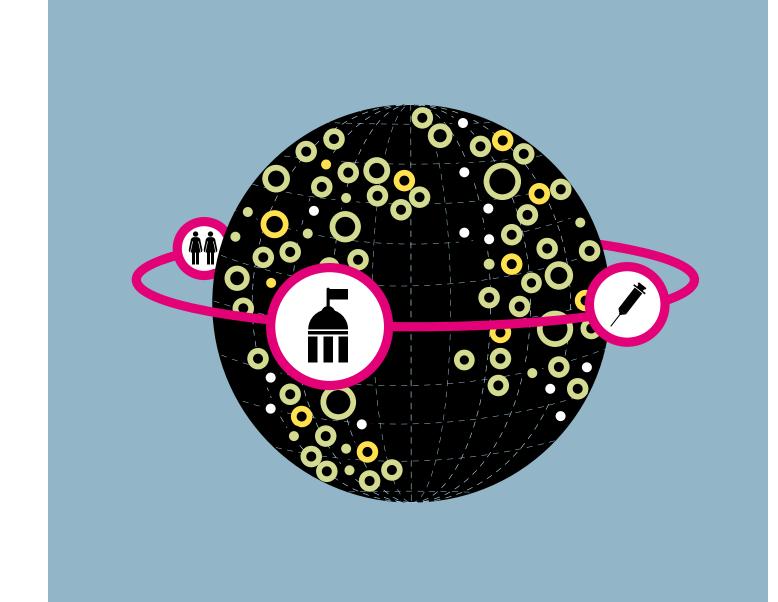


All countries commit to immunization as a priority.

Committing to immunization as a priority first and foremost means recognizing the importance of immunization as a critical public health intervention and the value that immunization represents in terms of health and economic returns. Countries demonstrate a commitment to immunization by setting ambitious but attainable national targets and allocating adequate financial and human resources to programmes to achieve these targets; ensuring that their national immunization plans are fully integrated into national health plans, with appropriate budgets and formulated with the participation of all major stakeholders; and demonstrating good stewardship and implementation of their national health plans. Country commitment to immunization does not, however, imply that immunization programmes will be prioritized or funded at the expense of other vital health programmes.

National legislation, policies and resource allocation decisions should be informed by credible and current evidence regarding the direct and indirect impact of immunization. Much of the evidence base exists but does not reach policy-makers, as those who generate the evidence are not always those who interact with these decision-makers. Collaboration between, on the one hand, technical experts who generate the evidence and, on the other, the champions of immunization who construct context-specific messages that highlight the importance of immunization within health and social services, can unequivocally articulate the value of immunization and how immunization supports equity and economic development.



All countries: Establish and sustain commitment to immunization; Inform and engage opinion leaders on the value of immunization; Strengthen national capacity to formulate evidence-based policies. Strategic Objective 1 page 37

Independent bodies, such as regional or national immunization technical advisory groups, that can guide country policies and strategies based on local epidemiology and cost effectiveness should be established or strengthened, thus reducing dependency on external bodies for policy guidance. These bodies can readily be supported by institutions or individuals charged with collating and synthesizing information required for informed decisionmaking. Regional support systems and initiatives, such as the PAHO ProVac initiative,⁷ can be expanded to support countries in strengthening their decision-making. It is important that national immunization technical advisory groups or their regional equivalents, engage with academia, professional societies, and other national agencies and committees, such as the vaccine regulatory agencies, national health sector coordination committees, and interagency coordination committees, in order to ensure a cohesive and coordinated approach to achieving national health priorities. Strong links between ministries of health, education⁸ and finance, as well as human resources and legislators are also essential for sustainable programme implementation.

Support and formal endorsement of national policies and plans at the highest political and administrative levels, nationally and subnationally, is considered essential for ensuring commitment and sustainability. Governments and elected officials are responsible for putting in place necessary legislation and budget allocations. As immunization is a strong indicator of the overall ability of the health system to deliver services, legislators should be encouraged to scrutinize, defend and closely follow immunization budgets, disbursements and immunization programme activities, both at the national level and within their respective constituencies. Civil society organizations can effectively advocate for greater commitment and hold governments accountable for commitments once they are made. Immunization programmes need to have management structures for programme implementation to be effective. Officials at the national and subnational levels responsible for implementation of the immunization plans can be held accountable for programme performance when they are sufficiently empowered to provide effective leadership and have the required management and programme monitoring skills.



Ensuring that national immunization plans are fully integrated into national health plans

For high- and middle-income countries, commitment to immunization should cover the same areas, but may also include maintaining or assuming the role of development partners. Together with global agencies, development partner countries can coordinate the sharing of information and best practices among countries, help bridge temporary funding gaps, and support capacity strengthening by working with stakeholders in different country settings.

TABLE 2: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 1 ALL COUNTRIES COMMIT TO IMMUNIZATION AS A PRIORITY.



Establish and sustain commitment to immunization.

ENSURE legislation or legal framework in all countries, including provisions for a budget line for immunization, and for monitoring and reporting.

DEVELOP comprehensive national immunization plans that are part of overall national health plans through a bottom-up process that includes all stakeholders.

SET ambitious but attainable countryspecific targets within the context of morbidity and mortality reduction goals.

SCRUTINIZE, defend and follow more closely immunization budgets, disbursements and immunization programme activities.

SUPPORT local civil society organizations and professional associations to contribute to national discussions on immunization and health.

Inform and engage opinion leaders on the value of immunization.

EXPLORE models to promote collaboration between the stakeholders that generate evidence on immunization and those who use it in order to set priorities and formulate policies.

DEVELOP and disseminate the evidence base on the public health value of vaccines and immunization and the added value of achieving equity in access and use of immunization.

DEVELOP and disseminate the evidence base for the broad economic benefits of immunization for individuals, households, communities, and countries.

INCLUDE immunization in the agendas of governing body meetings at all levels and in other social, health and economic forums.

Strengthen national capacity to formulate evidence-based policies.

CREATE, or strengthen existing, independent bodies that formulate national immunization policies (for example, national immunization technical advisory groups or regional technical advisory groups).

DEVELOP more effective ways for national regulatory agencies, health sector coordination committees, and interagency coordination committees to support immunization programmes as part of disease control programmes and preventive health care.

CREATE regional forums and peer-topeer exchange of information, best practices and tools.

CREATE expanded and more transparent mechanisms for aggregating, sharing and using information to monitor commitments.

