

2014  
ASSESSMENT  
REPORT OF THE  
GLOBAL VACCINE  
ACTION PLAN

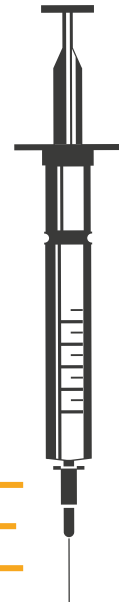
STRATEGIC  
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EXPERTS ON  
IMMUNIZATION





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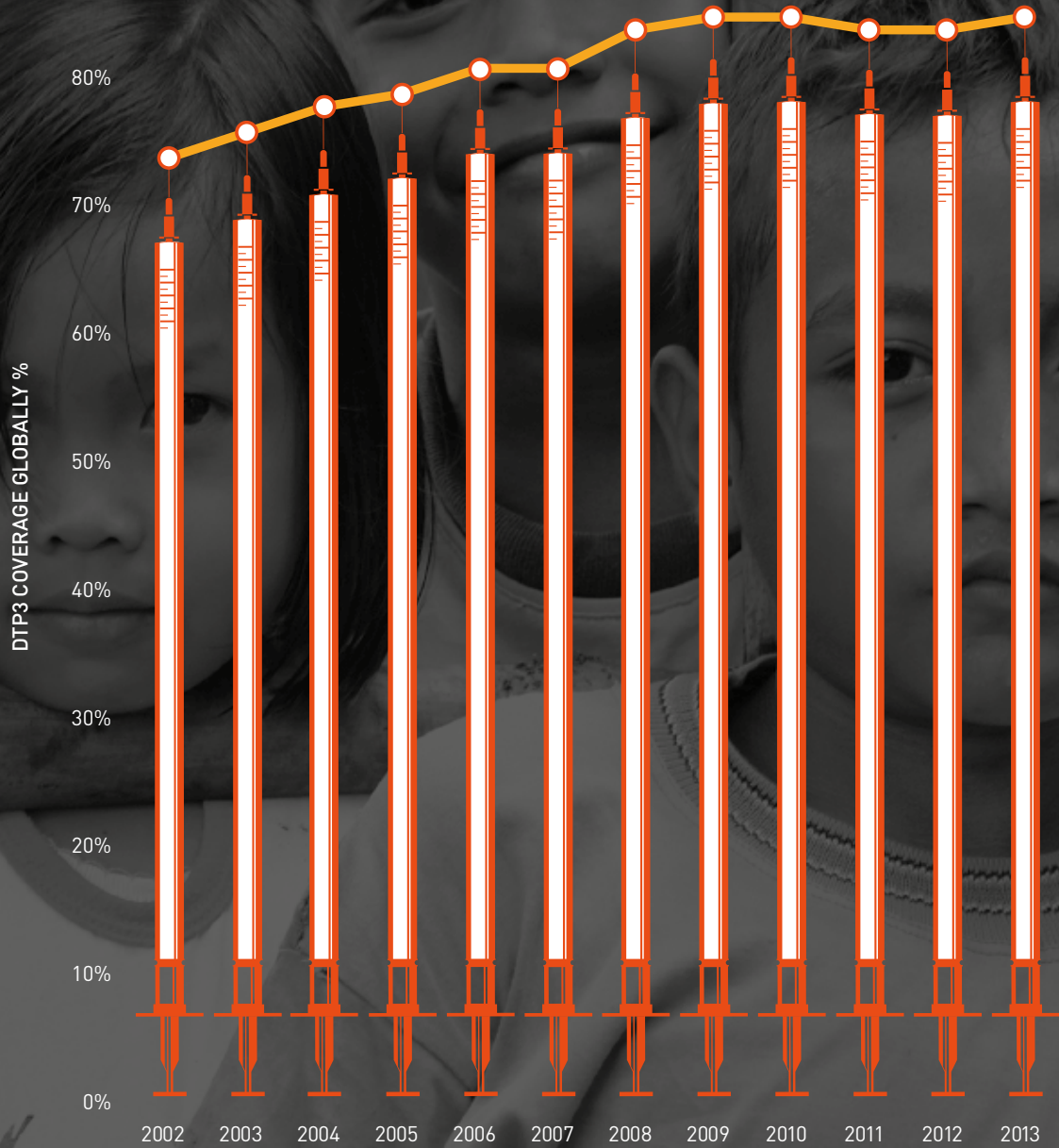
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# A TOUGH QUESTION

GLOBAL VACCINE ACTION PLAN STARTS...

...WHAT HAS CHANGED?



## EXECUTIVE SUMMARY

The Global Vaccine Action Plan has two great ambitions. First, to deliver vaccination to all - because 1.5 million children still die every year of diseases that can be prevented by the vaccines that humankind has developed. Second, to unleash vaccines' vast future potential - because their impressive history is just the foundation stone of greater achievements to come.

With these two great ambitions, the Global Vaccine Action Plan aims to make 2011-2020 the 'Decade of Vaccines'. This report provides an objective assessment of its progress to date.

### IN SAGE'S ASSESSMENT, PROGRESS IS FAR OFF TRACK.

The Global Vaccine Action Plan set six key immunization targets with deadlines at the end of 2014 or 2015. Just one of these six is on track to be achieved. Some have been missed multiple times before. The targets each relate to different vaccines and diseases, but common threads run throughout: failure to extend vaccination services to people who cannot currently access them at all, and failure to strengthen the healthcare system so that all doses of vaccine are reliably provided.

There is some reason for hope. There has been success in introducing new vaccines, and positive achievements in some countries. Major change is possible. The Global Vaccine Action Plan was created to end the inequity in vaccination worldwide, and hence to save millions of lives. This need remains as important and urgent as ever. It is not acceptable that the plan is failing to deliver at the scale that is required.

This report establishes five areas for priority action:

- Three years after its start date, implementation of the Global Vaccine Action Plan is patchy and slow. All countries and organizations that have committed to this endeavour should re-examine the level and nature of their contributions, and urgently make the improvements necessary to achieve results.
- Poor quality and use of data is substantially impeding programme management and improvement.
- The affordability and supply of vaccines need to be urgently examined. Each may be causing a significant problem for a large number of countries, and the current lack of proper information hinders understanding and corrective action.
- Basic failures of integration mean that healthcare workers are repeatedly missing easy opportunities to offer vaccinations when people attend clinics with other problems.
- Vaccine delivery is impeded by disruptive situations, including war and major disease outbreaks (such as Ebola, currently). Such situations will always exist. Vaccines must be delivered despite them.

The SAGE recommends that countries, their technical partner agencies and donors address this report and its recommendations with the greatest possible urgency.



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## THE GLOBAL VACCINE ACTION PLAN IS VITAL

Vaccines are remarkable. They protect people from diseases that otherwise scar, kill and maim. They prevent an estimated 2 to 3 million deaths a year<sup>1</sup>. They are what we seek when a new disease appears. Relative to their great benefit, their cost is small.

### **Vaccines have an impressive history and an exciting future....**

Widespread vaccination was one of the great 20th century public health revolutions, and their future holds greater promise still. Amidst increasing focus on the growing burden of non-communicable disease, the importance of communicable disease and of vaccines must not be forgotten. In 2014, the World Health Organization has declared two Public Health Emergencies of International Concern – the Ebola crisis in West Africa, and the international spread of poliovirus. Both are communicable diseases. Polio is vaccine-preventable and Ebola may soon become so. Vaccination will make an important contribution to the health-related Sustainable Development Goal. By keeping deadly and mutilating communicable diseases in check, vaccines are – and will remain – essential to maintaining and expanding health gains. They can be ‘game changing’ in tackling future outbreaks and epidemics. Vaccines can already prevent some cancers that are caused by viruses. They will increasingly be able to prevent non-communicable diseases, and to benefit individuals of all ages. For all of these reasons, it is important that the future potential of vaccines be unleashed. This is one of the great ambitions expressed by the Global Vaccine Action Plan.

### **...but the most pressing need is to get them to everybody**

Vaccines’ future is exciting, but the biggest need is in the present. According to the most recent WHO estimate, 1.5 million children die every year of diseases that could be readily prevented by vaccines that already exist<sup>2</sup>. This represents gross inequity. A small proportion of the world’s children simply do not receive the basic, cheap, life-protecting vaccines that parents elsewhere take for granted. Other children receive some doses, but dysfunctions in the healthcare system mean that they do not reliably receive all of the doses that they should. There is a pressing need to improve the reach and reliability of vaccine delivery, so that they properly protect all people.

To address these needs, the Global Vaccine Action Plan has two vital ambitions. First, to bolster the reach and reliability of vaccine delivery, so that all people reap the great benefits of vaccination. Second, to realize vaccines’ future potential. In setting these two great ambitions, the Global Vaccine Action Plan aims to make 2011-2020 the ‘Decade of Vaccines’.

### **This report provides an objective assessment of progress.**

It is produced by the Decade of Vaccines Working Group of the Strategic Advisory Group of Experts on Immunization (SAGE), based on analysis and deliberations throughout the year. This report makes recommendations to countries, which have primary responsibility for delivering the Global Vaccine Action Plan. It also makes recommendations to the countries’ technical partner agencies. A detailed Global Vaccine Action Plan Secretariat Report informed the Working Group’s deliberations. This covers every indicator in the Global Vaccine Action Plan monitoring and evaluation/accountability framework. This Secretariat Report is available online, along with detailed country-specific data for each of the major indicators described in this report<sup>3</sup>.

<sup>1</sup><http://www.who.int/topics/immunization/en/>

<sup>2</sup>[www.who.int/immunization/monitoring\\_surveillance/burden/estimates/en/](http://www.who.int/immunization/monitoring_surveillance/burden/estimates/en/) (estimates from 2008)

<sup>3</sup>GVAP Secretariat Report and country-specific data available at: [www.who.int/immunization/global\\_vaccine\\_action\\_plan/en/](http://www.who.int/immunization/global_vaccine_action_plan/en/)

### IN BRIEF

Global Vaccine Action Plan’s two great ambitions:

(1) Vaccination for all – because 1.5 million children still die of vaccine-preventable diseases

(2) Unleash vaccines’ vast future potential

## VACCINATION FOR ALL

### PROGRESS FAR OFF TRACK

The Global Vaccine Action Plan envisaged a world in which everybody enjoys life free from vaccine-preventable diseases. It wants to extend the full benefits of vaccination to all people, regardless of where they are born, who they are, or where they live.

