EXECUTIVE SUMMARY

In 2016, some progress was made towards the goals set out in the Global Vaccine Action Plan. The year saw the fewest number of cases of wild poliovirus ever reported, and three more countries were certified as having achieved maternal and neonatal tetanus elimination. Nine additional countries have introduced new vaccines. Overall DTP3 vaccination coverage increased, but by only 1% to 86%. Progress therefore still remains too slow for most goals to be reached by the end of the Decade of Vaccines in 2020.

Furthermore, multiple global, regional and national issues threaten further progress, and have the potential to reverse hard-won gains. Economic uncertainty, conflicts and natural disasters, displacement and migration, and infectious disease outbreaks all pose major challenges to immunization programmes. At the same time, there are concerning signs of complacency and inadequate political commitment to immunization – as well as a global lack of appreciation of its power to achieve wider health and development objectives.

Additional risks include growing levels of vaccine hesitancy and the worrying rise in stockouts disrupting access to vaccines – related primarily to shortcomings in vaccine procurement and distribution but also to some extent to vaccine production. The continued marked underperformance of certain countries relative to others within their region – ‘outlier’ countries – remains of grave concern.

The potential impact of the phase-out of funding for polio eradication is also of concern. It is vital that the polio transition remains sufficiently flexible that it does not jeopardize ongoing outbreak control efforts or critical surveillance activities and post-eradication certification processes. Furthermore, there is a significant risk that wider surveillance activities and routine immunization programmes, and hence global health security, could be compromised during the polio transition. The potentially simultaneous phasing out of polio and Gavi funding and technical support is of further concern.

These risks threaten to slow the extension of vaccines to under-served populations and heighten global inequalities in vaccine access. As the Decade of Vaccines draws to a close, there is a need to intensify global efforts to promote immunization and to address the systemic weaknesses that are limiting equitable access to life-saving and life-changing vaccines, particularly in outlier countries and middle-income countries.

The recommendations made in the Strategic Advisory Group of Experts on Immunization (SAGE) 2016 Assessment Report informed the development of World Health Assembly Resolution WHA70.14, approved in May 2017, and remain a high priority. In light of the risks highlighted, SAGE also calls for a broadening of the dialogue, to align immunization with emerging global health and development agendas, including the sustainable development goals, global health security, universal health coverage and the battle against antimicrobial resistance. A concerted effort is also required to address outlier countries, through a multidimensional, system-wide approach, recognizing that complex issues require multifaceted solutions and that civil society organizations have important contributions to make.

Through these and other measures, progress can continue to be made towards GVAP goals and the ground laid to exploit the full potential of immunization post-2020.
RECOMMENDATIONS IN BRIEF

See page 27 for more detailed versions of these recommendations.

1. **Broadening the dialogue:** The immunization community should ensure that immunization is fully aligned and integrated with global health and development agendas, including global health security, universal health coverage and the battle against antimicrobial resistance.

2. **Funding transitions:** Until polio eradication is achieved, financial and technical support provided through the Global Polio Eradication Initiative, Gavi and WHO should be maintained in at least the 16 polio priority countries to ensure the success of eradication efforts and to mitigate the risks to infectious disease surveillance, routine immunization and global health security more generally.

3. **Polio and communicable disease surveillance:** Countries in all regions should ensure they maintain effective poliovirus surveillance capacities through the polio endgame and beyond, and build on the polio surveillance platform to strengthen surveillance for other communicable diseases, especially measles and rubella.

4. **Outlier countries:** WHO regional offices should work with countries experiencing the greatest difficulties in achieving GVAP goals to develop and implement multidimensional remediation plans, integrating existing national improvement plans.

5. **Maternal and neonatal tetanus:** The immunization community should make concerted efforts to achieve elimination by 2020, in particular by exploiting compact pre-filled auto-disable devices to extend the reach of immunization.

6. **Displaced and mobile populations:** WHO should synthesize existing knowledge on reaching displaced and mobile populations – including individuals escaping conflict zones or natural disasters, economic migrants, seasonal migrants, those moving to urban centres, and traditional nomadic communities – to identify good practice and gaps in knowledge.

7. **Hesitancy:** Each country should develop a vaccine hesitancy management strategy and crisis response plan.

8. **Civil Society Organizations:** Countries should broaden and deepen their engagement with CSOs to enhance the performance and reach of their national immunization programmes.

9. **Technical capacity-building:** WHO regional offices should work with regional and global partners to support national technical capacity-building, adopting a multidimensional approach and leveraging regional and national institutional capacities and expertise as well as global tools and resources.

10. **Vaccine access:** WHO regional offices and UNICEF should work with countries to identify and systematically address procurement and other programmatic issues affecting vaccine access.

11. **Vaccine supply:** UNICEF, WHO and global partners should continue and expand efforts to map current and anticipated vaccine supply and demand for routinely used vaccines, with a particular focus on vaccines most at risk of supply shortages.

12. **Middle-income countries:** WHO regional offices should support middle-income countries in their regions by leveraging all opportunities to promote the exchange of information, the sharing of lessons learned and peer-to-peer support.
PAHO deworming and vaccination campaign in Honduras
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1. INTRODUCTION

In 2016, SAGE published a mid-term review of the Global Vaccine Action Plan, which noted the slow speed of progress towards GVAP’s eradication, elimination, coverage and other goals. The mid-term review made a number of recommendations to accelerate progress (see Box). These recommendations informed the development of World Health Assembly Resolution WHA70.14, approved in May 2017, which made a series of recommendations to Member States and WHO in order to strengthen immunization and achieve the GVAP goals.

Among other recommendations, the WHA resolution urged Member States to:

• strengthen the governance and leadership of national immunization programmes
• improve monitoring and surveillance systems to ensure that policy and programmatic decisions are based on up-to-date data to optimize performance and impact
• expand immunization services beyond infancy
• mobilize domestic financing, and
• strengthen international cooperation to achieve the GVAP goals.