⁷ ProVac is a package of tools to support: (i) the estimation of cost-effectiveness and epidemiological and economic impact of new vaccines; (ii) training; and (iii) the strengthening of national infrastructure for decision-making.

⁸ Especially important for delivering immunization to older children and adolescents through school health programmes and for monitoring school entry requirements with immunization.



Individuals and communities understand the value of vaccines and demand immunization as both their right and responsibility.

Significant improvements in coverage and programme sustainability are possible if individuals and communities understand the benefits and risks of immunization; are encouraged to seek services; are empowered to make demands on the health system; and have ownership of the planning and implementation of programmes within their local communities. Although there has generally been a high demand for vaccination services, accessing hard-to-reach populations, attaining higher coverage levels and achieving equity objectives may require additional approaches to stimulate demand for vaccination.

Generating individual, household and community demand will require using traditional platforms more effectively as well as new strategies to convey the benefits of immunization, emphasize immunization as a core component of the right to health and encourage greater use of services. New efforts could take advantage of social media and approaches used by commercial and social marketing efforts to promote immunization and address concerns. New mobile and Internet technologies should also be utilized, drawing on the experiences and successes of other innovative public health campaigns. Communications and social research to identify the barriers to and drivers of vaccination should inform the development of context-specific messages. Lessons on vaccines and immunization should be included in the primary school education curriculum. Multisectoral approaches that promote efforts, such as female education and empowerment, will help improve utilization of immunization and health services in general.



sustainability are possible if individuals and communities understand the benefits and risks of immunization

Where appropriate, programme strategies could also include measures to provide an incentive both to households to seek immunization services and to health care providers to improve their performance in vaccinating children, particularly those that have not been reached previously. At the household level, conditional cash transfer programmes often include vaccination of children as a requirement for receiving household income transfers. There is evidence that such programmes may have a positive impact on immunization coverage rates, even in countries with high coverage rates, and particularly for more marginalized populations. Because conditional cash transfer programmes are often administered in countries as part of a broad package of social protection or poverty alleviation measures, these programmes provide an opportunity to link immunization programmes and health ministries with other broader development initiatives, including those administered by other ministries.

At the health facility level, both households and health care providers can be further motivated by in-kind gifts at the time of vaccination, or by giving performance-based financing bonuses to providers. There is some early evidence to suggest that performance-based financing of immunization services leads to increasing numbers of children being vaccinated, although more rigorous analysis of the impact of performance-based financing on immunization is still being carried out.

Providing incentives to health care workers and households through monetary and in-kind gifts has implementation challenges that need to be carefully addressed. These schemes need to respect the autonomy of beneficiaries. Social research is also needed to determine the conditions under which incentives contribute to improved coverage and the types and levels of incentives that are appropriate for a given context. Demand-generation activities must be coupled with mechanisms to ensure reliability of vaccine supply.

Some reasons for hesitancy are undoubtedly amenable to improved communications and advocacy initiatives designed to counteract growing anti-vaccination lobby groups and to increase understanding of the value of vaccines or of the danger of diseases. However, others are best addressed by ensuring the quality of the services provided. Individuals will be less hesitant to use services if they

Demand-generation activities must be coupled with mechanisms to ensure reliability of vaccine supply



perceive the quality of those services to be acceptable. They are more likely to come to vaccination sessions when scheduled services are convenient and predictably available; when practical counselling is offered about where and when to come for vaccination and why, and about what to expect following vaccination; when the health workers have a welcoming attitude; when waiting times are reasonable; and when services are offered without charge. Health care workers should receive training in effective communication to enable them to deal with the media and with local communities when there are reports of serious adverse events following immunization, in order to allay fears and tackle vaccine hesitancy.

Bringing about change will require the participation of individuals, households and communities in the development and implementation of all demandgeneration strategies. It will also require new and stronger community-based advocates with local knowledge, credibility and the front-line experience necessary to drive change. The participation of in-country civil society organizations will be crucial to develop strong advocacy efforts and should be supported by capacity building. Here again, an effort that promotes collaboration between evidence generators and evidence users could provide training for champions and link with local social and professional networks, which are an important source of grass-roots immunization champions. This will especially be required as country programmes embrace a life-course approach to immunization. Current advocates must recruit new voices—potentially including educators, religious leaders, traditional and social media personalities, family physicians, community health workers and immunization champions. Researchers and technical experts will also have an important role in creating greater community awareness and providing credible responses to misinformation regarding immunization.

Generating individual and community demand will reinforce country commitment to vaccines and immunization (<u>strategic objective 1</u>). Activities to generate demand for vaccines and immunization should build on the broader movement in order to help people to hold their governments accountable for access to health services.



There is some early evidence to suggest that performance-based financing of immunization services leads to increasing numbers of children being vaccinated

TABLE 3: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 2 INDIVIDUAL AND COMMUNITIES UNDERSTAND THE VALUE OF VACCINES AND

DEMAND IMMUNIZATION AS BOTH THEIR RIGHT AND RESPONSIBILITY.



Engage individuals and communities on the benefits of immunization and hear their concerns.

ENGAGE in a dialogue which both transmits information and responds to people's concerns and fears.

UTILIZE social media tools and lessons learnt from commercial and social marketing efforts.

LEVERAGE new mobile and Internet-based technologies.

INCLUDE immunization in the basic education curriculum.

CONDUCT communications research.

Create incentives to stimulate demand.

CREATE incentives for households and health workers in favour of immunization, where appropriate, while respecting the autonomy of beneficiaries (for example, cash or in-kind transfers, bundling of services, media recognition).

CONDUCT social research to improve the delivery of immunization services and the ability to meet the needs of diverse communities.

Build advocacy capacity.

RECRUIT new voices, including those of educators, religious leaders, traditional and social media personalities, family physicians, community health workers, and trained immunization champions (among others).

TRAIN health-care workers in effective communication techniques, especially to address vaccine hesitancy and to respond to reports of serious adverse events following immunization in order to maintain trust and allay fears.

ENGAGE, enable and support in-country civil society organizations to advocate the value of vaccines to local communities and policy-makers and local and global media.

CREATE national or regional advocacy plans that involve incountry civil society organizations.

LINK global, national and community advocacy efforts with professional and academic networks.

