Global Immunization Policies Recommendations

This article describes one of World Health Organization’s core functions i.e. that of issuance of immunization policy recommendations at the global level and its importance, impact and limits together with highlighting recent and forthcoming changes. It describes the challenges to foster the Global immunization vision and strategy of WHO and UNICEF. This strategy aims to ensure that all age groups have access to the full range of vaccines, with their potential to reduce mortality when integrated with other health interventions. The article highlights the role and modes of operating of the immunization Strategic Advisory Group of Experts and its interaction with other WHO advisory committees on immunization including the Global Advisory Committee on Vaccine Safety and regional technical advisory groups. It develops the type of information and evidence needed for the committee to take its recommendations and emphasizes the need for a cycle of feed-back that includes necessary surveillance and presents the committees products. Recommendations on vaccine use are published in the form of position papers in the Weekly Epidemiological Record (WER) and the process followed to publish these position papers is described. The article finally discusses the communication dimension. Measles and Hib are used as examples to show the impact of WHO recommendations.
Formulating recommendations – Challenges and procedures
Policy development framework
SAGE (Strategic Advisory Group of Experts)
Terms of reference
Interaction with other key advisory committee (Expert Committee on Biological Standardization (ECBS), Global Advisory Committee on Vaccine Safety)
Vaccine Position Papers
Impact of recommendations
Measuring the impact of recommendations
Better communication for greater impact
This article summarizes the World Health Organization’s normative role in the field of vaccines and immunizations, and the importance, impact and limits of its mandate. It also describes the challenges which need to be taken up to ensure that new vaccines are introduced quickly in developing countries and to adapt to the new vision and strategy of WHO and UNICEF. This strategy aims to ensure that all age groups have access to the full range of vaccines, with their potential to reduce mortality when integrated with other health interventions. Globally, three committees play an important normative role: the Strategic Advisory Group of Experts, the Global Advisory Committee on Vaccine Safety and the Expert Committee on Biological Standardization. WHO recommendations on vaccine use are published in the form of position papers in the Weekly Epidemiological Record (WER). Work is currently under way to update recommendations more quickly and to improve transparency and communication as regards WHO’s normative role.

Since WHO launched its Expanded Programme on Immunization (EPI) in 1974, immunization, together with progress in hygiene and sanitation, has revolutionized child

1 The authors are World Health Organization staff members. The opinions expressed in this article are those of the authors and do not necessarily represent the decisions, official policy or opinions of the World Health Organization.
health worldwide by preventing millions of deaths. Smallpox was eradicated in 1979 and poliomyelitis has now been eliminated in most countries [1].

However, not all children benefit fully from the advantages of immunization. In many developing countries, immunization services are less accessible to children than in wealthier countries. Lack of political commitment and weak health service delivery systems are sometimes to blame. The poorest children generally have access to a narrower range of vaccines. According to WHO-UNICEF estimates, in 2005 at least 28 million infants had not received three doses of diphtheria-tetanus-pertussis (DTP) vaccine, despite global coverage of 78% [2].

This article summarizes WHO’s global normative role in relation to vaccines, the importance and limits of this role, and describes recent and forthcoming changes. More detailed information on advisory mechanisms, including the mandates of the principal committees and WHO products and recommendations, can be found on the WHO web site (http://www.who.int/immunization/en/).

**WHO mandate and goals: challenges and development of needs**

**WHO role and mandate**

WHO is the world body responsible for setting standards and formulating policies and recommendations on vaccines and immunization. This role is both acknowledged and expected and is set out in WHO's Constitution, signed by the 193 Members States, which recognizes WHO as a specialized agency under Article 57 of the Charter of the United Nations whose objective is the attainment by all peoples of the highest possible level of health [3].