It also requested the WHO Secretariat to:

• continue supporting countries to achieve regional and global vaccination goals
• scale up advocacy efforts to improve understanding of the value of vaccines and urgency of meeting the GVAP goals

The recommendations made in the mid-term review and reinforced by the WHA resolution remain equally relevant this year. For 2016, SAGE has built on their foundation, providing a series of recommendations that set the agenda for the remaining years of the Decade of Vaccines and begin to anticipate a successor to GVAP for 2020 and beyond.

Since progress on research and development (R&D) goals is reviewed every two years and was covered in the mid-term review, this report does not include discussion of R&D objectives. Detailed information about progress against GVAP indicators can be found in the Global Vaccine Action Plan Secretariat Report 2017.
2. HIGHLIGHTS OF THE YEAR

Maternal and neonatal tetanus: Three additional countries and one province – Equatorial Guinea, Indonesia and Niger, and the Punjab province of Pakistan (home to more than 110 million people) – achieved maternal and neonatal tetanus elimination in 2016. Maternal and neonatal tetanus has now been eliminated throughout the South-East Asia region. With two additional countries (Haiti and Ethiopia) being certified in 2017, elimination has now also been achieved in the Region of the Americas, leaving just 16 countries and three regions still affected as of September 2017.

Hepatitis B control: Immunization programmes in the Western Pacific region have averted an estimated 7 million deaths and 37.6 million chronic hepatitis B cases among children born between 1990 and 2014. Before hepatitis B vaccine was introduced, hepatitis B transmission was hyperendemic throughout most of the region, with an estimated prevalence among 5-year-old children greater than 8%.

Measles elimination: The Region of the Americas was verified as having eliminated measles in 2016. In addition, seven additional countries were verified free of measles in 2016, bringing the total number of countries verified as having interrupted the transmission of measles to 24 in the European region, two in the South-East Asian region, and seven in the Western Pacific region.

Coverage in challenging contexts: Despite the challenging situation in Syria, 240,000 children received at least one immunization in 2016. In Yemen, coverage has been remarkably stable. Such achievements speak to the resilience and dedication of immunization staff on the ground, civil society organizations (CSOs) and the support mobilized by the international donor community. Nevertheless, it remains to be seen whether this performance can be maintained given the devastating impact of conflict on health service infrastructure.

Growing technical support: The number of national immunization technical advisory groups (NITAGs) has doubled since 2010. NITAGs and regional immunization technical advisory groups (RITAGs) provide an independent source of expert advice to countries and can play a pivotal role in the development of effective national immunization programmes.

Procurement and price transparency: Some 144 countries submitted vaccine price information to the Vaccine Product Price and procurement (V3P) initiative in 2017. Incorporating data provided by UNICEF and WHO, the V3P database now covers 84% of all WHO Member States and 95% of the world’s birth cohort. V3P is providing unprecedented levels of price transparency, which has facilitated negotiation and collaboration among countries in the European region, resulting in savings of up to 25% on vaccine procurement.

Humanitarian crisis situations: In 2016, a mechanism was established by WHO, Médecins Sans Frontières, UNICEF and Save the Children, in discussion with vaccine manufacturers, to accelerate access to affordable vaccines in humanitarian emergency situations. The Humanitarian Mechanism was launched in May 2017, and by September 2017 it had already been used five times to facilitate access to affordable vaccines in crisis situations.

Political commitment: In 2016, the Ministerial Conference on Immunization in Africa laid the groundwork for the landmark Addis Declaration on Immunization (ADI), including 10 commitments to achieve universal and equitable access to immunization in Africa. The ADI was endorsed by Heads of State from across Africa at the 28th African Union Summit in early 2017, signalling political support for immunization on the continent at the highest possible level.
3. KEY INDICATORS

Last year’s mid-term review of GVAP reported that most indicators were off-track, and that a significant change of pace would be required if 2020 targets were to be achieved. The data for 2016 show improvements in some areas but in general not sufficient to provide confidence that 2020 targets will be reached. The following graphics summarize the current status of key coverage and other indicators in 2016.

WILD POLIOVIRUS CASES CONTINUE TO FALL
Number of new cases of paralytic poliomyelitis due to wild poliovirus

- 2010: 359 cases in 9 countries
- 2015: 74 cases in 2 countries
- 2016: 37 cases in 3 countries

The number of cases of wild poliovirus fell in 2016, to the lowest level yet recorded. Wild poliovirus continued to circulate in an area spanning parts of Afghanistan and Pakistan, and in Nigeria. The countries concerned have launched aggressive outbreak control action plans to interrupt wild poliovirus transmission, backed up in Nigeria by a broader regional outbreak response coordinated with neighbouring countries.

MATERNAL AND NEONATAL TETANUS
ELIMINATION REMAINS OFF-TRACK
Number of priority countries verified for elimination

- 2010: 0 priority countries
- 2011: 0 priority countries
- 2012: 0 priority countries
- 2013: 0 priority countries
- 2014: 0 priority countries
- 2015: 0 priority countries
- 2016: 0 priority countries

The numbers of neonatal tetanus deaths fell by 96% between 1998 and 2015.
Three additional countries achieved maternal and neonatal tetanus elimination in 2016 – Equatorial Guinea, Indonesia and Niger. Elimination was also achieved in the Punjab, the most populous province of Pakistan. Following Indonesia’s achievement, the entire South-East Asia region has eliminated maternal and neonatal tetanus. Two additional countries – Haiti and Ethiopia – achieved maternal and neonatal tetanus elimination in 2017, leaving 16 countries yet to reach this target as of September 2017.

MEASLES AND RUBELLA ELIMINATION TARGETS HAVE NOT BEEN MET

The Region of the Americas is the only region to have achieved measles elimination. In addition, 24 countries in the European region, two in the South-East Asia region and seven in the Western Pacific region have been verified as having interrupted transmission of measles. However, between 2010 and 2016, global routine measles vaccine coverage stagnated at 85%. Globally, coverage with a second dose of measles-containing vaccine (MCV2) was 64%; just 26% of countries reached the MCV2 target of 95%. Some 41% achieved a similar MCV1 target, meaning that 20.8 million infants did not receive their first dose of measles-containing vaccine.

