

Bacille Calmette-Guérin (BCG) vaccines - Session 11

Introduction to the session

Tracey Goodman (IVB/WHO)
Working Group Focal Point

SAGE meeting, 17-19 October 2017



Albert Calmette
(1863-1933)



Camille Guérin
(1872-1961)

Preparation of this session

- BCG Working Group established September 2016
- Two Working Group meetings (March & August 2017), and regular telephone conferences
- Systematic reviews - on safety and efficacy/effectiveness of BCG
- Modelling on impact of delaying BCG vaccination
- BCG shortages

WG members

- **Charles Wiysonge**: MRC, South Africa (Chair) (**SAGE Member**)
- **Kari Johansen**: ECDC, Sweden (**SAGE Member**)
- **Safaa Al-Khawaja**: MoH, Bahrain
- **Pamela Bakkabulindi**: MoH, Uganda
- **Sang Nae Cho**: Yonsei University College of Medicine, South Korea
- **Nigel Curtis**: University of Melbourne, Australia
- **Mark Hatherill**: University of Cape Town, South Africa
- **Guangxue He**: Chinese CDC, China
- **Helen McShane**: University of Oxford, England
- **Elizabeth Maleche Obimbo**: University of Nairobi, Kenya
- **Jeffrey Starke**: Baylor College of Medicine, USA

GACVS – **Punam Mangtani**, LSHTM, UK

WHO Secretariat – IVB, HIV/AIDS, TB, Leprosy, EMP



The Global Burden of TB, 2015



All forms of TB

Estimated number of cases

10.4 million

142 per 100,000

- 1 million children
- 3.5 million women
- 5.9 million men

Estimated number of deaths

1.8 million*

- 210,000 in children
- 500,000 in women
- 1,100,000 in men

HIV-associated TB

1.2 million (11%)