To this end, Article 2 of the Constitution states that the Organization shall act as the directing and co-ordinating authority on international health work and shall establish and maintain effective collaboration with the United Nations, specialized agencies, governmental health administrations, professional groups and such other organizations as may be deemed appropriate.
Article 2 also stresses the need: (1) to promote co-operation among scientific and professional groups which contribute to the advancement of health; (2) to provide information, counsel and assistance in the field of health; (3) to assist in developing an informed public opinion among all peoples on matters of health; and (4) to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products.

All these points obviously apply to immunization, thus requiring an appropriate mechanism to formulate policies, recommendations, regulations and standards for immunization emerging from consensus based on scientific evidence, consultation and exchanges with industry and any other stakeholders represented by WHO. This activity is one of WHO’s strategic priorities [4, 5].

**Challenges and development of needs**

**Vaccine availability**

When EPI was instituted, WHO defined thematic guidelines for developing countries on how to effectively plan, implement and manage access to essential vaccines. Quite rightly, the initial phase of this programme focused on immunizing infants and pregnant women, selecting a limited number of the vaccines available at that time (BCG, measles, pertussis, diphtheria, tetanus and poliomyelitis). This quickly improved global immunization coverage [1]. The aim was to use available immunization tools to produce the maximum impact on avoidable mortality. Efforts in the 1980s to implement the universal immunization of children brought about a rapid increase in immunization coverage. In the 1990s, global immunization coverage in excess of 70% was maintained with basic EPI vaccines, yet this success masked large disparities between and within countries. While in some developing countries immunization rates increased significantly, elsewhere, for example in sub-Saharan Africa, they fell and millions of children were left exposed to potentially fatal childhood diseases [1].
There have been considerable changes in the field of immunization in the last ten years. In response to the challenges of a rapidly changing and increasingly interdependent world, WHO and UNICEF have jointly drafted a Global Immunization Vision and Strategy 2006–2015 [6]. Its goal is to protect as many people as possible against more diseases by expanding the reach of immunization to every eligible person and ensuring that immunization is high on every health agenda. The strategy aims to increase, or at least sustain, very high levels of vaccine coverage, not just for infants but for all age groups, introduce new vaccines and link immunization with the delivery of other health interventions. Immunization and related interventions set out in this strategy will play an important role in achieving the Millennium Development Goals [7]. This global strategy was drawn up against a background of increasing demand for vaccines, rapid progress in developing new vaccines and technologies, continuing health-sector development, increasing vulnerability to pandemics and other health emergencies and more potential opportunities for partnerships.

Pending the development of vaccines against major communicable diseases (HIV/AIDS, malaria and tuberculosis), other new vaccines (against rotavirus, pneumococcus and human papillomavirus) have already been licensed and are now available. Other vaccines are available but underused (for example vaccines against Japanese encephalitis, yellow fever, and Haemophilus influenzae type b [Hib]). Figure 1 (adapted from [5]) illustrates schematically how deaths can be prevented either by optimizing the use of existing vaccines or introducing new vaccines.
### Table 1: Future Vaccines and EPI Vaccines

<table>
<thead>
<tr>
<th>Future Vaccines (from 2011)</th>
<th>New or underused vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV/AIDS</td>
<td>Meningococcus</td>
</tr>
<tr>
<td>Malaria</td>
<td>Human papillomavirus</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Rotavirus</td>
</tr>
<tr>
<td>Dengue</td>
<td>Pneumococcal disease</td>
</tr>
<tr>
<td></td>
<td>Typhoid</td>
</tr>
<tr>
<td></td>
<td>Cholera</td>
</tr>
<tr>
<td></td>
<td>Haemophilus influenzae type b</td>
</tr>
<tr>
<td></td>
<td>Hepatitis</td>
</tr>
<tr>
<td></td>
<td>Rubella</td>
</tr>
<tr>
<td></td>
<td>Japanese encephalitis</td>
</tr>
<tr>
<td></td>
<td>Influenza</td>
</tr>
<tr>
<td></td>
<td>Yellow Fever</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EPI vaccines routinely included in immunization programme</th>
<th>Year vaccine available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles</td>
<td>1960</td>
</tr>
<tr>
<td>Poliomyelitis</td>
<td>1980</td>
</tr>
<tr>
<td>Tetanus</td>
<td>2000</td>
</tr>
<tr>
<td>Pertussis</td>
<td></td>
</tr>
<tr>
<td>Diphtheria</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 1. Potential impact of vaccines on mortality.** Each spot represents, in approximate and schematic form, the comparative disease burden estimated for 2002 for each of the diseases indicated (for example, the estimated residual measles burden was 610 000 deaths). The light green area represents prevented deaths.
Financial investment