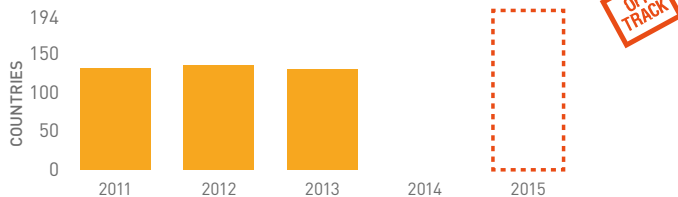
This progress is best measured using the six immunization-specific targets of the Global Vaccine Action Plan with deadlines that are fast approaching:

- **DTP3:** National vaccination coverage of 90% in all countries by 2015, with no district's coverage less than 80%
- **Introduction of under-utilized vaccines:** At least 90 low or middle income countries to have introduced one or more such vaccines by 2015
- **Polio:** No new cases after 2014 ('interruption of transmission')
- **Maternal and neonatal tetanus:** Global elimination by end-2015
- **Measles:** Elimination from three WHO regions by end-2015
- **Rubella:** Elimination from one WHO region by end-2015

**In SAGE's assessment, only one of these six targets is on track to be achieved.** Most have seen very poor progress indeed, and some have already been missed multiple times before. These have a strong common thread. They are about improving the reach and reliability of vaccination services, so that children who are not yet properly immunized can be accessed.

### DTP3: NATIONAL VACCINATION COVERAGE OF 90%

TARGET: ALL 194 COUNTRIES BY 2015



National DTP3 coverage is the most important indicator in the Global Vaccine Action Plan. It is a direct measure of children receiving three doses of this crucial vaccine. Also, if a country has high DTP3 coverage, it has systems in place that can also deliver other vaccines. Broader still, DTP3 is a useful descriptor of how well a healthcare system is functioning. With all of these in mind, it is very disappointing to see this important target so far off track.

In 2013, 129 countries vaccinated at least 90% of their children with three doses of diphtheria-tetanus-pertussis containing vaccine ('DTP3'). The Global Vaccine Action Plan's target is for this number to reach 194 – that is, all countries – by the end of 2015. As the graph shows, the number of countries achieving 90% has not improved between 2011 and 2013. A full one-third of countries are yet to reach this target. The unavoidable conclusion is that progress towards the end-2015 target is far off-track.

### IN BRIEF

GVAP end-2014/end-2015 targets: five out of six are off-track

No improvement in national DTP3 coverage (a vital measure)



This simple graph shows only one measure, but further examination of the data only confirms stagnation. Globally, the total number of unvaccinated children remains at 22 million, with just a hint of improvement this year.

The Global Vaccine Action Plan also set an important district-level target. This aims to boost equity – to avoid, for example, a country achieving 90% national coverage but having coverage of 99% in its capital and just 60% in a poor rural area, for example. Unfortunately, it is not possible to comment on progress towards this target. District data are not available, or are invalid, from almost half of countries. This reflects a wider problem with the quality and use of vaccination data, described later.

The flat-lining of DTP3 coverage is not good news. But there are some positives:

- Over recent years, several new vaccines have been introduced. Particularly thanks to the support of Gavi, their coverage has grown rapidly. Some feared that introducing new vaccines would strain systems and cause global DTP3 coverage to drop. This has not been the case.
- Progress on DTP3 coverage has been made in some countries. Important examples are Ethiopia, Indonesia and Nigeria. Each has achieved some reduction in its number of unvaccinated children.

The major contextual challenges should also be remembered. Several of the countries with very low vaccination coverage are affected by war or other conflict – including Central African Republic, Somalia and Syria.

Unfortunately, this does not alter the overall conclusion. This vitally important target of the Global Vaccine Action Plan is way off track.

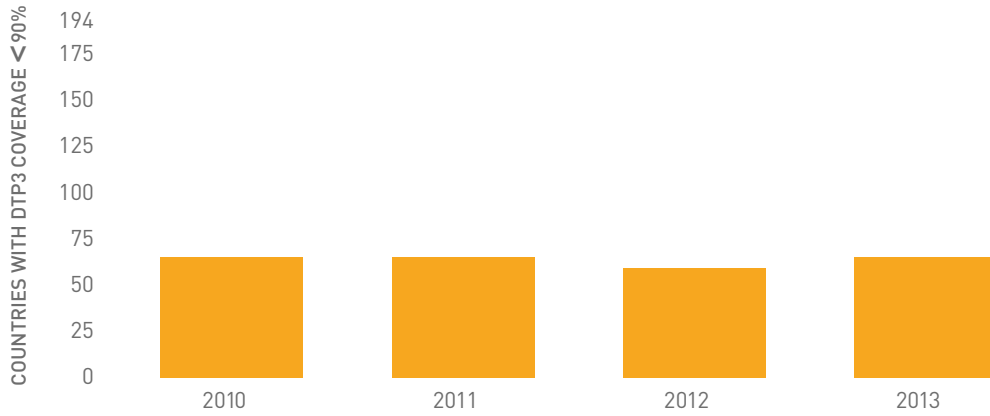
## IN BRIEF

Insufficient district-level DTP3 data

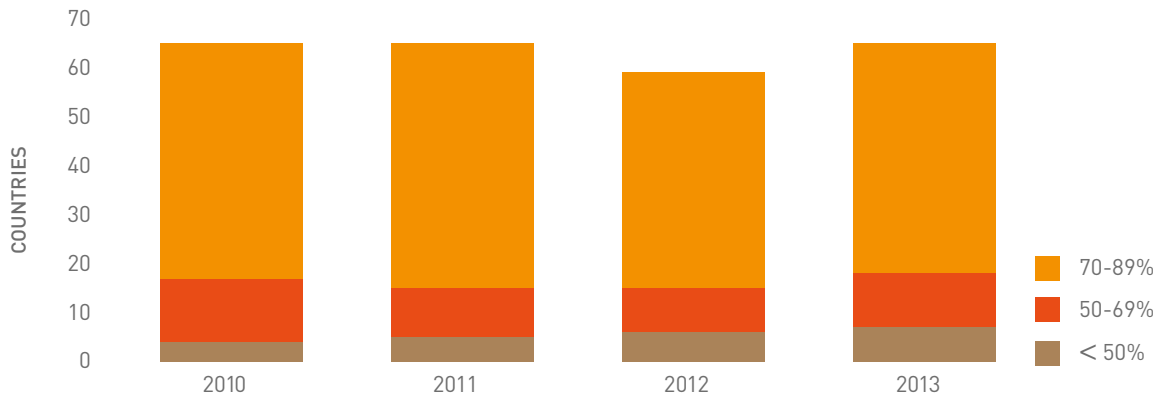
Despite some positive news, DTP3 flat-lining is deeply disappointing

**DTP3 COVERAGE: FLAT-LINING, WHICHEVER WAY YOU LOOK AT IT**

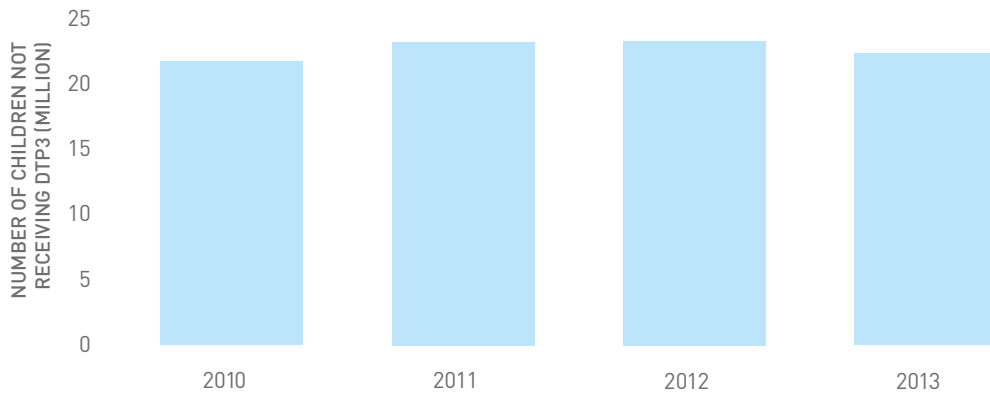
ONE-THIRD OF THE WORLD'S 194 COUNTRIES ARE NOT ACHIEVING 90% NATIONAL COVERAGE, AND THIS HAS NOT CHANGED FOR FOUR YEARS...