The establishment of Regional Verification Commissions and National Verification Committees for measles elimination has helped to refine understanding of the barriers to elimination and build stronger national commitment to elimination goals. Regional Verification Commissions have been established in the Region of the Americas and in the European, South-East Asian and Western Pacific regions; planning for the establishment of Regional Verification Commissions for the African and Eastern Mediterranean regions began in 2016.

The Region of the Americas is also the only region to have achieved rubella elimination. Two WHO regions still do not have rubella elimination or control targets. Some 152 countries have introduced rubella vaccines, with national coverage ranging from 42% to 99%.
Coverage of three doses of the diphtheria–tetanus–pertussis vaccine (DTP3) is used as a proxy indicator of the performance of national immunization programmes. Globally, coverage was almost unchanged at 86%, masking variation between regions and within countries, with some seeing an increase in coverage and others a decline (or no change, while not reaching the target coverage of 90%).

Because of their large populations, just six countries account for around half of the total number of unvaccinated children. While some countries – notably India, Ethiopia and the Democratic Republic of the Congo – have made significant gains in DTP3 coverage since 2010, in other countries the numbers of unvaccinated children have not fallen or have even increased.
The GVAP new vaccine introduction target (new vaccine introductions in 90 low- and middle-income countries) was met in 2015. The number of such countries that have introduced new vaccines has continued to rise, reaching 108 in 2016; 78% of such countries have now introduced at least one new vaccine since 2010 and sustained use for at least a year.

A total of 65 countries introduced more than one vaccine, with the largest number of introductions occurring in the African region. The most commonly introduced new vaccine has been pneumococcal conjugate vaccine, followed by rotavirus vaccine.
4. CONCERNS

This year’s indicator data confirm the trend observed in previous years and suggest that many of the GVAP goals will not be attained by 2020. Despite some progress, coverage levels are in general not increasing as rapidly as might have been hoped. It is disappointing that maternal and neonatal tetanus has yet to be eliminated and measles outbreaks continue to occur in several regions because of inadequate vaccine coverage. These are diseases that can, and should, be prevented.

Civil unrest has undoubtedly had an impact on coverage in a number of countries. However, signs of slippage in coverage over time in some previously well-performing countries, potentially hinting at dwindling political commitment to immunization, are a cause for concern, as are more rapid declines in countries facing acute health challenges, suggestive of a lack of resilience in immunization programmes. Although the investment made by national governments in immunization has been steadily increasing, a decline in the European region is worrying.

**Polio endgame:** The phasing out of funding to countries from the Global Polio Eradication Initiative has potential implications for both polio eradication and routine immunization, as well as global health security more generally. With poliovirus still circulating, albeit in only a few countries, polio is rightly still considered a Public Health Emergency of International Concern. It is essential that concerted efforts continue in affected and surrounding areas to interrupt transmission and achieve eradication, that these activities are adequately funded, and that the polio transition is sufficiently flexible to adapt to the changing situation in and around affected areas.

However, with polio eradication yet to be achieved, there is a risk of a mismatch in the timing of polio eradication and the polio programme transition. In some countries in regions where polio has been eliminated, surveillance is slipping; yet, in a globally connected world, poliovirus reintroduction remains a very real risk. Furthermore, in some countries polio eradication resourcing is being phased out before polio transition plans have been finalized, raising concerns about the long-term capacity for acute flaccid paralysis and poliovirus surveillance and the ability of countries to undertake the activities required for post-eradication certification.

Outbreaks of circulating vaccine-derived poliovirus (cVDPV) are a further reminder of the need to maintain a strong focus on polio control. In 2016, three countries were affected by cVDPV, and additional cVDPV cases were reported from two further countries in 2017. Maintaining effective surveillance and high vaccine coverage levels remain essential for preventing cVDPV outbreaks.
In some countries, resourcing and infrastructure for polio eradication have also been used to support other important surveillance activities and routine immunization programmes. As a result, where countries are unable to address the funding gap themselves, there is a significant risk that a phasing out of polio funding will undermine countries’ infectious disease surveillance capacity and compromise national immunization programmes. As well as potentially affecting key GVAP indicators such as measles vaccine coverage, this could also have significant implications for disease control and global health security more generally. It is essential that polio transition plans identify mechanisms to maintain the support for essential activities and resources required both to ensure a polio-free world and to safeguard surveillance and routine immunization activities integral to the protection of communities and control of other infectious diseases.

A further point of concern is the possible simultaneous phasing out of support in countries affected by both the polio funding transition and a transition out of Gavi support. It is vital that these two processes are undertaken in a coordinated manner to minimize the potential impact of loss of resources and technical support on routine immunization programmes and associated functions such as surveillance.

**Outlier countries:** Globally, coverage in certain Member States is markedly below that achieved by other countries within the same region, and often has been for extended periods. In some cases, factors such as civil strife, natural disasters or acute economic disruption can be considered mitigating factors, but in other cases the causes of low coverage levels are less clear. Whatever the causes, low coverage levels leave large numbers of citizens at risk of preventable infectious disease, while also posing a challenge to regional and global health security.

Outlier countries show persistently low national DTP coverage levels

In 2016, eight countries had DTP3 coverage of less than 50%

Change in DTP coverage between 2010 and 2016 in countries with coverage below 60% in 2016.
Since the reasons for low coverage levels are likely to vary from country to country, there is a need to adopt a tailored approach and to assess systematically the local factors that are affecting the performance of these immunization programmes. Recognizing that complex situations are not amenable to ‘quick fixes’, it will be important to undertake a thorough multidimensional, system-wide diagnostic assessment of the current situation within such countries (see Box).

This diagnostic assessment can be used to develop comprehensive system-wide remediation plans that outline the steps required to establish a high-performing and sustainable national immunization programme able to reach currently underserved populations within countries. These plans should integrate existing improvement plans and have a strong focus on the development of monitoring and evaluation frameworks to support effective implementation.

Given their understanding of local situations and context, this process should be led by WHO regional offices working in close collaboration with each country to develop culturally and context-specific plans, drawing on regional experience of effective approaches and good practice. CSOs may also have important insights to offer. Global partners should commit to supporting the implementation of national remediation plans.

