2016 MIDTERM REVIEW OF THE GLOBAL VACCINE ACTION PLAN

STRATEGIC ADVISORY GROUP OF EXPERTS ON IMMUNIZATION

EXECUTIVE SUMMARY

At the midpoint of the Global Vaccine Action Plan, or GVAP (2012-2020), the Strategic Advisory Group of Experts on Immunization (SAGE) remains gravely concerned that progress toward the goals to eradicate polio, eliminate measles and rubella, eliminate maternal and neonatal tetanus, and increase equitable access to lifesaving vaccines is too slow. Despite improvements in individual countries and a strong global rate of new vaccine introduction, global average immunization coverage has increased by only 1% since 2010.

In 2015, 68 countries fell short of the target to achieve at least 90% national coverage with the third dose of diphtheria-tetanus-pertussis vaccine. Not only that, 26 countries reported no change in coverage levels and 25 countries reported a net decrease in coverage since 2010. The 16 countries that have made measurable progress since 2010 are to be commended for reaching more people, especially vulnerable and marginalized members of society with immunization. Some of the countries with the highest numbers of unvaccinated people have made the most progress, including the Democratic Republic of the Congo, Ethiopia and India, and even though coverage targets have not been achieved in these countries, they are moving forward in the right direction.

The 111 countries that entered the decade with high immunization coverage and sustained it through 2015 are already setting their sights on more aggressive goals, additional vaccines, and more equitable coverage. Immunization programmes in these countries can lead the way by increasing access to other public health interventions and providing a platform for the delivery of preventive health services throughout the life course. Vaccine research and development is progressing rapidly, and an expanding pipeline of new vaccines underscores the need to build health systems that can reliably reach new target age groups.

The members of the SAGE are steadfast and passionate believers in the power of immunization to give individuals and their families a better start in life and to protect people from a growing array of debilitating illnesses. Immunization is one of the world's most effective and cost-effective tools against the threat of emerging diseases and has a powerful impact on social and economic development. Recognizing the role that immunization plays in ensuring good health and the role that good health plays in achieving sustainable development, the SAGE has supported the inclusion of immunization indicators to measure progress toward the Sustainable Development Goals.

The next four years present unprecedented opportunities for countries to leverage the attention and support that immunization receives and apply it for the benefit of people everywhere. Strident efforts on the part of all countries and immunization stakeholders are required to catch up and achieve GVAP goals by 2020.

The SAGE has made nine recommendations which are detailed at the end of this report:

1. Demonstrate stronger leadership and governance of national immunization systems
2. Prioritize immunization system strengthening
3. Secure necessary investments to sustain immunization during polio and Gavi transitions
4. Improve surveillance capacity and data quality and use
5. Enhance accountability mechanisms to monitor implementation of Global and Regional Vaccine Action Plans
6. Achieve elimination targets for maternal and neonatal tetanus, measles, rubella and congenital rubella syndrome
7. Resolve barriers to timely supply of affordable vaccines in humanitarian crisis situations
8. Support vaccine R&D capacity in low- and middle-income countries
9. Accelerate the development and introduction of new vaccines and technologies

TABLE OF CONTENTS

1. PROGRESS ON INDICATORS

Now at the midpoint of GVAP implementation, the SAGE notes that while some progress has been made in individual countries, midpoint targets were missed for polio eradication, neonatal tetanus elimination, measles and rubella elimination and routine immunization coverage. The current pace of progress must change if GVAP goals are to be achieved by 2020.

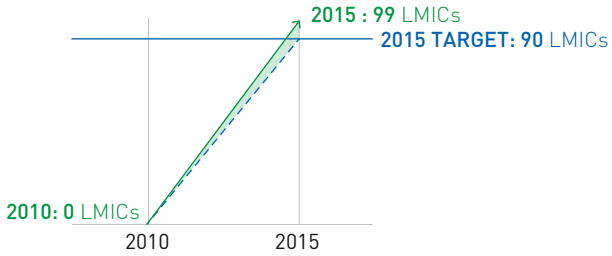
The current pace of global progress must change if GVAP goals are to be achieved by 2020

GVAP TARGETS FOR 2015 WERE MISSED IN ALL BUT ONE CATEGORY

EXCEEDED

VACCINE INTRODUCTION:

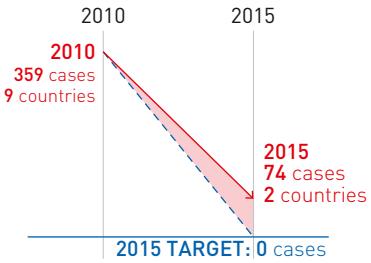
Number of low- or middle-income countries (LMIC) to have introduced one or more new or under-utilized vaccine since 2010



MISSED

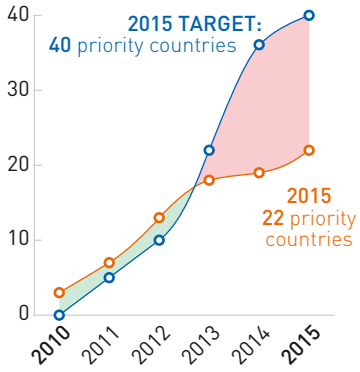
POLIO:

Number of new cases of paralytic poliomyelitis due to wild poliovirus



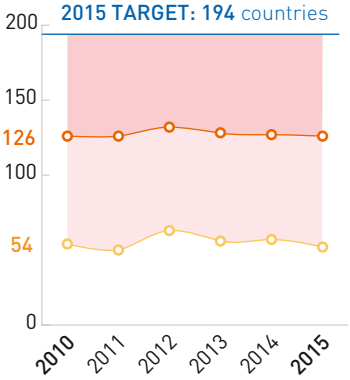
MATERNAL AND NEONATAL TETANUS ELIMINATION:

Number of countries verified for elimination



COVERAGE AND EQUITY:

Number of countries with national vaccination coverage of 90%, with no district's coverage less than 80%

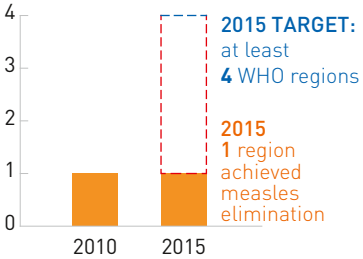


2015
126 Countries achieved 90% national coverage for DTP3

2015
52 Countries achieved 90% national coverage and no districts coverage less than 80% for DTP3

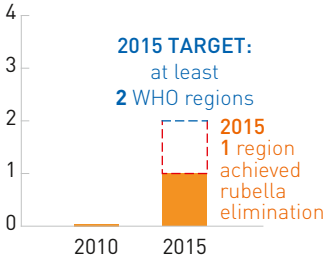
MEASLES:

Number of WHO regions to achieve measles elimination



RUBELLA:

Number of WHO regions verified for rubella and CRS elimination

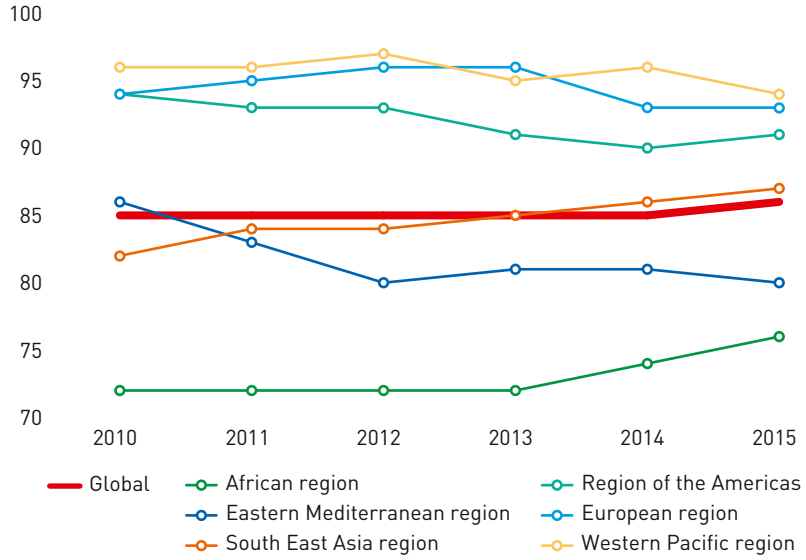


Source: WHO-UNICEF Joint reporting Forms, 2010-2015

IMMUNIZATION COVERAGE AND EQUITY TARGETS

Since 2010, there has been only a marginal overall improvement in the indicator measuring vaccine coverage and equity.[1] While 126 Member States (65%) achieved at least 90% coverage with DTP3 in 2015, most had already achieved this goal before the decade began. Only 15 additional countries have achieved this level of coverage since 2010. Further, a scant 52 Member States (27%) out of 88 with valid district-level data have achieved equity targets of national level coverage of ≥90% and coverage of ≥80% in every district.

COVERAGE WITH DTP3 HAS REMAINED RELATIVELY UNCHANGED SINCE 2010



Source: WHO and UNICEF Estimates for National Immunization Coverage (WUENIC), 2010 – 2015

The overall change in global average coverage with DTP3 was 1% between 2010 and 2015

Among the 68 countries[2] that have not yet achieved national-level coverage of 90% or higher, 16 (8%) have made progress, while 25 countries (13%) report a net decrease in coverage since 2010. Another 26 countries (13%) have seen no net change in DTP3 coverage since 2010. Only one country that started the decade with coverage above 80% reported a net increase in coverage by 2015, underscoring just how difficult it is to increase coverage above 80%. The overall change in global average coverage with DTP3 was 1% (from 85% to 86%) between 2010 and 2015.

Among the countries that are showing progress, India, Ethiopia and the Democratic Republic of the Congo stand out because they are all counted among the twenty countries with the largest numbers of unvaccinated people, and their efforts to increase coverage are making a difference in closing the immunization gap. These efforts need to expand to reduce the socio-economic and geographic inequities that still persist in each of these countries.

Countries with stagnant or decreasing coverage tell a different story. A small subset of countries is struggling to provide reliable immunization services in the face of political instability and emergency situations. Syria, Yemen, and South Sudan are counted among them. The majority of countries with coverage below 90% are failing to meet targets despite relatively stable and predictable environments. Here, factors such as weak health infrastructure, less than optimal governance, and lack of integration leading to missed opportunities for immunization play larger roles.

[1] This indicator counts the number of countries achieving 90% national coverage with the third dose of diphtheria-tetanus-pertussis containing vaccine (DTP3), with all districts achieving coverage greater than or equal to 80%.

[2] South Sudan joined WHO in 2012, therefore is not included in 2010-2015 trends analysis .

DISEASE CONTROL TARGETS

There are three indicators measuring progress toward disease elimination and eradication goals. All three targets were missed in 2015. A disappointing setback in polio eradication was the emergence of several cases of wild poliovirus in Nigeria in 2016, after more than 24 months with no reported cases across the whole African continent. This virus has circulated undetected since 2011 in an area of the country with very limited access to health services, signaling a worrisome chink in the armor for polio surveillance. Progress was made in maternal and neonatal tetanus elimination (MNTE), with 22 countries validated for MNTE since 2010 but 18 countries have yet to achieve this goal. While such progress is positive, it is sluggish; it is the third time a global target has been set and missed for maternal and neonatal tetanus elimination.

It is the third time a global target has been set and missed for maternal and neonatal tetanus elimination

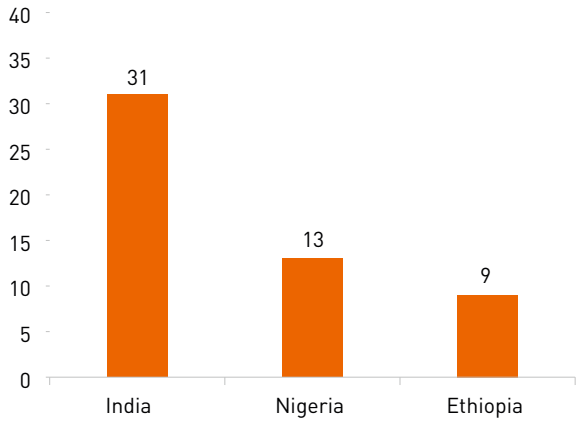
Measles and rubella elimination is also progressing slower than expected. Since 2010, global measles incidence has decreased by 21% from 50 cases per million to 39.3 in 2015, which is substantially higher than the global 2015 target of fewer than five cases per million population. Measles outbreaks have occurred in numerous countries – a result of sub-optimal immunization coverage through both routine services and campaigns, along with increased susceptibility in older age groups. While outbreaks are being reported, the quality of the outbreak data do not always provide the comprehensive information required to take corrective actions. Surveillance for measles remains weak in many countries with low reporting sensitivity, limiting the ability of country managers to use data for programmatic and strategic decision-making. Rubella control lags even further behind, as 45 Member States still have not yet introduced the vaccine and two regions (African and Eastern Mediterranean) have not yet set rubella elimination or control targets. One region (the Americas) successfully eliminated the endemic transmission of rubella and congenital rubella syndrome and was verified in 2015.

The International Expert Committee declared Rubella/Congenital Rubella Syndrome and Measles as eliminated in the region of the Americas respectively in 2015 and 2016

45 Member States have not yet introduced rubella vaccine

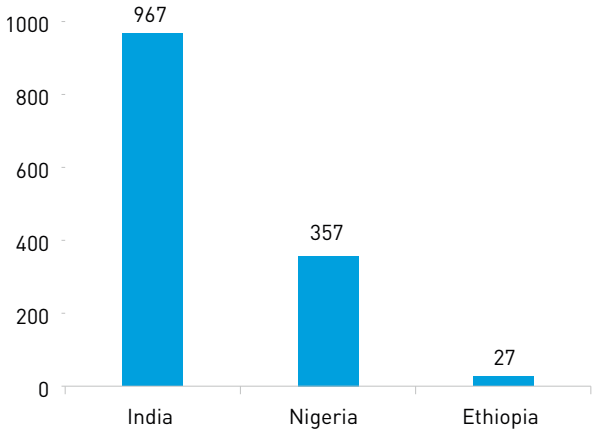
THE POTENTIAL IMPACT OF REDUCED POLIO RESOURCES IN THE THREE COUNTRIES WITH THE HIGHEST MEASLES BURDEN IS DRAMATIC

Contribution (%) to global measles mortality



Source: WHO, Department of Evidence, Information and Research estimates for child causes of death, 2000-2015 (updated 5 February 2016).