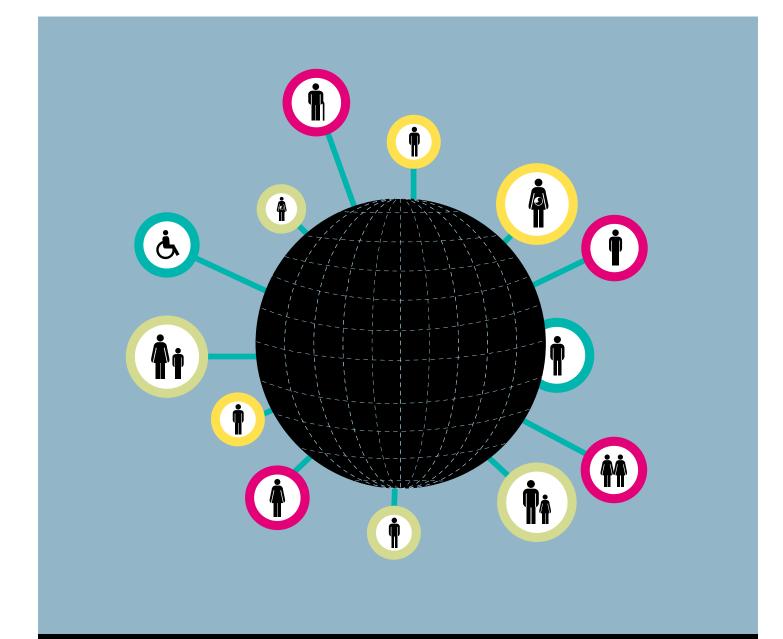




The benefits of immunization are equitably extended to all people.

Today, four out of every five children receive at least a basic set of vaccinations during infancy and are therefore able to lead healthier, more productive lives. Unfortunately, this means one child in every five is not being reached. In this decade, the benefits of immunization should also be more equitably extended to all children, adolescents and adults. Achieving this strategic objective will mean that every eligible individual is immunized with all appropriate vaccines—irrespective of geographic location, age, gender, disability, educational level, socioeconomic level, ethnic group or work condition—thereby reaching underserved populations and reducing disparities in immunization both within and between countries. Because disease burdens tend to be disproportionately concentrated in more marginalized populations, reaching more people will not only achieve a greater degree of equity, but will also achieve a greater health impact and contribute to economic development. Furthermore, disease eradication and elimination goals cannot be met without achieving and sustaining high and equitable coverage.

In 2002, WHO, UNICEF and other partners introduced the concept of "Reaching Every District", a first step toward achieving more equitable coverage. Through its various operational components, which include re-establishing outreach services, providing supportive supervision, engaging with communities, monitoring and use of data and district planning and resource management, the Reaching Every District strategy was able to expand the provision of immunization services. Similarly, initiatives aimed at disease eradication and elimination or rapid mortality reduction have used strategies, such as national or subnational immunization days (for poliomyelitis eradication) and supplementary immunization activities (for measles and rubella elimination,



Achieving this strategic objective will mean that every eligible individual is immunized with all appropriate vaccines—irrespective of geographic location, age, gender, disability, educational level, socioeconomic level, ethnic group or work condition

page 46

Strategic Objective 3

measles mortality reduction and neonatal tetanus elimination). More recently, strategies collectively referred to as periodic intensification of routine immunization have been used to extend immunization to the unreached, packaged together with other primary health care interventions.

Even these strategies continue to miss populations, for example those that reside outside traditional social and governmental structures. To sustain the gains of these historical efforts and to achieve and sustain disease control goals, the Reaching Every District strategic approach should be recast as "Reaching Every Community". To attain more equitable coverage, the definition of community should be expanded beyond geographically defined communities. Reaching every community will mean aiming to encompass every eligible individual, even those beyond typical government outreach.

Reaching every community will call for an understanding of the barriers to access and use of immunization; it will also require the underserved to be identified, and micro-plans at the district and community levels to be reviewed and revised in order to ensure that these barriers can be overcome. The rapid expansion of information technology should be leveraged to establish immunization registries and electronic databases that will allow each individual's immunization status to be tracked, timely reminders to be sent when immunization is due and data to be accessed easily to inform actions. The introduction of unique identification numbers could be a catalyst for the establishment of such systems.

Drawing on the experiences of successful poliomyelitis vaccination campaigns, decentralized planning and outreach should be used to reach populations that are remote or nomadic or that have been historically marginalized. New strategies for reaching the urban poor and urban migrants will also be necessary. Given the tenuous and evolving community structures and the inadequate security involved, new approaches to community outreach will be especially critical for reaching these groups. This is all the more true in view of the fact that sometimes the most unifying force in these urban and peri-urban areas is a shared and deep-seated mistrust of outsiders, especially governments.

The Reaching Every
District strategic
approach should be
recast as "Reaching
Every Community"



Implementing strategies to reach all underserved populations will require engagement with the nongovernmental sector, including civil society organizations and private sector organizations, and will need to involve all aspects of immunization including advocacy, social mobilization, service delivery and monitoring programme performance. To support such collaboration, governments should allocate increased resources to underserved communities and ensure that programmes have sufficient, well-trained personnel to execute strategies effectively. Partnerships across government sectors (for example, with educational institutions) and coordination with programmes that focus on vulnerable populations will be essential. In addition, efforts to provide high-quality immunization services to all children will need to continue unabated in order to protect gains already recorded.

page 48

Global Vaccine Action Plan

Strategic Objective 3



Creating strategies for reaching individuals throughout their life course

There are other dimensions of equity that merit consideration during the Decade of Vaccines (2011–2020), including disparities between countries, adolescent and adult immunization, and immunization during emergencies.

Historically, it took decades before new vaccines used in high-income countries became available in low- and middle-income countries. Steps are being taken to address this inequity, including the introduction of new vaccines, with the support of the GAVI Alliance. However, much more needs to be done to sustain and extend these gains, particularly to middle-income countries.

A "life-course" approach must also be taken in order to make the benefits of immunization available to all those at risk in every age group. As diseases are being successfully controlled through infant immunization, the need to boost immunity to sustain and extend these gains is increasingly being recognized. In addition, new and existing vaccines that are beneficial for school children, adolescents and adults at special risk—such as health workers, immunocompromised individuals, animal handlers, and the elderly—(for example, vaccines against human papillomavirus, influenza and rabies) are now available and being increasingly used. The success of efforts to eliminate maternal and neonatal tetanus and the benefits to both women and infants of influenza vaccination during pregnancy have increased interest in exploring the development of other vaccines that could be used during pregnancy (for example, group B streptococcus or respiratory syncytial virus vaccines). This will mean creating strategies for reaching individuals throughout their life course, and developing plans for the systems that will monitor and track progress.