**CORE ASPECTS OF A MULTIDIMENSIONAL FRAMEWORK FOR IMMUNIZATION SYSTEM ASSESSMENT**

- Political commitment
- Domestic funding
- Monitoring and evaluation
- Roles and responsibilities (national and devolved)
- Accountability (national and devolved)
- Planning/microplanning
- Human capacity within immunization programme
- Education, training and supervision
- Vaccine management and supply chain infrastructure

- NITAGs and independent technical advice
- Other national technical assets
- Regional collaboration/RITAG engagement
- Surveillance
- Safety monitoring
- CSO engagement in immunization programme
- Social engagement
- Hesitancy assessment and planning
5. EQUITY

A fundamental principle of GVAP is that all people should benefit from immunization, irrespective of where they are born, who they are, or where they live. This year’s data continue to show that the benefits of immunization are shared unevenly, both between and within countries. Promoting more equitable access to immunization must remain a core ambition globally and nationally.

It is encouraging that new vaccine introduction targets are being met, but it is clear that the speed of introduction varies markedly across the world. While Gavi funding has clearly had a major impact on new vaccine introductions in many low- and middle-income countries, some Gavi-eligible countries have not taken advantage of this opportunity, and introductions in Gavi-ineligible middle-income countries has lagged significantly.

Within countries, socioeconomic status remains a significant factor affecting access to immunization, and equity gaps appear to be closing only slowly. With equity such a fundamental principle, it is essential that countries gather district-level and sociodemographic data that enable equity gaps to be assessed and addressed.

The largest equity gaps are typically seen in countries with low levels of vaccine coverage. General strengthening of national immunization programmes would therefore be likely to reduce equity gaps. Even so, achieving true equity is likely to require specific approaches to target populations that are hard to reach, for geographic or sociocultural reasons. There is a need to build the evidence base on how such hard-to-reach populations can be accessed effectively, ensuring that lessons learned are captured and shared, and good practice established and implemented.
Many countries show high levels of inequality in DTP3 coverage between richest and poorest populations.

Wealth quintile differential in percentage points

Latest available survey data (2008-2015)

Progress towards equality in coverage is difficult to judge due to the limited numbers of countries reporting DTP3 coverage by wealth quintile, although this increased from 64 to 84 Member States (43%) between 2015 and 2016. For those countries providing data, 59 (70%) met the target of a 20% or smaller difference in coverage between the wealthiest and poorest population quintiles; 25 had a quintile differential greater than 20%. Those with the greatest differences in coverage generally had relatively low national DTP3 coverage rates.

In 15 out of 28 countries with data for more than one year, the equity gap decreased, but in eight countries it increased and in five it was unchanged. Hence there is little evidence of significant progress in the closing of equity gaps.

Maternal and neonatal tetanus: Maternal and neonatal tetanus differentially affects the poorest, most neglected and underserved populations, making the disease an important indicator of health inequality. Indeed, achieving and maintaining maternal and neonatal tetanus elimination could be adopted as a key indicator of universal health coverage, given its strong association with social disadvantage.

Maternal and neonatal tetanus elimination also offers an important opportunity to address health service integration. Maternal immunization could be readily envisaged as a component of the WHO comprehensive programme of antenatal care.

Great progress has been made towards the elimination of maternal and neonatal tetanus, with the number of associated deaths falling from more than 780,000 in 1988 to 34,000 in 2015 and the number of countries affected dropping to just 16 by September 2017. In 2000, 18% of children born were at risk of neonatal tetanus (their mothers were not immunized against tetanus); this figure fell to 10% in 2010 and 5% in 2016. Nevertheless, the remaining cases were all preventable, and the ultimate target must be zero.

Maternal and neonatal tetanus elimination is a key GVAP goal, and one that is within reach. As the Decade of Vaccines draws to a close, SAGE again urges countries to re-energize their drive towards maternal and neonatal tetanus elimination by 2020. Although several countries are on track to achieve the milestones set out by SAGE in 2016 for elimination by 2020, Papua New Guinea and Sudan are falling behind.
Regional collaboration and the access to technical expertise and experience offered by RITAGs have a potentially critical role to play in identifying and overcoming implementation barriers. An investment case for maternal and neonatal tetanus elimination is currently being developed in collaboration with UNICEF, WHO and UNFPA.

Achieving the goal of elimination would be greatly facilitated by access to compact pre-filled auto-disable devices, which would expand the range of health workers able to contribute to maternal tetanus immunization programmes and enhance access to the most hard-to-reach populations. The funding case for deployment of such devices should be developed and assessed as rapidly as possible and, once the technology is available, countries should identify how best to exploit its potential at a local level to achieve the elimination goal.

**Mobile populations:** Among the groups least likely to benefit from immunization services are displaced people and other mobile populations. This grouping covers a wide range of situations, including individuals escaping conflict zones or natural disasters, economic migrants, seasonal migrants, those moving to urban centres, and traditional nomadic communities.

In 2015, an estimated 244 million people, or 3.3% of the world’s population, lived outside their country of origin. Given current geopolitical realities, these numbers are unlikely to fall. The global immunization community will therefore need to consider the long-term implications of these trends for national immunization programmes facing considerable additional demands and the presence of vulnerable populations at risk of infectious disease outbreaks.

An important step forward has been the development by the WHO, UNICEF, Médecins Sans Frontières, and Save the Children of the Humanitarian Mechanism, launched in 2017. This mechanism has been designed to enable CSOs, governments and UN agencies to quickly procure affordable vaccine supplies on behalf of populations facing humanitarian emergencies and lacking access. By September 2017, the mechanism had been used five times, but so far only to provide access to pneumococcal conjugate vaccine.

Nevertheless, not all displaced and mobile populations are associated with humanitarian crises or are covered by the emergency humanitarian mechanism, and additional long-term solutions are required. Such vulnerable populations raise a number of challenges, including a potential lack of country ‘ownership’ of non-nationals, movement of migrants across multiple countries, the need to build trust with vulnerable communities, and the possibility that migrants become geographically disbursed and hard to track.