Current number of full-time-equivalent polio-funded staff working on measles and rubella in the countries with the highest measles mortality*



Source: Boston Consulting Group study in Afghanistan, Angola, Chad, DR Congo, Ethiopia, India, Nigeria, Pakistan, Somalia, South Sudan for the Global Polio Eradication Initiative, 2015

* The current full-time-equivalent number is calculated using the % of time dedicated to measles and rubella by the total number of polio-funded staff.

NEW VACCINE INTRODUCTION

Since 2010, 99 low- and middle-income countries (73%) have introduced at least one new and under-utilized vaccine (excluding IPV) to their national immunization programme and sustained vaccine use for at least 12 months, making a total of 160 vaccine introductions. Gavi, the Vaccine Alliance has provided support to 64 of these countries. Of the 99 countries that have introduced at least one vaccine, 47 have introduced and sustained more than one vaccine, including 14 upper-middle income countries, 19 lower-middle income countries and 14 low-income countries.

160 vaccine introductions have been made in 99 countries since 2010

RESEARCH AND DEVELOPMENT

Every two years, the SAGE reviews progress against research and development (R&D) goals. These goals include the licensure and launch of a vaccine against one or more major currently non-vaccine preventable diseases and the licensure and launch of at least one platform delivery technology.

In July 2015, the first malaria vaccine to be assessed by a regulatory agency received a positive opinion from the European Medicines Agency (EMA). This step is a pre-requisite for a WHO policy recommendation and licensure for the use of the vaccine in national immunization programmes. A vaccine against dengue has been licensed in multiple countries and at least two other candidate dengue vaccines are in Phase III trials, with several other candidates in earlier clinical development. In November 2016, enrollment will begin for a Phase III clinical trial of an HIV vaccine among South African adults.

TB vaccines have proven extremely difficult to develop, as there is no correlate of protection to guide vaccine design. However, innovative trial designs, new animal models, a new Human Model Consortium and incorporation of novel immunologic approaches and technologies, such as micro-array patches, have breathed new life into TB vaccine R&D and expanded the pipeline.

A new blueprint guiding R&D responses to emergencies has allowed Zika vaccine development to progress at unprecedented speed

Candidate vaccines against other priority diseases, including universal influenza vaccine and vaccines for maternal immunization, such as respiratory syncytial virus (RSV), group B strep, tetanus toxoid and pertussis are moving through preclinical and clinical development.

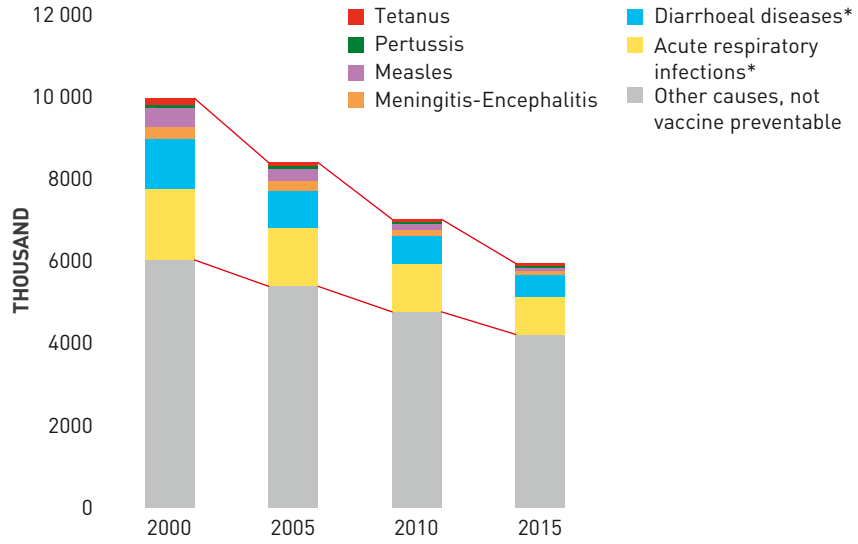
In response to the threat of new emerging pathogens, WHO has developed a blueprint to guide an R&D response to emergencies. The section on vaccines was informed by lessons learnt during the development of Ebola vaccine. Applying this blueprint to Zika vaccine development has allowed R&D to progress at an unprecedented speed.

2. SAGE VIEWPOINT

A bright spot at the midpoint of the GVAP is the rate of new vaccine introduction in low- and middle income countries and the impact this suggests for under-five morbidity and mortality. While modeling studies are not available to quantify the vaccine-attributable decrease in mortality in children under five, the step decline in pneumonia and diarrhoea morbidity and mortality that was measured in a few countries following the introduction of pneumococcal and rotavirus vaccines, respectively, suggests a significant contribution. As long as new vaccine introduction can be expanded further in more countries that continue to have high rates of deaths due to pneumonia and diarrhoea, high and equitable coverage with these vaccines remains a winning strategy for public health impact.

High and equitable coverage with new vaccines remains a winning strategy for public health impact

VACCINES HAVE BEEN KEY CONTRIBUTORS TO THE GLOBAL REDUCTION IN UNDER-FIVE MORTALITY SINCE 2000



Source: WHO, Department of Evidence, Information and Research estimates for child causes of death, 2000-2015 (updated 5 February 2016).

**Note: The reduction in mortality for vaccine-preventable diseases counts the impact of other interventions. Not all diarrhoeal diseases or acute respiratory infections are vaccine-preventable.*

The SAGE is also pleased to note the substantial progress made in vaccine R&D, particularly toward HIV, malaria, dengue, and tuberculosis vaccines.

The rapid progress made in vaccine R&D since 2010 underscores the urgent need to expand clinical trial capacity in low- and middle-income countries, strengthen the ability of NRAs to evaluate and license vaccines and technologies, and begin implementation research for vaccines and platform delivery technologies much earlier in the process.

Progress in vaccine R&D underscores the urgent need to expand clinical trial capacity, strengthen NRAs, and begin implementation research earlier

MAJOR CONCERNS

The good news regarding new and future vaccines, however is shadowed by the unhurried global progress toward achieving other GVAP targets. There are still 19 million un-vaccinated and under-vaccinated children in the world, representing the least privileged members of society: those who are fleeing disaster, marginalized, dispossessed or simply uncounted. Each day that such populations are excluded from the benefits of immunization represents a lost opportunity to build stronger and healthier communities.

The current pace of global progress toward achieving GVAP targets is too slow

Repeatedly missing targets for eradication and elimination goals results in prolonged and more expensive campaigns that ultimately threaten global enthusiasm for such endeavors and undermine community demand for immunization services. Insufficient funding for disease control initiatives, particulary in non-Gavi countries, has stymied efforts to introduce rubella-containing vaccine, conduct high-quality measles campaigns among older age groups, and commit to or achieve national and regional elimination goals. The poor quality of campaigns in many countries has not sufficiently limited the circulation of infectious diseases, resulting in outbreaks that must be managed using resources that might be better spent on routine immunization services.