390,000

Multidrug-resistant TB MDR/RR

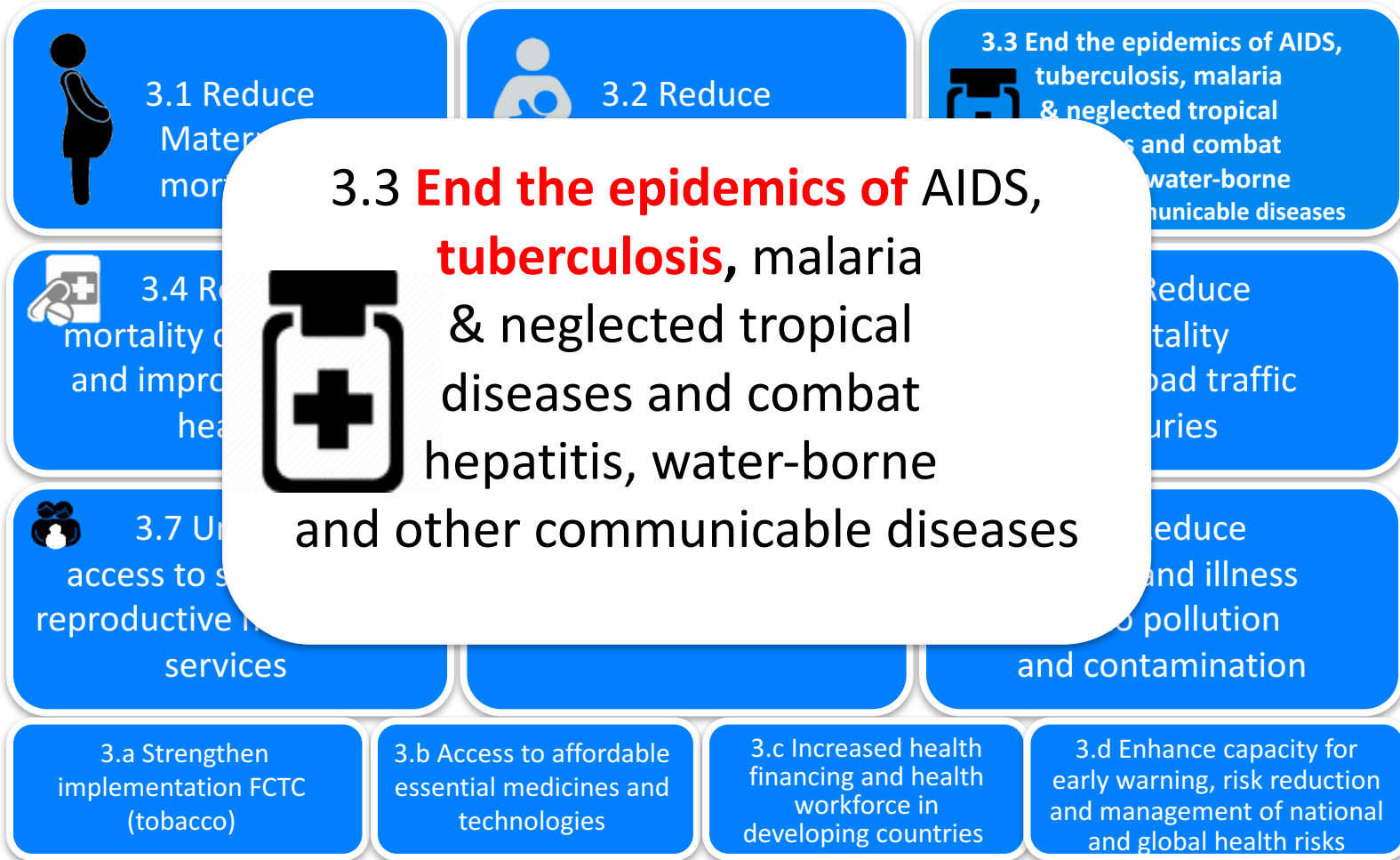
480,000

580,000

190,000

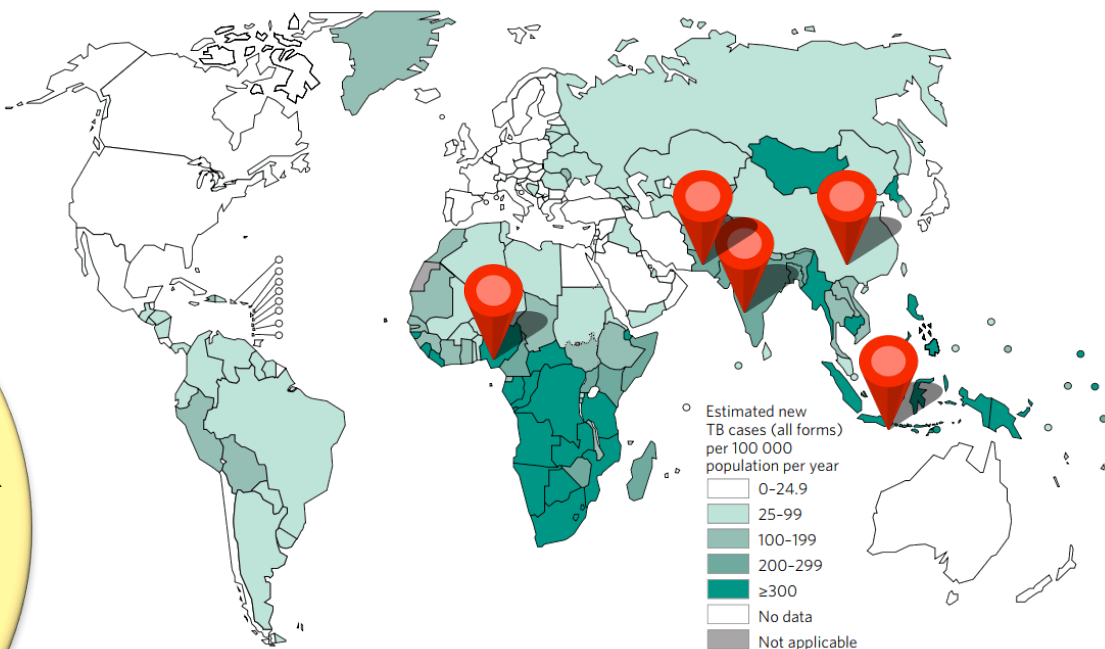
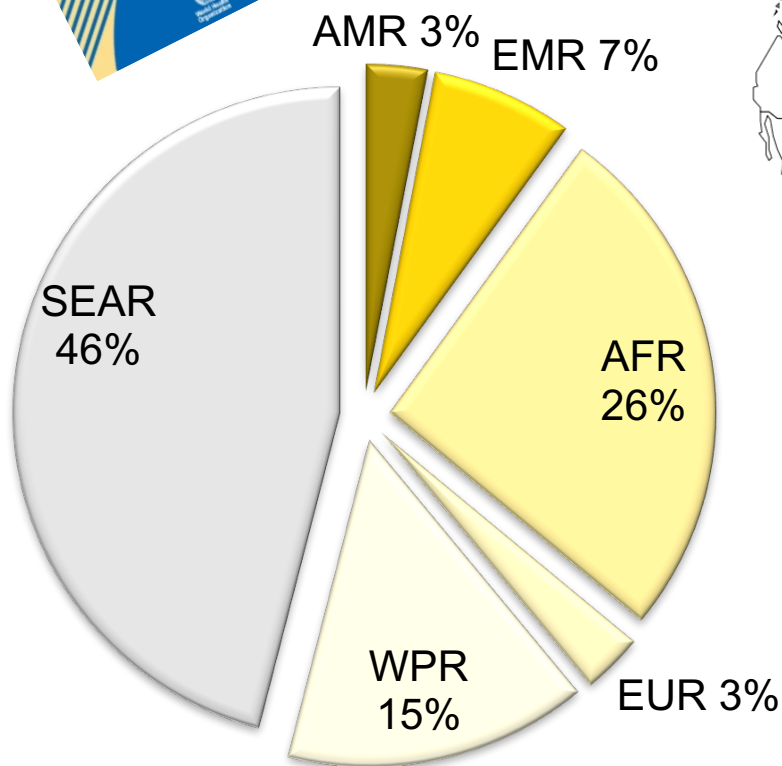
Source: WHO Global TB Report 2016
Including deaths attributed to HIV/TB*

