Health Security in Africa: the importance of local vaccine development and manufacturing

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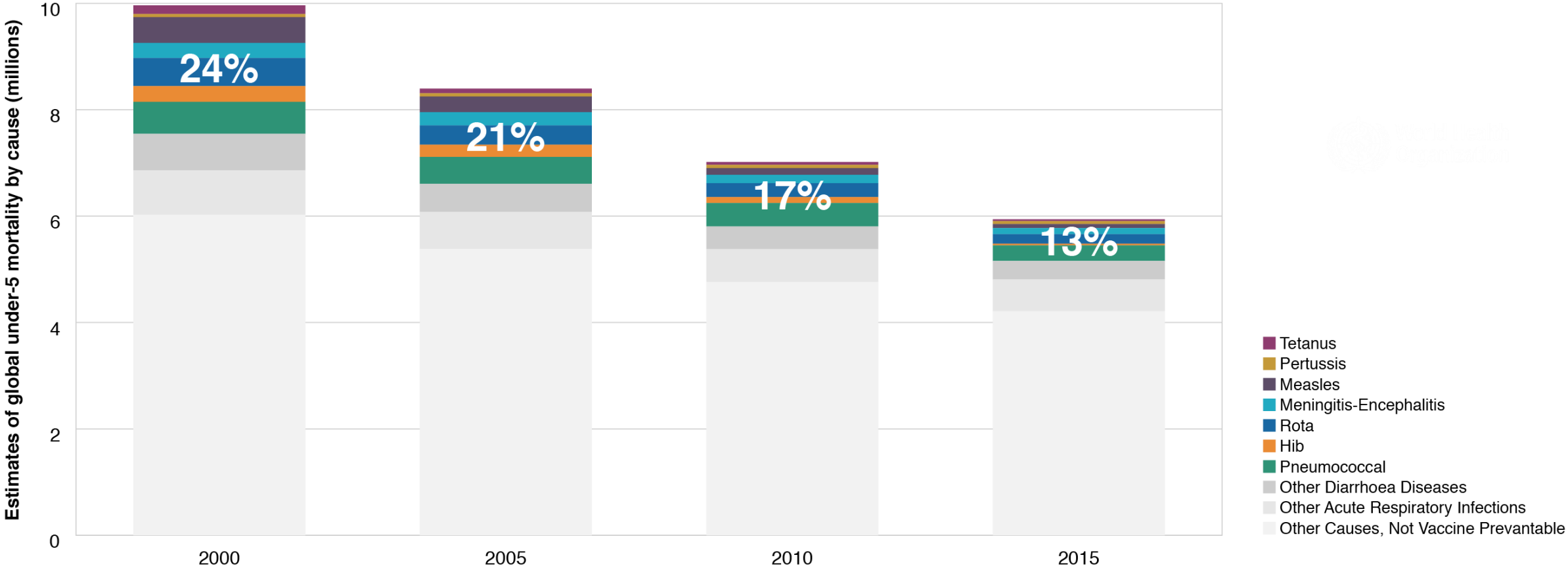
AVMI –AGM, Freetown, 24-25 Sept 2018

Presentation Outline

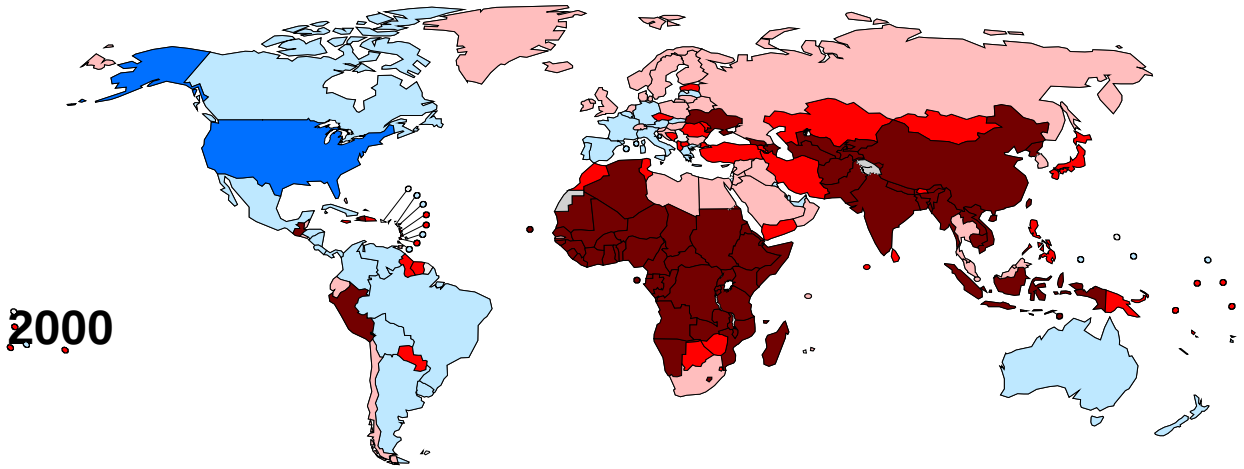
- Progress in the use of vaccines in RI and in emergency response to outbreaks
- Main supply constraints
- Looking forward: the importance of local vaccine development and production
- AVMI role

Vaccines work, but vaccine preventable diseases are still a significant cause of under-5 mortality



Source: Rota: Preliminary data (US Centers for Disease control), Hib and PCV: John's Hopkins University, other causes: WHO - Global Health Observatory

Number of Vaccines/Antigens Introduced Nationwide in Immunization Schedules

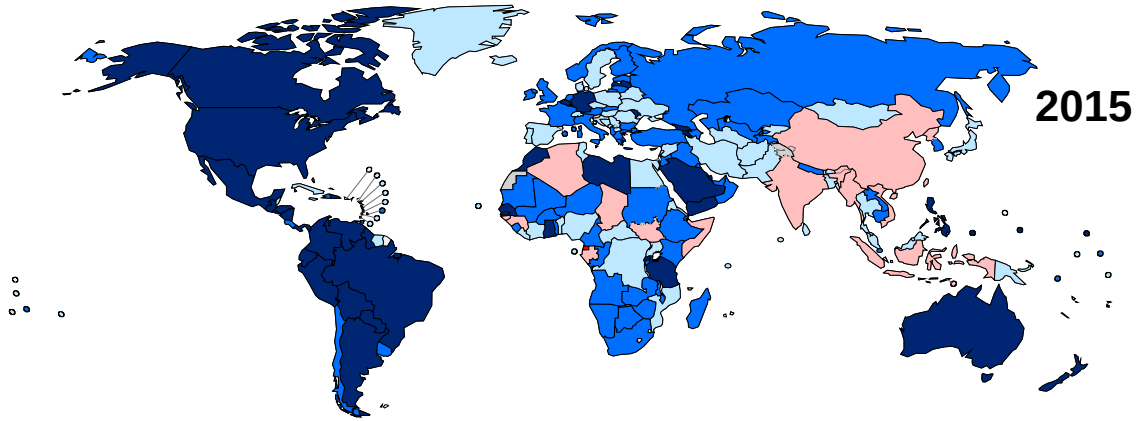


Selected antigens are :
Diphtheria, Tetanus, Pertussis,
Measles, Polio
Hepatitis B,
Heamophilius Influenza type B,
Pneumococcal conjugate
Rotavirus
Rubella

5 antigens (DTP, Measles and Polio)
6 antigens
7 antigens
8 antigens
9 antigens
10 antigens
Not applicable
Not available

Data Source: WHO/IVB Database, 2015

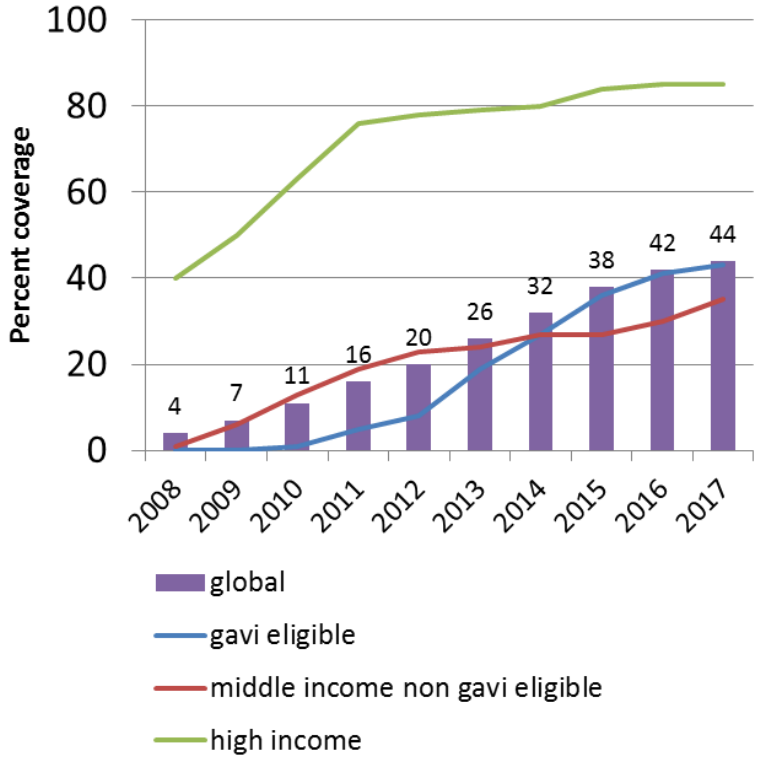
Map production: Immunization Vaccines and Biologicals, (IVB), World Health Organization



New vaccine introduction Pneumococcal and Rotavirus vaccine

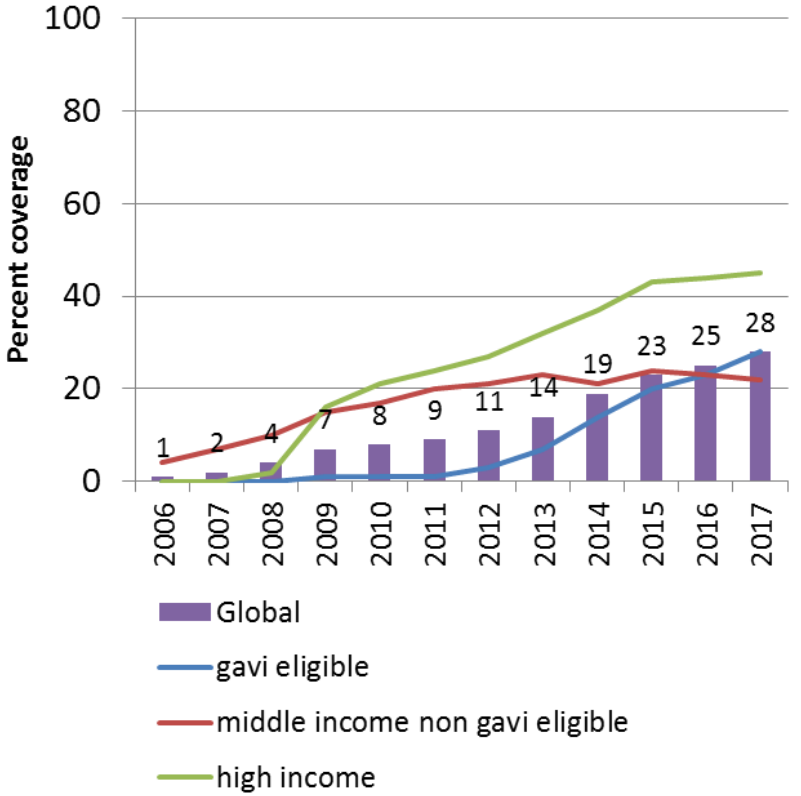
Pneumococcal vaccine

introduced in 140* member states



Rotavirus vaccine

introduced in 97** member states



New vaccine introduction

is lagging in middle income countries.

Newly available vaccines are being added as part of the life-saving vaccination package – such as those to protect against meningitis, malaria and even Ebola. On the other hand, vaccines to prevent against major killers of children such as rotavirus, a disease that causes severe childhood diarrhoea, and pneumonia, have been around for over a decade. But the use of rotavirus and pneumococcal conjugate vaccines is lagging behind.

