Compilation of presentations delivered either at meetings of the SAGE Working Group (WG) on Maternal and Neonatal Tetanus Elimination and Broader Tetanus Prevention or at the WHO TechNet Consultation, March 22-25, 2003 Antalya, Turkey and referenced in the September 2016 report of the WG

1. "Impact of Delivery Technologies on Increased Access", BASICS II, WHO TechNet Consultation, March 22-25, 2003, Antalya, Turkey.
2. "TT Uniject: Programmatic Needs vis-á-vis Availability", Azhar A Raza, UNICEF, SAGE WG on MNTE and Broader Tetanus Prevention, August 17-19, 2016, Geneva, Switzerland.
3. "India: Achieving MNT Elimination – Health Systems Approach", Rakesh Kumar, Government of India, SAGE WG on MNTE and Broader Tetanus Prevention, March 30-April 1, 2016, Geneva, Switzerland.
4. "Critical operational challenges to achieving at least 80% protection at birth from MNT in high risk districts", Jane Soepardi, Ministry of Health, Indonesia, SAGE WG on MNTE and Broader Tetanus Prevention, March 30-April 1 2016, Geneva, Switzerland.
5. "'New' Vaccination Platforms and Opportunities for TTCV Boosters", Tracey Goodman, WHO, SAGE WG on MNTE and Broader Tetanus Prevention, August 17-19, 2016, Geneva, Switzerland.
6. "HIV prevention through voluntary medical male circumcision and TTCV gaps for males," Liz Miller, Public Health England and Julia Samuelson, WHO Department of HIV/AIDS, SAGE WG on MNTE and Broader Tetanus Prevention, August 17-19 2016, Geneva, Switzerland.

BASICS II

Impact of Delivery Technologies on Increased Access:

BASICS II

for

WHO TechNet Consultation

March 22-25, 2003

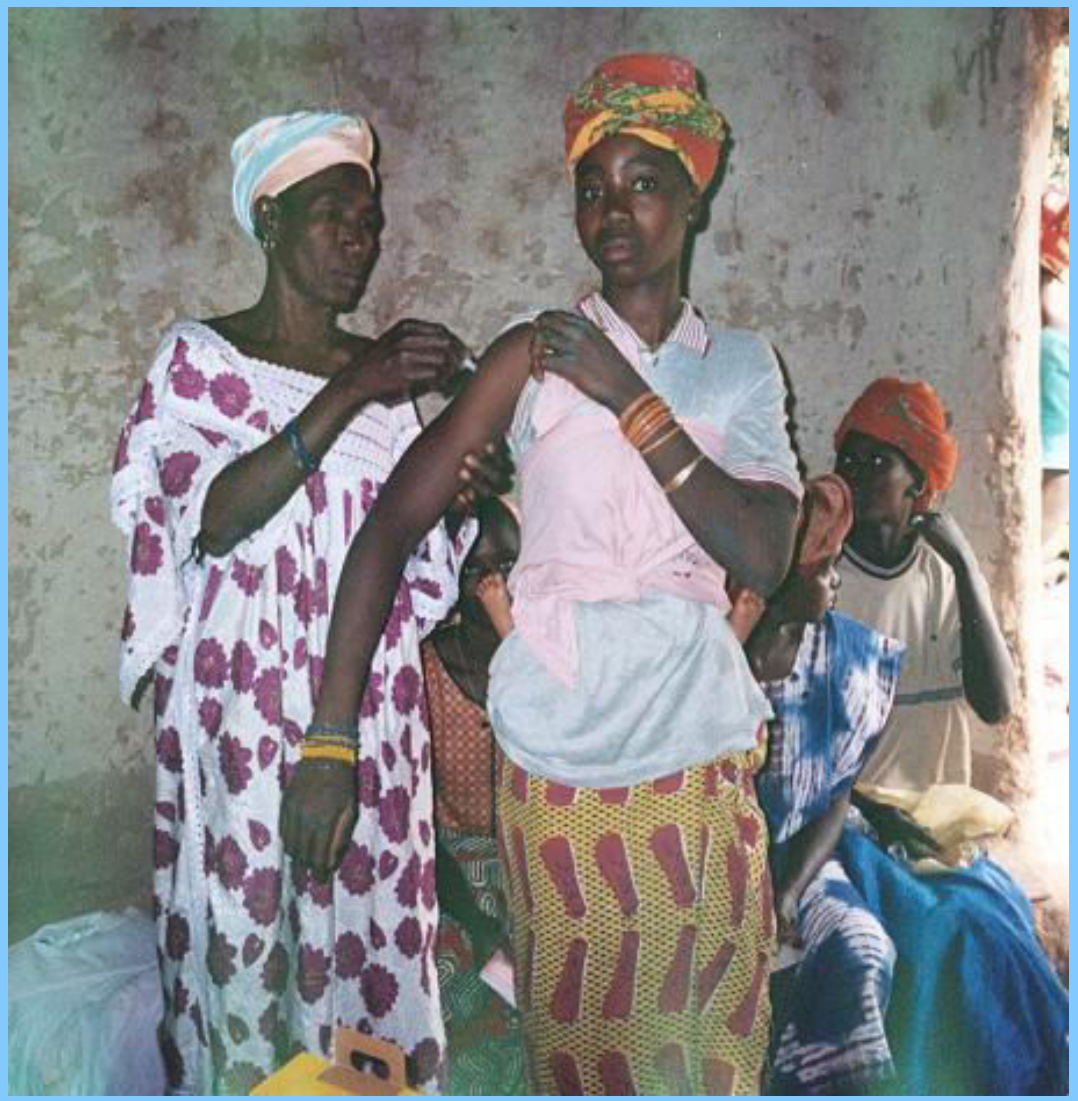
Antalya, Turkey

USAID

TT-UNIJECT Report Mali/PATH

Lydia A. D'Alois,
Operations & Evaluation
Research Technical Officer

Bréhima Sanogo,
Sidibé Diarra,
Jules Millogo,
BA Plowman, and
Robert Steinglass

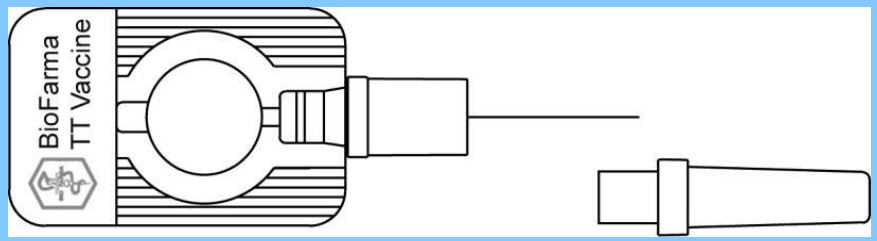


Goal

- Use TT-Uniject as an adjunct to regular program
  - in areas that are less accessible and
  - with populations that are less accessible.

Prefilled TT-Uniject

- Single-use
- Device combines AD syringe + needle (fine, small)
- Individually packaged with heat-sensitive indicator



Study Purpose

- Determine if traditional birth attendants (TBAs) who are participating as community-based volunteers (CBVs)
  - could successfully use TT-Uniject in Mali, and
  - would be accepted by the population for vaccinating women against tetanus

Comparison to Previous studies

Charac-teristic	*Mali – Tetanus*	*Bolivia – Tetanus[1]*	*Indonesia – Hepatitis B[2]*
Type of vaccinator	CBV, self-employed, mostly TBAs	Not specified, but apparently CBV	Trained village mid-wives in Indonesian MOH Healthy Start for CS program
Selection for parti-cipation	Selected by village	Unknown	Midwives selected to participate in health program
Education and literacy	Majority uneducated and illiterate	Not specified, but some education and literate[3]	Not specified, but at least some education and literate
Prior injection experience	Presumed none	About half had experience	Routinely vaccinating for several years

Program Method

Approach for incorporating volunteers into administering TT injections :

- Vaccinators would be volunteers who are TBAs.
- They would be selected by their respective community, that is, they would be community-based volunteers (CBVs).
- CBVs' capacity would be tested during MNTE campaign held in 6 districts, using TT-Uniject in 2 districts accessible for supervision and with typical coverage, and AD syringes with multi-dose vaccine vials in the 4 other districts.

Program Method, cont'd

Selection of CBVs:

District health officer (DHO) requested Area Health Officers (AHO) to talk to town chiefs to select local CBV to be trained to vaccinate reproductive-aged women with TT-Uniject:

- One CBV per town
- Selection based on 3 criteria:
  - acceptability by the majority of townspeople
  - physical capacity to use UNIJECT
  - interest in participating in the activity

Program Method, cont'd

Training of CBVs:

- TOT fashion: 2 national trainers - each trained a DHO and the AHOs of a single district. In turn, AHOs trained their own CBVs.
- First training was for 2 days (before 1st MNTE round, June 2002).
- Nominated CBVs who were unable to perform during 1st training were deselected.
- 1 day refresher session preceded 3rd round (2/03).

Evaluation Methods

Three indicators:

1. % CBVs who correctly used TT-Uniject (measured by performance indicator, PI)
2. % of CBVs' clients who were satisfied having CBV give vaccination (with TT-Uniject)
3. Immunization data (coverage and drop-out) in districts using TT-Uniject should be similar to those of the 4 districts using AD syringes administered by health personnel.

