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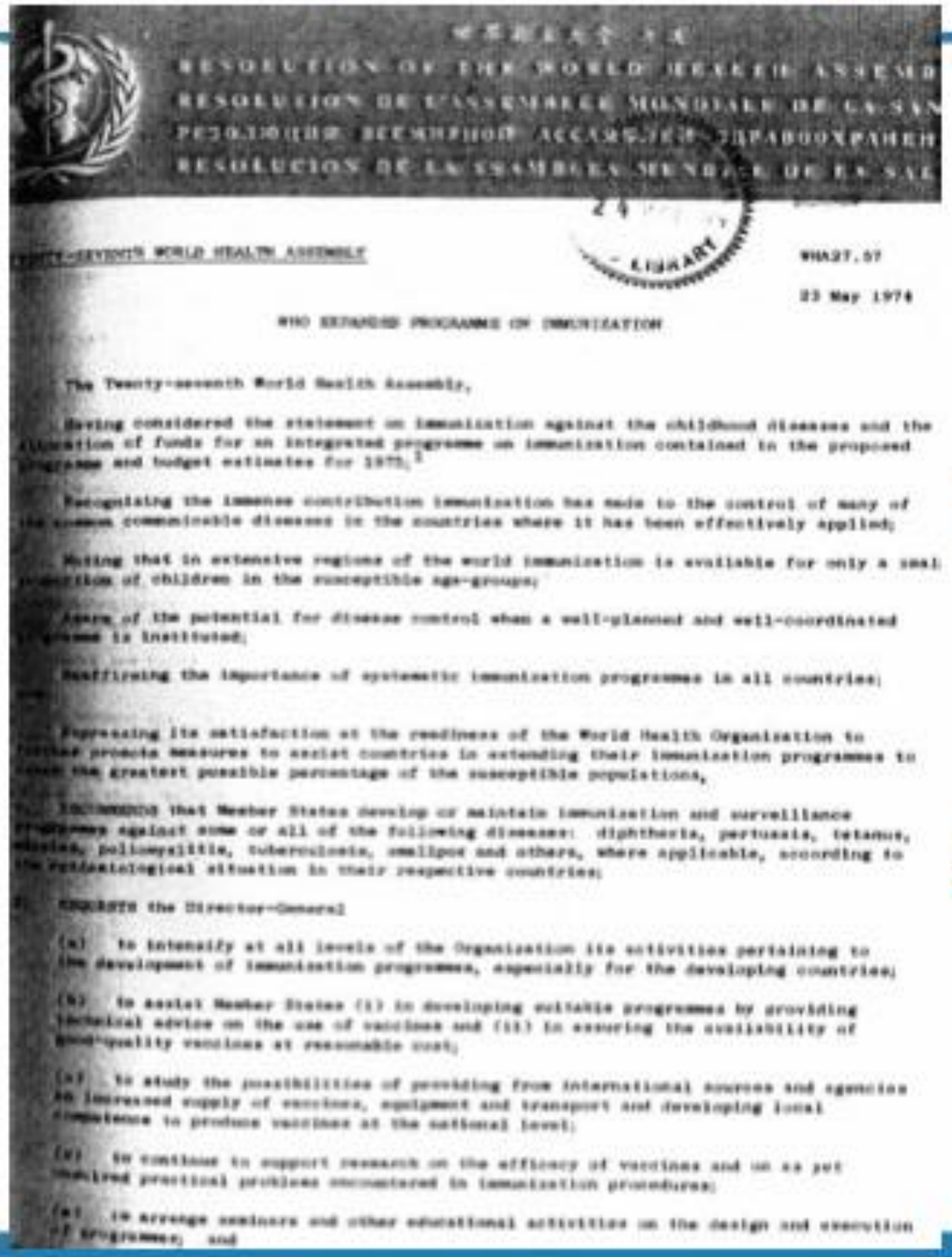
World Health Organization

December 6, 2016

World Health Organization

WHA Resolution on WHO Expanded Programme on Immunization (EPI)



RESOLUTION OF THE WORLD HEALTH ASSEMB
RESOLUTION DE L'ASSEMBLÉE MONDIALE DE LA SAN
РЕЗОЛЮЦИЯ ВСЕМИРНОЙ АССАМБЛЕИ ЗДРАВООХРАНЕН
RESOLUCIÓN DE LA ASAMBLEA MUNDIAL DE LA SAL

TWENTY-SEVENTH WORLD HEALTH ASSEMBLY

WHA27.57

23 May 1974

WHO EXPANDED PROGRAMME ON IMMUNIZATION

The Twenty-seventh World Health Assembly,

Having considered the statement on immunization against the childhood diseases and the allocation of funds for an integrated programme on immunization contained in the proposed programme and budget estimates for 1975;[1]

Recognizing the immense contribution immunization has made to the control of many of the common communicable diseases in the countries where it has been effectively applied;

Noting that in extensive regions of the world immunization is available for only a small proportion of children in the susceptible age-groups;

Aware of the potential for disease control when a well-planned and well-coordinated programme is instituted;

Reaffirming the importance of systematic immunization programmes in all countries;

Expressing its satisfaction at the readiness of the World Health Organization to further promote measures to assist countries in extending their immunization programmes to cover the greatest possible percentage of the susceptible populations,

1. RECOMMENDS that Member States develop or maintain immunization and surveillance programmes against some or all of the following diseases: diphtheria, pertussis, tetanus, measles, poliomyelitis, tuberculosis, smallpox and others, where applicable, according to the epidemiological situation in their respective countries;

2. REQUESTS the Director-General

(a) to intensify at all levels of the Organization its activities pertaining to the development of immunization programmes, especially for the developing countries;

(b) to assist Member States (i) in developing suitable programmes by providing technical advice on the use of vaccines and (ii) in assuring the availability of good-quality vaccines at reasonable cost;

(c) to study the possibilities of providing from international sources and agencies an increased supply of vaccines, equipment and transport and developing local competence to produce vaccines at the national level;

(d) to continue to support research on the efficacy of vaccines and on as yet unsolved practical problems encountered in immunization procedures;

(e) to arrange seminars and other educational activities on the design and execution of programmes; and

The twenty-seventh World Health Assembly

- Recognizing immense contribution of immunization
-

1. Recommends
   that Member States develop or maintain immunization and surveillance programmes.. according to the epidemiological situation in their respective countries

2. Requests the WHO DG
   - **To assist member states (i) in developing suitable programmes by providing technical advice on the use of vaccines and (ii)** in assuring availability of good quality vaccinesat reasonable costs

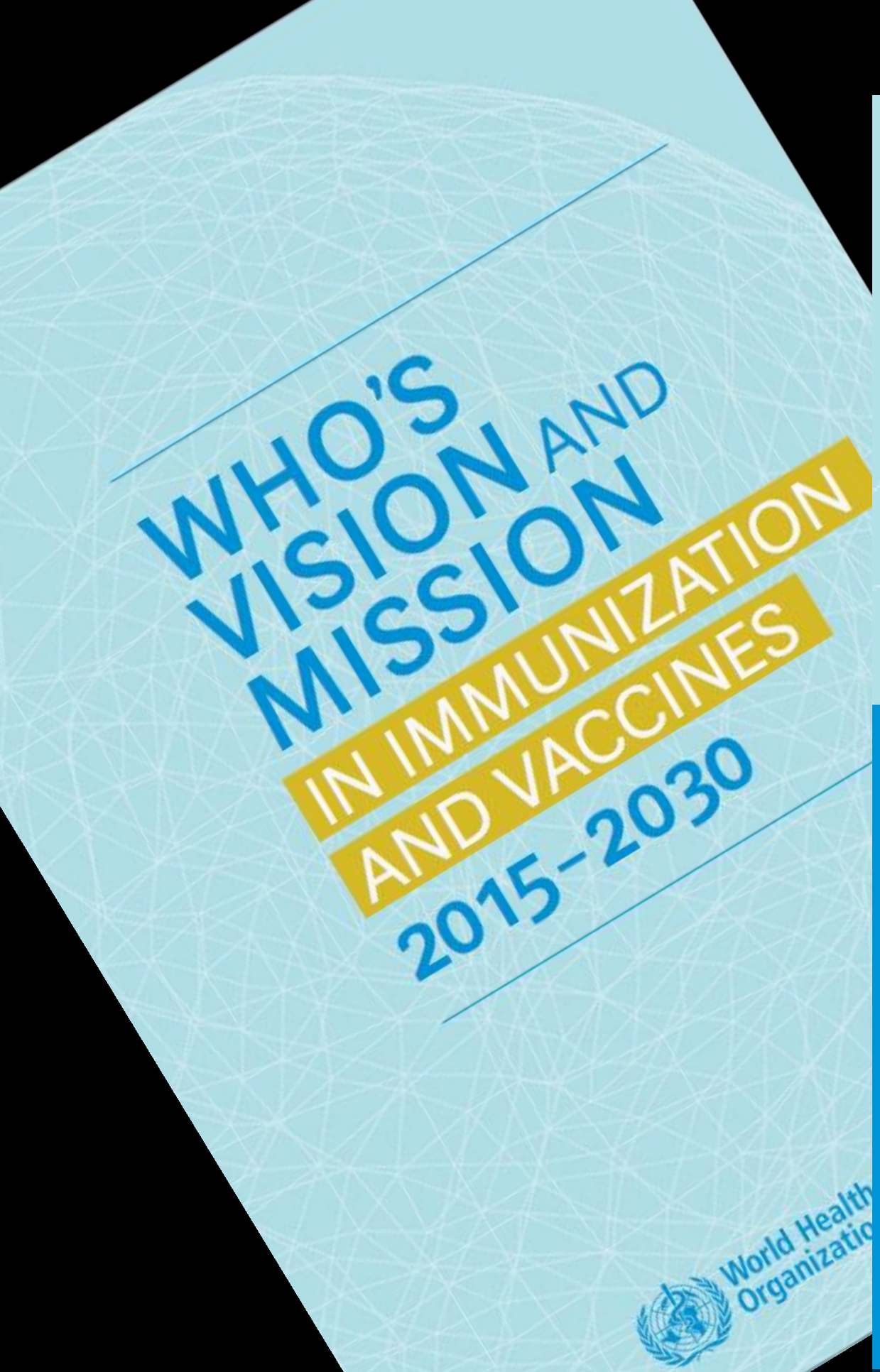
WHA27.57, Fourteen Plenary meeting – 23 May 1974

Global Vaccine Action Plan

2011–2020

Goals of the Decade of Vaccines (2011–2020)

- Achieve a world free of poliomyelitis
- Meet global and regional elimination targets
- Meet vaccination coverage targets in every region, country and community
- Develop and introduce new and improved vaccines and technologies
- Exceed the Millennium Development Goal 4 target for reducing child mortality



OUR VISION:

The highest attainable standard of health for all individuals and communities by preventing disease.