SDG 2030 Goals & TB





TB incidence: countries & regions



27% in India

9-10% each: Indonesia & China

5-6% each: Nigeria & Pakistan



The End TB Strategy: 2016-2035

- BCG Vaccine

PILLAR 1

Integrated, patient-centered TB care and prevention

PILLAR 2

Bold policies and supportive systems

PILLAR 3

Intensified research and innovation

Government stewardship and accountability, with monitoring and evaluation

Building a strong coalition with civil society and communities

Protecting and promoting human rights, ethics and equity

Adaptation of the strategy and targets at country level, with global collaboration

TARGETS

MILESTONES

2020 2025

SDG*

2030

END TB

2035

Reduction in number of TB deaths

compared with 2015 (%)

35%

75%

90%

95%

Reduction in TB incidence rate

compared with 2015 (%)

20%

50%

80%

90%

TB-affected families facing catastrophic costs due to TB (%)

0%

0%

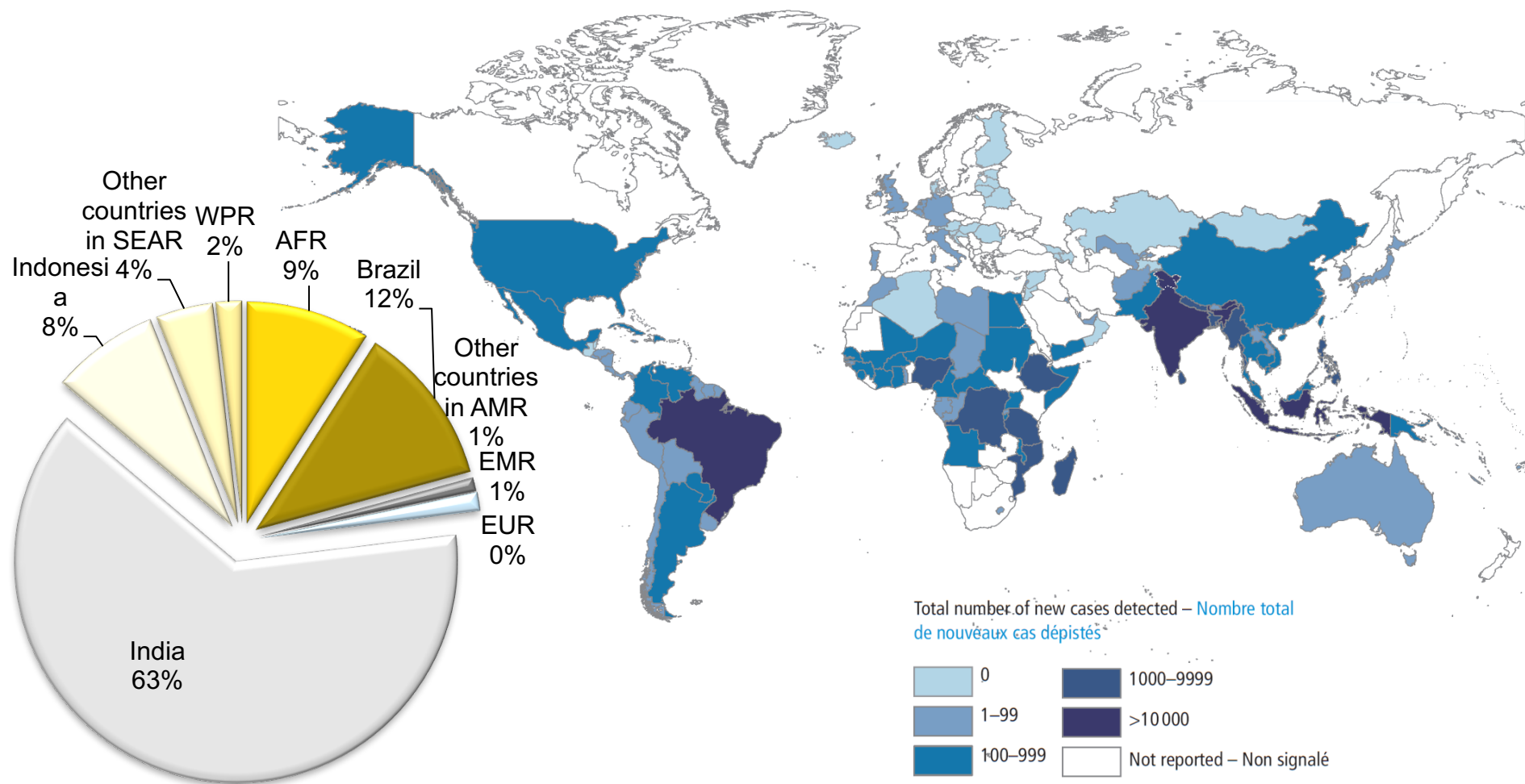
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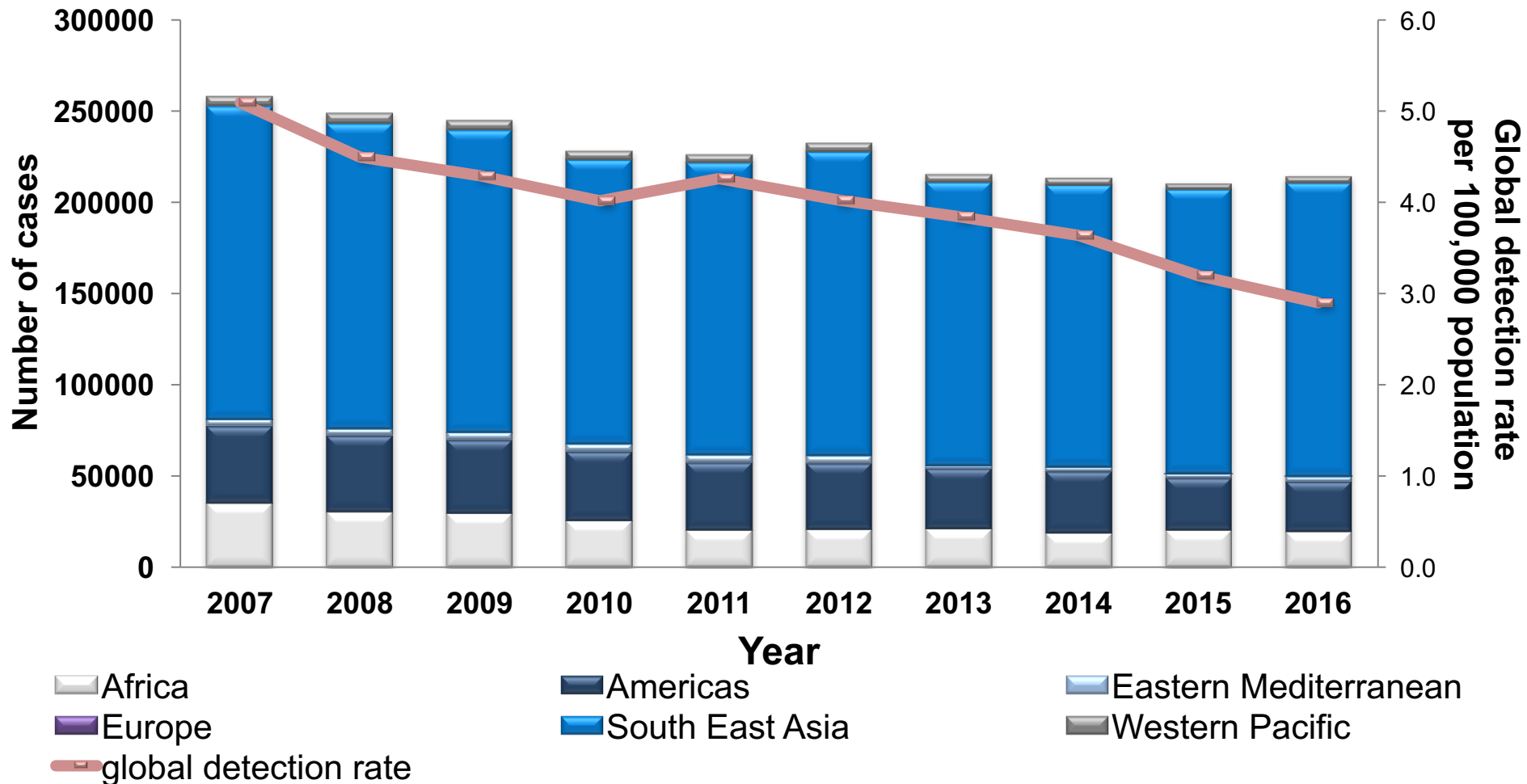


