



Global Vaccine Action Plan

Strategic Advisory Group of Experts on Immunization

Assessment Report 2013

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*For information on the Decade of Vaccines and the Global Vaccine Action Plan please visit
WHO webpage www.who.int/immunization/global_vaccine_action_plan/en/*

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List of abbreviations

CRS	Congenital Rubella Syndrome
CTC	Controlled-Temperature Chain
cVDPV2	Vaccine Derived Polio Virus 2
DoV	Decade of Vaccines
DTP vaccine	Diphtheria-Tetanus-Pertussis vaccine
GAPD	Integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea
GVAP	Global Vaccine Action Plan
IMB	Independent Monitoring Board
IPV	Inactivated Poliovirus Vaccine
JRF	Joint Reporting Form
MDG	Millennium Development Goal
MS	Member States
NITAG	National Immunization Technical Advisory Group
NT	Neonatal Tetanus
OPV	Oral Poliovirus Vaccine
SAGE	Strategic Advisory Group of Experts (SAGE) on Immunization
SHA	System of Health Accounts
UNICEF	United Nations Children's Fund
V3P	Vaccine Product, Price and Procurement Project
WHO	World Health Organization
WUENIC	WHO and UNICEF Estimates of National Immunization Coverage

Executive summary

Vaccines and immunization have created a healthier world. Progress is being made towards polio eradication, measles and neonatal tetanus deaths are on the decline and new vaccines are being introduced into the national programmes of low and middle-income countries with associated reductions in morbidity and mortality. Still, national governments, development partners and international agencies must invest more to meet the Decade of Vaccines' (DoV) goals of disease eradication or elimination and to reduce mortality and morbidity from vaccine preventable diseases.

Data quality improvement

Accurate immunization coverage and disease surveillance data are critical for making better programmatic decisions, meeting immunization targets and monitoring progress toward disease reduction. Hence, data quality improvement is selected as the theme for the 2013 Global Vaccine Action Plan (GVAP) progress report. In many countries, the quality of currently available data are inadequate to inform the proper management of the immunization programmes and often programme managers in these situations lack confidence in the available data for decision making. High quality data provide the cornerstone for accountability at all levels. National governments must take the responsibility to have the right data available at the right time and at the right places for the effective and efficient implementation of their national programmes by making greater investments for the improvement of data quality as well as enhance data transparency.

Improvement of data quality has to become the highest priority for all stakeholders. Priority should be placed on improving immunization coverage and vaccine-preventable disease surveillance data. Development partners and technical agencies must collaborate to establish a step-by-step, country-tailored approach to strengthen data quality at all administrative levels and provide guidance to countries on validating coverage and surveillance data. National Immunization Technical Advisory Groups (NITAGs) should play an important role to independently monitor progress and data quality at the national level. Regional Technical Advisory Groups should support and catalyze activities of the NITAGs.

The availability of new information and communications technologies provides an opportunity for improving the recording, reporting and analysis of immunization data at all administrative levels.

In order to improve data quality, the Strategic Advisory Group of Experts (SAGE) recommends that:

- *Countries should conduct regular, timely reviews of data, including data quality, at all administrative levels, including the districts level, to monitor programme performance.*
- *All countries should establish systems to monitor sub-national data (district level) and report sub-national coverage estimates to WHO by 2015.*
- *National programmes should develop plans to make use of new information and communication technologies to improve their immunization information systems and improve data quality on vaccine coverage and disease surveillance. Technical agencies should promote and provide guidance to countries for using these tools.*
- *Technical agencies should review, revise and standardize the methodology for collection and analysis of vaccine coverage survey data, including the use of sero-surveys.*

Improving immunization coverage

Currently, only 59 (30%) countries were assessed to be meeting the coverage target of at least 90% nationally and 80% in every district (or similar administrative level) with three doses of DTP-containing vaccines (DTP3) in children ≤ 12 months of age. Many countries—mainly in the African, Eastern Mediterranean and South-East Asia regions—will not meet routine immunizations coverage targets by 2015. Even more worrying is that immunization coverage has remained low, stagnant or even decreasing in several of these countries. These countries should urgently intensify efforts to improve programme performance, utilizing administrative and survey data to direct their corrective actions. Civil society needs to be meaningfully engaged in policy dialogues so that reasons for low coverage are better understood and interventions are tailored to address identified problems. Countries, agencies and all development partners must engage with the vaccine industry to closely monitor the global supply of vaccines and ensure sufficient supply into the future. They should anticipate and take timely actions to mitigate the risks of vaccine supply shortfalls that contribute to low coverage.