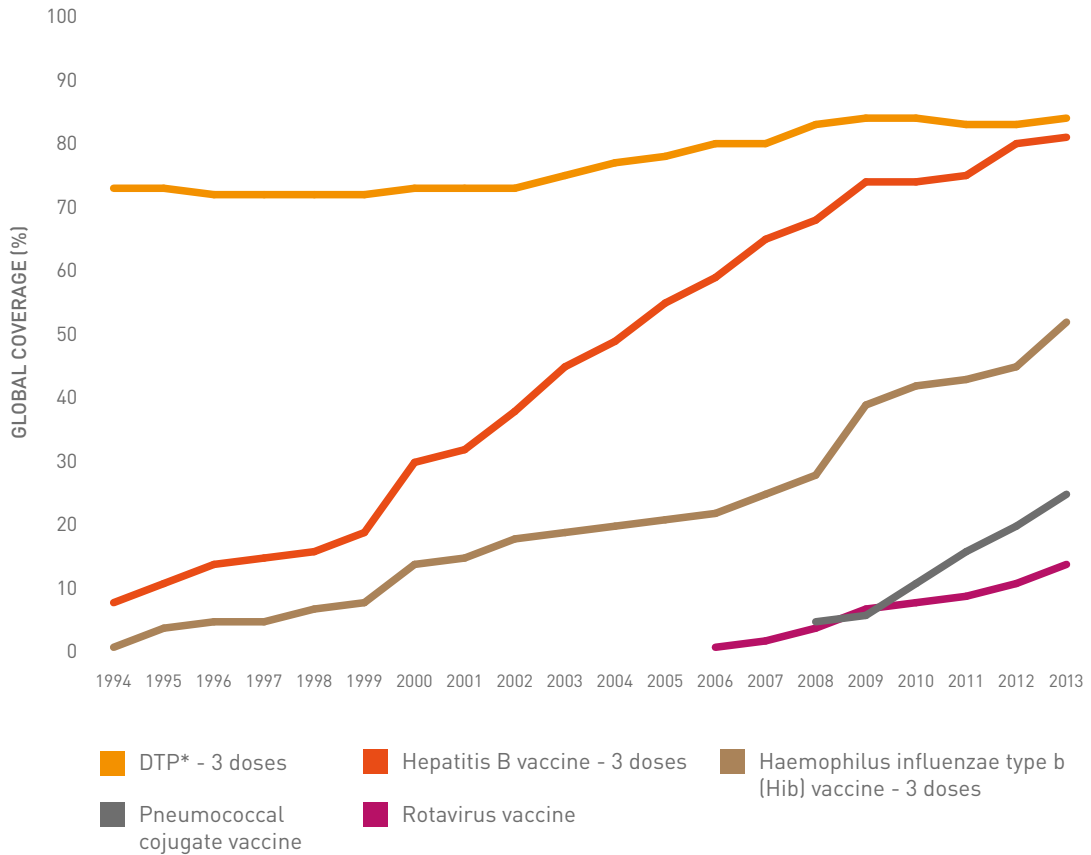
LOOKING CLOSER, THE NUMBER IN THE LOWEST BANDS IS GETTING WORSE NOT BETTER...



...AND THE TOTAL NUMBER OF UNVACCINATED CHILDREN HAS BASICALLY NOT CHANGED.



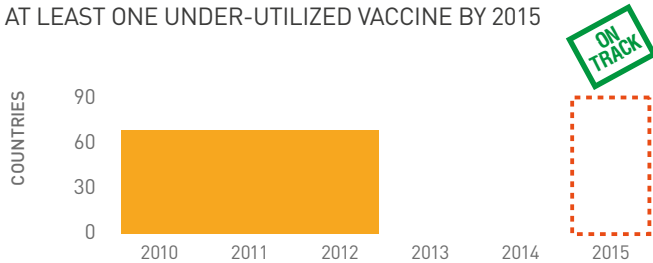
**MAJOR CHANGE IS POSSIBLE: ALTHOUGH DTP3 COVERAGE HAS HIT A PLATEAU, NEWER VACCINES HAVE BEEN INTRODUCED AT AN IMPRESSIVE PACE**



\*DTP = diphtheria, tetanus and pertussis-containing vaccine

**INTRODUCTION OF UNDER-UTILIZED VACCINES**

TARGET: 90 LOW OR MIDDLE INCOME COUNTRIES INTRODUCE AT LEAST ONE UNDER-UTILIZED VACCINE BY 2015



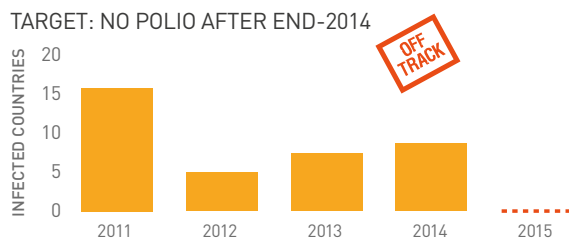
Good progress is being made towards this target. Between 2010 and 2012, 68 low and middle income countries introduced an under-utilized vaccine<sup>4</sup>. They actually introduced a total of 85 vaccines, because some countries introduced more than one. All of these introductions were sustained for at least a year. The most common new introduction was

<sup>4</sup>Hib-containing, pneumococcal, rotavirus, Human Papillomavirus (HPV) vaccine, rubella or Inactivated Polio Vaccine (IPV)

pneumococcal vaccine. There were some supply constraints for both this and for rotavirus vaccine. These constraints have now eased, so additional introductions are now likely.

The SAGE welcomes the progress towards this important target. It represents a continuation of promising work, particularly over the last decade, in accelerating new vaccine introduction.

## POLIO



The Global Vaccine Action Plan's target was for wild poliovirus transmission to be stopped globally before the end of 2014. This important target will now certainly be missed.

Promising progress was made in 2011 and 2012 – India stopped polio transmission, several longstanding outbreaks were brought to a halt, and type 3 poliovirus was probably stopped. But from late 2012 into 2013, the situation deteriorated. In Pakistan, polio vaccinators were killed. The virus spread internationally. This caused substantial outbreaks in Syria and the Horn of Africa and led, in 2014, to WHO declaring a Public Health Emergency of International Concern. In 2014, valuable progress has been made in containing these outbreaks. Strong progress has also been made in Nigeria, which for years has fed polio transmission across a whole band of Africa. Most of the cases of polio in the world are now in Pakistan.

The Global Polio Eradication Initiative was established in 1988. It set a target of stopping global polio transmission by the year 2000. When this was missed, the target date was moved to 2005, then 2012, then 2014. This will therefore be the fourth time that a target for stopping global polio transmission has been set and missed.

The fact that progress is being made is welcomed. Repeated failure to stop polio transmission comes at real cost. People (mainly young children) are being paralysed by, and in some cases dying from, a disease that should have been consigned to history years ago. Until every country in the world has stopped polio transmission, an intensive and expensive effort is needed to protect the rest of the world from the virus being imported. The Global Polio Eradication Initiative costs US\$1 billion a year. It needs to continue, and to complete its work as quickly as possible.

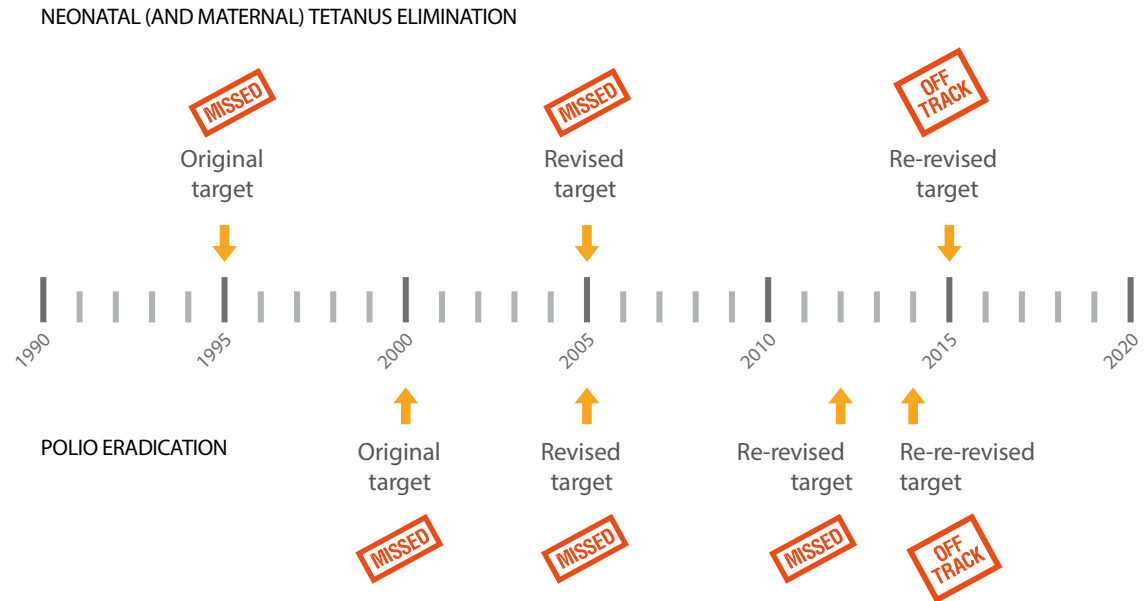
## IN BRIEF

Good progress against polio, in the face of incredible challenge

Pakistan of major concern, and coming months vital for Nigeria

Global 'stop transmission' target will be missed - again

THE HABIT OF MISSING MAJOR VACCINATION TARGETS UNDERMINES GLOBAL TRUST IN THESE EFFORTS...



...AND HAS A REAL AND SUBSTANTIAL COST

**50,000**

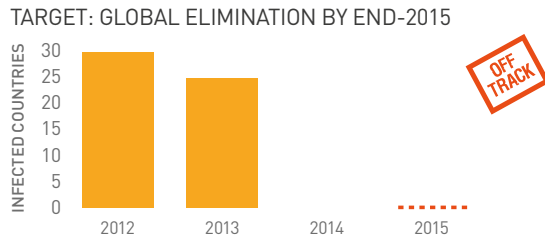
In 2010, 15 years after the original tetanus elimination target, at least 50,000 babies died the horrible death of neonatal tetanus\*

**US\$1 billion**

In 2014, 14 years after the original polio eradication target, the Global Polio Eradication Initiative cost US\$1 billion, which could otherwise have been spent elsewhere

\*No data are available since 2010, but it is likely that tens of thousands are still dying every year

## MATERNAL AND NEONATAL TETANUS



When a newborn baby contracts tetanus, its face and jaw lock until the baby cannot feed. The baby suffers from severe muscle spasms and convulsions. After a week of this agony, almost all infected babies die. The babies who die of neonatal tetanus are born in some of the poorest parts of the world. Its persistence is a sharp reminder of gross inequity.

Newborns and mothers are put at risk of tetanus by unclean deliveries and poor umbilical cord care. The infection can be prevented by improving this hygiene, and by vaccinating women who are pregnant or of child-bearing age. Application of these simple measures can eliminate maternal and neonatal tetanus as a public health problem (even though the tetanus bacterium itself cannot be totally eradicated).