Evaluation Methods, cont'd

Data Collected in TT-Uniject districts by:

- A survey of CBVs and their clients during round 3 by two different methods comprising four aspects:
  1) Observation of :
     - CBVs administering TT-UNIJECT
     - Site after completion of vaccination campaign in a town
  2) Interviews with:
     - CBVs
     - One client of each CBV surveyed
- Focus groups conducted just after 3rd round with
  - Area Health Officers
  - CBVs
- MNTE immunization data collected during 3 rounds

Evaluation Methods, cont'd

Performance indicator (PI) to measure % of CBVs who correctly used TT-Uniject, based on 8 tasks:

- 1. Correctly determines vaccine vial monitor (VVM)
- 2. Easily opens package
- 3. Correctly activates device
- 4. Uses sterile technique
- 5. Injects in correct body location
- 6. Completely empties reservoir
- 7. Does not recap needle
- 8. Places device directly into sharps container

Sample Selection

For survey (observations and interviews):

Number of CBVs, by District

Districts (*Cercles*)	Population of Women Aged 15 – 49 yrs	Number of CBVs		
		Trained for 1st Round	Sampling List[1]	Selected for Study[2]
Bla	53,500	188	210	114
Bougouni	88,548	417	446	290
Total	**142,048**	**605**	**656**	**404**

Sample Selection, cont'd

For focus groups:

- All AHOs in the district were to participate (22 in Bla, 23 in Bougouni).
- Each AHO invited one CBV. Selection was by convenience, e.g., available to attend, had a way to get there, invited by AHO (so 22 in Bla and 23 in Bougouni).

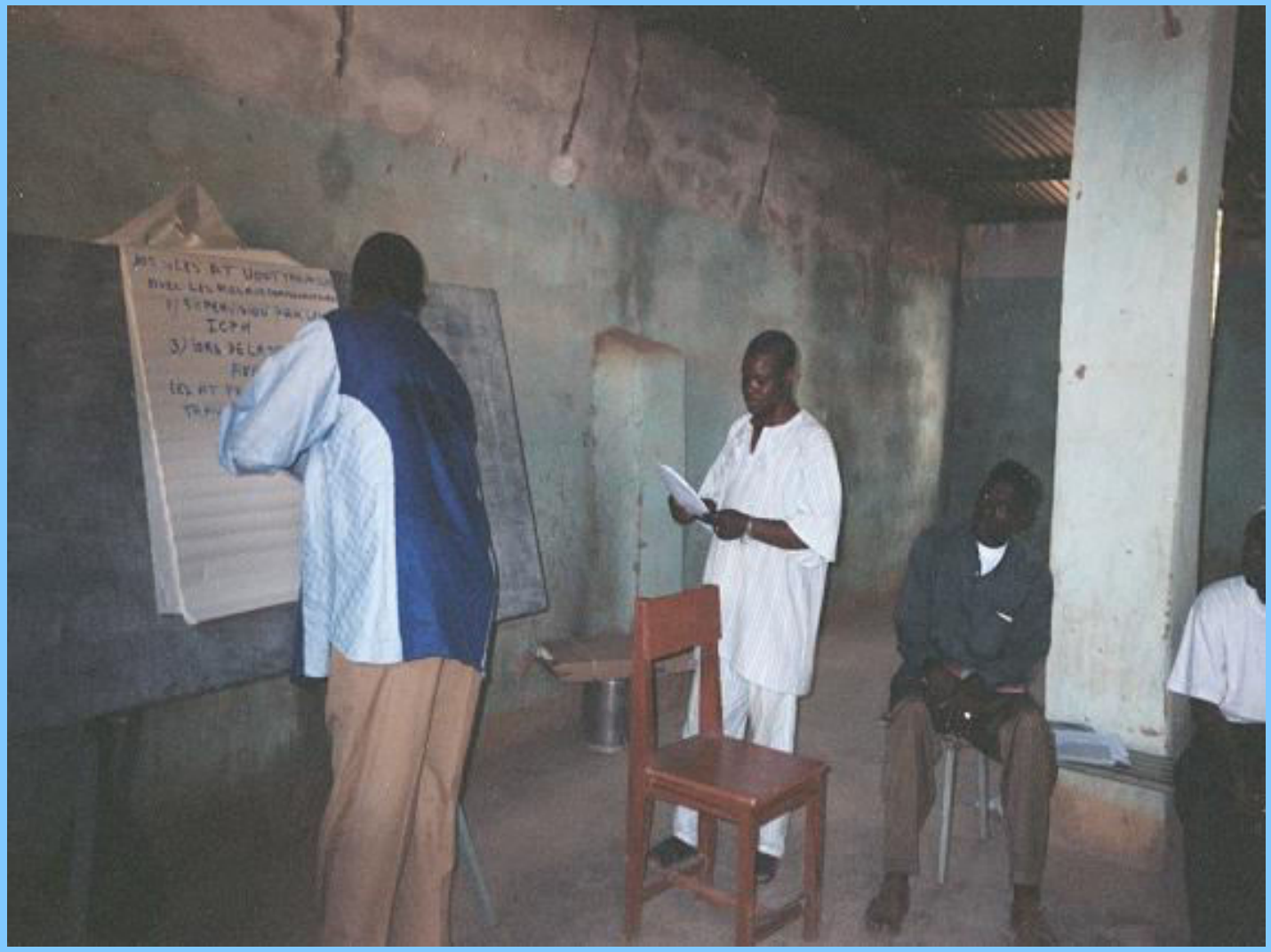
Results

Data were collected by survey and focus groups between February 17 – 25, 2003

- 4 focus groups were conducted, 1 each of CBVs and AHOs in each of the 2 districts
- 182 site observations were conducted
- 346 CBVs and clients were surveyed

Results

Results: Focus Groups



Results: Focus Groups, cont'd

Number of Focus Group Participants, by District

	AHOs	CBVs
Bla	22	17
Bougouni	20	18
Total	42	35

Results: Focus Groups, cont'd

Summary of key aspects (AHOs + CBVs)

- Method by which CBV was recruited:
  - Actual method of selection was
    - primarily by general assembly (all of Bla and 42% of Bougouni)
    - in Bougouni, next most popular method was by town chief in collaboration with the village health committee (26%)
  - Most AHOs and CBVs were satisfied with the method of selection
  - Most AHOs were satisfied with most of the CBVs selected
  - A number of AHOs suggested that there should be more stringent adherence to the criteria when selecting the CBV (improve standardization of selection)
- Training of CBV:
  - 17% of AHOs did not agree to have one or more CBVs vaccinate after 1st training, before round 1 (all were in Bla)
  - Half of AHOs trained other CBVs after 1st training
  - Most CBVs said they learned in one session

Results: Focus Groups, cont'd

- Perception of the community's view:
  - Townspeople agree to having CBV vaccinate: 1/3 of Bla's and almost all of Bougouni's AHOs thought this. (Yet the survey showed 9 out of 10 clients would return if CBV were vaccinating and/or if UNIJECT were used.)
  - Rumors: CBVs thought that their participation helped reduce rumors, but AHOs thought that it didn't.

Results: Focus Groups, cont'd

- Stated advantages of having CBVs help:
  - Increased coverage: both AHOs and CBVs thought this, and that it was because CBVs
    - mobilize the population and
    - they know who's missing
  - Improves work efficiency: AHO's said it reduces their (immunization) work load, allowing them to do other things (that CBVs can't do).

Results: Focus Groups, cont'd

- CBVs routinely administering TT-Uniject:
  - Both groups thought this was possible
  - Both groups said pay was not necessary
  - AHOs suggested implementing this

    through immunization outreach with AHO as supervisor and the (existing) community health worker (*relais*) serving as the link between AHO and CBV.

Results: Focus Groups, cont'd

- Characteristics of CBVs in focus groups with respect to work as a TBA:
  - Bla (N=17):
    - Practicing TBAs = 4 (23%)
    - Apprentice TBAs = 7 (41%)
    - Who aren't TBAs = 6 (35%)
  - Bougouni (N = 18):
    - Practicing TBAs = 16 (89%)
    - Apprentice TBAs = 2 (11%)

Results: Survey

Results: Survey, cont'd

Characteristics of volunteers

- Age: 57% >45 years of age (4% < 30 yrs)
- Residence in village: 75% since marriage
  15% since birth
- Schooling: 78% had none
- Literacy courses: 47% had taken some

Results: Survey, cont'd

Practice as a TBA:

- How long had she been a TBA (years)?
  - about 40% had been a TBA for 5 or more years
  - 33% for one year or less
- Had she provided prenatal counseling during the 10-11 wks prior to interview?
  - 53% had counseled someone (about 1 per wk)
- How many deliveries had she assisted during the 10-11 wks prior to interview?
  - 70% had assisted at deliveries (usually about 2 every 3 wks)

Results: Survey, cont'd

- Training of community-based volunteer:
  - 63% had the originally planned training
  - 17% had only one training (either one of the planned trainings or an ad hoc training)
  - 10% had the originally planned training plus an extra training (36, of whom 31 were from Bla)
  - 7% had 2 trainings, but not the planned two
  - 3% said they had no special instruction

Results: Survey, cont'd

- Supervision during UNIJECT administration:
  - 97% had at least one person near her, with 58% of these having someone so close they could touch her
  - 75% were constantly watched or checked
  - 6% were not watched at all

Results: Survey, cont'd

Performance Indicator:

- 4 out of 10 successfully executed all 8 tasks
- 9 out of 10 :
  - Used sterile technique
  - Injected at correct arm site
  - Didn't recap needle
  - Correctly disposed of the device

Results: Survey, cont'd

- The task that posed the most difficulty was emptying the reservoir – 1 out of 4 did not completely empty the reservoir.