In order to improve immunization coverage, SAGE recommends that:

- *Countries falling short of reaching coverage targets should urgently identify barriers and bottlenecks and implement targeted approaches to increase and sustain coverage based on a systematic review of community and district levels data.*

- Countries with a DTP1-DTP3 dropout rate greater than 10% should review programme policies and performance and urgently implement measures to reduce dropout.
- All countries should establish or strengthen capacity for vaccine pharmacovigilance to detect and respond to adverse events to enhance confidence in immunization programmes.

Accelerating efforts to achieve disease eradication or elimination

As the world nears the final stages of the polio eradication effort, the challenges to achieve success have increased. It is imperative that all stakeholders now redouble their efforts to complete the job, as failure would represent a failure not only for the immunization community but for public health. Efforts toward meeting this goal should also strengthen immunization programmes and health systems, using the Polio Global Eradication Initiative assets and knowledge.

All countries are urged to establish national action plans to introduce at least one dose of inactivated polio vaccine by the end of 2015 and switch from the use of trivalent oral polio vaccine to bivalent oral polio vaccine once absence of all circulating Vaccine Derived Polio Virus 2 (cVDPV2) is confirmed globally for at least 6 months.

While the DoV 2012 milestone for NT elimination was met (10 additional countries eliminated NT by 2012, defined as less than one case per 1,000 live births in each district), the goal of NT elimination is one that has been long delayed. Since this is a relatively easy goal to achieve, it is critical that all future milestones are met and the verification of elimination in all remaining countries is achieved by 2015.

Measles and rubella/congenital rubella syndrome (CRS) elimination, while long accomplished in the region of the Americas, is a new challenge for other regions. Currently, in addition to the region of the Americas, only the Western Pacific Region is on track for reaching the regional measles elimination target; the African, Eastern Mediterranean and European regions are not on track and the South East Asian region has only just established an elimination goal and target year. Political commitment at all levels is needed to secure the investments required to achieve measles and rubella/CRS elimination.

Ninety-five per cent coverage with two doses of measles containing vaccines is required in all districts and nationally (through routine immunization and/or supplementary immunization activities) to achieve measles elimination. Furthermore, it is essential that measles and rubella surveillance is increased to meet verification standards, monitor progress and take timely action.

To accelerate progress towards achieving measles and rubella and CRS elimination, SAGE recommends that all countries should:

- Establish or update their national plans to accelerate measles and rubella/CRS elimination. These should include details for strengthening overall health and immunization systems in order to ensure that the 95% vaccination coverage targets nationally and in all districts are met.
- Strengthen case-based surveillance for measles and rubella and ensure timely and complete reporting and establish or strengthen surveillance for congenital rubella syndrome.

Enhancing country ownership of national immunization programmes

Optimal performance requires that countries take ownership of their national programmes, establish good governance and invest the required resources. This requires that countries have processes to track immunization expenditures, identify resource gaps and take measures to fill the gaps.

The GVAP calls upon countries to report their national immunization expenditures (on per person basis). However, the data quality on immunization expenditures are inadequate to draw conclusions about expenditure trends.

NITAGs provide a means for national governments and other stakeholders to receive unbiased, critical advice on policy recommendations and for monitoring the successes and failures of the programmes. Even though the number of NITAGs that meet the functionality criteria has increased significantly in recent years, it is noted that many countries are still lagging behind in the establishment of a NITAG, particularly in the African and West Pacific regions. NITAGs' capacities to use evidence-based approaches need to be further strengthened with the support of all technical agencies and development partners.

To improve country ownership, SAGE recommends that:

- Countries should improve processes to track and report immunization expenditures using the System of Health Accounts (SHA).¹
- Countries should establish and/or strengthen NITAGs and utilize them to advise on policy recommendations.

¹ The System of Health Accounts (SHA) is a framework developed through a collaboration between OECD, the European Union and the World Health Organization, for the systematic description of financial flows related to health care. The aim of SHA is to describe the health care system from an expenditure perspective both for international and national purposes (http://www.who.int/nha/sha_revision/en/)

Introduction

The DoV GVAP is unprecedented in scope and aim. The vision: a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases. The mission: by 2020 and beyond, ensure that all people receive the full benefits of immunization, regardless of where they are born, who they are, or where they live.

Endorsed by the 194 Member States (MS) at the World Health Assembly in 2012, the GVAP provides the roadmap to a future in which millions of lives are saved, worldwide productivity is boosted through reduction in morbidity and disability and access to existing vaccines for people in all communities is more equitable.

This ambitious goal has brought together the efforts of civil society, governments, donors, industry, philanthropy and academia. It has placed a strong emphasis on evidence-based, country-led prioritization and planning.