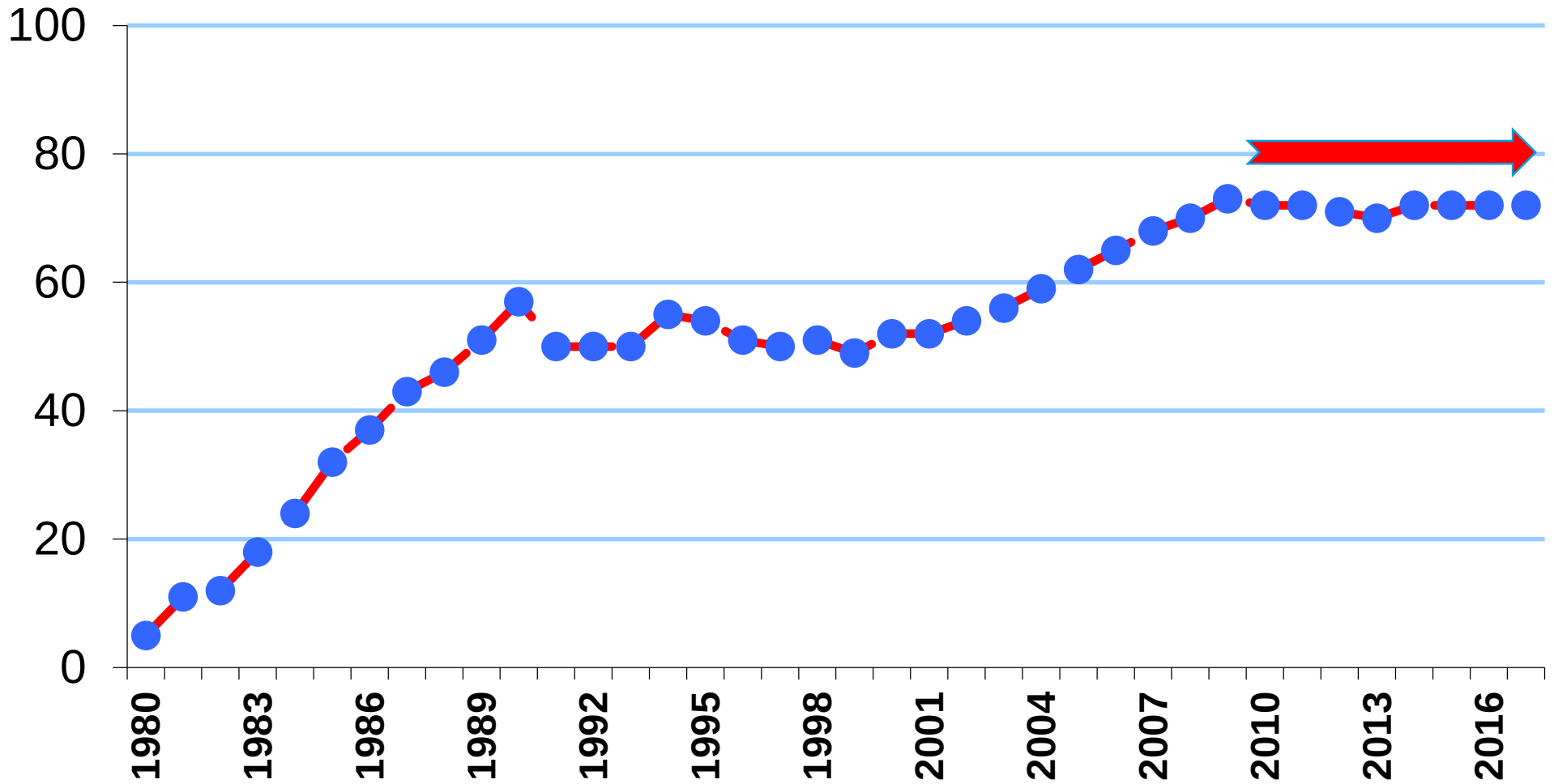
In 2017, global coverage for rotavirus was only 28 % and 44% for PCV. Vaccination against both these diseases has the potential to substantially reduce deaths of children under 5 years of age, a target of the Sustainable Development Goals.

unicef World Health Organization

* Includes partial introduction for 5 countries

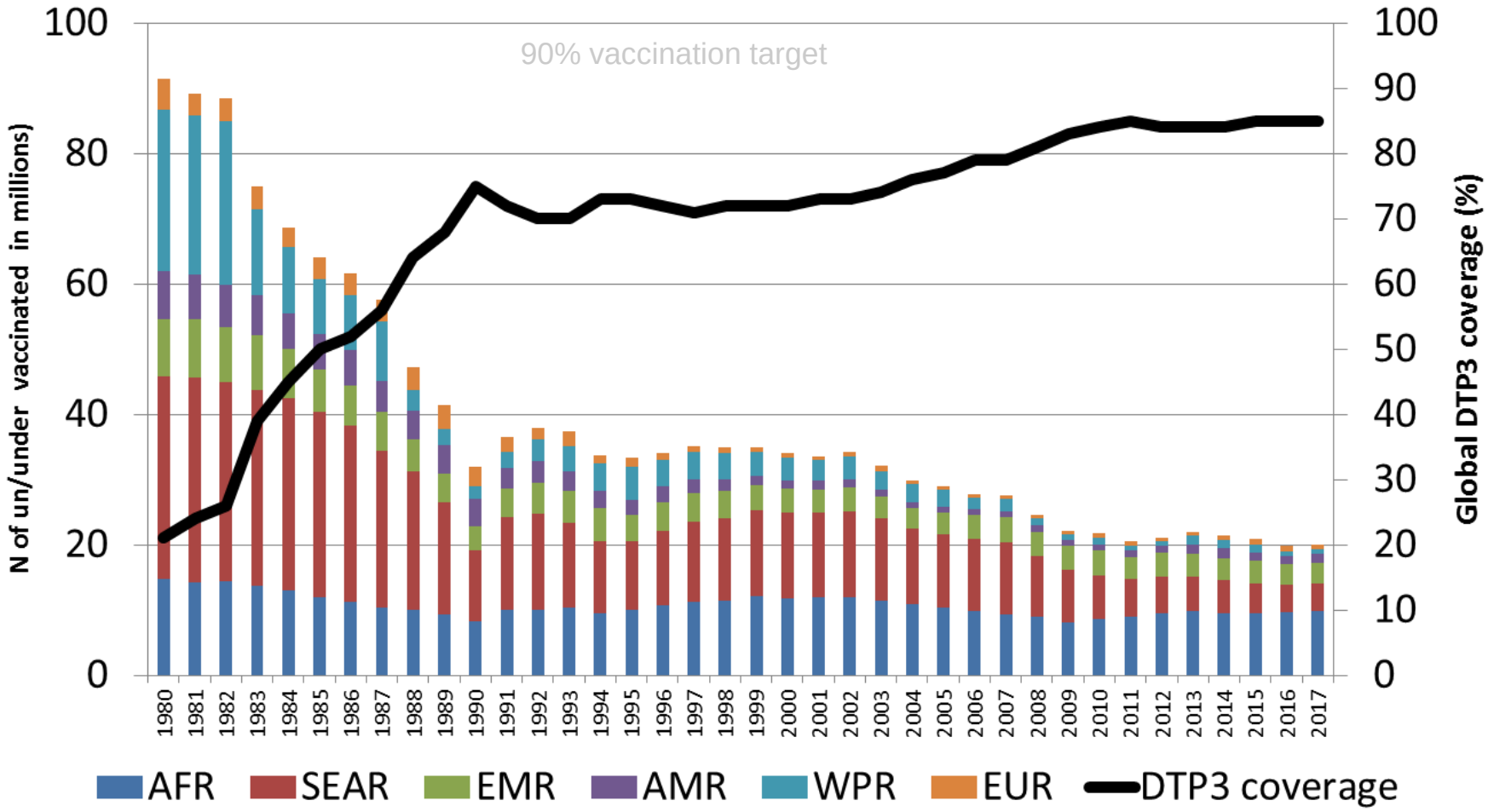
**includes partial introduction for 6 countries

DTPcv3 coverage, African region, 1980-2017



Source: WHO/IVB database, 2018
Data as of July 2018

Global DTPcv3 Coverage and Number of Unvaccinated and Under-vaccinated Infants by WHO Region

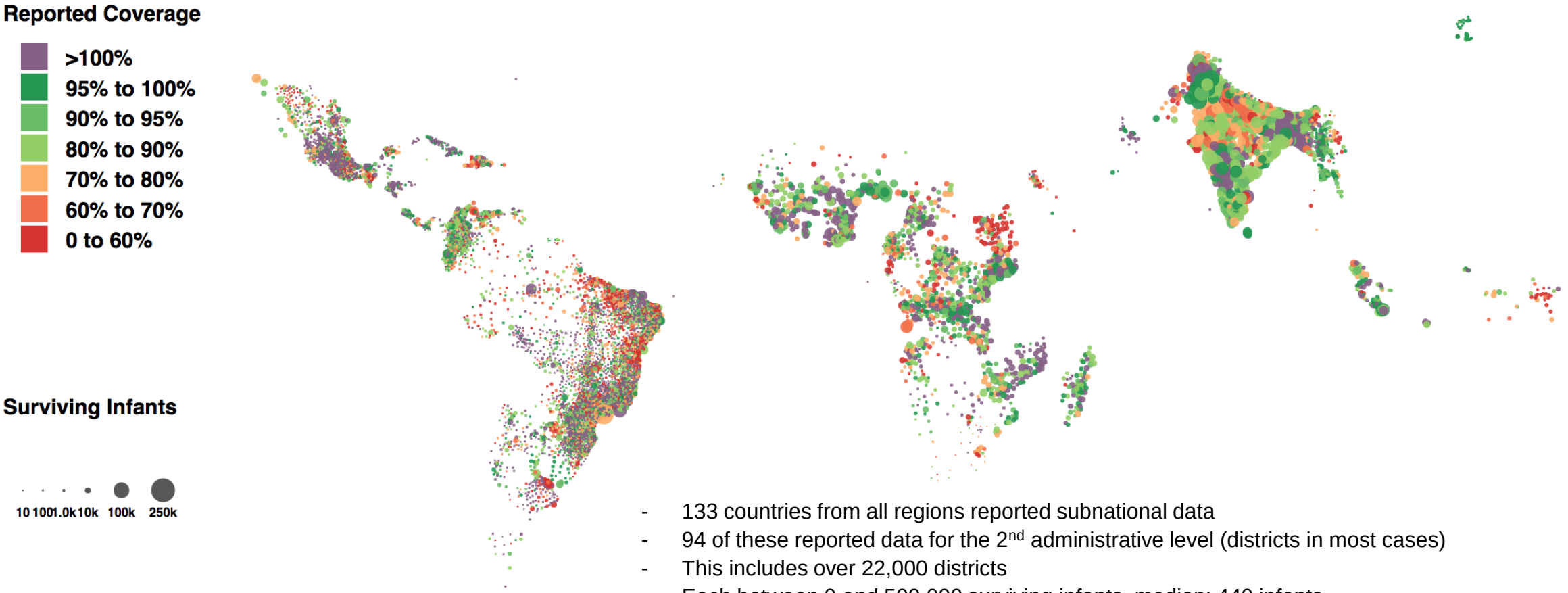


DTP3 coverage remains at 85% in 2017, leaving 19.9 million children vulnerable to vaccine preventable diseases

Since 2015, the percentage of children who received their full course of three dose diphtheria-tetanus-pertussis (DTP3) routine immunizations remains at 85%, with no significant changes in any region during the past year. This falls short of the global immunization coverage targets of 90%, one of the targets set out in the Global Vaccine Action Plan.

Out of 20 infants, 2 are completely left out, while 1 started but didn't complete the 3-dose course.