In the past, the entire range of EPI vaccines used in the immunization schedules recommended by WHO used to cost just over a dollar. Even though the cost of the Hib vaccine has come down considerably, a single dose still costs more than two dollars. New vaccines in developed countries cost more than 100 dollars per dose, while the per capita gross domestic product (GDP) of the 72 countries eligible for funding from the GAVI Alliance\(^2\) is less than US$ 1000 US dollars (for the poorest it is less than US$ 300). In terms of using vaccines in routine programmes, the gap between rich and poor countries has widened over the years; new life-saving vaccines have been marketed at prices that are unaffordable to most low-income countries [1].

However, cost is just part of the problem. Mechanisms to ensure the long-term financial sustainability of new vaccines are also needed. The inadequacy of disease surveillance and reporting systems in some countries has made it difficult to evaluate the disease burden and the potential return on investment in new vaccines relative to other public-health priorities. Low or uncertain demand at the outset can have a long-term impact on both the supply and price of a new vaccine and in developing countries faced with low and/or uncertain demand, manufacturers will restrict production volumes accordingly. Once the plant size has been decided, it becomes very expensive to scale up production at a later date. This explains why prices remain high for low volumes of production [1, 8].

Over the next ten years, an unprecedented range of new technologies and vaccines, which could potentially be added to immunization programmes, will become available. These will be vaccines against diseases for which other preventive or therapeutic health interventions are available, thus forcing countries to make a choice. Problems such as poor knowledge of vaccine safety and regulations and inadequate cost-effectiveness

---

\(^2\) The GAVI Alliance (formerly known as the Global Alliance for Vaccines and Immunization) is a public-private sector partnership that aims to improve access to vaccines in poor countries. GAVI partners include governments, UNICEF, WHO, the World Bank, the Bill and Melinda Gates Foundations, the vaccine industry, public health institutions and non-governmental organizations. The GAVI fund provides resources for the Alliance’s programmes. The Alliance provides a forum for partners to work towards common goals and strategies and coordinate their efforts.
studies on different immunization strategies will have to be addressed before countries can make any rational evidence-based decisions.

It will also be necessary to decide, in the light of conclusive data, whether the reduction in morbidity justifies the financial investment in a given vaccine and which of these products is the best investment in the light of limited national resources, and in particular, which will be the easiest to integrate into immunization programmes and will have the best overall impact on public health.

Two new funding initiatives - the International Finance Facility for Immunization (IFFIm) and Advance Market Commitments - have recently been added to the GAVI Alliance funding; together these represent potential aid of several billion dollars for developing, buying and introducing new vaccines [1, 9]. A clear and robust global policy-making process will facilitate the setting of international development priorities, investment priorities for donors such as the GAVI Alliance and manufacturing priorities for companies in order to focus on appropriate products, since any problems in these areas could lead to costly errors and delays.

