



GUIDE FOR DEVELOPING
NATIONAL IMMUNIZATION
POLICIES IN THE WHO
AFRICAN REGION



World Health
Organization

REGIONAL OFFICE FOR **Africa**

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IN THE WHO AFRICAN REGION**

**WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR AFRICA
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CONTENTS

	Page
ABBREVIATIONS AND ACRONYMS	VII
DEFINING A POLICY	XI
SUMMARY	XIV
CONTEXT	1
BACKGROUND	5
PURPOSE OF THE GUIDE	11
I. ENABLING ENVIRONMENT	15
Principle 1: State obligations.....	15
Principle 2: Participation.....	18
Principle 3: Value and benefits	21
II. OPERATIONAL ENVIRONMENT	25
Principle 4: Integration.....	25
Principle 5: Leveraging	29
Principle 6: Innovation	32
Principle 7: Evidence.....	35
Principle 8: Oversight	38
III. LIFE-COURSE VACCINATION	45
Principle 9: Life-course	45
Monitoring policy implementation	48

ANNEXES

1. EXAMPLE OF A VACCINATION SCHEDULE	51
2. GLOBAL ROUTINE IMMUNIZATION STRATEGIES AND PRACTICES (GRISP).....	54
REFERENCES	59

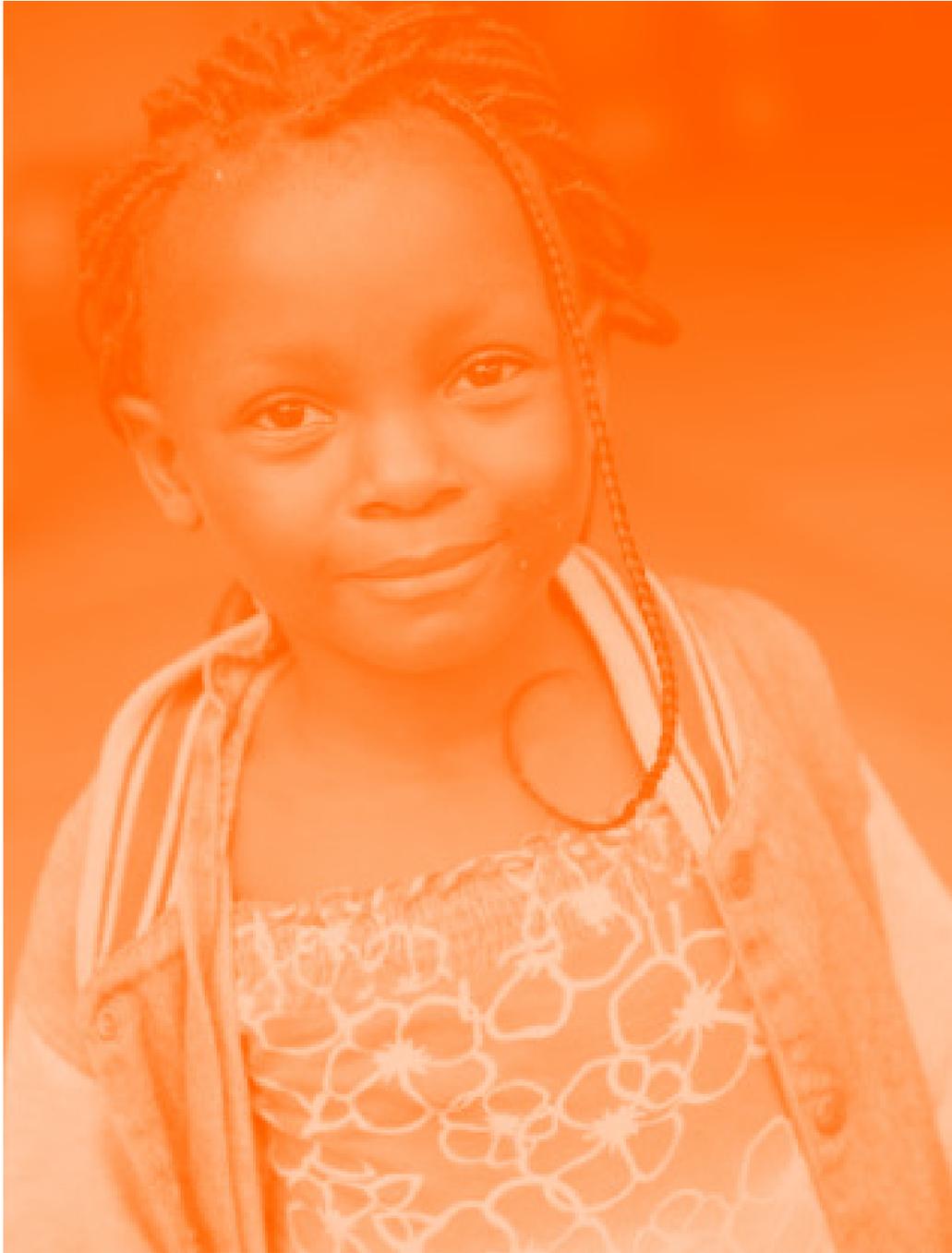


ABBREVIATIONS AND ACRONYMS

AEFI	Adverse Event Following Immunization
AFRO	WHO Regional Office for Africa
ANC	Ante-natal Care
AVW	African Vaccination Week
BCG	<i>Bacille Calmette-Guérin</i> Vaccine
cMYP	Comprehensive Multi-Year Plan
CSO	Civil Society Organization
CTC	Controlled Temperature Chain
DTP	Diphtheria Tetanus Pertussis Vaccine
EPHR	Electronic Personal Health Record
EPI	Expanded Programme on Immunization
FBO	Faith-Based Organization
GAVI	Global Alliance for Vaccines and Immunization
GIVS	Global Immunization Vision and Strategy
GMP+	Growth Monitoring Programme Plus
GRISP	Global Routine Immunization Standards and Practices
GVAP	Global Vaccine Action Plan
HBV	Hepatitis B Vaccine
HIS	Health Information System
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus Vaccine
ICC	Inter-Agency Coordinating Committee
IHR	International Health Regulations

IMCI	Integrated Management of Childhood Illness
IPD	Immunization Plus Day
IPV	Inactivated Poliovirus Vaccine
LLIN	Long-Lasting Insecticidal Nets
MCV	Measles-Containing Vaccine
MUAC	Mid-Upper Arm Circumference
NCD	Noncommunicable Disease
NITAG	National Immunization Technical Advisory Group
NGO	Non-Governmental Organization
NRA	National Regulatory Authority
PATH	Programme for Appropriate Technology in Health
OPV	Oral Polio Vaccine
PCV	Pneumococcal Conjugate Vaccine
PDA	Personal Digital Assistant
PENTA	Pentavalent Vaccine
PIRI	Periodic Intensive Routine Immunization
RITAG	Regional Immunization Technical Advisory Group
ROTA	Rotavirus Vaccine
SAM	Severe Acute Malnutrition
SDD	Solar-Direct-Drive
SDG	Sustainable Development Goal
SWG	Stakeholder Working Group
Td	Tetanus Diphtheria Vaccine
Technet	Technical Network for Strengthening Immunization Services
TT	Tetanus Toxoid Vaccine

UCI	Universal Child Immunization
UNICEF	United Nations Children's Fund
VVM	Vaccine Vial Monitor
WHO	World Health Organization
WPRO	WHO Western Pacific Regional Office
YF	Yellow Fever



DEFINING POLICY

A public policy relates to courses or principles of action proposed by a government. It is often published, and if widely acceptable, is adopted in order to reach specific long-term goals. Policies are designed to influence and determine all major decisions and actions; all activities take place within the boundaries set by them. Policies are usually supplemented by decrees or legislation defining in greater detail how, by whom and when actions should be undertaken, and with what resources. They also put in place responsibility and accountability mechanisms that support implementation.

Policy guidance should not be confused with technical guidance. The latter articulates the processes and procedures employed to express policies in action in day-to-day operations. In the area of immunization, for example, main considerations for technical guidance would relate to planning immunization programmes, delivery practices, performance, coverage, integration into the health system, communication, management, and financing.

Policy formulation usually follows a standard format, which includes:

1. A *purpose statement*, outlining why the policy is being issued, and what the desired effect or outcome will be (its public health, fiscal, or economic impact; its feasibility of implementation);
2. A *statement of principles* that underpin the policy;
3. An *applicability and scope statement* describing who the policy will affect, and which actions will be affected by the policy; the desired targets (avoiding any unintended consequences, where possible); and an indication of any modifications to organizational behaviour that the policy will create;
4. An *effective date*, that is, the date on which the policy will enter into force, and the duration of the policy;
5. A *responsibilities section* indicating which parties and organizations will be responsible for implementing individual policy statements;
6. An indication of *performance assessments* and the periodicity of reviews.

Some policies may also contain additional sections, such as Background, which outlines the reasons, history and intent of the policy, and Definitions which provide clear and unambiguous terms and concepts used in the policy.

Health policy refers to decisions, plans, and actions that are undertaken to achieve specific health care goals within a society. An explicit health policy can achieve several goals: it can define a vision for the future, which in turn, helps to establish targets and points of reference for the short and medium term; it can also outline priorities and specify the expected roles of different groups; finally, it can help build consensus and inform people.¹

Difference between policy and law is mainly that policy is a principle that guides decision making, while a law is a rule enforced by an institution. Policies are only documents and not law, but these policies can lead to new laws.





SUMMARY

There is strong demand from countries in the WHO African Region for guidance on how policies can be adopted for their national immunization programmes. Such policies should be consistent with global goals, such as Sustainable Development Goals (SDGs) and Global Vaccine Action Plan (GVAP) targets. They should also be in accord with the targets of the Regional Strategic Plan for Immunization 2014–2020,² and with global and African political agreements and compacts on health and immunization. Such policies provide the framework for technical guidance in implementing immunization programmes.

The basic hallmark in the development of policies for any immunization programme is a focus on evidence-based development of recommendations, and also on innovation and best practices. Immunization policies are part of a hierarchy of policy statements, starting with the country's vision, as contained in its Constitution or other set of development policies, followed by the national health policy within which immunization policies are embedded.³ Any policy consideration for the immunization programme should be consistent with the national health policy and the country's overall development vision and policies.

This Guide clusters policy considerations under an enabling environment, an operational environment, and the life-course approach benefitting all age groups. The Guide focuses on principles relating to state obligations; broad partnerships; the value and benefits of immunization; immunization as an integral part of the public and private health care sub-systems; leveraging of community capacities; innovation, including technology; evidence-based decision-making; oversight; and the life-course.