Likewise, targeted plans are needed to ensure access to immunization during humanitarian crises, outbreaks and in conflict zones. These plans should include a focus on communication and provision for the development of vaccine stockpiles.

Social and operational research is needed to inform the design and test the effectiveness of the delivery strategies mentioned above. Key areas of focus for this research could include identifying the main causes of low coverage in particular areas and communities, assessing economic barriers to immunization, understanding the best approaches for reaching individuals of various ages, and assessing the most effective incentives for reaching different groups.

TABLE 4: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 3 THE BENEFITS OF IMMUNIZATION ARE EQUITABLY EXTENDED TO ALL PEOPLE.



Develop and implement new strategies to tackle inequities.

RECAST "Reaching Every District" to "Reaching Every Community" in order to deal with inequities within districts.

ENGAGE underserved and marginalized groups to develop locally tailored, targeted strategies for reducing inequities.

INTRODUCE appropriate new vaccines into national immunization programmes (see also objective 5).

ESTABLISH a life-course approach to immunization planning and implementation, including new strategies to ensure equity across the life span.

PREVENT and respond to vaccinepreventable diseases during disease outbreaks and humanitarian crises, and in conflict zones.

Build knowledge base and capacity for enabling equitable delivery.

TRACK each individual's immunization status, leveraging immunization registries, electronic databases and national identification number systems.

TAKE advantage of community structures to enhance communication and deliver services (for example, traditional birth attendants, birth registries).

INVOLVE civil society organizations in community outreach and planning.

DEVELOP new approaches to community engagement for urban and peri-urban areas.

TRAIN health workers and civil society organizations in engaging communities, in identifying influential people who can assist in planning, organizing and monitoring health and immunization programmes, as well as community needs, and in working with communities to meet those needs.

CONDUCT operational and social science research to identify successful strategies to reduce inequities and improve the quality and delivery of immunization services.

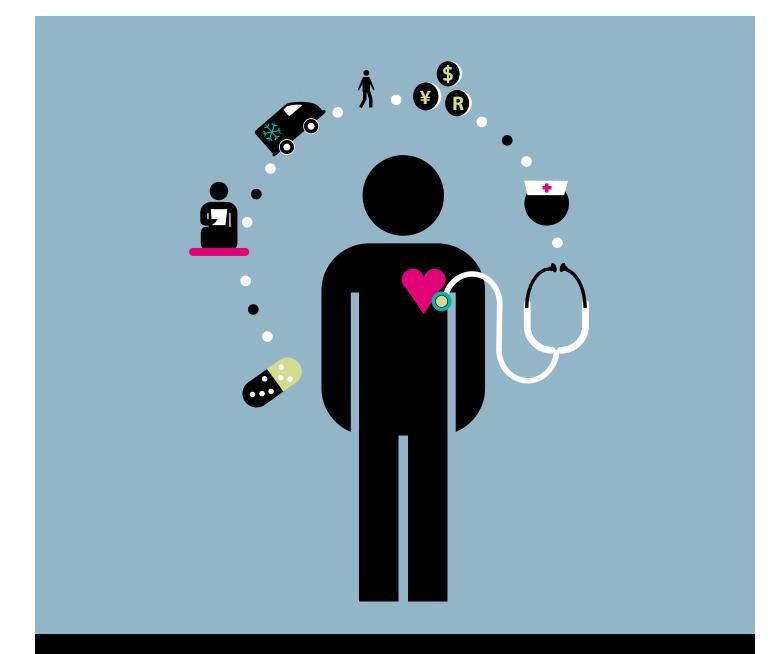


Strong immunization systems are an integral part of a well functioning health system.

The success of national immunization programmes in introducing new vaccines, attaining goals for quality, equity and coverage, and becoming financially sustainable depends upon a well functioning health system. The many interconnected components of an immunization system require multi-disciplinary attention in order to build a cohesive, non-fragmented and well-functioning programme that coordinates and works in synergy with other primary health care programmes.

Health systems encompass a range of functions from policy and regulation to information and supply chain systems, human resources, overall programme management and financing. Health systems include both the public and private sectors, and in some countries the private sector can play a valuable role in educating households about the need for and benefits of vaccination, as well as providing health care. Some of these functions have been dealt with in other sections of this document. This section discusses the actions required to foster greater coordination between immunization and other programmes within health systems and to strengthen the information, human resources, supply chain and logistics components of health systems.

Immunization service delivery should continue to serve as a platform for providing other priority public health interventions, such as those for vitamin A supplementation, deworming, and insecticide-treated bednets. Other priority programmes should also serve as a platform for delivering immunization. Every contact with the health sector should be used as an opportunity to verify immunization status and provide immunization where indicated. Furthermore,



Immunization service delivery should continue to serve as a platform for providing other priority public health interventions



Coordinating immunization with integrated primary health-care programmes may also facilitate social mobilization efforts

as new vaccines become available that target some but not all pathogens that cause particular syndromes, such as pneumonia, diarrhoea and cervical cancer, it is important that their introduction be an opportunity to scale up the delivery of complementary interventions. For example, the vaccines against pneumococcus and rotavirus should be complemented with other actions to protect, prevent and treat related respiratory and diarrhoeal diseases.

New vaccine deployment should therefore be accompanied by comprehensive disease-control plans both within countries and globally. Coordination of immunization with other services should take place at all levels of a country's programmes, involve outreach efforts and participation by health centres, and be a part of programme management. Coordinating immunization with integrated primary health-care programmes may also facilitate social mobilization efforts, helping to generate community demand for services (strategic objective 2) and address inequity (strategic objective 3). Additionally, efforts should be made to ensure that global vaccine programmes focused on eradication and elimination goals (for example, poliomyelitis and measles campaigns) do not operate in silos. The choice of mechanisms to promote greater interaction and coordination between different programmes should be made by countries according to their local context. The synergies and efficiencies as a result of integration and coordination will be particularly beneficial in countries with fragile health systems.

Access to timely high-quality information is essential for effective immunization. Critical information includes process indicators that allow programmes to monitor their performance and take corrective action, and outcome indicators that measure the impact of programmes. Output and impact indicators need to be analysed along with expenditures in order to identify bottlenecks and best practices and to gauge overall programme efficiency (value for money). Immunization information systems need to be linked to broader health information systems, while remaining readily accessible and meeting immunization programme needs.

