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## WHO's Vision and Mission in Immunization and Vaccines 2015 – 2030

Dear WHO staff and partners,

WHO's Vision and Mission in Immunization and Vaccines describes WHO's strategic focus and key roles in achieving the goals of the Global Vaccine Action Plan, across all areas of work and all levels of the organization continuing into the next 15 years.

The strategic directions described in this document are consistent with ongoing WHO reform and aligned with the Sustainable Development Goals. They reinforce WHO's longstanding role as an international leader, setting norms, establishing policies, and reaching international agreement on health priorities. They also bring forward more focused roles for WHO in providing technical assistance and managing knowledge and data.

WHO's Vision and Mission illustrates how the organization plans to evolve its critical role in immunizations and vaccines to meet the needs of future health programmes. It will be used to guide internal decisions about where to focus resources, at what level of the organization, and in which strategic directions.

WHO staff at all levels has participated in the development of this document. By sharing it with our partners and stakeholders, we hope to show how WHO will achieve its mandate over this exciting period of transition and expansion in the field of immunization.

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# WHO's Vision and Mission in Immunization and Vaccines 2015 – 2030

*Vaccines prevent disease. Vaccines avert deaths. Vaccines promote health.*

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## 1. Preamble

Between 2010 and 2015 more than 5 million deaths<sup>1</sup> were averted annually thanks to vaccinations delivered around the world. This estimate does not include the impact of rotavirus vaccine and pneumococcal vaccines, for which no estimates are available. Immunization continues to be one of the most powerful and cost-effective interventions in public health.

In the past two decades, the scope of immunization has expanded significantly as new vaccines and delivery technologies have been introduced into routine immunization programmes worldwide. The same period has witnessed a proliferation of actors in the global arena that promote immunization and help vaccines reach an ever-larger number of children, adolescents and adults. The horizon is filled with prospects of new vaccines, delivery technologies and systems.

In 1974, a World Health Assembly resolution launched the Expanded Programme on Immunization (EPI) to immunize children worldwide with six vaccines. Since then, the World Health Organization (WHO) continues to act as the global authority on immunization in accordance with its constitution and obligation to its 194 Member States. In an increasingly interdependent global environment, WHO has and will continue to focus on its core roles in immunization: to set norms and standards; convene global expertise; develop, promote, and facilitate adoption of new guidelines; and monitor national and global achievements and progress.

To further articulate how these roles will evolve over the next 15 years, WHO developed a new Vision and Mission for Immunization and Vaccines for the period 2015 – 2030. This document presents the key focus areas and a series of strategic directions that define our core business for the future coinciding with the new Sustainable Development Goals era.<sup>2</sup>

The scope of this document includes work on immunization and vaccines taking place across all levels of WHO. A new articulation of WHO's mission, vision and strategic directions will enable the organization to better anticipate and respond to the opportunities and challenges of the immediate future. It will position WHO with the capacity and competencies needed to fulfil its mandate and streamline its core functions at global, regional and country levels. It will assist WHO in positioning itself clearly within on-going implementation of the Global Vaccine Action Plan (GVAP)<sup>3</sup> and prepare itself for the decade following the current GVAP: 2020 to 2030. It will also provide the basis for future global and regional plans.

This document was developed through a process that included consultations with immunization teams in all WHO regional offices and a range of meetings with other key staff in all departments engaged in vaccines and immunization work in its headquarters office in Geneva and in selected country offices. Two distinct pieces of work were undertaken to inform the work: a historical review

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<sup>1</sup> Based on WHO estimates of deaths averted from diphtheria, tetanus, pertussis and measles and Ehreth's estimates (EhrethJ: Vaccine 21 (2003) 596 - 600) of deaths prevented from Hib, HepB, polio and TB. Additional deaths are prevented with the increasing uptake of vaccines against *Streptococcus pneumoniae* and rotavirus.

<sup>2</sup> [Open Working Group Proposal for Sustainable Development Goals](#). New York, United Nations, 2015 (Document A/68/970).

<sup>3</sup> [Global Vaccine Action Plan 2010 - 2020](#). Geneva, World Health Organization, 2012.

of 40 years of EPI illustrates the main determinants for EPI successes (Annex 4) and a survey among users of WHO products and services identifies responsibilities that WHO does well and those areas that could be done equally well by partners (Annex 5). This research helped WHO identify areas where we have a unique role and comparative advantage and areas that could be phased out.

Recognizing that immunization programmes have and will continue to undergo rapid change, we shaped our mission and strategic focus areas around a set of assumptions about the environment in which immunization programmes will operate in 2030. The new environment for immunization is described below:

### **What will 2030 look like?<sup>4,5</sup>**

By 2030, the immunization environment may look very different than it does today.

Countries are experiencing broad demographic and economic changes. Already, there are more people living in middle-income countries than in low-income countries. Increased economic stability will provide countries more ownership over their immunization programmes, and countries will require less technical assistance to make decisions and address problems. More countries will have sufficient capacity for regulatory affairs and prequalification at the regional and country levels, and will be less reliant on WHO's prequalification process at the global level.

The sustainable development goals will have provided direction for economic and social development. Health indicators will be broader, encompassing communicable and non-communicable diseases as well as emerging burdens from accidents and environmental threats. Prevention will continue to be important, and attention will continue to be directed to interventions that are considered cost-effective.

More vaccines will be available to protect against more diseases throughout the human life course. Immunization will likely become part of an integrated package of disease prevention strategies, meaning that immunization services will be accompanied by other services and delivered in more places, including schools, homes, and pharmacies. New, easier-to-use immunization delivery technologies may be more widely available, making it possible for non-health personnel to deliver immunization. Electronic devices and software systems will make data collection and analysis easier and more powerful, enabling managers and health staff to more efficiently identify and reach people previously missed by immunization and to tailor services to the most optimal delivery methods.

Disease elimination and eradication programmes will continue to exist, but as part of stronger health systems that have regular and reliable contact with communities, even those in remote and hard-to-reach areas. Routine and campaign immunization services will be managed in a single platform.

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<sup>4</sup> *Twelfth Global Programme of Work*. Geneva, World Health Organization, 2014 ([http://www.who.int/about/resources\\_planning/twelfth-gpw/en/](http://www.who.int/about/resources_planning/twelfth-gpw/en/), accessed 9 September 2015)

<sup>5</sup> Chaferhoff M, Schrade C, and Suzuki E. *Analysing proposals for reform of the global health architecture*. London, Chatham House Royal Institute of International Affairs, Centre on Global Health Security, 2015.