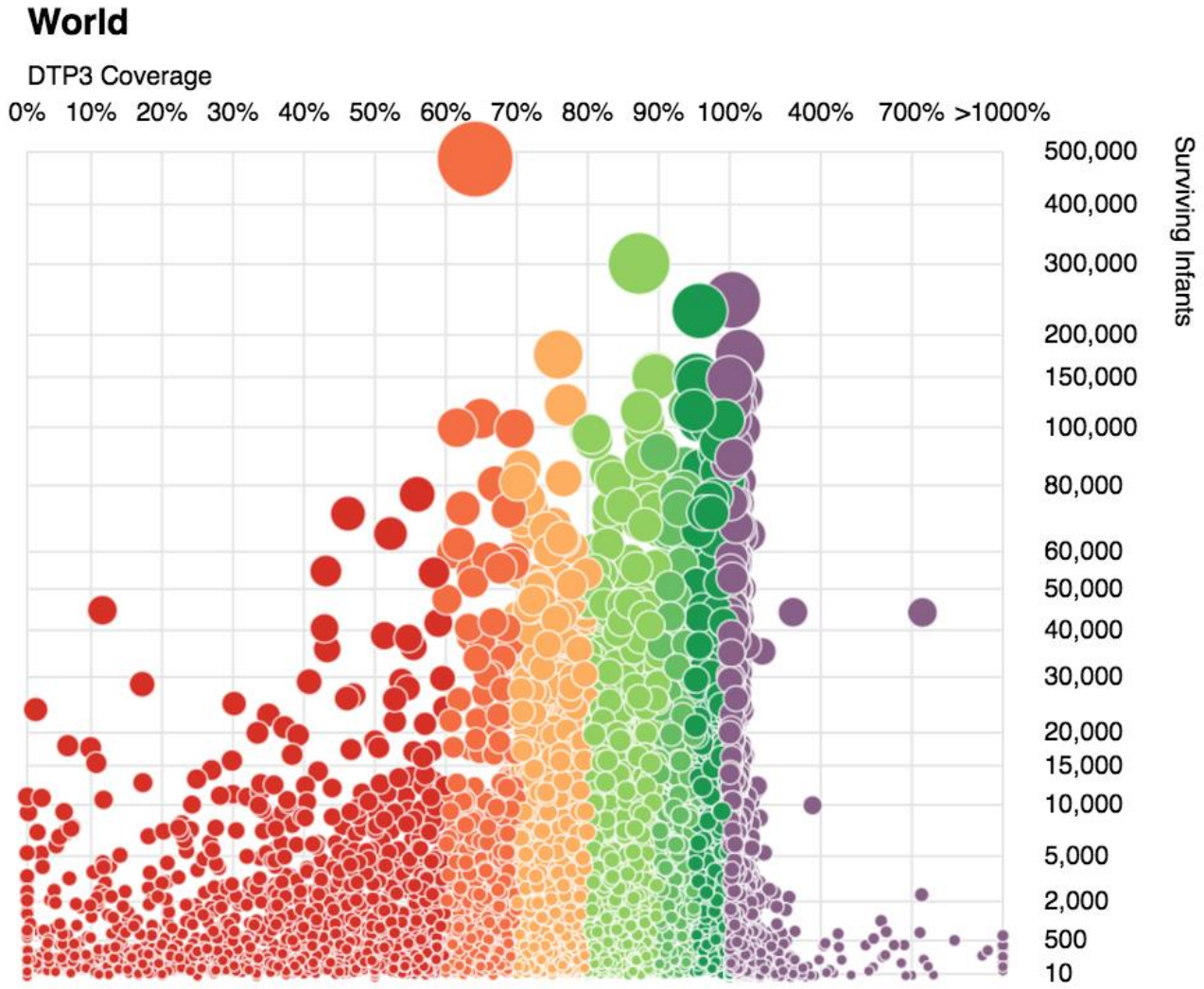
WHO and UNICEF collected subnational data at global level for the first time



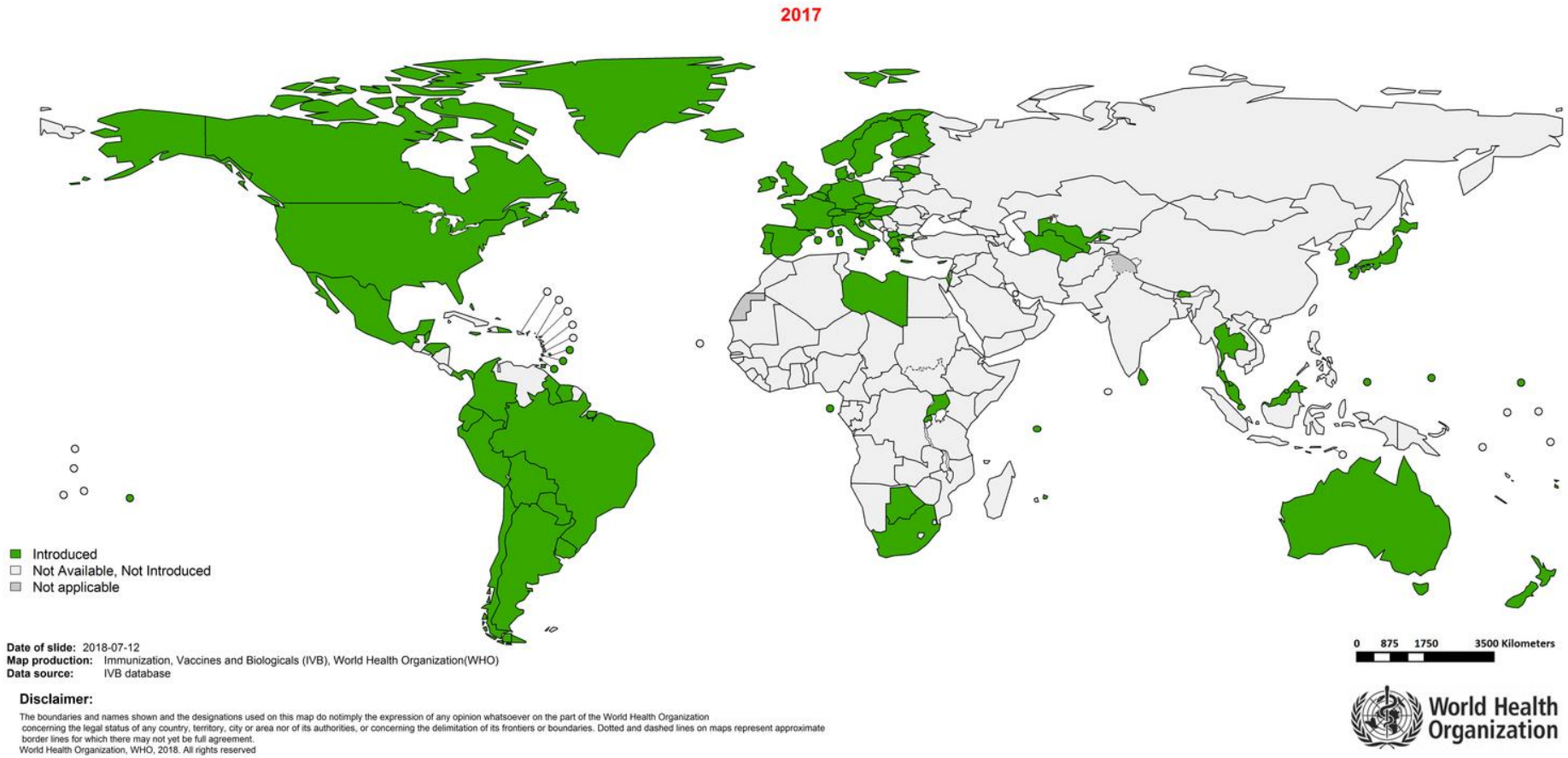
- 133 countries from all regions reported subnational data
- 94 of these reported data for the 2nd administrative level (districts in most cases)
- This includes over 22,000 districts
- Each between 0 and 500,000 surviving infants, median: 440 infants

Source: Data reported by Member States to WHO

Data show large differences in coverage and size of districts. Data quality is an issue.

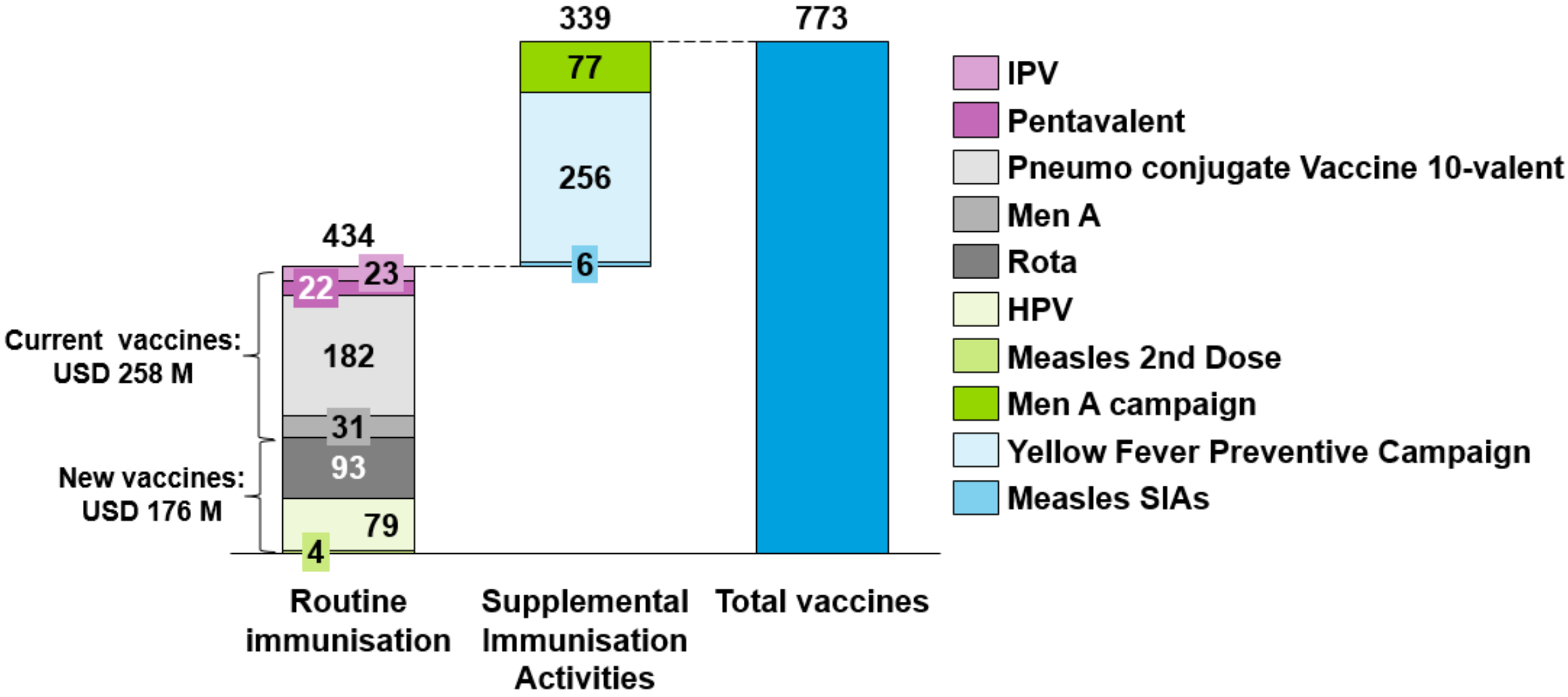


Only 1 out of 5 fifteen years old girl lives in a country with HPV vaccine in national immunization schedule