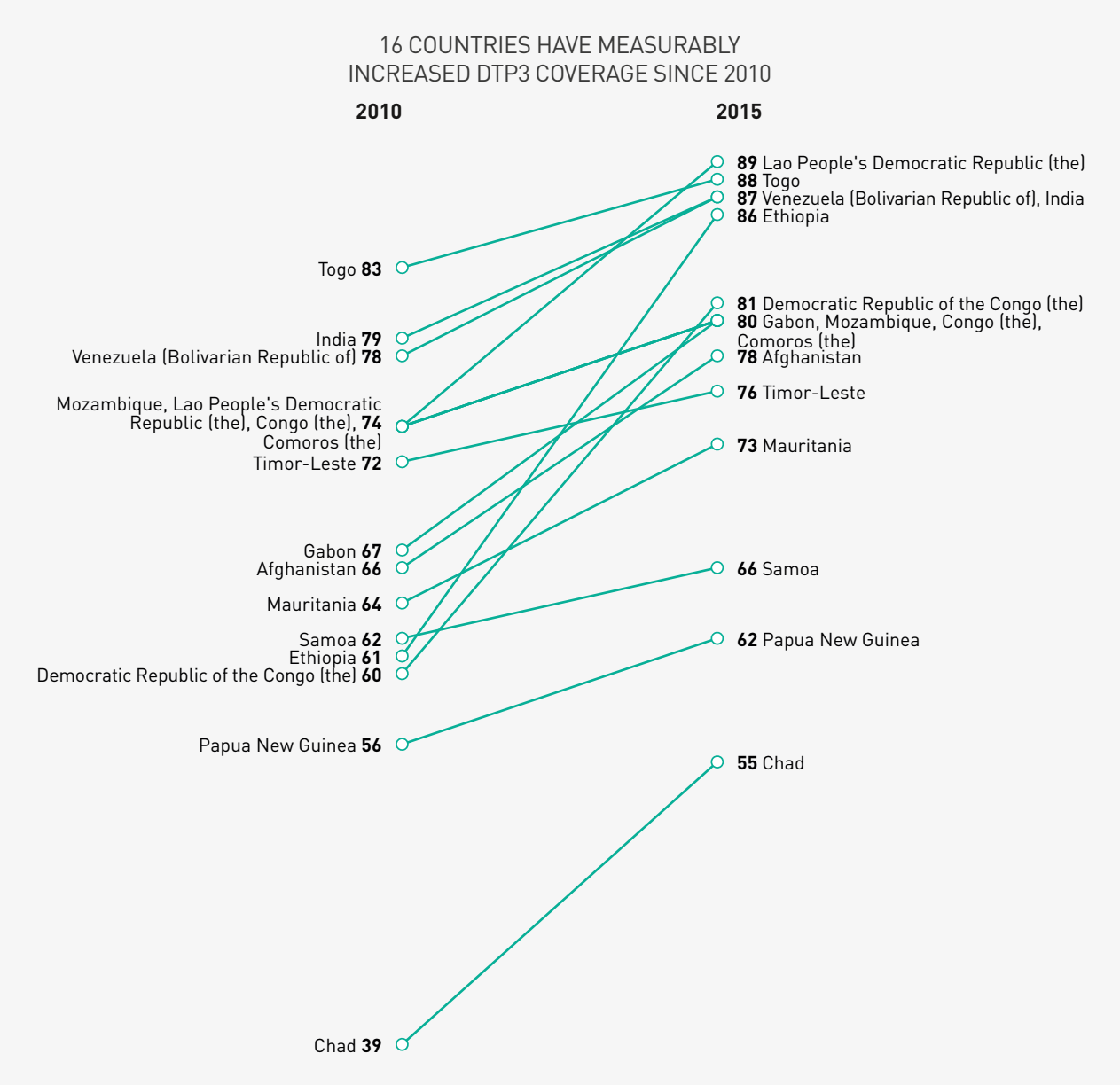
Ultimately, an immunization programme that cannot deliver services to the majority of the population is a signal of a weak health system, one that is less resilient to in the face of emergency situations and the very real threat of global introductions of emerging pathogens like Ebola, Yellow Fever and Zika viruses.

Weak immunization programmes are less resilient in the face of emergencies and less able to manage and recover from the introduction of emerging pathogens

At the midpoint of the GVAP, the SAGE is concerned that more countries haven't embraced the opportunity to strengthen immunization programmes and harness the global energy and enthusiasm that seems to be growing for vaccines. Countries must make more concerted efforts to strive for and reach GVAP goals by 2020, and those countries that have achieved or made forward progress toward achieving GVAP goals must work to sustain those efforts over time.

3. AREAS OF STRENGTH

A deeper look at the countries that improved immunization coverage since 2010 confirms what is already known about what it takes to change immunization programme performance for the better.



Source: WHO and UNICEF Estimates for National Immunization Coverage (WUENIC), 2010-2015

Leadership. There are several outstanding examples of how courageous and committed leadership can change immunization performance for the better. More than 116 Member States have formed independent National Immunization Technical Advisory Groups (NITAGs) to guide decision-making on vaccine introductions, immunization schedules and immunization policies. Uganda and Nepal are among the first countries in their regions to enact immunization laws to mandate vaccination and establish a mechanism whereby donors, individuals and private sector entities can contribute to a national immunization fund. Elected leaders in the Democratic Republic of the Congo have formed a Parliamentarian Network to secure funds and monitor disbursements and activities that have been promised by the government. For the moment, Uganda has not seen progress in national coverage since 2010, however coverage

in Nepal increased from 82% to 91% and coverage in the Democratic Republic of the Congo has increased from 60% to 81% since 2010.

Investment in health systems. Leadership has also been demonstrated in the form of meaningful investments in health systems and health workforces. Ethiopia recently built 16,000 new health centers, purchased 2,000 battery-free solar refrigerators for facilities lacking access to electricity, trained a new cadre of paid health extension workers and established a health development "army" of three million volunteers to facilitate access to immunization throughout the country. Since 2010 when these investments were first made, immunization coverage in Ethiopia has soared from 61% to 86%. Similarly, India has made new investments in health systems, replacing and repairing cold chain equipment, training thousands of Accredited Social Health Activist workers, and using microplanning to support immunization. This and an intensification of services through campaigns resulted in DTP3 coverage jumping from 79% to 87%, meaning two million more children received vaccination services in 2015 than in 2010. The SAGE will be watching with interest to see if this progress can be sustained over time.

Health system investments in Ethiopia have contributed to coverage improvements from 61% in 2010 to 86% in 2015

Dedicated people. The day-to-day work of providing reliable immunization services can be difficult in low-resource environments. Immunization and technical staff face countless frustrations and bottlenecks that they doggedly overcome in a sometimes thankless environment of high pressure and expectations. Too often, health workers are not sufficiently paid or wait months for payment, and the weight of the immunization programme is carried on their shoulders. We commend the civil society organizations, agency staff, volunteers and particularly community-based health workers who risk their lives in fragile states and conflict areas in places like Syria, Yemen and South Sudan to provide immunization services to communities living in those areas. It is thanks to these people that, for example, no less than 41% of the population was immunized in Syria in 2015.