- 8 out of 10:
  - easily opened the package
  - easily activated the device
  - correctly made a decision using the VVM

Results: Survey, cont'd

- Mean performance indicator (MPI) was 7.1 out of possible 8.0 (SD=1.1).
- 3 out of 4 had a value of at least 7.0
- MPI was significantly greater for Bla, 7.4 ± 0.7 versus 7.0 ± 1.2 for Bougouni
- MPI was significantly greater for CBVs <46 years of age, 7.4 ± 0.8 versus 6.9 ± 1.2
- The differences between districts and between age groups was due to a much lower MPI for older women in Bougouni

Results: Survey, cont'd

- TBA experience: No association with MPI
- School: can't analyze (78% had no schooling)
- Literacy:
  - MPI was greater for those who had literacy courses but not significantly so.
  - There were interactions between having taken literacy courses, age, and district.
- Training: MPI was lower for those with 3 trainings versus 1 or 2 trainings, perhaps because AHO felt the CBV needed supplemental training.
- Supervision: No association with MPI

Results: Survey, cont'd

Injection Safety:

- 99% of the CBVs disposed of the Uniject in a safety box
- 5% admitted to having stuck herself (but not someone else) at some time with the Uniject needle

Results: Survey, cont'd

Client Satisfaction:

- 4% said this was her first injection
- 3 out of 4 had previously received injections and said the injection that day was less painful
- 8 out of 10 thought it was good to have the CBV do the injection (6% didn't think so)
- Virtually 100% said she would come back
  - For a vaccination given by the CBV
  - For a vaccination with Uniject
  - For a vaccination by the CBV with Uniject

Results: Survey, cont'd

Results: Survey, cont'd

Injection Safety - Site Observations

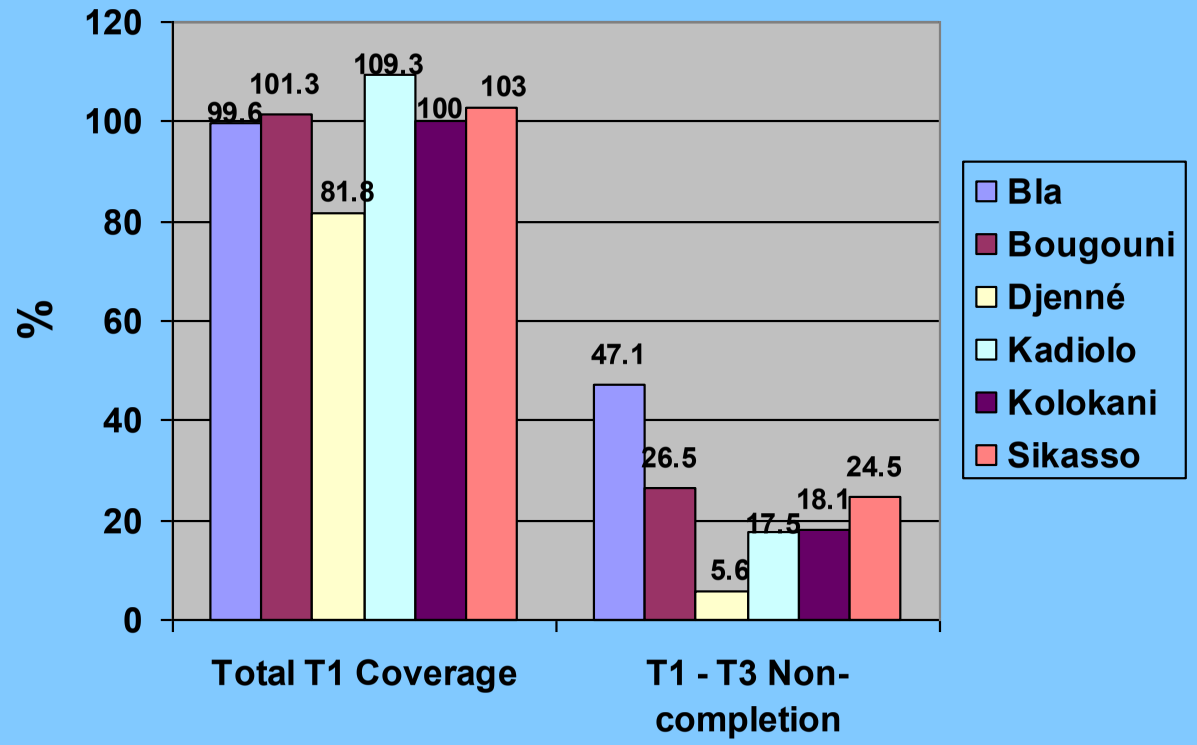
(N = 182)

- 99% used the safety box
- 10% also had other boxes
- 98% of volunteers took the boxes to a health person; 2% did nothing with them
- 99% of the boxes were taken away by health personnel; the other 1% was appropriately disposed of

Results: MNTE Data

Total % of Women with T1 after 3rd Round and T1 – T3 Non-complete Vaccination, by District

(TT-Uniject districts are first 2 on left)



Conclusions

Regarding CBV's capacity to use TT-Uniject:

- CBVs, including nonliterate CBVs, can be trained to safely and correctly use TT-Uniject
- Training may impact performance

Regarding acceptance of CBV administered TT-Uniject:

- CBVs vaccinating women are accepted by communities in Mali
- TT-Uniject is accepted by communities in Mali

Conclusions, cont'd

Regarding costs of CBVs administering TT-Uniject:

- CBVs are willing to participate in routine vaccination as unpaid community volunteers
- Health staff believe that CBVs can routinely vaccinate using TT-Uniject as unpaid community volunteers
- Such participation can be done without additional costs beyond training costs

Conclusions, cont'd

Other implications:

- Health staff felt that CBVs in this role reduce their own immunization work load to allow them to do other health work
- Health staff and CBVs thought that CBVs may help increase coverage by
  - Mobilizing population
  - Better identification of those needing vaccination
  - Reducing rumors

Next Steps

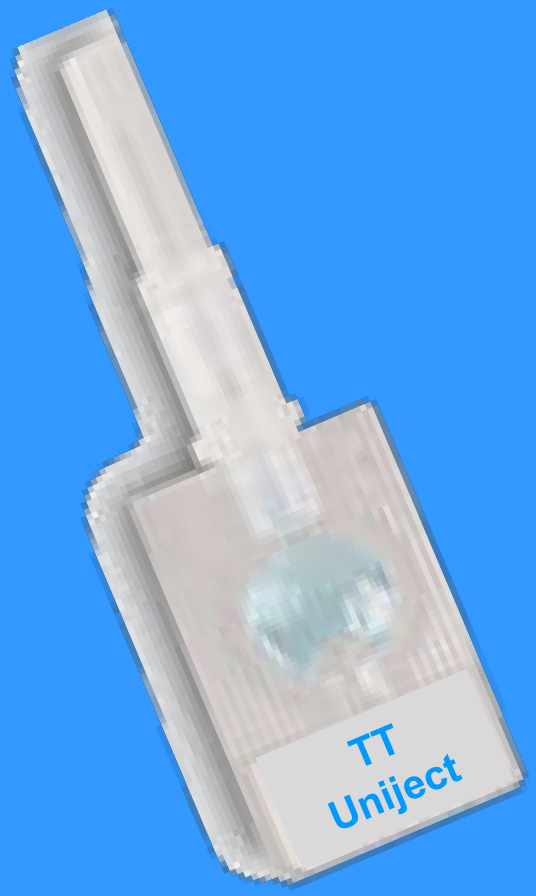
- Develop strategy and procedures for incorporating CBV administered TT-Uniject into routine vaccination
- Revise training materials to accommodate adult learners who are predominantly non-literate learners

CBVs with TT-Uniject Can Overcome Social Barriers

SAGE Working Group for MNTE
2nd face-to-face meeting

TT Uniject:

Programmatic Needs vis-á-vis Availability



Azhar A Raza
Immunization Specialist UNICEF
Geneva, 17 August 2016

unicef

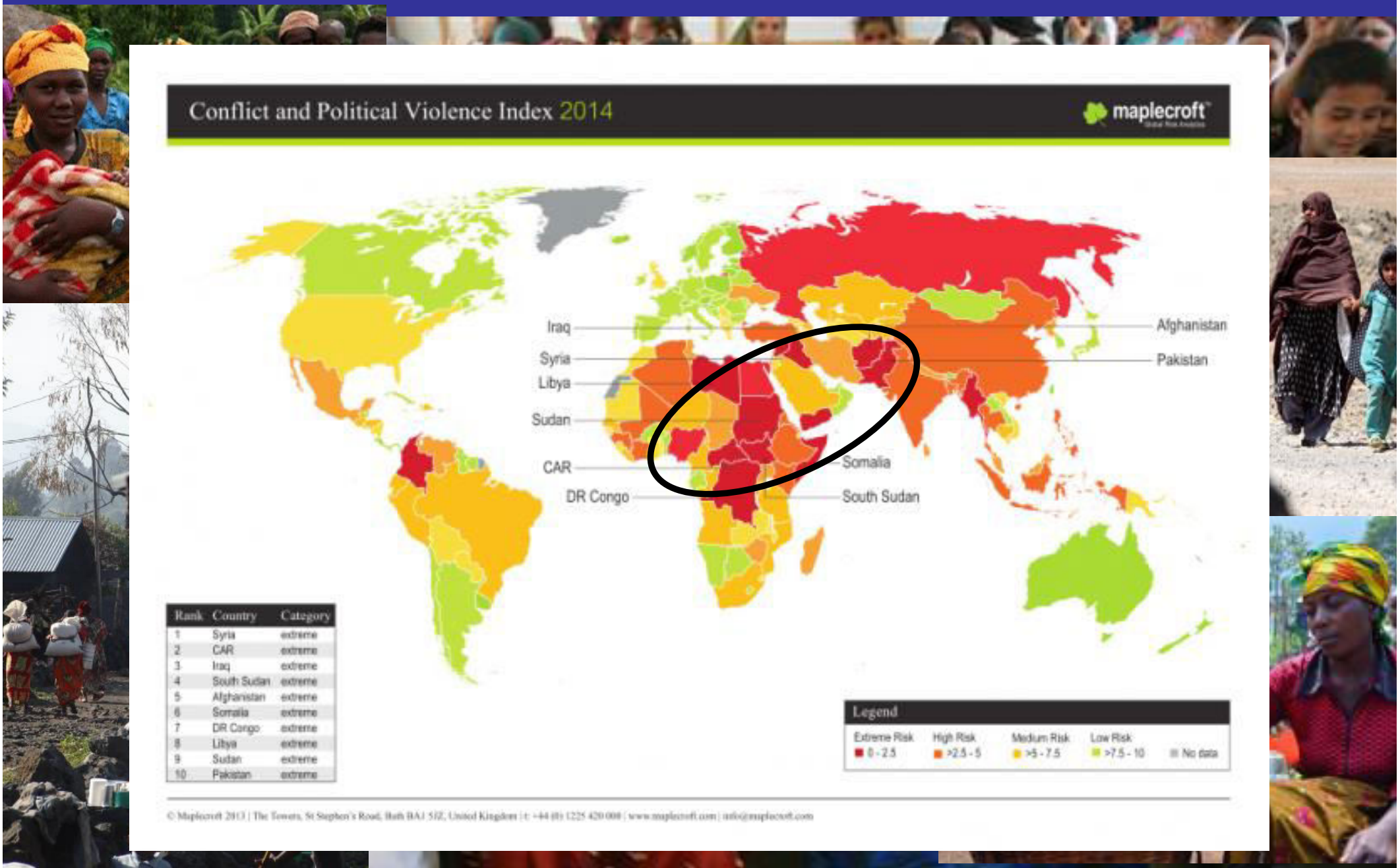
UNFPA

World Health Organization

Presentation Outline

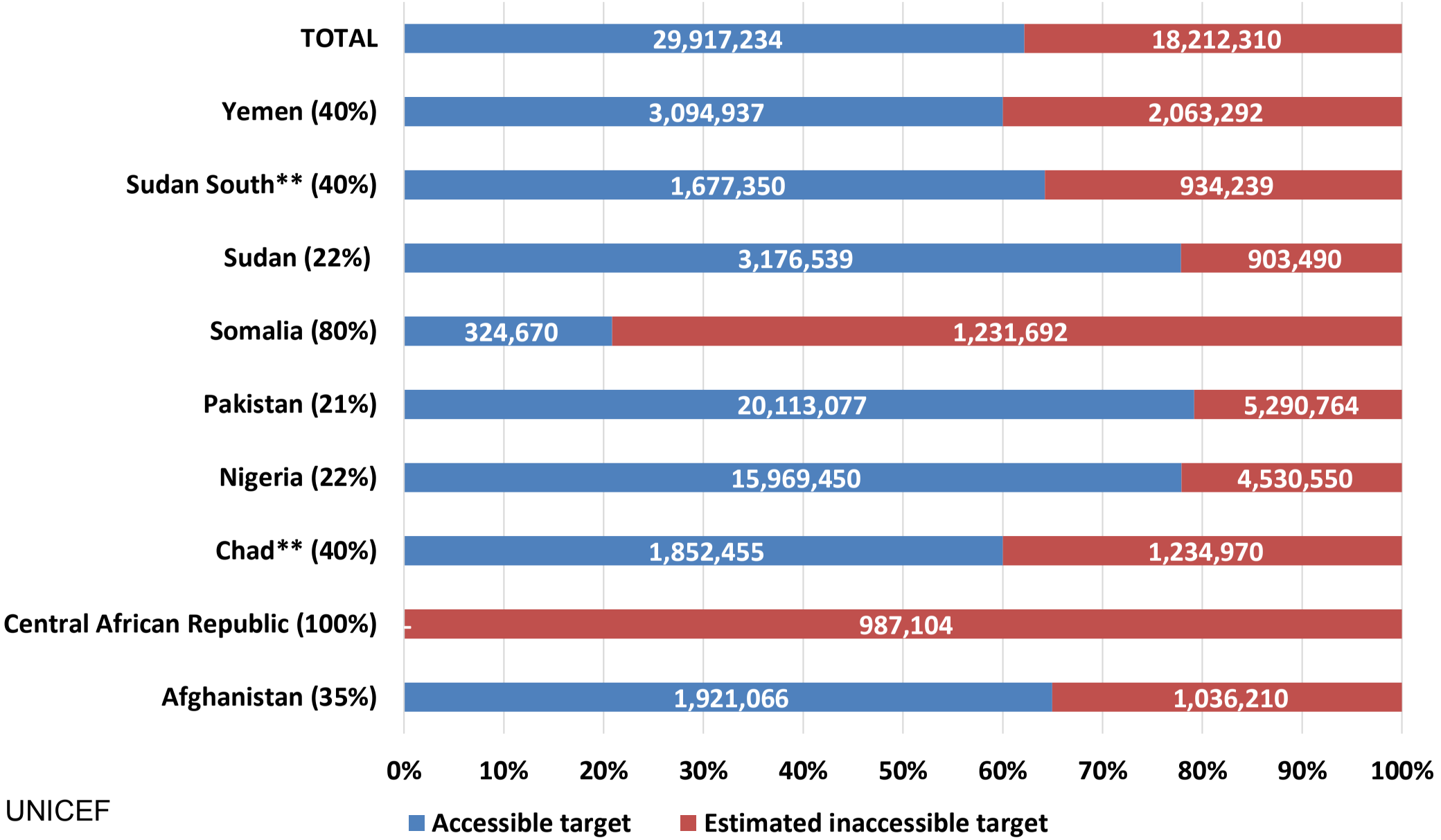
- Why needed programmatically?
- Operational advantages and past experience
- Resources required and estimated timeline
- Availability in global market
- Manufacturers capacity & priorities
- Forecast 2017-2020
- Next steps

9 out of 18 remaining MNT risk countries have prevailing issues of conflict and insecurity!!!



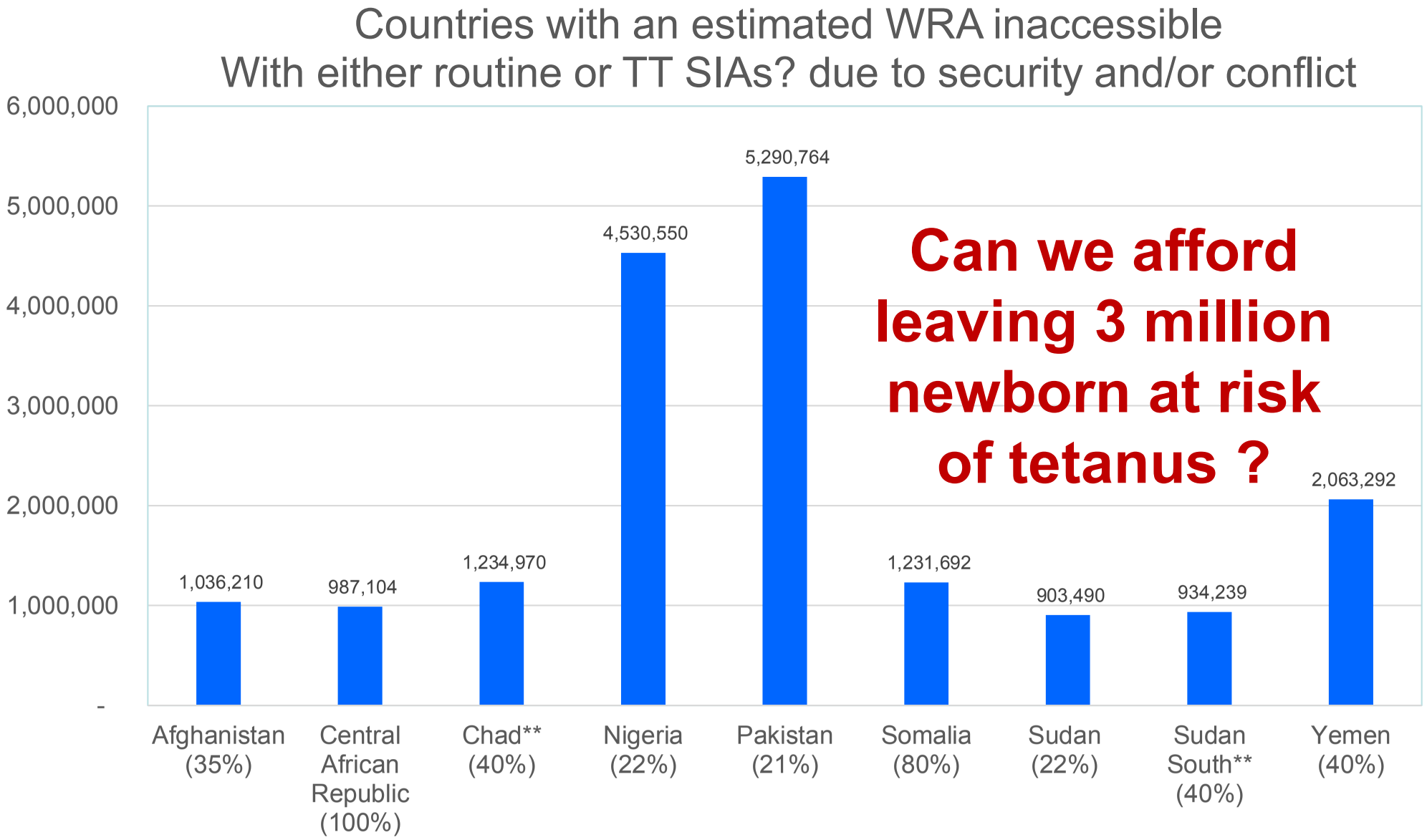
Rank	Country	Category
1	Syria	extreme
2	CAR	extreme
3	Iraq	extreme
4	South Sudan	extreme
5	Afghanistan	extreme
6	Somalia	extreme
7	DR Congo	extreme
8	Libya	extreme
9	Sudan	extreme
10	Pakistan	extreme