The obligations of the state to provide quality immunization services to all, and the duties of each individual to be vaccinated or ensure that

their children are vaccinated, are at the heart of accountability in the immunization programme. The financing environment is changing, with increasing recourse to co-financing as countries graduate from GAVI support. This puts the onus on them to increase their own financing, but also to explore alternative sources of funding. Broad participation by national, local and international stakeholders, with countries themselves at the helm, will be necessary if these countries are to expand and sustain their immunization programmes — even as new vaccines are being introduced. Innovations in technology, such as mobile health (mHealth) and Controlled Temperature Chain (CTC), can help enhance the efficiency, effectiveness and the long-term sustainability of immunization programmes.

At country level, NITAG make decision-based on evidence generated from high quality up-to-date data, and oversight mechanisms based on transparency of operations. This enhance the trust of both the general public and other contributors to the immunization programme. Moreover, the value of immunization to the society in terms of the deaths, diseases, hospitalizations and disabilities averted, and the attendant economic savings, largely justify the investments made in the programme.

Immunization is an integral part of the health system, and delivery of service should thus be integrated with other interventions demanded by the public in particular, due to the inability of newer vaccines to fully prevent disease. Integration is a challenge and calls for a significant change in mindset, with goals and funds being shared across health interventions. It can cause a temporary decline in immunization; this has to be recognized by all stakeholders, but the pay-off associated with meeting the community with a package of services which they demand can, in the longer term, enhance people's trust in the health system and in vaccination. A life-course approach to vaccination, from birth to old age, increases the opportunity to provide additional health services, with a focus on preventive health measures, while addressing emerging challenges such as noncommunicable diseases.



Adolescents drive the life-course approach to immunization in the sense that they are the first age group that can rationally understand the value and benefits of vaccination. That understanding, in turn, shapes positive life-time health behaviour for themselves and their children deep into the future. It should be noted that immunization can be an entry point for other adolescent health interventions. In fact, it can convert them into actors for health promotion, thereby influencing the wider community.

Continuous and structured mobilization of key actors is central to analyzing, adapting and adopting the policy considerations identified, and to making them pertinent to each country's own unique characteristics. Independent experts organized in a NITAG can provide evidence-based advice for immunization-related policy decisions that take account of local epidemiological, social contexts, and also a broad variety of other factors such as vaccine

characteristics and their harms and benefits, cost-effectiveness, feasibility and acceptability, etc. Research groups, committees investigating adverse events following immunization, policy performance evaluators and other expert groups are equally important in providing undistorted information about vaccines and vaccination in order to ensure that individual and community confidence in immunization remains high. An ICC, and more pragmatically a smaller and more inclusive stakeholder working group (SWG), can support specific plan development, organize resource mobilization, and guide and monitor programme performance.

Maintenance of individual and collective stakeholder dialogue and organization of national forums help to generate and disseminate information on progress in a transparent manner; they also produce constructive feedback. Communicators and innovators are drawn in to enhance the capabilities and reach of the immunization programme. Communities are motivated to provide resources to bridge financial gaps and ensure that vaccines are secured. Commitments from multiple ministries ensure that vaccination reaches all groups in a life-course approach. Multiple departments in ministries of health ensure that workforce requirements are met, and that information and regulatory systems are in place. Engagement with private for-profit and not-for-profit providers as well as civil society organizations can enhance coverage and increase equity in access to immunization services.

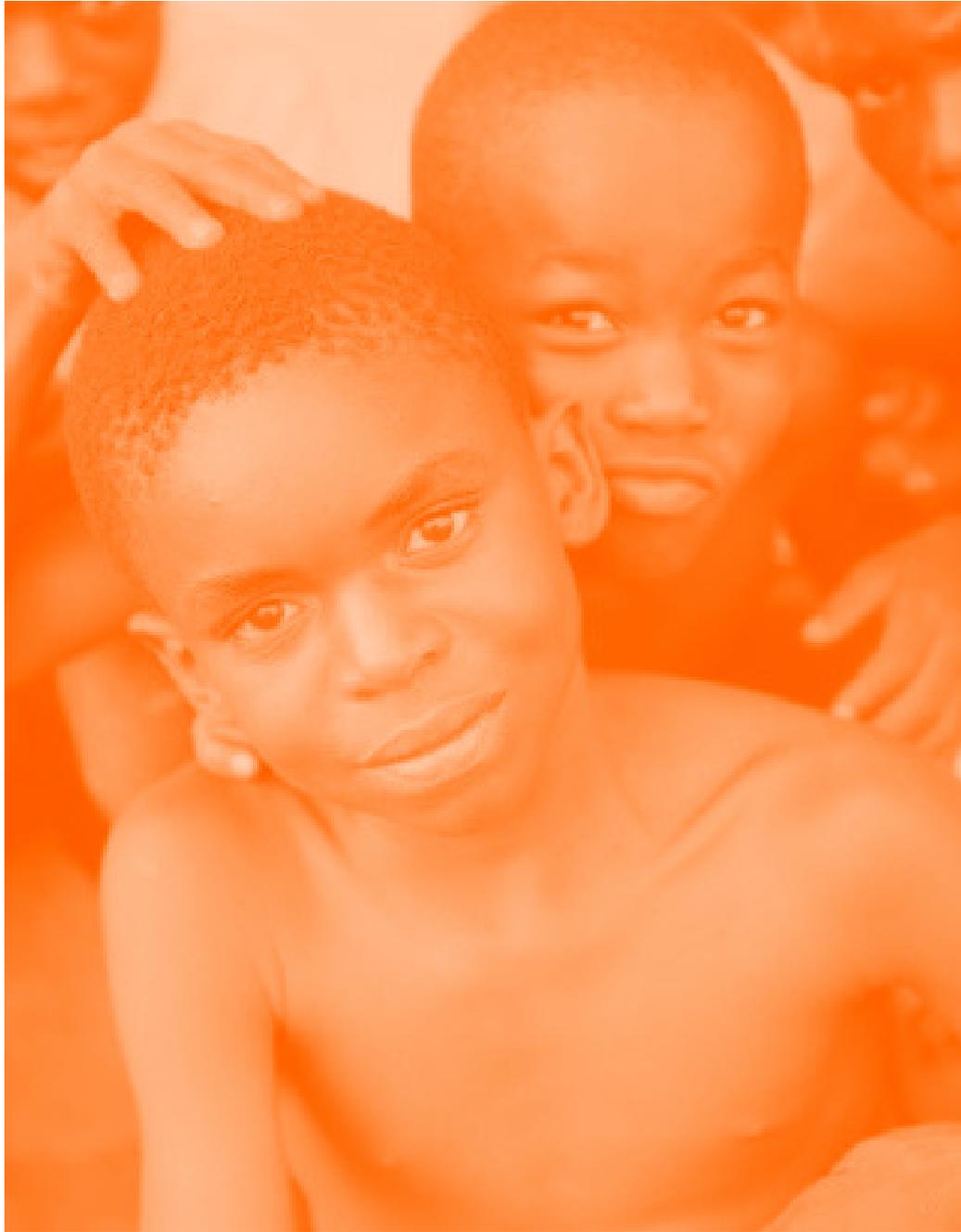
This mobilization requires dedicated capacity both in the immunization programme and at decentralized levels. Smart ways of securing capacity include co-opting stakeholder staff to augment standing capacities in the programme. There is a cost to developing sound policy and translating it into legislation and plans. The same is true of workforce and technological enhancements. At the same time, the programme may need to absorb costs related to its integration into the broader health care system. Returns on investment in immunization are considerable. They are potentially even more so, and can increase the trust of the public in the health system, if a more integrated approach is adopted.

The Guide identifies key policy considerations for the successful implementation of strategies by national immunization programmes. Countries will have to assess what policies they already have in place and what modifications and additions are required to enhance their programme. The period prior to development of the cMYP⁴ may be the most appropriate time to conduct a policy assessment since it coincides with the comprehensive review of the immunization programme.

While the Guide provides a comprehensive approach to policy development across nine principles, it is recognized that countries may proceed in stages. However, a national policy statement on immunization which can be put into the public domain, should at a minimum:

1. Underscore the purpose of immunization and the need for individual as well as collective protection, both as a right and as an obligation;
2. State the advantages of immunization as they relate to specific diseases or vulnerabilities, and indicate any possible adverse events associated with vaccination and how to report them;
3. Illustrate the societal value of immunization in improving the quality of life and securing economic benefits;
4. Indicate how immunization fits into the national health plan, and emphasize the coherence and mutual reinforcement between immunization and other services of the national health system;
5. Make reference to global and African compacts and agreements that commit the country to achieving and funding universal immunization;
6. Define how the integration of immunization services with other components of primary health care will be structured;
7. Stress the need for the full participation of all stakeholders in planning and implementing immunization services;
8. Describe ways in which communities can engage themselves in supporting the immunization programme;

9. Indicate the importance of parents registering their children at birth to ensure that they are counted in the planning of immunization services;
10. Specify who is eligible for specific vaccines and what schedule needs to be followed;
11. Indicate if there are specific legal requirements related to completing vaccinations, such as entry to nursery or school;
12. Indicate that everyone should have a complete personal record of his or her vaccinations from birth;
13. Highlight the respective roles of public health services, private medical practitioners, and NGOs in providing vaccinations;
14. Indicate the additional health services that may be available at vaccination sessions for both the persons being vaccinated and those accompanying infants and children to vaccination;
15. Describe the multiple venues for vaccination;
16. Confirm if vaccination is free, and if not, specify the situations in which there may be an out-of-pocket charge, or coverage by health insurance or other financing mechanism;
17. Specify the reasons for a policy decision and how universal immunization will be achieved (where a component of the immunization programme is being phased in);
18. Indicate what information on the immunization programme will be publicly available, and the means of disclosure that will be used;
19. Assert the need for quality vaccines and best practices in immunization, and indicate how and by whom these quality standards will be enforced and verified;
20. Define responsibilities for the implementation of the national policy;
21. Describe the accountability mechanisms related to the implementation of the national policy, and indicate how stakeholders, including the public, will be made aware of achievements and barriers;
22. Determine the date of entry into force of the policy and the context that may warrant its revision.



CONTEXT

Sustainable Development Goal 3 (SDG3) endorsed by all countries at the UN General Assembly in September 2015 calls for ensuring healthy lives and promoting well-being for all at all ages by the year 2030.⁵ From a global perspective, immunization is integral to the achievement of at least four of the targets under SDG3.⁶ The Africa health strategy,⁷ which coincides with the 2016–2030 period of the Sustainable Development Goals, prioritizes:

1. Better inter-sectoral collaboration;
2. The central importance of health system strengthening;
3. Better leveraging of community strengths;
4. Public, private and other partnerships;
5. More systematic management of disaster risks.

