IMMUNIZATION TODAY
AND IN THE NEXT DECADE

2018 ASSESSMENT REPORT OF THE GLOBAL VACCINE ACTION PLAN

STRATEGIC ADVISORY GROUP OF EXPERTS ON IMMUNIZATION

World Health Organization

WHO/IVB/18.11

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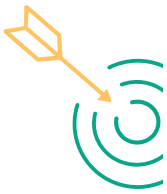

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CONTENTS

Immunization saves an estimated **2–3 million lives** every year

EXECUTIVE SUMMARY

Immunization has proven the test of time as one of public health's most cost-effective interventions. In 2017, the number of children immunized – 116.2 million – was the highest ever reported. The Region of the Americas achieved maternal and neonatal tetanus elimination, leaving only 15 countries yet to achieve elimination. Since 2010, 113 countries have introduced new vaccines, and more than 20 million additional children have been vaccinated.

Nevertheless, this year starkly illustrates **how easily hard-won gains are lost.** Because of low coverage nationally, or pockets of low coverage, multiple WHO regions have been hit with large measles and diphtheria outbreaks causing many deaths. The continued detection of circulating vaccine-derived poliovirus is further evidence that national immunization programmes are not achieving the goal of reaching every child.

To spur action, the Global Vaccine Action Plan set ambitious goals, and it remains the case that most targets will not be met by the end of the Decade of Vaccines in 2020. DTP3 and first-dose measles vaccine coverage have plateaued globally at 85%. Progress towards the eradication of wild poliovirus and the elimination of measles, rubella, and maternal and neonatal tetanus is currently too slow to be achieved by the end of the decade.

This picture provides a backdrop for discussions of the future of immunization after 2020, the final year of the Decade of Vaccines. The next decade is likely to be **volatile and uncertain.** Continuing mass urbanization and migration, population growth, geopolitical uncertainty and conflict, and natural disasters and environmental disruption will present major challenges to national immunization systems.

To meet these challenges, the immunization community must seek to **maintain its hard-won gains but also aim to do more and to do things better,** which may involve doing things differently. Equity must continue to be a strong driver, to ensure that everyone enjoys the benefits of immunization, including the most disadvantaged, marginalized and hard-to-reach populations, particularly those displaced or otherwise affected by natural disasters and conflict.

Integration will be central to achieving future goals. Partnerships have been key to the successes of the Global Vaccine Action Plan, and will be critical to the future. **Immunization is a central pillar of universal health coverage,** providing an infrastructure on which effective and equitable health systems can be constructed. Through this integration, immunization can contribute to multiple Sustainable Development Goals as well as **global health security and the battle against antimicrobial resistance.**

Countries will be at the heart of a future immunization strategy. Regions will have a key role to play in supporting the development of national immunization systems, while global immunization partners will continue working together to create an enabling environment for immunization.

As attention now turns to strengthening immunization post-2020, 2017's outbreaks are a sobering reminder that no country can take its eye off the ball: effective national immunization systems require ongoing nurturing, political commitment and public support. All countries need to see immunization systems as core to their health systems, and all citizens need to see immunization as a basic human right. In their absence, countries, regions and the world as a whole are less healthy, less safe and less prosperous. We become complacent at our own peril.

An additional
4.6 million
infants were vaccinated in 2017 compared to 2010

INTRODUCTION

The Global Vaccine Action Plan, launched in 2011, set out goals and objectives for the immunization community for the decade to 2020. Its vision was of a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases.

The Global Vaccine Action Plan, developed by the immunization community and endorsed unanimously by the global health community at the World Health Assembly (WHA), set ambitious goals and targets to catalyse a concerted global drive to minimize the burden of vaccine-preventable diseases in every country. Global immunization partners – WHO, Gavi, the Vaccine Alliance, the Bill and Melinda Gates Foundation, UNICEF and the US National Institute of Allergy and Infectious Disease – pledged to work together and with other immunization stakeholders to make this happen.

The Global Vaccine Action Plan includes five goals and six strategic objectives. A set of specific indicators and targets was developed to support monitoring and evaluation, with progress reported annually through a comprehensive Secretariat Report and this summary Assessment Report. Reporting on research and development (R&D) indicators takes place every two years, including this year.

There will never come a point at which immunization is no longer required. Every year, more than 130 million new babies are born – each equally deserving of protection against vaccine-preventable diseases. Exciting opportunities exist to extend the benefits of immunization to additional age groups, and to introduce new vaccines and vaccine delivery technologies. Hence, as the Decade of Vaccines draws to a close, a new plan is needed to guide countries and immunization partners through the next decade.

To ensure continuity, development of a new strategy needs to begin before the end of the Decade of Vaccines in 2020.

Hence, as well as reviewing progress against Global Vaccine Action Plan targets and objectives, this Assessment Report also suggests a pathway towards the development of a post-2020 strategy, building on lessons learned during the Decade of Vaccines. It also reflects on the key contextual factors and themes that will shape a successor global immunization strategy.

1. HIGHLIGHTS OF THE YEAR

- 116 million infants received the recommended three doses of DTP worldwide in 2017, the most ever
- The number of under-vaccinated children fell by over 1.8 million between 2010 and 2017
- Three additional countries achieved maternal and neonatal tetanus elimination – including Haiti, enabling the Region of the Americas to achieve elimination
- The number of functional National Immunization Technical Advisory Groups (NITAGs) has increased by 140% since 2010
- The Western Pacific Region has achieved its lowest ever incidence of measles and its first two countries were verified as having eliminated rubella
- Immunization activities in the South East Asia Region averted an estimated 622,000 measles deaths in 2017
- The African Region has seen a 130% increase in government expenditure on immunization since 2010
- In the Region of the Americas, 33 out of 49 countries have established a platform for immunization of pregnant women
- The Eastern Mediterranean Region maintained DTP3 coverage at 81%, despite eight out of 22 countries being affected by humanitarian emergencies
- Two countries in the European Region increased their measles vaccine coverage by more than 10%

But...

- 19.9 million children were under-vaccinated in 2017
- Four out of six regions experienced significant measles outbreaks
- Several countries and one region lost their measles elimination status
- Two out of six regions suffered major diphtheria outbreaks
- A major outbreak of yellow fever in Brazil has been challenging to control
- 11 countries that had previously achieved 90% DTP3 coverage failed to reach this target in 2017
- Circulating vaccine-derived poliovirus was detected in three regions
- Only seven countries reported no vaccine hesitancy in 2017

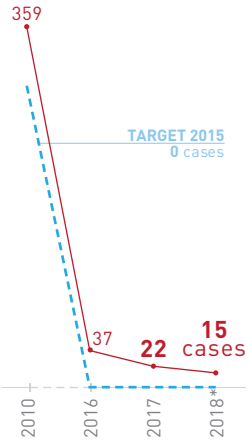
UNICEF procured over
2.4 billion
doses of vaccines for 100 countries in 2017

2. KEY INDICATORS

The following graphics summarize the current status of key coverage and other indicators in 2017.