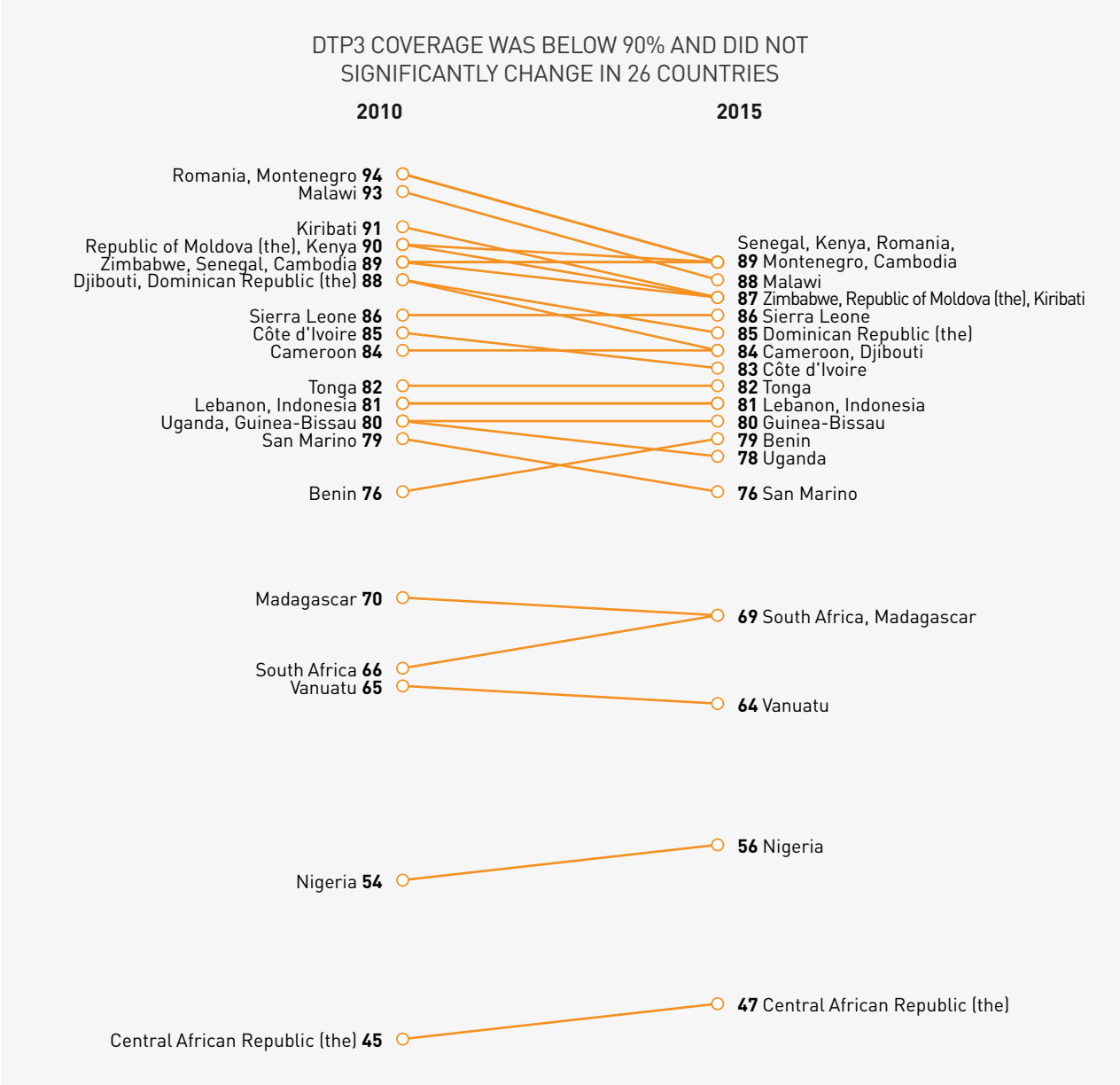
We commend the civil society organizations, agency staff, volunteers, and particularly community-based health workers who risk their lives in fragile states and conflict areas to provide immunization

Known interventions. With three decades of experience to draw from, immunization staff at all levels have developed an arsenal of tools and strategies for achieving high performance in almost any environment. Applying the Reaching Every Community strategy in 22 districts in Chad, for example, has paid off, contributing to hard-won coverage gains from 39% to 55%. Progress in Nigeria is notable as well, particularly given the size and complexity of the country. Government and partner support for the immunization programme has grown, and the response to recent polio cases has been swift. A lot of effort has been put toward improving primary health care in recent years resulting in coverage gains from 49% to 56% since 2014. More of this effort is needed to bridge the divide between current and desired coverage, but the trend is in the right direction.

Accountability. Global, regional, and national commitments to immunization, plans, budgets and activities are only hollow promises when no one is accountable for their completion. At the global level, the GVAP has been a positive mechanism to hold WHO Member States, UN agencies, and other global immunization partners to their word and take notice when progress is off track. The recent Ministerial Conference for Immunization in Africa, attended by Ministers of Health from 70 Member States in the African and East Mediterranean regions, is a good example of leveraging Regional Vaccine Action Plans to hold Ministers of Health to account for overseeing progress along an agreed set of indicators. Country-level accountability mechanisms have been harnessed in several countries, using civil society organizations, legal frameworks and National Immunization Technical Advisory Groups (NITAGs) to oversee the implementation of immunization plans and track progress toward agreed targets.

4. AREAS OF VULNERABILITY

Although each country is unique, there are several common factors that inhibit progress and limit the quality and outcomes of immunization programmes.



Source: WHO and UNICEF Estimates for National Immunization Coverage (WUENIC), 2010-2015

Low commitment. The most common and corrosive force found within countries with stagnant or declining coverage is a general lack of interest and commitment to immunization at all levels. In countries with low commitment or apathetic leadership, immunization programmes suffer from lack of sufficient and/or reliable funds, inadequate human resource capacity and low motivation to address chronic bottlenecks that hinder performance. While vaccine affordability remains a legitimate concern for a subset of countries, it does not always excuse a lack of domestic investment in immunization programmes. Domestic investment in immunization services must increase even further, especially in countries transitioning from Gavi support. This investment is worthwhile and provides ample return in the form of lower long-term healthcare costs and higher proportions of the population able to contribute to

Domestic investment in immunization services must increase even further, especially in countries transitioning from Gavi support

community vitality and economic viability. Improving coverage with the vaccines currently in the schedule is the most economically sound strategy available to countries to ensure that when newer, more expensive vaccines are introduced, they have a powerful impact on health and the economy.

Inaccessibility and weak surveillance. Physical or political inaccessibility is another obstacle facing immunization programmes. Whether a community is inaccessible because of a lack of trust, lack of roads or lack of supplies, unimmunized pockets of the population should give countries cause for concern. Surveillance is especially important in these areas, as diseases can circulate and spread to other areas. The recent polio resurgence in Nigeria is a sobering example of the consequences that can arise when populations are out of reach of both immunization and surveillance systems.

Some countries with decentralized health systems have experienced five or more years of prolonged confusion over roles and responsibilities within the immunization programme

Poor governance. Poor government oversight has resulted in very costly declines in immunization performance in several countries. In a handful of countries, procurement issues have resulted in persistent stockouts, such that families no longer seek or expect immunization services from their local health posts. Not surprisingly, these issues demotivate health staff and take a toll on the quality of services. Some countries with decentralized health systems have experienced five or more years of prolonged confusion over roles and responsibilities within the immunization programme, with inadequate accountability mechanisms and oversight from national and district levels. When this happens, district level funding for immunization can vary widely with almost no transparency into how resources are prioritized, making it impossible to orchestrate immunization improvements across districts.