In 1989, the World Health Assembly resolved to eliminate neonatal tetanus by 1995. This was not achieved. In 1999, the Maternal and Neonatal Tetanus Eradication Initiative launched, setting a target date of 2005, subsequently shifted to the 2015 target date that is endorsed by the Global Vaccine Action Plan. Meanwhile, tens of thousands of newborn babies continue to die from tetanus (some 58,000 according to the latest data, which are from 2010).

It should be considered deeply unacceptable that this disease, wiped out from most of the world, still affects its poorest people. Its first global elimination target was missed 20 years ago. And now this target – set at end-2015 as one of the first tangible targets of the GVAP – is set to be missed yet again.

Some progress is being made. The SAGE particularly commends India and China for their sustained focus. China has eliminated the disease as a result, and India is making good progress towards doing so in 2015. Both India and China have focused substantially on hygienic delivery, using skilled birth attendants and encouraging women to give birth in health centres. This approach has the great advantage of also improving maternal and neonatal care more generally.

The goal of eliminating tetanus is embarrassingly underfunded. For 2015, the funding gap (US\$90m) dwarfs the funds available (US\$10m) by a factor of nine. If this persists, it is simply inconceivable that the global elimination goal will be achieved by 2015, or any time soon after.

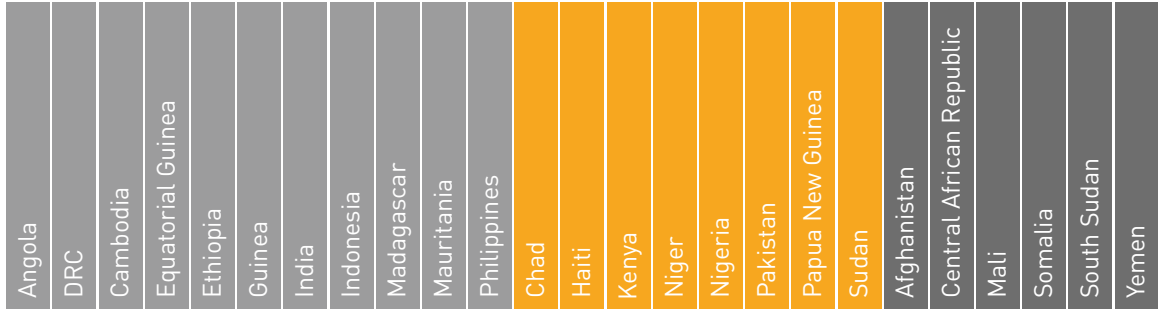
### IN BRIEF

Tetanus: a horrible disease

End-2015 elimination goal off-track, and missed twice before

Gross underfunding: urgent action needed

**NEONATAL AND MATERNAL TETANUS: 25 COUNTRIES STILL NEED TO ELIMINATE**

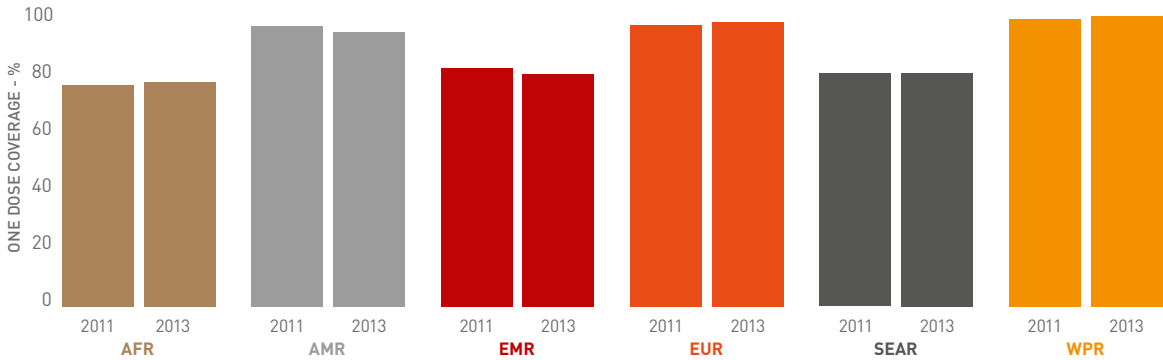


11 COUNTRIES ARE CLOSE TO ELIMINATION

8 COUNTRIES ARE DRASTICALLY BEHIND DESPITE RELATIVELY STABLE POLITICAL SITUATIONS

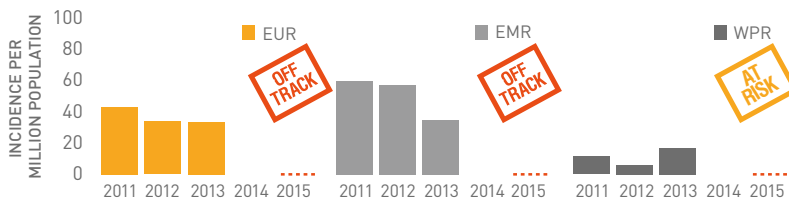
6 COUNTRIES ARE BEING SET BACK BY POLITICAL INSTABILITY

**MEASLES: ONE-DOSE COVERAGE LITTLE CHANGED IN TWO YEARS**



**MEASLES**

TARGET: ELIMINATION FROM THREE MORE REGIONS\* BY END-2015



The measles vaccine has saved millions of lives. Measles mortality and morbidity has fallen by 90% since its introduction. At the turn of the millennium, 500 thousand people (mainly children) died from measles. By 2012, this figure had fallen by three-quarters – to 122 thousand.

Three WHO regions have vowed to wipe out measles altogether by the end of 2015. All regions have vowed to do so by the end of 2020. Unfortunately, as with polio and tetanus, these grand words are not being matched by the funding and action to make them a reality.

\*Four regions in total, including AMR. Data for other regions are in the GVAP Secretariat Report

The three regions aiming for elimination by the end of 2015 are EMR, EUR and WPR. Of these, EMR and EUR are markedly off track. WPR was making the strongest progress, but this was set back in 2013 by major outbreaks in China, Philippines and Vietnam. Each region can point to some areas of good progress. But nobody could reasonably conclude that any of the regions is on track to eliminate measles by 2015.

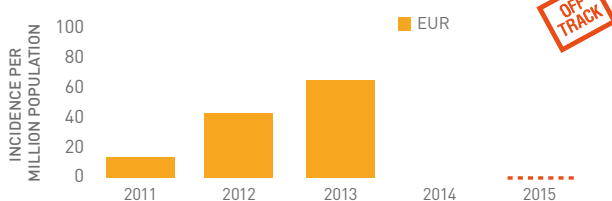
Eliminating measles is not easy. It requires 95% coverage in every district. Even if national coverage is above 95% (as it is in many countries in EMR, EUR and WPR), just one weak district is enough for this highly contagious virus to continue circulating.

Globally, coverage has not changed over the last five years. It remains stubbornly at 84%. This is high enough coverage to prevent hundreds of thousands of deaths, but not enough to eliminate measles transmission. Measles incidence has halved over the last three years, but the number of countries with ongoing transmission has only fallen slightly. And getting from 84% nationally to 95% in every district is a very long way to go before the year 2020. Six large countries have a particularly important role. Democratic Republic of the Congo, Ethiopia, India, Indonesia, Nigeria and Pakistan are responsible for more than four-fifths of all measles cases worldwide.

One WHO region – AMR – eliminated measles in 2002. But Brazil has become re-infected, and transmission has continued there for more than a year. Three regions (SEAR, AFR and EMR) still have coverage of 80% or less. This is a very long way from the 95% in every district that will be required to eliminate measles. A huge amount of work and political commitment lies ahead if their elimination goals are to be achieved, as is pledged for the end of the decade.

## RUBELLA

TARGET: ELIMINATION FROM ONE REGION BY END-2015



Work to eliminate rubella lags behind that for measles. Again AMR leads the way – rubella was eliminated there in 2009. Globally, rubella vaccine coverage is just 40%. One third of countries have not yet introduced the vaccine. Surveillance is weak, so the burden of rubella is not well understood. The Global Vaccine Action Plan aims for five regions to have eliminated rubella by 2020, but so far only two have established such a goal – AMR for 2010 (which was achieved) and EUR for 2015, which is not on track. SEAR has established a 2020 goal of accelerating rubella control, but this is not an elimination goal.

Combination vaccines allow children to be protected against measles and rubella simultaneously, at a small additional cost for the combination vaccine. Failure to use this vaccine in the measles elimination effort is a major missed opportunity to simultaneously eliminate rubella (which is

\*Two regions in total, including AMR. Data for other regions are in the GVAP Secretariat Report

## IN BRIEF

Measles vaccine is a major lifesaver

Elimination targets not on track

95% coverage required in every district: A long way to go

Rubella lags far behind measles: A missed opportunity



actually more easily eliminated than measles). There is no good reason why rubella should be lagging behind measles in the way that it is.

### THE COMMON THREADS: SYSTEMS, INTEGRATION, WILL

Each of these targets is about a different vaccine or disease, but the common threads are strong. The route to achieving all of these targets is through **strengthening immunization systems**. There is no mystery to it – once vaccination coverage is raised to a high enough level, these viruses and bacteria will have nobody to infect. There are two parts to this strengthening:

1. Reaching those who are completely unvaccinated, by extending services to them – those who live in remote or inaccessible areas; those who are nomadic; those who are part of a marginalized social group. In short, putting a stop to the persistent inequity in the distribution of vaccines.
2. Better serving those who are under-vaccinated – who receive some vaccine doses, but are not reliably covered in the way that they should be. Improving this reliably involves strengthening the healthcare system in a number of ways. It means having enough healthcare workers, with the right skills. It means having the records, the facilities, and the cold chain. It means strengthening links between the different parts of the system. It means having skilled managers who can oversee and improve the system. Importantly, these are the building blocks of any healthcare system – vital for vaccination, and far more besides.

So the targets are disease-specific, but the improvements needed to achieve them are largely shared. Such efforts should therefore be integrated as tightly as possible, both with one another, and with other work to improve and deliver healthcare.

A further common thread is political will. These targets can all be achieved if countries truly want to achieve them. They will not be achieved otherwise.