OUR MISSION:

To support all countries to deliver quality immunization services as part of an integrated, people-centred platform of disease prevention that spans the human life-course.

Immunisation programmes are more ambitious and complex than ever before

THEN …1970's

3.8 Billion Global population

Infants

All countries 4 vaccines
6 diseases

NOW….2016

Global population 7.3 Billion

Pregnant women
Women Childbearing Age
Adolescents
Children
Infants

>12 vaccines All countries
>15 diseases

>3 vaccines Some regions
>3 diseases

>7 vaccines High risk popn.
> 10 diseases

>3 vaccines Certain countries
>6 diseases

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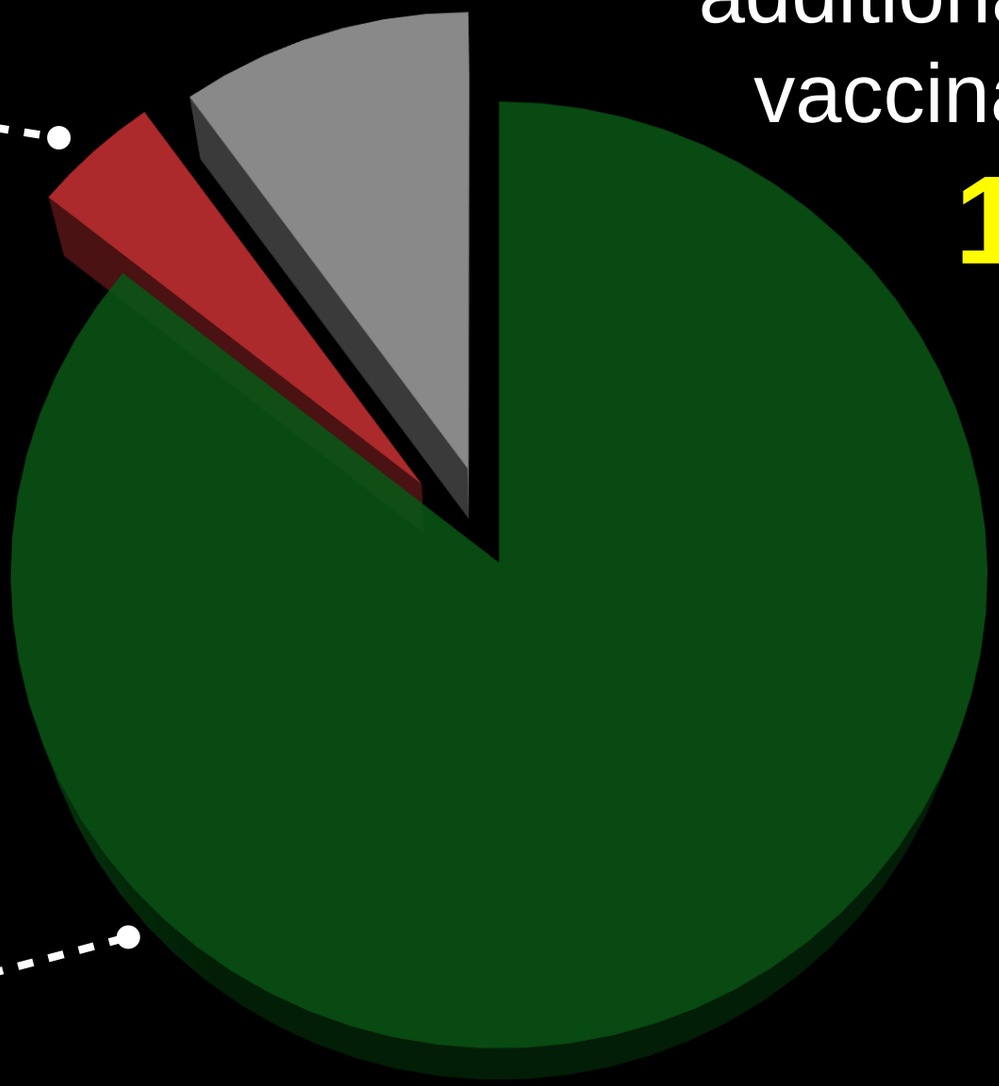
Infants in the world according to their DTP3 vaccination status, 2015

13.5 M
additional infants to be vaccinated to reach
100%

5.9 M
additional infants to be vaccinated to reach
90%



116.1 M
infants vaccinated
86%

Source: JRF 194 WHO Member States. Updated on 18 July 2016

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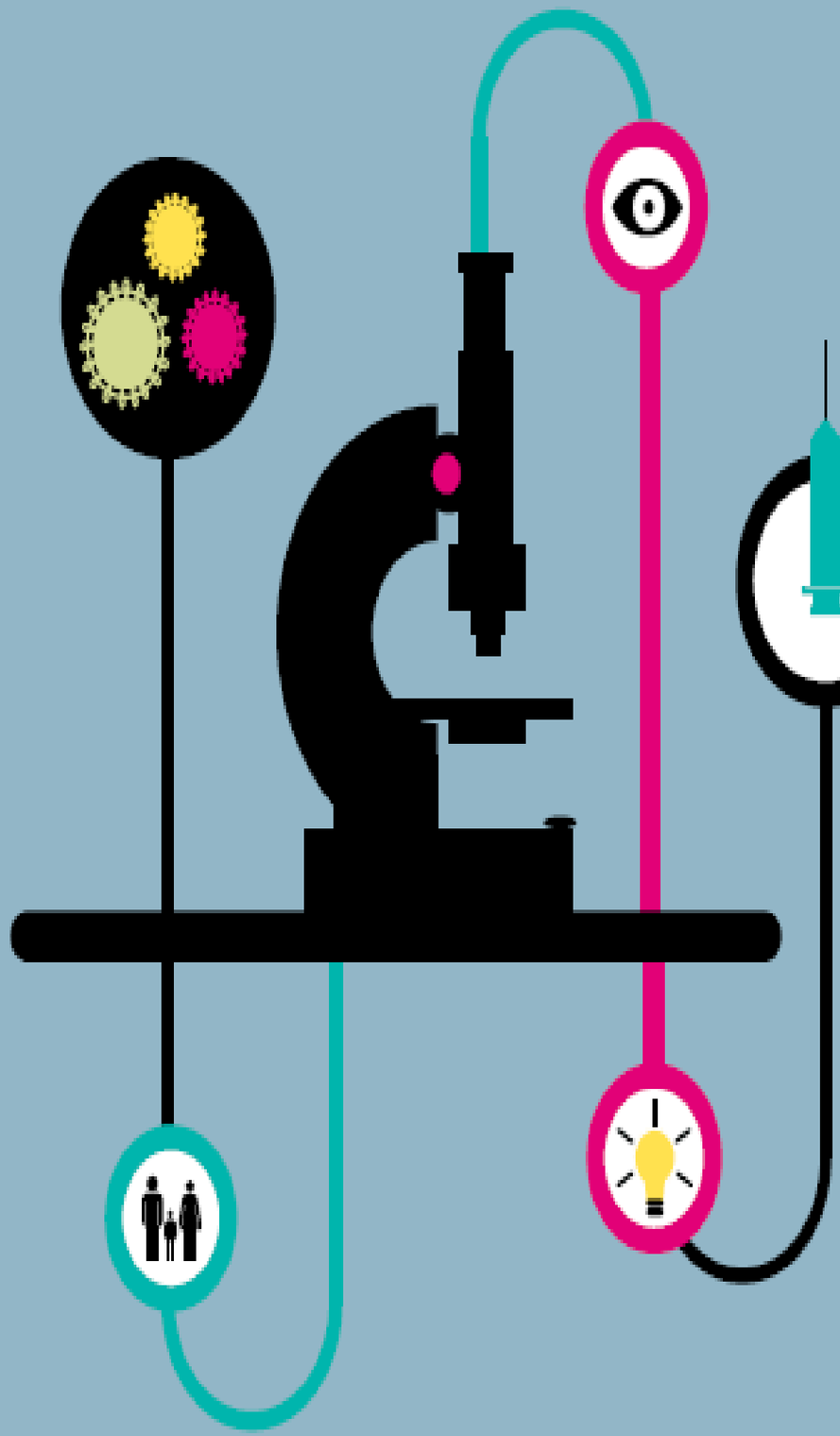
High level advocacy to ensure sustained international support for immunisation

Initiative for Vaccine Research (IVR)



Vaccines/products licensed and currently in use

Research to minimize barriers & improve coverage of vaccines currently in use

Research to improve methods for monitoring of immunization programs

Research to conduct impact evaluation of vaccines in use

Research to generate evidence to optimize existing policy recommendations or develop new ones

Candidate vaccines/ products under development

Research to generate evidence to inform policy for candidate vaccines at advanced stages of development

Research to accelerate licensure of vaccines in earlier clinical phase of development

Research to promote and accelerate development of vaccines in early development

Immunization & vaccines related implementation research advisory committee (IVIR-AC)

- Agenda setting and prioritization of implementation research in immunization which may include identifying potential research projects/issues and, where necessary, also reviewing the proposed methodologies for conducting such research.

- Review progress of implementation research and advise/guide researcher/research groups as appropriate.

- Review best practices relating to methods for conducting and reporting on quantitative immunization and vaccines-related research.

- IVIR-AC subcommittees to address specific subjects in greater depth before review by IVIR-AC

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AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS

PLAN OF ACTION

MAY 2016

World Health Organization

a global strategy and preparedness plan

a convening mechanism and an instrument to articulate technical guidance

A BLUEPRINT to catalyse R&D activities for emerging pathogens with potential to lead to PHEIC

Approaches currently being used to improve preparedness under the R&D Blueprint.