More successful immunization programmes will lead to fewer people falling ill and dying from vaccine-preventable diseases, and demand for immunization may begin to drop. In such an environment, health priorities are expected to shift to the prevention and control of non-communicable diseases. Immunization services and demand for those services must be more purposefully maintained.

Fragile states will continue to exist, and the disparity between health outcomes in stable and fragile countries may continue to increase. These countries will require ongoing support to maintain reliable immunization services amongst larger age groups and more difficult-to-access populations.

## 2. Vision

Our vision statement presents where we want to be in the future and the impact that we intend to have on health in the world.

Our vision:

***The highest attainable standard of health for all individuals and communities by preventing disease.***

## 3. Mission

Our mission statement presents the purpose and focus of our work in immunization and vaccines over the next 15 years.

Our mission:

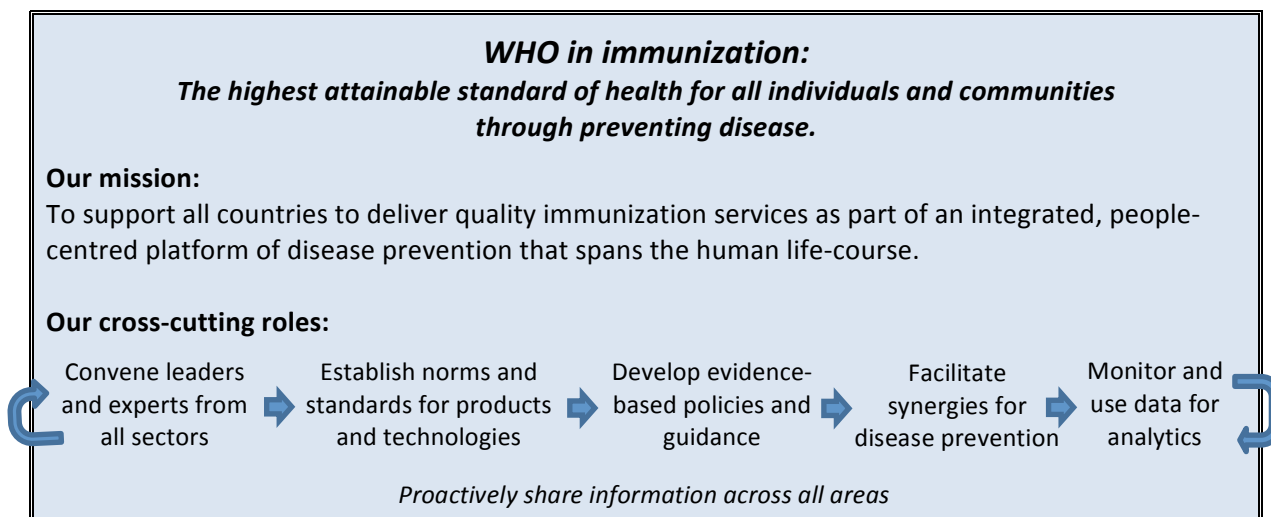
***To support all countries to deliver quality immunization services as part of an integrated, people-centred platform of disease prevention that spans the human life-course.***

## 4. WHO's strategic focus and cross-cutting roles

### 4.1 The strategic framework

*Our heart and soul.*

This framework is intended as a stand-alone summary of WHO's mission, vision, and strategic directions, that shape and drive the organization's work in vaccines and immunization.



<b>Our strategic focus:</b>	
<p><b>“Vaccines”</b> <i>Encourage and support research that is used to inform norms and standards. Identify necessary regulatory pathways to accelerate the development, licensure and introduction of new vaccines and related technologies and strategies.</i></p> <p><b>Strategic directions:</b></p> <ol style="list-style-type: none"> <li>Promote the development of new vaccines and vaccine delivery technologies to meet public health priorities</li> <li>Establish norms and standards for vaccines and delivery technologies</li> <li>Ensure vaccines and delivery technologies are of assured quality</li> </ol>	<p><b>“Immunization”</b> <i>Collect and share evidence that countries use to inform their choice of strategies to ensure that vaccines are available, affordable and accessible to all.</i></p> <p><b>Strategic directions:</b></p> <ol style="list-style-type: none"> <li>Support national immunization systems to become more effective and efficient</li> <li>Monitor and analyse global and regional immunization data</li> <li>Ensure the sustainability of immunization programmes</li> <li>Apply behavioural sciences to immunization</li> <li>Sustain immunization services in emergencies</li> <li>Lead disease elimination and eradication efforts</li> </ol>
<p><b>Principles aligning how we work:</b></p> <ul style="list-style-type: none"> <li>Accountable</li> <li>Country-led</li> <li>Interconnected and interdependent</li> <li>Efficiency-driven</li> <li>Impact oriented</li> </ul>	

## 4.2 The strategic directions

### *Our mind and body*

Our strategic directions look both upstream at the development and regulation of vaccination and delivery technologies and downstream at the implementation of immunization services. These dual strategic areas were selected based on consultation across WHO regional and headquarters (HQ) offices, with input from selected country offices, and have informed our nine strategic directions through 2030.

For each strategic direction a specific approach has been defined with a view toward where we expect to be in 2030. These strategic directions and approaches are presented in Annex 1.

## 4.3. Roles that cut across all areas of work

### *Our brain*

As we look to the future, we recognize the areas of work where WHO is already acknowledged—both internally and by partners—as playing a critical role across technical streams. Regardless of the area of immunization—e.g., measles elimination, outbreak response, new delivery technologies or supporting national immunization systems to become more effective and efficient—WHO’s leadership in these cross-cutting roles is and will remain necessary and consistent. We also identify a few expanded roles that WHO considers both vital and important—these include adopting broader strategies for disease prevention and increasing our capacity to collect and analyse data.

The cross-cutting roles presented below describe how WHO will work over the next 15 years.

- **Convene leaders and experts from all sectors.** WHO’s role in convening experts in immunization is well established and globally critical. Whether it is to convene ministries of health and immunization managers to discuss regional issues, getting all partners within the country to meet and agree on implementation plans, or bringing together global experts across a range of disciplines to recommend evidence based policy, WHO is recognized as a trusted convener at national, regional and global levels.
- **Establish standards for products and technologies.** WHO’s normative role and standard-setting for vaccines, biologicals and technologies is relied upon by countries, private companies, United Nations (UN) agencies and partners to ensure that immunization products are effective, safe and suitable for all people around the world. WHO is recognized as a neutral broker and thus has a unique role to play in this sphere that is not—and some argue cannot—be filled by others.