These priorities can be seen within the broader vision of the African Union's Agenda 2063⁸ in which critical enablers focus on people's ownership and mobilization, Africa's own resources, accountable leadership, democratic institutions, and changed attitudes. African ministers for health, finance, education, social affairs, and local government attending the Ministerial Meeting on Immunization in Africa, held in Addis Ababa, Ethiopia, in February 2016, reaffirmed their commitment to continued investment in immunization programmes.⁹ Within the WHO African Region, the aim is to ensure achievement of universal immunization coverage by 2020.¹⁰

These political compacts, global and African, are the initiatives for which governments will be held accountable. They will be required to act taking into account different national realities, capacities and levels of development, and in compliance with national policies and priorities. It is assumed that these compacts will drive national and international public finances, together with other public and private

funding, generating significant resource flows from which immunization programmes can benefit. There is positive synergy between these compacts and the Regional strategic plan for immunization 2014–2020.¹¹ The importance here is for principal national immunization actors to be fully engaged in these political processes in order to safeguard progress in immunization programmes that has been made in the last three decades, expand access, achieve equity, and ensure that 'every shot counts'.





BACKGROUND

The Regional strategic plan for immunization 2014–2020 coincides with the period of the Global vaccine action plan (GVAP), the aim of which was to operationalize the vision¹² of the Decade of vaccines by delivering universal access to immunization. The strategic plan during this period can, therefore, be seen as an initial contribution to the Africa health strategy. It will also help to achieve targets under SDG3 by specifically:

1. Reducing the maternal mortality ratio to less than 70 per 100 000 live births;
2. Reducing neonatal mortality to less than 12 per 1000 live births;
3. Reducing under-five mortality to less than 25 per 1000 live births.

The guiding principles of the strategic plan – country ownership and leadership; shared responsibility, partnership and mutual accountability; equitable health outcomes; integration; sustainability; and innovation – provide the basis on which strategic directions are set. The principles require that:

1. All countries commit to immunization as a priority;
2. Individuals and communities understand the value of vaccines and demand immunization as both their right and their responsibility;
3. The benefits of immunization should be equitably extended to all people;
4. Strong immunization systems should be an integral part of a well-functioning health system;
5. Immunization programmes should have sustainable access to long-term funding and quality supplies;
6. Country and regional communication, and research and development innovations should maximize the benefits of immunization.

The Strategic plan was endorsed by the WHO Regional Committee for Africa in November 2014.¹³ The Regional Committee urged Member States to develop comprehensive multi-year and annual plans,

commit to allocating adequate human and financial resources to immunization, mobilize and empower communities, and enhance and sustain multi-sectoral collaboration.

These principles and strategic directions, together with the recommendations of the Regional Committee and commitments under global and African political compacts, point to a set of priority policies that need to be developed, sustained, monitored and modified based on emerging evidence. Policies should also take account of important new directions that have been emphasized in the Strategic plan. They include:

1. Moving from supply-driven to demand-driven community immunization approaches, with Member States mobilizing local communities;
2. Moving from globally-driven immunization agendas to nationally-owned immunization programmes, with increased national budget allocations;
3. Going from single-stream programme structures to integrated health system approaches, with routine immunization as the bedrock of all immunization activities within a robust primary health care (PHC) system;
4. Placing greater emphasis on the life-course approach to immunization.

In a survey carried out in 2013 by the WHO Regional Office for Africa, only 19 out of 46 countries provided written copies of policy or technical guidelines for their immunization programme. Of those provided, many did not capture all areas of immunization, and almost none was backed by a legal framework in place.¹⁴ The country policy guidelines reviewed¹⁵ contained some principles relating to:

Political commitment;	Community participation and social mobilization;
Regulatory issues relating to immunizations;	Integrated approach
Co-ordination and leadership;	Accessibility, equity, affordability and sustainability;
Transparency, accountability and efficiency;	Quality of services and safety.

The country guidelines reviewed provided some direction for immunization programmes, mainly with regard to implementation issues.^{16,17,18} While it was seen that there was variance from specific WHO recommendations in terms of the vaccines administered, progress was observed in the broadening of schedules. In this context, current data on vaccines¹⁹ show the following for the African Region:

Vaccine in schedule at national scale	Number of countries (n=47)
Birth dose of HBV	7
Birth dose of OPV	38
HPV	8
IPV	37
MCV2	17
PCV	36
Rotavirus	29

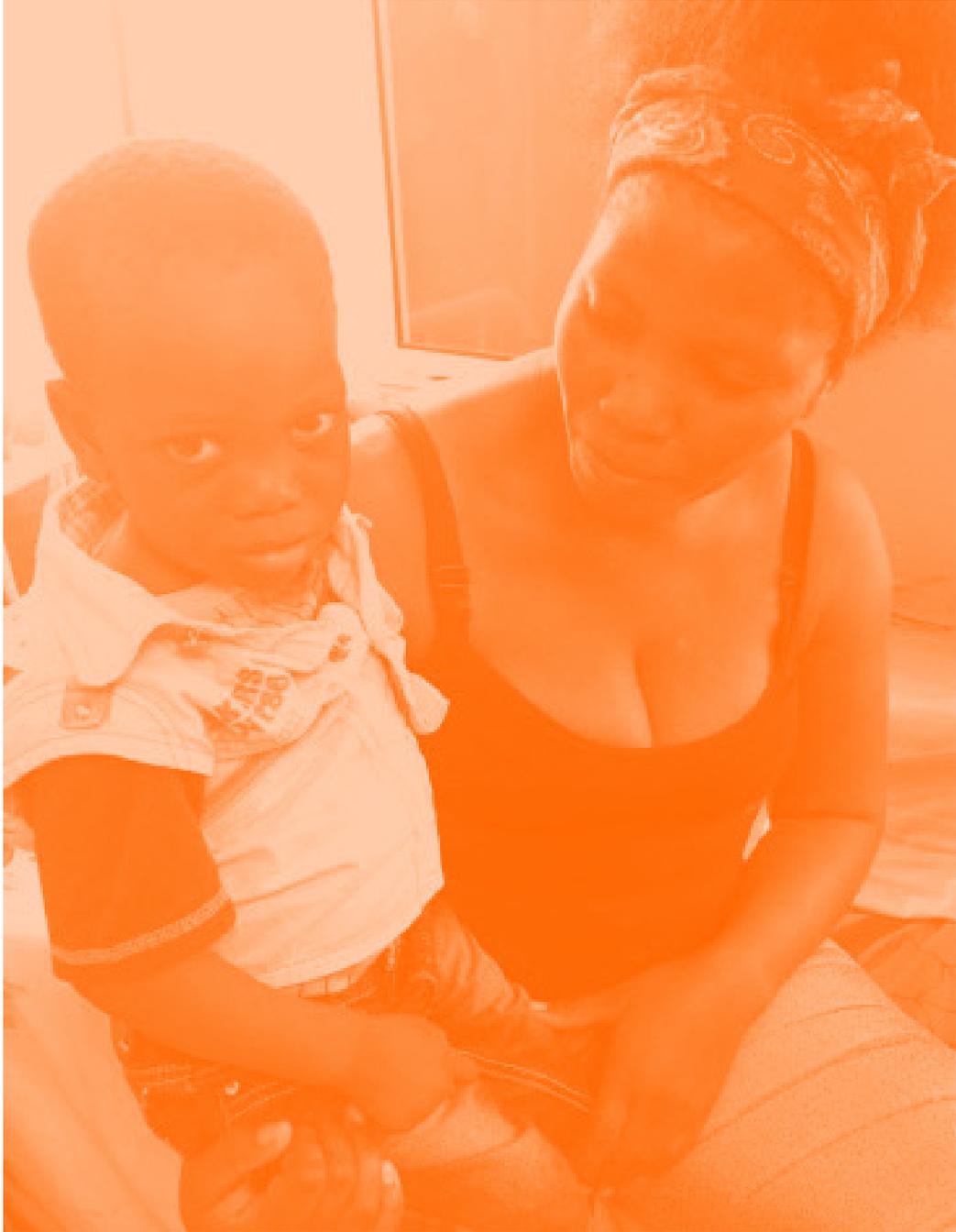
Overall, the survey resulted in a set of recommendations, recognizing that developing and implementing immunization policies involves research, information sharing with key leaders and decision makers, advocacy, the involvement of different areas of government, and assessment of the political, social and economic context. The survey called on WHO to maintain an updated public health policy catalogue or registry at the WHO Regional Office for Africa. That catalogue or registry should be easily accessible to governments, stakeholders and partners, in order to help countries in policy development, dissemination, training, implementation, and practice.

Immunization programmes have evolved from the launch of the Expanded programme on immunization (EPI) in 1974, through Universal child immunization (UCI) of the 1980s, the inception of Global alliance for vaccines and immunization (GAVI) in 2000, Global immunization

vision and strategy (GIVS) in 2006, to the current Decade of vaccines and the Global vaccine action plan (GVAP). A wide range of newer and more expensive vaccines has been introduced, and immunization now covers everyone throughout the life-course.

Furthermore, there is the renewed commitment to providing universal immunization, with a greater focus on national funding, as countries graduate from GAVI support. A new approach to policy development is required that takes account of the broader environment surrounding immunization, along with the increased complexity of the latter, including cross-border challenges, the quest for a more structured approach, and increased harmonization of content.





PURPOSE OF THE GUIDE

The Guide identifies key policy considerations needed for the successful formulation of strategies by national immunization programmes. It is important to note that all countries have a national health policy, necessarily broad in approach, that in most cases indicates immunization as a public health priority under government responsibility and accessible to all, regardless of socioeconomic status, or other consideration. Any policy being considered for the immunization programme needs to be evaluated for consistency with the national health policy and the country's overall development vision and policies.

For immunization specifically, policies can be crafted to fit different perspectives. They can relate to budget ring-fencing, for example, as an illustration of a policy at societal level; or they can make vaccination compulsory for school entry. On the other hand, determining that no eligible persons should be denied immunization unless they present with recognized medical contraindications relates more to the operational level. However, deciding on a vaccination schedule takes into account both societal and operational considerations.

Where immunization is publicly funded, policies still need to recognize the potential opportunity costs for groups targeted for vaccination. Those opportunity costs may indeed constitute barriers to attendance at vaccination sessions,²⁰ especially for low income groups. Additionally, there is a growing private for-profit and not-for-profit market for immunization services that needs to be regulated. From a regional perspective, a certain level of harmonization of policies is desirable for cross-border collaboration, given the reality that infectious diseases do not recognize political boundaries, as multiple outbreaks have demonstrated.