It is this emphasis on evidence that strongly informs the recommendations to national governments, international organizations and development partners. While immunizations have had a great effect on public health, much more work is required to meet the DoV' ambitious goals.

If the goals of the DoV are achieved, hundreds of millions of cases of vaccine preventable diseases and as many as 26 million deaths from these diseases will be averted. The mortality rate of children under the age of five will drop, life expectancy will increase and economies will gain billions of dollars of productivity. The prospect of a healthier, more prosperous future can be achieved—but MS, development partners, international agencies and other stakeholders must make the proper investments and remain focused to make these aspirations a reality.

In this report, SAGE presents a review of the progress with the implementation of the GVAP and makes recommendations for actions required to meet the goals and objectives of the plan. These observations and recommendations are based on reports provided by the DoV GVAP Secretariat (Bill & Melinda Gates Foundation, GAVI Alliance, United States National Institute of Allergy and Infectious Diseases, United Nations Children's Fund (UNICEF) and World Health Organization (WHO)) and some stakeholders.² The GVAP secretariat report used information provided by MS through the WHO and UNICEF Joint Reporting Form (JRF) and the surveillance reports as well as numerous other sources of information such as household surveys and other WHO databases.

Timely and high-quality data are essential for countries to be able to properly manage their immunization programmes. Without high-quality data, it is not possible to take timely action to improve programme performance, to prevent outbreaks of vaccine-preventable diseases or limit their spread.

The need for improved data quality is the most pressing issue that needs to be addressed at this time so that effective monitoring and evaluation of the DoV GVAP can be undertaken.

It is crucial that national governments, development partners and international organizations take urgent action, including with available innovative tools and technologies, to tackle this key issue.

1. Provide the cornerstone for accountability

High-quality data allow governments to ensure that their immunization programmes are efficient and reach their national targets. Without good data, there can be no accountability and immunization programmes will continue to perform poorly in many countries.

The SAGE noted that while all countries have national data sets, they are frequently of low-quality or out-of-date, thus undermining efforts to monitor programmes. Only good quality contemporary data can be used if progress towards national indicators is to be usefully monitored.

The SAGE noted with concern that the currently available data are of insufficient quality to reliably monitor progress. At the beginning of the decade, the improvement of data quality must be made a high priority by MS.

The responsibility of collecting and reporting quality data in a timely fashion falls to national governments.

It is not enough to simply collect statistics. National governments and other stakeholders should collect, monitor, analyse and use data to inform decision-making. The increasing availability of and access to

new information and communication technologies offer an opportunity to make data recording, reporting and analysis more accurate, timely and efficient. However, in many settings, a significant change in mind-set is needed in order to make use of the data that are available.

An essential component in increasing data quality is an improvement in recording and reporting data through administrative health information systems. Household surveys may also be used to validate administrative coverage data, provide supplemental data required to monitor programme performance and identify important determinants of un- or under-vaccination. However, surveys cannot be used to manage an immunization programme on a day-to-day basis. Innovative rapid assessment methods can help address specific issues instead of the more expensive and labour-intensive household surveys.

While the availability of high quality coverage data is key to proper management, it is also essential that countries invest in strengthening their surveillance systems to be able to document that the programme is having its desired impact in controlling the targeted diseases.

RECOMMENDATIONS :

For national programmes

- Make the improvement of data quality a high priority and increase investments in monitoring systems.
- Conduct annual reviews of data, including data quality, to monitor programme performance at all administrative levels. Actively engage NITAGs in this review process.
- Promote (and consider providing incentives for) reporting accurate immunization data from private service providers and professional organizations to make the data more complete and provide a clearer and broader picture of coverage levels.
- Use all available national and subnational household surveys to collect immunization data and validate administrative coverage data.
- Ensure there are designated, well-trained and supervised professionals for data management.

For DoV GVAP technical agencies

- Promote and provide guidance on new information and communication technologies to improve the recording and reporting of data.
- Review, revise and standardize the methodology for collection and analysis of survey data, including the use of serosurveys. The methods should provide explicit guidance on choice of sample size and the use of clinic records as a source of immunization data when immunization cards are not available.
- Channel immunization data reporting through only one institution, not both WHO and UNICEF; the national and regional offices of these agencies must take responsibility for assessing quality and completeness of country reports before they transmit the data to the global level.

2. Maintain focus on elimination and eradication targets

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The first major goal during the DoV is the interruption of wild poliovirus transmission, and the plan presents ambitious goals for the elimination or control of measles, neonatal tetanus, rubella and Congenital Rubella Syndrome (CRS). These goals are possible but requisite political and financial support is not guaranteed and regional progress has been uneven.