- **Develop evidence-based policy recommendations and guidance.** WHO's role in establishing policy recommendations and guidance across all areas of immunization—from data collection to new vaccine introduction to stockpile management—remains critical for maintaining equitable, efficient and consistent immunization programmes around the world. Countries routinely look at WHO policy recommendations and guidance when developing their own strategies, programmes and implementation plans. Expert groups such as the Strategic Advisory Group of Experts on immunization (SAGE) are particularly important, as partners in bilateral agencies, foundations, and private companies refer to SAGE recommendations when planning their immunization services support and products. Similarly, the work of regional technical advisory groups is crucial to tailor policy to the specific needs and contexts of each WHO region.
- **Facilitate synergies for disease prevention.** WHO will increasingly play a key role in helping countries meet international norms, implement national health plans and identify synergies across health services that can result in more effective and efficient health systems. Providing technical guidance on programme implementation is also a critical role that WHO will increasingly address from the regional and country level.
- **Monitor and use data for analytics.** With support from Member States, academic partners and national institutes, WHO provides a nexus for the consolidation, analysis, and dissemination of data and information across all immunization and vaccine preventable disease areas. WHO will continue to validate data for quality and reliability so it can be used to inform priorities, activities and plans, and support decision-making processes at all levels. As electronic information systems begin to proliferate in developing country health systems, WHO will work with countries to extract the most useful data that can be used to make decisions and inform global and regional health strategies. WHO will also use state-of-the-art analytics and data visualization technologies to analyse data and use it to prioritize investments and develop new prevention goals.

#### 4.4 Responsibilities of each level of the organization

##### *Our arms and legs*

Over the period 2015 to 2030, there will be a gradual shift in the critical roles of the different levels of the organization. The overall intention is to narrow the focus of HQ to areas where a global approach is required and strengthen and enhance the roles of the regional and country offices.

The table below illustrates the major roles that the global, regional, and country-level WHO offices will play. More information on the division of responsibilities is provided in Annex 2.

Table 1. Some examples of key roles for the organization at its three levels

<b>Core Role</b>	<b>HQ</b>	<b>Regional Office</b>	<b>Country Office</b>
<b>Convene leaders and experts from all sectors</b>	More actively involve Civil Society Organizations in setting policies and monitoring their implementation.		
<b>Establish norms and standards for products and technologies</b>	Promote the harmonization of international norms and standards and regulatory procedures across all countries.	Help strengthen national regulatory agencies or regional regulatory mechanisms to progressively reduce the need for prequalification systems.	
<b>Develop evidence-based policies and guidance</b>	Develop behavioural strategies to address hesitancy and demand.	Help tailor global strategies and support their regional implementation.	Support countries to establish their own national policies and strategies related to immunization and disease control and prevention.
<b>Facilitate synergies for disease prevention</b>	Identify opportunities for collaboration across health programmes to improve disease prevention services.	Facilitate inter-country and inter-regional coordination and collaboration on immunisation and elimination and control of vaccine-preventable diseases.	
		Support countries and partners' internal and external fundraising efforts, and align external assistance with country needs and priorities.	
<b>Monitor and use data for analytics</b>	Enable better internal and external global decision-making by sharing the best available global immunization data using analytics and visualizations.	Support inter-country collaboration to obtain quality data and conduct regional immunization and disease risk analyses.	Promote the use of new ideas and technologies (including information and communications technologies) to make data collection and use more effective and efficient.

## 5. Principles aligning how we work

### *Our pulse*

WHO has identified five principles to guide our decisions and actions through 2030. These principles are relevant at both an individual and collective level and are meant to facilitate a shared understanding WHO's interests and goals at each level of the organization. We expect these principles to translate into behaviours that define a common culture for how those who work in vaccines and immunization at WHO approach our work and how we relate to colleagues and partners.

Our principles are aligned with the WHO reform and thus in step with on-going programmatic and managerial changes at WHO.<sup>6</sup> For example, the WHO reform has a stronger country-focus and introduces more rotation and mobility for human resources, which will strengthen regional and country capacity and facilitate more interaction between all levels of the organization. It will thus enhance several of the principles described below.

#### **Accountable**

- Acknowledge and take responsibility for meeting our objectives and commitments by setting and enforcing clear expectations at all levels
- Maintain high ethical and professional standards by asserting an evidence-based and independent perspective

#### **Country-led**

- Follow governments' lead and help them take ownership of their decisions and plans
- Invite country participation in regional- and global-level dialogue
- Cultivate and reinforce country-level capacity to sustain immunization achievements

#### **Interconnected and interdependent**

- Seek and foster synergies across health areas that have the potential to optimize outcomes
- Strengthen internal and external collaborations that can speed or enhance outcomes

#### **Efficiency-driven**

- Work efficiently, i.e., seek maximum results from limited resources
- Provide timely access to data and information so that all actors can react and work quickly
- Streamline processes that make it easier to collaborate with internal and external colleagues

#### **Impact-oriented**

- Draw attention to new issues, encourage ongoing learning and innovation, and actively promote successful ideas and initiatives
- Set priorities and allocate resources in alignment with the delivery of results
- Improve programme performance, so that everyone who needs vaccines has reliable access
- Promote equity in immunization

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<sup>6</sup> *Our Reform Story*, Geneva, World Health Organization, 2013 ([http://www.who.int/about/who\\_reform/change\\_at\\_who/strategic\\_vision/en/#.VfBavnjiLU4](http://www.who.int/about/who_reform/change_at_who/strategic_vision/en/#.VfBavnjiLU4), accessed 9 September 2015).

## 6. The role of WHO with its partners

### *Our family*

WHO has always worked closely with partners to set norms and standards, provide direct guidance and seek financial support for Member States. Without the ideas and contributions of partners, none of last decade's successes in immunization would have been possible.

Since the EPI launched in 1974, the number and type of partners involved in immunization has increased dramatically (see Annex 3). WHO partners in immunization include: the countries themselves (Ministry of Health, other Ministries, technical agencies), financial partners, manufacturers, UN agencies, international technical agencies, bilateral agencies and projects, and civil society organizations.