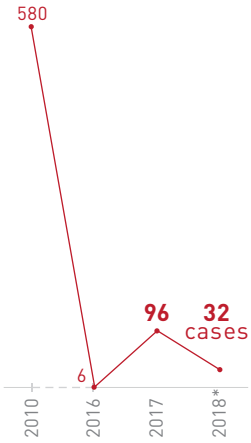
WILD POLIOVIRUS AND CIRCULATING VACCINE-DERIVED POLIOVIRUS CONTINUE TO BE DETECTED

Number of new wild poliovirus infections



*4 September 2018

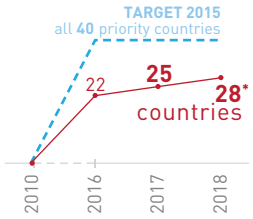
Number of new cases of circulating vaccine-derived poliovirus



*4 September 2018

THREE ADDITIONAL COUNTRIES ACHIEVED MATERNAL AND NEONATAL TETANUS ELIMINATION IN 2017 BUT GLOBAL ELIMINATION BY 2020 IS UNLIKELY

Number of priority countries verified for maternal and neonatal tetanus elimination

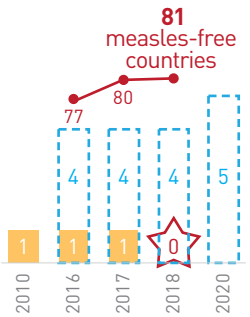


*Anticipated

MEASLES OUTBREAKS IN 2017 LED THE REGION OF THE AMERICAS TO LOSE ITS MEASLES ELIMINATION STATUS IN 2018

Number of regions and countries achieving elimination

MEASLES

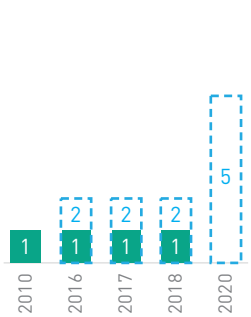


TARGET 2020
Five WHO regions

2018
Measles is again endemic in all regions

Number of regions achieving elimination

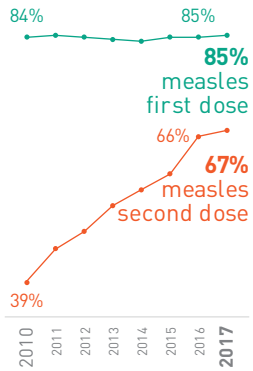
RUBELLA



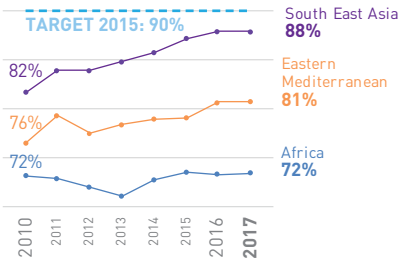
TARGET 2020
Five WHO regions

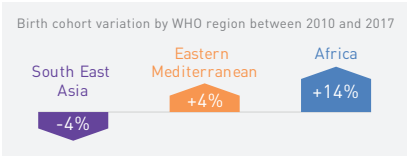
2018
Only one region rubella-free

GLOBAL COVERAGE OF FIRST-DOSE MEASLES VACCINE HAS PLATEAUED BUT SECOND-DOSE COVERAGE HAS INCREASED SIGNIFICANTLY

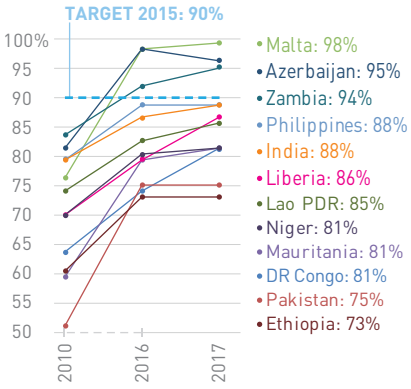


DTP3 COVERAGE HAS INCREASED SIGNIFICANTLY IN THE EASTERN MEDITERRANEAN AND SOUTH-EAST ASIA REGIONS AND BEEN MAINTAINED IN THE AFRICAN REGION DESPITE A BIG INCREASE IN ITS BIRTH COHORT





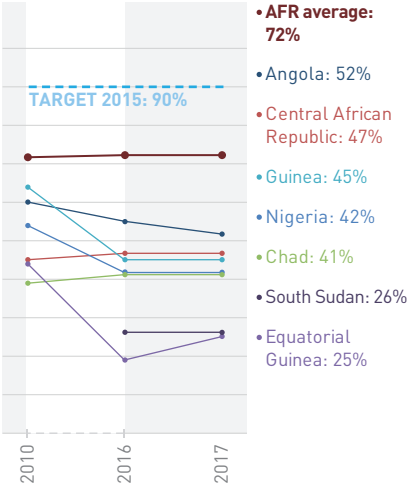
COUNTRIES ACHIEVING THE GREATEST INCREASES IN DTP3 COVERAGE 2010–17



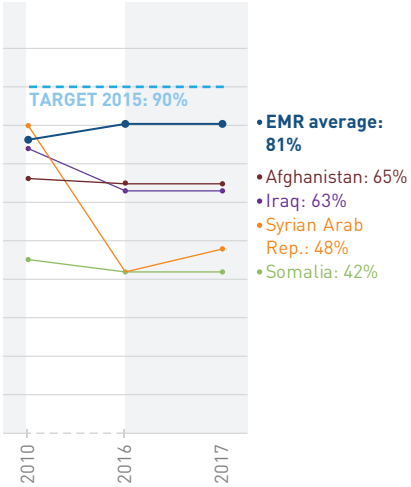
Excluding countries with a population less than one million.