The Guide covers three principal dimensions relevant to immunization programmes, and for which policy development is needed:

1. An *enabling environment*, that looks at societal factors and the involvement of a multitude of stakeholders;
2. An *operational environment*, that is mainly within the purview of the ministry of health, and the links of the latter to other ministries, providers and direct supporters;
3. *Life-course vaccination* component that goes beyond childhood vaccination to cover all population groups, from birth to the end of life.

The basic hallmark of policy development for immunization programmes is a focus on innovation and best practices, where unique partnerships of stakeholders, new and disruptive technologies, accountable systems, and data-driven insights introduce dynamic change and evolution in the way decisions are taken, capacities strengthened, and strategies designed and implemented.²¹





I. ENABLING ENVIRONMENT

Principle 1: State obligations

State obligations under the right to health and human rights conventions to which the state is party, and in which this right is entrenched, are fully exercised, as are the responsibilities of individuals and parents on behalf of children to be vaccinated for the public good.

The right to health is embedded in Article 25 of the Universal Declaration of Human Rights, proclaimed by the United Nations General Assembly in 1948²² and in Article 16 of the African Charter on Human and Peoples' Rights (the Banjul Charter), adopted by the Organization of African Unity in 1981.²³ The Banjul Charter has been ratified by all African Member States, with the exception of the recent nation of South Sudan, and is increasingly used by national courts.²⁴

These instruments confirm the obligations of Member States to take the necessary measures to protect the health of their people. The Banjul Charter also clearly states in Article 27 the duty of each individual to have due regard for the rights of others and the common interest, which is central to the success of immunization, and for preventing the spread of communicable diseases. The obligations of the state and the duties of each individual are at the heart of the co-production of health, recognizing that, in Africa, individual and contextual factors are closely associated with coverage and better immunization outcomes.^{25,26,27,28}

Countries have primary ownership and responsibility for providing effective and quality immunization services for all.²⁹ This requires an institutional response at the national and local level, with the support of international partners. The response is both political and technical. The political response ensures that policies, resources and capacities are available, and that relevant legislation is in place as called for in called for in GVAP Strategic objective 1. The technical response involves providing guidance for the development of strategies and plans for the immunization programme.

A legal framework should be carefully considered to ensure that everyone's right to immunization and everyone's responsibility to be vaccinated are protected. Such a framework should reference the country's over-arching vision and plans, health policies and strategies, and specific responsibilities for public health. Mechanisms for compliance or consent should be articulated, including whether there is a requirement of full immunization for school entry. Compliance with vaccination can be secured in an Immunization Act, and additional immunizations can be made mandatory in the case of new infections and epidemics, with individual failure to comply resulting in punitive measures ranging from fines to possible imprisonment.³⁰ It is the responsibility of each country to assess the appropriate means of securing compliance. The public should be made fully aware of their responsibilities for vaccination; but they should also have the right to voice any failure by government to provide vaccinations.

Countries must have dedicated budget lines for immunization at national level and sub-national levels where the government operates in a decentralized manner. This information can (should) be captured in an Immunization Act or similar legislation as well, in order to protect financial commitment through changes in administration, etc. Attention should be paid to the need to remove bottlenecks in the budget process, and to the timely disbursement of funds.³¹ Polio legacy planning must ensure, wherever feasible and appropriate, the transfer of capabilities, assets and processes to other health priorities.³² Governments must also have in place an appropriately resourced National Regulatory Authority (NRA) that approves the production, import and use of vaccines and immunization-related supplies, as well as independent bodies such as National Immunization Technical Advisory Groups (NITAG) that advise them for evidence based decision making.

An important related factor for immunization is the need for universal birth registration, which gives each person an identity and assurance of recognition everywhere as a person before the law, as enshrined in

Article 6 of the Universal Declaration of Human Rights.³³ This registration provides the health service with the number of newborns entering each cohort that needs to be vaccinated, and is vital for accurate planning and follow-up.³⁴

State obligations should also include specific measures that should be in place to respond to emergencies, whether these be new infections, human displacements, or potential disruptions such as climate change, where the immunization programme is necessarily a key component of the broad health response required. The newly-formed WHO Health Emergencies programme provides pointers for readiness, preparedness, risk assessment, event grading, and incident management, and is already in discussions with the African Union on the deployment of emergency medical corps.³⁵ The World Bank Group has also recently launched a Pandemic Emergency Funding Facility (PEF), which aims to insure the world's poorest countries against the threat of a pandemic.³⁶

Policy considerations

1. The national health policy includes full details on the state's obligation to make immunization services of optimal quality and availability accessible and affordable to all.
2. A legal framework is in place to ensure that individual and societal responsibilities for vaccination are upheld, with clearly-defined compliance measures.
3. A law and implementation mechanism is in place for ensuring universal birth registration, providing an identity to each individual, and guaranteeing accuracy in the number of birth cohorts.
4. Measures are implemented to inform the public of their responsibilities for vaccination, and to document and act upon government failure to provide vaccinations.
5. The national budget, and sub-national budgets as indicated, include specific allocations for the immunization programme within the health sector budget, and means for timely disbursements.
6. Capacities are in place to assess epidemiological risks posed by new infections, acute humanitarian emergencies, emerging health threats, and priority actions to take.³⁷
7. Fully-functional and resourced National Immunization Technical Advisory Groups (NITAG) and National Regulatory Authority (NRA) are in place.



Principle 2: Participation

Broad participation by all local, national and international stakeholders is actively secured to reinforce national ownership and leadership.

Participation is a central theme of the Africa Health Strategy and the Africa Agenda 2063. A structured response addressing global, regional (African) and national goals and targets entails multi-sectoral and multi-level participation and collaboration within government, on the one hand, and on the other, outreach to non-governmental stakeholders, providers, and international partners.

A national political forum for immunization held periodically, can act as a centrepiece for participation, pulling together key government ministries and leading political figures (e.g., state or provincial

governors, parliamentarians, party leaders) with accountabilities for legislating, managing, funding and communicating the immunization programme. The landmark 2016 Ministerial Conference on Immunization in Africa firmly signaled the importance of engaging diverse sectors of government.³⁸

Support from heads of state can further empower countries to increase efforts to reach universal immunization within the broader goal of universal health care. Each country is responsible for determining how best to maintain a meaningful and supportive political forum that advances the immunization programme. In addition, peer exchanges between countries, including ministries for health and finance, together with other governmental, non-governmental and international stakeholders, can help promote momentum for changes in immunization programmes. These can also help to overcome identified obstacles, particularly on sustainable financing and cross-border challenges.³⁹

Interagency coordinating committees (ICCs), functioning under the basic principle of national ownership and leadership, provide a platform for co-ordination and collaboration among stakeholders in decisions on long- and short-term plans. Until now, this function of ICCs has not been fully performed, and more inclusive participation may be warranted. Other government departments, such as the ministries for finance, education, labour, youth and sports, are key actors in implementing and financing immunization programmes. Other teams in ministries of health that are in charge of disease prevention, health system strengthening, and the health information system, need to be engaged, along with private health care providers.

While participation of all stakeholders is important, establishing a small manageable stakeholder working group (SWG) may be more effective in developing strategies and plans based on approved policies. Blocks of stakeholders, such as funding bodies, technical partners, non-governmental organizations, private providers, and civil society organizations can each nominate one or two representatives to take

part in the deliberations of the SWG, along with principals from the main government agencies. These representatives would then have the responsibility of interacting with their specific stakeholder blocks.

Political and technical responses cannot operate in isolation. Comprehensive and planned inclusion should be pursued through stakeholder dialogues, where political, technical, provider and community representatives come together individually or collectively to develop a shared understanding of issues, evidence and plans of action.⁴⁰ This dialogue requires considerable preparation, leadership and openness, and needs to be systematically documented and evaluated.

Policy considerations

1. Commitment at the highest level of government and by political and civil authorities to universal immunization is secured, publicly stated and maintained, through a national political forum.
2. All stakeholders (the government, non-governmental organizations, private, professional associations, civil society organizations (CSOs), faith-based organizations (FBOs), community leaders, consumers' representatives) are mobilized to participate in developing short- and long-term immunization plans, through ICCs and SWGs.
3. Close relationships are fostered with domestic and external funding bodies to ensure that funding flows are secured, and feedback on the use of funds is provided.
4. Private for-profit and not-for-profit providers are actively encouraged to participate in developing and implementing an immunization programme.
5. The contribution of local authorities (state, provincial) to foster community dialogue and stimulate demand for immunization and access to quality services is secured and supported through orientation and training, with different approaches adopted for rural and urban areas.



Principle 3: Value and benefits

Societal leaders and the general public at large understand the value and benefits of vaccines and vaccination for protecting individual and public health.

There are two inter-related aspects to determining the value and benefits of vaccines and vaccination. The first relates to reduction in morbidity and mortality resulting from vaccine-preventable diseases.⁴¹ The second aspect weighs the economic benefits to individuals and the society resulting from the prevention of specific diseases. These benefits include averted medical costs and reduced time spent by parents and health care workers caring for sick children and family members.⁴² At the regional level, it has been estimated that investments in immunization in Africa from 2011 to 2020 will yield a 16-fold return in averted illness costs.⁴³

A more thorough investigation of the impact of vaccination should, however, look not just at direct medical cost savings and averted illness, but also at the effects on cognitive development, educational attainment, labor productivity, income, savings, investment, and fertility.^{44,45} There are as yet no known specific assessments that have been made in African countries in this regard.⁴⁶ Each country, with the potential enlistment of its National immunization technical advisory group (NITAG), should decide on how to use available evidence to generate additional data in order to determine the value that vaccines and vaccination represent, especially in a way that non-health-sector stakeholders will understand.

From another perspective, public trust in vaccines can vary widely, and building trust depends on understanding perceptions about vaccines and vaccine risks, past experiences, religious or political convictions, and socioeconomic status.^{47,48} Measuring and monitoring trust levels and focusing on deliberate efforts to build trust in vaccines are important steps to reducing vaccine confidence gaps when they occur.⁴⁹ Engagement with and listening to public and community leaders and representatives are key actions to take, and are just as important as being transparent about decision making, and being honest and open about uncertainty and risks.