These common threads illustrate why the Global Vaccine Action Plan is so valuable. It aims to end inequity in vaccination. It aims to pull the vaccination goals together - with one another, and with broader healthcare system strengthening. It is countries' joint expression of their will to use the great tool of vaccination to protect global public health, and achieve momentous goals.

But the final common thread, at the moment, is that all of the end-2014 and end-2015 targets are off-track. The next section of this report looks at what needs to change.

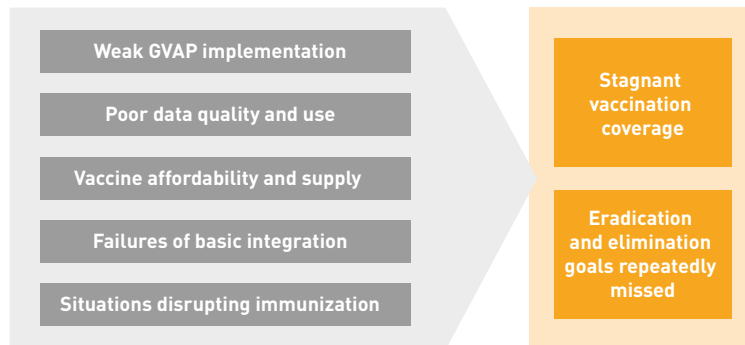
### IN BRIEF

Common threads to all targets: strengthening systems, political will

# VACCINATION FOR ALL

## FIVE PRIORITY PROBLEMS

The Global Vaccine Action Plan is far off track. In response, the SAGE recommends that actions focus particularly on addressing five priority problems. Each problem is major, but each can be tackled, with a reasonable expectation that doing so will improve progress considerably.



### 1. WEAK GVAP IMPLEMENTATION

**Three years after its start date, implementation of the Global Vaccine Action Plan is patchy and slow. All countries and organizations that have committed to this endeavour should re-examine the level and nature of their contributions, and urgently make the improvements necessary to achieve results.**

Declaring that 2011–2020 should be the 'Decade of Vaccines' was a helpful start, but by itself achieves little. The creation of a Global Vaccine Action Plan is useful, but the document's mere existence has little effect – as is being seen. As ever, the key lies in implementation.

It would be tragic if the opportunity to use the Global Vaccine Action Plan is not taken. The Global Vaccine Action Plan has major strengths:

- It pulls the strands of global vaccination work together. These strands inter-link. Working on them in combination is far better than treating them as standalone goals and programmes.
- It shines a spotlight on the need to deliver vaccines equitably and to realize vaccines' future potential. It should help countries and partners hold one another to account for doing so.
- Through the World Health Assembly, it was adopted by all Member States of the World Health Organization.
- A wide array of fora and organizations were involved in its development and launch. They can contribute to achieving its goals.

As it stands, implementation is patchy and slow. It is little surprise that progress towards its targets is so consistently off-track. It is worrying to hear that a number of countries and some key stakeholders are barely aware of the plan.

Notably, measles elimination is a major stated priority for which the required structures – particularly national verification committees and regional verification commissions – have not yet been fully established.

## IN BRIEF

Getting back on track: Five priority problems to tackle

GVAP: a great opportunity, full implementation now urgent

These have a vital technical role, and also help demonstrate countries' true commitment to the goal.

The World Health Assembly endorsed the Global Vaccine Action Plan in 2012. More than two years on, most of the WHO regions are only now on the cusp of having Regional Vaccine Action Plans agreed by their regional committees of health ministers. It is disappointing that they did not do so in 2012 or in 2013. Now, at least, these regional plans need to be quickly developed and implemented. The SAGE will ask for a formal report from each region every year. It is important that there are solid mechanisms for monitoring and for exchange of best practices. The World Health Assembly resolution on the Global Vaccine Action Plan asked that from 2013, regional committees hold a special annual session in which countries report on progress, lessons learnt, challenges and plans. Every country endorsed the Global Vaccine Action Plan. Every country needs to urgently develop its own plan to contribute, before any more of the decade slips away. Accountability is a crucial part of implementation. Countries' plans need to specify not just what they intend to do, but what monitoring and accountability mechanisms they will use to be sure that it gets done.

Civil society organizations were involved in producing the Global Vaccine Action Plan. They now need to be involved in producing results. They can (and in some places already do) deliver vaccines, mobilize volunteers, help improve data quality, and help people to understand the value of vaccines. They need to be involved in a proper way. Governments should consider devolving specific tasks to civil society organizations, then holding them accountable for the results. Conversely, civil society organizations can play a useful role in holding governments to account.

Two influential global fora played a pivotal role in establishing the Global Vaccine Action Plan. At the World Economic Forum in Davos in 2010, Bill Gates challenged the world to make this the 'Decade of Vaccines'. At the World Health Assembly in 2012, health ministers accepted the challenge on behalf of their countries, endorsing the Global Vaccine Action Plan. The participants in both of these fora wanted this plan. They now have an important role to play in helping to implement it.

The implementation of the Global Vaccine Action Plan needs a hefty injection of urgency. The plan strikes at the heart of global health inequity. It involves building up vaccination services as a fundamental building block of healthcare. This major opportunity needs to be taken.

#### THE SAGE RECOMMENDS THAT:

- The Director-General of WHO convene a special session at the 2015 World Health Assembly for countries with routine vaccination (DTP3) coverage of less than 80%, to which each minister of health is asked to report on their challenges, plans and timelines to improve coverage to meet the GVAP goals.
- The SAGE's GVAP assessment reports remain as standing items at the World Health Assembly until 2020.
- The failure to achieve the 2013 milestone for MNT elimination is related to a large extent to the funding gap. Partners should lead a concerted effort to fill this gap, by refreshing the communication approach and seeking novel partners for this vital, and repeatedly missed, goal.

#### IN BRIEF

Civil society role crucial

Major delays in agreeing regional action plans

Hefty dose of urgency required

- Regions and countries rapidly finalize their own vaccine action plans based on the GVAP, using this assessment report as a further guide and establishing bodies to guide and monitor implementation.
- Countries give CSOs substantially more formal involvement in the delivery and improvement of vaccination services, establishing clear responsibilities for which they are accountable.
- After consulting with their respective Regional Technical Advisory Group, every region establish a regional verification commission, and after consulting with their respective National Immunization Technical Advisory Group, every country explore options for establishing a national verification commission, to scrutinize and monitor progress towards the measles and rubella elimination targets.
- The heads of the GVAP Secretariat agencies (the Bill and Melinda Gates Foundation (BMGF), Gavi, the National Institute of Allergy and Infectious Diseases (NIAID), WHO and UNICEF) meet to consider this report and to agree on specific corrective actions.
- The heads of GVAP Secretariat agencies report to the 2015 World Economic Forum in Davos on the plan's establishment, its lack of progress so far and what fora participants – who supported the Decade of Vaccines concept in 2010 – can do to help its implementation.
- Following adoption of the GVAP and subsequently revision and adoption of regional and national plans, countries have the responsibility to ensure that immunization goals are shared, discussed and fully adopted by health care workers.

## 2. POOR DATA QUALITY AND USE

### **Poor quality and use of data is substantially impeding programme management and improvement**

Our 2013 GVAP Assessment Report said that improving data quality should be the number one priority for vaccination programmes, and for the vaccination infrastructure globally. This remains the case. At the 2014 World Health Assembly, a number of countries supported this priority. Having accurate data is the foundation for performance improvement, from the local level up. Used well, data are the cornerstone of accountability – demonstrating whose performance is strong and whose is weak. If data are accurate, even simple analysis can provide important insights on which to improve coverage. By contrast, managing a programme with poor quality data is like navigating through the fog with an out-of-date map.

There are few data to describe countries' human resource capacity, and this is of particular concern in relation to the quality of data. If frontline staff are over-worked, accurate recording of data can be one of the first things that is missed particularly if they have little reason to think of data as important. Programme managers need to have sufficient time and skill to improve and use data.

Key technical agencies are acting to improve data quality, in several areas. Appropriately, they are particularly focusing on data being accessible at the right time and in the right format, so that they are usable as well as accurate. They are working to improve the availability, design and use of home-based records, which are the most basic building block of data capture in some countries. It is vital to improve healthcare facilities'

records too, because these provide community level administrative data. They are working to improve target population estimates, and are standardizing survey methods. They are also looking at how technology can improve the recording, reporting analysis and use of data. This is a long-term process. Electronic systems have an important role to play, but are no panacea. Some countries and regions are making strong use of health information systems, and it is important that this learning is spread. Having data is only the first step towards using them to make improvements.

As data quality is improved, it should be anticipated that the reported level of vaccination coverage may change (it might increase, it might decrease). Programme managers should be reassured that having accurate data is what matters the most.

Data quality and use should be a top-of-the-agenda item. The SAGE will return to this issue in its future Global Vaccine Action Plan Assessment Reports.

#### THE SAGE RECOMMENDS THAT:

- Countries invest in improving data quality at the local level, and use data to strengthen accountability and to improve understanding of what the programmatic issues are.
- Technical agencies further develop and deploy tools to help countries with the practical task of improving the quality and use of data, with limited personnel available to do so.

### 3. VACCINE AFFORDABILITY AND SUPPLY

**The affordability and supply of vaccines need to be urgently examined. Each may be causing a significant problem for a large number of countries, and the current lack of proper information hinders understanding and corrective action.**

No vaccination programme can function without vaccine supply. In 2013, more than 40% of low and middle-income countries suffered a national-level stockout of at least one vaccine that lasted at least one month. This information comes from data reported by countries to WHO and UNICEF using the Joint Reporting Form. The problem is affecting countries of all sizes. If anything, 40% may be an under-estimate.

This is a shocking finding. Yet these data came as no surprise to technical agency staff who are in touch with many countries day to day. They describe some countries having vaccine stockouts every month, for different reasons.