Maintaining immunization despite migration within countries or across borders, either voluntary or forced, will be a major future challenge for the global immunization community, but a vital step in the journey towards equitable access to immunization services. As a first step, there is a need to collate existing knowledge on best practices for reaching different categories of mobile populations, to identify knowledge gaps and provide a basis for the development of strategies to address the immunization needs of such vulnerable populations.
6. CONTEXT

While many core principles and key aspects of an immunization programme are shared, implementation and the success of national programmes are heavily dependent on local political, economic, geographic, demographic, social, environmental and other factors. Efforts to improve coverage and the performance of national immunization programmes will need to acknowledge and take account of these local contextual and cultural influences.

Country-level analyses clearly indicate how such wider contextual factors can affect national immunization programmes. Falling oil and commodity prices have had a major impact on many countries’ economies, in some cases leading to cuts in health service and immunization programme budgets. Conflict inevitably has an impact on health service infrastructure, while major disease outbreaks may lead to the shifting of resources or lessening of attention on routine immunization. Vaccine hesitancy can rapidly undermine coverage of specific vaccines, often in highly localized settings.

Conversely, local political commitment can help to maintain and improve coverage levels, even under difficult circumstances. This emphasizes the crucial point, made in last year’s recommendations and reiterated in the 2017 WHA Resolution, that countries must assume strong ownership of their immunization programmes, and take responsibility for developing their programmes to reach currently underserved populations.

Hesitancy: Vaccine hesitancy is a prime example of a local context-specific factor that can have a dramatic impact on coverage. Vaccine hesitancy is of growing concern, and one that increasingly affects countries across the full range of income strata. Effects can be highly localized: certain high-income European countries have experienced significant hesitancy episodes related to specific vaccines yet, interestingly, there has been little evidence of a ripple effect, with concerns largely not spreading across country borders.

Globally, data on vaccine hesitancy have been collected only since 2014, but country response rates have already surpassed 80% (although survey data are available in only 33% of countries). A large majority of countries are reporting issues with hesitancy, but the nature of these issues varies by region and country income level. One risk is that immunization concerns are co-opted to serve political purposes.
Countries vary greatly in their preparedness for hesitancy ‘outbreaks’ or declining coverage, with middle-income countries in particular typically lacking the capacity to manage hesitancy challenges.

Given the potential for hesitancy to have a major impact on coverage, it is important that all countries take steps to understand both the extent and nature of hesitancy at a local level, on a continuing basis. There are a range of tools by which this can be achieved, including population surveys, media and social media monitoring, and through community dialogue. Allied to this work is the need to develop strategies for building and maintaining trust with communities – an area where health workers and CSOs can play valuable roles. The final key aspect is a plan for responding effectively to major hesitancy ‘outbreaks’.

With only a minority of countries not reporting any experience of vaccine hesitancy, it is important that all countries develop comprehensive national hesitancy management strategies, encompassing regular assessment of local hesitancy, trust building, and emergency response planning. With the evidence base growing on how hesitancy can be forestalled and mitigated, there is also a need to extend efforts to capture lessons learned and share best practice.

**Civil society organizations**: CSOs can play a key role in advancing immunization, across a range of domains. It is important that countries consider both the range of CSOs with which they engage, and the breadth of activities to which CSOs might contribute.

CSOs have well-established roles in community mobilization and in helping immunization programmes access particular hard-to-reach populations. But they can also contribute directly to immunization services, play roles in education and dissemination of knowledge, and be an important source of technical expertise. On the national stage, CSOs can play a critical role in advocacy and in holding governments to account. They also have the potential to make significant contributions to national hesitancy management strategies.

Countries need to consider extending the range of organizations involved in immunization programme development, planning and operations. Bodies such as professional societies, academic institutions, religious and political organizations, philanthropic bodies, patient support groups, and community organizations may all have valuable contributions to make. In effect, countries should consider how they can best make the local environment ‘CSO-friendly’ for involvement in immunization programmes.

In addition, there is a need to understand better the contributions made by CSOs, to capture important lessons learned and to share best practice. It can be difficult to assess rigorously the impact of CSOs on immunization at the national level. The CSO Reporting Framework, developed for Gavi-supported countries, is an important step in this direction, and this new tool should be widely adopted, ideally also beyond Gavi-supported countries.

The advocacy function of CSOs can be aided by legislation laying down citizens’ rights to immunization services, which provides a critical tool enabling CSOs to hold politicians to account. Indeed, at a national level, immunization can be strongly advanced through effective partnerships between the executive, the legislative system and civil society. More generally, there is a need to understand the variety of ways in which legislation and regulation have been used to advance the cause of immunization (including its use to address hesitancy), the impact of such measures, and the contextual factors that have influenced their effectiveness. A synthesis of the evidence on the use of legislative and regulatory instruments could guide national efforts to advance the immunization agenda.
Effective, robust and sustainable immunization programmes are fundamental to achieving the GVAP goals. Increasing coverage is becoming an ever-greater challenge, as more hard-to-reach populations need to be accessed, the number of vaccines to be delivered rises, and the ages of vaccine recipients becomes more diverse. By establishing robust programmatic infrastructures, countries have a platform on which to expand their reach, extend their scope, and promote integration with other health, welfare and development services.

Adopting a multidimensional approach (see above) is an important step in assessing programme functions and identifying ways in which they can be strengthened. Evidence of its effectiveness comes from India, which has achieved impressive gains in coverage following a comprehensive national overhaul of its immunization programme, driven directly from the Prime Minister’s office. This political commitment has been matched by increased investment in immunization services, a strong emphasis on technical capacity-building, detailed monitoring and evaluation with clear lines of accountability at national, state and district levels, and extensive community mobilization.

NITAGs, RITAGs and the Global NITAG Network all have potentially important roles to play in the strengthening of national immunization programmes, with NITAGs being specifically referenced in the 2017 World Health Assembly resolution. The number of countries with NITAGs complying with six basic process indicators has grown significantly since 2010, reaching 83 (42% of countries) in 2016. Recent progress has been particularly marked in the African and Western Pacific regions.