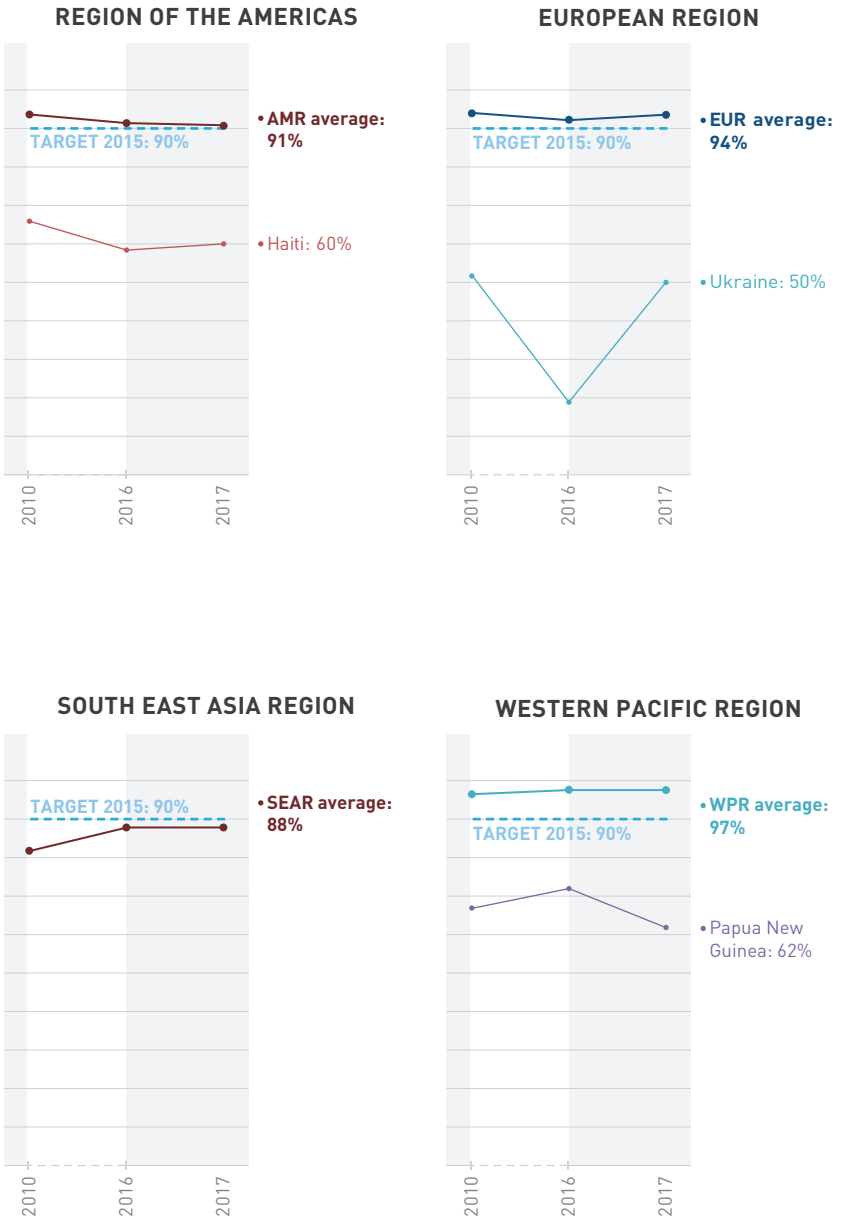
COUNTRIES SHOWING THE MOST MARKED DEVIATION FROM REGIONAL DTP3 COVERAGE

AFRICAN REGION



EASTERN MEDITERRANEAN REGION

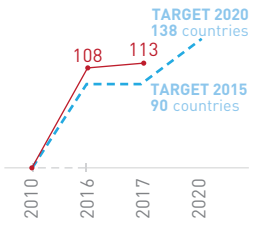




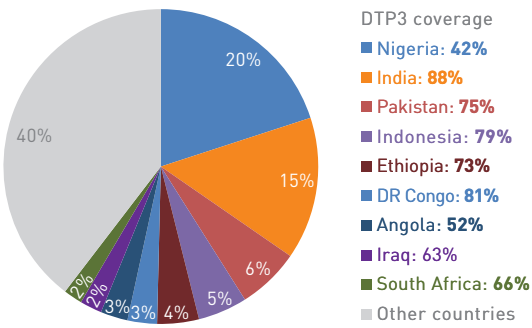
Note: only countries with DTP3 coverage below 65% have been represented.

NEW VACCINE INTRODUCTIONS REMAIN ON TRACK BUT AT RISK OF STALLING

Number of low- and middle-income countries that have introduced at least one new or underutilized vaccine since 2010



COUNTRIES IN WHICH THE 20 MILLION UNDER-VACCINATED CHILDREN LIVE AND THEIR RESPECTIVE DTP3 COVERAGE RATES



3. FRAGILE GAINS

A surge in outbreaks during 2017 is a timely reminder that hard-won gains are easily lost, even in countries with well-established health systems. Without constant attention, national immunization systems can easily deteriorate, particularly when faced with political and economic upheaval.

Outbreaks: Measles elimination took a step back in 2017. Although the incidence of measles has more than halved since 2010, it increased in 2017 from 19 to 25 cases per million, with increases seen in four out of six WHO regions. Significant outbreaks occurred across the globe, and a major outbreak in Venezuela, also affecting other countries in the Region of the Americas, led to the re-establishment of endemic measles transmission in Venezuela (but not so far in other countries in the region).

Outbreaks in North America and in Europe emphasize that measles can easily spread even in countries with mature health systems. Due to ongoing outbreaks, measles is again considered endemic in Germany and Russia. Measles outbreaks have been seen in countries reporting good national vaccine coverage, evidence of immunization gaps and highlighting the need to ensure high sub-national coverage, particularly among vulnerable populations.

There are also concerns about the widespread use and quality of supplementary immunization activities (SIAs). While nearly 200 million children were reached through SIAs in 2017, in less than half were coverage rates in excess of 95% achieved. Although they can be an important way of immunizing remote populations and rapidly addressing coverage gaps, SIAs are costly and labour-intensive; strengthening routine immunization systems would reduce the need for SIAs, as well as the costs associated with treatment of measles and resulting lost productivity – the cost of dealing with an outbreak can be 20 times the cost of the vaccinations that could have prevented it.

More positively, global coverage of a second dose of measles-containing vaccine (MCV2) increased to 67% in 2017 and 86% of countries have introduced MCV2 into their national immunization programmes. However, coverage rates globally remain inadequate to effectively control measles.

In 2017 and 2018, measles outbreaks have occurred in the Region of the Americas, the Eastern Mediterranean, the European and the South East Asia Regions

Between 2000 and 2016, measles vaccination prevented an estimated

20.4 million deaths

Although four additional countries were verified as having eliminated rubella, and global coverage for rubella-containing vaccine exceeded 50% for the first time in 2017, coverage varies markedly between regions and 24 countries have still to introduce a rubella vaccine into their national immunization programmes.

Polio: Although the number of cases of wild poliovirus declined in 2017, polio eradication remains highly challenging. Intensive and innovative activities have been undertaken to immunize remote populations in northern Nigeria and surrounding areas; no new wild poliovirus cases were detected in the African Region in 2017 but surveillance gaps remain a concern. Data from the first half of 2018 point to the persistence of wild poliovirus circulation in the other endemic area, spanning Afghanistan and Pakistan.

Equally concerning is the continuing detection of circulating vaccine-derived poliovirus in 2017 and 2018, in the Democratic Republic of the Congo, Nigeria, the Syrian Arab Republic, Somalia and Papua New Guinea. This highlights worrying inadequacies in national immunization systems that leave countries at risk of importation and the emergence of circulating vaccine-derived poliovirus, and ill-equipped to monitor and maintain polio-free status in the future.

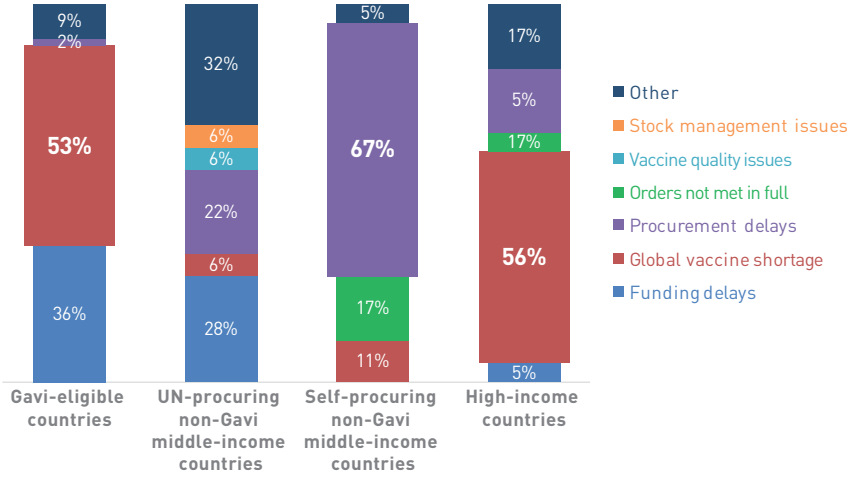
The extension plan for the Global Polio Eradication Initiative is a welcome development – polio eradication must be completed. The potential for the extension plan to deliver synergistic benefits should be energetically explored – as well as securing and sustaining polio eradication, the plan should provide important opportunities to strengthen national immunization systems, including surveillance.

The WHA recommendation that polio transitions should go in tandem with eradication is also timely. Uncertainties in polio transition planning, and the potential impact of polio transitions on national immunization systems, including surveillance infrastructures, are a significant concern. There is an urgent need to finalize and implement national polio transition plans, ensuring that rigorous investment cases are developed that, in addition to securing and maintaining poliovirus eradication, also strengthen national immunization systems.

Vaccine supply: Fewer countries experienced stockouts in 2017 (70) than in 2016 (73), but numbers remain well above the 2020 target (25). The causes of stockouts remain diverse. High-income and Gavi-eligible countries were particularly affected by global vaccine supply issues, while procurement delays were significant in middle-income countries. Gavi-eligible and UN-procuring countries were also affected by funding delays. Some 69 countries were affected by sub-national stockouts, which in 78% of cases led to an interruption of immunization services.