This is deeply worrying. It might be having a major impact on the availability of vaccines in healthcare facilities, which in turn would impede coverage. More information is needed. First, what is the scale of the problem? "At least one stockout for at least one month" does not illustrate the full number and duration of stockouts. Second, how badly is this affecting vaccine availability in healthcare facilities? It is possible that local supply is not being affected, if the national stockouts are quickly dealt with. On the other hand, it may be affected substantially. It is also possible that local stockouts are occurring even when vaccines are available in a national store. Third, why is this happening? What is the root cause? Are countries not organizing vaccine

#### IN BRIEF

Data quality remains top priority

Poor data stifles progress

Good work ongoing to improve data quality and use

supply well? Is there a cash flow problem? Or are there real problems with the global availability and supply of some vaccines?

This needs full and urgent investigation. There is a pressing need to better understand the root cause in each context. Understanding and fixing these will make vaccination systems more robust and may measurably contribute to increases in global vaccination coverage.

**Vaccine affordability** is crucial. Vaccines can only be provided to all who should benefit if they can be sustainably purchased, but at a price that also provides sufficient reward and incentive for industry. There has been particular concern about the affordability of newer vaccines for middle-income countries that do not receive Gavi funding (because they are ineligible for it, or because they were previously eligible but have now graduated from Gavi support). There is concern that for some countries and certain vaccines, price may be the main barrier to introduction, and that for other countries, vaccine procurement costs may take too great a bite out of the overall healthcare budget and therefore not be sustainable.

Information on vaccine prices (complemented by other data) is key to assessing affordability and market dynamics. Both UNICEF and the PAHO Revolving Fund now make price information available for the vaccines that they buy through pooled procurement. Many countries finance and procure vaccines on their own, though, and price information for these countries is sparse.

To address this, recent global efforts have tried to collect vaccine price information from countries. There have been two main initiatives: the Vaccine Product, Price and Procurement (V3P) database, and a pilot in two regions of WHO/UNICEF Joint Reporting Form. (In future, the V3P database will be the main mechanism for reporting and recording price data from countries and the Joint Reporting Form will provide a link to this.) . To date, only 17 countries have provided information to the V3P - and in just one case is this data validated and cleared for public sharing. Another 27 countries provided information through the pilot Joint Reporting Form mechanism, but it was far from comprehensive. In short, there is a real shortage of information about how much countries are paying for vaccines.

Because vaccine pricing is not transparent, the affordability of vaccines for countries cannot be properly evaluated. Why the lack of transparency? The price collection mechanisms are relatively recent, so countries may not yet be fully aware of them or their importance. It is also known that some countries accept confidentiality clauses with manufacturers, in exchange for perceived preferential pricing, but it is unclear to what extent this may impact reporting.

It is vital that greater transparency be brought to this important area. This is crucial to evidence-based assessment of the scale and scope of market imbalances, and will allow solutions to be developed once the problems are understood. It will enable open and fair discussions about appropriate levels of financing for procurement, and how vaccine pricing differs among countries.

Self-procuring countries may believe they hold little power in vaccine markets that are often dominated by very few firms, and in which they may lack market knowledge and deep expertise in procurement and

## IN BRIEF

National vaccine stockouts in 40% of low and middle-income countries in 2013

Need urgent investigation into scale, impact and why

negotiation. But countries can exercise more control over these issues than they may realize, particularly if they commit to sharing information and working together. Solutions that meet their needs can be facilitated by others, but should be driven by their input. This begins with, but is not limited to, price information.

The pharmaceutical industry has played a vital role in developing vaccines and making these accessible, particularly through Gavi. They have a crucial role to play in achieving the great ambitions of the Global Vaccine Action Plan. Achieving a proper balance between affordability and industry incentives can be complicated, but SAGE recognizes it as essential to achieving sustainable increases in coverage and realizing the benefits of new vaccines. Market transparency is critical in achieving this.

Two important issues of vaccine availability have been described – the first to do with supply, the second to do with affordability.

#### THE SAGE RECOMMENDS THAT:

- Technical agencies conduct urgent assessments of (i) the extent to which the reported national-level stockouts are affecting local vaccine supply and delivery, and (ii) the root causes of these stockouts.
- Countries are requested to change the rules of the game on vaccine affordability, to create transparency which is in their interest. They can do this by making pricing information publicly available, and by collaborating with WHO and all technical agencies to develop solutions.
- Technical partners support countries to improve the transparency of vaccine pricing. Technical agencies themselves should do everything possible to share pricing data.

#### 4. FAILURES OF BASIC INTEGRATION

**Basic failures to integrate mean that healthcare workers are repeatedly missing easy opportunities to offer vaccinations when people attend clinic with other problems.**

How often does it happen that a child is overdue for a vaccination, attends a healthcare facility for another reason, and is not offered the vaccination while he or she is there? A recent meta-analysis<sup>5</sup> suggests that a full one-third of children who come to healthcare facilities are due a vaccine but are not offered it. Every time this happens, an easy opportunity is missed. People often talk about how difficult it is to 'reach the last child', but many of these children are passing right in front of our eyes and not being vaccinated.

Not only children are affected. The same study shows that almost half of women of child-bearing age were not offered tetanus vaccination when they attended a healthcare facility for another reason. These problems have existed for many years. Data suggest that there has been little improvement in them over the last 20 years.

The first reason for this is basic failure of integration and joined-up thinking. Women come to an antenatal clinic, at which the healthcare worker is not thinking about vaccination and so offers vaccine neither to the women nor to their accompanying children. Yet the next morning, the same healthcare worker is running a vaccination clinic. Children are brought to see a nurse because they have a mild illness, and nobody asks to see their vaccination

#### IN BRIEF

Vaccine affordability – price transparency crucial

Middle-income countries may be at particular risk

Countries, technical partners and pharma-industry need to address this together

<sup>5</sup>Shiruti A, Agence de Medecine Preventive, 2014

card. Yet the day before, the same room was full of children with vaccination cards. In short, it is as if the left hand does not know what the right hand is doing. This is how programmatic silos at global and national level can unfortunately affect what happens in healthcare facilities. Even when the same staff delivers the different services, they are too often not well linked together.

Once the problems are identified, simple solutions can work well. The design and use of healthcare records can be changed, to prompt staff. If there are not enough staff, community volunteers can help. Fixing this problem also needs to be part of improving integration within healthcare more generally.

There is another important reason why opportunities are missed, which has a different solution. If a healthcare worker sees a child with a mild febrile illness, he or she may believe that this is a contraindication to giving a vaccine. Field experience suggests that this is likely a widespread problem. This issue needs to be dealt with through clear evidence-based guidance, clearly communicated to healthcare workers.

#### THE SAGE RECOMMENDS THAT:

- Countries conduct studies to understand how opportunities to vaccinate people are being missed by healthcare workers and their systems, and act to reduce their incidence.
- WHO discuss and develop guidelines on how to fully integrate vaccination into the operation of all aspects of the healthcare system and to address missed opportunities to vaccinate.
- Countries ensure that healthcare workers understand and follow WHO or national guidelines on what does, and does not, contraindicate vaccination, particularly in relation to childhood febrile illness, so that vaccines are not avoided unnecessarily.

### 5. SITUATIONS DISRUPTING IMMUNIZATION

**Vaccine delivery is impeded by disruptive situations, including war and major disease outbreaks (such as Ebola, currently). Such situations will always exist. Vaccines must be delivered despite them.**

When armed conflict starts, vaccination coverage tends to plummet. Less than half of children in Central African Republic, Somalia and Syria received three doses of DTP vaccine in 2013. Unfortunately, the world is never free of war. It forms part of the environment in which vaccines must be delivered. With an ambition to extend vaccination to all people, conflict cannot be an exception.

The link between war and poor coverage is not absolute. In Afghanistan, DTP3 coverage is at least 70%. When polio spread into Syria, a number of partners mounted a quick and effective vaccination response. There is a lot to learn from these, and other, situations in which good progress is made in the face of adversity. In response to war, vaccination programmes must have a plan for refugees, for receiving communities, and for those left behind.

War is not the only disruptive environment in today's world. Earthquakes and major climatic events can severely disrupt vaccination. Other health

#### IN BRIEF

Missed opportunities: Children, pregnant women and adults are attending healthcare facilities but not being vaccinated



emergencies can do so also. The current Ebola outbreak is a prominent example of this. Vaccination rates are already dropping. The attention of frontline healthcare workers is being diverted, and providers are frightened to deliver services. Vaccination programme managers are being seconded away, to help in the Ebola response. Supply chains are disrupted. Even populations' trust of healthcare services, and therefore of vaccination, risks being impaired. Measles outbreaks are already occurring in Ebola-affected countries, and outbreaks of others vaccine-preventable diseases are likely to follow.

There needs to be specific focus on minimizing the disruption that situations like war and outbreaks (including the Ebola outbreak) cause to vaccination. Complex and difficult situations are a fact of life, and global vaccination programmes need to become more resilient in the face of them. There is currently WHO guidance, developed with input from SAGE, on how immunization can help mitigate the risks associated with humanitarian emergencies – but not on how routine immunization (or equivalent) services can be continued in spite of these and other challenges.

#### THE SAGE RECOMMENDS THAT:

- WHO expand its existing guidance on immunization in humanitarian emergencies to detail how routine and other immunization services are best maintained despite disruptive situations such as war and disease outbreaks.

#### IN BRIEF

Vaccination despite conflict – can and must be done

Ebola – major threat to vaccination

Disruptive situations inevitable: must succeed regardless

# UNLEASHING VACCINES' FUTURE POTENTIAL

## BASELINE REPORT

Most of this report has been about making full use of the vaccines available today. The other ambition of the Global Vaccine Action Plan is about the future:

Vaccines have vast future potential. Their development and use has already saved millions of lives, but vaccine science has enormous further potential. In future generations, vaccines against HIV and malaria could make these diseases go the same way as diphtheria, smallpox and polio have before them.

The Global Vaccine Action Plan sets ambitious and important research and development goals. It aims, by the end of the decade, for at least two major new vaccines to have been developed, licensed and launched:

- **A universal flu vaccine.** This would stop the need for annual re-vaccination to protect against the seasonal influenza epidemics in which up to half a million people currently die. It would also eventually protect against flu viruses with pandemic potential.
- **A vaccine for another disease of major public health relevance that is not currently vaccine-preventable.** To assess progress towards this goal, the SAGE examines the current state of vaccine research for a sample of seven infectious diseases<sup>6</sup>. These seven were chosen because they represent a range of different infection types. Tracking them provides a reasonable assessment of how vaccine science is progressing overall. They are a sample, not a priority list.