In this section, we illustrate the many ways in which WHO works with partners to help achieve our Vision and Mission in Immunization and Vaccines between now and 2030.

### **1. Financial partners**

Foundations, official development agencies, and Gavi, the Vaccine Alliance have been providing financial and technical support to both countries and WHO allowing great achievements in morbidity and mortality reduction over the past decades. Ongoing support from donors complemented by increasing spending from countries themselves will ensure that recent achievements are sustained and that programmes will continue to improve in all countries.

*WHO will support the work of financial partners by:*

- Highlighting areas where financial and technical support is most needed
- Providing technical support to countries and defining norms, standards, policies and strategies for immunization
- Monitoring and evaluating national, regional and global programmes and strategies for immunization

### **2. Manufacturers**

Providing adequate quantities of efficacious, safe and cost-effective vaccines and equipment is a prerequisite for strong programmes and an essential element in strengthening health security. Manufacturers of vaccines and immunization technologies, including those in low- and middle-income countries, are key partners for providing pre-qualified vaccines and other immunization technologies to countries.

*WHO will support the work of manufacturers by:*

- Providing guidance on how current and future vaccines and immunization technologies can be adapted to fit the needs and constraints of low-resource settings
- Developing country capacity to regulate vaccine safety and efficacy and harmonize regulatory requirements across regions

- Helping countries more accurately forecast vaccine needs and mobilize the resources required to purchase vaccines

### **3. United Nations agencies and global initiatives**

Many UN agencies and global initiatives include immunization activities in their purview. Their collaboration is crucial to ensure that immunization is integrated across all strategies and programmes and, inversely, that immunization is a useful complement to ensure successful implementation of other health interventions.

*WHO will support the work of other UN agencies and global initiatives by:*

- Integrating related health and other development strategies into immunization programmes, where possible
- Improving health systems so that other health interventions benefit from strong immunization programmes
- Coordinating with other UN agencies and global initiatives to provide technical and financial support to countries
- Coordinating the production and use of quality data

### **4. Technical partners**

The category “technical partners” covers a range of different institutions: international technical agencies and non-governmental organizations, universities and research institutes, scientific societies, and individual consultants and consulting companies.

Some of these institutions have been granted the status of WHO Collaborating Centres. This status, granted after several years of strong partnership, reinforces the link between institutions and provides stronger alignment between WHO objectives and the collaborating centres’ activities.

*WHO will support the work of technical partners by:*

- Drawing upon their expertise and knowledge when developing WHO norms, standards and policies
- Validating and sharing monitoring and evaluation data collected from national, regional and global immunization programmes

### **5. Civil Society Organizations (CSOs)**

Historically, the relationship between WHO EPI and civil society, including CSOs, has been relatively weak. However, civil society organizations have been increasing their involvement and support of immunization programmes worldwide and both WHO and CSOs stand to benefit from stronger collaboration and cooperation. Whereas WHO plays a leading advisory role to country governments, CSOs are often the immunization stakeholders closest to communities and populations.

As CSOs continue to expand their interest in immunization, particularly in relation to the GVAP implementation, WHO will proactively engage with CSOs and help them advocate for vaccines and immunization, support Member States and remain relevant and evolving players in global health.

*WHO will support the work of civil society by:*

- Involving civil society representatives as full participants in immunization programme planning, implementation, monitoring and reporting, and meetings and events.
- Normalizing the relationships between government and civil society with regards to immunization

## Annex 1: Strategic areas and directions

### STRATEGIC AREA: Vaccines

#### **1.1 Strategic Direction: Promote the development of new vaccines and vaccine delivery technologies to meet public health priorities**

Research and development (R&D) for new and improved vaccines and vaccine delivery technologies is central to all efforts to prevent diseases with significant morbidity, mortality and economic burden, especially in low and middle-income countries.

WHO has been involved in vaccine and delivery technology R&D for many years, facilitating productive dialogue with manufacturers and helping research institutes and manufacturers prioritize R&D investments. Over the next 15 years, WHO will continue to work with manufacturers and research institutes to recommend vaccine R&D priorities and foster the development of new technologies that can be used to meet public health priorities, such as thermostable, community-provided vaccines and needle free delivery devices.

#### **Approach:**

- Develop global agendas for R&D around vaccines and delivery technologies that address public health priorities of low and middle-income countries and formulate new research needs and promote the development of research partnerships.
- Help define target attributes and development pathways for novel vaccines/combinations and delivery technologies using preferred product characteristics (PPCs) and other guidance documents to address future implementation challenges.
- Created streamlined and accelerated development pathways for vaccines and delivery technologies by: encouraging collaboration among research centres and WHO collaborating centres, including those located in low and middle-income countries; facilitating technical support for research projects; providing expert advice on intellectual property, and facilitating technology transfer, when appropriate.

#### **1.2 Strategic Direction: Establish norms and standards for vaccines and delivery technologies**

One of WHO's core roles is to establish and promote global norms and standards for medicines and devices that safeguard the quality, safety and efficacy of vaccines and delivery technologies. WHO also works with countries to translate global norms and standards into regional and national regulatory practice. In 2014, the portfolio of WHO standards for biological substances extended to over 70 written standards and 300 international biological reference preparations.

Over the next 15 years, as countries begin to take on more regulatory responsibility for medicines and devices, WHO will promote regulatory convergence of international norms and standards. WHO will also seek to improve its norms and standards process so it can quickly assimilate scientific advances in production and control of vaccines and devices into the normative process.

**Approach:**

- Convene expert committees and promote international laboratory collaborations to set norms, standards and reference preparations and develop standards for new vaccine candidates.
- Promote the use of internationally-agreed norms and standards among all relevant international and national actors.
- Achieve convergence of international norms and standards in support of a globalized supply chain.
- Monitor scientific advances in vaccine and delivery technology production and control and translate them into evolving norms and standards.

**1.3 Strategic Direction: Ensure vaccines and delivery technologies are of assured quality**

Prequalification is a process established to ensure that vaccines and delivery technologies purchased by UN procurement agencies are consistently safe and effective under conditions of use by national immunization programmes. As national regulatory authorities become stronger and increasingly align their procedures with those of stringent National Regulatory Authorities (NRAs) or regional regulatory mechanisms, WHO expects that the need for the prequalification systems will gradually reduce to be used only in exceptional circumstances.