The proportion of vaccine doses of assured quality has risen from 72% in 2010 to
96% in 2017

CAUSES OF STOCKOUTS VARY
BETWEEN DIFFERENT CATEGORIES OF COUNTRY



These data point to the need to understand the origins of funding and procurement delays, as well as to strengthen forecasting, procurement practices, budgetary management and stock management within national immunization systems. Global vaccine shortages remain a concern; as well as contributing to gaps in coverage, they have the potential to undermine trust in immunization programmes. They are being addressed through initiatives such as the **Market Information for Access to Vaccines (MI4A),** one aim of which is to provide more clarity on global supply and demand to ensure vaccine availability. There are also encouraging signs of growing vaccine manufacturing capacity in low- and middle-income countries, underpinned by strong political support in many such countries.

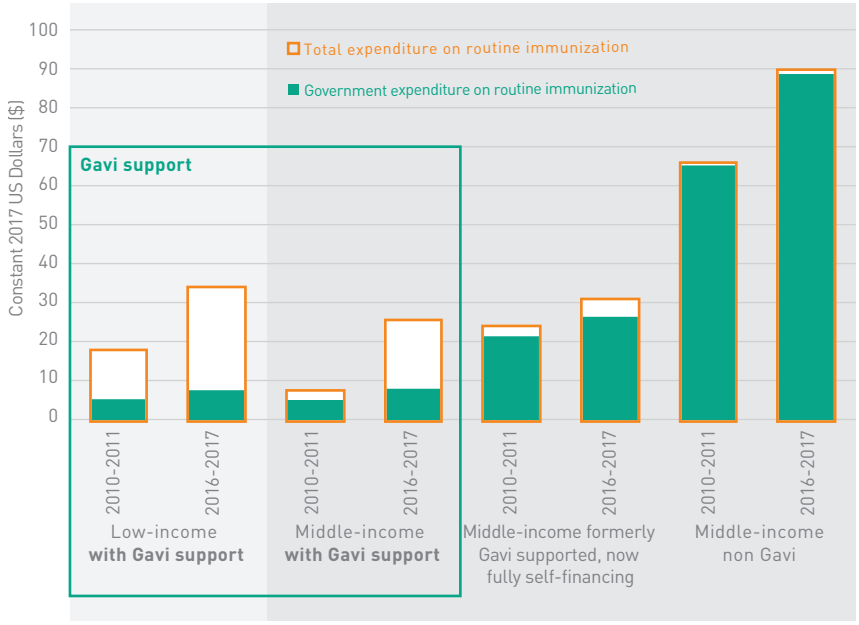
National ownership and political commitment: Achieving high coverage is fundamentally dependent on the effectiveness of people-centred national immunization systems. While national wealth inevitably has some influence on population access to immunization services, it is far from the only factor. Countries are making political decisions on resource allocation. Significant variation is seen in national commitments to immunization systems, and in immunization system performance as a function of national wealth. Countries such as Bangladesh, Cuba, Burundi, Eritrea and Rwanda show excellent coverage despite limited resources.

Currently, no global target exists for measles or rubella elimination at a national level. Despite this, several countries have made strong national commitments to strengthen their measles and rubella immunization programmes. Opportunities exist for other countries to follow their example and develop a similar national commitment to enhance MCV1, MCV2, rubella, poliovirus and other vaccination.

Globally, expenditure on national immunization systems has been growing, but this masks significant regional and national variation. Expenditure growth has exceeded 60% between 2010 and 2017 in the Western Pacific, African and South-East Asia Regions but has been lower elsewhere. Among Gavi-eligible countries, donor funding contributed significantly to increased expenditure, although government contributions also increased – by 130% in the African Region. The typically high cost of new vaccines means that self-sufficiency and introductions are hard to achieve simultaneously. Hence, although absolute government expenditure has grown, as a proportion of total expenditure it has fallen from 78% to 57%.

TOTAL EXPENDITURE ON IMMUNIZATION AND SOURCES OF EXPENDITURE VARY SIGNIFICANTLY BETWEEN DIFFERENT CATEGORIES OF COUNTRY

Annual expenditure on routine immunization per live birth



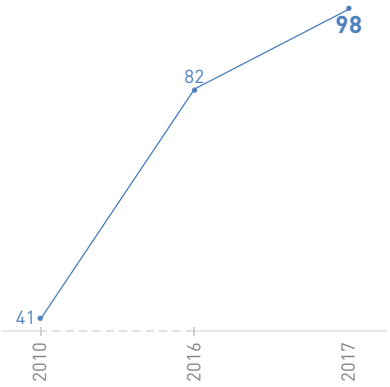
The MI4A/V3P database now includes vaccine price data for 84% of the world's countries and 95% of the world's birth cohort

57 additional
countries have established functional NITAGs since 2010

It is now widely recognized that enhanced access to immunization in countries is only partly dependent on financial support for vaccine procurement. Countries also need technical assistance to develop their national immunizations systems, based on a full system-wide assessment spanning issues such as procurement and financial management, demand and hesitancy, and the logistics of vaccine delivery and administration to recipients. Global immunization partners and regions are playing a key role in needs analyses and in the provision of peer support, while Gavi has also increased its emphasis on technical assistance. However, middle-income countries remain less able to benefit from technical support (see below).

Ultimately, the development of effective national immunization systems depends on high levels of political commitment. It is important that this commitment is not merely symbolic, but translates into concrete strategies and action plans. It is equally importantly to guard against complacency – high coverage is a goal that must be achieved each and every year.

THE NUMBER OF COUNTRIES WITH FUNCTIONING NITAGS INCREASED BY 20% IN 2017



TARGET 2020
All 194 countries have a functional NITAG

Central to country ownership are functioning **National Immunization Technical Advisory Groups (NITAGs),** which showed further encouraging growth in 2017. NITAGs are a national asset: they act both as a technical resource and as an independent advisory body enabling national authorities and policymakers to make evidence-based decisions. A total of 134 countries now report the existence of a NITAG and 98 report a NITAG meeting six functionality process criteria – a 20% increase over 2016. The development of NITAGs is being supported by Regional Immunization Technical Advisory Groups (RITAGs) and a Global NITAG Network, which held its inaugural meeting in 2017.

Sub-regional NITAGs, as established in the Caribbean, may be an answer to the difficulties experienced by small countries which are unlikely to have sufficient technical capacity for individual national groups. There is also a need to move beyond process indicators to assess the effectiveness of NITAGs and their contribution to national policymaking and practice.

Demand and hesitancy: Immunization programmes need to be designed so that individuals and communities understand the value of vaccines and demand immunization. Stimulating demand – the active seeking of services – requires attention to multiple issues, including community engagement, service quality and accountability, and responses to adverse events or other challenges. Engaging with civil society will help to generate a positive environment for immunization, while framing immunization as a basic human right and central to the development agenda can be an important driver of political accountability.

A wide range of stakeholders – communities, frontline health workers, Civil Society Organizations (CSOs) and 'immunization champions' – have important roles to play in fostering demand. Ensuring the quality of service delivery is essential – parents' experience at clinics and their interactions with health workers can significantly influence their future vaccination choices.

Working to stimulate demand will also help to prevent hesitancy. Since 2014, the number of countries reporting data on hesitancy has steadily increased, reaching 83% in 2017, while the number of countries undertaking an assessment of hesitancy has risen to 37%. Only seven countries reported a complete absence of hesitancy, evidence that the issue has become a truly global challenge.

Hesitancy linked to lack of awareness/knowledge continues to decline, and risk/benefit concerns remain the most often-cited reason for hesitancy (but represent less than 30% of the total responses, illustrating the wide diversity of issues underlying hesitancy). Of particular concern is the increasing politicization of immunization. Immunization has been exploited to mobilize political support, while in some cases vaccine refusal is being driven by extreme political agendas that prevent populations from being immunized. In addition, social media accounts have been used to provoke debate about immunization safety to undermine trust in national authorities.