However, there remains a need to ensure that NITAGs function effectively. In particular, to perform their roles as independent advisory bodies, NITAGs need to maintain high levels of transparency and of disclosure and management of relevant interests. Some countries may also require innovative solutions for NITAG development, such as small island nations with small populations (but which collectively account for large numbers of people).

Regional collaboration will be important for increasing the numbers of NITAGs and strengthening their contributions to national immunization programmes. Specifically, RITAGs have the potential to support the establishment and development of NITAGs, particularly by enhancing their capacity for evidence-based review. The Global NITAG Network, which held its formal inaugural meeting in 2017, provides additional opportunities for boosting the role of NITAGs and for sharing good practice, particularly through the NITAG Resource Centre.
Technical capacity-building: Many of the issues facing immunization programmes worldwide reflect shortfalls in technical capacity rather than just economic constraints. There is an ongoing need to enhance capacity, typically in situations where few additional resources can be mobilized.

It is therefore increasingly important to identify ways to make the best possible use of existing resources, leveraging local, regional and global opportunities to enhance technical capacity. The WHO, for example, has developed a range of resources and e-learning tools, and has established key norms and standards. There may also be opportunities to draw on technical expertise within local academic and training institutes (an approach adopted in India). Local CSOs, including the private immunization sector, may also represent a source of expertise or, with appropriate training, could be integrated into national programmes to expand capacity.

Given the likely importance of local and contextual issues, assessments of technical capacity-building needs should be carried out at a regional level. This would also provide opportunities for peer-to-peer learning. RITAGs could also make a major contribution to such assessments and to subsequent capacity-strengthening initiatives. A multidimensional approach should be adopted for the assessment of needs and in the development of capacity-building plans, to ensure a comprehensive system-wide analysis is carried out.

The number of stockouts continues to rise
Number of countries reporting a national vaccine stockout

The number of countries reporting a national stockout rose again in 2016, continuing a recent trend of increasing disruptions in vaccine supply. Some 73 countries reported 131 national-level stockout events for at least one vaccine for an average duration of 51 days in 2016. These 73 countries account for 38% of WHO Member States and represent 34% of the world’s birth cohort. The vaccine supplies most commonly affected were of DTP-containing vaccines and poliovirus vaccines.
Countries of all income levels were affected by stockouts, although the causes tended to vary. Stockouts in high-income countries were generally caused by vaccine shortages but in other countries were often linked to factors such as inaccurate forecasting and delays in procurement.

**Vaccine access: Programme expertise:** The increasing incidence of stockouts and disrupted access to vaccines is of growing concern. The majority of these stockouts, especially outside high-income countries, are a result of internal (in-country) issues rather than vaccine production, such as inaccurate forecasts, stock management issues and procurement delays.

Ensuring reliable access to vaccines should be a core function of national immunization programmes. Well-established procedures exist to guide demand assessment and forecasting, procurement, and distribution, and principles of good practice outlined to ensure continuity of supply (for example, not relying on single manufacturers). The alarming rise in stockouts suggests there is a need to develop the capacity of programmes in effective procurement and stock management, again by adopting a multidimensional framework. Given the likely influence of local contextual issues, assessments of capacity development needs should be led at a regional level, enabling countries to share lessons learned and best practice and to provide peer-to-peer support.

One tool that could support such efforts is the Vaccine Product Price and Procurement (V3P) database. A total of 144 countries submitted 2016 vaccine price information to V3P, three times as many as in the preceding year. Just four years since its launch, V3P has therefore created high levels of price transparency covering 84% of all WHO Member States and 95% of the world’s birth cohort.

V3P data confirm that pooled procurement mechanisms, such as those managed by PAHO and UNICEF, do manage to secure lower vaccine prices. This does not simply result from bulk purchasing but reflects the importance of other factors that can affect pricing (such as long-term commitments and payment guarantees). For self-procuring countries, V3P can also be used as a tool to support collaborative purchasing. In the European region, health authorities in three Baltic nations – Latvia, Estonia and Lithuania – have collaborated on procurement of three vaccines, and use of V3P enabled the countries to secure significant savings on vaccine costs.

**Vaccine access: Production issues:** Supply-side factors and vaccine manufacturing capacity are also limiting access to vaccines used in routine immunization programmes, including inactivated polio vaccine.
Hence there is a need to assess whether global vaccine manufacturing capacity is sufficient to meet current and anticipated demand for the different vaccines and combination vaccines used in routine immunization programmes. A thorough assessment needs to be undertaken of current and projected manufacturing capacity, integrating and expanding relevant ongoing work such as the WHO’s Vaccine Shortage Project and the Healthy Markets initiative jointly developed by Gavi, UNICEF, and the Bill and Melinda Gates Foundation.

**Middle-income countries:** Middle-income countries collectively account for a large proportion of the world’s population, including 73% of the world’s poorest people. Many are facing significant challenges in sustaining and developing their national immunization programmes. The economic development of many such countries has not progressed as anticipated, and those ineligible for Gavi funding have limited alternative sources of financial support for their immunization programmes. Furthermore, the number of countries in this situation will rise as countries transition out of Gavi support.

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**INTRODUCTION OF PNEUMOCOCCAL CONJUGATE VACCINE HAS BEEN SLOWER IN GAVI-INELIGIBLE MIDDLE-INCOME COUNTRIES**

There are concerning signs in some regions of declining coverage within middle-income countries, highlighting the risk that hard-won gains can be easily lost in the absence of continued commitment to immunization programmes. There is also some evidence that ‘shocks’ to national health systems – such as major disease outbreaks – can affect coverage, hinting at underlying fragility in immunization programmes.

Purchase of vaccines represents the biggest single contributor to the costs of immunization programmes in middle-income countries. Gavi-ineligible middle-income countries do not have access to the preferential pricing associated with Gavi support. Important efforts are being made to limit price increases for countries transitioning from Gavi support. Potentially, middle-income countries could seek to manage procurement costs through greater use of pooled procurement mechanisms (UNICEF, PAHO Revolving Fund) or collaborative procurement, facilitated by the V3P price transparency database.