**Goals and nature of WHO recommendations**

WHO provides norms, standards and reference products for the manufacture and control of vaccines. These standards are intended for manufacturers and national regulatory authorities and are used as a basis for the prequalification process [10]. WHO provides this prequalification service to UNICEF and other United Nations agencies to assess the acceptability, in principle, of vaccines for purchase by these agencies, the aim being to ensure that the vaccines are safe and effective [10]. WHO recommendations for vaccine use are intended primarily for the Governments of Member States, specifically at the government agencies responsible for decision-making, implementation of immunization programmes, surveillance of vaccine-preventable diseases, and vaccine safety and licensing, and national advisory committees. Recommendations can also be helpful to the donors and principal partners of immunization programmes, for example UNICEF
and the GAVI Alliance, non-profit organizations, international professional associations or bilateral or multilateral partners, in adjusting their country programmes and assistance, including vaccine procurement. The recommendations are also useful to the pharmaceutical industry for establishing an investment strategy, and to research institutes and WHO staff.

These recommendations can be particularly helpful within the framework of a (necessarily coordinated) global strategy for controlling or eradicating diseases, for example the programmes to eradicate poliomyelitis and neonatal tetanus or the measles mortality reduction initiative. Immunization has both an individual and a collective impact through group immunity that can protect a number of non-immune individuals, or even the whole population, once sufficient coverage (which varies with the disease) has been achieved. Low immunization rates in certain countries and epidemic outbreaks pose a serious threat to non-immune children and adults throughout the world. The rapid development of international travel and mass population movements are increasing the risks of infection. Growing health interdependence means that immunization in one country can affect the incidence of disease in another. Thus in the early 1990s, an international health emergency was declared in Eastern Europe when low immunization rates and an economic crisis triggered a major diphtheria epidemic which claimed almost 30 000 lives. Before the epidemic could be brought under control, the disease had also spread to Germany, Finland, Norway and Poland [1]. More recently, the lack of progress in immunizing children against poliomyelitis in the last four countries where the virus is still endemic, especially Nigeria, is jeopardizing its eradication. Between 2005 and 2006, the polio virus was exported from Nigeria to 23 other countries in the African region, and also to Indonesia [9].

When necessary, WHO conclusions and recommendations can be used to confirm vaccine safety and efficacy, particularly in countries with limited resources or where national regulatory authorities for medicines and vaccines are not yet fully operational. Because vaccines can now be directly introduced in developing countries without first being used in developed countries, the development of tools to evaluate vaccine safety is
more important than ever, especially in situations where there are widespread questions and allegations about vaccine safety.

**Procedure for the formulation of recommendations**

**Formulating recommendations – Challenges and procedures**

WHO receives recommendations from external advisory committees comprising panels of experts and high-level scientific groups from various geographical and institutional backgrounds (e.g. universities, governments and research institutions). These committees' deliberations are issued in the form of recommendations to the WHO Director-General or her representative who use this information to set WHO immunization policy. The experts act in their own capacity, not on behalf of the country or organization they represent. Although opinions and contributions are of course sought from these organizations, the final decision must remain free from any conflict of interest. To be effective, the information must be easily comprehensible and accessible to users.

WHO has fine-tuned the procedures it uses to issue recommendations by focusing on potential conflicts of interest, multiculturalism and proper geographical representation. Independence from donors, the Organization’s awareness-raising role and the transparency of the decision-making process must also be guaranteed.

One of the main challenges is speedy implementation and dissemination of recommendations and conclusions, thereby avoiding delays in the large-scale use of new products, and the ability promptly to adapt programmes to needs. Another challenge is to ensure that WHO immunization policies are coordinated with the wider framework of other possible preventive interventions and policies to control diseases, for example immunization against the human papillomavirus and future immunization against malaria.

**Policy development framework**
Internationally, WHO provides recommendations via three main groups: (1) the Strategic Advisory Group of Experts (SAGE); (2) the Global Advisory Committee on Vaccine Safety (GACVS); and (3) the Expert Committee on Biological Standardization (ECBS) (see below for descriptions). It also has other, more specific, technical groups; some are standing bodies while others work on an ad hoc basis. Another body, the WHO/UNAIDS Vaccine Advisory Committee of the Initiative for Vaccine Research, is specifically tasked with reviewing research strategies from a scientific and technical perspective and defining priorities.