New ways of analysing country responses are now needed to provide a clearer picture of demand and hesitancy issues at a national level, recognizing that the latter covers a spectrum of attitudes from outright rejection to passive acceptance, and is subject to multiple influences from groups with widely differing agendas. Further work is required to understand hesitancy issues at national and sub-national levels (many hesitancy issues are highly context-specific). Deeper insights into the factors influencing immunization decision-making should underpin the development of tailored strategies to promote local demand for immunization services and to address specific hesitancy issues. The European Region, for example, is capturing learning on national strategies to address hesitancy and demand-related challenges which may hold lessons for other regions.

To meet the need for more evidence on the factors affecting uptake and demand for immunization services, UNICEF is working with WHO, the US Centers for Disease Control and Prevention, and the Bill and Melinda Gates Foundation to establish a Hub for Vaccination Acceptance and Demand. The Hub will harness the expertise and resources of a wide range of immunization stakeholders, building a global resource for addressing demand-related challenges and coordinating technical support to countries.

By the end of 2017, Gavi had enabled

58 countries

to introduce pneumococcal vaccine, which has saved the lives of more than

500,000 children

in poor countries

4. EQUITY

A core principle of immunization is that everybody has an equal right to immunization services, no matter who they are or where they are from. Despite some progress, this goal is far from being achieved.

A Strategic Objective of the Global Vaccine Action Plan was that the benefits of immunization should be equitably extended to all people. Equity was broadly conceived to encompass access irrespective of geographic location, age, gender, disability, educational level, socioeconomic level, ethnic group or work condition.

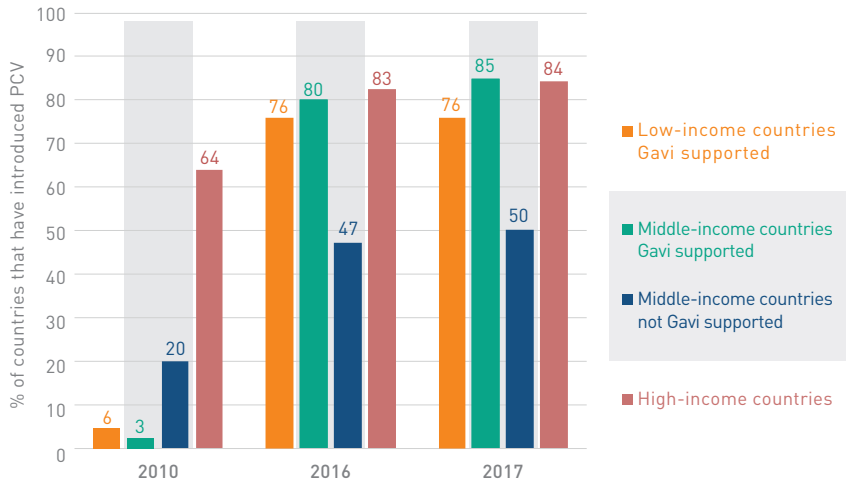
International inequalities: Vaccine coverage rates continue to vary substantially between countries and regions. Six countries achieved 90% DTP3 coverage for the first time in 2017, but 11 that had hit this target in 2016 fell below it in 2017. Eight countries had DTP3 coverage of less than 50% in 2017. As a result, nearly 20 million children were under-vaccinated in 2017.

As well as factors such as conflict, national wealth inevitably influences immunization system performance, as judged by vaccine coverage. However, the correlation is far from absolute – many low- and middle-income countries achieve unexpectedly high coverage given their economic status and a number of higher-income countries are under-performing. While the support of partners such as Gavi has obviously had a major impact, the 'over-performing' countries clearly indicate that low coverage is not inevitable. Furthermore, the recent gains achieved by countries such as Costa Rica, India, Kazakhstan and Zambia illustrate that innovative actions, driven by high-level political commitment, can have a major impact on coverage.

Support from Gavi has had an enormous impact in enabling many low- and middle-income countries to introduce new vaccines. However, there are widespread concerns that **middle-income countries** ineligible for Gavi support are not making anticipated immunization gains.

Middle-income countries account for almost three-quarters of the world's poorest people and have a birth cohort three times the size of that of low-income countries. Non-Gavi middle-income countries are diverse, and many face complex immunization challenges. These countries, which are almost entirely self-financing, do not benefit from Gavi preferential pricing, nor are they eligible for Gavi-financed technical support. Even with expanding immunization budgets, non-Gavi middle-income programmes are showing strain, as can be seen in the slow pace of adoption of vaccines such as pneumococcal conjugate vaccine (PCV). This is a situation of concern today, but also highlights future risks to sustainability for Gavi-transitioning and fully financing countries that have yet to contend with non-preferential pricing.

MIDDLE-INCOME COUNTRIES THAT ARE NOT GAVI-SUPPORTED LAG BEHIND IN PCV INTRODUCTION



There is also a growing realisation that economic constraints are only one obstacle to the availability of vaccines in middle-income countries (and low-income countries). Often, technical assistance to build effective, robust and sustainable national immunization programmes is of at least equal importance. This points towards models in which international support is based on national capacities and development needs rather than just income levels.

Reflecting this perspective, the African Region has developed a categorization system based on the capacity or maturity status of immunization programmes within its countries. This has been used to develop a 'maturity grid' in which countries are placed in one of four tiers according to the maturity of their immunization programmes. This categorization is being used to shape tailored programmes of support for countries as well as a long-term plan to develop countries' immunization capacities in a stepwise fashion. Other agencies have developed similar categorization criteria to ensure more targeted support for countries.

Within-country inequalities: No new data are available on sub-national differences in coverage associated with socioeconomic status. This remains an important gap to be addressed. The number of countries achieving 80% DTP3 coverage across all districts remained unchanged at 39 (20%).However, 74 countries (38%) do not report data of high enough quality for sub-national comparisons to be made. More granular data collection is essential if sub-national variations in coverage and coverage gaps are to be addressed.

A recent analysis of childhood immunization coverage in 10 Gavi priority countries identified several factors associated with inequalities in coverage. These included mother's education level, mother's age at birth and birth order, but not sex of child. Household economic status had a significant impact on likelihood of immunization. Although urban–rural divides in coverage were seen, these appeared to reflect the impact of poverty.

The majority of vaccine-preventable deaths globally now occur in middle-income countries

In Nigeria, children of older, well-educated, well-off mothers in the south were

300 times more likely to be vaccinated

than children with teenage, uneducated, poor mothers in the north-west

Socioeconomic inequalities tended to be highest in countries with lowest national coverage (although Chad has both low national coverage and low variation in coverage, while Tanzania has both relatively high coverage and low variation). In countries with higher coverage, urban-rural inequalities were typically lower, and inequalities instead tended to reflect exclusion of marginal populations. Some countries report district-level or even lower-level data, providing a more granular view of inequalities to guide corrective actions.

A growing set of toolkits are available to increase coverage in underserved populations and pockets of unvaccinated children in remote districts. In addition, UNICEF and the Bill and Melinda Gates Foundation have established a high-level **Equity Reference Group (ERG),** which will review innovative ideas, new approaches and best practices, and make recommendations for guidance, policies and programming to reduce inequities.

The ERG, which includes global experts from within and outside the immunization community, has identified three priority populations – the urban poor, children affected by conflict and insecurity, and children living in remote rural areas. Nevertheless, further efforts may be required to cope with the profound challenges presented by mobile populations, including economic migration, urbanization, and displacement by conflict or natural disasters.

CSOs have a potentially critical role to play in expanding access. As well as contributing to the delivery of immunization services, enhancing access to communities in volatile sociopolitical situations and among hard-to-reach communities, they can also play key advocacy roles locally and nationally, and hold governments and delivery partners accountable.