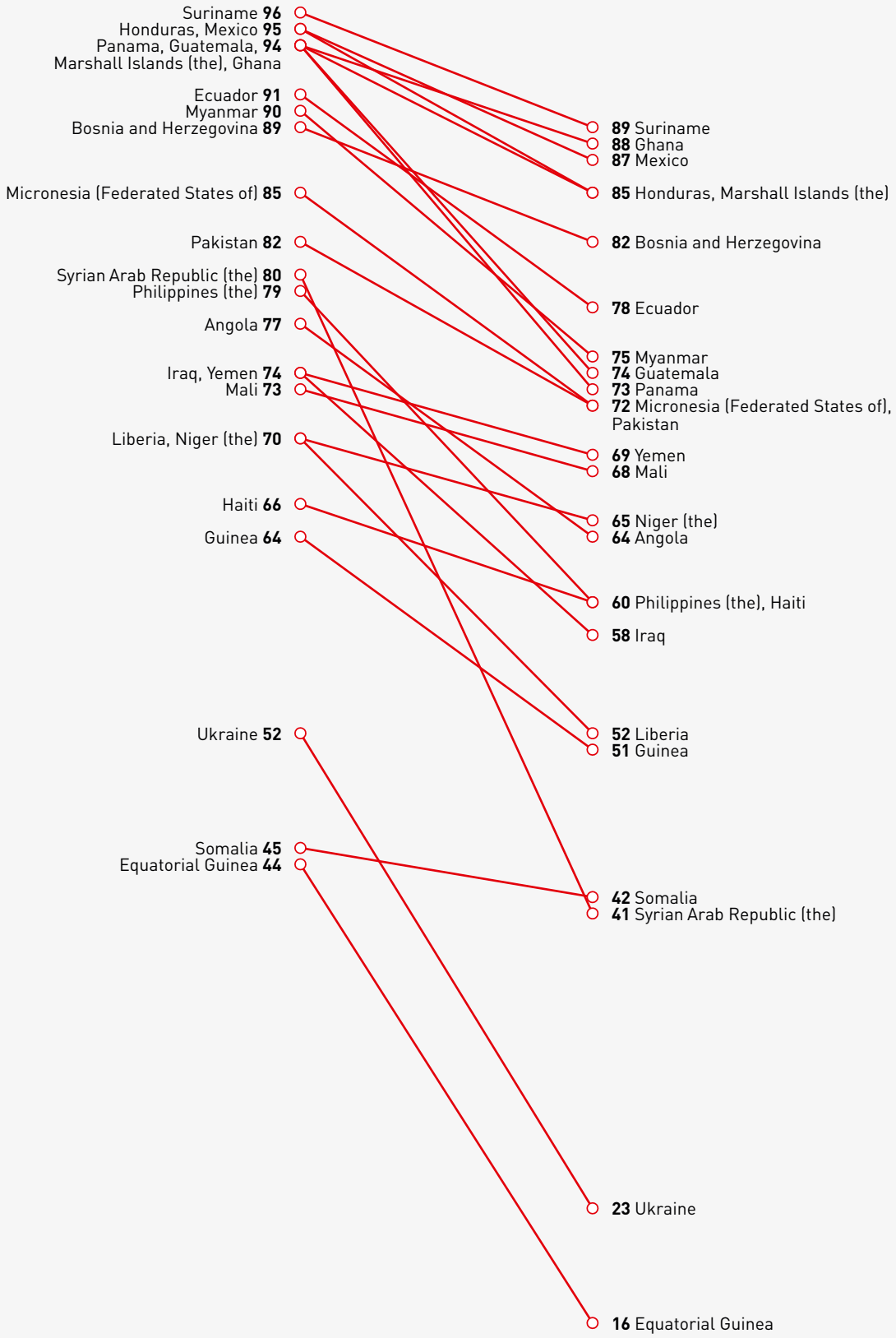
Outdated data culture. The SAGE has raised the issue of poor quality data each year since writing GVAP assessment reports. The lack of reliable data and the failure to use data make decisions at all levels of government is pervasive and troubling. Few countries have a method of collecting immunization data from the private sector. Similarly, few countries have the ability to analyze data to locate unimmunized pockets. Even coverage data can vary widely between administrative reports and surveys, making it very difficult to know how well or poorly programmes are doing, and what to prioritize next. After improving the accuracy of immunization data collected in Mexico, for example, the country reported coverage levels almost 10 percentage points lower than previous years. The SAGE commends the Mexican government for this work because it has succeeded in making under- and unimmunized populations visible to the health system. As countries reach higher levels of coverage, their data will need to become more granular and specific. District level coverage is now requested in WHO-UNICEF Joint Reporting Forms, but the availability and quality of that data remains deficient.

As countries reach higher levels of coverage, their data will need to become more granular and specific

Disconnect. There is a persistent disconnect between immunization and the broader health system agenda. Immunization stakeholders are underrepresented in Universal Health Care discussions, leaving immunization priorities overlooked and opportunities lost to leverage immunization for the benefit of other health programmes. Disconnect also exists between global, regional and country bodies, making it difficult to communicate needs and coalesce on desired outcomes. Despite a recommendation for Regional Committees to oversee implementation of Regional Vaccine Action Plans, it appears that very few Regional Committees are tracking progress and holding countries to account. At the country level, a surprising lack of awareness of the GVAP persists in many places. Areas of disconnect represent major missed opportunities for better collaboration and synergies both within immunization and across health disciplines.

There is a persistent disconnect between immunization and the broader health system agenda

DTP3 COVERAGE DECLINED BETWEEN
2010 AND 2015 IN 25 COUNTRIES



Source: WHO and UNICEF Estimates for National Immunization Coverage (WUENIC), 2010-2015

Conflicts and emergencies. Conflicts and emergencies continue to be a concern, not just for communities living in fragile areas, but also for regions that are affected by large influxes of migrants and refugees. At the moment, host countries are required to locate, enumerate and vaccinate large populations that are either passing through or permanently relocating to the area. While some countries are making valiant efforts to manage the influx, others are quickly overwhelmed by the increased burden and cost.

Outbreaks. Disruptive and expensive outbreaks of vaccine-preventable diseases drain immunization resources and highlight inadequacies in both routine and supplemental immunization services. In 2015, large yellow fever, measles, and cholera outbreaks occurred in Africa, posing major challenges to immunization programmes in affected countries. Learning to manage outbreaks and simultaneously maintain immunization services will be key to building more resilient health systems that can withstand the strains of outbreaks and emerging diseases.

At the moment, host countries are required to locate, enumerate and vaccinate large populations that are either passing through or permanently relocating to the area

5. THREATS TO FUTURE PROGRESS

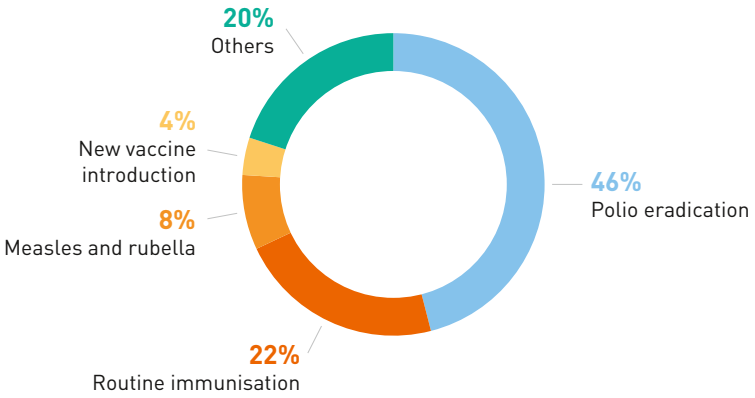
Looking ahead to the next four years, there are some key issues that pose a real threat to our ability to achieve GVAP goals and protect more lives through immunization.