Monitoring of immunization coverage and dropout rates has been in place since the launch of the Expanded Programme on Immunization to ensure programme effectiveness. Although the quality and timeliness of data reporting have improved steadily over the years, the quality of administrative coverage data is still inadequate in many countries. Furthermore, the use of data in order to take corrective action at district and community levels is still unsatisfactory. New approaches to immunization tracking through unique identification numbers (discussed in strategic objective 3) can improve the quality of immunization coverage data and facilitate the development of comprehensive immunization registries. New technologies, including hand-held communication devices and mobile phones, can support this effort and facilitate data sharing. Armed with higher-quality data and new data-analysis tools, programme managers at all administrative levels can use information to improve programme performance, allocate funding appropriately, and track progress more effectively.

Disease surveillance is critical for informing decision-making on the adoption of new vaccines and on the strategies for their use in their respective national programmes. Such surveillance is also essential for monitoring the impact of immunization and changes in disease epidemiology, and for supporting sustained use. Robust epidemiological data will also be crucial for understanding vaccine effectiveness and guiding priorities in the research and development community, and will help to identify the areas where research and development is most needed (strategic objective 6). Disease surveillance platforms need to be strengthened to improve the quality and sharing of information. This will include strengthening laboratory capacity for microbiological confirmation of diagnosis and for tracking the spread of diseases using molecular typing techniques.

Global Vaccine Action Plan



On rare occasions, adverse reactions can affect the health of vaccine recipients. More frequently, coincidental health events can follow immunization and may be wrongly attributed to vaccines. In both instances, it is extremely important to detect and analyse promptly serious adverse events following immunization. To assist low- and middle-income countries in managing such important issues, WHO and its partners have developed the Global Vaccine Safety Blueprint. This strategic plan will enable the countries concerned to have at least minimal capacity for vaccine safety activities; it will also enhance capacity for vaccine safety assessment in countries that introduce newly developed vaccines, that introduce vaccines in settings with novel characteristics or that both manufacture and use prequalified vaccines; and it will establish a global vaccine safety support structure. Implementing the Global Vaccine Safety Blueprint strategies to build capacity for safety surveillance during the Decade of Vaccines (2011–2020) will ensure that everyone everywhere receives the safest vaccines possible and that safety concerns are not a cause of hesitancy in using vaccines.

Ensure that everyone everywhere receives the safest vaccines possible and that safety concerns are not a cause of hesitancy in using vaccines The increasing complexity of immunization programmes and ambitious new goals, mean that more trained health workers are needed to manage the increased burden of work, including programme managers at the national and subnational levels as well as front-line workers who deliver services and interact directly with communities. Programme managers need to be equipped with technical knowledge about vaccines and immunization, as well as with management skills. Front-line health workers, who deliver not only vaccinations but also primary health care interventions and health education, need coordinated, comprehensive and very practical pre- and in-service training, with updated, relevant curricula and post-training supervision. Health-care workers need to be able not only to explain why immunization is important, but also to give advice to individuals and communities on nutrition, create a healthier environment and recognize the danger signs when someone falls ill. Immunization programmes should ensure that this training and supervision is effectively extended to community-based health workers. Civil society organizations can help with training and coordinating such workers.

Health workers can only be effective if sufficient supplies (vaccines, supplements and medicines) are available when they need them. The influx of new vaccines has outstripped the capacity of the current cold-chain system in many countries. Thus, supply chains and waste management systems urgently need to be expanded and made more efficient and reliable. They should be streamlined to maximize effectiveness. They should also take into account and make an effort to minimize the environmental impact of energy, materials and processes used for immunization both within countries and globally. The availability of new technologies provides the opportunity to innovate, not only to improve immunization supply chain management, but also to seek increased synergies with other sectors and supply systems for other health interventions. Another potential area of innovation concerns understanding the lessons learnt from private-sector practices and supply chain management. In addition, tasks that could be outsourced to private sector companies in order to create greater efficiency should be explored.



The availability of new technologies provides the opportunity to innovate

Global Vaccine Action Plan



Front-line health workers need coordinated. comprehensive and very practical pre- and in-service training

It will be essential to ensure that immunization supply systems are staffed with adequate numbers of competent, motivated and empowered personnel at all levels. Likewise, improvements to health information systems should also support the management of resources, helping staff to ensure that adequate quantities of vaccines are always available to meet demand. Efforts to strengthen supply chains should be implemented in such a way that they benefit both immunization programmes and broader national health efforts.

Developing stronger, more efficient, comprehensive approaches to disease control and immunization will require health ministries to take the lead in strengthening and coordinating immunization programmes and health systems more broadly, including engaging civil society organizations, academia and private practitioners. They can draw on the expertise of academics to help develop and deploy new tools and approaches to service delivery. Civil society organizations can contribute to the development of integrated programmes so that they are aligned with local realities and incorporate community-based human resources. Communities can ultimately hold their governments accountable by demanding integrated services. Regional and global organizations can also help by ensuring that data and best practices are shared in and across countries and that country programmes have access to analytical tools. Development partners can provide supplemental financial resources if needed.

TABLE 5: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 4 STRONG IMMUNIZATION SYSTEMS THAT ARE AN INTEGRAL PART OF A **WELL-FUNCTIONING HEALTH SYSTEM.**



Develop comprehensive and coordinated approaches.

ENSURE that global vaccine programmes focusing on eradication and elimination goals (for example, poliomyelitis and measles campaigns) are incorporated into national immunization programmes and do not operate independently.

ENSURE that new vaccine deployment is accompanied by comprehensive plans to control targeted diseases.

ENSURE coordination between the public and private sectors for new vaccine introduction, reporting of vaccine-preventable diseases and administration of vaccines, and ensure quality of vaccination in the public and private sectors.

CONSIDER the inclusion of vaccines (as appropriate to national priorities) in health programmes across the life-course.

Strengthen monitoring and surveillance systems.

IMPROVE the quality of all administrative data concerning immunization and promote its analysis and use at all administrative levels to improve programme performance.

DEVELOP and promote the use of new technologies for collection, transmission and analysis of immunization data.

FURTHER strengthen and expand disease surveillance systems to generate information for decision-making, monitoring the impact of immunization on morbidity and mortality and changes in disease epidemiology.

ENSURE capacity for vaccine safety activities, including capacity to collect and interpret safety data, with enhanced capacity in countries that introduce newly developed vaccines.

Strengthen capacity of managers and frontline workers.

ENSURE that immunization and other primary health-care programmes have adequate human resources to schedule and deliver predictable services of acceptable quality.

INCREASE levels of pre-service, inservice and post-service training for human resources, and develop new, relevant curricula that approach immunization as a component of comprehensive disease control.

PROMOTE coordinated training and supervision of community-based health workers.