Improving and sustaining trust in vaccines and vaccination will need the committed involvement of opinion leaders in society such as government officials; parliamentarians and elected representatives; civil society, business and community leaders; sports champions and cultural leaders; journalists, social media and emerging super-users of mobile networks.⁵⁰ Each country should have a set of champions it can call upon to support immunization and enhance trust, and specific means of mobilizing them. The medical community also has an important role to play in placing value on immunization. Therefore, giving medical students as well as health workers in the field a quality education in disease prevention and vaccination needs to be stressed.⁵¹

Policy considerations

1. A value protocol is in place for (a) quantifying the incidence of vaccine-preventable diseases; (b) estimating their burden on and cost to the health system and households; and (c) quantifying the potential savings to be achieved with vaccination.
2. The capacity exists to collect and analyze the data required to populate the protocol for determining the value of vaccines and vaccination done by the NITAG.
3. On-going dialogue is taking place with civil society, community leaders and consumer representatives to fully understand their perception about the benefits and risks derived from vaccination.
4. Communication experts are on board to translate specific findings into readily understandable messages geared to specific audiences across the society, including parents, carers and other target populations benefitting from vaccination.
5. A roster of opinion leaders and immunization champions is in place and is continuously being updated; their involvement has been defined by specific terms of reference and a rolling action plan.
6. All communication channels are open and are being used to reach target populations with messaging; a feedback mechanism exists to gauge receptivity to messages.





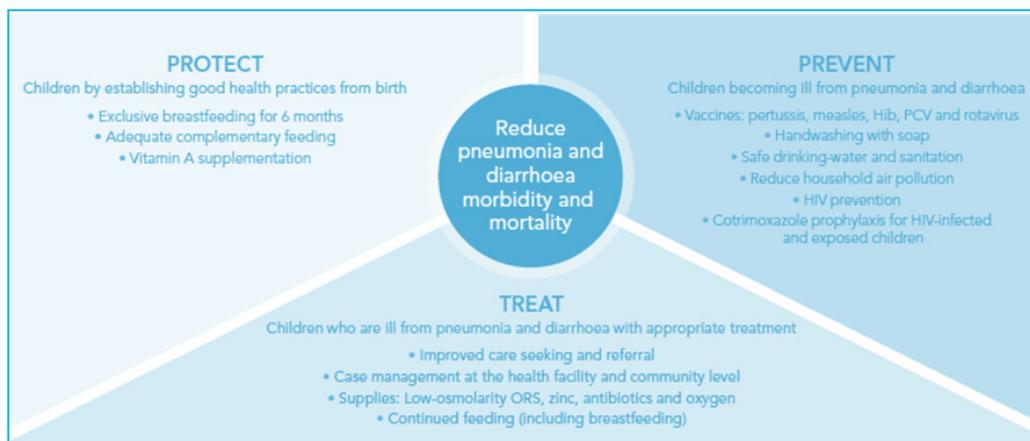
II. OPERATIONAL ENVIRONMENT

Principle 4: Integration

Integration of immunization services with additional health services achieves equitable access to quality immunization and related disease-control actions.

It is recognized that an approach to national health development that focuses on individual programmes in isolation is often counterproductive, and risks even greater fragmentation and competition than has been seen in the past.⁵² Integration is as much a change of mentality as it is a restructuring of specific operational processes.⁵³ A specific call from the WHO Regional Office for Africa has already been made for a change in approach from treating single diseases to promoting health, and investing in strong national health systems.⁵⁴ Aid and technical assistance have to be negotiated and accepted, consistent with government integration aims.⁵⁵

For pneumonia and diarrhoea, two of the major killers of young children in the Region, various integrated actions across sectors in protection, prevention and treatment are required, in a broader approach to disease control.⁵⁶



Immunization service delivery can continue to serve as a springboard for providing other priority health interventions that are largely preventive in nature. Vitamin A supplementation, de-worming, and the provision of long-lasting insecticidal nets are already features complementing vaccination. But due consideration should be given to delivery of a broader set of interventions around vaccination contacts, including during special events such as the Mother and Child Health Days, African Vaccination Week (AVW), etc.⁵⁷ Opportunities for integration need to differentiate between vaccination sessions in a health facility and those held during outreach activity.

A health system, like any other system, is a set of inter-connected parts that must function together to be effective, with changes in one area having repercussions elsewhere.⁵⁸



The following building blocks of the health system encompass the eight core components of routine immunization:⁵⁹

Health system building blocks	Core components of routine immunization
Leadership and governance	1. Governance, organization and management; 2. Policy, standards and guidelines;
Human resources	3. Human resources;
Medicines and technologies	4. Vaccine, cold chain and logistics management;
Financing	5. Sustainable and dedicated financing;
Information	6. Communication and community partnerships; 7. Data generation and use;
Service delivery	8. Service delivery.

For effective joint planning and implementation, the immunization programme should be familiar with the different parts that make up additional health services delivered with the immunization programme. The ability and capacity of health workers to effectively manage integration should be assessed and strengthened through training. In the same vein, the materials and supplies they need should be readily available. Scaling up education and training, and improving motivation beyond financial incentives for health workers, are actions that should be considered.⁶⁰

- Integration requires thoughtful and measured planning, but the potential impact of integration for families and communities can be significant.⁶¹ Micro-planning should be expanded to include all targeted vaccination and non-vaccination interventions.
- Challenges to integration, however, include logistical difficulties, time-intensive interventions ill-suited for immunization delivery, concern for harming existing services, inadequate overlap of target age groups, and reduced immunization performance.⁶²
- While integration may carry the risk of lowering immunization programme performance, at least in the initial stages, experience reveals gains from an operational perspective in planning and intersectoral coordination, training and supervision, community

participation, pooled funding, and monitoring.⁶³ Depending on resource availability, countries should consider prioritizing integration in communities with a higher disease burden.⁶⁴

Integrating vaccine supply chains with those for other health products provides opportunities for efficiency enhancement, with benefits from economies of scale and scope.⁶⁵ The integration of vertical funding has been seen to strengthen the whole health system.⁶⁶ Greater transparency in forward-looking resource commitments and the consolidation of external financing channels can facilitate the development of integrated approaches.⁶⁷

Integration should also consider the potential of private for-profit and private not-for-profit providers. A policy of engagement with the private for-profit subsector aimed at increasing provision of immunization services may be an effective strategy for increasing uptake.⁶⁸ Not-for-profit providers, principally NGOs, do play an important role in providing immunization services, although this is often not recognized at national level.⁶⁹ Contracting out services to private sector providers can be successful when there are well-defined and accepted programme goals, and where well-established contractual relationships exist, including in data sharing and systematic monitoring.



Policy considerations

1. Immunization is integrated into a broader disease-control and health promotion strategy, with joint planning, micro-planning, stakeholder coordination, training, supervision, and resources management.
2. Equity considerations prioritize integration in marginalized populations in rural and urban areas.
3. Additional selected health interventions are included in school vaccination sessions and in other vaccination locations reaching specific target populations.
4. An adequate quality workforce has been mobilized, trained and motivated to deliver vaccination, along with other selected health interventions, to target populations.
5. A consolidated supply-logistics system in the health sector is in place to ensure efficient procurement and distribution of goods; the system avoids duplication, controls costs, and ensures quality and accountability.
6. An integrated health management information system covers all disease-control interventions, including immunization, with specific indicators measured to assess performance.
7. Vertical funding streams are integrated into the health system and transparently managed.
8. Private for-profit and not-for-profit providers are fully engaged in the delivery of immunization services based on specific contractual relationships.

Principle 5: Leveraging

Leveraging of community strengths improves planning and implementation of immunization programmes, and the rapid response to outbreaks and humanitarian emergencies.

Ensuring demand for immunization is critical to achieving the goals that have been set for the immunization programme. Participation of service users in planning, governance and quality improvement processes can help to make health services and health professionals more responsive to the needs of their clients and the wider community.^{70,71,72} Seasonal migration patterns can be captured

through these dialogues, and adjustments made to plans so that higher demand is not met by low allocations, leading to vaccine stock-outs.⁷³

Women's groups, children and adolescents can be particularly effective in supporting the immunization programme. For adolescents especially, investments in their health and well-being pay a three-fold dividend of benefits now, into future adult life, and for the next generation of children.⁷⁴ The focus on user participation, including community involvement, should be locally driven and in sync with local characteristics, which may be different for rural and urban locations.⁷⁵

Tapping into the strengths of the community can use their organizational ability; but it can also mobilize their human and financial resources, consistent with the continent's push to mobilize African resources. Community health committees can coordinate and support different activities and provide leadership for the community, thereby facilitating broad community participation.⁷⁶ Similarly, community health workers can be instrumental in expanding immunization coverage, but their success is dependent upon regular and reliable support and supervision, adequate incentives, and the recognition that they are accountable to their communities.^{77,78}

Increased mobilization of national and local resources is important; it helps the gradual move away from high dependency on international aid which is becoming less reliable and uncertain over the longer term.^{79,80,81,82} For this reason, novel methods are needed not only to fill financing gaps but also to finance the increasing number of new vaccines to save lives in countries that are too poor to afford them.⁸³ This implies the need to look beyond the public and traditional aid sectors to sourcing funding in a broader community context.

Remittances to Africa from the diaspora in 2010 were estimated at over US\$ 50 billion; this is higher than all overseas development aid which stands at US\$ 43 billion.⁸⁴ There is increasing interest in leveraging these financial flows for development financing, including during

considerations leading up to the SDG framework.^{85,86} At the local level, hometown associations are one mechanism for receiving funds from the diaspora; indeed, the latter is a potential source of funding for the immunization programme.⁸⁷ There is also potential for significant increases in indigenous philanthropy, crowd funding and crowd investing, with the growing recognition that the concentration of wealth has increased inequality.^{88,89,90} At the same time, individual user financing and community health insurance schemes should be considered.^{91,92}

Policy considerations

1. Communities are organized and mobilized to support the immunization programme through women's and adolescent groups, community health committees, and community health workers;
2. Children and adolescents, as vaccine recipients and future parents, are being educated in school and other educational and out-of-school settings on the value and benefits of vaccines and vaccination;
3. Community-driven funding mechanisms are explored for their potential to support the immunization programme, including the diaspora, indigenous philanthropists, crowd funding bodies and investors, insurance schemes and individual payments;
4. A dedicated capacity is in place at national and local levels to leverage community strengths, in close coordination with civil society groups.



Principle 6: Innovation

Innovation, including the application of new technologies, enhances efficiency, effectiveness and the long-term sustainability of the immunization programme.