Maternal and neonatal tetanus: Immunization against maternal and neonatal tetanus, targeted for elimination by 2020, is often used as a measure of equitable access, as the infection disproportionately affects the most disadvantaged. By the end of 2017, 25 out of 40 priority countries had achieved maternal and neonatal tetanus elimination. In 2017, three additional countries (Ethiopia, Haiti and Philippines) achieved elimination, while two countries, Kenya and Chad, completed activities to prepare for validation in 2018.

An investment case has been completed for the remaining priority countries and will be used to mobilize resources for the completion of global maternal and neonatal tetanus elimination. The estimated cost is US$200m. A business case for use of compact pre-filled auto-disable (Uniject) devices to reach remote populations was not approved by the Gavi Alliance Policy and Programme Committee, following an unfavourable analysis of its likely cost-effectiveness. Alternative strategies will need to be developed to reach currently excluded populations, especially in remote rural settings.

Countries yet to achieve elimination include many affected by conflict, major disease outbreaks or environmental challenges. There is a realistic prospect that nine countries (Angola, Chad, Democratic Republic of the Congo, Kenya, Mali, Papua New Guinea, Guinea, South Sudan and Sudan) will achieve elimination by 2020, with firm political commitments and partner support. Achieving elimination on schedule in the remaining countries, Afghanistan, Central African Republic, Somalia, Nigeria, Pakistan and Yemen, appears unlikely without a significant change in the speed of progress.

Since 2014, an additional
10 countries
have eliminated maternal and neonatal tetanus, averting an estimated
81,000 newborn deaths

13 million children
are under-vaccinated as a result of conflict

5. HUMANITARIAN EMERGENCIES

In a volatile and uncertain world, geopolitical instability and natural disasters can devastate health systems, undermine the performance of national immunization systems, and generate substantial numbers of displaced people. Special mechanisms are needed to deal with the exceptional circumstances generated by humanitarian crises.

In 2017, conflict continued to affect multiple global regions. Civil strife can severely undermine public health infrastructure, including immunization services, while mass displacement of people creates challenges for neighbouring countries as well as internally. The UN estimates that more than half the population of Syria has been displaced, at least 6 million internally and 5 million externally. Lebanon hosts 2.2 million Syrian refugees (who now account for one fifth of its total population) and Jordan more than 1.2 million. Globally, the UN estimates that 68.5 million people have been forced to flee their homes due to war, violence and persecution in 2017 – nearly 1% of the total global population.

Within the **Eastern Mediterranean Region,** 30 million people were displaced during 2017. An estimated 60% of hospitals in Syria have been closed, destroyed or rendered only partly functional; 50% of hospitals in Yemen are non-functional. Around 60% of health workers in Syria have either left the country or been killed. Under these circumstances, dedicated healthcare staff and international aid agencies have had remarkable success in maintaining coverage levels in Syria and Yemen. DTP3 coverage rose in Syria by 6% to 48% and dropped only slightly in Yemen to 68% (although there are some questions about the reliability of data collected under such difficult circumstances).

Around a million displaced **Rohingya** from Myanmar – more than half of them children – presented a major challenge to the Bangladesh public health system. International partners have worked with the Government of Bangladesh and national agencies to immunize refugees and prevent infectious diseases, with remarkable success – 4.5 million vaccine doses have been delivered to displaced Rohingya. Despite challenging conditions, outbreaks have been restricted to diphtheria, triggering a further mass vaccination campaign against diphtheria.

In the Region of the Americas, a deteriorating socioeconomic situation in **Venezuela** has had a significant impact on its health infrastructure, including its immunization services.The resulting measles and diphtheria outbreaks have also spread to other countries in the region. Having been free of diphtheria for 24 years, Venezuela has now experienced more than 1600 suspected cases between 2016 and the middle of 2018. The resurgence of measles has also led the region to lose its measles elimination status, just two years after it was secured in 2016.

On average,
44,500 people
were forced to abandon their homes every day in 2017

Humanitarian relief operations have provided emergency immunization supplies among displaced populations, with an increasing emphasis on delivery of multiple vaccines (and additional interventions) to maximize every opportunity to reach displaced individuals. In 2017, the WHO published **Vaccination in Humanitarian Emergencies: Implementation Guide** to provide practical guidance and advice to immunization task forces. The new guide complements an updated version of Vaccination in Acute Humanitarian Emergencies: A Framework for Decision Making. The year also saw Gavi announce a **fragility, emergencies and refugees policy,** to enable it to respond more flexibly to challenging national circumstances.

Over the longer term, there is a need for a coherent and comprehensive global policy on protracted humanitarian crisis situations that also takes into account the challenges faced by countries hosting large numbers of displaced people and the need to track the immunization status of individuals as they move between and within countries. Delivery of immunization services to vulnerable groups is likely to depend on use of a variety of different models, tailored to local circumstances.

A further challenge will be maintaining public health function in emergency outbreak situations. As well as its severe direct impact, the 2014–16 Ebola outbreak also had a major impact on wider public health in affected countries. One consequence was a significant reduction in childhood immunization, potentially leading to as many vaccine-preventable deaths as caused by Ebola directly. Disrupted immunization programmes also provide opportunities for the emergence and spread of vaccine-derived poliovirus, as occurred in Guinea in 2014–15.

An estimated
258 million
people are living in a country other than their country of birth

An estimated
445,000 people
died of malaria in 2016

Three African countries have begun pilot implementation studies of the RTS,S/AS01 malaria vaccine

In 2017, 1.8 million people became newly infected and 940 000 people died from HIV-related causes globally

6. RESEARCH AND DEVELOPMENT

Progress is being made in the development of new vaccines against infectious disease threats such as malaria, HIV/AIDS and tuberculosis (TB). Research also has the potential to play a much bigger role in the identification, development and evaluation of innovations to enhance access to and acceptability of vaccines and immunization services.

One of the five goals of the Global Vaccine Action Plan is to develop and introduce new and improved vaccines and technologies. The R&D focus is on potentially vaccine-preventable diseases responsible for a high global burden of disease, including malaria, HIV/AIDS, TB and seven other priority infections, and new technologies to facilitate vaccine delivery or wider use of vaccination.

The most advanced **malaria vaccine,** RTS,S/AS01 (Mosquirix®), has achieved a positive scientific opinion from the European Medicines Agency and is undergoing pilot implementation studies in three African countries. There are some concerns about its efficacy and safety, and further studies may be required to evaluate alternative dosing regimens and schedules. Encouragingly, multiple other vaccine candidates are at various stages of clinical evaluation, targeting different points in the malaria parasite life cycle.

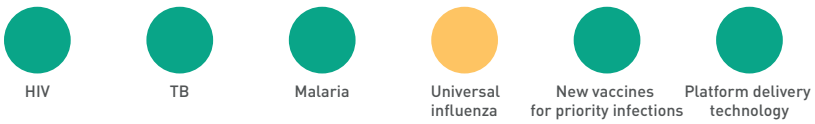
Vaccine development for HIV remains an immense technological challenge, not least because of its great variability and mutability. However, the field has taken heart from the RV144 trial in HIV, the first to demonstrate protective efficacy, albeit modest. The laboratory identification of broadly neutralizing antibodies – recognizing multiples strains of HIV – has provided further impetus. As well as enabling studies that are informative for vaccine design, broadly neutralizing antibodies could be manufactured and used directly in prevention. The HIV vaccine pipeline includes multiple candidate vaccines undergoing clinical and pre-clinical evaluation.

Although a vaccine for **TB,** BCG, already exists, the current forms offer incomplete protection and have several drawbacks. Different vaccines may also be required to achieve different objectives in TB, such as prevention of initial infection or prevention of activation of latent TB. A wide range of candidate vaccines are progressing through clinical evaluation, with several showing positive results in early phase clinical trials.

Progress towards a **universal flu vaccine** has been more challenging, although a variety of vaccine candidates are in early stages of clinical evaluation. One complication relates to the definition of 'universal' – sometimes used to refer to vaccines against just influenza A strains, against influenza A and B strains, or against these and 'exotic' strains acquired from other species.