A Improving coordination & fostering an enabling environment

1. Building an effective governance & coordination framework
2. Outlining innovative transparent and aligned funding processes
3. Encouraging effective communication

B Accelerating Research & Development processes

1. Assessing epidemic threat & defining priority pathogens
2. Developing R&D roadmaps to accelerate evaluation of diagnostics, therapeutics & vaccines
3. Outlining appropriate regulatory & ethical pathways

C Developing new norms and standards adapted to the epidemic context

1. Supporting expansion of capacity to implement adequate study designs
2. Developing guidance & tools to frame collaborations and exchanges
3. Anticipating evidence needs to inform regulatory review and policy development

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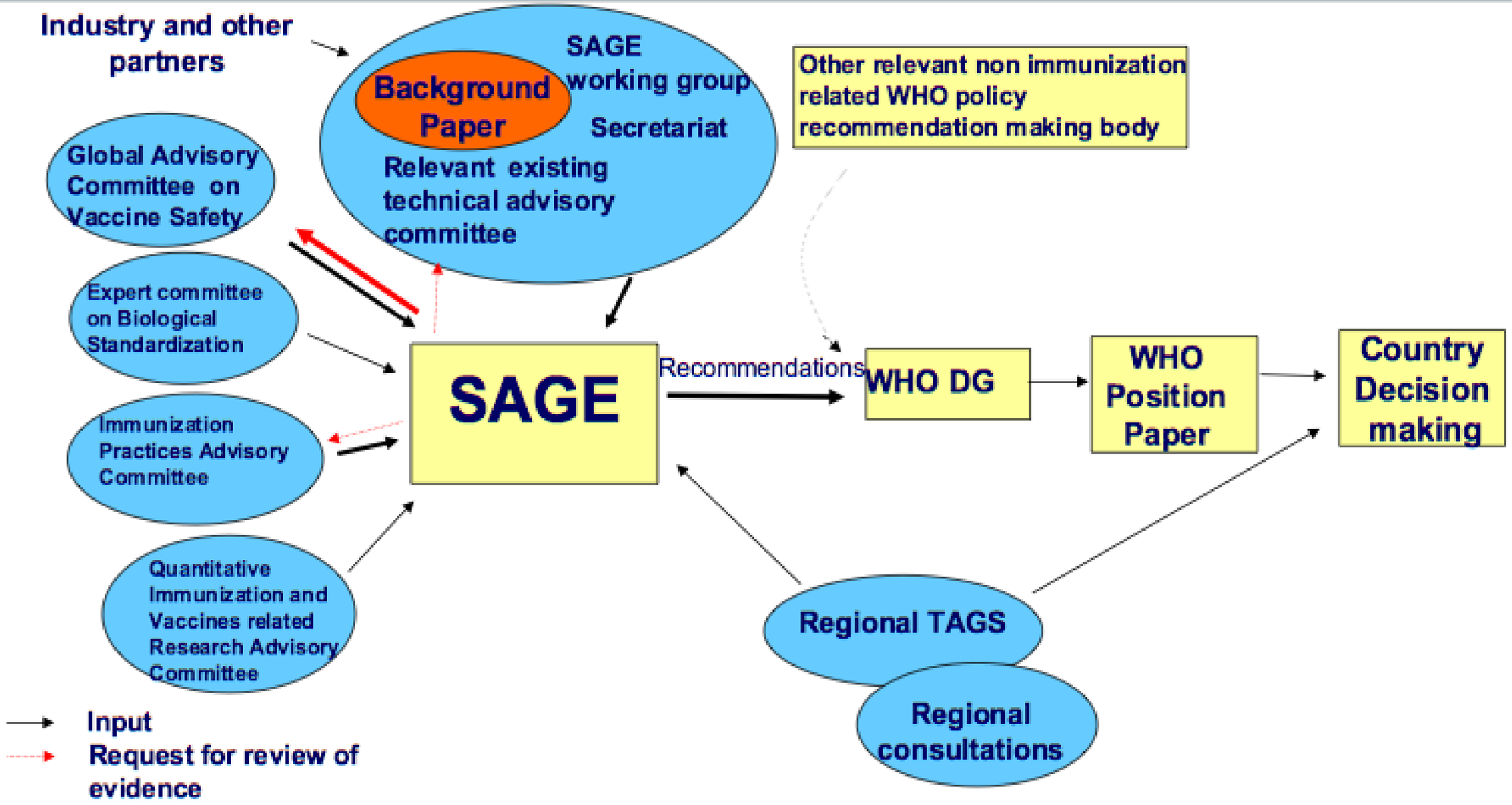
Connecting the Blueprint with other international efforts

Strategic Advisory Group of Experts (SAGE)

- Principal advisory group to WHO for vaccines and immunization (from research to delivery of immunization and linkages with other health interventions - all vaccines, all ages) → reports directly to DG and involves all relevant WHO departments

Pathways for WHO recommendations on vaccine use



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Factors that are taken into consideration by SAGE when making recommendations

- disease epidemiology and clinical profile;
- the benefits and harms of the options;
- values pertaining to the importance of the desirable and undesirable effects;
- equity considerations;
- feasibility and resource implications including economic considerations;
- social values and preferences, and acceptability;
- health-system opportunities, and
- interaction with other existing intervention and control strategies.

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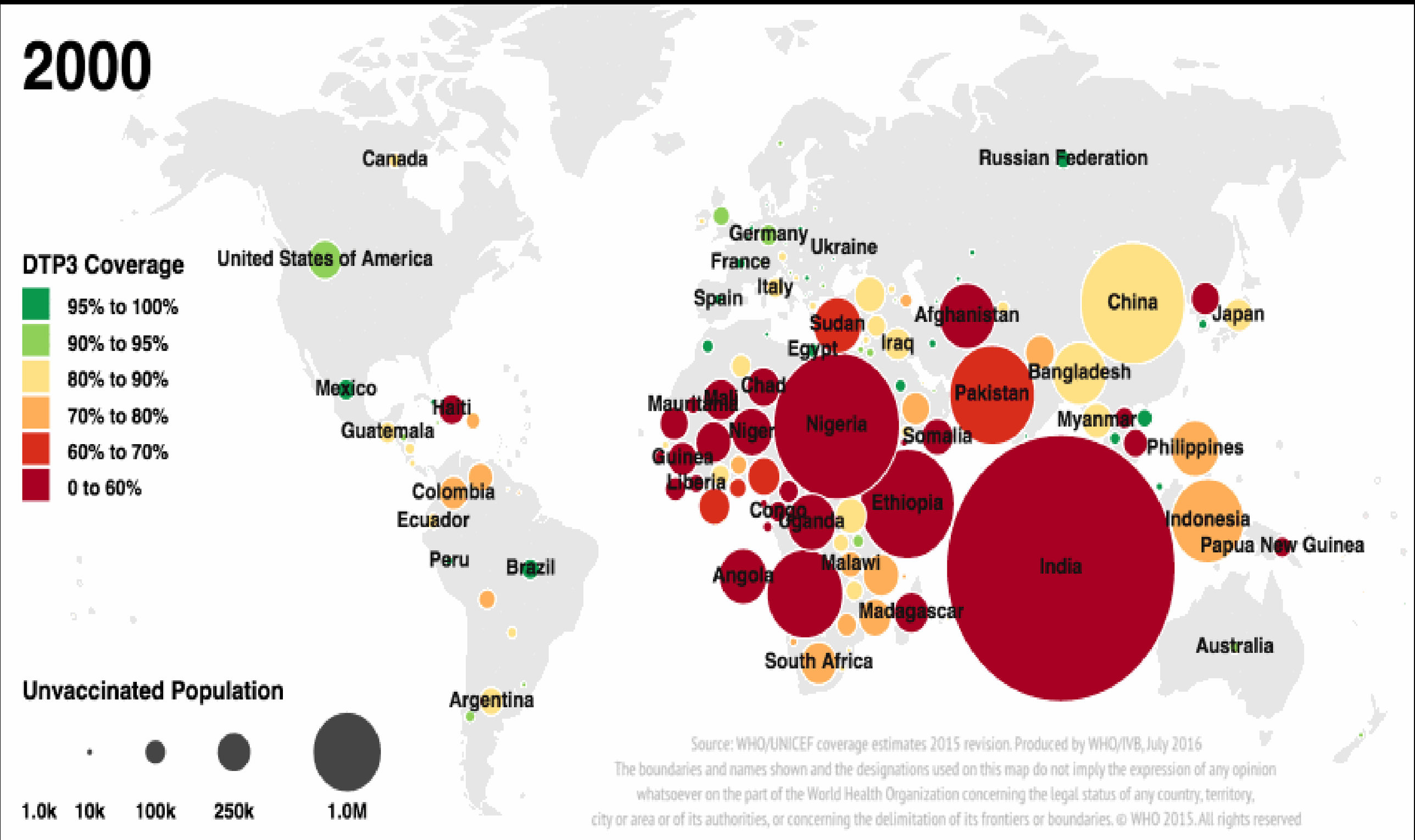
Appendix 1. Specific factors which underpin the development of SAGE recommendations[40]