The plan also aims, by the end of the decade, for **proof of concept of a vaccine that prevents HIV, malaria or TB with 75% or greater efficacy**<sup>7</sup>. These three diseases together cause three million deaths a year. Only TB currently has a vaccine in use. It is only 50% effective and, given in childhood, does not prevent disease in adulthood.

## PROGRESS: A FULL PIPELINE, BUT SLOW FLOW

In 2014, the GVAP Secretariat summarized progress towards each of these important goals. For the rest of the decade, the SAGE will examine progress every two years, using this 2014 summary as a baseline<sup>8</sup>.

For each of HIV, TB and malaria, the vaccine development pipeline is well populated. For TB, 13 candidate vaccines are the subjects of clinical trials. Many of these would be given as boosters to the existing BCG vaccine. For malaria, there are now 30 candidate vaccines under trial. Most aim to prevent infection with the malaria parasite from causing disease. Others work differently, aiming to prevent infected individuals from transmitting the disease to others. For HIV, there is currently a list of 40 candidate vaccines - but most are still in pre-clinical development, and many may not progress beyond this phase.

A candidate vaccine's prospects of reaching licensure increase substantially as it passes successfully through the phases (I to III) of

<sup>6</sup>The sample of seven infectious diseases is: dengue, hepatitis C, cytomegalovirus, respiratory syncytial virus, group A streptococcus, leishmaniasis, and helminth infections.

<sup>7</sup>The definition of this indicator will be re-visited by the Working Group

<sup>8</sup>There is no single source global record of the number of candidate vaccines under development. The numbers presented here come from clinical trial databases and from experts, but may not be wholly complete.

## IN BRIEF

GVAP sets important, ambitious research and development goals

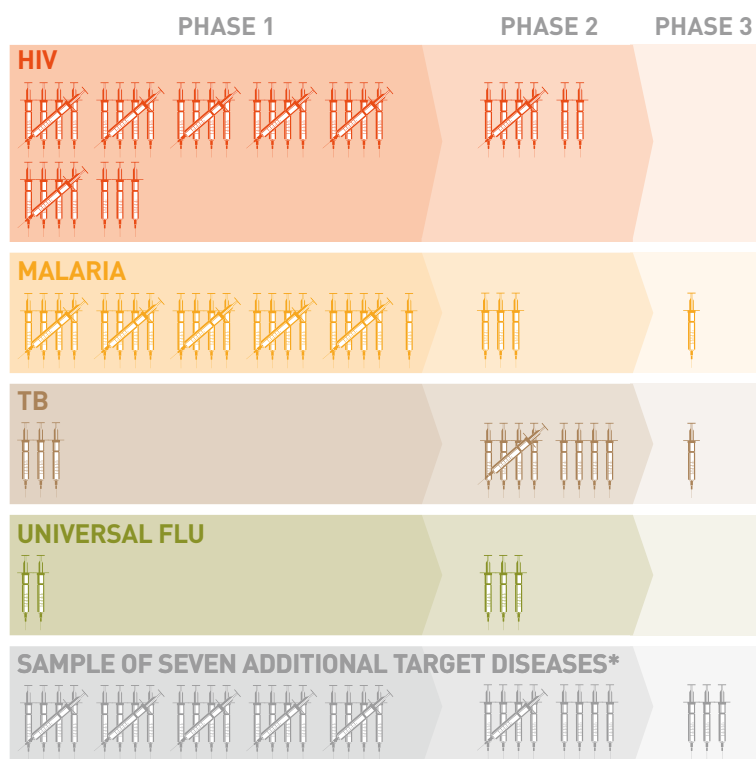
clinical trials. One malaria and one TB vaccine are currently in phase III trials. The malaria vaccine is furthest advanced. Depending on its trial results, expected in late 2014, it might be licensed in 2015. This is a welcome development, but this vaccine is unlikely to meet the GVAP's target of 75% efficacy.

Five universal flu candidate vaccines are in clinical trials. Detailed analysis, available in the GVAP Secretariat Report, illustrates that a good range of technologies and approaches are being employed to address the major scientific challenges that flu presents. Of note, the definition of what constitutes a universal flu vaccine leaves room for interpretation.

Finally, across the sample of seven other diseases, a total of 37 candidate vaccines are currently in clinical trials. Three (one for each of dengue, cytomegalovirus and schistosomiasis) are in phase III trials. A wide range of approaches is being tried. In sum, this represents a promising volume of research. As stated above, this is only a sample of seven diseases. Notably, accelerated trials to develop an Ebola vaccine are also being undertaken.

For all of these diseases – particularly HIV, malaria and TB – there are important preventative strategies that do not involve vaccination and have been widely employed to good effect. A highly effective vaccine would be a major additional contribution.

### THE VACCINE PIPELINE: CLINICAL TRIALS IN PROGRESS



The volume of research is promising, but the scientific challenges and technical barriers are very great. As it currently stands, the SAGE does not expect a universal flu vaccine to be licensed by the end of the decade. There is greater hope that a vaccine against another disease will be licensed and launched.

## THE BOTTLENECKS

Developing vaccines is inherently complex. It involves stretching the boundaries of scientific knowledge. Few candidate vaccines make it through the rigorous phases of trial. Accepting this, the strategic question for the SAGE is: Are conditions optimal for vaccine research and development to proceed as fast as possible, or is anything other than the inherent scientific challenge standing in the way of progress?

A number of bottlenecks are slowing progress:

- Supporting the research base – many great research ideas are not receiving resources, limiting the number of candidate vaccines and so the chances of developing effective vaccines.
- Lengthy clinical trials – pre-clinical research has been accelerated, but clinical trials are increasingly taking longer and costing more. Efficiency could be improved through innovative trial designs and developing new validated biological markers for safety and efficacy.
- Clinical trial reporting - There are too often delays and even biases in the publication of clinical trial results. Failing to publish clinical trial results in a timely manner introduces risk and inefficiency. Rapid development requires timely sharing of knowledge. Otherwise people make scientific, policy and funding decisions that are not as fully informed as they could be. A WHO committee (the Product Development for Vaccines Advisory Committee) is developing an approach that WHO could take to tackle this issue. The SAGE emphasizes that WHO and other parties will need to work together and take a hard line to resolve this problem.
- Development pathways – Manufacturers and regulatory agencies should continually look for ways to increase the speed of the vaccine development and licensing process. Delays in developing vaccines cost lives. In response to the current Ebola outbreak, regulators have shown substantial flexibility, employing innovative and rapid means of assessing the safety and efficacy of new therapeutic agents. Acceleration is possible when lives are on the line. Lives are continually being lost, and acceleration – whilst maintaining safety – should be a constant aim.
- Coordination – many different parties are working towards vaccine development. There is greater potential, particularly for TB and HIV, for them to be more in more open, frequent dialogue with one another.

The GVAP research and development goals are ambitious – but their achievement would save millions of lives. Only two things should be allowed to limit the speed of vaccine development: the inherent complexity of the scientific task, and the necessity of ensuring safety.

## IN BRIEF

Tackling process bottlenecks can speed up scientific development

## NEW TECHNOLOGIES FOR VACCINE DELIVERY

The process of giving a vaccine can be improved in so many ways. Needle-free devices can reduce the risk of spreading infection. Pre-filling of syringes can increase the number of children vaccinated per hour. Injecting into the skin, instead of muscle, can allow smaller doses to be given. These innovations, and many more, are described in the GVAP Secretariat Report. Given their potential benefits, it is disappointing that no new vaccine delivery technology has been launched in a low or middle income country since 2010.

The technical challenges are not small. New delivery methods often require extensive investment in testing and manufacturing equipment, and to be attractive must provide substantial improvements over the current technologies. Greater clarity amongst developers about what countries want will help focus attention on the approaches that hold the greatest promise. Countries and the global technical agencies need to clearly communicate what products would be most desirable.

Some products have been developed but not yet launched. The GVAP technical agencies can do more to encourage and support countries in introducing improved vaccine delivery methods. Cost is a particular consideration. The new technologies often cost more per dose given. Most countries take the cost of the vaccine and the consumables (syringes, needles, etc.) into account when they decide which to purchase. A more complete calculation would consider the full costs of vaccination – including the training of personnel, and the time taken to give vaccine – and the full benefits of different methods, such as improved safety. WHO is developing a ‘total system cost effectiveness framework’ to help countries conduct this fuller calculation. This need not be over-complex, and must be rapidly developed and deployed. It is an important step in demonstrating the benefits of new technologies, where these exist, and therefore in incentivizing industry to develop them and bring them to market.

There is unrealized transformative potential here – both from individual innovations and from their deployment in combination. The SAGE GVAP Working Group will revisit progress in two years and hopes to see considerable change.

## VACCINE DISTRIBUTION

Vaccines are distributed far and wide, from their place of manufacture to the hands of the millions of healthcare workers who administer them. This requires many different technologies, particularly to transport, refrigerate and monitor the vaccine. Every year, new technologies are developed and are ‘prequalified’ by WHO, indicating to countries that they are judged effective and safe. There are now 252 such vaccine delivery products. This represents a 50% increase since 2010.

The distribution challenge is particularly compounded by the need to keep most vaccines cold throughout their journey. Manufacturers are therefore showing interest in the idea that some vaccines might safely be transported and stored at a somewhat higher temperature, at least for the last part of their journey. This ‘controlled temperature chain’ (rather than the normal ‘cold chain’) could be cost-saving, helpfully reducing the requirement for refrigeration, which can be a challenge in remote areas with unreliable electricity.

## IN BRIEF

New ways of giving vaccines – great promise here

Technologies may cost more to buy but create savings down the line

Controlled-temperature chain: unrealized potential

One vaccine, MenAfrivac, has been licensed and used in a controlled temperature chain. This has been very successful and provides a model for what can be achieved. Manufacturers are clearly interested in having other vaccines similarly licensed, which is a positive development.