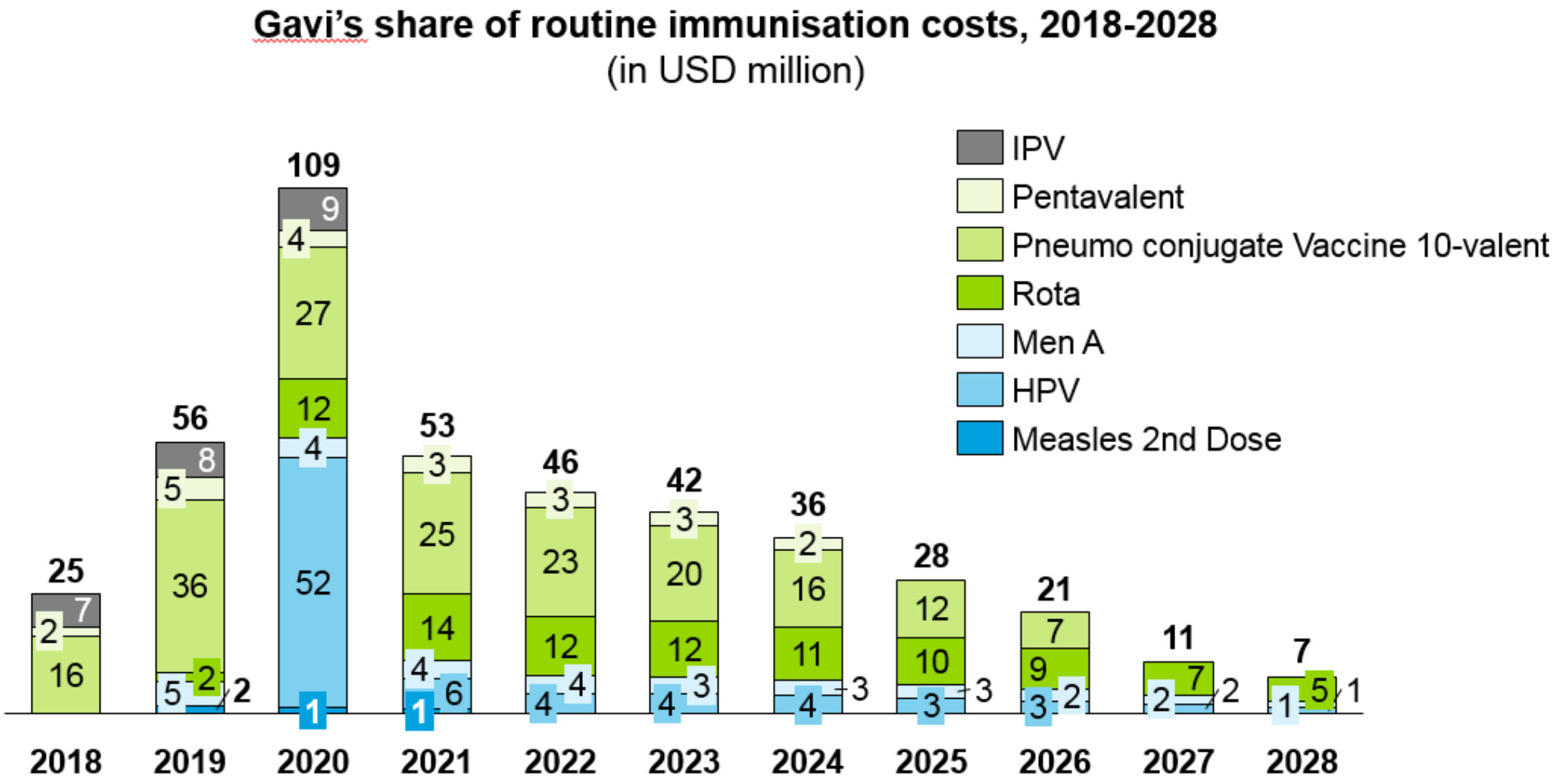


NIGERIA

Gavi's share of vaccine costs
(in USD million)



NIGERIA


Gavi's share of routine immunisation costs, 2018-2028
(in USD million)
IPV
Pentavalent
Pneumo conjugate Vaccine 10-valent
Rota
Men A
HPV
Measles 2nd Dose
2018
25
7
2
16
2019
56
8
5
36
5
2
2
2020
109
9
4
27
12
4
52
1
2021
53
3
25
14
4
6
1
2022
46
3
23
12
4
4
2023
42
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2025
28
12
10
3
3
2026
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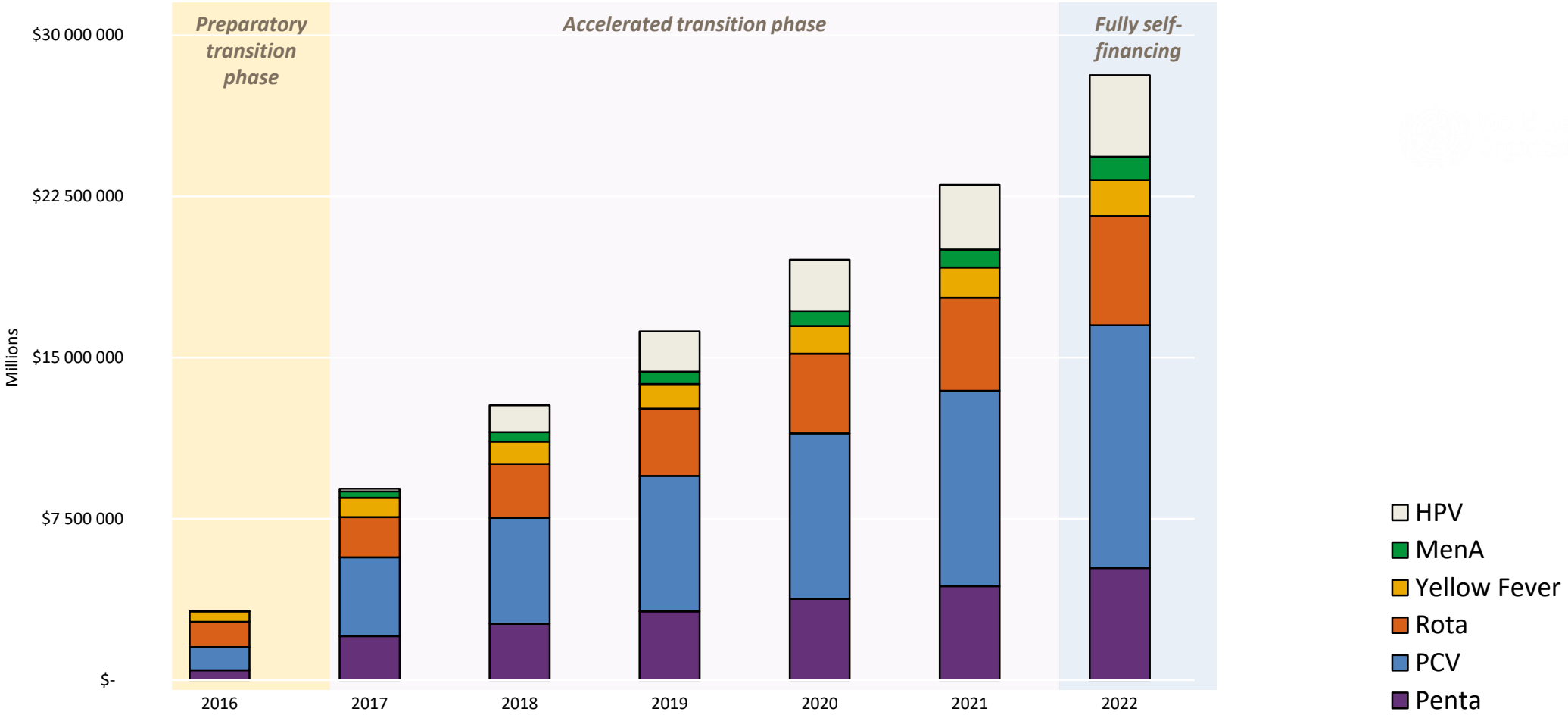
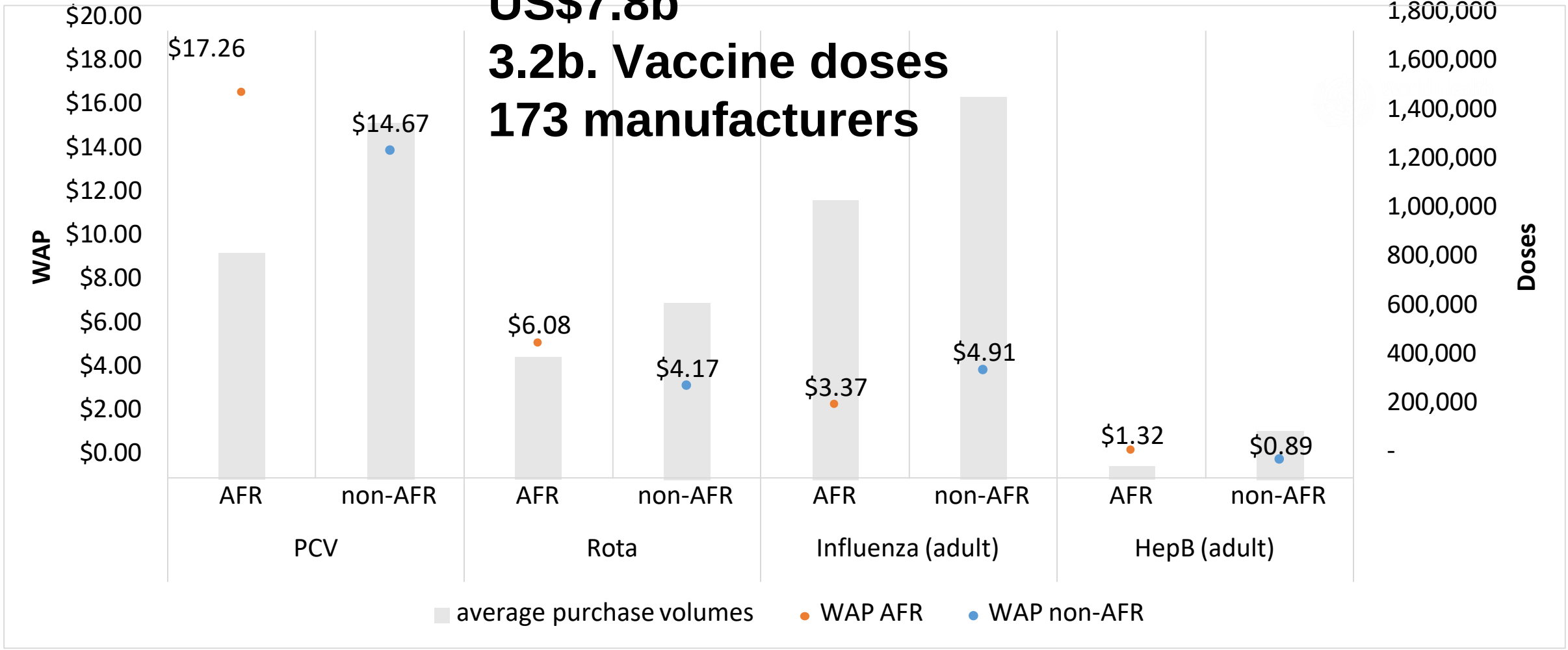
2
2028
7
1
5
1

Ghana: Cost for Gavi co-financed vaccines



Non-Gavi MICs in the Afro region pay higher prices for PCV, Rota and Hep B than other self-procuring MICs

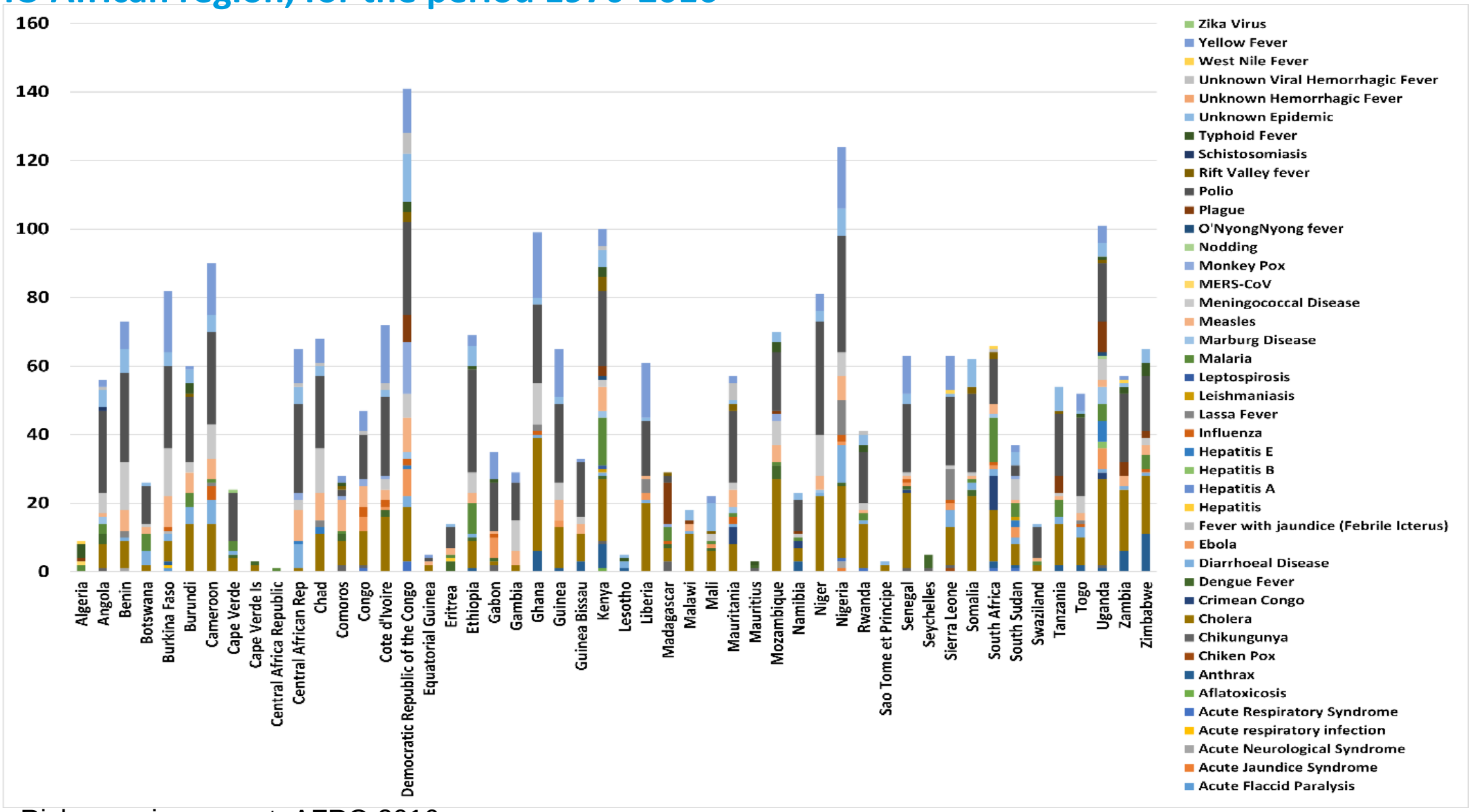
2016:
US$7.8b
3.2b. Vaccine doses
173 manufacturers