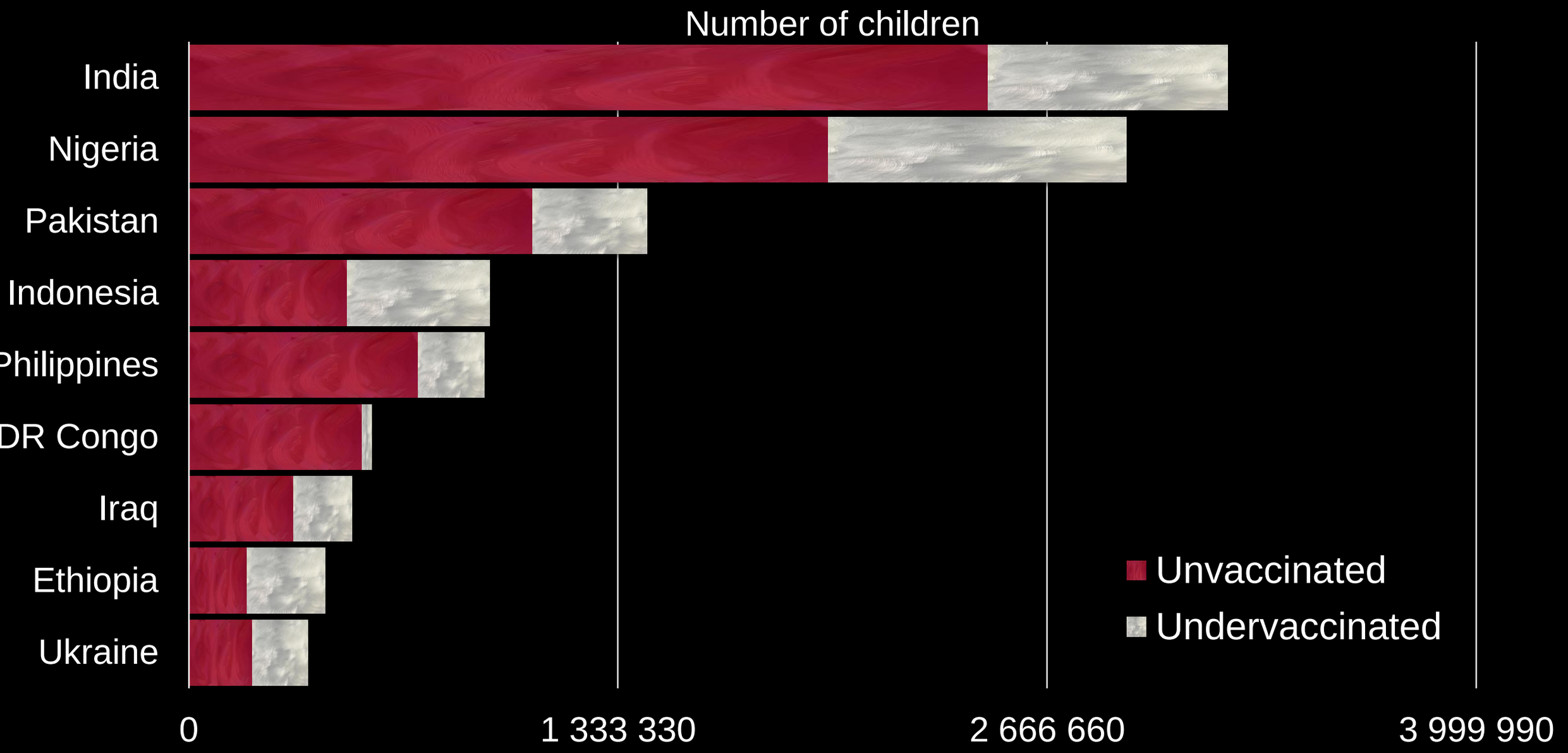
Main factors	Specific elements
Epidemiologic features of the disease	-disease burden, including age specific mortality, morbidity, and social impact -specific risk groups -epidemic potential -disease occurrence over time (i.e. secular trends) -serogroup or serotype distribution (for serogroup or serotype specific vaccines) -changes in epidemiological features over time.
Clinical characteristics of the targeted disease	-clinical management -disease severity and fatality -primary/secondary/tertiary care implications -long-term complications and medical care requirements.
Other options for disease control and prevention	-existence of other prevention and control options.
Vaccine and immunization characteristics	-efficacy -effectiveness and population impact of the vaccine (including herd immunity) -safety (serious adverse events and reactogenicity profile) -indirect effects (potential impact on strain selection, herd immunity, potential safety concerns of live attenuated vaccines in contacts of vaccines, serotype replacement) -cold chain and logistical concerns -vaccine availability -vaccine schedule(s) -social and programmatic acceptability of the schedule(s) -ability to reach the target populations -ability to monitor programme impact.
Economic considerations	-cost of illness -vaccine and vaccine delivery costs -potential for vaccine price reductions -cost-effectiveness of immunization programmes -affordability of immunization.
Health system considerations	-possible interactions with other interventions and control strategies -possible impact of vaccine introduction on the wider health system.
Social impacts	-possible impact on social equality and inequality.
Legal considerations	-possible legal requirements for implementation.
Ethical considerations	-possible ethical considerations.

Significant progress have been achieved over the last 15 years



Source: WHO/UNICEF coverage estimates 2015 revision. Produced by WHO/IVB, July 2016

The 10 countries with most under-vaccinated and un-vaccinated children, 2015



Source: WHO/UNICEF coverage estimates 2015 revision. July 2016
Immunization Vaccines and Biologicals, (IVB), World Health Organization.
194 WHO Member States. Date of slide: 19 July 2016

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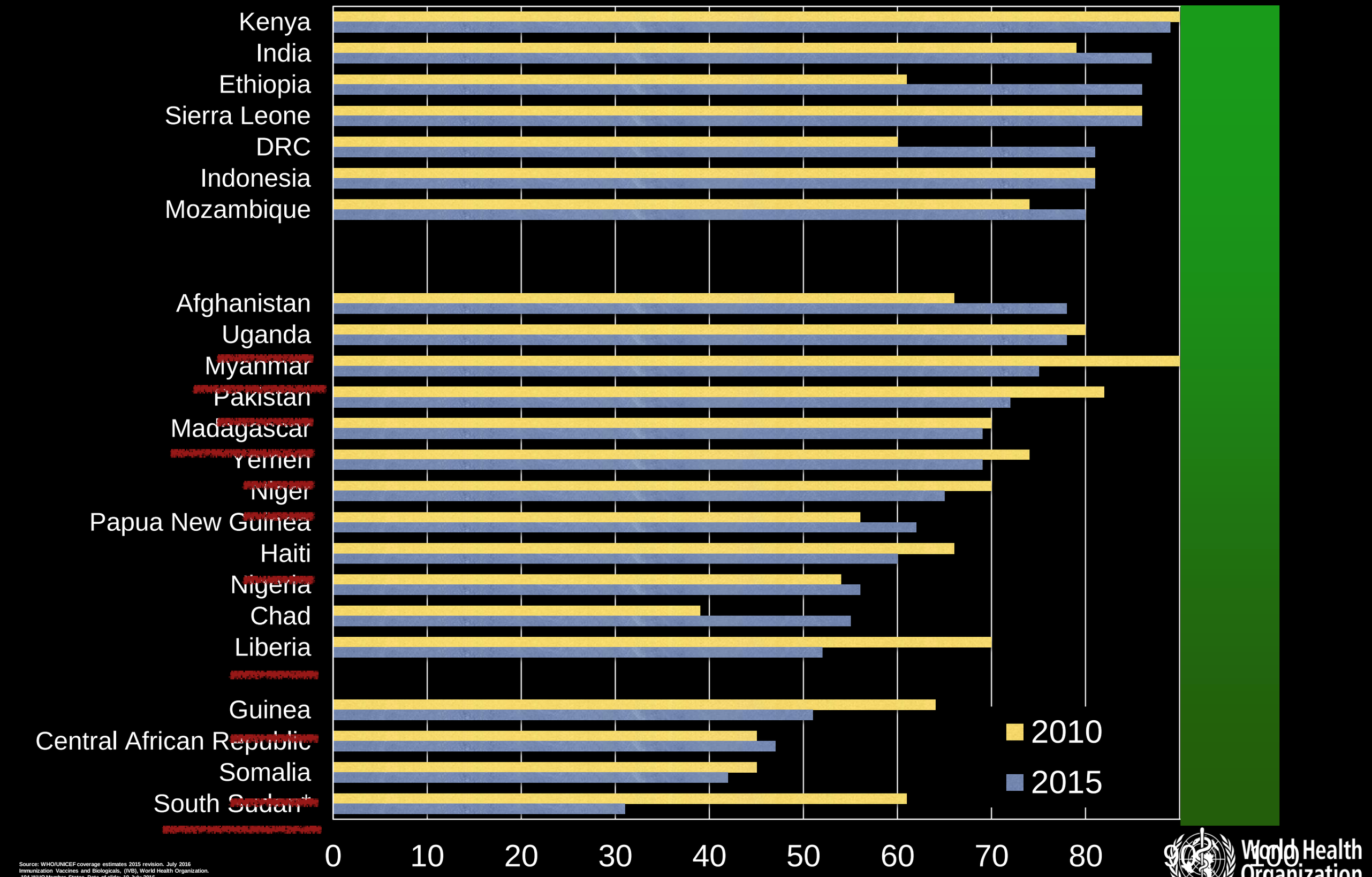
DTPcV3 coverage in selected countries, 2010-2015



Source: WHO/UNICEF coverage estimates 2015 revision. July 2016
Immunization Vaccines and Biologicals, (IVB), World Health Organization.
194 WHO Member States. Date of slide: 19 July 2016

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Coverage of interventions across the continuum of care, 2015

[a] Median national coverage of 75 countries, based on most recent survey 2009 or later.

Source: WHO, 2015. Health in 2015: From MDGs to SDGs. WHO. http://www.who.int/gho/publications/mdgs-sdgs/en/

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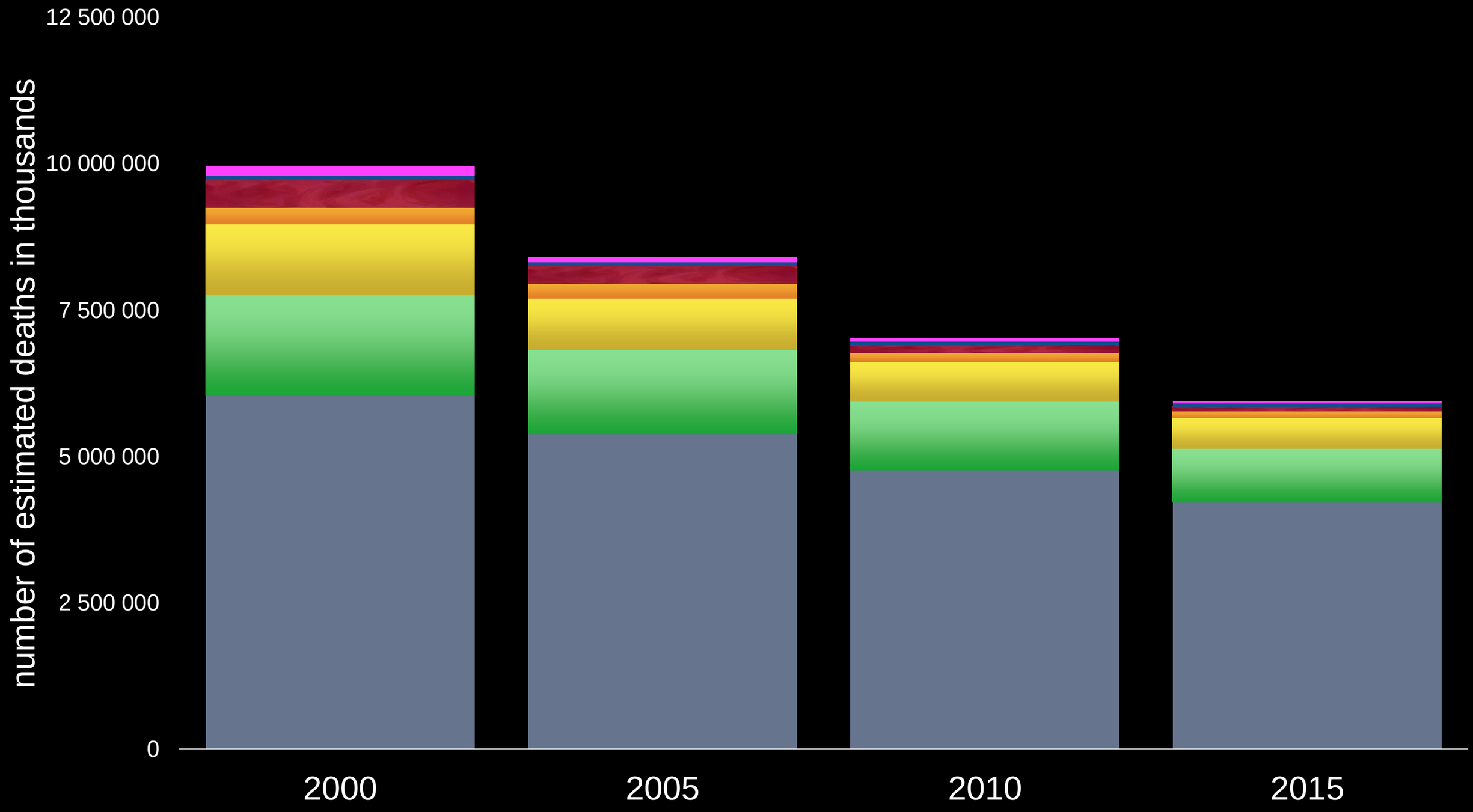
Vaccines have been contributors to the global reduction of under 5 mortality