Strengthen infrastructure and logistics.

INNOVATE to improve cold-chain capacity and logistics, as well as waste management.

MINIMIZE the environmental impact of energy, materials and processes used in immunization supply systems, both within countries and globally.

STAFF supply systems with adequate numbers of competent, motivated and empowered personnel at all levels.

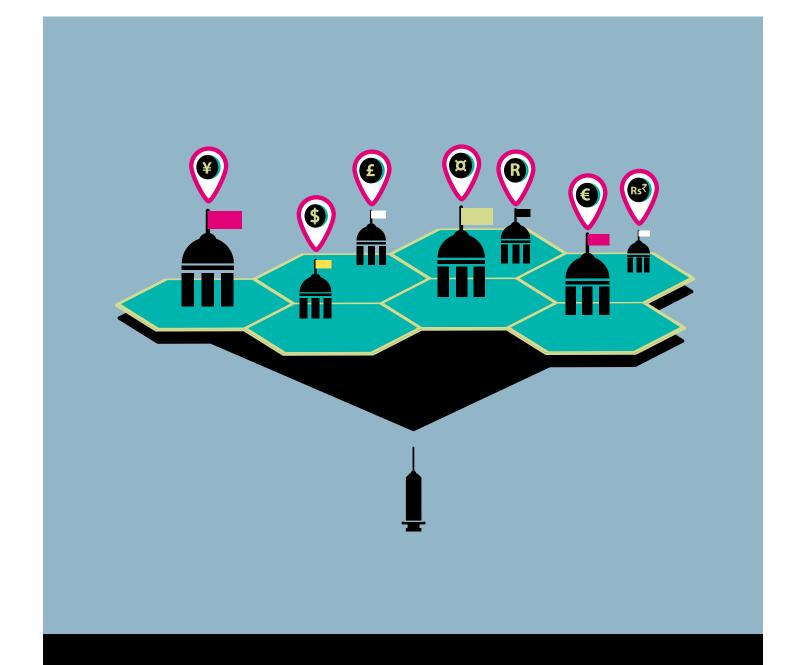
ESTABLISH information systems that help staff to track the available supply accurately.



Immunization programmes have sustainable access to predictable funding, quality supply and innovative technologies.

To meet goals of the Decade of Vaccines (2011–2020), actions must be taken both within countries and globally to increase the total amount of available funding for immunization from both countries and development partners. Countries should ensure the financial sustainability of national immunization programmes through regular evaluation of resource needs; efficiency in service delivery; availability of adequate domestic financing; and resource mobilization from development partners to meet any funding gaps. Governments also need to explore alternative and innovative financing mechanisms for health and immunization. Some countries have established trust funds or use dedicated tax revenues, among other strategies. In addition, it is important to move beyond budgets and into expenditures. Governments can improve vaccine access and prevent shortages of vaccines, immunization equipment or health workers by assuring that budgeted funds are disbursed in an ongoing and timely fashion that responds to programmes' needs.

Although the financing of immunization services is first and foremost a core responsibility of governments, development partners should support national strategies through more predictable, longer-term financing, and should also explore the next generation of innovative financing mechanisms. Emphasis needs to be placed on mutual accountability between countries and their development partners in terms of immunization financing. One possible



Actions must be taken both within countries and globally to increase the total amount of available funding for immunization

Global Vaccine Action Plan



A crucial but often overlooked key driver underpinning all these interventions is the quality assurance of vaccines

approach is to undertake annual resource tracking of immunization financing from partners and governments alike. For both countries and development partners, evidence-based advocacy and policy efforts should be focused on obtaining a renewed commitment to past funding pledges.

There is also a need to improve the allocation, accountability and sustainability of funding. Coordinating funding support from development partners and other external sources to target national budget priorities will ensure that funds are addressing the most pressing country needs. Funding allocation strategies should be revised periodically to confirm they are achieving goals, such as eradication and elimination of disease, as quickly and as effectively as possible. Feedback loops should be established to enhance programme sustainability, results and impact. One potential methodology to explore is a pay-for-performance funding system. However, the merits of this approach must be balanced against the importance of ensuring the predictability of funding, the risks of creating perverse incentives, and the fact that implementation of such a scheme requires high-quality data. This would include linking international, national, and local funding distribution to specific performance metrics and leveraging the resulting metrics to promote programme improvement.

Innovative pricing and procurement mechanisms are needed to alleviate funding pressure and to support the development and scale-up of new and existing vaccines. Innovations will be particularly important for those lower-middleincome countries that do not have access to the PAHO, UNICEF and GAVI Alliance pricing and procurement mechanisms. Mechanisms to explore include differential pricing using new approaches to define price tiers and pooled negotiation or procurement methods for lower-middle-income countries. Current pooled procurement models exist in both the vaccines and pharmaceuticals markets. One example is the PAHO revolving fund pooled procurement and short-term credit mechanism. This and other models could be assessed and modified to best suit the needs of the lower-middle-income countries and the individual vaccine markets.

The provision of long-term sustainable funding will be an incentive to manufacturers, thereby improving supply security. In addition, supply-side interventions are needed. A growing proportion of affordable vaccines that are used to immunize the world's population are manufactured in middle- and lower-middle-income countries. In the coming decade, these countries will not only have a requirement to ensure the quality, safety and efficacy of vaccines used domestically, but also a growing global obligation to protect and enhance the security of the global immunization enterprise. Potential supply-side interventions to ensure quality, safety and efficacy include identifying and disseminating best practices in manufacturing and quality control, investing in research and development capabilities, and initiating technology transfers and co-development agreements.

A crucial but often overlooked key driver underpinning all these interventions is the quality assurance of vaccines. Good-quality assurance relies crucially on effective standardization, which ensures that each vaccine product can be manufactured consistently and also enables multiple manufacturers to make similar products of the same quality. Normative processes to achieve globally harmonized standards for vaccines already exist, including international biological reference materials, but action is needed to strengthen global standardization.



page 62 Global Vaccine Action Plan

Strategic Objective 5 page

In addition, each country should develop the capacity to monitor and assure the safe use of vaccines, in line with the strategy defined in the WHO Global Vaccine Safety Blueprint initiative (as discussed under strategic objective 4). Action should also be taken to strengthen national regulatory systems and develop globally harmonized regulations in order to ensure that the increasing demand for regulatory reviews can be managed in an effective and timely manner. This is an issue not just for low- and middle-income countries involved in technology transfer, but also for regulatory agencies in high-income countries where expertise and resources need to be maintained. These supply-side interventions need to be based on solid business cases developed by countries to ensure the impact of these significant and long-term investments.