The internet and the mobile telephone have become key platforms for delivering health care, and are able to run a wide range of programmes and applications that are specific to health.⁹³ There has been a significant scale-up in the use of RapidSMS across Africa, which technology allows health workers to receive and share information using mobile phones. Health workers are thus capitalizing on the fact that Africa has become the fastest-growing mobile region, with nearly 500 million users. However, countries in the WHO African Region have been the least active in terms of adopting mobile health (mHealth) initiatives, which encompass the use of mobile phones, Personal digital assistants (PDAs), tablets, mobile applications and wireless medical devices.⁹⁴ Constraints include competing priorities, inadequate human and financial resources, poor connectivity, reluctance to use information and communication technologies in the health sector, and the absence of a conducive policy environment at the national level.^{95,96}

Although many countries are experimenting with mHealth, most efforts in this regard have been limited to a specific project or setting. Yet, the principal need in this area is to use mHealth to strengthen the health system in its entirety, including increased vaccination coverage. Efforts so far have focused on institutional record keeping, but it may be just as important to pay attention to records kept at home. This would imply having electronic records in the home either on a card with a magnetic strip or on a chip. Both media can easily be updated, and are always with the individual. This can be critical where there are movements of people, either voluntarily to urban areas or rapidly escaping humanitarian emergencies or natural disasters. The development of electronic personal health records (EPHR) in sub-Saharan Africa has been largely driven so far by HIV treatment

programmes.^{97,98} Collaboration between projects and departments is important for the development of electronic health records systems, and to avoid development in isolation.^{99,100}

Africa has pioneered the implementation of the first vaccine used in a controlled temperature chain (CTC), through meningitis A campaigns, using MenAfriVac™ produced by the Serum Institute of India.^{101,102,103} In a modeling exercise where MenAfriVac™ was kept at or near ambient temperatures for up to 4 days during a mass vaccination campaign in Chad, a 50% drop in the cost of the cold chain and associated logistics was estimated.¹⁰⁴ The main criteria put out by WHO for CTC apply only to vaccines used in campaigns and special strategy settings. Further, the vaccines must have been tested for safety and stability, licensed by the appropriate regulatory authority, pre-qualified by WHO, and must have a vaccine vial monitor (VVM) and a peak threshold temperature indicator (PTTI).¹⁰⁵ The GVAP has included a specific indicator for CTC: 'Number of vaccines that have either been re-licensed or licensed for use in a controlled temperature chain at temperatures above the 2°C–8°C range" (under Strategic Objective 6).¹⁰⁶

There are cost savings in, and logistical advantages to, using a vaccine in a CTC. WHO has recently issued a guideline for the stability evaluation of vaccines for use in a CTC. PCV13 has been pre-qualified by WHO for use in a CTC; it has, however, not yet been recommended for use by programmes, and several other vaccines are being considered for their potential compliance with CTC. Vaccine manufacturers, for their part, are cautious about performing additional tests or taking the regulatory actions required for labeling their vaccines as CTC-compliant, without a clear indication from countries about demand. It will be important for countries to become familiar with vaccine use in a CTC, to assess which vaccines they would prioritize, and to determine potential demand.¹⁰⁸ National regulatory authorities would also have to become fully familiar with CTC compliance requirements, and to have the capacity to evaluate and release CTC-compliant vaccines.



Logistics is another area where innovations can be considered. Globally, 78% of health facilities in low- and lower-middle-income countries are equipped with cold chain equipment that is either not functional or obsolete.¹⁰⁹ Developments in cold chain technology are being pursued, including the WHO pre-qualification of three new battery-free Solar-direct-drive (SDD) refrigerators.^{110,111} Details are also available at http://www.who.int/immunization/documents/general/WHO_IVB_17.01/en/. Some bottlenecks in the vaccine supply chain can be removed by increasing transport frequency or by eliminating one stage from the supply chain.^{112,113} Efficiencies can also be achieved through consolidated shipping of vaccines together with other health products, especially at the district level and below.

Cost, the wider economic effect, challenges of distribution, human capacity, and energy supply are all factors that determine whether a technology can be deployed in a resource-poor setting or not. Even where these conditions are met, the most promising technology can still struggle to gain acceptance due to the hesitation of people to use it.¹¹⁴ Countries will need to track innovation in vaccine delivery

technologies¹¹⁵ and cold chain equipment in order to estimate potential demand. It is this potential demand that manufacturers will analyze in order to further consolidate the way they produce and market such technologies. The Technical network for strengthening immunization services (Technet) can facilitate this tracking of innovation.¹¹⁶

Policy considerations

1. Information-sharing between health service providers and the public is greatly expanded using mobile technologies;
2. mHealth applications are analyzed and adopted as indicated, so that the health management information system can benefit from real-time data submission, analysis and feedback;
3. Electronic personal health records (EHRs) are assessed together with other health departments, and adopted for incorporation into the health management information system and for home retention;
4. Innovations in vaccine delivery technologies and cold chain equipment are tracked and potential country demand estimated for manufacturers to assess the market size, including demand for an increased number of heat-stable vaccines to be used in a CTC;
5. The capacity and ability of National Regulatory Authorities is enhanced to facilitate the rapid assessment and release of CTC-compliant vaccines and new vaccine delivery technologies;
6. Cost containment measures are introduced in logistics, forecasting, procurement and other areas that increase resource availability.

Principle 7: Evidence

Decision-making is based on evidence generated by up-to-date quality data.

Understanding the benefits of vaccines and vaccination; convincing stakeholders to actively participate in the immunization programme; setting up legal frameworks; integrating immunization into the broader health system; applying new technologies; conducting surveillance;

innovating: all this requires evidence based on up-to-date quality data. More importantly, quality data provide accuracy in the performance of the immunization programme. They also provide a firm basis for setting goals in short- and long-term plans, thus enabling the conduct of effective on-going assessments and periodic evaluations. Finally, quality data help trigger alerts to the existence of adverse events following immunization (AEFIs). Some of the latter may need investigation. It is critical for supervisors at each level of the health system to have ready access to performance data in order to identify gaps and challenges, but also to discuss and decide on remedial measures.

Evidence demonstrates that immunization information systems can create or support a number of effective actions aimed at both implementation of the immunization programme and accountability. Surveillance, for example, should be conducted for diseases and conditions considered to be of public health importance, this, based on the list of diseases and syndromes in the national health information system (HIS), and in line with International Health Regulations (IHR).^{118,119}

The introduction of new vaccines challenges decision makers due to uncertainties surrounding the benefits of immunization and return on investment. Because new vaccines typically cost more than traditional vaccines, economic evidence has acquired greater prominence among decision makers, who need to know which interventions represent 'value for money'.^{120,121} As vaccines increase in price, wastage is also a growing concern for many immunization programmes. It is, therefore, important to have updated information on which multi-dose vials of vaccines can be kept open for extended periods of time. This minimizes vaccine wastage and ensures vaccine safety.¹²²

Information on the burden of the disease to be prevented by a vaccine, on the prevailing treatment costs for patients with the disease, and on the efficacy of a vaccine, is critical for determining cost-effectiveness. When planning a new vaccine introduction, countries

should also consider the impact of the 'backlog cohort' of age-eligible children born before the introduction of the vaccine, especially in the first 3 months of introduction¹²⁵, but countries intending to conduct such activities would have to plan resources for those extra doses that are not funded by GAVI. .

A broad approach to social, behavioral, epidemiological, economic, and health system research is necessary to identify on-going barriers to implementation of the immunization programme, and how to overcome them.^{126,127,128} Barriers may include lack of knowledge, climate and location, socio-economic status, social norms, birth order, size of family, family mobility, social and political instability, health workforce attitudes, and financial and legal considerations.^{129,130} This underscores the importance of supporting research that is led by people embedded in the contexts in which results can be used. Health sector professionals should be involved in the design, conduct and interpretation of research.^{131,132,133}

The formation of independent national immunization technical advisory groups (NITAGs) has been advocated by WHO as a means of providing national authorities with information, and facilitating evidence-based decisions on policies and strategies relevant to the immunization programme. Challenges to the effective functioning of NITAGs, such as human resource constraints in the ministry of health preventing them from serving as the secretariat, political interference over evidence-based decision-making, and lack of financial support, do have to be overcome.¹³⁴ The WHO Regional Office for Africa has set up a Regional immunization technical advisory group (RITAG) to advise the Regional Director on overall regional policies and strategies, including measures needed to strengthen country NITAGs.¹³⁵

Policy considerations

1. The HIS ensures the availability of quality data for all aspects of the immunization programme, with dedicated human and financial resources;
2. New vaccine introduction is based on specific evidence related to burden of disease, vaccine effectiveness, affordability, programme cost-effectiveness, and assurance of sustained supplies;
3. Social, behavioral, epidemiological, economic and health system research significantly increases understanding of key barriers to universal immunization coverage, and how to remove them in order to determine the overall value of immunization;
4. Disease surveillance requires a legislative framework that takes account of International Health Regulations (IHR); this is key to determining needs for epidemic outbreak response, and for evaluating the impact of immunization;
5. Protocols are in place to rapidly identify and investigate AEFIs;
6. Performance measures are enhanced through quality data management on coverage, financial flows and gaps, and operational lessons learnt;
7. Partnerships with specific research institutions enhance the ability to carry out independent peer-reviewed research and evaluations relevant to the immunization programme;
8. Independent technical advisers are available in a NITAG to support evidence-based decision-making.

Principle 8: Oversight

Oversight ensures technical and scientific quality and financial accountability, and maintains continued public trust in the immunization programme.

Improving the efficient use of resources and strengthening accountability are central aims in the Transformation agenda of the Secretariat of the WHO African Region, as it plays its leadership role in health development in Africa.¹³⁶ In each country's immunization programme, primary responsibility lies with individuals, communities,

governments, and health professionals, as recipients and providers of immunization respectively. Other stakeholders are responsible for supporting the achievement of the goals of the immunization programme. Accountability is based on all stakeholders having agreed-upon, clearly-defined and coordinated responsibilities which they exercise through the transparent use of human and financial resources.

Transparency is a fundamental principle governing oversight and accountability, and involves disclosure of reliable and useful information, an observer's right to know, a duty to disclose, and a means of disclosure.¹³⁷ It helps to make the results of the immunization programme more visible, even as it spurs prevention of any notion of sub-standard implementation or corruption which can undermine support for the programme.¹³⁸ The GAVI policy on transparency and accountability¹³⁹ includes principles that can be adapted to each country's situation. Each country should determine what information to put in the public domain to best serve the immunization programme. Financial flows normally provide the best indicator of cost-effectiveness and absence of corruption. Procurement is also a



particular area where transparency is needed, especially with regard to the price of vaccines, given the rapidly increasing share of vaccine costs in the overall funding requirements of the immunization programme. Both UNICEF and WHO publish the price of vaccines on an on-going basis.^{140,141}

The introduction of new vaccines presents specific challenges with respect to transparency. Economic decision-making tools used to explore the potential impact of various interventions and policy options, need to be transparent in terms of model structure, parameter values, sources of data, and the validation process.¹⁴² This can help mitigate any biases due to external pressures from public or private sources to introduce new vaccines.