Source: WHO V3P

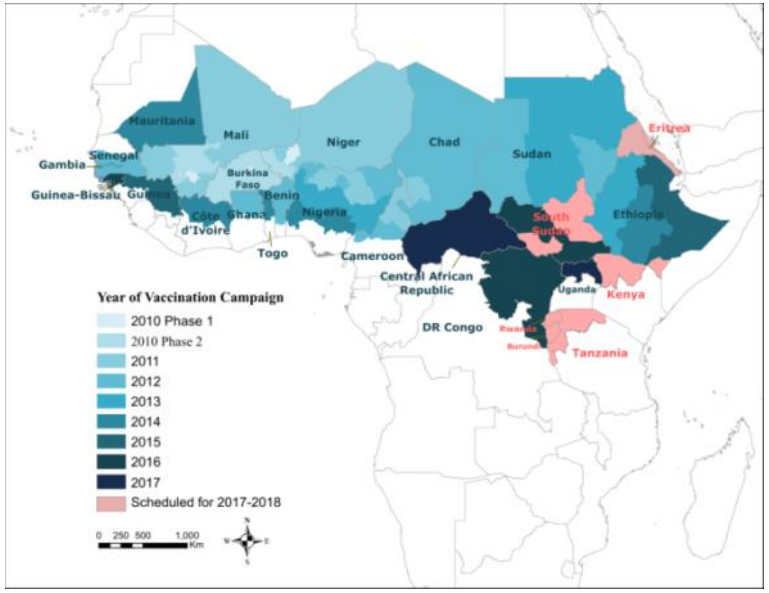
Increasing systematic use of vaccine in emergency response to outbreaks

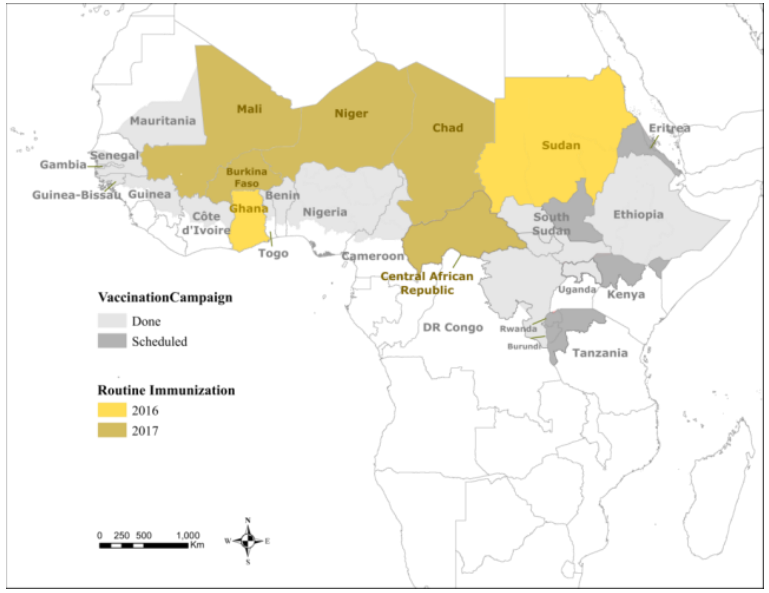
All the outbreak and epidemic events by disease in the countries of the WHO African region, for the period 1970-2016



Source: Risk mapping_report, AFRO 2016

Meningitis A: 30,000 deaths averted since 2010 in the African Meningitis belt





300,000,000 vaccinated

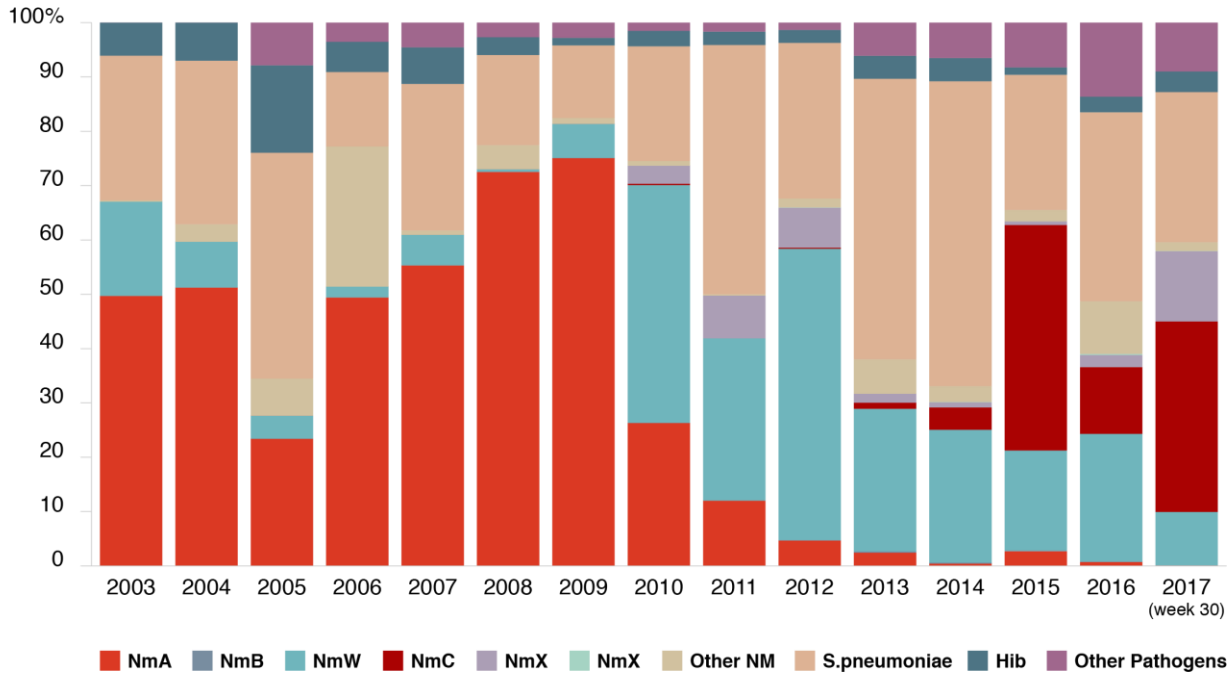
300,000 cases averted

30,000 deaths averted

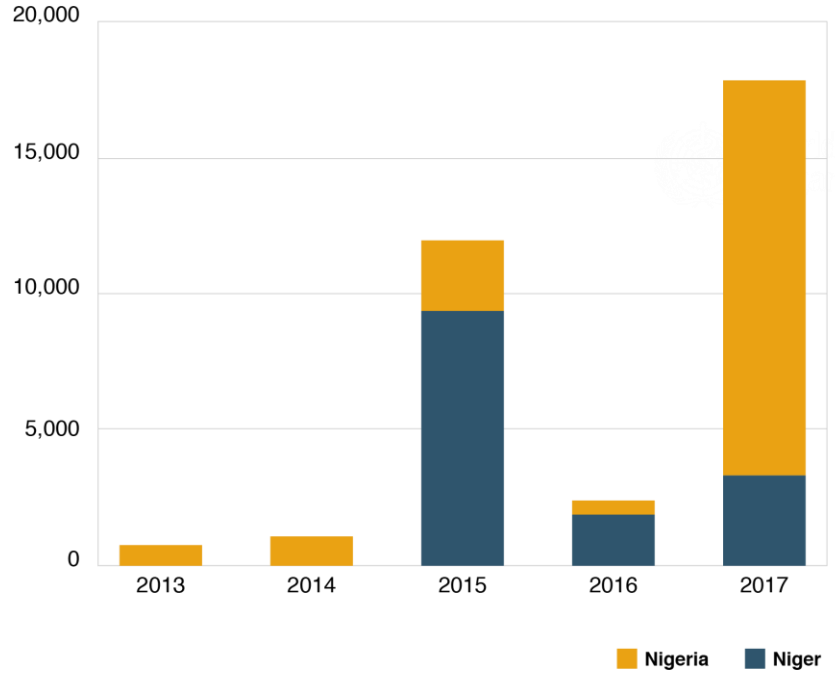
Source: Meningitis Vaccine Project

MenAfriVac has effectively reduced prevalence of Men A, while other strains remain a challenge