Polio eradication remains an urgent health priority and would represent a major milestone in public health. However, it is unlikely that the same levels of external funding that were raised for polio eradication will be available for the elimination or control of other diseases—so it is critical that countries invest adequate resources and use appropriate strategies to be able to tackle these other diseases.

Three WHO regions—Africa, Europe and the Eastern Mediterranean—are not on track to meet their regional measles elimination goals. Several countries in these regions are also at risk to miss the interim global targets for 2015 to increase coverage of routine immunization to greater than 90% at the national level and 80% in every district, reduce measles incidence to fewer than five cases per million and reduce measles mortality by 95% (compared to 2000). Efforts to control rubella and CRS are also not getting the required attention in many regions and countries.

While the DoV 2012 milestone for NT elimination was met (10 countries eliminated NT

by 2012, with elimination being defined as less than one case per 1,000 live births in each district and maintenance of elimination based on annual WHO and UNICEF district data spread sheet), the goal of NT elimination is one that has been long delayed. Since this is a relatively easy goal to achieve, it is critical that all future milestones are met and the verification of elimination in all remaining countries is achieved by 2015.

RECOMMENDATIONS FOR POLIO :

For national programmes

- Implement the recommendations of SAGE and the polio Independent Monitoring Board (IMB) to establish national action plans to introduce inactivated polio vaccine and switch from the use of tOPV to bOPV.

For DoV GVAP technical agencies, development partners

- Document and adopt best practices—including dashboard, accountability, micro planning, risk assessment and outbreak preparedness and response—to improve other elimination efforts and routine immunization.
- Support countries in their transition from tOPV to bOPV/IPV, including assistance in securing an adequate vaccine supply.

RECOMMENDATIONS FOR NT ELIMINATION :

For national programmes

- Establish targeted approaches to reach socially disadvantaged people. These approaches should include civil society as partners.
- For countries that have eliminated NT: Establish action plans to sustain elimination. These plans should include details on strengthening surveillance and reporting.

For DoV GVAP technical agencies, development partners

- Help countries improve surveillance as part of a comprehensive vaccine-preventable disease surveillance programme, including the development of guidelines to document the maintenance of elimination status.
- Encourage the introduction of appropriate technologies to help deliver vaccines, especially to marginalized and disadvantaged people.

RECOMMENDATIONS FOR MEASLES ELIMINATION

For national programmes

- Garner domestic political support to ensure adequate funding of measles elimination and surveillance programmes.
- Establish strategies and action plans that include details on strengthening overall health and immunization systems, identifying ways to reach disadvantaged populations, identifying and responding to outbreaks, improving case-based surveillance, encouraging the use of micro-planning and using supplementary immunization activities to help fill immunity gaps.
- Take proactive measures to address vaccine hesitancy.

For DoV GVAP technical agencies, development partners

- Promote measles elimination and increase its prominence in the global health agenda.
- Support country efforts with advocacy, outbreak investigation, outbreak response and response to vaccine hesitancy.
- Establish strategies for strengthening surveillance for measles that builds upon the acute flaccid paralysis surveillance platform.
- Promote the use of new technology and operational research in order to increase immunization coverage.

RECOMMENDATIONS FOR RUBELLA AND CRS ELIMINATION

For national programmes

- Raise and sustain political support to leverage measles elimination strategies to simultaneously control or eliminate rubella and CRS.
- Strengthen rubella surveillance by building on the polio and measles surveillance platform and establish a surveillance platform for CRS.
- For countries that have not yet introduced rubella vaccine: Develop action plans for introducing rubella-containing vaccine into routine immunizations, based on a review local epidemiology to determine the target age group and use of measles supplementary immunization activities to achieve timely control of rubella while minimizing the risk for paradoxical increase in CRS.

For DoV GVAP technical agencies, development partners

- Support modelling to estimate disease burden of CRS where surveillance is too weak to provide the required data.
- Secure sufficient supply of rubella-containing vaccine by clearly communicating demand forecasts to the vaccine industry (with sufficient advance notice) and working to overcome existing or future barriers to sufficient supply.

3. Revitalize efforts on 90/80

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By 2015, all countries should reach 90% national immunization coverage and 80% in every district (or equivalent administrative unit) with three doses of diphtheria-tetanus-pertussis-containing vaccine (DTP3). By the end of the decade, all countries should reach similar goals for all vaccines included in their national programmes.

In 2012, only 30% of countries met the target of at least 90% coverage nationally and 80% in every district (or equivalent administrative unit). In several countries, coverage is below 80% and has remained stagnant; in some regions, warfare, civil strife and large-scale migration have resulted in sudden drops in coverage.