World Health Organization

Forgotten but not gone...2016 Leprosy (cases = 214,783)



Trend in global leprosy case detection, 2007-2016



The 2016-2020 strategy at glance

2016-2020 GLOBAL LEPROSY STRATEGY



- ⊙ Zero disease
- ⊙ Zero transmission of leprosy infection
- ⊙ Zero disability due to leprosy
- ⊙ Zero stigma and discrimination



Further reduce the global and local leprosy burden



INDICATORS	2020 target
Number of children diagnosed with leprosy and visible deformities	0
Rate of newly diagnosed leprosy patients with visible deformities	<1 per million
Number of countries with legislation allowing discrimination on basis of leprosy	0

Developing WHO Leprosy Guidelines

Dec 2016

- Application to GRC (WHO-HQ)

Apr 2017

- GDG established

Apr-May 2017

- Literature review

30-31 May 2017

- GDG meeting with recommendations

Aug 2017

- Draft “zero” of Guidelines

Sep 2017

- Review by External Review Group

Sep 2017

- Review by Steering Committee

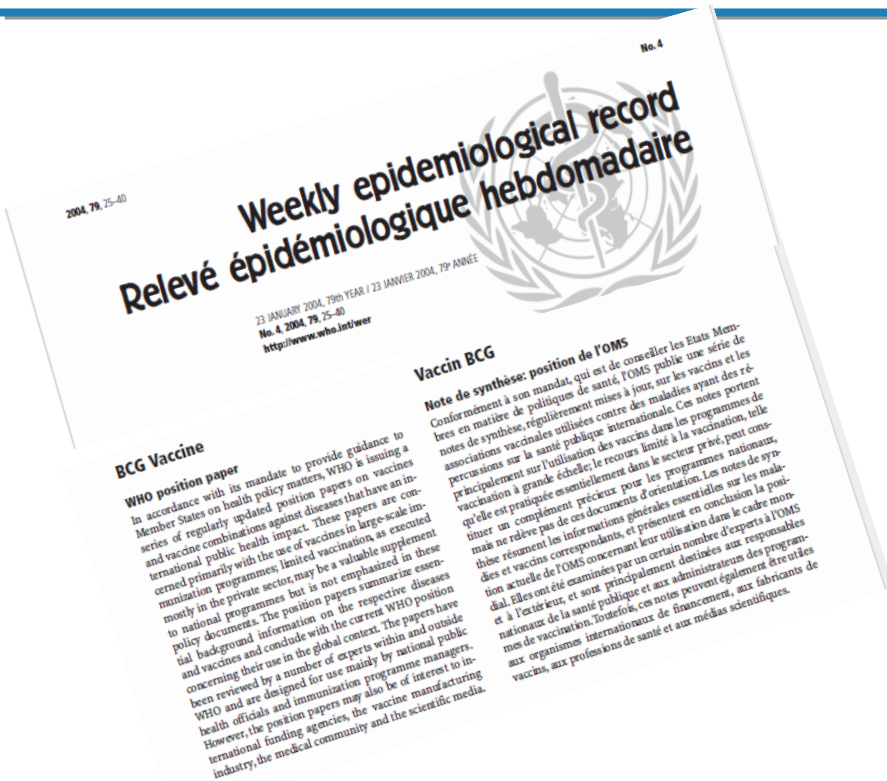
Oct 2017

- Submission of final draft of Guidelines to GRC

End 2017

- Leprosy Guidelines

2004: WHO Policy Recommendation BCG



- In countries with high TB burden
- 1-dose to “all infants”, as soon as possible after birth
- “All healthy” neonates
- No revaccination or boosters
- Low burden TB countries may limit to infants of high-risk groups (or skin test negative older children)
- No recommendation on use of BCG against leprosy

www.who.int/wer/2004/en/wer7904.pdf

2007: WHO Policy Recommendation Infants at risk of HIV infection

HIV+

Weekly epidemiological record Relevé épidémiologique hebdomadaire

25 MAY 2007, 82nd YEAR / 25 MAI 2007, 82^e ANNÉE
No. 21 2007, 82, 181-196
<http://www.who.int/wer>

Revised BCG vaccination guidelines for infants at risk for HIV infection

Background

Following a review of relevant data, the Global Advisory Committee on Vaccine Safety (GACVS) has revised its previous recommendations¹ concerning bacille Calmette-

¹ See No. 3, 2007, 82, pp. 18-24.