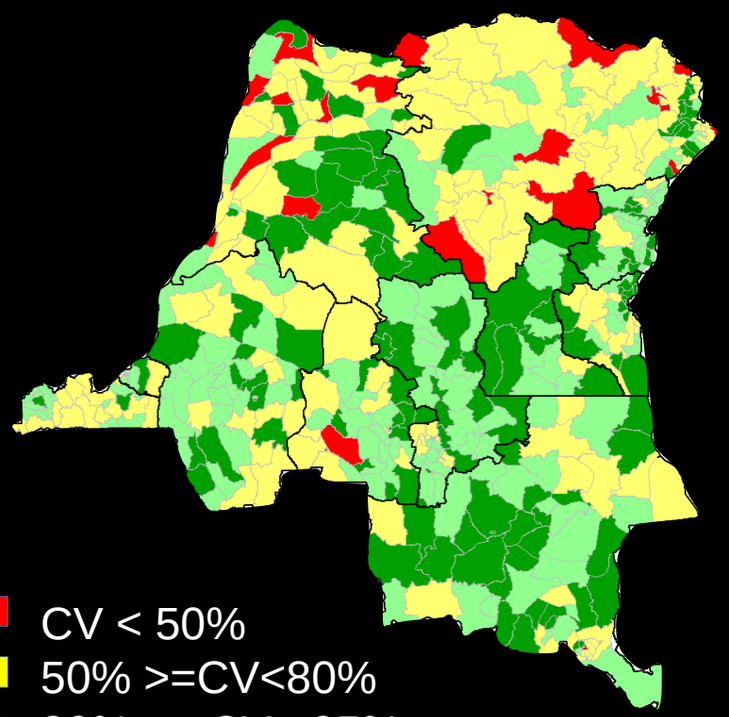


Source= WHO

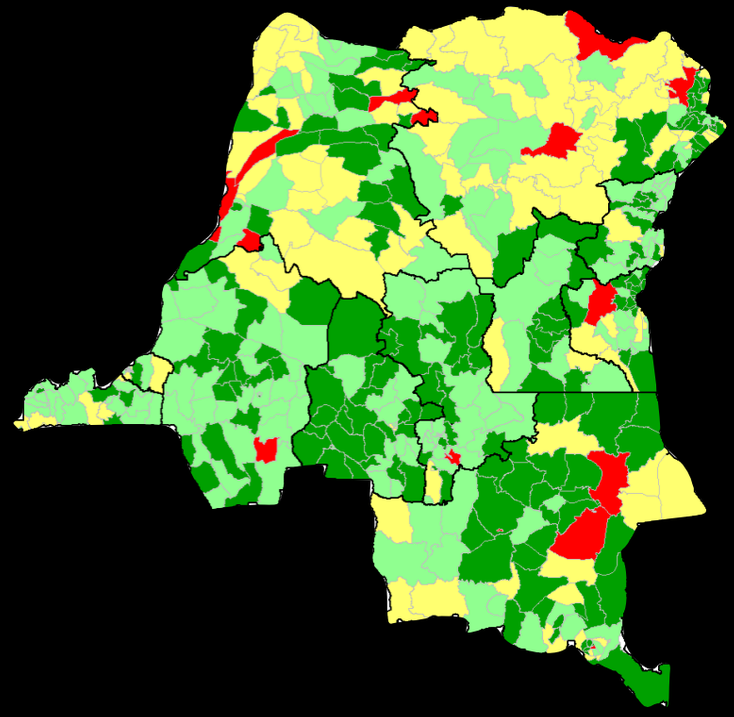
World Health Organization

Measles vaccine coverage in DRC, 2011-2016

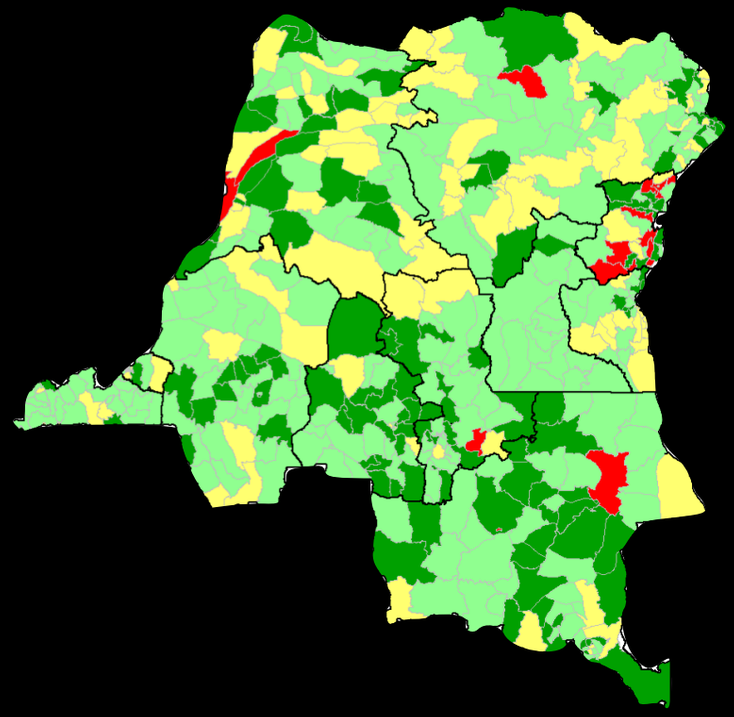
2011



2012

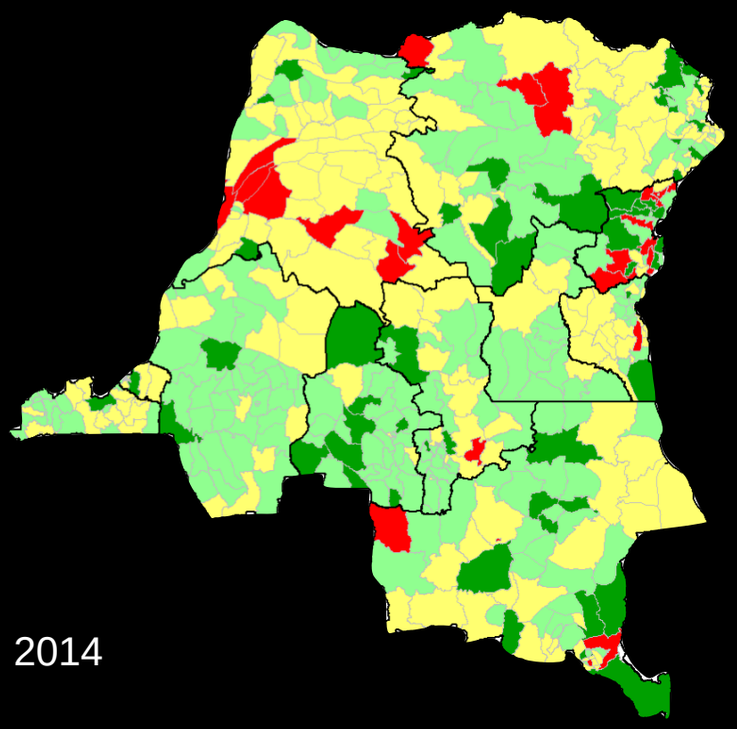


2013

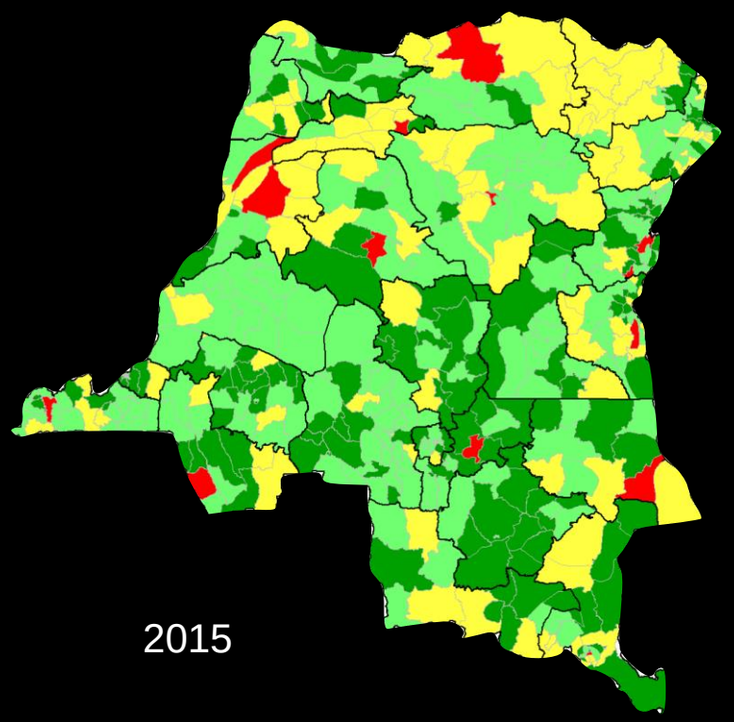


CV < 50%
50% >=CV<80%
80% >= CV <95%
CV >=95%

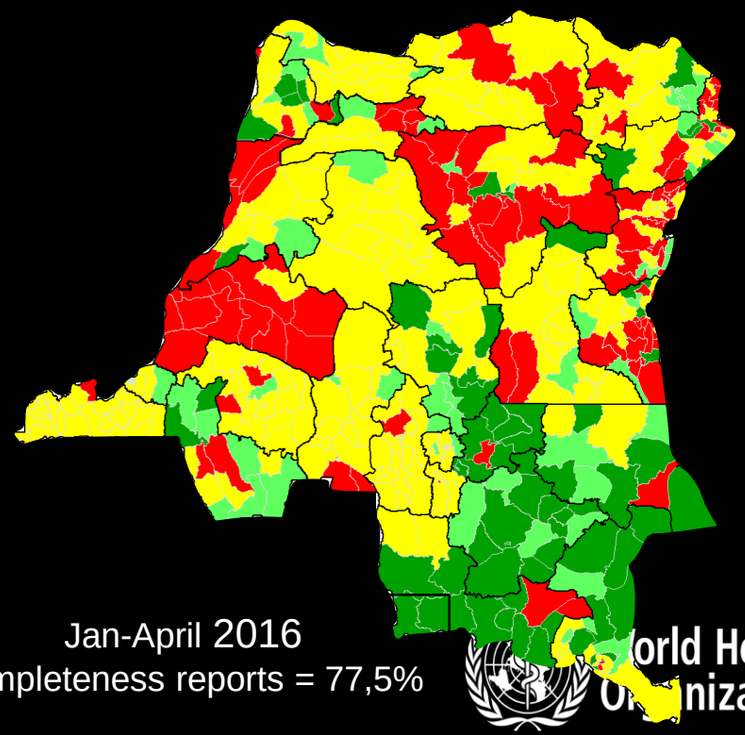
2014



2015



Jan-April 2016
Completeness reports = 77,5%