On the other hand, progress in many middle-income countries is also being held back by a lack of technical capacity. At a regional level, the sharing of good practice and exchange of technical knowledge and experience should
be improved to enhance national technical capacities, including procurement capabilities. Global collaborations and technical resources could also be leveraged to support technical capacity-building.

As well as these important short-term measures, after the Decade of Vaccines concludes in 2020, it will be important to reassess the situation of middle-income countries and how they can best be supported to achieve immunization goals.
8. CONCLUSIONS

Despite the enormous value of immunization to humankind, significant numbers of infants, children and adults still do not have access to immunization services and do not reap the benefits that many take for granted.

Ensuring that all people gain access to immunization, regardless of who they are and where they live, remains a fundamental global challenge. Looking forward, this challenge will need to be met in a changing world, characterized by large-scale conflict and civil strife, global warming and natural disasters, economic uncertainty, growing vaccine hesitancy, and multiple displaced and mobile populations.

One way in which the global immunization community can respond to these challenges, and spread further the benefits of immunization, is to recognize and reinforce the alignment between immunization and emerging global health and development agendas. The Sustainable Development Goals represent a holistic framework to health, wellbeing and development towards which immunization has much to offer. Global health security, universal health coverage and combating antimicrobial resistance are all global agendas to which immunization can and should be contributing.

A key principle to communicate will be common interests and the mutual benefits of closer alignment. Immunization platforms provide a way to reach a significant proportion of national populations, which could be leveraged to enhance other aspects of health, welfare and development. Immunization can help to combat global health threats such as antimicrobial resistance and infectious disease outbreaks. There are also key shared interests in areas such as surveillance, laboratory capacity-building and technical skills development.

A further important aspect of this shift in emphasis will be the growing application of immunization beyond childhood. A broader life-course perspective on immunization further emphasizes the importance of considering immunization within the context of integrated health delivery across the entire life course and health systems strengthening.

Opportunities also exist to strengthen the dialogue with other sectors, including business, economic and financial sectors, as well as with the diverse CSO sector. Again, such dialogue could stress mutual benefits – the health and economic benefits that immunization delivers and how the worlds of business and finance could support immunization financially or through technological or other innovations. Broadening the dialogue could help to re-energize immunization, addressing the risk not just of stalled progress but actual regression.

ACHIEVING TARGETS

Achieving elimination and control targets – and sustaining them into the future – will require an ongoing and unwavering commitment to immunization. There are no short cuts or quick fixes. Progress will depend on maintaining a commitment to immunization and quest for constant improvement at global, regional and national levels. Extending coverage will not be easy, and building more effective immunization programmes will necessarily depend on systematic and multidimensional analyses of current situations and future needs, recognizing the importance of local realities and contexts. While there is undoubtedly a place for global support and resources, there are powerful arguments for regional responses tailored to local contexts and cultures.

There are growing opportunities for countries at a regional level, or at a similar stage of economic development, to collaborate and learn from one another, enabling them to make best use of inevitably limited resources. In addition, the international donor community has a vital role to play in providing the technical and financial support necessary to catalyse lasting change.
A further key theme is the **importance of research and the generation of evidence to support the most effective use of resources**. There is an increasing need to capture and share lessons learned, and to explore the impact of innovative new approaches. New technologies – from digital tools to drones – may provide novel ways to achieve step changes in coverage and close equity gaps.

As the Decade of Vaccines draws to a close, the global immunization community can reflect on the millions of lives that have been saved because more people have gained access to vaccines. Post-2020, **the challenge will be to ensure that these gains are protected and further extended** – to ensure more vaccines reach more people more rapidly.
9. RECOMMENDATIONS

GENERAL

1. Broadening the dialogue: The entire immunization community should ensure that immunization is fully aligned and integrated with global health and development agendas, including global health security, universal health coverage and the battle against antimicrobial resistance, and that dialogue is strengthened with additional constituencies such as the business and financial sectors

Main responsibility: Immunization community; other key stakeholders: countries

Subsidiary recommendation:

1b. Joint External Evaluations: An assessment should be made of immunization-related inputs into national Joint External Evaluations for Global Health Security, the immunization community’s contribution to the development of national evaluation reports, and the reference made to immunization in these reports

Main responsibility: WHO regional offices, countries

CONCERNS

2. Funding transitions: Until polio eradication is achieved, financial and technical support provided through the Global Polio Eradication Initiative, Gavi and WHO should be maintained in at least the 16 polio priority countries to ensure the success of eradication efforts and to mitigate the risks to infectious disease surveillance, routine immunization and global health security more generally

Main responsibility: Gavi, Global Polio Eradication Initiative; other key stakeholders: countries

3. Polio and communicable disease surveillance: Poliomyelitis laboratory and epidemiological surveillance capacities should be maintained in countries across all regions throughout and beyond the polio endgame and certification process, and built upon to strengthen surveillance for other communicable diseases, especially measles and rubella

Main responsibility: Countries; other key stakeholders: partners, immunization community

4. Outlier countries: Comprehensive multidimensional assessments should be undertaken in countries experiencing the greatest difficulties in achieving GVAP goals and used to develop bespoke and costed remediation plans addressing systemic weaknesses, integrating existing improvement plans and including a strong focus on monitoring and evaluation frameworks to support effective implementation

Main responsibility: WHO regional offices, countries; other key stakeholders: partners

EQUITY

5. Maternal and neonatal tetanus: Concerted efforts should be made to achieve global elimination by 2020 and sustain thereafter, particularly by exploiting the opportunity to expand coverage to underserved populations through use of compact pre-filled auto-disable devices

Main responsibility: Immunization community, Gavi (pre-filled devices); other key stakeholders: countries, CSDs

6. Displaced and mobile populations: Existing knowledge on reaching displaced and mobile populations – including individuals escaping conflict zones or natural disasters, economic migrants, seasonal migrants, those moving to urban centres, and traditional nomadic communities – should be synthesized to identify good practice, innovative new approaches and gaps in knowledge