Supervision has to be a mainstay of oversight in all immunization programme activities. It should take place as frequently as needed, and its content should be well-defined. Appropriate incentives should be in place for this to occur. In this regard, supportive supervision, which can also include self-assessment, fosters a collaborative approach to strengthening health worker performance and immunization services.^{143,144} Supportive supervision has been shown to be an effective tool for improving performance, but allocating sufficient resources to making it successful requires careful consideration.

Supervision should be supplemented by peer assessments of health workers through periodic meetings. These enhance learning and performance when conducted around a set of common experiences. They also serve to give feed-back on supervision frequency and quality. Ultimately, the sessions achieve downward supervision at the same time as horizontal learning and upward assessment are taking place. And what results is a multi-source feedback opportunity, which is an effective means of measuring performance.¹⁴⁵

The involvement of NITAGs, ICCs, national AEFI expert committees and SWGs can all contribute to oversight of the immunization programme in their respective roles and responsibilities. Such involvement also ensures that the right tools for data collection have been used, and that appropriate methods of analysis have effectively been employed. At the same time, performance assessments should be used in national forums, stakeholder dialogues, and community health committee meetings not only to enhance trust in the implementation of the programme but also to secure stakeholder participation and support.

Another level of oversight relates to the conduct of regular audits that are carried out according to standing national procedures, and any additional requirements that have been agreed to with stakeholders individually or collectively. Further verification of performance can be achieved through surveys, including cluster sample surveys of coverage, plus specific surveys carried out to identify specific barriers and the means to overcome them. Periodic evaluations may enhance stakeholder confidence, but these must be weighed against the costs involved, which can often be high.





Policy considerations

1. Each stakeholder has a clear set of responsibilities to the immunization programme upon which its performance is assessed;
2. Transparency is achieved through disclosure of pertinent information based on the public's right to know, the duty of the public sector to disclose, and having the means of disclosure in place;
3. A supportive supervision system is in place for the whole immunization programme; it incorporates a multi-source feedback, and sufficient resources have been allocated for successful implementation;
4. The NITAG provides the Government with technical and scientific guidance and verification, proposes national norms and standards for immunization consistent with international best practice, and facilitates continued appropriateness of strategies on oversight;
5. The ICC and the SWG review the performance of the immunization programme, and provides recommendations for increased efficiency and impact in the use of technical, material and financial resources;
6. National forums provide avenues for feedback and dialogue to a broad number of stakeholders;
7. Audits are carried out according to national public services standards, and any additional requirements agreed to with the stakeholder(s);
8. Periodic surveys and evaluations give credence to the effectiveness and impact of the immunization programme.



III. LIFE-COURSE VACCINATION

Principle 9: Life-course vaccination

Vaccination targets all age groups and groups-at-risk in a life-course approach, within the limits of the resources available.

The Regional strategic plan for immunization 2014–2020 clearly recognizes that the scope of immunization has broadened to cover all age groups, from newborn to the elderly¹⁴⁶ highlighting the importance of boosters, for protection throughout life. This is a significant evolution and means that the health system has to know in detail the characteristics of each population group it covers, and who is reached from each health facility.^{147,148} Each population group should be analyzed by age to determine their vaccination needs^{149,150,151,152} as per the WHO immunization summary tables available at http://www.who.int/immunization/policy/immunization_tables/en/ and the opportuneness of providing them with additional health services. Different locations may become outreach vaccination points such as the home, community centres, schools, youth centres, workplaces, etc. Additional health services provided during a vaccination session will depend on the type of immunization strategy used.

For Africa, additional services can be provided at fixed centres, in outreach posts, by mobile outreach teams, during drives for periodic intensification of routine immunization (PIRI), during Immunization Plus Days (IPDs), and in the context of the Growth Monitoring Programme Plus (GMP+).¹⁵³ Packages of additional health services should be based on the continuum of care, with particular reference to family planning, safe abortion care, and maternal, newborn and child health.^{154,155}

Detailed micro-planning should cover all services being provided. There are opportunities, for example, to expand adolescent health interventions, but selected interventions should be simple and quick to deliver since health workers are likely to face significant logistic and time constraints during vaccination visits. Attention can be paid to

increasing the prevention of noncommunicable diseases (NCDs) in adults, given the alarming rise in chronic health conditions in Africa.¹⁵⁷ In the case of infants and children attending vaccination sessions with a parent or carer, the latter should also receive appropriate services related to their age group. Vaccination records need to be kept for the entire population.

Decisions about optimal vaccination schedules involve evidence on vaccines, disease epidemiology, and operational considerations; they also require regular updating. The process of reviewing the schedule should be based on the best context-specific data on disease, impact assessment, predictions of cost-effectiveness, opinions of local experts, and information on applicability to local health systems.¹⁵⁸

Each country should review current WHO guidelines and develop a life-course vaccination schedule. It should also determine the additional services that might be implemented, using the schema and the table in Annex 1 as a guide.

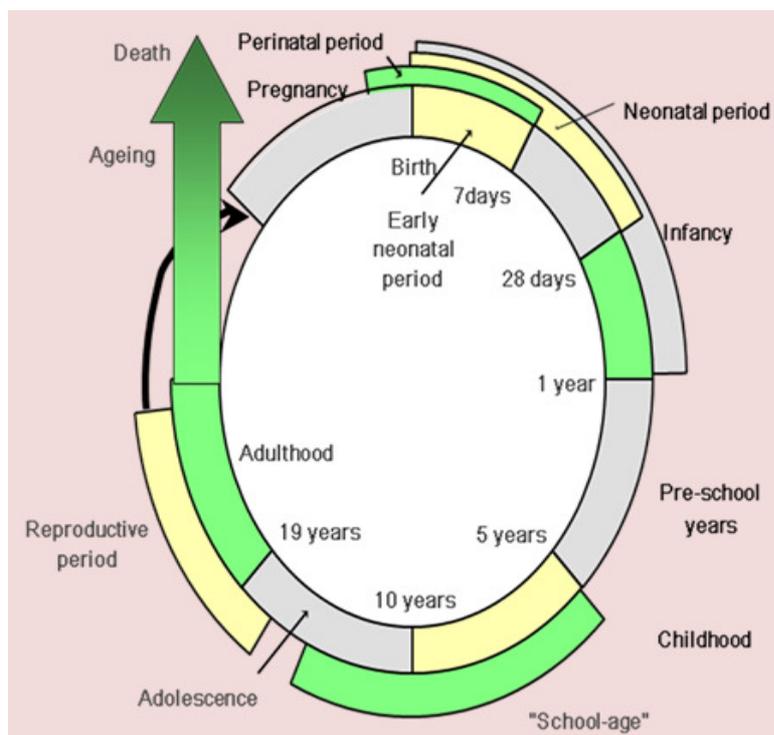
Currently, there is momentum towards adding to the immunization schedule of pregnant women vaccines that have been proven safe for them, in order to protect them and, at the same time, secure increased transmission of anti-bodies to their babies. Influenza is projected as the first possible such addition; it will protect pregnant women and their newborns in the absence of a licensed vaccine that can be administered in the first six months after birth.

Other target populations include those at risk of specific diseases, immune-compromised persons and health workers.¹⁵⁹ Health worker vaccination will depend on their immunization status and their level of exposure to infectious diseases. Antigens of concern for health workers are hepatitis B, polio, diphtheria, measles, rubella, meningitis, and influenza. Recommendation for vaccination for this group are available at http://www.who.int/immunization/policy/Immunization_routine_table4.pdf?ua=1. Programmes to ensure that health workers are vaccinated against these diseases should therefore

be put in place. It is recommended that proof of immunity be required for measles and rubella (if rubella has been introduced) prior to employment.

Specific attention should be paid to the situation of low-birth-weight infants, as these infants are specifically vulnerable to vaccine preventable diseases and evidence shows that health workers may incorrectly delay vaccination. Targeted education of caregivers and health workers emphasizing that low birth weight is not a contraindication to vaccination is warranted in this regard.¹⁶⁰

The country's vaccination schedule should be considered as dynamic. Therefore, it should be reviewed during preparation of the annual work plan, during preparation for the comprehensive multi-year plan every three to five years, and whenever a national EPI review is taking place.¹⁶¹ Adjustments can be made based on the evidence available.