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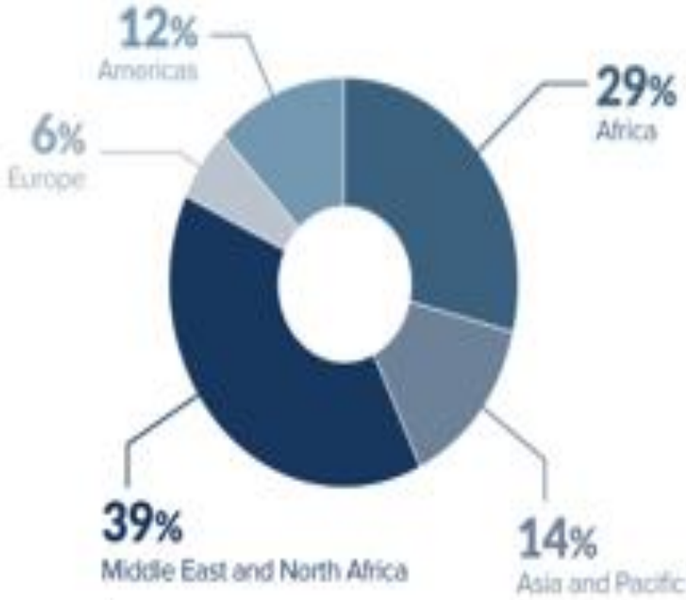
We are now witnessing the highest levels of displacement on record

Refugees
21.3 million
16.1 million under UNHCR mandate
5.2 million Palestinian refugees registered by UNRWA

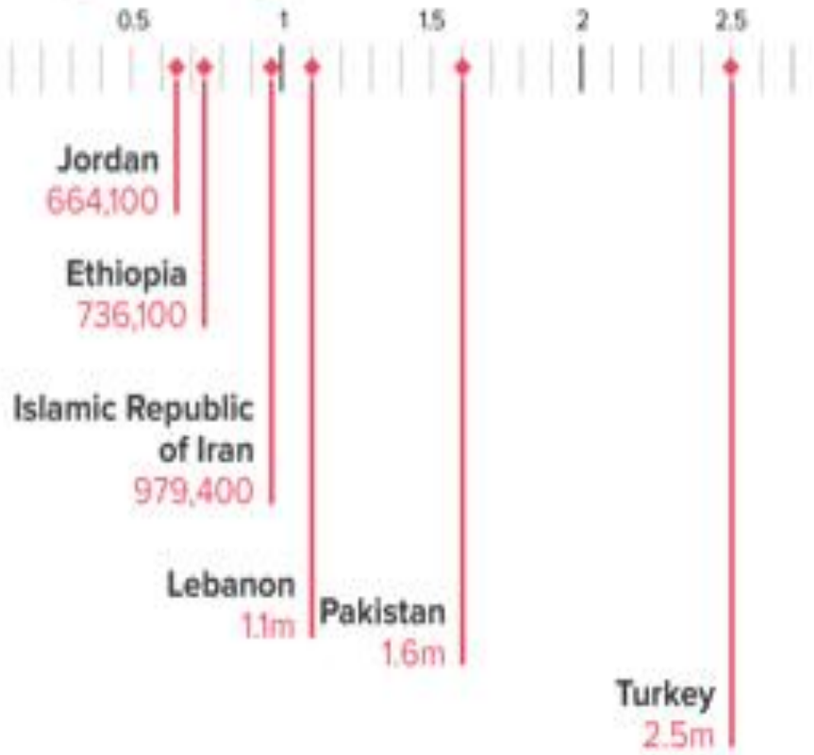
Stateless people
10 million

Where the world's displaced people are being hosted

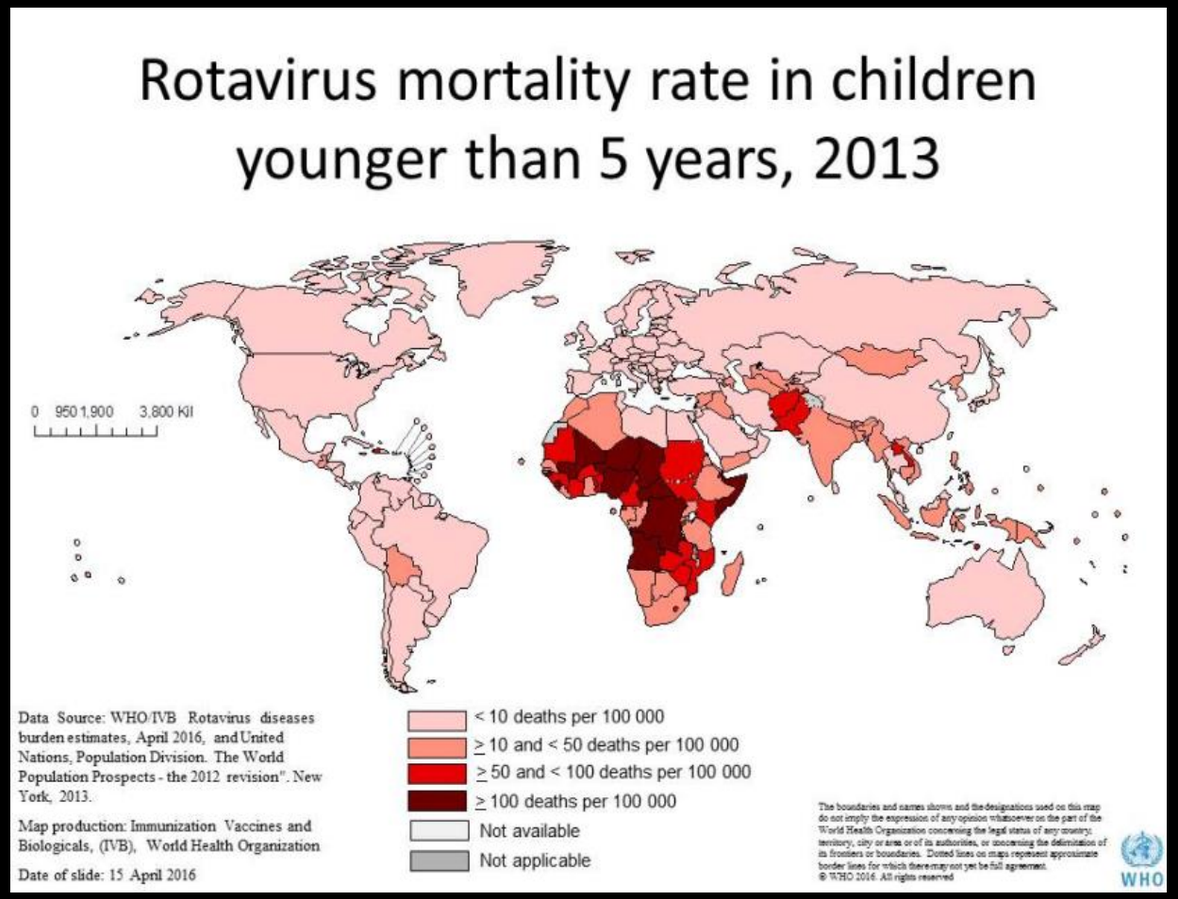


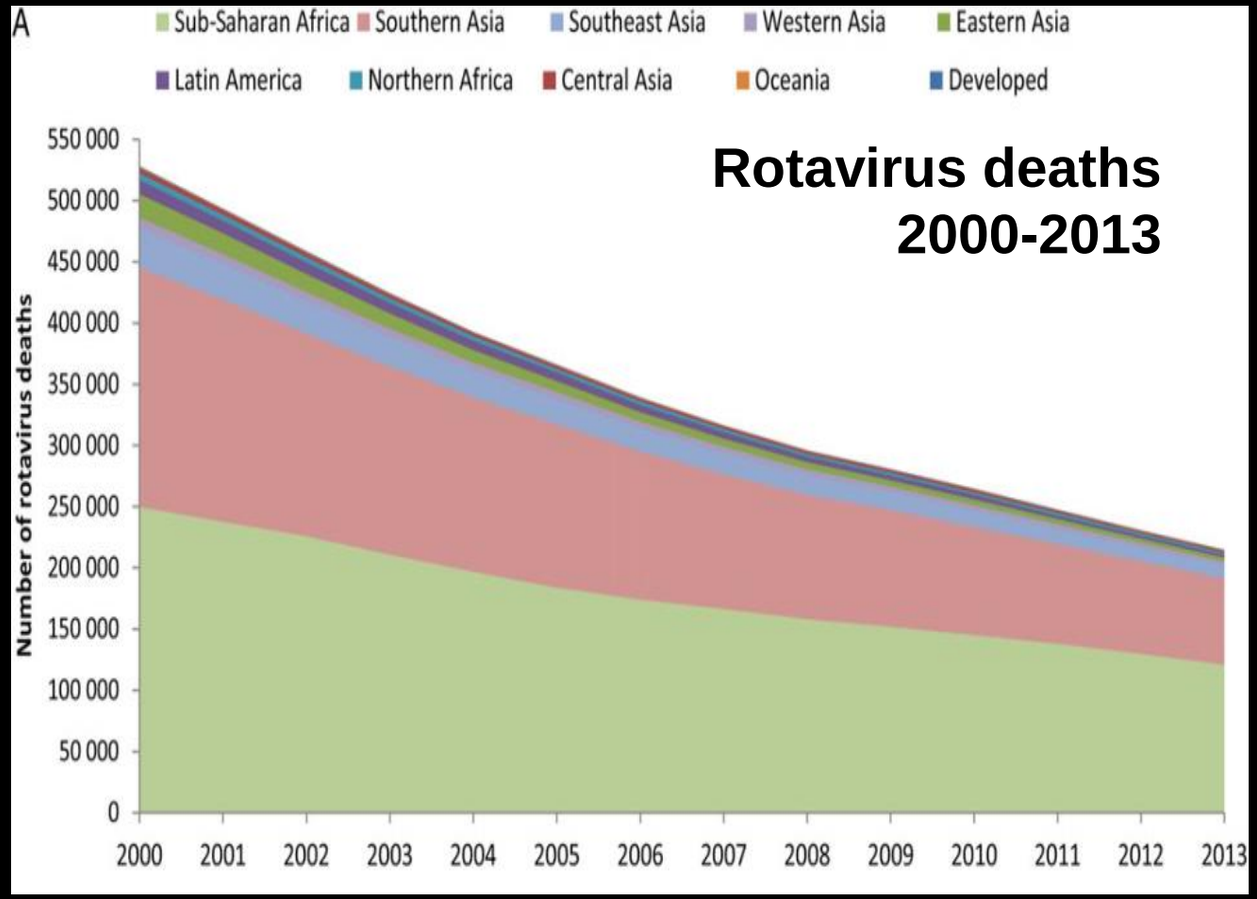
54% of refugees worldwide came from three countries