In an effort to build sufficient regulatory capacity in countries, WHO will continue to work with regional and national regulatory bodies to implement globally-accepted norms and standards so that all countries have access to safe, effective and high-quality vaccines and delivery devices.

**Approach:**

- Guide the development of stronger national regulatory systems.
- Expedite the registration of vaccines and devices.
- Convene expert committees to assess the degree to which vaccines and delivery technologies meet the needs of recipient countries
- Promote post-marketing surveillance of prequalified delivery technologies and vaccines to inform decision-making and any revisions to product specifications.



## STRATEGIC AREA: Immunization

### 2.1. Strategic Direction: Support national immunisation systems to continuously become more effective and efficient

WHO's central role in immunization puts it in a unique position to set ambitious global goals and galvanize national, regional and global commitment to achieve those goals. Over the next 15 years, WHO will support Member States to provide quality immunization services as part of stronger and more integrated health systems. In this context, WHO will focus less on the provision of direct technical assistance and more on establishing necessary enabling functions that empower Member States to strengthen their own national systems.

#### Approach:

##### **Seek political commitment for immunization through legislative and policy changes.**

- Gain appropriate political commitment from WHO Member States to prioritize immunisation and establish common global and regional vaccine-preventable disease (VPD) control goals.
- Facilitate inter-country and inter-regional coordination on immunisation and VPD elimination and control.
- Promote in-country legislation that secures budget lines for vaccines and immunisation, requires immunization for school entry, and facilitates the equitable and universal access to and use of immunisation services in the context of the country's health system (e.g., mandates for free-of-cost vaccination, mandates for reporting vaccination data from all sectors, etc.).

##### **Provide strategic and practical guidance to countries.**

- Convene multidisciplinary global and regional advisory bodies to formulate recommendations and provide guidance on immunisation policies, strategies and practices.
- Establish and strengthen national bodies such as National Immunisation Technical Advisory Groups (NITAGs) and NRAs to promote and facilitate in-country decision-making and oversight.
- Set the global and regional agenda for, and facilitate the implementation of operational and economic research to inform decisions on disease prevention, and more effective and efficient immunisation services.
- Develop frameworks and tools to evaluate the impact of immunization on disease and socioeconomic indicators.
- Promote life course approaches to immunisation and integrate vaccination activities with broader disease-prevention efforts.

##### **Support programme planning, budgeting and financing.**

- Support the development of strategic multiyear and annual operational plans that respond to programme evaluations and are aligned with government budget cycles.
- Support Member States, as requested, with internal and external fundraising efforts and help align external support to country needs and priorities.

**Involve new actors and introduce new technologies to improve implementation.**

- Involve civil society and other actors in government-led health planning and in health system strengthening to promote equity and universal access to immunisation.
- Use workforce development and the adoption of new technologies, systems, and practices to support monitoring, evaluation and improvement of supply chains, service delivery, micro-planning, and in-country financial flows.

**Provide guidance and tools to help countries with monitoring and evaluation, disease surveillance and Adverse Events Following Immunization.**

- Support countries to establish appropriate, externally accredited surveillance laboratories and surveillance systems that provide information on the burden and epidemiology of VPDs.
- Increase the use of immunization and surveillance data to monitor immunization system performance and inform strategic, managerial, and operational decisions at national, subnational and local levels.
- Support countries to establish and/or strengthen pharmacovigilance systems to detect, investigate and respond to Adverse Events Following Immunization (AEFI) and improve vaccine safety.
- Promote the use of new ideas and technologies (including information and communications technologies, or ICT) that improve the accuracy, efficiency, and effectiveness of data collection and use.

**2.2 Strategic Direction: Monitor and analyse global and regional immunization data**

The collection, analysis, and use of data to monitor and evaluate national immunization programme performance from a global and regional perspective is a priority for WHO, its Member States, and immunization partners. Data analysis is also crucial for WHO and its partners to establish global/regional immunization policies and to monitor progress towards achievement of their objectives.

Over the next 15 years, WHO will continue to collect and validate coverage and vaccine management data to monitor programme performance and identify issues countries are facing. Data from surveillance systems (including disease incidence and AEFI rates) will also be used to develop global/regional immunization policies that are evidence-based and tailored to countries' needs.

**Approach:**

- Remain the prime source of immunization data and analytics at regional and global levels.
- Use innovative technologies to collect, interpret, share and use data while minimizing the reporting burden for Member States.

- Gather immunization data from all levels in a single global repository that WHO and partners can use to develop evidence-based global/regional immunization policies.
- Support better internal and external decision-making by disseminating accurate and timely immunization data and by using state-of-the-art analytics and visualizations.

### **2.3 Strategic Direction: Ensure the sustainability of immunization programmes**

As the economic status of countries improves, more middle-income countries have begun to assume responsibility for their immunization programmes without or with very limited external financial resources. To date, donors and partners have provided investments to offset the cost of purchasing and implementing new vaccines and achieving more ambitious goals, however national governments with sufficient economic means are expected to maintain much larger and more complex immunization programmes over the long-term.

Over the next 15 years, WHO will coordinate with key immunization partners to help these countries achieve stronger and more sustainable immunization programmes by focusing on four key areas: enhanced decision-making capacity for immunization, increased political commitment, increased demand for immunization services and more timely access to affordable vaccine supply.

#### **Approach**

- Support countries to make timely, evidence-based decisions about vaccine policy and programme choices by building internal capacity to generate evidence and strengthening national decision-making mechanisms (such as NITAGs).
- Help countries build stronger political and legislative support for immunization programmes and secure more dependable domestic financing.
- Work with countries to improve both the reliable and timely supply of vaccines to immunization posts and maintain high demand for immunization services from the community.
- Improve vaccine price transparency and address major barriers that limit countries' access to affordable and timely supply of vaccine.

### **2.4 Strategic Direction: Apply behavioural sciences to immunization**

In the last 40 years, most of WHO's concentration has focused on vaccine technologies and the many components required for effective service delivery, detailed planning and costing, skilled managers and vaccinators, and monitoring systems.

We are learning that while infrastructure and technologies are indeed important to the success of immunization programmes, the actors involved in immunization (i.e., caregivers, communities, health workers, logisticians, and decision-makers) and their knowledge, behaviours, and interactions are vital to achieving our immunization goals.