Bacteriological profile of meningitis outbreaks, 2003-2017

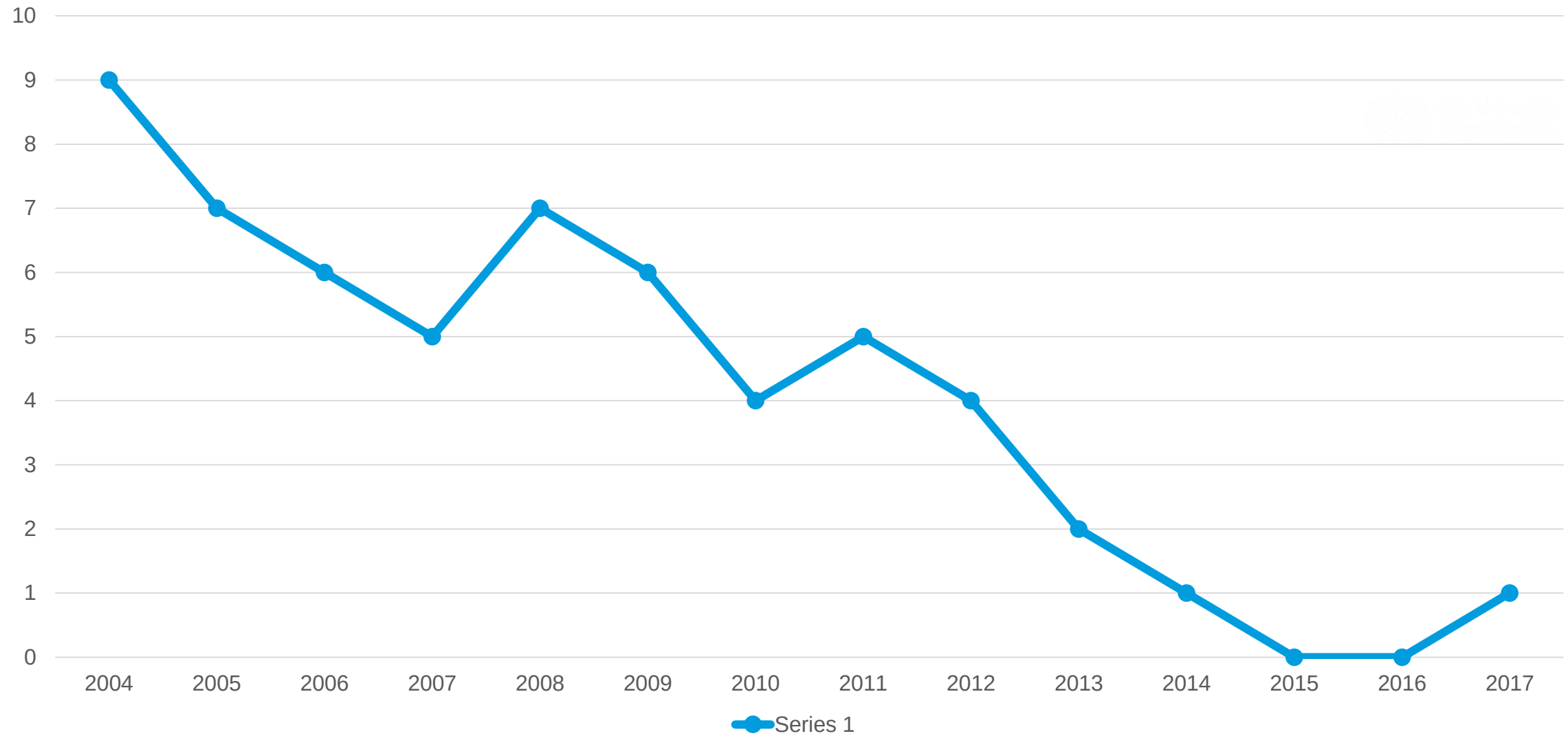


Large scale Nm C outbreak in Nigeria/Niger, 2013-2017

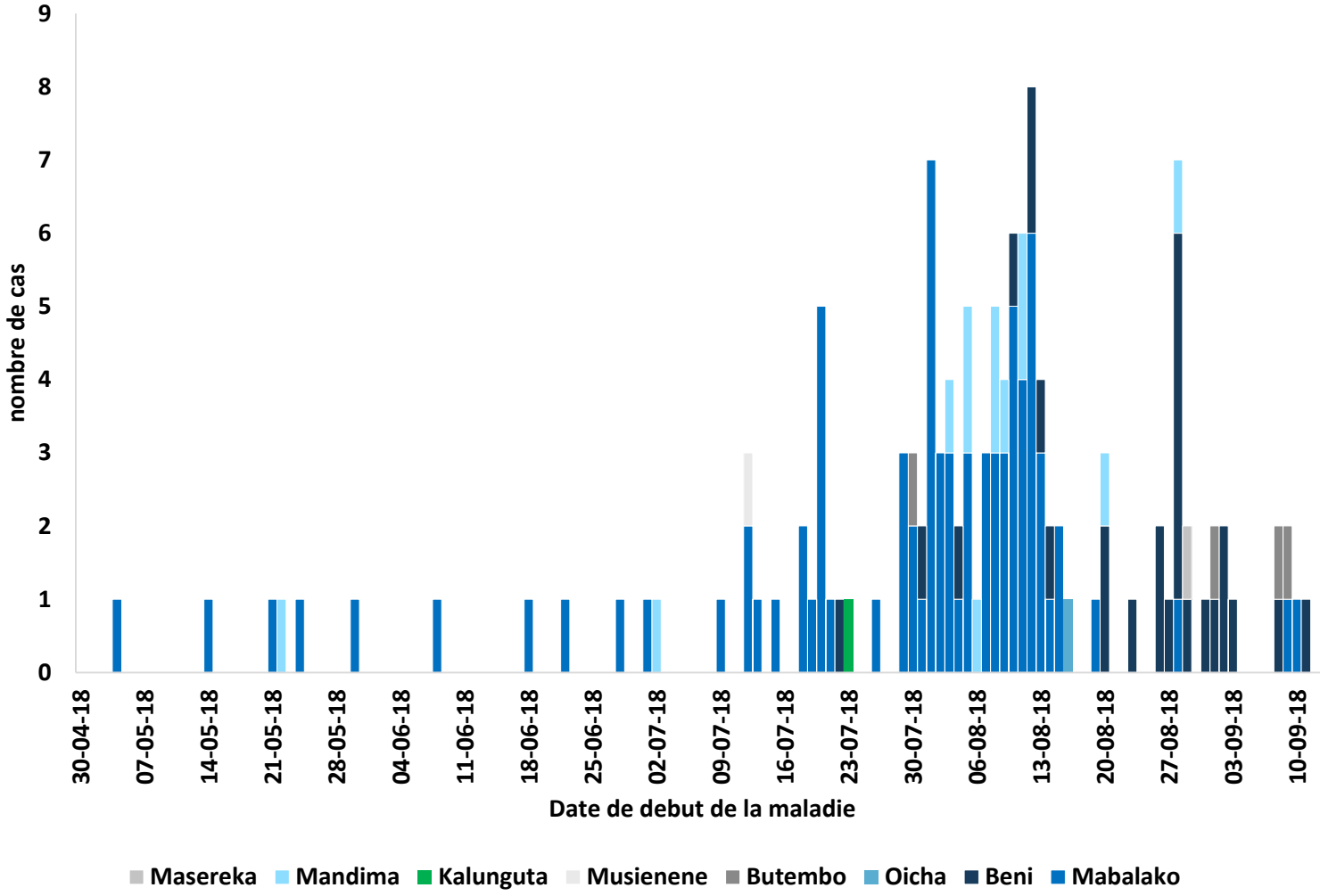


Source: Meningitis Vaccine Project

REPORTED YF OUTBREAKS: WEST AFRICA 2004-2017



Ebola Virus outbreak in DRC: confirmed and probable cases by date of disease onset and by district, as of mid Sept 2018



Use of investigational rVSV-ZEBOV vaccine in the Ebola outbreak in DRC, As of 21 Sept 2018

- 60 rings defined
  - Include contacts and contacts of contacts of all recently confirmed cases in the last 4 weeks
  - 25 rings of HCWs and FLWs

- To date 11,109 eligible and consented and vaccinated people
  - 4,368 HCWs and FLWs
  - 2,368 are children

What we know already about vaccine production

- **Establishing vaccine manufacturing is costly and difficult: Large cap-ex expenditure required and well as technical capabilities and expertise on production, pre-clinical and clinical trials, QMS and regulatory activities.**

- **Takes at least 10 years to establish if starting from scratch: facility design and construction, equipment purchase and installation, process optimization, preclinical testing, ph 1-3 clinical trials.**

- **Best to have a technology transfer partner (i.e an already established vaccine manufacturer) to transfer know-how, however can be difficult to find and one and must agree to their terms which often start with fill/finish operations before transferring full scale production, this can take even longer.**

What we know already about vaccine production

- **Even if not starting from scratch (i.e some facilities or buildings already in place) it will still take several years (to finalize process and conduct preclinical and clinical trials).**

- **Trained workforce essential which may be lacking in some countries.**

- **Market must be sufficient to sustain production:**
    - **Local commitment from Government essential**
    - **WHO PQ essential if considering purchase through UN agencies – therefore a fully functional NRA required.**

LOOKING FORWARD – SHOULD WE PRODUCE VACCINES IN AFRICA ?
Critical to expand local vaccine development & production in Africa

1. Sustainable supplies of vaccines, a security issue
2. African population growth
3. Burden of epidemic prone diseases
4. Global level “supporting” mechanisms recently established
5. Novel manufacturing technologies

Access to affordable vaccine supply is an issue that affects all countries at all the times… it is a security issue debated at WHA

Resolution 54.11 – WHA -May 2001

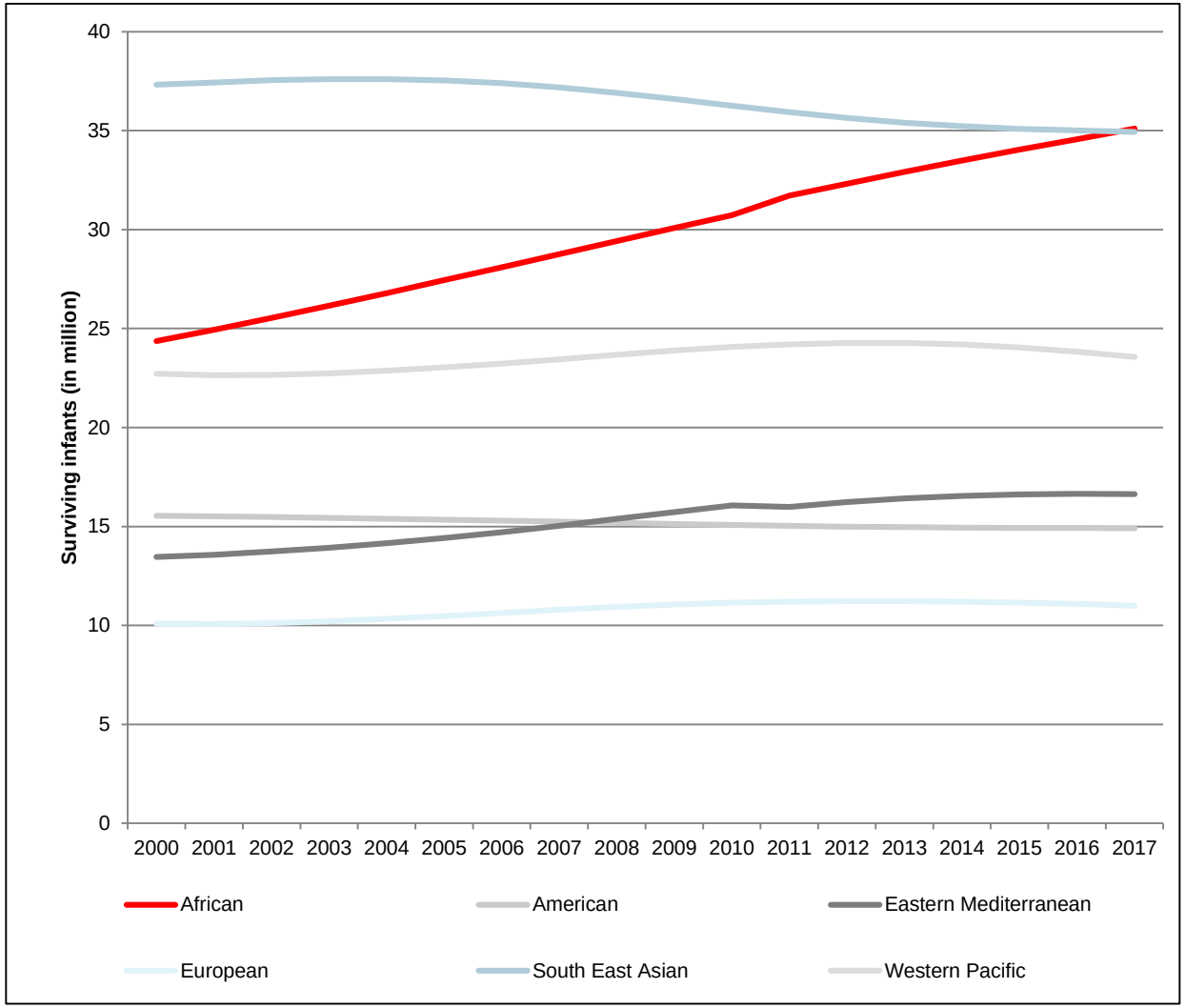
Obj. 5 Global Vaccine Action Plan - GVAP

Resolution 68.6 – WHA - May 2015

Resolution 69.25 – WHA – May 2016

SAGE Recommendation April 2015

Infant population growth, by region, 2000-2017



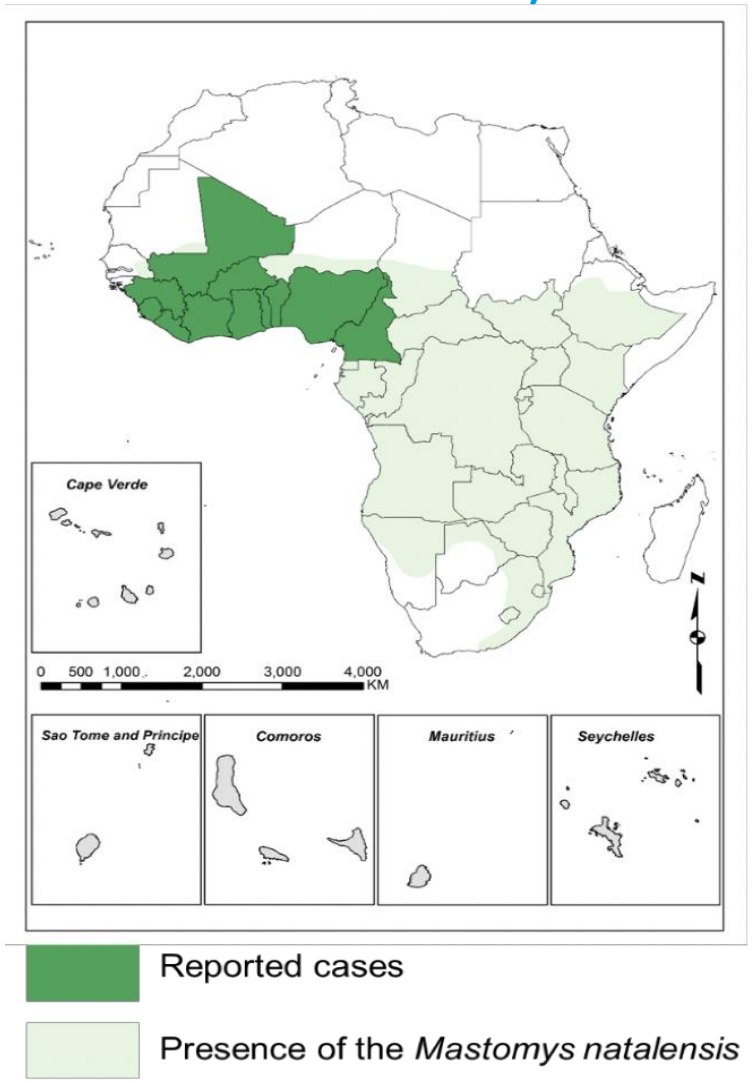
Africa population growth:

While population growth slows in the rest of the world, it continues to rise in Africa.