The immunization coverage target will be difficult to monitor and evaluate because of poor data quality, especially at the district level. Uncertainty about the size of the target population, changes in geographic boundaries and in the number of districts will make data quality issues on district level coverage hard to resolve. While Expanded Programme on Immunization managers often have great insight into country coverage and are aware of hot spots of low coverage, this knowledge may not always be used when immunization strategies are planned.

Other issues that hinder progress toward this goal include poor stock management and inadequate supply of vaccines in some low-performing countries.

Monitoring coverage and interpreting trends in coverage with all vaccines in the national programme is likely to be a challenge since the vaccines and schedules used vary by country and many countries will be adding vaccines to their national programme during the decade.

RECOMMENDATIONS

For national programmes

- For countries falling short of coverage targets: Urgently identify barriers and implement targeted approaches to increase and sustain coverage, based on systematic review of local data. Prioritize the review of policies, logistics, vaccine supply, service delivery, mapping of under- and unvaccinated populations and community demand as part of efforts to scale up coverage.
- For countries meeting the national coverage goal but failing to reach district-level coverage: Identify the districts with low coverage and initiate targeted action to increase coverage. Because of increasing urbanization worldwide, issues of inequity and under-immunization in peri-urban areas remain a concern. Analyse this issue and propose strategies to address these issues.

For DoV GVAP technical agencies

- Increase support to countries with low or stagnant routine immunization coverage to help identify barriers, implement actions to increase coverage and report annually on the measures they have taken. Countries with DTP3 coverage level of less than 70% or with stagnant coverage between 70% and 80% should receive the highest priority.
- Improve coordination among departments working to strengthen health systems.
- Help secure sufficient supply of vaccines by clearly communicating demand forecasts to the vaccine industry (with sufficient advance notice) and work to overcome existing or future barriers to sufficient supply.

For DoV GVAP secretariat

- Establish an indicator for a “fully immunized infant” for Goal 3.2, including a process and timeline for collecting and reporting data.
- Establish a process to collect district-level coverage data for all vaccines, not just DTP-containing vaccines.

4. Guarantee equitable access to immunization to all people

In addition to monitoring geographic equity through coverage at district or similar administrative levels, the GVAP also aims to increase the proportion of MS with a difference of less than 20% in coverage between wealth quintiles to 60% by 2015 and 75% in 2020.

Monitoring progress on these two equity indicators will be extremely limited because of unavailability and poor quality of data. Data on district-level immunization coverage are often of poor quality, and few countries have survey data reflecting inequities by wealth quintile.

RECOMMENDATIONS

For national programmes

- Collect and report district-level coverage data annually. Use these data to inform decisions at the district level. Provide incentives for innovative actions to improve quality and use data at the district level.
- Leverage other existing national and subnational surveys to collect data on equity.

For DoV GVAP secretariat

- Provide guidance to countries on validating district-level coverage data, take measures to improve reporting on district-level coverage and explore other methods to measure geographic equity in coverage (such as rural-urban disparities).
- Develop tools to facilitate district-level data analysis to inform actions at the district level.

5. Create stronger health systems

The health systems surrounding vaccine delivery play an important role in the fight against disease as immunization is an integral part of a well-functioning health system. Hence, three indicators that offer a glimpse at the strength of a country's immunization system were examined.

The GVAP calls for a decreasing trend in the dropout rate between the first and third doses of DTP3 vaccines. Dropout rates are a useful indicator to measure service utilization and missed opportunities but data quality is again an issue. Year-to-year changes in reported dropout rates are usually small. Given the issues with data quality, a change in dropout rates of 5% or less should be interpreted with caution. It was noted that in 2012, 36 (19%) of MS had a dropout rate $\geq 10\%$.

The action plan calls for all MS to sustain a DTP3 coverage level of 90% for three years by 2020. The SAGE believes there is a need to review the value of separately tracking sustained coverage over three years if the report of progress against the immunization coverage goal presents trends for several preceding years.

The action plan also calls upon all MS to have high-quality immunization coverage data by 2020. Use of the WHO and UNICEF Estimates of National Immunization (WUENIC) Grade of Confidence as an indicator of data quality needs review, since it does not provide an indication of the quality of the national administrative coverage data. Current results are dismal:

90% of countries receive a low or medium assessment, and the measurement is qualitative and not based on empirical data.

RECOMMENDATIONS

For national programmes

- For countries with a DTP1-DTP3 dropout rate of more than 10%: Review programme policies and performance and urgently implement measures to reduce dropout. In particular, review policies that lead to missed opportunities and increased dropout rates, institute tracking mechanisms and strategies for catch-up immunization, consider incentives for immunization completion and create policies to capture all the children targeted.