Révision des lignes directrices relatives à la vaccination par le BCG des nourrissons exposés au risque d'infection par le VIH

Généralités

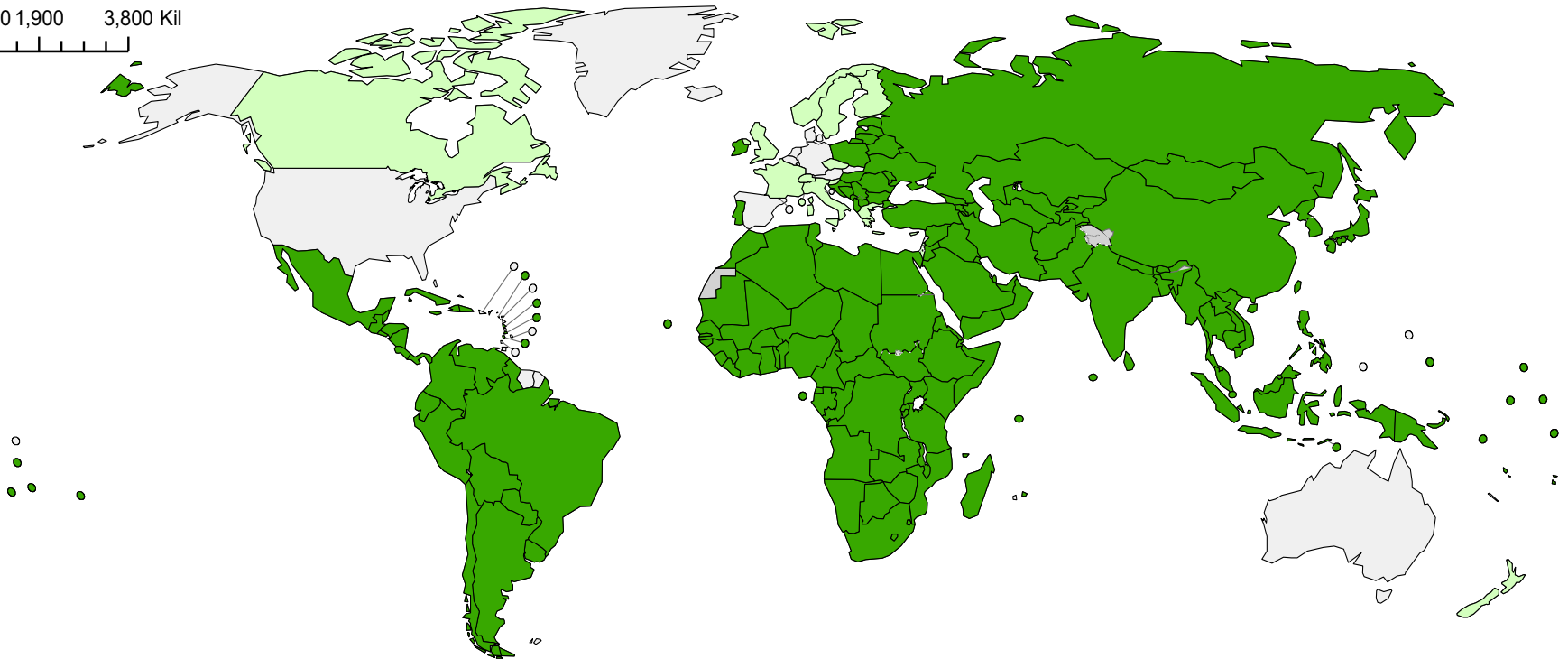
Suite à un examen des données pertinentes, le Comité consultatif mondial de la Sécurité vaccinale (GACVS) a révisé ses recommandations antérieures¹ relatives à la vaccination par le

¹ Voir N° 3, 2007, 82, pp. 18-24.

- Children know to be HIV+, even if asymptomatic, should **NOT** be immunized with BCG
- Infants born to HIV-infected mothers where early HIV diagnostic testing can be performed, BCG can be deferred until diagnostic testing results are available.