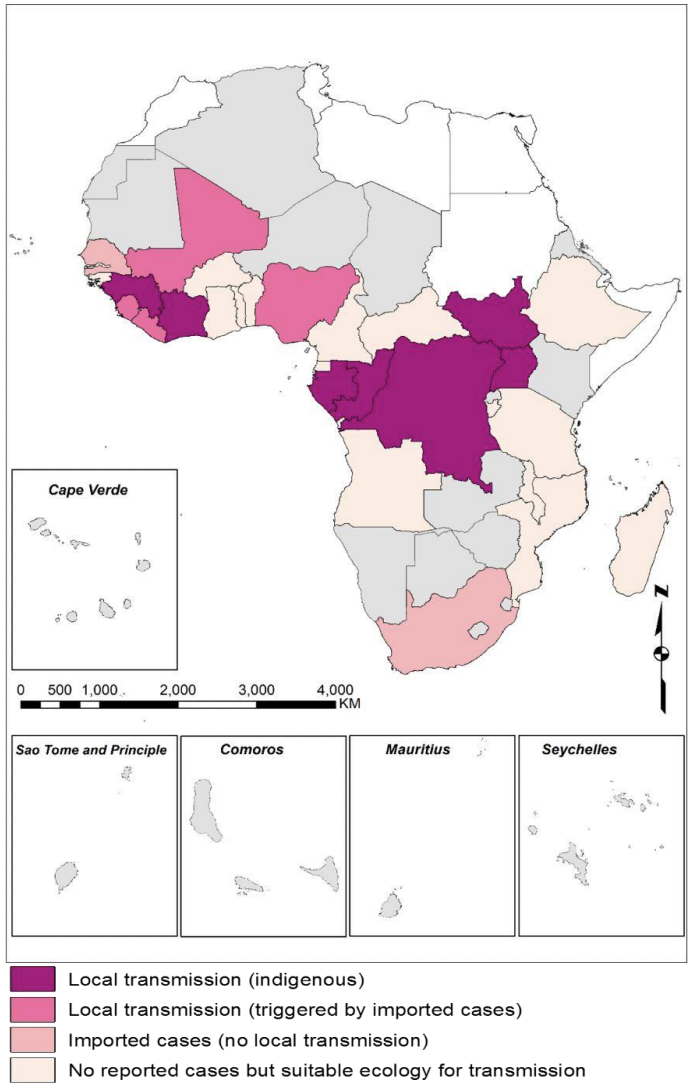
The continent of Africa is now home to 1.2 billion (up from just 477 million in 1980).

By the year 2050, annual increases will exceed 42 million people per year and total population will have doubled to 2.4 billion, according to the UN Population Division.

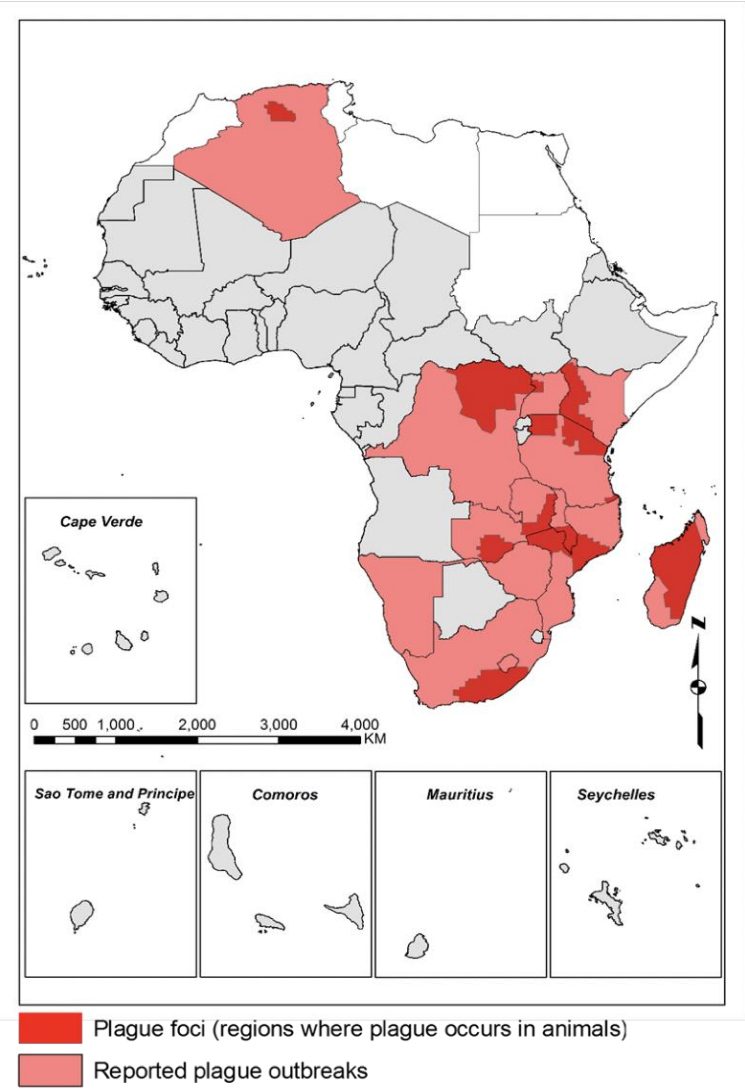
Lassa fever virus ecological zones (based on reported cases and potential environmental risk factors)



Ebola virus ecological zones



Plague ecological zones



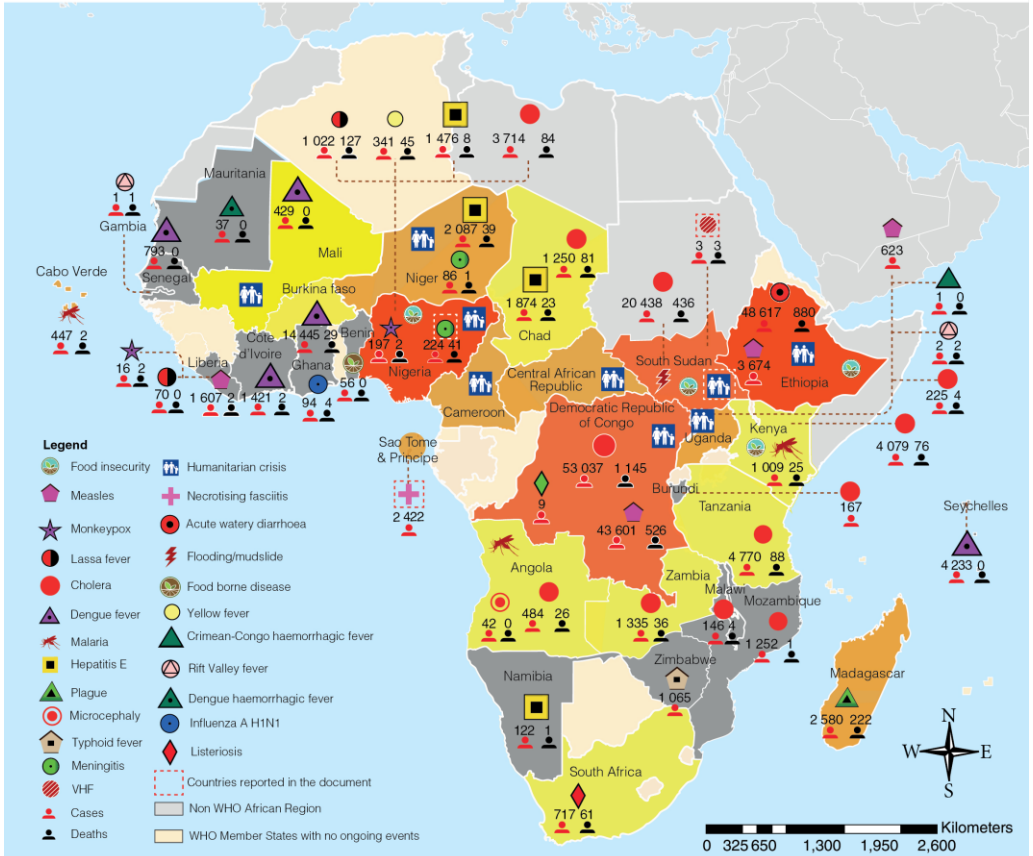
Source: Risk mapping_report, AFRO 2016

WEEKLY BULLETIN ON OUTBREAKS AND OTHER EMERGENCIES

Week 1: 30 December 2017 - 5 January 2018
Data as reported by 17:00; 5 January 2018

World Health Organization
REGIONAL OFFICE FOR Africa
WHO Health Emergencies Programme

3	50	44	9
New events	Ongoing events	Outbreaks	Humanitarian crises



2	6	8	34
Grade 3 events	Grade 2 events	Grade 1 events	Ungraded events
2	0	1	
Protracted 3 events	Protracted 2 events	Protracted 1 event	

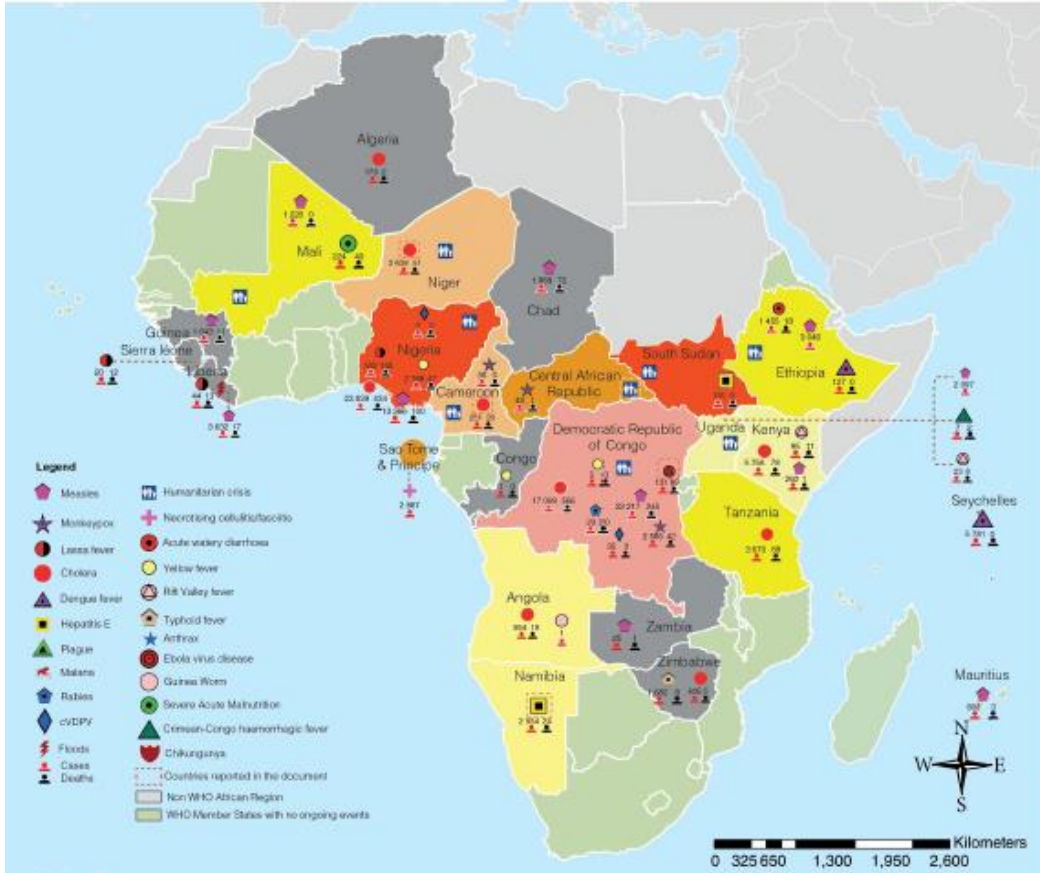
Health Emergency Information and Risk Assessment