Transitions. Polio and Gavi transition planning are underway, and planners are grappling with the consequences, especially for sustaining immunization coverage and introducing future vaccines. Polio-funded staff and resources are regularly used to support new vaccine introduction planning, disease surveillance activities, routine immunization services and outbreak response. In DRC, for example, polio staff were instrumental in the country's rapid response to a recent yellow fever outbreak. Polio staff were also used in Nigeria to contain the spread of Ebola. Nigeria has begun the Gavi transition process at a time when immunization coverage is still weak. Having introduced very few new and under-utilized vaccines, Nigeria is in a difficult position to achieve the GVAP goals without further Gavi support.

Without polio-funded staff, equipment, and surveillance systems, immunization programmes will be left with critical gaps in human resources and other assets, which could greatly inhibit progress toward and sustainability of GVAP goals.

Without Gavi support and Polio staff, equipment, and surveillance systems, immunization programmes will be left with critical gaps in human resources and other assets, which could greatly inhibit progress toward and sustainability of GVAP goals

POLIO STAFF SPEND MORE THAN HALF THEIR TIME SUPPORTING OTHER IMMUNIZATION AND HEALTH SERVICES



Source: Boston Consulting Group study in Afghanistan, Angola, Chad, DR Congo, Ethiopia, India, Nigeria, Pakistan, Somalia, South Sudan for the Global Polio Eradication Initiative, 2015

6. CAUSE FOR HOPE

Despite legitimate concerns, the SAGE sees many reasons to be hopeful that immunization will provide the cornerstone for health programmes around the world for decades to come.

Polio endgame. The world is on the cusp of polio eradication and can achieve it by applying what is already known to work and maintaining focus. Achieving polio eradication is validation that the global community can come together to achieve a common goal. The switch from trivalent OPV to bivalent OPV occurred across the globe within a fortnight, and this with the successful phased introduction of IPV, demonstrates the power of political will and the strength of good governance. If this can be achieved even in countries where systems are weak, then similarly immunization coverage can also be improved.

Some countries are taking the power of immunization to heart and are reaping the benefits. They show us that achieving the GVAP is possible and that the impact is worth the investment and commitment

Success stories. Some countries are taking the power of immunization to heart and are reaping the benefits. They show us that achieving the GVAP is possible and that the impact is worth the investment and commitment. 17 countries made greater than 10% gains in coverage between 2010 and 2015 including highly populated countries like the Democratic Republic of Congo, Ethiopia and India. Still others, like Mexico and Uganda, took risks to change systems and improve outcomes for the better even if the payoff is still to come. Their stories offer lessons, new ideas and proven strategies for improving performance in different environments.

Return on investment. As reported in a recent article in Health Affairs, immunization with ten common antigens yields a 16:1 net return on investment in low- and middle-income countries during the Decade of Vaccines (2011 – 2020).[3] Factoring the value that people place on living longer and healthier lives, the return almost triples. Few other health intervention are as effective at minimizing the impacts of morbidity and mortality and ensuring good health and well-being for families everywhere.

Ripple effect. Immunization is a critical component of the health system without which universal health care cannot be realized. It is often a child's first contact with the health system and a potential platform for integrated preventive care from infancy through adulthood. The SAGE recently recommended using the Composite Coverage Index[4] to measure integration of health services. This indicator will be used to identify missed opportunities across four platforms of health services: immunization, family planning, maternal/newborn care, and case management of a sick child. The indicator already shows that immunization is an underused platform for delivering other critical health services along the life course.

Immunization is an underused platform that can be leveraged to deliver other critical health services along the life course

Unlocking further potential. Research and development efforts are accelerating the discovery and testing of an expanded portfolio of vaccine candidates against malaria, HIV, tuberculosis, influenza and RSV, among others. Platform delivery technologies are also being developed to make immunization easier to safely store, transport and deliver. These technologies, tested, licensed and deployed at scale will have a powerful impact on health and well-being around the world.

[3] Ozawa S, et al. Return on Investment from Childhood Immunization in Low- and Middle-Income Countries, 2011-20. Health Affairs 35: 199-207, No. 2, Feb 2016. Available from: URL: http://dx.doi.org/10.1377/hlthaff.2015.1086

[4] Composite Coverage Index: http://www.countdown2015mnch.org/about-countdown/countdown-data

7. WHY IMMUNIZATION MATTERS NOW MORE THAN EVER

Individuals. Immunization has proven potential to improve the health and well-being of individuals and family units, in all their forms. Vaccines are now available throughout the life course, protecting against some of the most common causes of death for children under five as well as for diseases that come later in life, including two forms of cancer (liver and cervical cancer).

Communities. As populations become increasingly urbanized and as conflicts and emergencies result in large population migrations, immunization programmes with high and equitable coverage have great potential to protect the world's most vulnerable from illness, disability and death.

Health systems. Immunization is a core component of Universal Health Care. It provides a foundation of infrastructure and staff, systems and tools that can expand the reach of all preventive services. At a time when health systems are under pressure, opportunities for the integration of immunization services must be actively sought. Immunization is a fundamental strategy to achieve other health priorities, from controlling viral hepatitis, to curbing antimicrobial resistance, to providing a platform for adolescent health and improving antenatal and newborn care.

Health security. Now more than ever we need health systems that are resilient and able to withstand—and even facilitate the control of—emerging diseases, outbreaks and other threats to health security. Immunization systems that are strong and resilient can be used to manage threats to health security and can more easily recover from such threats.

Sustainable development. Immunization is a key driver of sustainable development, enabling other development priorities such as education and economic development to take hold.

Immunization is a fundamental strategy to achieve other health priorities, from controlling viral hepatitis, to curbing antimicrobial resistance, to providing a platform for adolescent health and improving antenatal and newborn care

8. SAGE RECOMMENDATIONS

Four years ago at the World Health Assembly, all 194 Members States agreed to the goals of the Global Vaccine Action Plan (GVAP). These goals give focus and urgency to the Decade of Vaccines; their achievement will have a resounding impact on health. Not only do strong immunization programmes prevent disease, they facilitate compliance with international health regulations; contribute to the control of anti-microbial resistance; prevent outbreaks and provide an avenue for outbreak response; and contribute to sustainable development.

While the GVAP goals are ambitious, many countries, including some of the most resource-constrained, have capitalized on the health and economic benefits of vaccines and shown that achieving the GVAP goals within the Decade of Vaccines is not only possible, but necessary

THE SAGE RECOMMENDS THAT MEMBER STATES:

1. **Demonstrate stronger leadership and governance of national immunization systems.**
    a) Ministers at all levels should be strong immunization advocates within their countries and regions. These high-level officials should be able to convey the high return on investment, the urgency and value of investing more in and sustaining immunization programmes as an integral part of government-supported Universal Health Coverage packages.
    b) Governments are encouraged to enact laws that guarantee access to immunization, establish National Immunization Technical Advisory Groups (NITAGs) or equivalent groups, ensure that sufficient budgets are allocated to immunization each year and create mechanisms to monitor and efficiently manage funds at all levels (including those from the private sector).
    c) National leaders must take courageous decisions to upgrade systems, protocols and policies that are necessary to achieve and sustain high immunization coverage. Such upgrades might require redesigning supply chains, information systems and procurement policies, and reassessing roles and responsibilities in case the government decides to implement the decentralization of the health system.
    d) National immunization programme managers should report each year to their NITAGs or equivalent groups on progress made, lessons learnt and remaining challenges toward implementing National Immunization Plans and show how these plans are aligned to Regional and Global Vaccine Action Plan goals.