Making change happen with respect to sustainable funding will require commitments from governments and development partners to increase resources and improve programme efficiencies, as well as from additional countries joining the development partner ranks. Likewise, sustainable supply will require the multisectoral involvement of governments (for example, the science and technology, trade, industry and health sectors) in order to create an environment that helps suppliers to strengthen their capabilities. Emerging economies have a particularly important role to play in both cases, given their high rate of economic growth and the rapid expansion of the supply base there.

To increase alignment, activities currently performed by the UNICEF Supply Division and the GAVI Alliance to improve communication and coordination among countries, vaccine manufacturers and public-sector organizations should be further expanded. Countries need a forum where they can more clearly communicate expected demand for new vaccines and provide guidance on desired product profiles. This first-hand information would enable suppliers to make more informed product development and capacity planning decisions, thereby mitigating product development and supply risk. This information would also help development partners and other public-sector organizations to establish more defensible and reliable strategies and support plans. This forum could further be utilized to enable suppliers to accurately communicate the possible current and future range of pricing and supply to countries, and for countries to share information on and experience with vaccine procurement.

TABLE 6: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 5 IMMUNIZATION PROGRAMMES HAVE SUSTAINABLE ACCESS TO LONG-TERM FUNDING AND QUALITY SUPPLY.



Increase total amount of funding.

ESTABLISH a commitment for governments to invest in immunization according to their ability to pay and the expected benefits.

ENGAGE new potential domestic and development partners and diversify sources of funding.

DEVELOP the next generation of innovative financing mechanisms.

Increase affordability for middle-income countries.

EXPLORE differential pricing approaches to define explicit criteria for price tiers and the current and future prices to be made available to lower middle-income and middle-income countries.

EXPLORE pooled negotiation or procurement mechanisms for lower-middle-income and middle-income countries.

Improve allocation of funding in low- and middle-income countries.

STRENGTHEN budgeting and financial management in-country to better integrate financial and health care planning and priority setting.

COORDINATE funding support from development partners and other external sources.

EVALUATE and improve funding support mechanisms on the basis of their effectiveness in reaching disease goals.

BASE funding on transparency and objectivity in order to ensure the sustainability of programmes.

PROMOTE the use of cost and costbenefit arguments in fund raising, decision-making, and in defence of immunization funding.

EXPLORE pay-for-performance funding systems.

Secure quality supply.

BUILD and support networks of regulators and suppliers to share best practices and to improve quality assurance capabilities and quality control.

DEVELOP tools to strengthen global standardization of manufacturing and regulatory processes.

STRENGTHEN national regulatory systems and develop globally harmonized regulations.

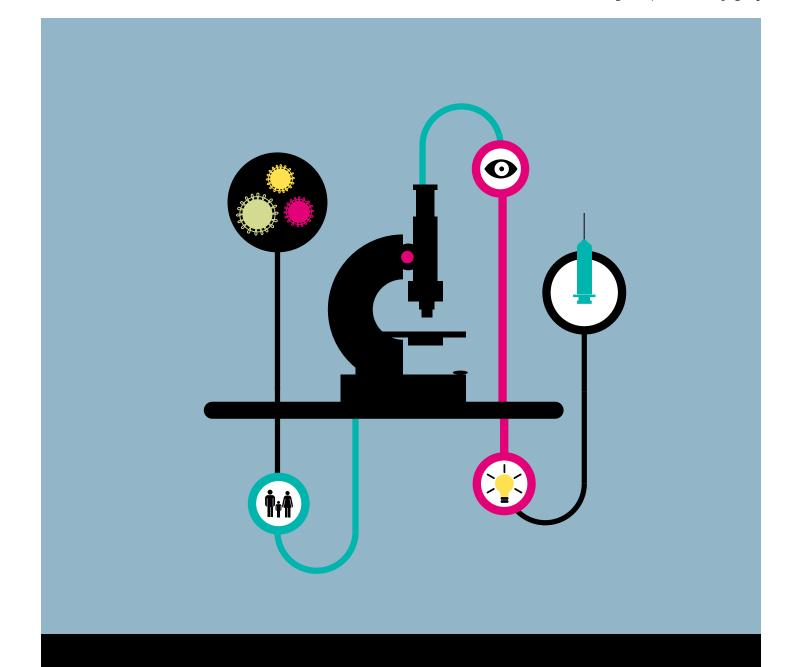
PROVIDE a forum where countries can communicate expected demand for vaccines and technologies and provide guidance to manufacturers on desired product profiles.



Country, regional and global research and development innovations maximize the benefits of immunization.

In the coming decade, targeted and innovative research and development efforts are needed across discovery, development and delivery. Innovative research and development efforts will lead to: (1) identification of mechanisms of protection and pathogenesis; (2) well-defined and novel antigenic targets for development of new vaccines; (3) development of bio-processing, formulation, manufacturing and delivery technologies for new and improved vaccines; and (4) development of disease-burden and cost-effectiveness data for in-country decision-making.

WHO has conducted a detailed study of disease prioritization and the Institute of Medicine in the United States of America is in the process of developing a model designed to assist decision-makers in prioritizing preventive vaccines based on health, economic, demographic, programmatic and social impact criteria, as well as scientific, technical and business opportunities. The Decade of Vaccines collaboration has not undertaken a vaccine or disease prioritization exercise. To complement the above efforts, a spectrum of research and development needs is presented across discovery, development and delivery, from which stakeholders can choose to invest according to their own priorities and perceptions of the return on their investments.



Research is needed to accelerate development, licensing and uptake of vaccines that are currently in early development

nage 66



Scientists from disciplines not previously engaged in vaccine research will need to be recruited

Across all research and development activities, increased engagement and consultation with end-users is needed to ensure that technologies and innovation are prioritized according to real demand and added value. New arrangements will also be required to facilitate the transfer of technologies and access to and sharing of associated information, while acknowledging and respecting intellectual property rights. In order to support this work and maximize its effectiveness of, scientists from disciplines not previously engaged in vaccine research (systems biology, nanotechnology, structural biology and metabolomics) will need to be recruited. Chemical and mechanical engineers, chemists and information technology specialists will also have key roles to play in this endeavour. In addition, capacity building and human resource development are needed in low- and middle-income countries to conduct research and development, including finding better ways to conduct operational research and evaluate immunization programmes. Research and development is being conducted in institutions of excellence in many low- and middle-income countries. This capacity is producing indigenous data, as well as fostering bilateral and multilateral collaboration in basic sciences and vaccine development. Capacity can be further strengthened through peer-to-peer training and exchanges between countries. Greater networking among research centres (from discovery to clinical trials) will facilitate the exchange of ideas and the efficient building of partnerships among institutions in high-, middle- and low-income countries.