For DoV GVAP secretariat

- Explore means for monitoring dropout rates annually especially for countries where WUENIC is derived from survey data.
- Drop indicator 4.2 (number of countries with DTP3 $\geq 90\%$ for three or more years) but report coverage time series as part of report on Goal 3.
- Develop and propose an alternate indicator to monitor immunization coverage data quality.

6. Develop and adopt new technologies

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The GVAP calls for investments in research to support the development of innovations that maximize the benefits of immunizations. Such innovations include the licensing or re-licensing of vaccines for use in a controlled-temperature chain (CTC) above the traditional range of 2-8°C and new vaccine delivery technologies.

While the progress on labeling vaccines for use in a controlled-temperature chain is encouraging, the SAGE believes that more effort is required to maximize the opportunities, while cautioning that efficacy and safety should not be compromised in this effort. It also believes the report on vaccine delivery technologies should include a narrative report that includes the extent of usage and impact of innovative products, as well as the availability of the new products.

RECOMMENDATIONS

For national programmes

- Strengthen regulatory capacity to inform local policies and use of products that may be stored and transported in a CTC.

For DoV GVAP technical agencies

- Consider the potential additional costs involved to get regulatory approval for products to be used in the controlled temperature chain and its impact on vaccine price.
- Consider further ways of incentivizing manufacturers to conduct the necessary studies to label their products for use in the CTC.
- Encourage and invest in the development of innovative cost-effective technologies to facilitate delivery of vaccines and increase immunization acceptance, as well as the utilization of these new technologies at country level.

7. Reach and exceed the MDG 4 target

Immunization has made a significant contribution to reducing child mortality, especially through the reduction in measles mortality. Immunization can make a further contribution through prevention of pneumonia and diarrhoea and by achieving high and equitable coverage with immunization.

The GVAP calls on countries to make optimal use of immunization to accelerate progress towards the achievement of the MDG 4 of a two-thirds reduction of childhood mortality compared to 1990 rates.

The SAGE believes that the contribution of immunization can be amplified by coordinating a scale up of complementary interventions (as recommended in the integrated Global Action Plan for Pneumonia and Diarrhoea (GAPPD)). While immunization itself might not play a large impact on neonatal mortality, provision of a birth dose of hepatitis B vaccine provides an excellent opportunity for delivering a package of interventions aimed at reducing neonatal mortality.

RECOMMENDATIONS

For national programmes

- Use the opportunity of immunization visits and the introduction of vaccines against pneumonia and diarrhoea to scale up the use of other proven cost-effective interventions to reduce child mortality.
- Use prenatal care appointments and postnatal care visits to promote knowledge and change attitudes about vaccination.

For DoV GVAP technical agencies

- Prioritize assistance to countries not meeting the MDG 4 target—especially the 75 Countdown countries—through global and regional programmes to increase coverage and reach the most vulnerable populations, including the promotion of the use of coordinated approaches and the scale up of complementary interventions, as outlined in the GAPPD.

8. Improve country ownership of immunization

RECOMMENDATIONS FOR IMMUNIZATION FINANCING

For national programmes

- Improve processes to track and report immunization expenditures.

For DoV GVAP secretariat

- Continue to report on immunization expenditures using data from the (JRF) because it allows countries the opportunity for self-analysis; however, work to improve the quality and completeness of reporting and highlight the limitations of the data in the narrative in future reports.
- Plan to progressively transition towards using the SHA to monitor immunization expenditures and strengthen country capacity to track their expenditures using this system.

RECOMMENDATIONS FOR NITAGS

For national programmes

- Establish and/or strengthen NITAGs and utilize them to advise on policy recommendations and to provide independent monitoring of progress with programme implementation and immunization data quality at the national level.

For DoV GVAP technical agencies and development partners

- For WHO and UNICEF regional offices, regional technical advisory groups and partners: Support countries in establishing and strengthening NITAGs. This is especially needed in the African and West Pacific Regions which are lagging behind other regions. Support includes advocacy, technical support and financial support.
- Promote a broader role for NITAGs beyond making recommendations for new vaccine introduction. This role includes participating in the process aiming at improving data quality.
- Sustain and further enhance the existing repository of information and tools (such as economic analysis models) to facilitate evidence-based decision making by the NITAGs.
- For the GAVI Alliance: ensure that the existence of a functional NITAG is included in future GAVI funds applications. GAVI should consider a requirement in applications for new and underused vaccines support to have a plan to establish NITAG.

For DoV GVAP secretariat

- Improve the data quality on the NITAG indicator with attention to missing or inconsistent data provided by MS through the JRF. This activity should be led by regional and country offices.



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The GVAP calls upon countries to adequately finance their national immunization programmes. However, the SAGE found that the data quality on immunization expenditures is too poor to draw conclusions about expenditure trends.