156 Countries with BCG in immunization schedule, 2016

0 950 1,900 3,800 Kil

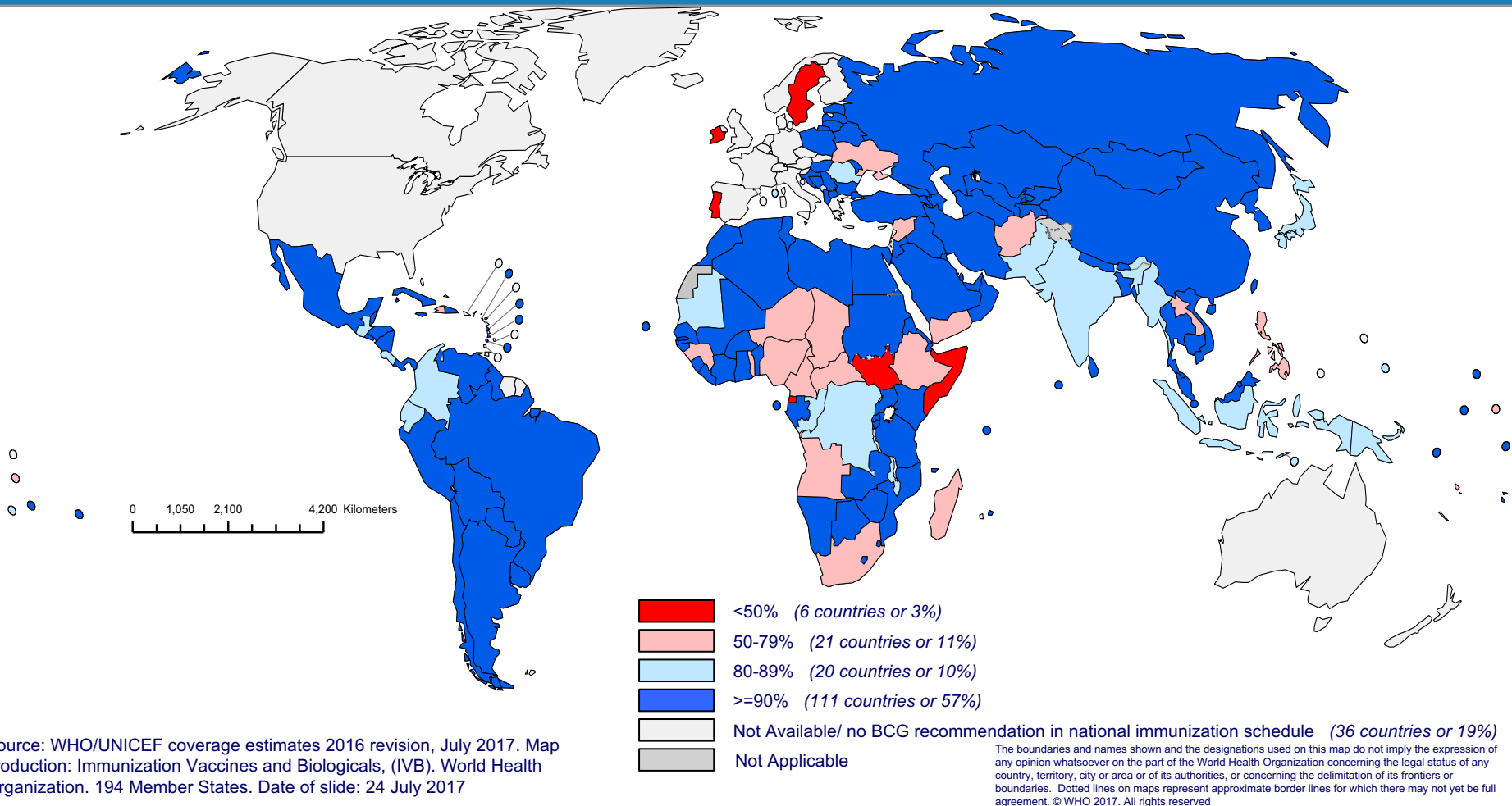


- BCG in Schedule (156 countries or 80%)
- BCG in schedule for defined risk groups (17 countries or 9%)
- Not Available/ no BCG recommendation in national immunization schedule (21 countries or 11%)
- Not Applicable