Despite increased recognition of the importance of these actors' roles and responsibilities, it is less clear how to facilitate and enhance their different forms of participation, especially given the interconnected exchanges between the various actors and their social context.

A field of research and practice in this area is beginning to open with new work streams emerging around vaccine hesitancy and demand generation. At the same time, we have yet to understand how behaviours, their determinants, and their connectedness collectively influence the programme outcomes we have been monitoring for decades.

A challenge remains in wholly understanding how behaviours are shaped by both constant and changing factors in immunization systems and how behaviours are then put into practice. Our focus will include an exploration of the links between the health system, frontline service providers, and the individuals and communities they serve, including factors that determine vaccine uptake such as trust and complacency. Moreover, our approach will be systematic and cross-cutting with the intent to establish a new area of technical expertise in the behavioural sciences to optimize immunization programmes.

**Approach:**

- Convene a network of experts around the world who can set a research agenda, synthesize and disseminate the evidence, monitor advances and manage the knowledge base around behaviours that influence the provision and demand for preventive health services.
- Develop guidance and support its application and adaptation based on the nature and context of the problem and desired objectives.
- Promote the integration of behavioural measures and indicators into routine monitoring to inform continuous learning and tailored programme implementation.

<b>2.5 Strategic Direction: Sustain immunization services in emergencies</b>
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The need for immunizations in non-epidemic disasters is often high and specific strategies must be in place to quickly and decisively respond to such disasters.

WHO's emergency response team will provide global coordination and leadership to ensure that proven and effective vaccines are available and rapidly deployed to tackle outbreaks of diseases such as yellow fever, cholera, meningitis, Ebola, and typhoid. This effort will reduce the risk and impact of emergencies by providing efficient access to, and use of safe, effective and affordable vaccines.

**Approach:**

- Strengthen country capacity for preparedness and resilience to epidemic and non-epidemic emergencies, including the development of effective surveillance systems.
- Develop guidance on the use of vaccines for outbreak response and emergencies.
- Ensure that appropriate vaccines are available for all potential vaccine preventable disease epidemics.
- Maintain international vaccine stockpiles for selected diseases to ensure an equitable access to sufficient vaccine quantities at an affordable cost.

- Support vaccine development where no vaccine exists and the development of new technologies for epidemic outbreak responses and disasters.

## **2.6 Strategic Direction: Lead disease elimination and eradication efforts**

Consistent with WHO's mission "to realize the full potential of vaccines", WHO will continue to lead efforts with key partners to eliminate Measles and Rubella, Hepatitis B and Maternal and Neonatal Tetanus and eradicate Poliomyelitis and other diseases where elimination or eradication is being endorsed as global or regional targets.

As current disease elimination and eradication efforts are achieved, WHO's role in new eradication and elimination efforts will shift from implementation to goal setting, partnership coordination, strategic development, monitoring and evaluation.

### **Approach:**

- Lead and coordinate new eradication and elimination goals.
- Set and develop strategies to achieve global regional control/elimination/eradication targets.
- Provide training, technical support and staff supervision to enhance country capacity for specific eradication strategies.
- Support global networks of WHO-accredited public health laboratories that can diagnose and track virus movement and therefore drive implementation.
- Mobilize resources necessary for elimination/eradication.
- Establish and oversee implementation of global/regional certification criteria.
- Oversee the post-eradication agenda for diseases such as polio.
- Develop containment standards for biologicals once targets are achieved (for eradication).
- Develop stockpiles and guidance to respond to outbreaks post eradication.

## Annex 2. Division of responsibilities between HQ, regional, and country offices

*This section outlines the roles and responsibilities of HQ versus regions versus country office. It will be discussed and revised with input from country, regional and headquarters staff every five years.*

**Table 2: WHO core roles envisioned for 2030 in immunization and vaccines**

	<b>Headquarters:</b>	<b>Regional Office</b>	<b>Country Office:</b>
<b>Convene leaders and experts from all sectors</b>	<p>Convene technical experts to guide global policies and set priorities.</p> <p>Secure global endorsement of key policies through the World Health Assembly.</p> <p>Strengthen coordination between each level of WHO and between WHO and key partners.</p> <p>Enhance and maintain relationships with collaborating centres, universities and academic bodies.</p> <p>Develop advocacy strategies and tools for global and national use.</p>	<p>Support Member States to engage in governing bodies.</p> <p>Convene regional intergovernmental meetings and working groups and establish inter-regional health platforms.</p> <p>Engage Member States in international initiatives and coordinate with regional and sub-regional entities on their participation in global health issues.</p> <p>Increase visibility of immunization and WHO's role in immunization.</p> <p>Hold governments accountable to implement priority immunization commitments.</p> <p>Strengthen capacity to present scientific evidence when communicating with policymakers and communities.</p>	<p>Advocate for immunization of all recommended age groups in health sector plans.</p> <p>Strengthen government capacity to coordinate with other ministries, private sector entities and external partners in all immunization areas.</p> <p>Support governments to convene and coordinate health response in emergencies.</p> <p>Ensure that the comprehensive multiyear plan is the guiding document for health sector planning.</p> <p>Advocate with governments for sufficient funding for immunization programmes.</p>
	Actively involve Civil Society Organizations in policy setting and		

	implementation discussions		
<b>Establish norms and standards for products and technologies</b>	<p>Set norms and standards with input from technical experts, regional offices, and country-level representatives.</p> <p>Promote the convergence/harmonization of international norms and standards and regulatory procedures across all countries.</p> <p>Foster an environment that enables countries to oversee their own implementation of norms and standards.</p>	<p>Adapt norms and standards to the regional context, as necessary.</p> <p>Monitor the implementation of norms, standards and guidelines at country level.</p> <p>Build country capacity to implement global and regional norms and standards.</p> <p>Strengthen NRAs and regional regulatory mechanisms to progressively reduce the need for prequalification systems.</p>	<p>Encourage countries to apply global norms and standards and adapt them into national/sub-national guidelines and regulations.</p> <p>Build capacity of technical working groups at country level (e.g. NITAG)</p> <p>Invite contributions from countries experts in developing/updating global and regional standards.</p> <p>Strengthen and support NRAs.</p>
<b>Develop evidence-based policy recommendations and guidance.</b>	<p>Develop policy recommendations and support countries to achieve global goals.</p> <p>Develop and coordinate integrated service delivery strategies.</p> <p>Develop outbreak preparedness and response plans.</p> <p>Adapt policies to reflect changes in the health/immunization environment (e.g., demographic shifts in migration, aging populations, etc.)</p> <p>Develop behavioural strategies to address hesitancy and demand.</p>	<p>Develop, adapt, and apply policies and strategies to the regional context.</p> <p>Communicate with countries about policy recommendations in a timely and efficient manner.</p> <p>Provide technical advice to countries involved in regional policy initiatives.</p>	<p>Encourage countries to adopt regional and global policies and strategies.</p> <p>Strengthen and support NITAGs.</p> <p>Solicit feedback from national technical experts on global and regional policies.</p> <p>Advocate for immunizations and provide reference for immunization policies to be included in country cooperation strategies (CCSs).</p>
<b>Monitor and</b>	Promote development	Monitor regional health	Monitor and evaluate