Policy considerations

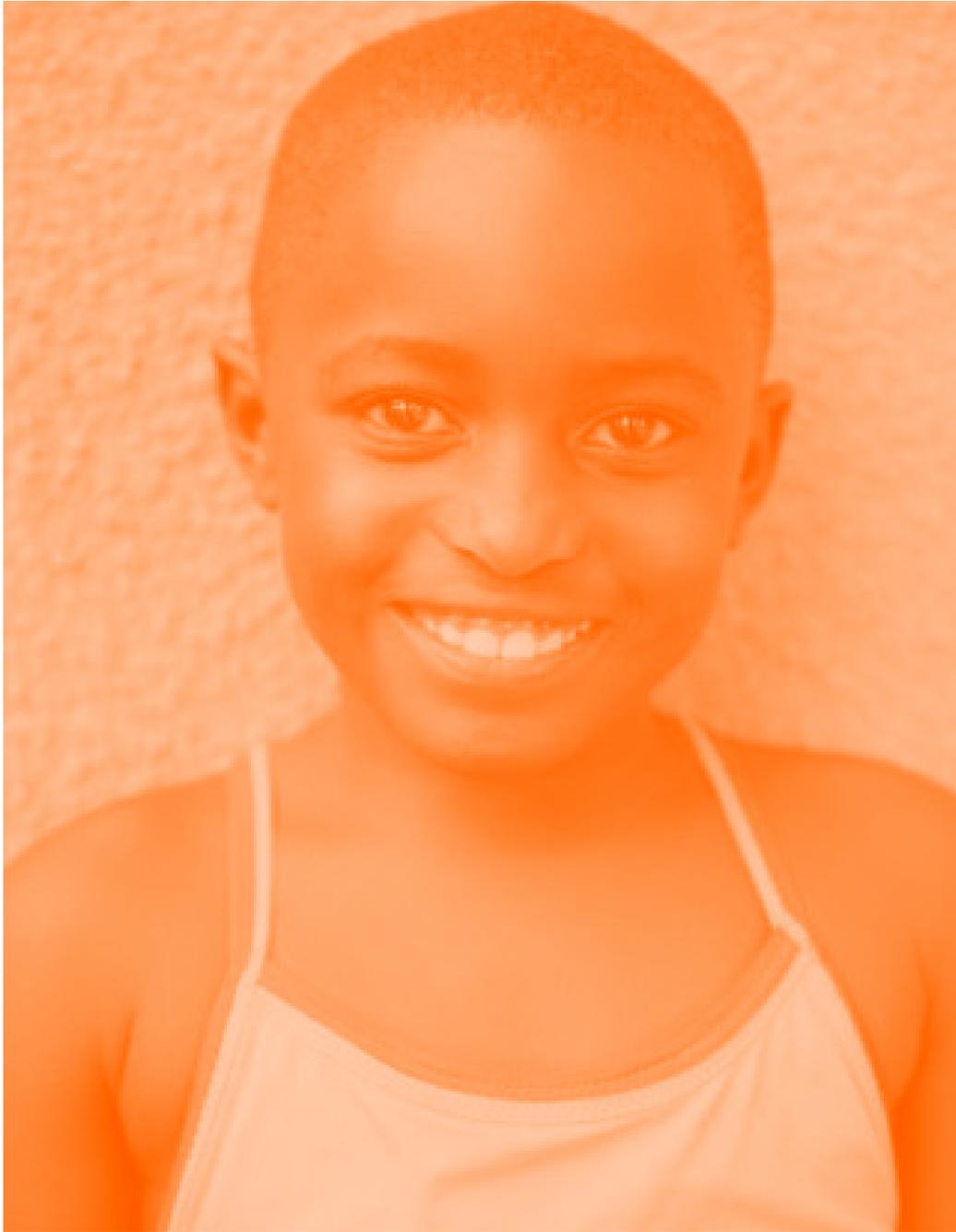
1. A life-course vaccination schedule is in place; it is regularly updated, as necessary, and widely disseminated to the public.
2. Additional health services at point of vaccination, based on a continuum of care, are identified, detailed and resourced, through agreements with responsible managers.
3. A listing of potential vaccination sites by locality, vaccine administration, and age group, are determined in coordination, as indicated, with the appropriate national and local authorities.
4. All individuals in target populations are identified by the health system, using a unique ID and a specific known location.
5. Micro-planning covers all age groups in the life-course vaccination schedule; it details outreach targets and frequency of contact, and includes the planning of additional health services at time of vaccination.
6. The elderly and individuals with compromised immune systems are known, informed of additional vaccinations recommended, and followed up to ensure that their vaccinations are complete.
7. A recommended schedule for pregnant women, with additional vaccines, is in place once global recommendations are made.
8. Low-birth-weight infants are specifically targeted to ensure that timely vaccination takes place.
9. Specific at-risk populations are identified and targeted for vaccination, as indicated in the schedule.
10. Health worker immunization status is known prior to employment, and indicated vaccination schedules (boosters and routine immunization) are set up for each health worker.

Monitoring policy implementation

The on-going relevance and applicability of policies for the national immunization programme need to be periodically evaluated and amended as necessary. This is the responsibility of the ministry of health. Evaluations are logically conducted prior to development of the comprehensive multi-year plan (cMYP). This allows the plan to



account for any policy changes or modifications enacted. The comprehensive review of the immunization programme, which informs the cMYP, will indicate the level of compliance with the policies in place, and the need to amend or add to existing policies. A specific protocol should be developed to evaluate policy implementation. The NITAG can play an important independent role both in developing a protocol and in evaluating policy implementation.



ANNEXES

ANNEX 1

Example of a Vaccination Schedule based on WHO recommendation for Routine immunization available at http://www.who.int/immunization/policy/Immunization_routine_table1.pdf?ua=1, accessed on 31 March 2017.

(wherein possible opportunities for additional health services are integrated)

AGE	VACCINES	ADDITIONAL SERVICES	VACCINATION LOCATION
BIRTH REGISTRATION – UNIQUE ID – (ELECTRONIC) PERSONAL HEALTH RECORD			
Birth	BCG(exception HIV) HepB	Birth weight; Screening for any neonatal complications; HIV screening; Promotion of exclusive breast-feeding with mother.	At health facility; Home visit if born at home (within first 30 days).
Birth–1 Year	Polio 3-4 doses (at least one dose of IPV with DTP) DTP: 3 doses PCV : 3 doses with DTP ROTA: Rotarix 2 doses, Rotateq 3 doses with DTP MCV 1 YF*one dose with MCV1 Meningitis* Dengue*	Infant check-up (4 contacts); IMCI; Vitamin A; De-worming; Malaria control (LLIN); Nutritional surveillance (exclusive breast feeding; MUAC); SAM identification (at time of MCV1); Supplementary feeding; Promotion of early stimulation.	At health facility; Planned community outreach.

ANNEX 1 CONTINUED

AGE	VACCINES	ADDITIONAL SERVICES	VACCINATION LOCATION
BIRTH REGISTRATION – UNIQUE ID – (ELECTRONIC) PERSONAL HEALTH RECORD			
1–5 Years (Pre-school)	MCV 2 DTP containing Booster on 2 nd year of life at 1-3 years Td booster at 4-7 years	IMCI; Vitamin A; De-worming; Malaria control (LLIN); Nutritional surveillance (MUAC); SAM identification (at time of MCV2); Supplementary feeding.	At health facility; Planned community outreach.
SCHOOL ENTRY – PROOF OF CHILDHOOD IMMUNIZATION COMPLETION			
Girls 9–15 Years (School age, adolescents)	HPV girls at 9-14 years Td at 9-15 years YF for travelers if not received in infancy	Check-up; De-worming; Health promotion – sexuality education, reproductive health, alcohol, tobacco, STD and HIV risks, avoidance of early and unwanted pregnancies, risks of unsafe abortions, early marriage, dental hygiene; healthy life-style; Nutrition education (including prevention of obesity).	At health facility; At school; Planned community outreach (out-of-school girls) , religious centres (out-of-school adolescents).
Pregnant women	TT containing vaccine (Td) Influenza	ANC; Nutrition education; Food supplementation; De-worming; Anti-malarial prophylaxis; HIV testing; ART (if HIV+).	At health facility; Planned community outreach.

ANNEX 1 CONTINUED

AGE	VACCINES	ADDITIONAL SERVICES	VACCINATION LOCATION
SCHOOL ENTRY – PROOF OF CHILDHOOD IMMUNIZATION COMPLETION			
Adults 18–65 Years	YF for travelers if not received in infancy	Screening for health or medical problems, including for noncommunicable diseases; Health promotion – family planning, safe abortion care, healthy life-styles; Nutrition education (including prevention of obesity); HIV testing; ART (if HIV+).	At work; At health facility; Planned community outreach.
Adults over 65 Years	PCV** Meningitis (where indicated) Influenza	Healthy ageing assessments; Screening for health or medical problems, including for chronic and multiple conditions; Health and nutrition promotion; Supplementary feeding; ART (if HIV+)	At home; At health facility; Planned community outreach.
* where indicated			
** PCV WHO position paper 2012: “Further data are needed from different epidemiological settings on the impact of large-scale PCV vaccination of individuals >50 years of age in order to establish the relative priority of immunization programmes in that age group.			
Many industrialized countries recommend polysaccharide (PPV23) to older age groups, but “in resource-limited settings where there are many competing health priorities, evidence does not support routine immunization of the elderly and high-risk populations with PCV23.”			

ANNEX 2

Global routine immunization strategies and practices (GRISP)¹⁶³

The purpose of GRISP is to reassert routine immunization as the foundation for sustained decreases

in morbidity and mortality from vaccine-preventable diseases throughout the life-course of all individuals.

Its objectives are:

- (a) to contribute to country efforts towards sustained routine immunization programmes;
- (b) to set global priorities the attainment of immunization for all persons targeted;
- (c) to ensure that the routine immunization activities and plans of partners and stakeholders at the global, regional and country levels are coordinated;
- (d) to ensure that new vaccine introduction, accelerated disease control and prevention, and programme monitoring activities are aligned, the joint goal being routine immunization programme support both in relation to coverage improvement and system strengthening efforts.

GRISP proposes nine transformative investments as a call to action for governments, donors and partners to transform national programmes and the work of global partners. The chart below indicates how the policy principles set out in this Guide provide a governing framework for the transformative investments, recognizing that more than one principle may be relevant to a particular investment.

Nine transformative investments for achieving better immunization outcomes	Policy principles governing transformative investments
 <p>NATIONAL TEAM</p> <p>1</p>	<p>Invest in a capable national team supplied with sufficient resources and given appropriate authority to expertly manage each country's national immunization programme;</p> <p>Societal leaders and the general public at large understand the value and benefits of vaccines and vaccination for protecting individual and public health;</p>
 <p>STRATEGIES TO REACH</p> <p>2</p>	<p>Invest in tailored strategies that identify under-vaccinated and unvaccinated persons and regularly provide them with the vaccines they need;</p> <p>Integration of immunization services with additional health services achieves equitable access to quality immunization and related disease-control actions;</p>
 <p>PLANNING CYCLE</p> <p>3</p>	<p>Invest in a coherent planning cycle, with strategic, comprehensive, multi-year and operational annual plans; these plans outline strategies and activities and indicate how they are coordinated and monitored quarterly;</p> <p>Broad participation by all local, national and international stakeholders is actively secured to reinforce national ownership and leadership;</p>
 <p>FUNDING FLOW</p> <p>4</p>	<p>Invest in ensuring that sufficient and adequately appropriated funds regularly reach the operational level of the programme;</p> <p>State obligations under the right to health and human rights conventions to which the State is party, and in which this right is enshrined, are fully exercised;</p>
 <p>VACCINATOR CAPACITY</p> <p>5</p>	<p>Invest in vaccinators and district managers by regularly and systematically building their capacity, strengthening their performance and providing supportive supervision;</p> <p>Oversight ensures technical and scientific quality and financial accountability, along with continued public trust in the immunization programme;</p>

Nine transformative investments for achieving better immunization outcomes	Policy principles governing transformative investments
 <p>6</p>	<p>Invest in modernizing vaccine supply chains and management to ensure that the correct amounts of the right potent vaccines are available at each vaccination session;</p> <p>Innovation, including the application of new technologies, enhances efficiency, effectiveness and the long-term sustainability of the immunization programme;</p>
 <p>7</p>	<p>Invest in an information system that identifies and tracks each person's vaccination status;</p> <p>Decision-making is based on evidence generated by up-to-date quality data;</p>
 <p>8</p>	<p>Invest in sustainably expanding routine vaccination schedules to cover every individual's life-course;</p> <p>Vaccination targets all age groups and at-risk-groups in a life-course approach, this, within the limits of the resources available;</p>
 <p>9</p>	<p>Invest in shared responsibility between communities and the immunization programme for delivery of immunization coverage at uniformly high levels, thanks to high demand and quality services.</p> <p>The leveraging of community strengths improves planning and implementation of the immunization programme and quickens response to disease outbreaks and humanitarian emergencies.</p>



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