There is also a technical advisory group for each of the six WHO regions – Africa, the Americas, the Eastern Mediterranean, Europe, South-East Asia and the Western Pacific – which submits technical opinions on immunization priorities and strategies in the light of particular regional epidemiological and social issues. These opinions are conveyed to the WHO regional directors who are, in turn, responsible for adapting global policies and recommendations to regional realities. Figure 2 shows how the advisory committees function.

**Principal WHO advisory groups in the normative field**

**SAGE (Strategic Advisory Group of Experts)**

SAGE was established in 1999 and is the principal advisory group to WHO on immunization. It provides the Director General with recommendations on issues ranging from research and development to vaccine administration and linkage with other health interventions. SAGE has recently adapted its activities to suit the requirements of WHO’s Global Immunization Vision and Strategy, as referred to above [6]. Its mandate is not restricted to childhood immunization but extends to all age groups and all vaccine-preventable diseases through systematic reviews by groups of scientific and technical experts [11]. Its proceedings are open to partners and observers and its conclusions and recommendations are published expeditiously (in English and French) in WHO’s Weekly Epidemiological Record and the WHO web site where the group's terms of reference and operational procedures are also cited (http://who.int/immunization/sage/en/index.html).
Expert Committee on Biological Standardization (ECBS)
The ECBS was established in 1947 to set global standards and criteria with a view to
guaranteeing the quality of vaccines and other biological products. These standards are
drafted through a process of global dialogue. The committee also develops and
disseminates reference preparations, i.e. international standards that are used as a
reference by manufacturers and regulatory authorities. These preparations are used to
calibrate regional, national or in-house working standards and often form the basis for
licensing and batch release. The International Laboratory for Biological Standards at the
National Institute for Biological Standards and Control (NIBSC) in the United Kingdom
is the reference laboratory used by the WHO to produce its reference preparations [9].
Historically, standards were established after a new vaccine had been licensed, but ECBS
must now be more proactive and step in at the beginning of the production cycle. ECBS
recommendations are published in the WHO Technical Report Series
information on the committee is available at the following address:

Global Advisory Committee on Vaccine Safety
The Global Advisory Committee on Vaccine Safety was established in 1999 to respond
promptly to vaccine safety issues of potential global importance. The committee does not
directly determine immunization policies, but it does express its scientific opinion on
vaccine safety, which could result in policy changes [12, 13]. The committee evaluates
questions of vaccine safety by thoroughly reviewing the latest developments in basic
science, epidemiology and clinical practice. All aspects of vaccine safety are covered,
whether of national or international interest. The committee works in close cooperation
with all interested parties including experts from national authorities, academic
institutions and the pharmaceutical sector. The committee is at liberty to request, monitor
and evaluate specific studies that seek to explore a possible link between vaccines or their
components and adverse effects. The impartiality of the committee is essential and
explains why its mandate is distinct from that of SAGE. The committee has on occasion
found the alleged harmfulness of certain vaccines to be unsubstantiated, yet has also promptly recognized, when the need has arisen, the link between a given vaccine and adverse effects [9]. In addition to the reports published in the Weekly Epidemiological Record, emphasis is placed on making information available via the web site where the committee’s findings on all the topics taken up can be consulted (http://www.who.int/vaccine_safety/en/index.html).

| SAGE WHO | • Global policies and strategies  
| Recommandations on vaccine use  
| Global solutions for regional/national challenges  
| Overall evaluation of the implementation of global and regional policies |
| Working groups | • Analysis and technical guidelines  
| Standards  
| International research agenda  
| Vaccine design |
| WHO international technical committees | • Regional policies and strategies  
| Identifying regional priorities |
Table 1: Operating framework of advisory committees on immunization