<p><b>use data for analytics</b></p>	<p>and use of innovative data system technologies.</p> <p>Support regional offices in data collection and analytics.</p> <p>Monitor and analyse global immunization data using best available analytics and visualizations to support decision-making.</p>	<p>trends by aggregating, validating, analysing, disseminating health-related data.</p> <p>Help countries use regional data to evaluate and strengthen immunization services.</p> <p>Work with countries to generate and interpret data, through modelling and prediction.</p> <p>Provide technical support to countries to link laboratory networks with data systems.</p>	<p>national immunization policies and programmes.</p> <p>Look for opportunities for countries to share information both within and outside the country.</p> <p>Help countries collect and use high quality data for action.</p> <p>Facilitate innovation by promoting new ideas and technologies (including ICT) to make data collection and use more effective and efficient.</p> <p>Build capacities of national authorities to build/sustain national health observatories.</p>
<p><b>Facilitate implementation and synergies</b></p>	<p>Coordinate support given to fragile countries.</p> <p>Organize decentralized networks of technical experts to support different aspects of immunization (e.g., supply chain, data quality/surveys, surveillance, etc.)</p> <p>Identify opportunities for synergistic approaches to service delivery and develop appropriate strategies.</p> <p>Coordinate emergency surge capacity.</p>	<p>Participate in the development of CCSs.</p> <p>Support country implementation of international commitments and legal instruments.</p> <p>Lead technical collaboration in countries with no WHO presence.</p> <p>Strengthen technical cooperation among countries and among regions.</p> <p>Provide surge capacity during crisis and emergencies.</p> <p>Give countries more responsibility for</p>	<p>Ensure that immunizations are included in the CCS.</p> <p>Provide quality information, technical advice, best practices and updated information related to governments' immunization policies, guidelines and programme activities.</p> <p>Assess capacity gaps and provide training where needed.</p> <p>Develop strong technical capacity at country level to assist in planning, policy formulation, implementation, and leadership.</p>



		<p>managing decisions, technical needs, and financial needs.</p> <p>Engage with and coordinate technical immunization partners.</p>	<p>Support national coordination emergency response</p> <p>Support annual and multi-year immunization planning.</p> <p>Develop multi-disciplinary teams of immunization experts within WHO.</p>
		<p>Facilitate inter-country and inter-regional coordination and collaboration on immunisation and VPD elimination and control.</p>	
	<p>Strengthen private-sector provision of immunization.</p>		
	<p>Work with countries and partners to support internal and external fundraising efforts, and align external support to country needs and priorities.</p>		

## Annex 3: Matrix of the areas of collaboration between WHO and its partners

**Table 1: Matrix of the areas of collaboration between WHO and all partners**

+++ Critical role for the success of the collaboration

++ Important role for the success of the collaboration

+ Moderate role for the success of the collaboration

	Provide technical support to countries in collaboration with WHO	Technical support to WHO			Provide financial support to WHO	Provide financial support to countries	Prioritize research orientation
		Produce evidence	Help define norms and standards and policies	Monitor and evaluate immunization programmes			
<b>Countries</b>							
- MoH		+	+	+++			
- Independent Agencies	++		++				
<b>Donors</b>			+		+++	+++	+
<b>Manufacturers</b>						+	+++
<b>UN and Global Initiatives</b>	+++		++			+	
<b>Technical Partners</b>							
- International Technical Agencies	+++	++	++	+++	+		+
- Universities and Research Institutions	+	+++	+++				++
- WHO Collaborating Centres	+++	+	+	+++	+		
- Scientific Societies	++	++	+++				++
- Individual Consultants	+++		+	+			
<b>CSOs</b>							
- International CSOs	+	+	+	+++			
- Local CSOs	+++			+++			

## Annex 4. Historic review of 40 years of Expanded Programme on Immunization

### Executive summary of the desk review

In 2015, WHO commissioned a consultant to undertake a desk study of historical trends and milestones in the field of vaccines and immunization, with the aim to explore underlying factors that have contributed to progress in the 40 years of the EPI.

The study identified the following trends from the immunization coverage data:

- Global immunization coverage has improved dramatically of the past 40 years.
- Immunization systems appear to be sufficiently strong to support new vaccines and antigens being added to the EPI programme (at global level), which can result in protection against more diseases.
- The gap in coverage between the first and third dose of a DTP containing vaccine has decreased, possibly indicating that systems have become stronger.
- Equity in immunization coverage has improved and the total number of unimmunised children has decreased.
- Coverage trends differ substantially between regions.

The number of conditions that are preventable by vaccines have increased since 1974 and immunizations now prevent disease, disability and death from cervical cancer, diphtheria, hepatitis B, measles, pertussis, pneumococcal and *Haemophilus influenzae* type b infections, polio, rotavirus diarrhoea, rubella and tetanus. Annual benefits from vaccination and global health improvements include around 6 million prevented deaths.

The desk study identified several factors that may have contributed to EPI progress including the standardised vaccination schedule; development and introduction of new antigens and vaccine combinations; greater equity of access between high and low income countries; and progress made towards polio eradication. With newer and additional vaccines the costs have increased but, thanks to partnerships such as Gavi, more expensive vaccines have become accessible to the poorest countries.

Technology developments and innovations relating to the cold chain, EPI management and health systems development efforts appear to have contributed to increased coverage of immunization. Initiatives such as the Universal Childhood Immunization (UCI) and other global and regional partnerships have further supported immunization improvements. WHO vaccine policy and technical guidance have also been instrumental in supporting the EPI at all levels, most notably WHO position papers and technical guidelines, recommendations from the Strategic Advisory Group of Experts (SAGE) and support by technical groups at regional and national levels.