Main responsibility: WHO Secretariat, UNICEF Secretariat; other key stakeholders: WHO regional offices, national partners, academic community, CSDs
CONTEXT

7. **Hesitancy:** Each country should develop a vaccine hesitancy management strategy, to include ongoing national assessment of vaccine concerns, trust-building and active hesitancy prevention, and crisis response plans
   
   Main responsibility: Countries; other key stakeholders: WHO regional offices, RITAGs, Global NITAG Network and associated technical experts, CSOs

8. **Civil Society Organizations:** Countries should aim to broaden and deepen their engagement with CSOs, expanding the range of CSOs with which they interact and extending their input into areas such as programme planning
   
   Main responsibility: Countries; other key stakeholders: WHO regional offices, CSOs

   **Subsidiary recommendation:**

   8b. **Legal frameworks:** A comprehensive global audit should be undertaken to document the ways in which legislation and regulation have been used to promote immunization at a national level, to identify how legal and regulatory instruments can best be applied in different contexts and for different purposes
   
   Main responsibility: WHO Secretariat; other key stakeholders: countries, WHO regional offices, CSOs

SUSTAINABLE PROGRAMMES

9. **Technical capacity-building:** Through a multidimensional approach, the technical capacity of countries’ immunization programmes should be systematically assessed and strengthened, by leveraging regional and national expertise and opportunities as well as global tools and resources
   
   Main responsibility: WHO regional offices, countries; other key stakeholders: RITAGs, NITAGS, Global NITAG Network, CSOs, local higher education institutions, WHO Secretariat

10. **Vaccine access: Programme expertise:** Multidimensional analyses should be undertaken to identify procurement and other programmatic issues affecting timely provision of vaccination, including to the most marginalized and remote populations, and used to develop more effective procurement, stock management and distribution plans
   
   Main responsibility: WHO regional offices, countries; other key stakeholders: RITAGs

11. **Vaccine supply:** Current and anticipated vaccine supply and demand for routinely used vaccines should continue to be mapped and constraints identified, integrating and expanding other relevant ongoing work and focusing on vaccines most at risk of supply shortages
   
   Main responsibility: UNICEF Secretariat, WHO Secretariat and other partners; other key stakeholders: manufacturers, WHO technical advisers

12. **Middle-income countries:** WHO regional offices should support middle-income countries in their regions by leveraging all opportunities to promote the exchange of information, the sharing of lessons learned and peer-to-peer support
   
   Main responsibility: WHO regional offices, countries; other key stakeholders: WHO Secretariat
ANNEX 1: SAGE DECADE OF VACCINES WORKING GROUP MEMBERSHIP

SAGE MEMBERS

- Nora Noni MacDonald (Chair of the Working Group), Professor of Paediatrics, Dalhousie University, Canada
- Yagob Yousef Al-Mazrou, Secretary General, Health Services Council of the Kingdom of Saudi Arabia, Saudi Arabia

EXPERTS

- Oleru Huda Abason, Member of Parliament, Parliament of Uganda
- Jon Kim Andrus, Adjunct Professor and Senior Investigator Division of Vaccines and Immunization Center for Global Health, University of Colorado, USA
- Narendra Arora, Executive director, International Clinical Epidemiology Network, India (SAGE Member from 2010 – 2016)
- Susan Elden, Health Adviser, The Department for International Development (DFID) London, UK
- Marie-Yvette Madrid, Independent Consultant, Geneva, Switzerland
- Amani Mahmoud Mustafa, Project Manager, Sudan Public Health Training Initiative, The Carter Center, Sudan (affiliation as of May 2014 and previously EPI Manager, Ministry of Health, Sudan)
- Rebecca Martin, Director of the Center for Global Health, US CDC, USA
- Helen Rees, Executive Director, Reproductive Health and HIV Research Institute, University of Witwatersrand, South Africa (former SAGE Chair 2010 - 2013)
- David Salisbury, Associate Fellow, Centre on Global Health Security, Chatham House, London, UK (previously Director of Immunization, Department of Health, UK and former SAGE Chair 2005 - 2010)
- Budihardja Singgih, Technical Director Australia Indonesia Partnership for Health Systems Strengthening, Jakarta, Indonesia
- Qinjian Zhao, Associate Dean, School of Public Health, Xiamen University, Xiamen, Fujian, China

WORKING GROUP SECRETARIAT

- Bill & Melinda Gates Foundation
- Gavi, the Vaccine Alliance
- United Nations Children’s Fund
- United States National Institute of Allergy and Infectious Diseases
- World Health Organization
ANNEX 2: SAGE MEMBERSHIP

• Alejandro Cravioto (Chair of SAGE), affiliated with the Faculty of Medicine of the Universidad Nacional Autónoma de México (UNAM), Mexico

• Rakesh Aggarwal, Professor of Gastroenterology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India

• Yagob Yousef Al-Mazrou, Secretary General, Health Services Council of the Kingdom of Saudi Arabia, Saudi Arabia

• Ilesh Jani, Director General, Instituto Nacional de Saúde (National Institute for Health), Mozambique

• Jaleela Jawad, Head of Expanded Programme on Immunization, Public Health Directorate, Ministry of Health, Bahrain

• Youngmee Jee, Director General, Centre for Pathology and Immunology, National Institute of Health, Korean Centre for Disease Control and Prevention, Republic of Korea

• Kari Johansen, Expert Vaccine Preventable Diseases, European Centre for Disease Prevention and Control (ECDC), Sweden

• Nora Noni MacDonald, Professor of Paediatrics, Dalhousie University, Canada

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• Firdausi Qadri, Director, Infectious Diseases Division, Head and Senior Scientist, Mucosal Immunology & Vaccinology Laboratory, icddr,b, Dhaka, Bangladesh

• Nicola Turner, Director Immunisation Advisory Centre, University of Auckland, New Zealand

• Frederick Were, Executive Director and Professor, Department of Paediatrics and Child Health, University of Nairobi, Kenya

• Charles Wiysonge, Director, South African Cochrane Centre, South African Medical Research Council, South Africa