<table>
<thead>
<tr>
<th>Countries</th>
<th>• Monitoring progress at regional level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• National policies and strategies</td>
</tr>
<tr>
<td></td>
<td>• Prioritising problems and identifying optimal solutions</td>
</tr>
<tr>
<td></td>
<td>• Implementing national programmes</td>
</tr>
<tr>
<td></td>
<td>• Monitoring impact</td>
</tr>
</tbody>
</table>

**Figure 2. Operating framework of advisory committees on immunization**

**Vaccine Position Papers**

WHO regularly updates position papers on vaccines and vaccine combinations that have an international public health impact and are used in large-scale immunization programmes. The position papers summarize available background information on the respective diseases and vaccines and conclude with the current WHO position concerning their use in a global context. These documents are the fruit of a wide-ranging consultation and review process by various interest groups and experts both inside and outside WHO. Since April 2006, the papers have been reviewed and approved by SAGE [14]. SAGE also takes part in setting priorities for drafting new position papers and updating existing ones. They are mainly aimed at national public health officials and immunization programme managers but they may also be of interest to international funding agencies, vaccine manufacturers, the medical community and the scientific media. Information is published in the Weekly Epidemiological Record and is available on the Internet (http://www.who.int/immunization/documents/positionpapers_intro/en/index.html).

**Impact of recommendations**

**Measuring the impact of recommendations**

Since their implementation depends on so many additional factors, it is not easy to evaluate precisely the impact of WHO policies and recommendations, yet the evidence shows that they do indisputably have an impact.
The adoption of EPI vaccines and schedules by a large number of developing countries and the extension of immunization programmes in the 1980s [1] are perhaps the most obvious evidence of the impact of global recommendations. Global recommendations to immunize against measles as part of a routine immunization programme, complemented by a second opportunity for immunization (as part of routine immunization or during large-scale supplementary immunization campaigns), have successfully reduced the number of deaths from measles. The international community has recently commended this strategy given that the measles mortality rate has fallen by 60% worldwide since 1999. This even exceeds the United Nations goal of reducing deaths from measles by 50% between 1999 and 2005 [15].

The picture is less satisfactory for more recently introduced vaccines. By the end of 2005, only 136 (87%) of the world’s 156 developing countries and economies in transition had included the hepatitis B vaccine in their national immunization schedules [2], despite the fact that WHO recommended universal immunization in 1991 [1, 16] and the vaccine has been available in rich countries since 1982. In industrialized countries, the general introduction of Hib vaccine more than 15 years ago has almost eradicated Hib-related disease in recent years. Despite a position paper in 1998 recommending its use [17], by the end of 2005 only 65 of the world’s 156 non-industrialized countries (42%) had introduced this vaccine [2]. In low-income countries, the uptake of these new vaccines has been greatly facilitated by recent assistance from the GAVI Alliance and the GAVI Fund. The scale of the disease burden in countries, the cost of vaccines and, in the case of the hepatitis B vaccine, the fear of adverse effects which subsequently turned out to be unfounded, have slowed the uptake of the these vaccines. In light of recent data, SAGE has reinforced its recommendation for the use of the Hib vaccine[11] and the current wording of the positions paper should facilitate its introduction: “In view of their demonstrated safety and efficacy, conjugate Hib vaccines should be included in all routine infant immunization programmes. Lack of local surveillance data should not delay the introduction of these vaccines” [14].
Recommendations also need to be adapted to each country. Their aim is not rigidly to harmonize all immunization schedules in a fixed pattern, but rather to offer a framework which countries can adapt to existing schedules and local epidemiological practices and data.

Conversely, it is also possible to determine whether countries are not complying with WHO recommendations. The administration of BCG boosters is an example of this. This practice is not recommended by WHO [18], but at the end of 2005 it was still being used by 22 countries [2], 15 of them in Europe. WHO has also recommended that countries should stop using the Rubini strain of the mumps vaccine due to its low efficacy [19]. On the other hand, despite being suspended in the European Union, the Urabe Am9 strain is still being successfully used in routine immunization programmes in a number of developing countries. Without the support of WHO recommendations, and given the media pressure, the use of vaccines containing the Urabe Am9 strain would probably have been discontinued, thereby risking stockouts due to the cost of other strains.