Financial support from the global health community has been crucial to immunization improvements in developing countries. Large investments were made in the 1970s and 80s but in the 1990s, donor funding began to decline. It rose again around 2000 and now includes support from new actors such as philanthropist organizations.

The review found that WHO leadership in the EPI is widely recognised. WHO has a normative role and is seen as the technical expert organization. WHO is further recognised for its work to safeguard vaccine safety and quality and is seen as a convener of partners at all levels.

## **Executive summary of interviews with thought-leaders**

In parallel with the desk review described above, WHO also commissioned a consultant to interview ten key informants selected by WHO as leaders or influencers in immunization. The interviews were conducted along a semi-structured question guide during March and April 2015.

In general, the informants perceived that the EPI programme was particularly successful from the late 1970s to the early 1990s. The 1990s was largely seen as a decade when donors and the health community lost interest in immunization with subsequent challenges in funding. This changed at the turn of the millennium when partners came together to create Gavi, the Vaccine Alliance and new actors entered the scene. The past decade has witnessed a positive development with substantially increased funding and several new vaccines becoming available to help countries combat their disease burden.

Key milestones identified by a majority of the informants include: the Universal Childhood Immunization (UCI), where a time-limited target of 80% immunization coverage by 1990 proved a powerful tool to focus attention and resources; cold chain innovation including the cold box and gas/kerosene fridges; the standardized immunisation schedule; training and capacity building, including the development of useful approaches, tools and guidelines such as supportive supervision, technical information sheets, coverage surveys, national programme reviews, planning tools and efforts to improve data quality.

While informants agreed about the trends and milestones, views differed substantially regarding the positive or negative effects on EPI of initiatives to eliminate or eradicate disease, most notably polio.

All informants recognised WHO's unique and instrumental role in the EPI and that without WHO, the world would not be where it is today in immunization. Informants suggested that the environment has changed since 1974, with many more actors and more funding becoming available for immunization. Informants viewed this as a positive development while recognising that this new landscape may present both opportunities and challenges for WHO. Informants were rather unanimous in their recommendation for WHO to focus on its current mandate, to be the recognised technical expert organization, to develop norms and standards (the Strategic Advisory Group of Experts (SAGE) was particularly noted), and to use its country, regional and international structures, including the World Health Assembly (WHA), to support and convene partners, including new ones. Informants underlined that WHO must work with utmost integrity and some suggested that WHO may have improve the way it communicates about its past and present achievements.

With regards to the future of the EPI, one informant suggested that there is a need for a fundamental transformation from a vaccine delivery platform focusing on immunisation coverage to a programme focusing on disease control.

## Annex 5: Summary of findings from the expectations survey

### What do partners expect from WHO in immunization?

Results from the expectations survey: summary

#### Overview

In January 2015 WHO launched a survey to understand what partners expect from WHO in immunization. The survey targeted global, regional and country level colleagues who work with WHO across all areas of vaccines and immunization—from vaccine development and prequalification, to new vaccine introduction, outbreak response and routine immunization.

In total, 35 persons responded to the survey, 56% from global level, 34% from country level and 10% from regional level. The survey response rate was approximately 39%, which is in line with standard online survey response rates of 24 to 40%. The respondents represented non-governmental organizations (36%), other UN agencies (32%), NITAG members (13%), donors (10%) and government (9%).

The 13 open-ended questions asked for input on areas that WHO does well and what could it improve on at each level of the organization. The questions also asked respondents for their input on the major challenges that hamper WHO's performance in immunization, the areas where WHO should focus its efforts and areas of work that could be done equally well by other partners. Finally, the survey asked for input on what innovative areas of work WHO should be exploring over the coming years.

#### Summary of key findings

Across the board, there was consensus that WHO's key role in immunization is to develop policies. Respondents also listed surveillance, data collection, prequalification of vaccines and equipment, and global coordination as core WHO roles.

Results were more mixed on technical support and research. While some participants felt these were areas WHO should lead, others felt that technical support, research, communications and cold chain were areas could be addressed equally well by other organizations. Respondents felt that WHO's performance in immunization is hampered by bureaucracy and a lack of focus, along with being too reliant on donor funding. In addition, WHO's personnel were seen as, in general, not being up to the task.

When asked what changes they would implement if they were in charge of immunization at WHO, respondents said they would improve coordination and collaboration with partners, improve relationships across all levels of the organization, ensure appropriate staffing and skills amongst staff, and integrate immunization activities (i.e., measles-rubella elimination, polio eradication, and routine immunization). Although less commonly than those areas mentioned above, respondents also said they would address the need for clear routine immunization guidance, strengthen surveillance, focus on resource mobilization at country level, implement the eradication strategies and change the way regions/country offices work to focus on concrete deliverables, rather than outputs.

The survey also asked respondents to identify the most innovative immunization related activity that WHO could undertake in the next 10 years. Responses highlighted the use of information technologies for impact (i.e., to improve data quality, to monitor immunization performance via SMS, to establish an electronic registry), vaccines and delivery system innovation (i.e., innovative vaccine storage and delivery strategies, more thermostable vaccines, simplified cold chain) and improving WHO itself (i.e., eradicating bad management, aligning behind one topic, and transitioning tasks to regional and country office, and eventually to ministries of health).

#### Global level feedback

At global level, respondents felt WHO did well at: setting policies and developing guidance, pre-qualification, SAGE, as well as convening experts and partners. They felt WHO/HQ needed to work on: coordination and coverage/data quality, developing more operational guidelines and ensuring better access to WHO information and policies.

#### Regional level feedback

At regional level, respondents felt WHO did well at: providing technical assistance, convening, EPI manager meetings, training, setting regional technical recommendations and managing relationships with ministries of health. They felt WHO/regional offices could improve on: coordination, being more open to working with partners, being more 'country focused' (i.e., providing more direct support to countries), being more innovative, and strengthening outbreak response and surveillance.

#### Country level feedback

At country level, respondents felt WHO did well at: providing technical assistance and working with the ministries of health, supporting NITAGs/Inter-Agency Coordination Committees and coordinating partners. They felt WHO/country offices could improve on: surveillance, coordination and collaboration, holding governments accountable, quality and timeliness of data, having the right human resources capacity and stronger capacity for outbreak response.