Vaccine development efforts for these diseases face multiple challenges. Although new field-deployable vaccines are still some way off, progress has been highly encouraging and there are realistic prospects that new vaccines will be available for use within the next decade or so. Significantly, great progress is being made in understanding the biology of infectious agents, how they interact with hosts during infection, and which aspects of the host immune response correlate with protection – new knowledge that will support the identification, design and evaluation of enhanced vaccines. Furthermore, new vaccine platform technologies and innovative methodologies, such as controlled human infection studies (now being carried out in disease-endemic countries), are offering great potential to accelerate the development of new vaccines. Vaccine platforms that can form the backbone of multiple vaccines are providing further exciting opportunities for new vaccine development.

R&D INDICATORS ARE MOSTLY ON TRACK



The Global Vaccine Action Plan also identified seven other priority infections for which new vaccines are required. Significant progress is being made for many of these infections, with new products undergoing clinical evaluation. There is a need to determine whether the initial Global Vaccine Action Plan list is still appropriate and whether new priorities should be identified, building on the work of the **WHO Product Development for Vaccines Advisory Committee (PD-VAC)** and the R&D Blueprint.

Innovative **delivery technologies,** including needle-free injection systems, offer the prospect of more convenient, safer and people-friendly delivery of vaccines. Many different approaches are under development, including several that are now WHO prequalified and ready for implementation. Significant progress is also being made in **diagnostic technologies,** particularly simple-to-use, rapid, point-of-care diagnostics, with great potential in infectious disease surveillance and epidemiological studies that inform the design and scope of vaccine clinical trials and immunization programmes.

More than 50 HIV
vaccine trials have been launched since 2010

490,000 people
developed multidrug-resistant tuberculosis (MDR-TB) in the world in 2016

At least 13 TB vaccines
are currently undergoing clinical trials

The 2014–16 Ebola outbreak cost three African countries at least

US$2.8bn

The experience with RTS,S/AS01 (Mosquirix®) and other interventions has highlighted the challenges not just of navigating regulatory pathways but also of overcoming a **second translational gap** at the post-phase III implementation stage. This experience is highlighting the critical importance of adopting a 'total systems effectiveness' approach to determine the potential programmatic, public health and financial impact of new products, extending evaluation beyond safety, efficacy and performance, and more generally of linking product development to the practicalities of field deployment.

Recent years have also seen tremendous progress in the development of coordinated global responses to **emerging and re-emerging infections.** The 2014–16 Ebola epidemic illustrated that the world was poorly prepared to manage emerging disease outbreaks, and in particular to carry out clinical research on new vaccines or other interventions. The **WHO R&D Blueprint** initiative is coordinating global efforts to develop new products, including vaccines, for infections of epidemic potential, and to establish mechanisms for their timely and ethical clinical evaluation in outbreak situations. The **Coalition for Epidemic Preparedness Innovations (CEPI)** is a new global initiative developing vaccines for emerging pathogen threats.

A further noticeable trend has been the growth of **R&D and manufacturing capacity in low- and middle-income countries.** This is seen as an important way of addressing global supply and affordability issues (as well as contributing to the economic development of low- and middle-income countries). Nevertheless, there remains a need to develop research and translational capacity in such countries, to promote participation in and leadership of research, and to build national regulatory and other capacity to facilitate local innovation and industrial development.

While much attention is given to product development, research can play a wider role in immunization, generating evidence across multiple domains to improve access to vaccines and immunization services. **Implementation research and delivery science** have key roles to play in rolling out and scaling up new approaches to healthcare delivery. **Operational research** can identify improvements in immunization system functions and decision-making. ***In silico* modelling** can help to identify bottlenecks and hurdles, and provides a way to assess the likely impact of possible solutions. Research can also be used to evaluate initiatives to stimulate demand or address hesitancy. New innovations will be particularly required to deliver services to hard-to-reach populations, and need to be rigorously evaluated. Collectively, these approaches can ensure that immunization is a rigorous evidence-based discipline.

7. THE FUTURE

Implementation of the Global Vaccine Action Plan has taught us much and will provide invaluable lessons for immunization post-2020. A new strategy will need to consider profound changes in global context, a growing awareness of the difficulty of the challenges presented by infectious diseases, and the opportunities offered by new technologies and ways of working.

A volatile and uncertain world: The context for the next global immunization strategy will be a world in which volatility and uncertainty are the norms. Large-scale population movements are likely to be commonplace, with continuing mass urbanization and displacements due to conflict, deterioration of fragile states, and the consequences of natural disasters and global warming. History suggests that we will at some point encounter new infectious diseases that represent a global pandemic threat.

Tough challenges: Polio eradication has been a chastening experience. Smallpox eradication inspired hope that other infectious diseases could also be consigned to history, but the final steps in polio eradication have been hugely challenging. Effective control of measles and rubella demands very high and consistent levels of vaccine coverage. Reaching those remaining groups not fully benefiting from immunization will be challenging for many countries. Special efforts and investment will be required to access the most disadvantaged communities.

Complacency and the risk of regression: Just sustaining immunization gains year on year will remain a significant challenge, particularly given anticipated population growth, notably in the African Region. All our gains are at risk of being undermined by complacency – immunization is a commitment we need to make in perpetuity. As the disruption and cost of outbreaks illustrate, neglecting immunization is a false economy. Or, to put it more positively, immunization is an investment that will continue to deliver long-term health and economic benefits far in excess of its immediate costs.

Recognizing shared interests: In response to these challenges, the global immunization community needs to recognize the importance of shared interests and work towards common goals. As a public health intervention with unparalleled population reach, immunization can provide a springboard for universal health coverage and underpin enhanced primary care, thereby contributing to national development. It also provides key tools to ensure global health security and to tackle antimicrobial resistance. Multiple opportunities therefore exist to engage with additional sectors and potential partners.

Immunization at the heart of healthcare: Immunization is a central pillar of universal health coverage, and at the heart of comprehensive and sustainable primary healthcare systems. Other disciplines can build on the immunization community's ability to reach populations in need, driving coalescence of integrated patient-centred healthcare systems. The increasing relevance of immunization across the entire life course provides a further compelling argument for integration.

Building on partnerships: The successes of immunization owe much to partnerships, which must remain core to future work. Effective global models of collaboration have been established to tackle complex problems, supporting enhanced access and coordinated research. Additional partnerships can be envisaged, for example with development assistance communities, recognizing the core role of health protection and promotion in sustainable development, with the private sector, which makes a major contribution to immunization in many settings, and with a wider range of CSOs.

The global urban population is projected to increase by
2.5 billion
by 2050, with almost 90% of growth occurring in Asia and Africa

Vaccine-preventable diseases account for the deaths of more than

500,000 children

under five years of age in Africa every year

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

Putting countries in the driving seat: Effective, robust and sustainable national immunization programmes will be the building blocks of a future immunization strategy. It is essential that countries take ownership and pride in their national immunization systems, identifying strategies to strengthen their capacity with the appropriate technical support from regions, global partners and RITAGs. Central to this approach will be rigorously developed business cases for immunization that clearly articulate the justification for support, including anticipated health and economic gains as well as the risks of inaction – not least the human and financial impact of outbreaks. They also need to identify robust approaches to governance and accountability. The risk of corruption must be acknowledged and explicitly addressed – a zero tolerance approach is essential.

Strengthening the basics: Systematic strengthening of national immunization systems will need to recognize the complexity of immunization systems – spanning all areas from forecasting and procurement systems, through logistics, including delivery of vaccines to individuals, information management, and demand stimulation and hesitancy management. Integration with other elements of healthcare delivery will add further complexity, as will the need to embed strategies to ensure greater coverage of disadvantaged and hard-to-reach communities. Such work will require ongoing commitments to quality improvements at all levels in the system – there are no 'silver bullets'.