NITAGs provide an opportunity for national governments and other stakeholders to receive unbiased, critical advice on policy recommendations and for monitoring the successes and failures of the programmes. The GVAP calls upon countries to create and strengthen NITAGs as part of the efforts to strengthen national ownership of the programme. The SAGE acknowledges and appreciates that the number of NITAGs that meet the functionality criteria has increased significantly in recent years. It should be noted, however, that many countries are still lagging behind in the establishment of a NITAG mainly because of the insufficient provision of technical support from the technical partners particularly in the African and West Pacific Regions and the lack of political engagement from some national authorities. NITAGs' capacities to use evidence-based approaches should be strengthened with the support of all technical agencies and development partners. Their role in improving data quality is crucial.

9. Build grassroots support

Community support for immunization is crucial and indeed can be the deciding factor in the eradication of a disease. The indicator included in the GVAP aims to monitor the percentage of MS that have assessed the level of vaccine confidence at a subnational level, as well as the trends in the number of people who choose not to receive vaccines because of a lack of confidence.

The SAGE found that the current indicators and report do not provide enough information to assess progress. Moreover, the idea of vaccine hesitancy is highly contextual and vaccine specific, making it difficult to create indicators that can appropriately collect, assess and interpret data on a global level.

RECOMMENDATION

For DoV GVAP secretariat

- Explore alternative indicators and methods for collecting data on vaccine hesitancy. Methods could include the use of coverage data and timeliness of vaccines as indicators, case studies about countering anti-vaccine messaging, human intelligence (including programme managers' views), behavioural research and meta-analysis of district health system data.

10. Strengthen surveillance systems

High-quality surveillance is fundamental to assessing whether immunization is achieving its desired impact and for the verification of disease elimination and control goals. It is also essential to generate evidence to use in the decision to add vaccines to the national programme, optimize schedules and monitor the impact of vaccines.

These factors are also essential for the sustainability and optimal use of new and underutilized vaccines.

The GVAP has set a target that every MS should have measles and rubella surveillance in place by 2015.

The SAGE found the surveillance quality and timely data reporting are inadequate to meet the national programme needs or for monitoring global and regional progress with immunization. Greater investments and technical assistance are required to strengthen surveillance systems.

RECOMMENDATIONS FOR MEASLES/RUBELLA

For national programmes

- Establish case-based surveillance systems for measles and rubella to ensure timely and complete reporting. Existing polio surveillance will be useful platform to build this surveillance.
- Establish surveillance for CRS.

For DoV GVAP technical agencies and development partners

- Provide guidance and technical support to countries and share best practices.
- Develop guidelines for conducting surveillance for CRS and support countries in establishing surveillance.

For DoV GVAP Secretariat

- Identify the countries, classify the causes of low performance and inadequate reporting of vaccine-preventable diseases and propose corrective measures.

RECOMMENDATIONS FOR SENTINEL SITE SURVEILLANCE

For national programmes

- *For Low- and middle-income countries:* Invest resources to establish or strengthen case-based sentinel site surveillance systems, including laboratory confirmation of vaccine-preventable diseases.

For DoV GVAP technical agencies and development partners

- Provide financial and technical support to low- and middle-income countries to strengthen sentinel site surveillance.
- *For WHO:* Develop quality indicators and assist countries in monitoring surveillance quality.

11. Ensure access to vaccines of assured quality

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For effective population based protection against vaccine-preventable disease, it is essential to maintain adequate supplies of good quality vaccines. The GVAP has set a target that 100% of vaccine doses used globally are of assured quality by 2020. Currently, inadequate vaccine supplies in some countries are affecting vaccine coverage and contributing to delays with introduction of new and underutilized vaccines.

Supply shortages at the point of service delivery may have a role in low coverage (more than at the national

level). However, more data are needed to document this possibility. Closer monitoring of vaccine stocks may be required to understand the reasons for supply shortages and for corrective actions.

Ensuring vaccine safety is of paramount importance. Aside from the personal harm that unsafe vaccines can cause, misplaced anxiety about vaccine safety can lead to hesitancy or refusals. Strong vaccine pharmacovigilance systems should be put in place in all countries to ensure that vaccines remain safe and that the population's trust in immunization activities over the long term is sustained. National governments, development partners and international organizations should collaborate to provide technical and financial support to countries in establishing or strengthening vaccine pharmacovigilance systems.

The WHO pre-qualification system has contributed to increasing access to vaccines of assured quality but the WHO system is struggling to fund and respond to the increased demand for this service and this may threaten the progress achieved in the past few years. In the long term, countries need fully functional regulatory agencies to ensure sustained universal access to vaccines of assured quality.