~40% of WRA inaccessible in 9/18 countries still at risk of MNTE



UNICEF

~18 million targeted women in 9 countries are repeatedly missed by routine and TT SIAs? !!



*** Chad and South Sudan may need it for one corrective round.*

The situation ideally warrant innovative technologies for service delivery

- A preparation that is easy to handle and use
- Its more safer to use in such circumstances
- That need less expertise to operationalize
- More stable on exposure to heat
- Usable by routine programme afterwards.

Past experience of TT Uniject

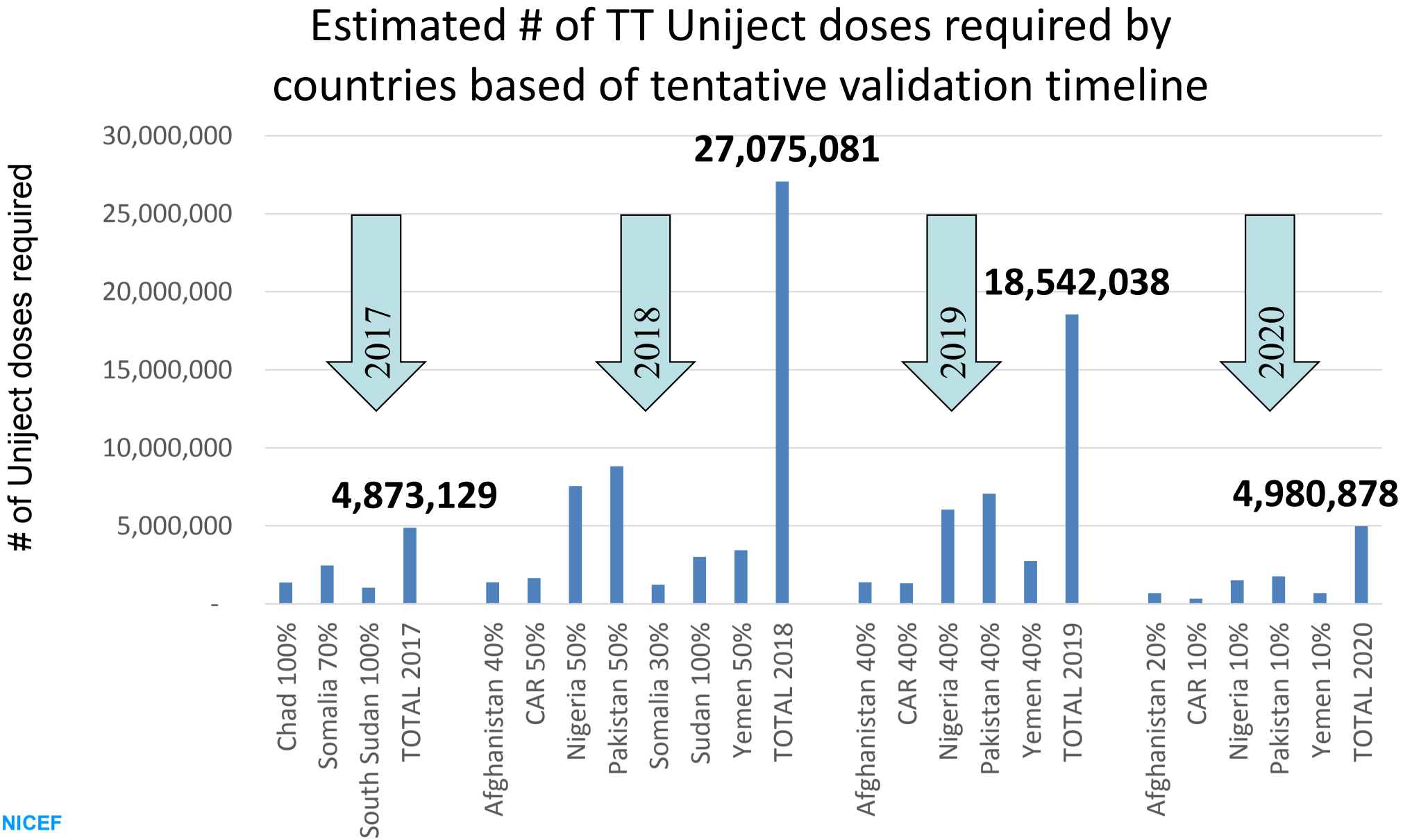
- Successfully used in past – pilot in 9 countries
- Prefilled device – that was easy to administer
- Used satisfactorily by community workers and volunteers
- Required very brief trainings / orientation
- No change in VVM despite being out of cold chain
- Was carried to remote sites even indoors without cold chain

9 million TT Uniject used
2002-2004

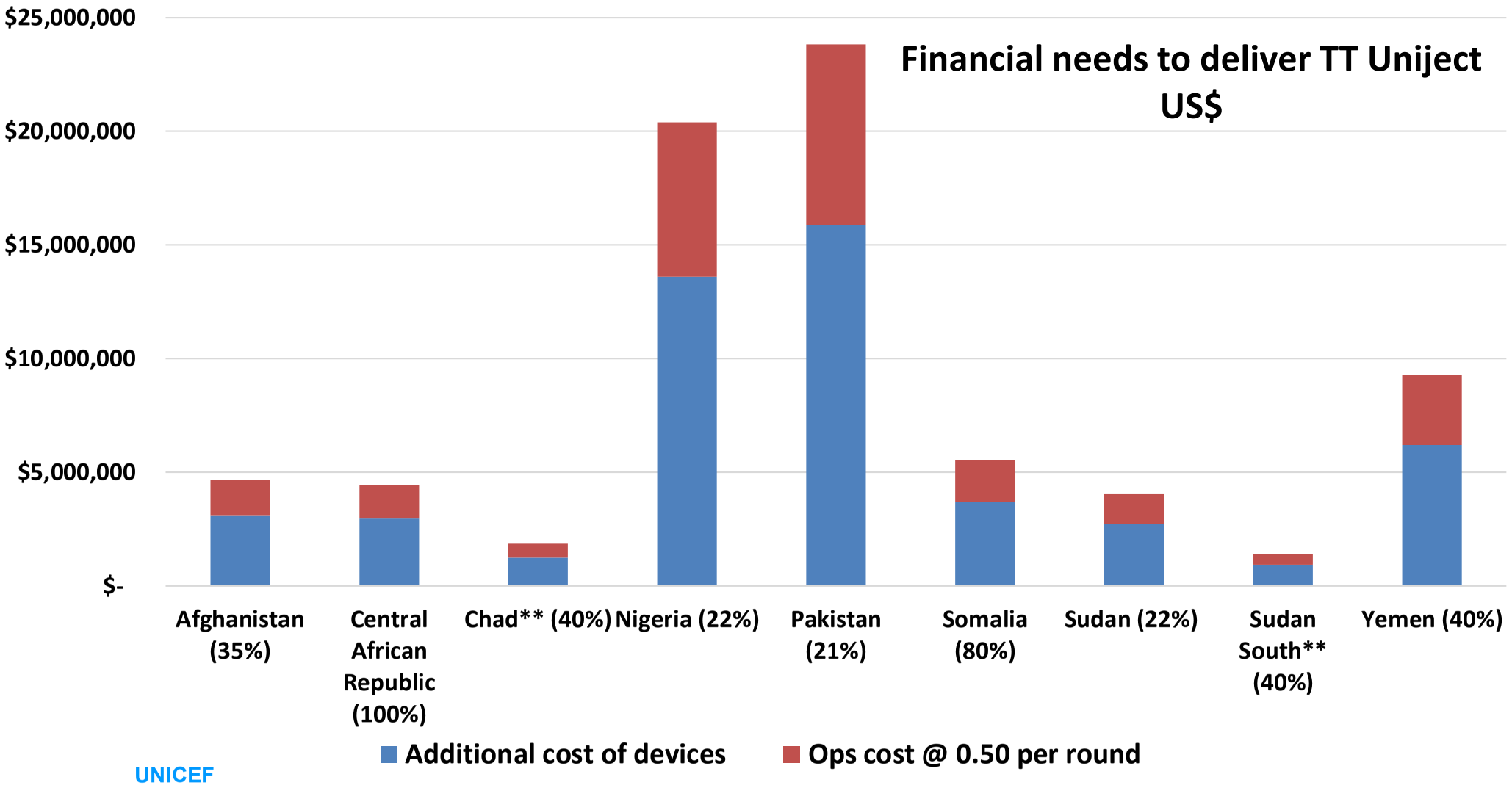
	Year of RD1	CBAW targeted	TT2+ coverage in SIAs with TT Uniject*
Afghanistan *(8 districts + Kabul city)*	2003	567,960	83.5%
Afghanistan	2004	650,000	TBD
Burkina Faso *(2 districts)*	2003	84,123	94.6% (RD1 only)
Ghana *(2 districts)*	2003	42,722	62.3%
Mali *(2 districts)*	2002	132,847	100.4%
Mali *(6 districts)*	2004	238,638	83.9%
Somalia *(15 districts)*	2004	50,521	78.8% (RD1 only)
Southern Sudan	2003	75,000	TBD
Southern Sudan	2004	175,000	TBD

Source: UNICEF/WHO MNT collected data
Data as of 30 April 2004

Annual Uniject forecast 2017-2020



An additional US$50 million will enable access to target 18 million WRA with 3 doses.



