Introducing new vaccines into the childhood immunisation programme in South Africa

Vaccines: with the exception of safe water, no other modality, not even antibiotics, has had such a major effect on mortality reduction. Immunisation has been called one of the best buys in health. This success has led to substantial efforts to develop new vaccines against a range of infectious agents responsible for significant childhood morbidity and mortality. As research and development, clinical trials, registration and marketing have become a lengthy, complex and expensive process, so too health authorities and donor organisations have weighed up the cost of a new vaccine in the light of efficacy and effectiveness, perceptions and priorities, and the capacity of a country to deliver and sustain expanded immunisation programmes. It is therefore not surprising that in many developing countries, often the very places where the vaccines are most needed, it can take decades before a new childhood vaccine is introduced.

In the context of global interdependence, the Global Immunization Vision and Strategy has been developed by the World Health Organization (WHO) and United Nations Children’s Fund (UNICEF) to facilitate the introduction of new vaccines and technologies, integrate other health interventions and strengthen immunisation programmes at local and global level. Innovative financing mechanisms, such as Advance Marketing Commitments, the International Finance Facility for Immunization (IFFIm) and buy-downs, have been developed to help bridge the new vaccine introduction gap.

South Africa, however, as a middle income country, is not unreasonably excluded from such indirect financial support. South Africa has in fact pledged to contribute to bond guarantees issued by the IFFIm.

Health professionals in South Africa, especially those interested in the control of infectious diseases, are in a good position to influence decision making in this regard, and some of the lessons learnt in the introduction of the new 7-valent pneumococcal conjugate vaccine and rotavirus vaccines together with the new diphtheria, tetanus, and poliomyelitis combinations may provide some insight into the process and help to strengthen advocacy for new and useful vaccines into the immunisation programme in South Africa. Medical scientists from South Africa have played a major role in preparing the ground for the introduction of Haemophilus influenzae type B vaccine, conjugated pneumococcal vaccine and rotavirus vaccine. The cost of vaccines has become a key issue in most countries. In 2009, the vaccine cost of a fully immunised child was estimated at R1,338 in the public sector and R4,103 in the private sector, constituting in both cases about a tenfold increase in 10 years.

This of course is only a proportion of the real cost of immunising a child, but considering that vaccines have become an increasingly significant cost, economic analysis and multi-year budget estimates have become a vital aspect of vaccine decision making. It is worth noting that Stats SA reports that 1,254,707 births were registered in South Africa in 2009.

The WHO has developed a useful set of guidelines on vaccine introduction, entitled Adding a vaccine to a national immunization programme: decision and implementation. Careful consideration of these guidelines should help to minimise problems which could lead to a loss of confidence on the part of health professionals and the public. Key aspects are: 1) policy issues: estimates of the disease burden, other possible public health priorities, public perceptions and professional opinion, vaccine efficacy, quality and safety, economic and financial issues; and 2) programmatic issues, vaccine presentation, supply issues and the capacity of the programme to handle the logistics associated with the new vaccine.

In this process, cost-effectiveness studies which compare the relative costs and outcomes or effects of different courses of action and fiscal impact studies, which tend to be broader in scope, examine how the introduction of a new vaccine will affect resources for other public health priorities. Budgets for new vaccines must be projected as specific items in multi-year plans at all levels of service delivery. It has happened also in South Africa that, when a new vaccine is introduced with extra budgetary funding, the following years the funds are allocated as part of the general provincial health budget and the vaccine has to compete uncomfortably with other important commitments and pressures.

Introducing a new vaccine also means revision of practice guidelines and training, cold chain logistics and manuals, Road-to-Health charts, computer information systems, education and communication, surveillance of adverse events, and of cases of the disease in question. Most importantly it will require ongoing support, supervision and problem-solving in the field.

Measuring the impact of a new vaccine depends on the estimate of the burden of disease, the effectiveness of the vaccine, programme logistics, the immunisation coverage achieved and, of course, the thoroughness of the monitoring and evaluation. The ultimate impact can often be markedly enhanced through a catch-up campaign for all under 5s. In South Africa, if the
introduction of hepatitis B vaccine for infants in 1996 had been accompanied by a catch up campaign for all under 5s, the drop in the incidence of liver cancer and chronic hepatitis would have been more rapid, effectively decreasing healthcare costs and increasing the number of quality life years gained in a far shorter period and more cost effectively. Introducing a new vaccine without a clear understanding of the epidemiology may have a negative impact if it increases the susceptibility to disease in certain vulnerable groups. The classic example is rubella vaccine. If introduced into the childhood immunisation programme but high coverage is not achieved, the natural endemic spread in small children is curtailed and so more children grow up lacking natural immunity, resulting in epidemics which tend to occur in older groups, including pregnant women. Such epidemics have in fact occurred, notably one reported in Greece in the 1980s.14 To some extent, we potentially face the same problem with the use of measles, mumps and rubella (MMR) vaccine in infants of families in the private sector (Prof Barry Schoub, personal communication). The introduction of MMR for girls at 12 years of age would decrease the risk of congenital abnormalities later in life.

In South Africa, as in many other African countries, we also need to start thinking seriously about the introduction of an immunisation schedule for adults, especially for health care staff.

Verweij and Dawson have suggested three ethical principles relating to vaccine introduction: a) that benefits and harms should be fairly and justly distributed, b) that there is reasonable access to information, including the risk of side-effects, and c) that participation, except in exceptional circumstances, should be voluntary, so that public trust in the programme would be honoured and protected.16 One area that we need to pay more attention to is how to communicate risk and benefit more effectively.

The current decision making process in South Africa goes through at least four major stages. The National Advisory Group on Immunisation, in consultation with local experts, makes a recommendation to the Director General of the national Department of Health. Senior officials in the Department of Health then consider the proposal in the context of the department’s overall mandate. The department may consult with other experts before going into interdepartmental and interministerial consultation with, at least, the Treasury. In the fourth stage, recommendations and supporting documents are taken to the National Health Council where, under the chairmanship of the Minister of Health, advisors and provincial ministers and heads of health departments discuss the proposal and implications. Provincial ministers and heads of health departments must agree to the proposal and budget implications and commit themselves to effective delivery. It is not difficult to see why, even if the resources are available and the commitment is there, the process takes time and persistence.

South Africa is conscious of its place in the world. Clear WHO recommendations,16 and the fact that a vaccine may have been introduced into the private sector and the routine immunisation programmes of other non-aligned countries (such as India, Brazil, Cuba and other African countries), do influence top-level decisions.

The introduction of the new pneumococcal, rotavirus, human papillomavirus and tuberculosis vaccines, and the prospects of developing effective vaccines against malaria and HIV, together with new technologies to deliver these vaccines more easily and effectively, hold the promise of markedly improving the health status of children worldwide.

With the cost and complexity of introducing new vaccines increasing dramatically, it is becoming more important that a significant proportion of health professionals, reporters, parents, teachers, and learners have a good understanding of the benefits, risks and costs of vaccines, and become active supporters of effective immunisation programmes and the introduction of new cost-effective and efficacious vaccines earlier, rather than later.13

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