The action plan also sets the goal of all low and middle-income countries having introduced at least one or more new or under-utilised vaccines by 2020 based on the analysis of their own needs. The SAGE makes no recommendations but notes the introduction of Hib, pneumococcal and rotavirus vaccines in low- and middle-income countries has been encouraging. However, delays with the introduction of these vaccines stemming from limited supply are concerning, especially since these vaccines could play an important role toward reaching MDG 4.

RECOMMENDATIONS

For national programmes

- Invest in strengthening the capacity of national regulatory authorities to ensure that all existing and future vaccines in a national programme are of assured quality.
- Establish or strengthen capacity for vaccine pharmacovigilance to detect and respond to adverse effects following immunization and to strengthen confidence in immunization.

For DoV GVAP technical agencies and development partners

- Continue supporting countries in strengthening regulatory capacity and vaccine pharmacovigilance.

For DoV GVAP secretariat

- Establish an indicator to monitor country capacity to conduct vaccine pharmacovigilance.
- Consider the possibility of a stock out indicator (even if stock out is more often linked to unavailability at the delivery point than on a national scale) including evaluating its usefulness for country reporting.

12. Immunization needs affordable vaccines

While the trend in the prices of vaccines procured through the United Nations agencies was positive, the SAGE found the objective for monitoring vaccine price trends were not clear enough. A well-defined objective will help to focus subsequent narrative reports on the most pertinent issues to vaccine pricing. The objective should be included in a narrative report to contextualize the data and to explain the dynamics of supply and demand as well as the determinants of the presented results.

The SAGE also believes the report was not comprehensive enough. Prices paid by self-procuring middle-income countries were not available; the relationship between price and volumes procured were not provided; the relationship between price, supply and the health of the markets was not fully addressed; there was no discussion about tier prices and pooled procurement; and there was no indication of private sector prices or prices paid by high-income countries.

RECOMMENDATIONS

For national programmes

- For self-procuring countries: Report public sector vaccine price information to DoV Secretariat agencies on an annual basis using the Vaccine Product, Price and Procurement (V3P) Project.

For DoV GVAP technical agencies

- Ensure enough resources are available to the secretariat to monitor this important objective; provide sustainable support to continue the V3P project activities and streamline and expand the project's activities within and outside WHO.
- Encourage broad stakeholder dialogue, including between buyers and sellers of vaccines, to achieve an optimum balance of supply security and value for money.
- For *WHO and UNICEF*: Request price information from countries through the JRF with the appropriate instructions and explanations and feedback to the countries.

For DoV GVAP secretariat

- Better define the objective for the indicator and report. Include more narrative to explore the relationship between vaccine prices, supply, demand, sources of funding and procurement volumes and mechanisms to better address the health of the vaccine market; make all possible attempts to secure information on prices in self-procuring middle-income countries, high-income countries and in the private market to get a full and comprehensive picture of the global vaccine market; and focus on processes and assess the impact of tiered pricing and pooled procurement mechanisms on vaccine prices. The report should also include case studies to highlight outliers and best practices to achieve optimal pricing.
- Focus subsequent narrative reports on key issues such as limited availability of relatively mature vaccines like measles-rubella and measles-mumps-rubella and determine how market conditions can help to improve security of supply; the link between IPV and the eradication of polio; vaccine price data and middle-income countries' access to quality and affordable vaccines; and priority vaccine of regional public health importance.

13. The next frontiers

Immunization continues to be one of the most essential public health interventions for all populations, and access to vaccines should be regarded as a human right. New vaccines and improved vaccine delivery technologies play a crucial role in fighting disease and saving lives.

The GVAP sets out an array of targets, including the licensure and launch of vaccines against major diseases that continue to kill millions of people in the developing world (such as HIV, tuberculosis and malaria). In addition, the on-going global impact of seasonal influenza and the threat of pandemic flu continue to drive the search for an influenza vaccine that provides broad protection against its various strains.

Since progress with immunization innovations is to be presented only every other year and no report was

made available in the 2013 secretariat report, the SAGE makes no recommendations on these indicators but notes the increasing importance of operational research to improve service delivery and increase community demand to achieve all immunization goals. The SAGE also notes the recent progress on a partially effective malaria vaccine and encourages continued research toward a more effective product.

It should also be noted that the sustained use of these vaccines after external support ends will be critical to realizing full benefits. Evidence and evaluation of the economic benefits of these vaccines should be considered, and fully functional NITAGs can play an important role in this process.

ANNEX: List of SAGE DoV GVAP Working Group Members

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 - GAVI Alliance
 - United States National Institute of Allergy and Infectious Diseases
 - United Nations Children's Fund
 - World Health Organization
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