SAGE recently adopted a recommendation advocating the worldwide use of the heptavalent pneumococcal conjugate vaccine [9], as well as a regional recommendation to use the two recently licensed rotavirus vaccines [11]. These recommendations helped to secure an investment for the purchase of these two vaccines by the GAVI Alliance Executive Committee, which will enable them to be used in some of the world’s poorest countries.

Certain facts bear out the view that WHO recommendations on the use of benchmarks and standards have a major impact. Guidelines on the use of cell substrates have been adopted by the International Conference on Harmonization as part of the licensing process [20]. The recently finalized guidelines on the bio-containment of influenza vaccines [21] are already in the process of being applied in seven countries. ECBS recommendations on the production and control of rabies vaccines, excluding those originating from the nervous tissue of mammals [21], have had an enormous impact, even
though some vaccines are still produced from sheep brain. Within the framework of the global Measles Initiative, WHO standards and the prequalification process as a whole have led to the availability of safe and effective vaccines in countries with the highest measles mortality rates, where the national authorities have been unable to carry out the necessary controls.

Not all recommendations have the same impact or are as useful in every country. Industrialized countries with sophisticated procedures, tailored to their situation, for the development of recommendations will pay less attention to position papers but will wish to know the position of GACVS on safety issues. The impartiality and credibility of WHO are important in this context. GACVS is increasingly cited as a reference and its pronouncements are used to dispel rumours. Its views are quoted directly by regulatory authorities, including in industrialized countries [22].

**Better communication for greater impact**

If countries are to make use of the recommendations (SAGE and WHO position papers published in the WER), these should not only be credible but accessible too. A recent (unpublished) survey of a group of decision-makers working in immunization-related areas indicated that 12% of them at most had had access to certain SAGE and GACVS reports and position papers. An external evaluation of the committees also revealed deficiencies in the accessibility and dissemination of WHO recommendations. Better communication of WHO policies is thus a top priority. The Department of Immunization, Vaccines and Biologicals is working towards this end by taking account of needs (e.g. translation) and using the most effective tools for disseminating information. SAGE and GACVS reports, and position papers on vaccines, will thus be translated into the six official languages of WHO (Arabic, Chinese, English, French, Russian and Spanish).

**Summary**

Global immunization policies and recommendations: objectives and process
The World Health Organization (WHO) has a dual mandate of providing global policies, standards and norms as well as support for member countries in applying such policies and standards to national programmes with the aim to improve health. The vaccine world is changing and with it the demands and expectations of the global and national policy makers, donors, and other interested parties. Changes pertain to: new vaccines and technologies developments, vaccine safety issues, regulation and approval of vaccines, and increased funding flowing through new financing mechanisms. This places a special responsibility on WHO to respond effectively. WHO has recently reviewed and optimized its policy making structure for vaccines and immunization and adjusted it to the new Global Immunization Vision and Strategy, which broadens the scope of immunization efforts to all age groups and vaccines with emphasis on integration of immunization delivery with other health interventions. This includes an extended consultation process to promptly generate evidence base recommendations, ensuring transparency of the decision making process and added communication efforts. This article presents the objectives and impact of the process set to develop global immunization policies, norms, standards and recommendations. The key advisory committees landscape contributing to this process is described. This includes the Strategic Advisory Group of Experts, the Global Advisory Committee on Vaccine Safety and the Expert Committee on Biological Standardization. The elaboration of WHO vaccine position papers is also described.

ACKNOWLEDGEMENTS
The authors would like to thank their colleagues in the WHO Department of Immunization, Vaccines and Biologicals for their contribution and in particular Alison Brunier and Mario Condé for their assistance in drafting this article.

REFERENCES