Addressing issues at the right level: While a future immunization strategy should have a country focus, regions and global initiatives will continue to play key enabling roles. Regions are best placed to develop locally tailored strategies to support countries, can recognize and respond to regional challenges, and can leverage regional assets to support individual countries. At the global level, partners can continue to advocate for immunization and coordinate financial support, undertake market shaping and other globally focused initiatives, and deliver training and other tools to facilitate immunization system strengthening. Within countries, immunization systems may need to incorporate sub-national strategies and mechanisms of devolved accountability.

Tailoring support: Countries vary in the maturity of their national immunization systems. International support for countries to develop their immunization systems should be based on national needs rather than simply measures of national wealth such as gross national income.

Building surveillance bridges: Infectious disease surveillance is central to immunization system function, as well as global health security. More needs to be done to strengthen laboratory capacity for both existing vaccine-preventable diseases and emerging infections, alongside support for community surveillance. More integrated approaches could also extend to national pharmacovigilance activities, to detect adverse events after immunization as well as reactions to other interventions.

R&D – maintaining the pipeline: Encouraging progress in new product development needs to be maintained, recognizing that all the 'quick wins' have likely been achieved and future product development will be challenging. Future vaccine introductions are likely to be more complex than in the past, with vaccines likely to have limited efficacy by themselves and consequently be used in conjunction with other interventions. These will present challenges to regulatory approval, health technology assessment and implementation. Strong links will be needed to ensure that R&D is guided by the needs and constraints of field use, but also that immunization programmes are aware of emerging new technological opportunities. Thought will also need to be given to issues such as financial sustainability of new product development and 'pull-through' to ensure continued investment, particularly for infections predominantly affecting resource-poor settings. Nimble approaches to R&D will be required to reflect rapidly changing epidemiology and emerging infectious disease threats. There is also much scope for research into vaccine scheduling and fractional dosing, as well as studies examining the impact of vaccine introduction on outcomes and disease burdens.

Research evidence: Research will also play a key role in enhancing the quality of national immunization systems, through implementation research, delivery science and operational research. Alongside less formal monitoring and evaluation, these activities will generate evidence to drive continual improvement in national immunization systems. In addition, innovative new approaches will be needed to widen access to services or enhance other aspects of immunization system function, from novel diagnostics to new approaches to demand generation, all of which will need to be rigorously evaluated. Much of this work needs to be led at a country level, emphasizing the importance of building immunization research capacity in low- and middle-income countries.

Making better use of data: Major new opportunities exist to leverage the power of immunization data, particularly to inform programme actions. As well as their value in monitoring and evaluation, national and sub-national data can support more effective central planning and local micro-planning to address coverage gaps. Exploiting the potential of data will require investments in IT infrastructure and data management and analysis, as well as integration with other relevant national ehealth initiatives. Development of programme staff skills and data science capacity at a national level will also be critical. Enhancing the granularity of immunization data collection and data quality will be fundamental to improved planning and decision-making.

Exploiting existing and new opportunities: With no major new vaccines on the immediate horizon, now is the time to focus on strengthening immunization systems and ensuring best use is made of existing vaccines. There is still considerable scope to expand use of vaccines in age groups beyond infants and further extend use of MCV2, PCV, rotavirus vaccine, human papillomavirus (HPV) vaccine, and hepatitis B vaccine (HBV) birth dose. Multiple innovations in vaccine delivery and in controlled temperature chain distribution will open up new opportunities to deliver services to even greater numbers of people, particularly the vulnerable and hard to reach.

Fostering demand and addressing hesitancy: Public attitudes to immunization vary across a spectrum from active support and advocacy to vocal hostility. Stimulation of broad-based public demand for immunization creates resilience to threats like vaccine hesitancy and promotes political accountability at national and local levels to ensure the responsiveness and quality of services. A future immunization strategy must build countries' capacity for community engagement, demand promotion, and trust building – activities that should be fully integrated into national immunization systems. Countries need to be prepared to effectively respond to vaccine-related events that can quickly undermine public trust and disrupt national immunization programmes. Demand-related issues like vaccine hesitancy are complex, and subject to multiple influences, from genuine safety concerns to manipulation of public perceptions for political ends. The need is pressing to better understand the drivers of and barriers to vaccination uptake and to build national capacities to develop and implement tailored strategies to promote demand for immunization services.

Staying close to reality: A future immunization strategy should place people at its heart. The focus should be on people and communities. Future immunization systems need to reflect the realities of healthcare delivery, particularly in low-income settings, where contact with health systems may be rare and an opportunity to achieve multiple health goals. By involving communities in the design, implementation and monitoring of services, such services are likely to be more sustainable, more acceptable and more appropriate to the needs of those that need services the most. A key challenge will be to identify how global, regional and national strategies and principles can be converted into actions that make a real difference to the lives of people across the globe.

Government expenditure on immunization has increased by 130% in the Africa Region since 2010

8. CONCLUSION

More people than ever before benefited from immunization in 2017. Although the world remains off track to reach many of the goals set out in the Global Vaccine Action Plan, these were designed to be ambitious and stretching, and it is important not to lose sight of the great progress that has been made. Even so, the consequences of not achieving global goals have been vividly illustrated with the resurgence of measles and diphtheria and the persistence of poliovirus and maternal and neonatal tetanus.

The final years of the Decade of Vaccines provide us with an opportunity to drive forward immunization in pursuit of the Global Vaccine Action Plan goals. Past successes illustrate what can be achieved by countries prioritizing immunization, producing integrated development plans, and working with national, regional and global partners on their implementation. Despite many challenges, between 2011 and 2017, an additional 20 million children were vaccinated – but we can do even better.

Now is the time to learn the lessons from the Decade of Vaccines to shape a post-2020 strategy that enables the world to sustain its hard-won gains and expand the benefits of immunization to those currently missing out and to older age groups. The next chapter of immunization must also be one of integration, with immunization consolidating its position as a pillar of universal health coverage and primary healthcare, and contributing to the safer, healthier and more prosperous world envisioned in the Sustainable Development Goals.

9. RECOMMENDATIONS

Countries, regions and global immunization partners should commit to developing an integrated post-2020 global immunization strategy:

- A comprehensive review should be undertaken of progress, impact and implementation of the Global Vaccine Action Plan to inform a post-2020 strategy.
- The monitoring and evaluation framework for the Global Vaccine Action Plan should be reviewed to inform the development of a revised framework for a post-2020 strategy.
- A post-2020 strategy should build on the lessons learned during the Decade of Vaccines and draw upon the key themes identified in this 2018 Assessment Report.

Global Vaccine Action Plan priorities, adapted to reflect changing contexts and lessons learned, should drive immunization activities until the end of the Decade of Vaccines:

- A major focus should be tailored country support to build and sustain robust and effective national immunization systems aligned with national plans for achieving universal health coverage.
- A best practice framework should be developed to ensure equitable access to immunization services for migrant, displaced and disadvantaged populations, including those affected by humanitarian emergencies.
- Nurturing individual and community demand for immunization should be given high priority within countries.

The contributions of research to immunization should be enhanced and expanded:

- Vaccine research and development (R&D): Connections between vaccine R&D and implementation communities should be further strengthened to ensure close collaboration in new product design, development and evaluation.
- Immunization systems: More use should be made of implementation, operational and other research to improve the performance of national immunization systems, and to evaluate innovations in service delivery to reach underserved populations.
- Immunization research capacity in low- and middle-income countries should be developed across all these areas.

Every $1
spent on childhood immunization returns
$44 in economic and social benefits

ANNEX 1: SAGE DECADE OF VACCINES WORKING GROUP MEMBERSHIP

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- World Health Organization

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