2. **Prioritize immunization system strengthening.**
    a) Countries should expand immunization services beyond infants and children to the whole life course, and determine the most effective and efficient means of reaching other age groups within integrated health service provision. New platforms are urgently needed to reach people during the second-year-of-life, childhood, adolescence, pregnancy, and into later adulthood.
    b) The 34 countries with DTP3 national coverage levels below 80% should accelerate the implementation of proven interventions to strengthen immunization systems as part of integrated health services. Countries, with advice from the NITAGs or equivalent, should identify and implement priority interventions, including human resource development, increase of domestic funding for immunization and improved quality and use of data.

3. **Secure necessary investments to sustain immunization during polio and Gavi transitions.**

   a) All countries should mitigate any risk to sustaining effective immunization programmes when polio funding decreases. Countries with large numbers of staff and resources issued from the Global Polio Eradication Initiative are requested to describe, in their polio transition plan, how they propose to maintain and fund critical immunization, laboratory and surveillance activities that are currently supported with polio funding and staff.

   b) In all countries transitioning from Gavi support, national and global immunization partners must advocate strongly and persistently for increased domestic financing to sustain immunization gains over time.

   c) Immunization donors must also look beyond their investments in Gavi to ensure that Gavi-transitioning and self-supporting countries as well as countries facing large decreases in polio funding have the necessary capacity, tools and resources to sustain immunization over the long term.

4. **Improve surveillance capacity and data quality and use.**

   a) All countries should strengthen and sustain their surveillance capacity by investing in disease detection and notification systems, routine analysis and data reporting systems, stronger laboratory capacity; establishing a clear process for investigating and confirming cases of vaccine preventable diseases; and responding to and preventing outbreaks.

   b) Decision-makers at all levels of the immunization programme are requested to use up-to-date data (i.e., disease surveillance, coverage, and programme delivery data) to guide programmatic and strategic decisions that reduce disease and protect at-risk populations.

THE SAGE RECOMMENDS THAT IMMUNIZATION PARTNERS:

5. **Enhance accountability mechanisms to monitor implementation of Global and Regional Vaccine Action Plans.**

   a) The leaders of GVAP secretariat agencies and global immunization partners should advocate forcefully and consistently in national and international fora for the urgency and value of accelerating the pace of global progress toward achieving the GVAP goals by 2020.

   b) WHO Regional Directors should make sure the progress towards the Global and Regional Vaccine Actions Plans is reviewed annually at Regional Committee meetings as requested in the WHA resolution WHA65.17. Reports prepared at the country level to review and discuss the progress made should be the basis of the discussion.

   c) Civil society organizations should describe how their work maps against different national immunization plans in their 2017 GVAP report, so that the geographic and programmatic scope of their work is more visible. Where possible, CSOs should also measure and share the impact of their work.

6. **Achieve elimination targets for maternal and neonatal tetanus, measles, rubella and congenital rubella syndrome.**

   The Maternal and Neonatal Tetanus and Measles and Rubella Initiatives are each requested to develop an investment case that specifies the additional funding required to achieve and sustain elimination targets in routine immunization programmes and use

the investment case to solicit necessary support from donors and national governments by the end of July, 2017.

7. **Resolve barriers to timely supply of affordable vaccines in humanitarian crisis situations.**

   International agencies, donors, vaccine manufacturers and national governments must work together to alleviate the financial burden placed on countries to buy and deliver vaccines for displaced populations at high risk of vaccine-preventable diseases and ensure a timely supply of affordable vaccines in humanitarian crisis situations.

THE SAGE RECOMMENDS THAT VACCINE RESEARCH AND DEVELOPMENT PARTNERS:

8. **Support vaccine R&D capacity in low- and middle-income countries.**

   a) R&D partners must continue supporting the expansion of regulatory capacity and clinical trial capacity by building upon models like the African Vaccine Regulatory Forum and the Developing Country Vaccine Regulators' Network, accelerating regulatory pathways for vaccines in emergency settings, and insisting on compliance with the existing WHO position to register clinical trials and report results in a timely manner.

   b) WHO and the Product Development for Vaccines Advisory Committee (PDVAC) should continue developing global consensus-based strategic goals and prioritizing R&D for vaccines and delivery technologies that address unmet needs in low- and middle-income countries.

   c) Researchers should support the development of high-quality, standardised animal models, standardized assays and human challenge models to streamline product development and provide better-quality information for product advancement decisions.

9. **Accelerate the development and introduction of new vaccines and technologies.**

   a) Researchers and investigators, worldwide, should accelerate the development of priority new vaccines and technologies from R&D to full-scale use.

   b) Implementation research must occur at the earliest possible stage of the clinical development process to reduce the delay between market authorization, financing and implementation of vaccines activities.

ANNEX 1: SAGE DECADE OF VACCINES WORKING GROUP MEMBERSHIP

SAGE MEMBERS

- Narendra Arora (Chair of the Working Group), Executive director, International Clinical Epidemiology Network, India (SAGE Member from 2010 – 2016)
- Yagob Yousef Al-Mazrou, Secretary General, Health Services Council of the Kingdom of Saudi Arabia, Saudi Arabia
- Alejandro Cravioto, Independent Consultant, Mexico

EXPERTS

- 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 Research Unit, 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)
- Oleru Huda Abason, Member of Parliament, Parliament of Uganda
- Jon Kim Andrus, Executive Vice President and Director of Vaccine Advocacy and Education, Sabin Vaccine Institute, Washington, DC, USA
- Susan Elden, Health Adviser, The Department for International Development (DFID) London, UK
- 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 States National Institute of Allergy and Infectious Diseases
- United Nations Children's Fund
- World Health Organization

ANNEX 2: SAGE MEMBERSHIP

- Jon Abramson (Chair of SAGE), Chair, Wake Forest University School of Medicine, Department of Pediatrics, USA
- Yagob Yousef Al-Mazrou, Secretary General, Health Services Council of the Kingdom of Saudi Arabia, Saudi Arabia
- Alejandro Cravioto, Independent Consultant, Mexico
- Ilesh Jani, Director General, Instituto Nacional de Saúde (National Institute for Health), Mozambique
- Jaleela Jawad, Head of Immunization, Public Health Directorate, Ministry of Health, Bahrain
- Kari Johansen, Expert Vaccine Preventable Diseases, European Centre for Disease Prevention and Control (ECDC), Sweden
- Terry Nolan, Head, Melbourne School of Population and Global Health, The University of Melbourne, Australia
- Kate O'Brien, Professor, International Health, Johns Hopkins Bloomberg School of Public Health, United States of America
- Andrew J. Pollard, Professor of Paediatric, Infection and Immunity University of Oxford, United Kingdom
- Firdausi Qadri, Director, Infectious Diseases Division, Head and Senior Scientist, Mucosal Immunlology & Vaccinology Laboratory, icddr,b, Dhaka, Bangladesh
- Claire-Anne Siegrist, Head, WHO Collaborating Centre for Vaccine Immunology, University Hospital of Geneva, Switzerland
- Piyanit Tharmaphornpilas, Senior Medical Advisor, Disease Control, Ministry of Health, Thailand
- Nikki Turner, Associate Professor and 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 Shey Wiysonge, Professor and Deputy Director, Centre for Evidence-based Health Care, Stellenbosch University, South Africa