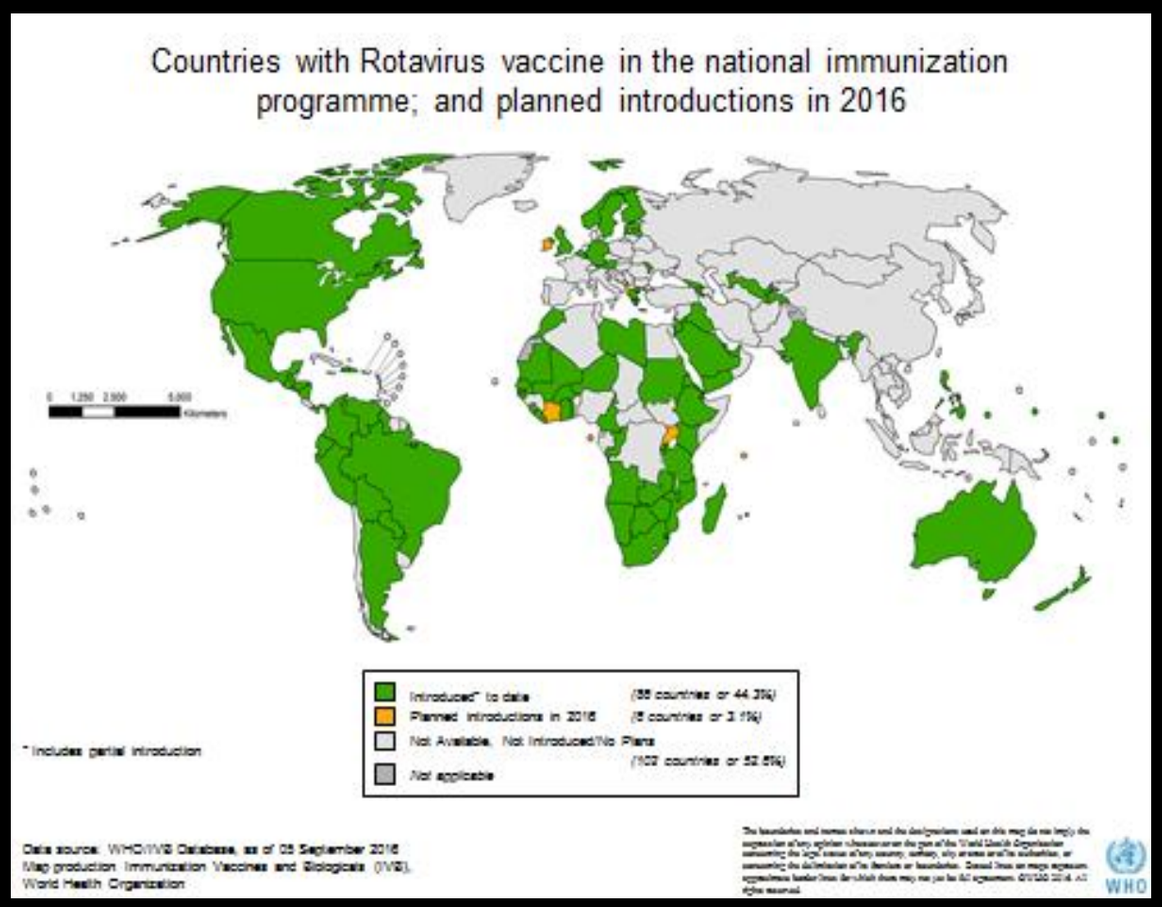
Top hosting countries



UNHCR
The UN Refugee Agency



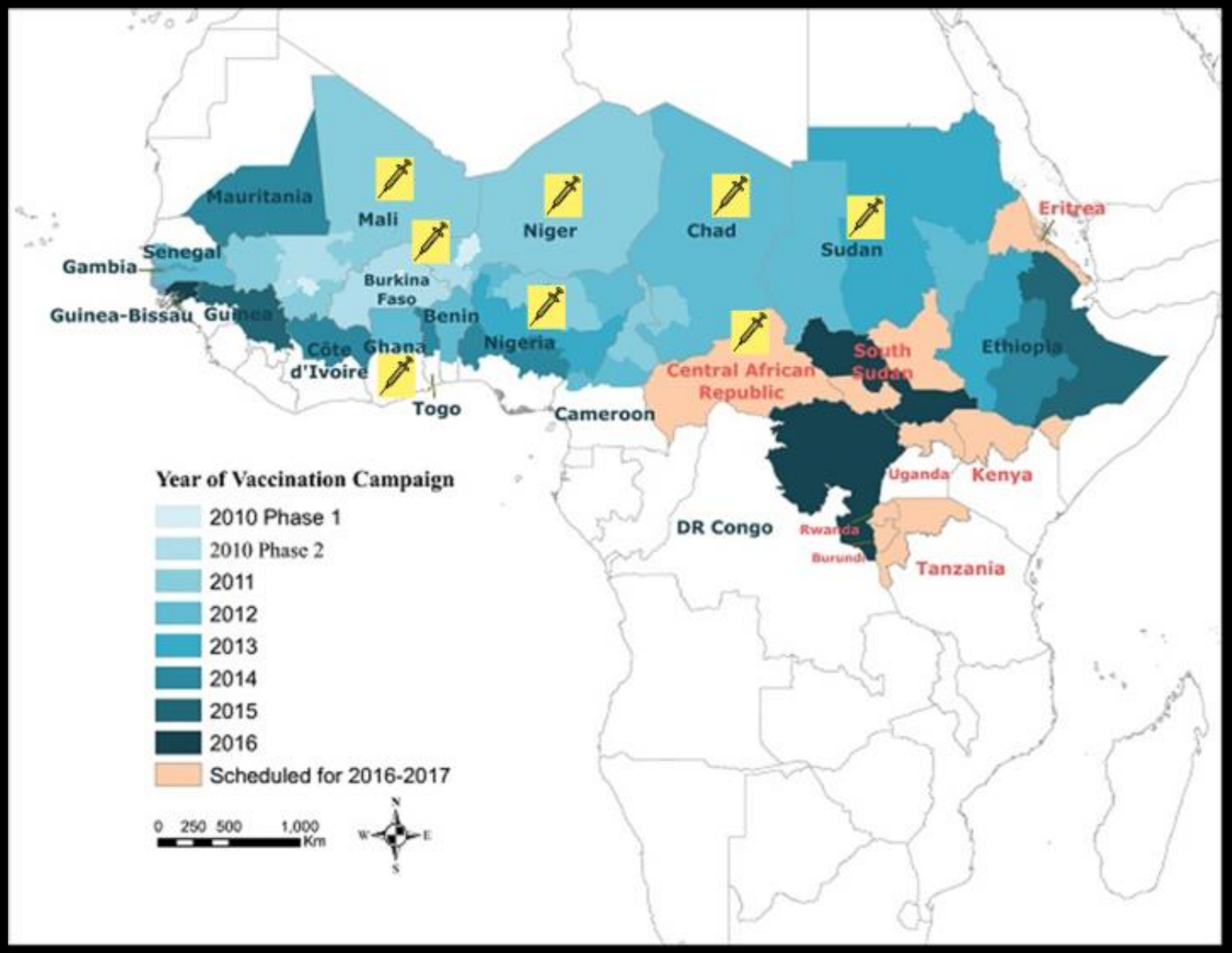




Rotavirus deaths have decreased over time.

But, countries with highest mortality rate are still not benefiting from vaccine

World Health Organization



Meningitis A vaccine

> 260 million immunized

19/26 countries conducted campaigns 1-29 year-olds

8/26 countries introducing in routine national EPI for 9-18 month-olds (2016-mid-2017)

71% decline in risk of meningitis (suspected cases)

>99% decline in risk of NmA meningitis (confirmed cases)

Elimination of NmA carriage in vaccinated & unvaccinated population up to 13 months after mass vaccination, when comparing pre- and post-vaccination carriage prevalence

94% reduction in incidence of meningitis in vaccinated vs. unvaccinated districts (suspected cases)

98% decrease in NmA carriage prevalence 4-6 months after mass vaccination vs. pre-vaccination

60% decline in risk of epidemics = risk of a district reaching the epidemic threshold