UNICEF

*** Chad and South Sudan may need it for one corrective round.*

Availability in global market

- At present, not readily available
- Only one WHO pre-qualified manufacturer – Biofarma
- TT Uniject is a registered product in many countries
  - 9 million doses used in 9 countries between 2002 & 2004
- The manufacturer has a valid registration of this product
- Current annual production capacity is close to 6 million in various batches.
- Due to prior commitments for HBV, the TT Uniject preparation will be earliest available in 2017.

UNICEF

Current Status - Biofarma

- 2nd Uniject filling plant is operational now
- Annual **production capacity** of Uniject doubled
- Currently 50% of production capacity earmarked for **HBV Uniject (birth dose)** – the *commitment with the Government of Indonesia (6 million units annualy)*
- Approximate **5-6 million TT Uniject** units can be made available per year
- **Production lag time is 4-6 months** – *that means for availability of first batch of Uniject in January 2017, the order need to be placed with guaranteed funds not later than August 2016.*

Current Status – Biofarma 2

- Cost per unit with VVM varies from $0.80 to $1.0
  - This includes cost of device ~ $0.23 (BD)
  - This is ex-factory price and covers transportation to Jakarta airport only.
  - Further transportation/shipment cost shall be borne by the consumer.

- The high cost is due to excessive wastage primarily from leakage and sealing
  - Estimated wastage rate vary from 5-10%

- **Td Uniject** is not a registered product.
  - Registration and pre-qualification is a lengthy process that need average 2-3 years.
  - Countries using Td – will need administrative instruction to use TT for SIAs

What Next!

- Need **endorsement** from SAGE
- **Readiness of countries** to use Uniject – policy and capacity.
- **Secure funding;** present business case to potential donors – *BMGF, Gavi, BD, Kiwanis, P&G, etc*.
- **Liaise with UNICEF SD** to follow-up on pricing and demand.
- Talk to **BD for possible donation** – extent and duration.

THANKS

BACKUP SLIDES

An additional $50 million will enable tetanus protection to the one missed repteadly.

Financial Needs for TT Uniject for MNTE Programme (July 2016)

No.	Country	Additional cost for Uniject		
		TOTAL Addl COST UNIJECT DEVICES	Ops Cost @ 0.50 per WRA per round	TOTAL
a	b	G=e+f	h	i
1	Afghanistan (35%)	$ 3,110,391	$ 1,554,315	$ 4,664,706
2	Central African Republic (100%)	$ 2,962,990	$ 1,480,656	$ 4,443,646
3	Chad** (40%)	$ 1,235,670	$ 617,485	$ 1,853,155
4	Nigeria (22%)	$ 13,599,351	$ 6,795,825	$ 20,395,176
5	Pakistan (21%)	$ 15,881,284	$ 7,936,145	$ 23,817,429
6	Somalia (80%)	$ 3,697,170	$ 1,847,538	$ 5,544,708
7	Sudan (22%)	$ 2,712,007	$ 1,355,236	$ 4,067,242
8	Sudan South** (40%)	$ 934,768	$ 467,120	$ 1,401,888
9	Yemen (40%)	$ 6,193,382	$ 3,094,937	$ 9,288,319
		$ 50,327,013	$ 25,149,257	$ 75,476,269

** Adjusted after subtracting cost of TT vaccine and devices (ADS + Safety Box)*

*** Chad and South Sudan may need it for one corrective round.*

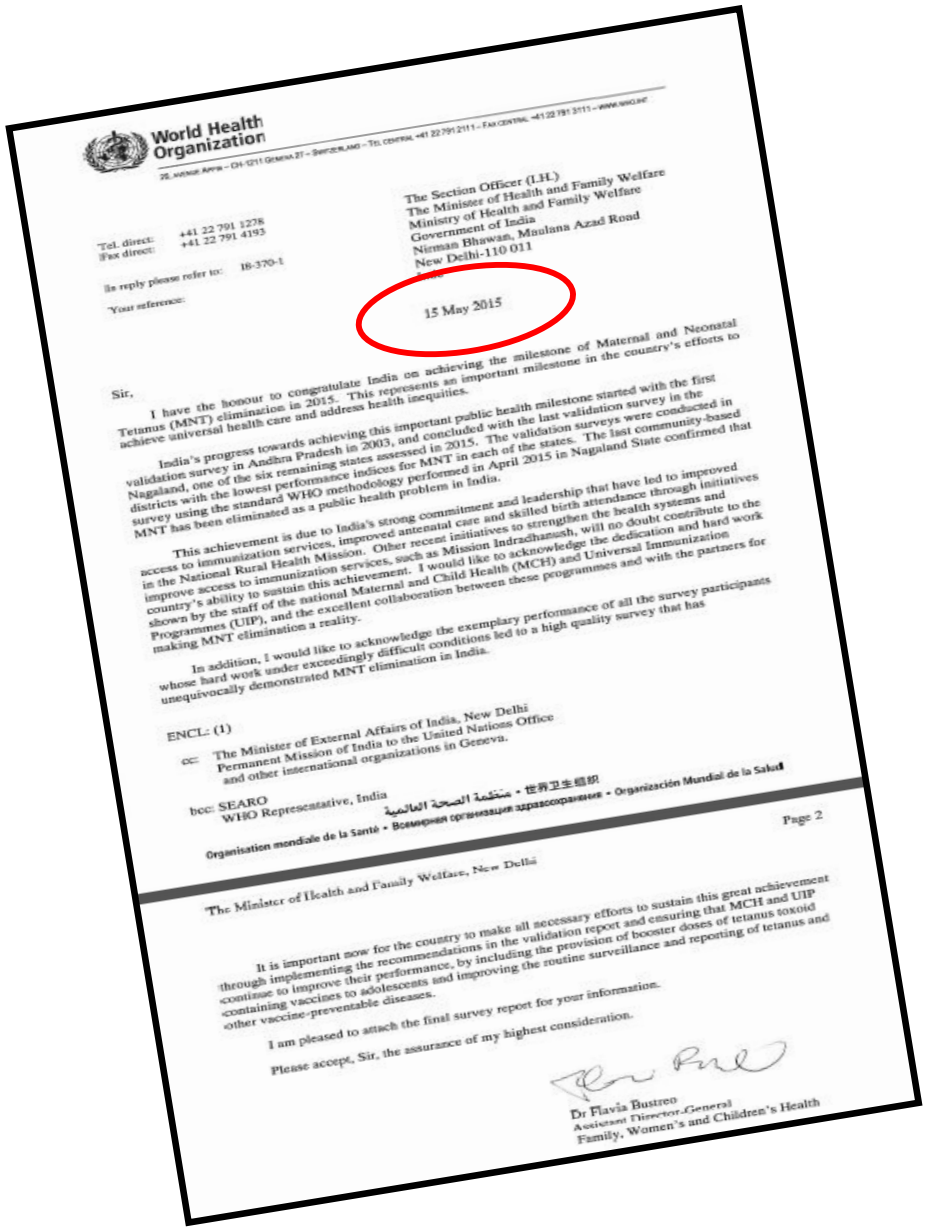
India: Achieving MNT Elimination- Health Systems Approach

Dr. Rakesh Kumar
Joint Secretary (RCH)
Govt. of India

सत्यमेव जयते

NATIONAL HEALTH MISSION

Elimination of MNT in 2015
Major Milestone achieved



World Health Organization

Tel. direct: +41 22 791 1278
Fax direct: +41 22 791 4193

In reply please refer to: IB-370-1

Your reference:

The Section Officer (LH)
The Minister of Health and Family Welfare
Ministry of Health and Family Welfare
Government of India
Nirman Bhawan, Maulana Azad Road
New Delhi-110 011

15 May 2015

Sir,

I have the honour to congratulate India on achieving the milestone of Maternal and Neonatal Tetanus (MNT) elimination in 2015. This represents an important milestone in the country's efforts to achieve universal health care and address health inequities.