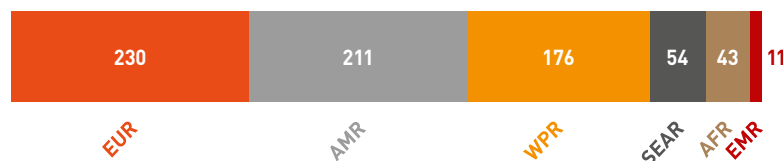
Countries are not yet jumping at the idea of controlled-temperature chain-licensed vaccines, though. In particular, they are concerned about causing confusion amongst vaccination staff who have, for decades, been trained on the importance of maintaining the cold chain. It is important that countries are helped with this. A controlled-temperature chain could be cost saving. Manufacturers will only continue to have vaccines re-licensed for controlled-temperature chain use if countries show interest in using them.

### VACCINE TRIALS: INSTITUTIONAL AND TECHNICAL CAPACITY

Every region of the world should have a solid base of countries competent in hosting and managing vaccine trials. The GVAP aims to achieve this by the end of the decade.

In the last year (May 2013-May 2014), 725 vaccine clinical trials were registered in 64 countries. There are trials in every region, but it is clear that some countries and regions have far greater capacity than others. In each region, between 28% and 45% of countries registered at least one trial – except for EMR, where just three countries (14%) did so.

#### 725 VACCINE TRIALS IN 64 COUNTRIES: MORE THAN HALF IN EUR AND AMR



Priority should be given to enhancing the capacity of regulatory committees and agencies. These play a crucial role in the planning, approval and oversight of clinical trials. They allow trials to proceed smoothly and safely. In AFR, there has been strong work on this front. This needs to continue, and other regions may wish to learn from it.

Greater research capacity is not just required in laboratories. Operational and implementation-focused research is also vital, to understand how to most effectively and efficiently deliver vaccines in practice.

The SAGE is concerned about a persistent trend of vaccine (and other) trials being carried out in a lower income country but overseen, analyzed and published by researchers from higher income countries. This does too little to build countries' own capacity to conduct trials. It is untenable and even ethically questionable. Those in lower income countries too often do the 'heavy lifting', the glory goes elsewhere, and talent is not developed in the way that it needs to be.

### IN BRIEF

Vaccine trials: strong regulatory bodies key

Researchers in lower income countries should lead work, not just do the 'heavy lifting' for others

## CONCLUSION

The Global Vaccine Action Plan was established for very good reasons, to meet major and important needs. Progress towards its key targets is clearly far off-track. This should cause alarm bells to ring loudly. Vaccines are not being delivered equitably or reliably. Through vaccination, diseases such as tetanus and polio should have been consigned to history several years ago – previous targets for doing so have repeatedly been missed.

The five off-track targets are closely related. They are not separate, competing endeavours, but close cousins. The key to achieving all of them lies in strengthening immunization systems.

There are clear areas in which focused action can produce considerable improvement. This report has identified five that are particularly important. If these are acted upon, real progress can be made.

The Global Vaccine Action Plan sets important ambitions. If countries and their partners are to achieve these, dramatic change is needed. If they can do so, millions of deaths will be prevented.

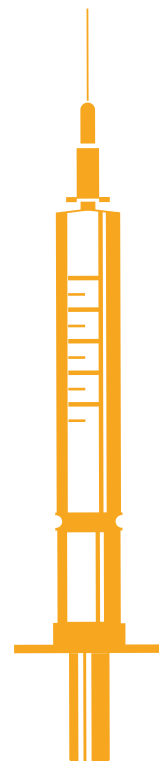
This report's recommendations need to be implemented with great urgency. The 'Decade of Vaccines' is one-third through, and the Global Vaccine Action Plan is an opportunity that should not be lost.

The SAGE, through its Global Vaccine Action Plan Working Group, will re-examine the situation annually.

This report has made 18 recommendations:

### **Weak GVAP implementation**

- The Director-General of WHO convene a special session at the 2015 World Health Assembly for countries with routine vaccination (DTP3) coverage of less than 80%, to which each Minister of Health is asked to report on their challenges, plans and timelines to improve coverage to meet the GVAP goals.
- The SAGE's GVAP assessment reports remain as standing items at the World Health Assembly until 2020.
- The failure to achieve the 2013 milestone for MNT elimination is related to a large extent to the funding gap. Partners should lead a concerted effort to fill this gap, by refreshing the communication approach and seeking novel partners for this vital, and repeatedly missed, goal.
- Regions and countries rapidly finalize their own vaccine action plans based on the GVAP, using this assessment report as a further guide and establishing bodies to guide and monitor implementation.
- Countries give CSOs substantially more formal involvement in the delivery and improvement of vaccination services, establishing clear responsibilities for which they are accountable.
- After consulting with their respective Regional Technical Advisory Group, every region establish a regional verification commission, and after consulting with their respective National Immunization Technical Advisory Group, every country explore options for establishing a national verification commission, to scrutinize and monitor progress towards the measles and rubella elimination targets.
- The heads of the GVAP Secretariat agencies (the Bill and Melinda Gates Foundation (BMGF), Gavi, the National Institute of Allergy and Infectious Diseases (NIAID), WHO and UNICEF) meet to consider this report and to agree on specific corrective actions.



- The heads of GVAP Secretariat agencies report to the 2015 World Economic Forum in Davos on the plan's establishment, its lack of progress so far and what fora participants – who supported the Decade of Vaccines concept in 2010 – can do to help its implementation.
- Following adoption of the GVAP and subsequently revision and adoption of regional and national plans, countries have the responsibility to ensure that immunization goals are shared, discussed and fully adopted by health care workers.

#### **Poor data quality and use**

- Countries invest in improving data quality at the local level, and use data to strengthen accountability and to improve understanding of what the programmatic issues are.
- Technical agencies further develop and deploy tools to help countries with the practical task of improving the quality and use of data, with limited personnel available to do so.

#### **Vaccine affordability and supply**

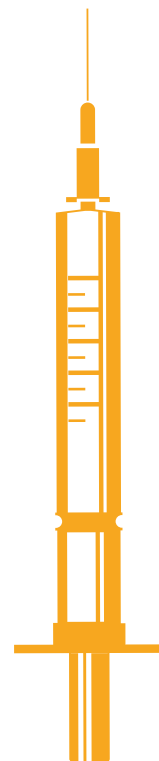
- Technical agencies conduct urgent assessments of (i) the extent to which the reported national-level stockouts are affecting local vaccine supply and delivery, and (ii) the root causes of these stockouts.
- Countries are requested to change the rules of the game on vaccine affordability, to create transparency which is in their interest. They can do this by making pricing information publicly available, and by collaborating with WHO and all technical agencies to develop solutions.
- Technical partners support countries to improve the transparency of vaccine pricing. Technical agencies themselves should do everything possible to share pricing data.

#### **Failures of basic integration**

- Countries conduct studies to understand how opportunities to vaccinate people are being missed by healthcare workers, and act to reduce their incidence.
- WHO discuss and develop guidelines on how to fully integrate vaccination into the operation of all aspects of the healthcare system and to address missed opportunities to vaccinate.
- Countries ensure that healthcare workers understand and follow WHO or national guidelines on what does, and does not, contraindicate vaccination, particularly in relation to childhood febrile illness, so that vaccines are not avoided unnecessarily.

#### **Situations disrupting immunization**

- WHO expand its existing guidance on immunization in humanitarian emergencies to detail how routine and other immunization services are best maintained despite disruptive situations such as war and disease outbreaks.





## ANNEX

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United Nations Children's Fund  
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## ANNEX

### ADDITIONAL RECOMMENDATIONS TO THE DECADE OF VACCINES / GLOBAL VACCINE ACTION PLAN SECRETARIAT

The SAGE's main recommendations are made within the body of this report. In addition, the SAGE Working Group on the Decade of Vaccines makes the following recommendations to the Decade of Vaccines Secretariat:

1. The heads of the GVAP Secretariat agencies (the Bill & Melinda Gates Foundation (BMGF), Gavi, the National Institute of Allergy and Infectious Diseases (NIAID), WHO and UNICEF) meet to consider this report and to agree on specific corrective actions.
2. The heads of GVAP Secretariat agencies report to the 2015 World Economic Forum in Davos on the plan's establishment, its lack of progress so far and what forum participants – who supported the Decade of Vaccines concept in 2010 – can do to help its implementation.
3. The following additions should be made to the GVAP Secretariat report in 2015:
  - a. A report from each WHO region on the implementation of its Regional Vaccine Action Plan.
  - b. A report from the GVAP Secretariat agencies setting out their response to, and actions taken to achieve, the recommendations addressed to them in the SAGE GVAP Assessment Report 2014.
  - c. A report from the GVAP Secretariat agencies on progress being achieved in improving data quality, including country case studies.
4. The GVAP Secretariat report in 2016 should include a wider landscape analysis of candidate vaccines in development, to supplement the analysis of vaccines against the sample of seven sentinel diseases reported in 2014. The Secretariat could perhaps attempt to list all vaccine trials in phase 2 and beyond.
5. Case studies should be written and disseminated to illustrate (i) the licensing of MenAfriVac for use in a controlled-temperature-chain, (ii) the impact of the introduction of one or more new vaccine delivery technologies.
6. A small number of countries (perhaps 3-4) should be invited to present to the SAGE GVAP Working Group in March 2015, to describe the actions that they are taking to improve vaccination coverage.
7. The definition of indicator 4.2 should be expanded to include technologies that improve safety and efficiency of vaccine delivery, as follows: "New platform delivery technology defined as a new mechanism for delivering vaccines to individuals that facilitates coverage, improves efficacy or safety, or reduces the cost of vaccine or delivery".
8. Work should continue to develop and/or select indicators that provide more valid and useful information about vaccine demand than the current indicators are able to.
9. Countries should be encouraged and helped to use the online GVAP immunization dashboard tools to review their performance.