Discovery and basic research will lay the groundwork for impact in future decades. Research at the interface between host and pathogen is needed to enable the development of new vaccines. Advancing knowledge of innate and adaptive immune responses will permit more rational vaccine design. Strengthening the understanding of immunologic and molecular characteristics of microbes through systems biology will permit the identification of new antigenic targets for vaccine development and effective ways of predicting protective immune responses and mechanisms of protection. Appropriate studies of host genetics and biomarkers will contribute to understanding the causes of variation in human population responses to vaccines, or susceptibility to adverse effects.

For the development of new and improved vaccines and vaccine technologies, the research and development community will benefit from adopting best practices in portfolio and partnership management, including the identification of early indicators of success and failure to inform milestone-based investments. The community should also consider new approaches to ensure promising vaccine candidates are advanced from discovery to development, particularly where market incentives are insufficient. This is especially important for vaccines to prevent "neglected" diseases.

Research is needed to accelerate development, licensing and uptake of vaccines that are currently in early development, including development of technologies for more efficacious and less expensive manufacturing of vaccines. Greater access to the technology and associated information for adjuvants and their formulation into vaccines is needed for advances in developing new and more effective vaccines. Non-syringe delivery mechanisms and vaccine packaging that best suit the needs and constraints of countries, as well as thermostable vaccines and new bioprocessing and manufacturing technologies, are priority research areas for accelerating the development of next-generation vaccines that are more effective, less expensive and easier to manufacture and deliver.



Non-syringe delivery mechanisms as well as thermostable vaccines are priority research areas Additionally, the elaboration and aggressive pursuit of a global regulatory science agenda will improve manufacturing efficiency, better characterize products, improve clinical trial design and safeguard the highest standards for vaccine safety and efficacy. The challenge is considerable in achieving understanding of the adverse effects, finding ways to avoid them and yet not compromising the known efficacy of the existing product—and without incurring the costs of developing, testing and registering a new product. In this dimension, research on animal models and in vitro systems that better predict safety and efficacy would shorten the time for developing safe and effective vaccines and for making them available to communities. Knowledge of the correlates of protection and safety will greatly help to bring these second-generation products to licensure and use.

With respect to delivery, priority areas to improve programme efficiency and increase vaccine coverage and impact should include research on the use of effective information through modern communication technologies and social research in order to understand the cultural, economic and organizational determinants of immunization. Health economic analysis will guide the introduction and prioritization of vaccines, and hence representative epidemiological, immunological and operational studies and studies of vaccine impact will be needed.

Operational research on the most effective delivery approaches is also needed in order to overcome the challenges posed by life-course immunization (newborn, infant, adolescent, pregnant women, elderly, among others) and vaccination in emergency and outbreak situations. Research on immunological interference effects and optimization of delivery schedules will be required as more new vaccines are introduced into routine programmes and immunization is extended beyond the first year of life. In the case of special populations, such as pregnant women, confirmation of safety will be particularly important. Furthermore, research is required in order to develop bio-markers for validating immunization coverage estimates and enabling better measurement of population-level immunity profiles. In addition, research to develop field-usable and cost-effective diagnostic tools for establishing etiology that are suited for use at point-of-care in low-income countries will be valuable additions to improving surveillance quality.



Concerted action among the research community, manufacturers, health professionals, programme managers, national immunization technical advisory groups, vaccine regulatory agencies and development partners will be needed to attain the full potential of research and development in the next decade. Methods and arguments for prioritization and allocation of scarce resources will have to be agreed upon by these groups, balancing the tensions between country-driven choices and the need for large-scale research efforts and markets in order to sustain development and commercialization. Health professionals, programme managers, vaccine regulatory agencies and national immunization technical advisory groups can help to identify areas where innovations could be made, and assess their real demand and added value. Development partners can help promote a judicious allocation of some resources for research and development, according to the agreed priorities. The research community and manufacturers will have prime responsibility for promoting innovation and pursuing the research agenda defined above.



Operational research on the most effective delivery approaches is also needed in order to overcome the challenges posed by life-course immunization

TABLE 7: SUMMARY OF RECOMMENDED ACTIONS FOR STRATEGIC OBJECTIVE 6 COUNTRY, REGIONAL, AND GLOBAL RESEARCH AND DEVELOPMENT INNOVATIONS MAXIMIZE THE BENEFITS OF IMMUNIZATION.



Expand capabilities and increase engagement with end-users.

ENGAGE with end-users to prioritize vaccines and innovations according to perceived demand and added value.

ESTABLISH platforms for exchange of information on immunization research and consensus building.

BUILD more capacity and human resources in low- and middle-income countries to conduct research and development and operational research.

INCREASE networking among research centres for efficient building of partnerships among the institutions of high-, middle- and low-income countries.

PROMOTE collaboration between traditional research disciplines and scientists from disciplines not previously engaged in vaccine research.

Improve programme efficiencies and increase coverage and impact.

RESEARCH the use of more effective information through modern communication technologies.

CONDUCT representative epidemiological, immunological, social and operational studies and investigations of vaccine impact to guide health economics analysis.

PERFORM operational research on improved delivery approaches for life-course immunization, and vaccination in humanitarian emergencies, so-called fragile States and countries in and emerging from conflict.

PERFORM research on interference effects and optimum delivery schedules.

PERFORM research to develop improved diagnostic tools for conducting surveillance in low-income countries.

Accelerate development, licensing and uptake of vaccines.

PROMOTE greater access to technology, expertise and intellectual property for adjuvants and their formulation into vaccines.

DEVELOP non-syringe delivery mechanisms and vaccine packaging that best suit the needs and constraints of national programmes.

DEVELOP thermostable rotavirus and measles vaccines.

DEVELOP new bioprocessing and manufacturing technologies.

DEVELOP a global, regulatory science research agenda.

ADOPT best practices in portfolio and partnership management for research and development.

Enable the development of new vaccines.

RESEARCH on the fundamentals of innate and adaptive immune responses, particularly in humans.

RESEARCH on immunological and molecular characteristics of microbes.

IMPROVE understanding of the extent and causes of variation in pathogens and human population responses to vaccines.



A spectrum of research and development needs is presented across discovery, development and delivery