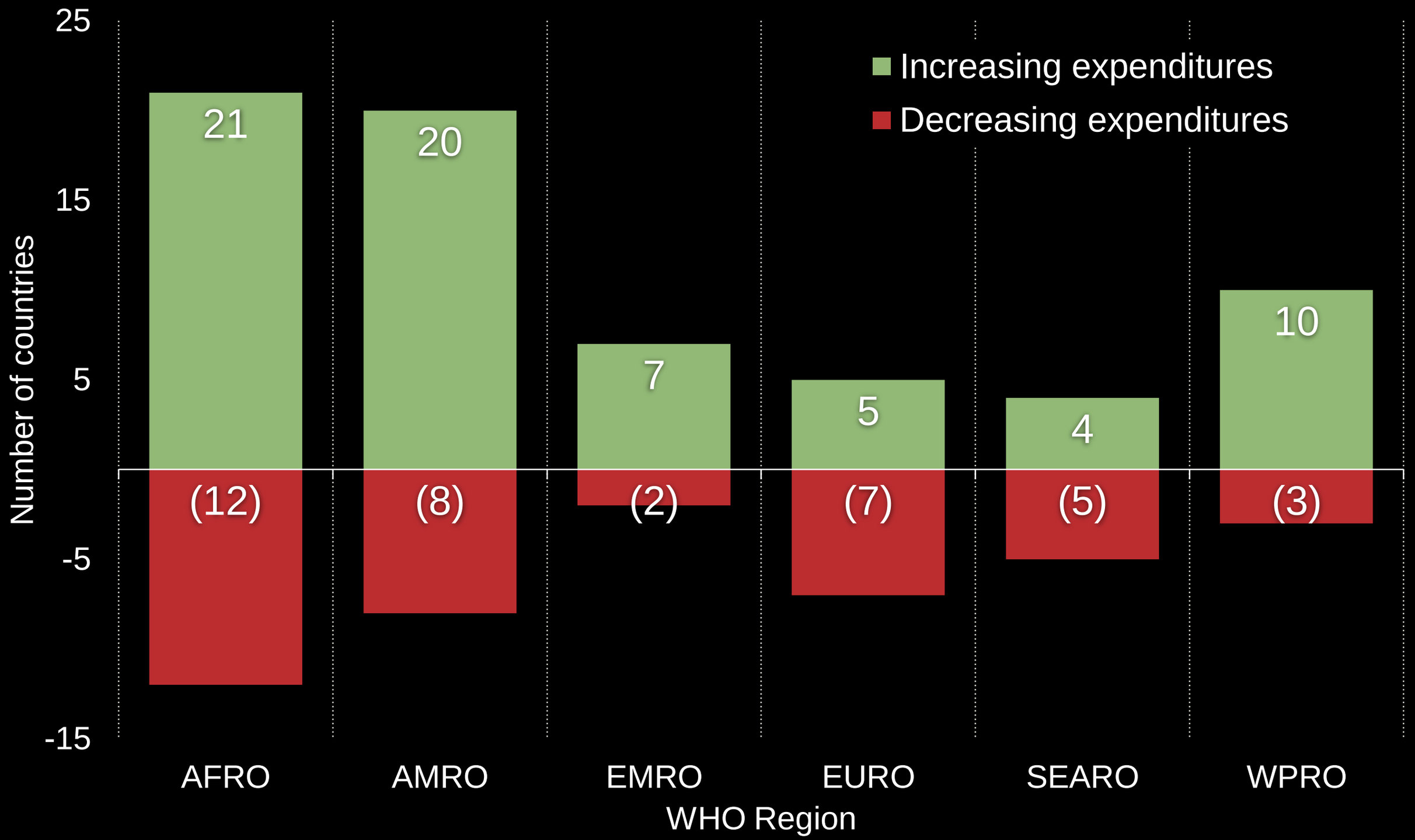
Increase in incidence of non-NmA meningitis not statistically significant

58% decline in incidence of meningitis (suspected cases)

>99% decline in incidence of NmA meningitis (confirmed cases)

lth Organization

Trends in country expenditures in the immunisation programme by Region (2010-2015)



Note: Number of countries reporting increasing/decreasing trends of Government Expenditure on Routine Immunization
Source: JRF, WHO-UNICEF

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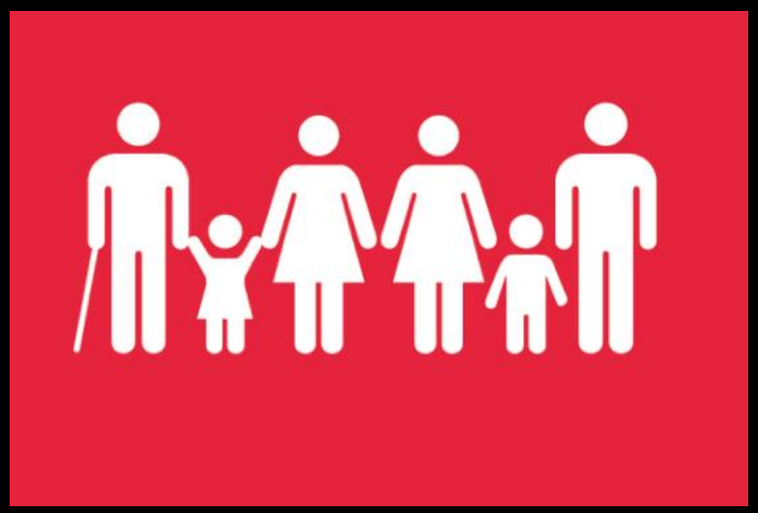
Immunisation has a broader impact in the communities

Productivity gains

Measles vaccination results in a 9.5% increase in future school enrolment for boys in Bangladesh



Community benefits

Rotavirus vaccination averts US$800,000 in catastrophic health expenditures, improving **household risk protection** in Ethiopia

Economic impacts

Rotavirus vaccination increases government **net tax revenue** by US$58 million over 50 years in Egypt

World Health Organization

Use vaccine research as an additional tool to achieve set goals

Position Vaccines research in emerging global agendas

Blueprint - R&D for diseases with a PHEIC potential

xxx

esearch to assess and enhance the impact of available vaccines

World Health Organization

Achieving worldwide vaccination goals will be a
difficult task, and finding approaches to ensure the continued development of effective vaccines is potentially more challenging.

Vaccines should be seen not as a cost that increases public health budget needs, but as an investment with long term and sustainable and large-scale impacts.

The benefits of the efforts to increase immunization coverage and vaccine access are likely to heavily outweigh the costs.

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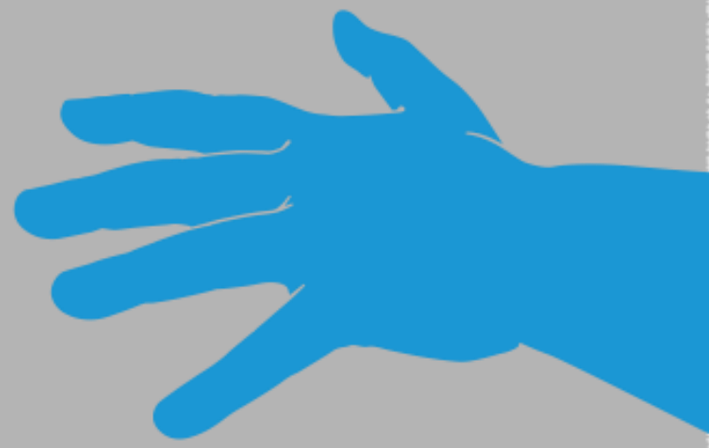
CLOSE THE IMMUNIZATION GAP



IMMUNIZATION FOR ALL THROUGHOUT LIFE

World Health Organization

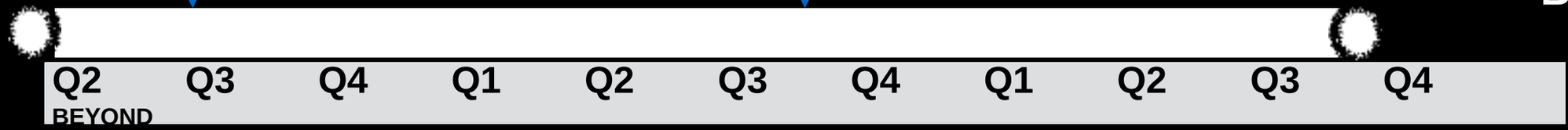
A

Improving coordination & fostering an enabling environment

Start mapping of key stakeholders to have an overview of existing initiatives & stakeholders

Scoping meeting Global Coordination Mechanism

Formalise and get operational a mechanism for improved and coordinated R&D preparedness and response capacity

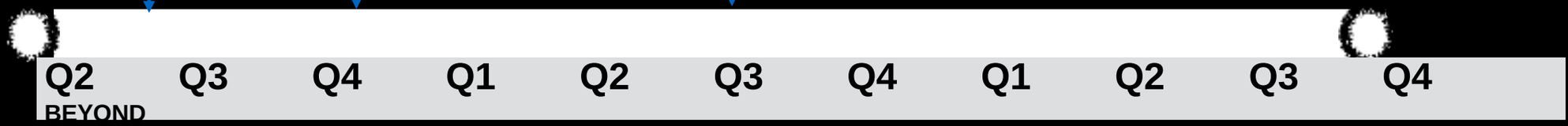


Building an effective governance & coordination framework

Consultation with stakeholders & identification of funding options

Average funding needs estimated

Report of financial options finalised and published

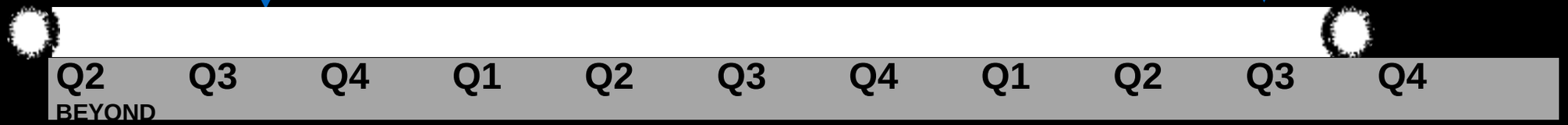


Outlining innovative transparent and aligned funding processes

Blueprint SAG and other consultations

Develop a template framework to streamline global stakeholder collaboration

Scientific interactions: Zika, Mers-Cov, … …



Encouraging effective communication

World Health Organization

B Accelerating Research & Development processes

Updated list of priority pathogens generated

1st priority list of pathogens developed

Prioritisation methodology set up

Review of prioritisation methodology

Assessing epidemic threat & defining priority pathogens

2015 | 2016 | 2017

Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4

BEYOND

Develop roadmaps for priority pathogens & generic TPPs

Prototype roadmap for MERS-Cov developed

Consultation process to identify & evaluate technology platforms

Methodology to develop roadmaps and to identify gaps in the development of products

Developing R&D roadmaps to accelerate evaluation of Dxs, therapeutics & vaccines

2015 | 2016 | 2017

Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4

BEYOND

Insurance options for clinical trials in the context of epidemics

Guidelines on regulatory evaluation outlined

Ethical guidelines in the context of epidemics

Outlining appropriate regulatory & ethical pathways

2015 | 2016 | 2017

Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4

BEYOND

World Health Organization

C Developing new norms and standards adapted to the epidemic context

Tools: Methods design discussion, decision tree, annotated generic protocol

Steps outlined to develop tools to inform discussions on trial designs

Draft tools available for vaccines

Wider consultation on tools for vaccines starts

Initiate work for therapeutics

Supporting expansion of capacity to implement adequate study designs

2015 2016 2017

Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 BEYOND

Biobanking platforms process initiated

Consultation on ownership, benefit sharing & IP

MTA capacity building tool

Developing guidance & tools to frame collaborations and exchanges

2015 2016 2017

Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 BEYOND

Develop global norms for sharing data & results during public health emergencies

SAGE recommendation on evidence need for policy making on Ebola vaccines

Consultation on data sharing

Consultation biobanking + decision tree data sharing WHO Statement Data sharing

Anticipating evidence needs to inform regulatory review and policy development

2015 2016 2017

Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 BEYOND

World Health Organization