technologies is one of the priority strategic areas highlighted by the Global Immunization Vision and Strategy of WHO and UNICEF. From 2000 onwards, largely through efforts supported by GAVI (Global Alliance for Vaccines and Immunization), Hepatitis B, Hib and yellow fever vaccines have been introduced in developing countries. The use of combined vaccines, particularly the so-called pentavalent vaccine (DTPwHepB+Hib) in most GAVI supported countries of the WHO/AFRO region has contributed significantly to the success of the introduction of those new/underused vaccines.

To be successful and reliable, new vaccine introduction should follow a rational process and different steps should be considered as part of decision making: (1) what is the burden of disease to be prevented in terms of morbidity (incidence, prevalence, complications, hospitalisations, disability) and mortality; (2) is there a good intervention, i.e. is the vaccine efficacious and effective, safe and acceptable for the target population; (3) what is the cost of the new vaccine and of its implementation and what is its comparative effectiveness with other vaccines/interventions in terms of health gains (most often expressed in DALYs or QALYs = disability adjusted life years or quality adjusted life years). To these ends cost-effectiveness estimates look for efficiency of the financial resources invested in comparison with other health interventions.

Based on burden of disease, vaccine efficacy and quality, and acceptable cost-effectiveness, a decision can be taken that a new vaccine merits introduction as a priority public health initiative. Before a final decision on introduction of a new vaccine, two other steps are of major importance: (1) can the finances be found to pay for the new vaccine; and (2) what are the programmatic implications, in other words can the immunization programme cope with all the new activities to be implemented.

Industrialised countries finance their vaccine programmes with domestic sources of funding (national or subnational tax revenues, public or private health insurance, user fees). Developing countries have already great difficulties to fund their traditional EPI programmes; for introduction of new vaccines they have to rely largely on external sources of financing (e.g. GAVI and the GAVI Fund, International Finance Facility for Immunisation (IFFIm) and international development cooperation support implemented as budget support, sector wide approaches (SWAPs), debt relief proceeds, and project grants from bilateral and multilateral organisations, international NGOs and philanthropic institutions). The major question here is the sustainability of tapping these external resources, but a major flow of funds from the North to the South seems to be assured at least until the year 2015.

For the next step, the following criteria need to be considered to judge if the National Immunization Programme is ready to introduce a new vaccine: (1) is there already full benefit with existing vaccines (high coverage, limited drop-out, two-dose measles, etc.); (2) is it financially sustainable; (3) is the cold chain functioning and is there a well performing vaccine management system; (4) are vaccine stocks well managed (good forecasting etc.); (5) are immunizations safe and is there a functioning monitoring system for adverse events; (6) is there a high quality disease surveillance system for major VPDs in place to allow monitoring of process and evaluation of impact.

Finally, all relevant programmatic issues should be addressed and sustainable financing should be secured before the final policy decision to introduce a new vaccine will be given the green light.

The above described process is actually ongoing among national and international health policy decision makers regarding the introduction of new vaccines such as pneumococcal, rotavirus, meningococcal and HPV vaccines. It is easy to understand that for low but also for middle income countries this is a major challenge in the coming years.