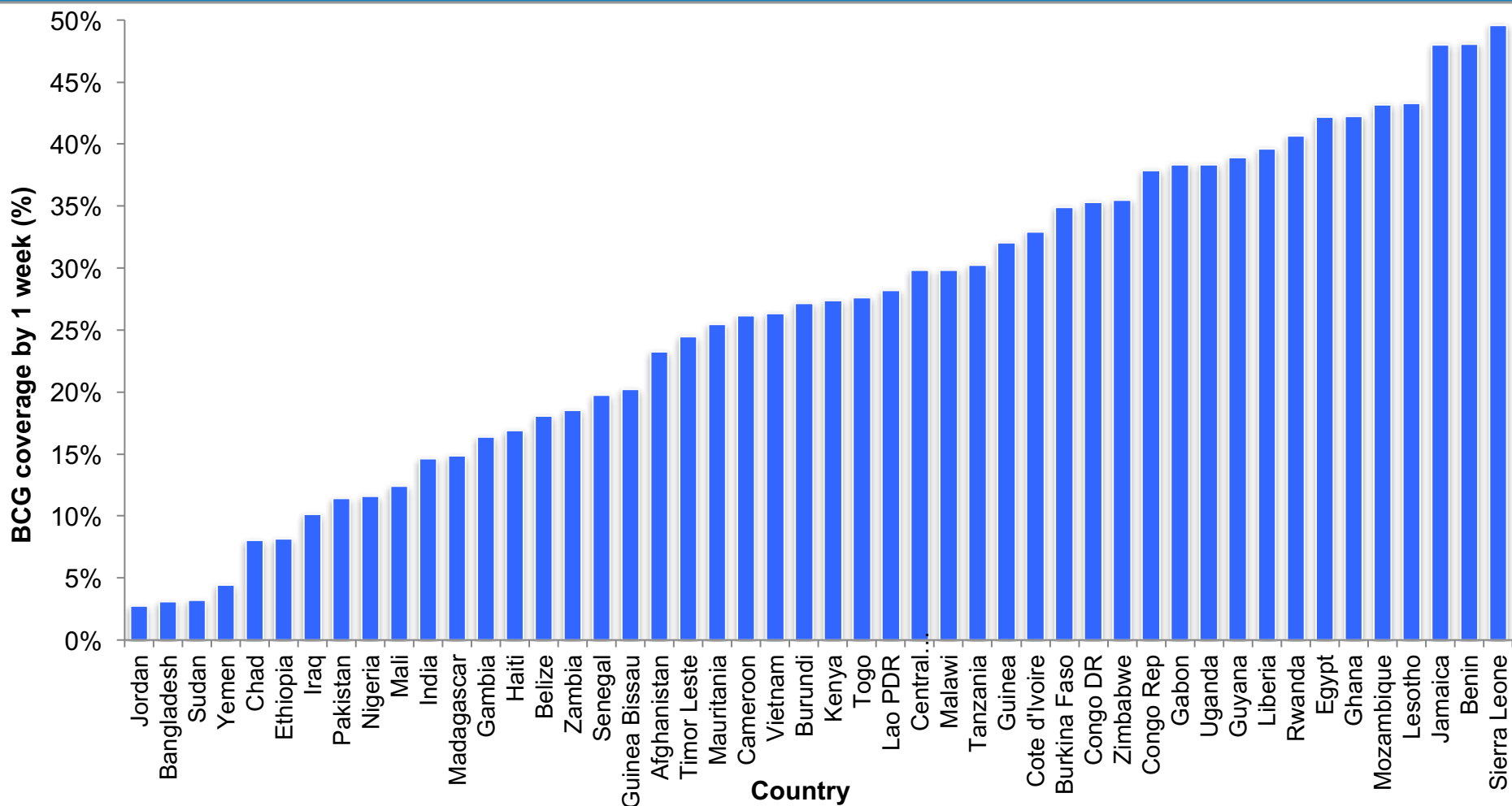
Source: WHO/UNICEF Immunization Database from country reported data (JRF) as at 05 September 2017. Map production: Immunization Vaccines and Biologicals, (IVB). World Health Organization. 194 Member States.
Date of slide: 18 September 2017

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Immunization coverage with BCG at birth, 2016



Timeliness of BCG vaccination among countries with birth dose recommendation



Questions to SAGE

- Most of the recommendations will remain as the current WHO recommendations
 - Does SAGE reaffirm the current recommendations?
- The Working Group identified **3 topics** as crucial
 1. Should we reemphasize BCG vaccination at birth?
 2. Should we recommend BCG vaccination against *M. leprae* and other nontuberculous mycobacterial infections?
 3. Is a recommendation for HIV exposed, immunocompetent HIV/infected individuals on ART acceptable?