India's progress towards achieving this important public health milestone started with the first validation survey in Andhra Pradesh in 2003, and concluded with the last validation survey in the Nagaland, one of the six remaining states assessed in 2015. The validation surveys were conducted in districts with the lowest performance indices for MNT in each of the states. The last community-based survey using the standard WHO methodology performed in April 2015 in Nagaland State confirmed that MNT has been eliminated as a public health problem in India.

This achievement is due to India's strong commitment and leadership that have led to improved access to immunization services, improved antenatal care and skilled birth attendance through initiatives in the National Rural Health Mission. Other recent initiatives to strengthen the health systems and improve access to immunization services, such as Mission Indradhanush, will no doubt contribute to the country's ability to sustain this achievement. I would like to acknowledge the dedication and hard work shown by the staff of the national Maternal and Child Health (MCH) and Universal Immunization Programmes (UIP), and the excellent collaboration between these programmes and with the partners for making MNT elimination a reality.

In addition, I would like to acknowledge the exemplary performance of all the survey participants whose hard work under exceedingly difficult conditions led to a high quality survey that has unequivocally demonstrated MNT elimination in India.

ENCL: (1)

cc: The Minister of External Affairs of India, New Delhi
Permanent Mission of India to the United Nations Office
and other international organizations in Geneva.

bcc: SEARO
WHO Representative, India

Organisation mondiale de la Santé • Всемирная организация здравоохранения • 世界卫生组织 • منظمة الصحة العالمية • Organización Mundial de la Salud

Page 2

The Minister of Health and Family Welfare, New Delhi

It is important now for the country to make all necessary efforts to sustain this great achievement through implementing the recommendations in the validation report and ensuring that MCH and UIP continue to improve their performance, by including the provision of booster doses of tetanus toxoid containing vaccines to adolescents and improving the routine surveillance and reporting of tetanus and other vaccine-preventable diseases.

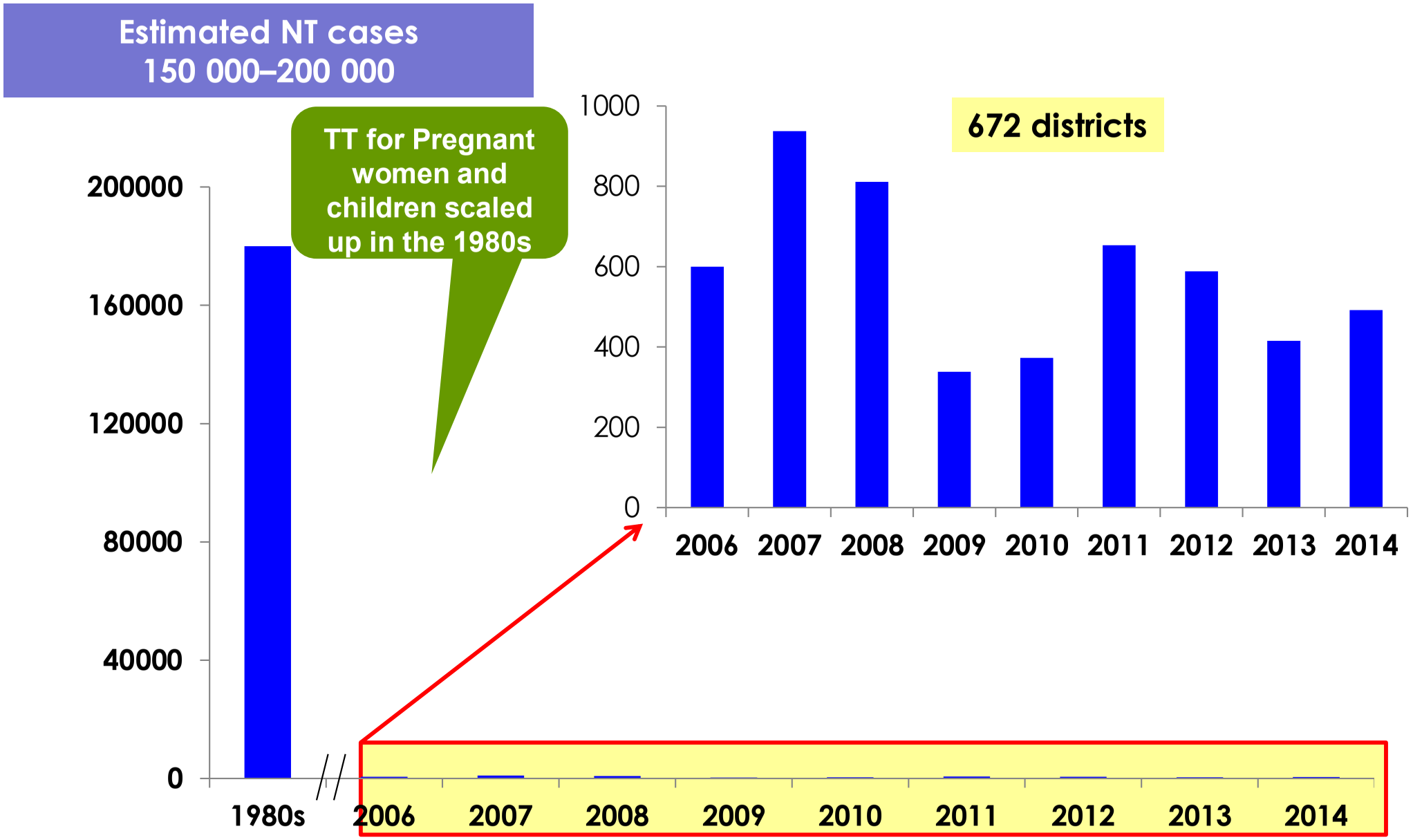
I am pleased to attach the final survey report for your information.

Please accept, Sir, the assurance of my highest consideration.

Dr Flavia Bustreo
Assistant Director-General
Family, Women's and Children's Health

15 May 2015:
"WHO congratulates India on achieving the milestone of MNTE"

Estimated neonatal tetanus cases, India



Data source: JRF data from 2006 onwards

How was this milestone achieved?

Neonatal Tetanus (NT) control and elimination strategies

1. **Systematic vaccination of pregnant women attending antenatal care (ANC) with tetanus toxoid (TT) containing vaccine**

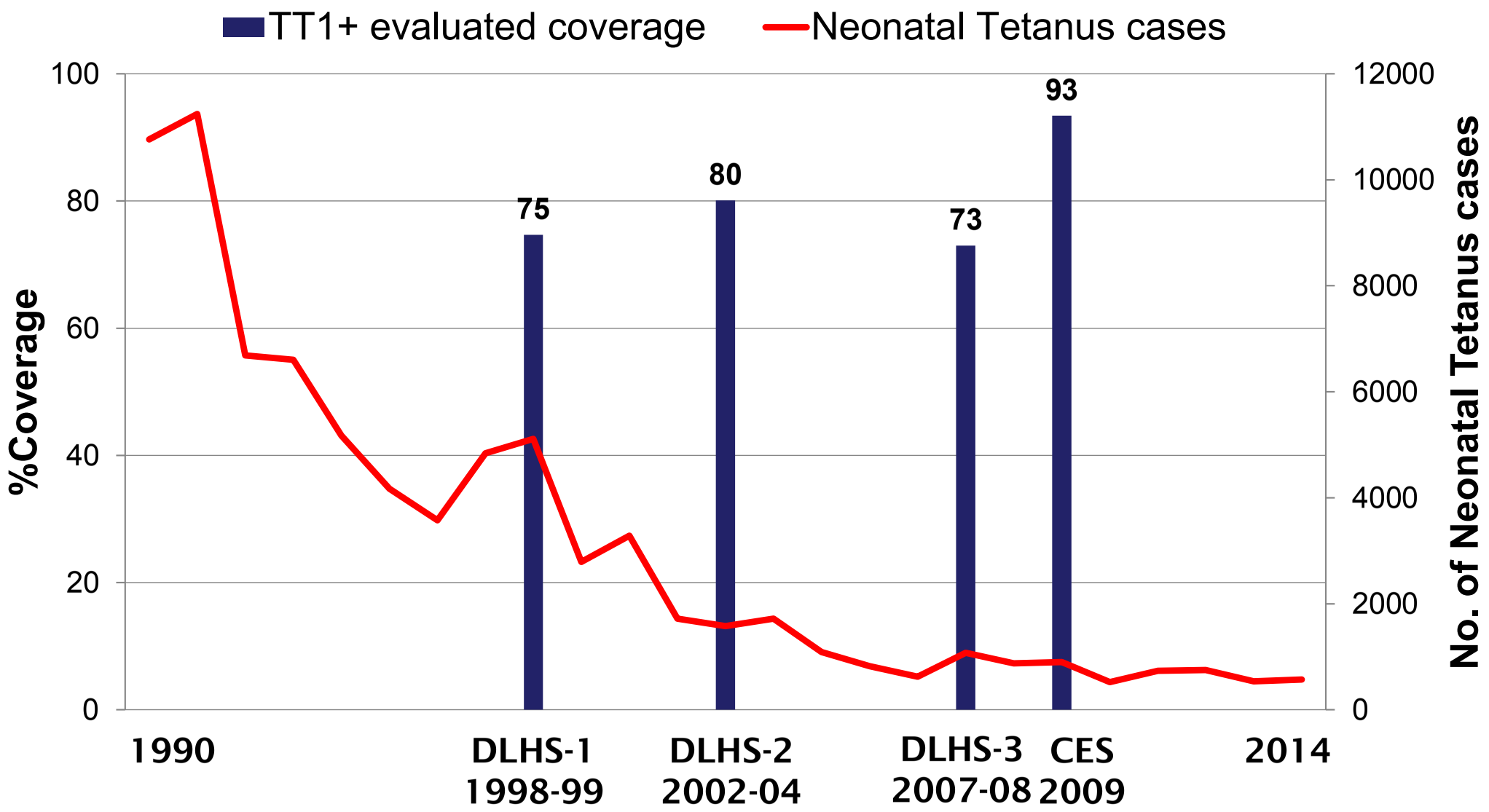
2. **Demand creation through conditional cash transfers (JSY) and Supply side strengthening (JSSK); and promotion of skilled birth attendance/ SBA (institutions births & home births attended by trained medical personnel) under the National Health Mission (NHM)**