WEEKLY BULLETIN ON OUTBREAKS AND OTHER EMERGENCIES

Week 36: 1 - 7 September 2018
Data as reported by 17:00; 7 September 2018

World Health Organization
Africa
WHO Health Emergencies Programme

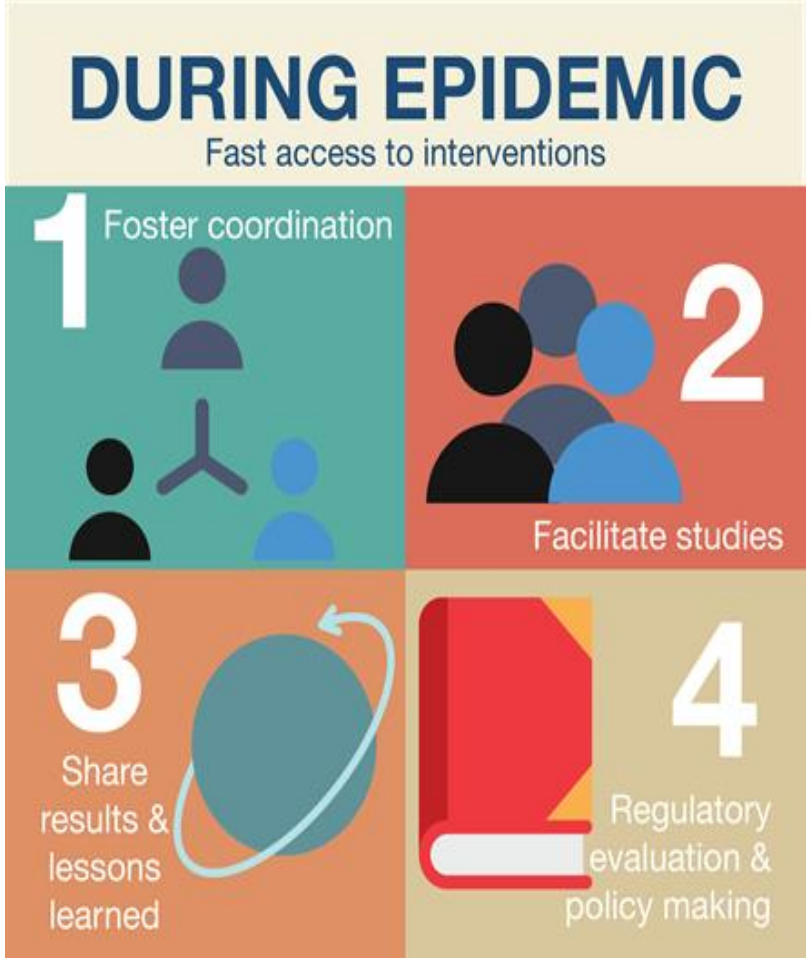
1	54	44	11
New event	Ongoing events	Outbreaks	Humanitarian crises



Graded events †

2	4	7	33
Grade 3 events	Grade 2 events	Grade 1 events	Ungraded events
2	2	4	
Protracted 3 events	Protracted 2 events	Protracted 1 events	

WHO VACCINES R&D Blueprint - Ebola/Marburg, Lassa, Nipah and CCHF



Source: WHO, 2018

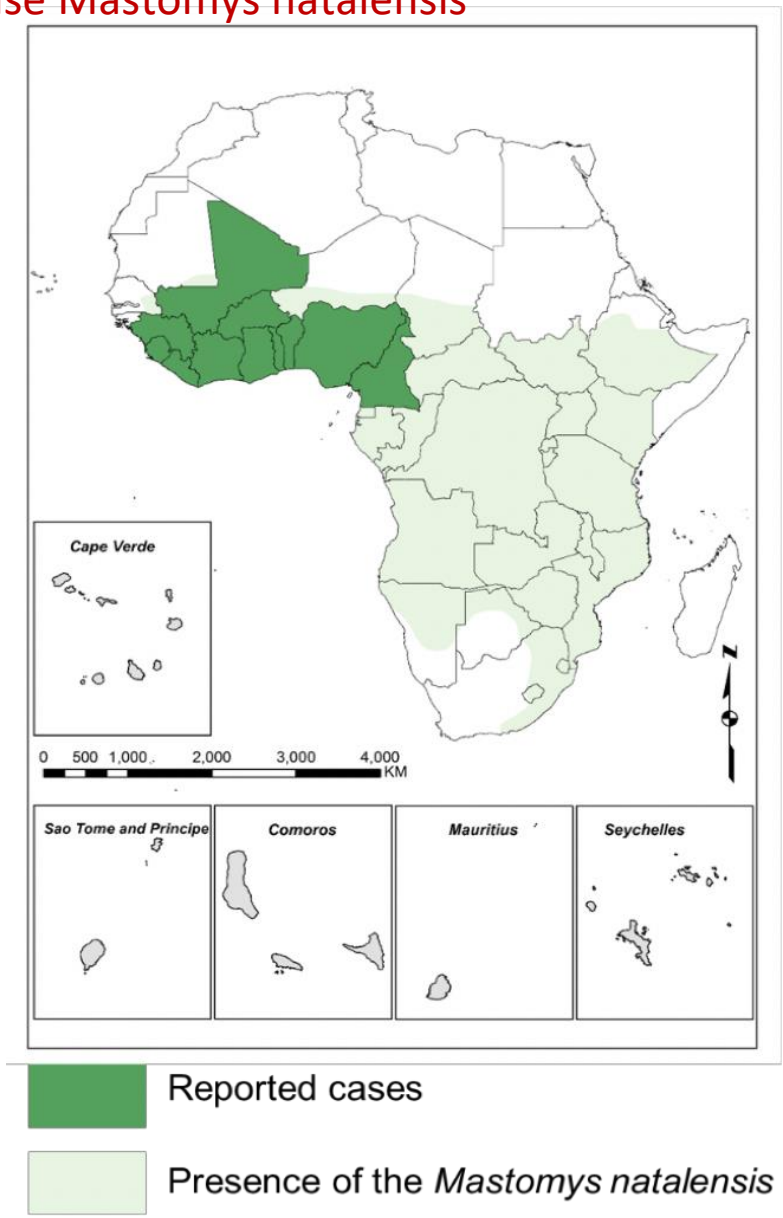
Lassa Vaccine R&D: Research Priorities

Complete preclinical evaluation of candidate LASV vaccines for safety, tolerability, immunogenicity, efficacy, correlates of protection, and estimation for duration of immunity and identify the most promising candidates to move forward.

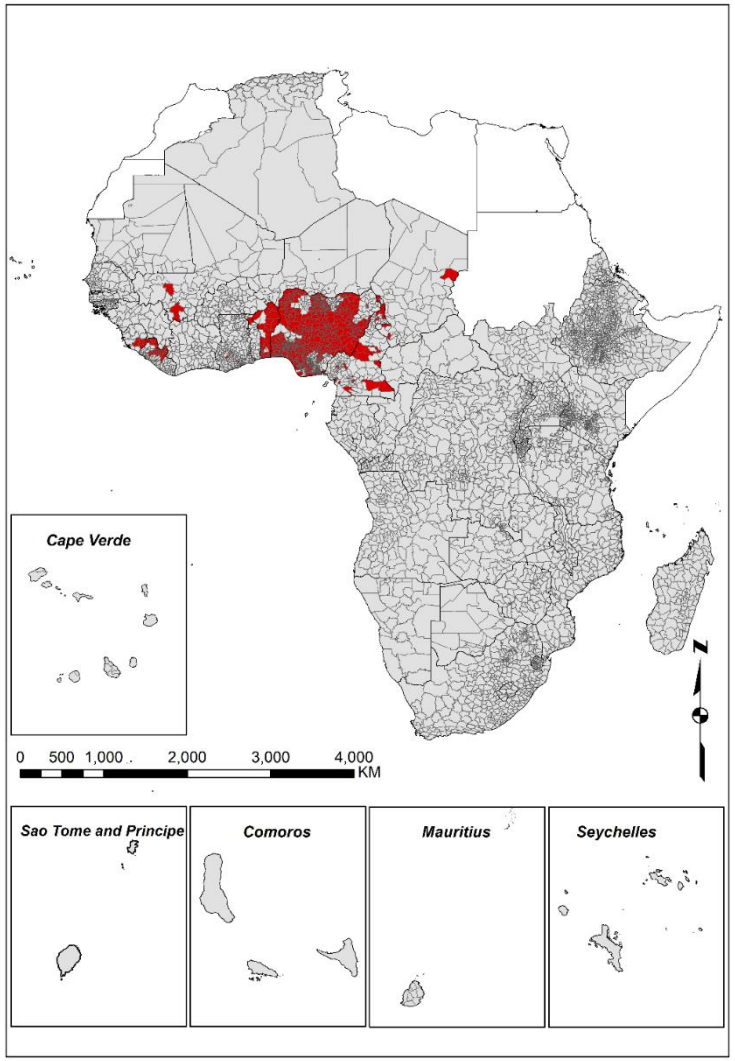
Conduct clinical trials of promising vaccine candidates (including early trials in non-affected areas or in affected areas as feasible) to determine dose regimen and assess safety, tolerability, and efficacy in various groups, including vulnerable populations.

Source: WHO, 2018

Lassa fever virus ecological zones mapped using a combination of reported cases and potential risk based on environment factors that support the habitation by the mouse Mastomys natalensis



District map of reported Lassa fever virus cases reported from 1989 to 2016. Some outbreaks have only being reported at national and could not be linked to a district



Source: Risk mapping_report, AFRO 2016

Consider acquiring novel manufacturing technologies

- **Low capital investment**
- **Use of local expertise while securing consistency in production performance**
- **Limitation of risks (simple & automated reproducible quality)**
- **Flexible production using same facilities**
- **Low volume while keep low production pricing**

Example UIVERSELLS http://www.univercells.com/about-us/

AVMI role is crucial …

Supporting country decision-making processes and business model evaluations

Contributing to capacity strengthening and building partnerships

Advocating for sustained access & viable vaccine development and production in the continent, building from the Heads of State Declaration on Immunization

African Vaccine Manufacturing Initiative (AVMI)

African Heads of State political commitment to immunisation

Addis Declaration on Immunization (ADI)

"To ensure and facilitate universal access to immunisation by allocating adequate domestic resources and securing new investments to strengthen national immunisation programmes as well as mount strong advocacy campaigns to achieve the Global Vaccine Action Plan goals and overall health care delivery systems"

* endorsed by Heads-of-State at AU Summit on 31 January 2017.

To summarize …

Local vaccine development and production in Africa is a must to support Africa's growing needs and specific disease burden:

- **Critical to reduce dependency vis-à-vis suppliers that may switch to other business models (threatening access to vaccines presentations used in the region)**

- **Disease burden specific for Africa may not be business attractive especially when it comes to low volume vaccines needed to fight emerging diseases**

The expansion of the current production capacity requires commitment and investments for the manufacturing facilities, the relevant activities (clinical trials; NRA strengthening); funding for procurement

Alternative solutions would still require adequate financing to secure viable supplies

The role of the AVMI is key to make this a reality within the next 10-15 years.

AFRICA'S PROBLEMS-

Thank you !