3. **Intensive behaviour change communication targeting communities to reduce harmful cord care practices.**

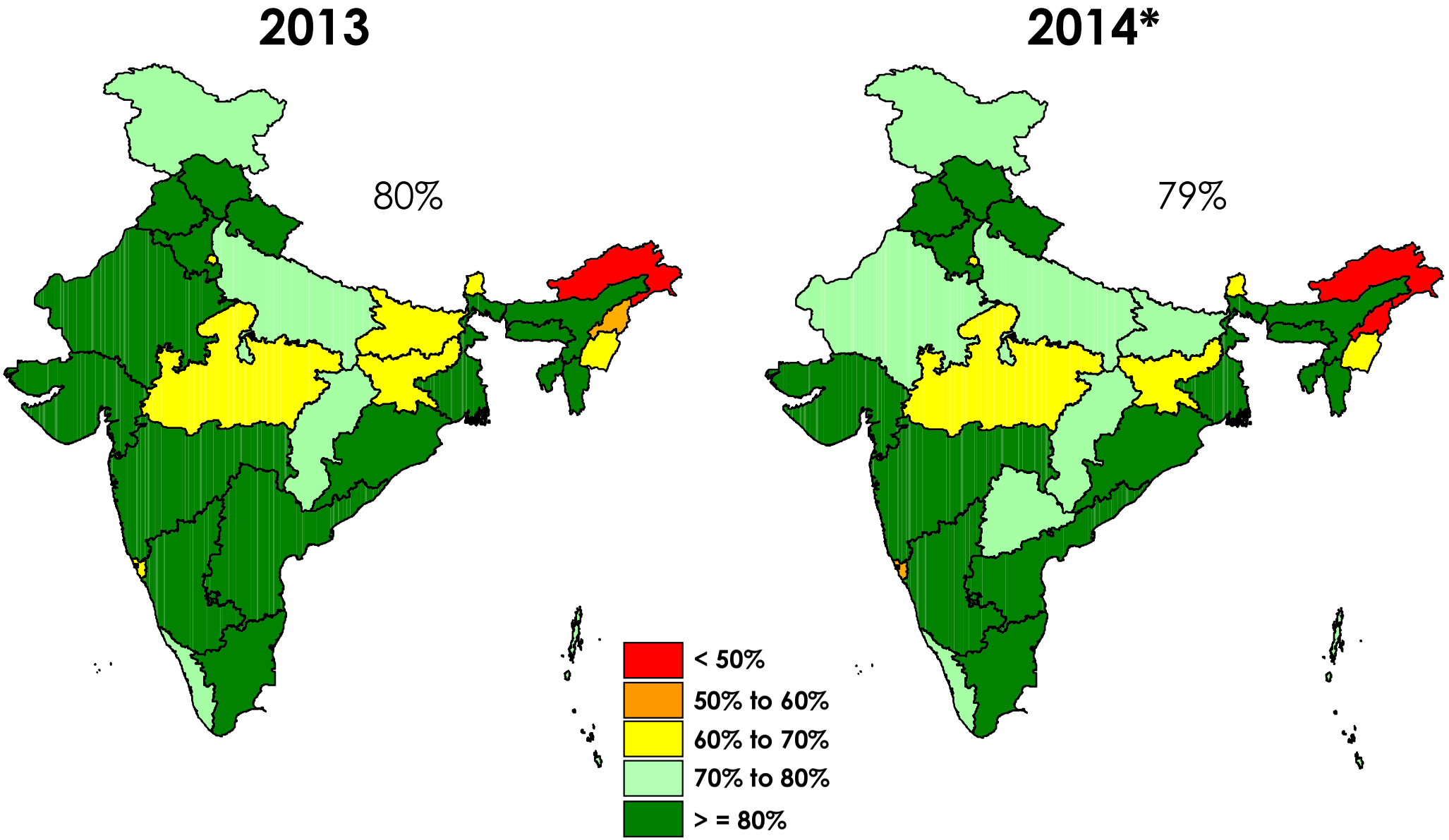
1. Interventions undertaken to improve TT coverage in pregnant women and children

- Two doses of TT, 4 weeks apart, offered to all pregnant women,
  - If next pregnancy is within 3 years, 1 booster TT dose is provided
- Introduction of TTCV during infancy and childhood
  - Three doses of DPT at 6, 10 and 14 weeks
  - Two booster doses of DPT/DT at 16–24 months and 5–6 years
  - TT dose at 10 years and 16 years
- TT SIAs targeting areas at risk in weak performing states of MP, Rajasthan, UP, West Bengal
- Strengthening of immunization services through inclusion of **400,000 high risk areas** identified through polio in **Special Immunization Weeks** (SIWs)

Introduction of TT vaccine under National Immunization Programme since 1983 led to rapid decline in no of NT cases



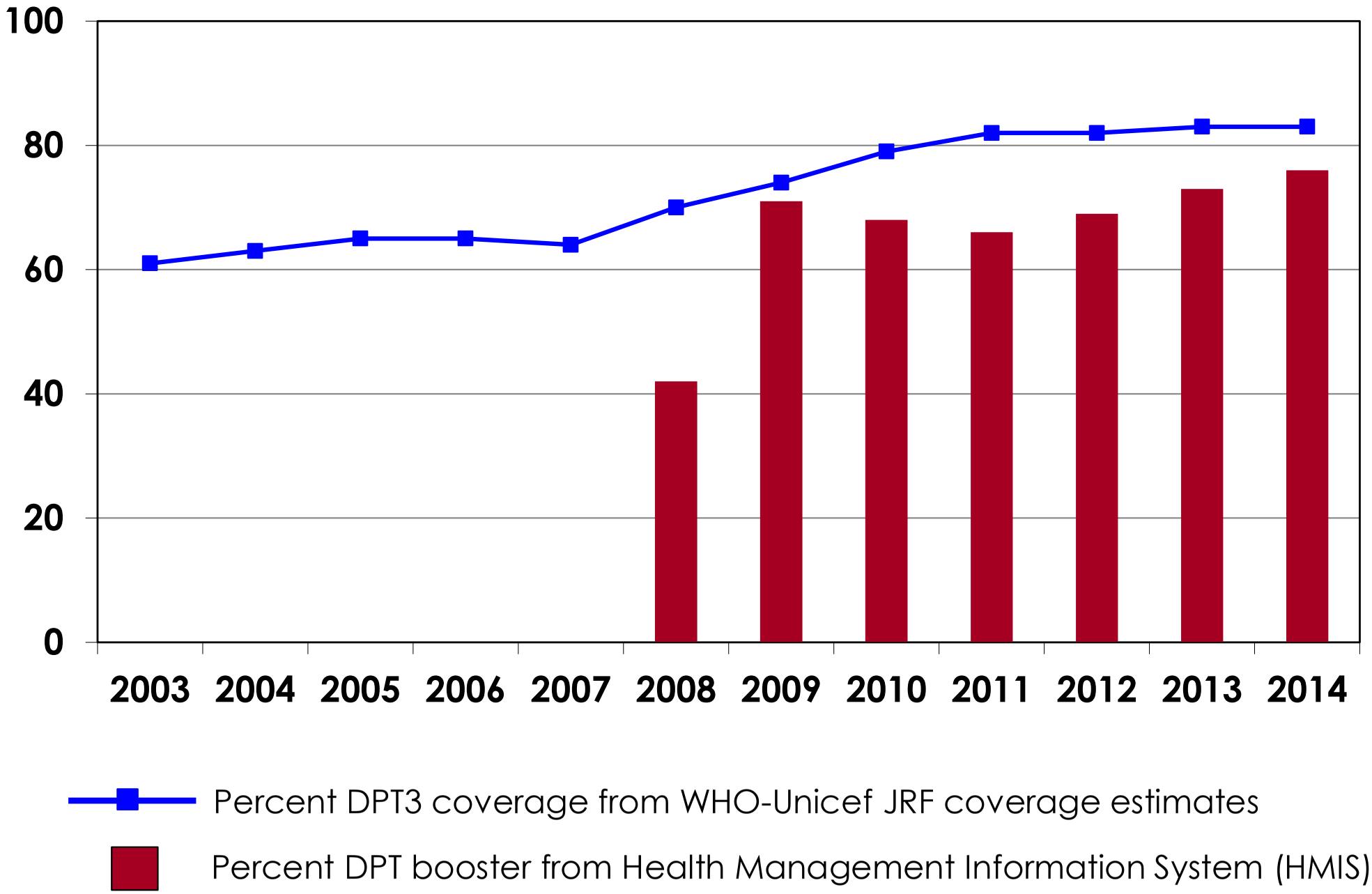
TT2+ injection received during pregnancy



HMIS: Health Management Information System

* Data as on 2 May 2015

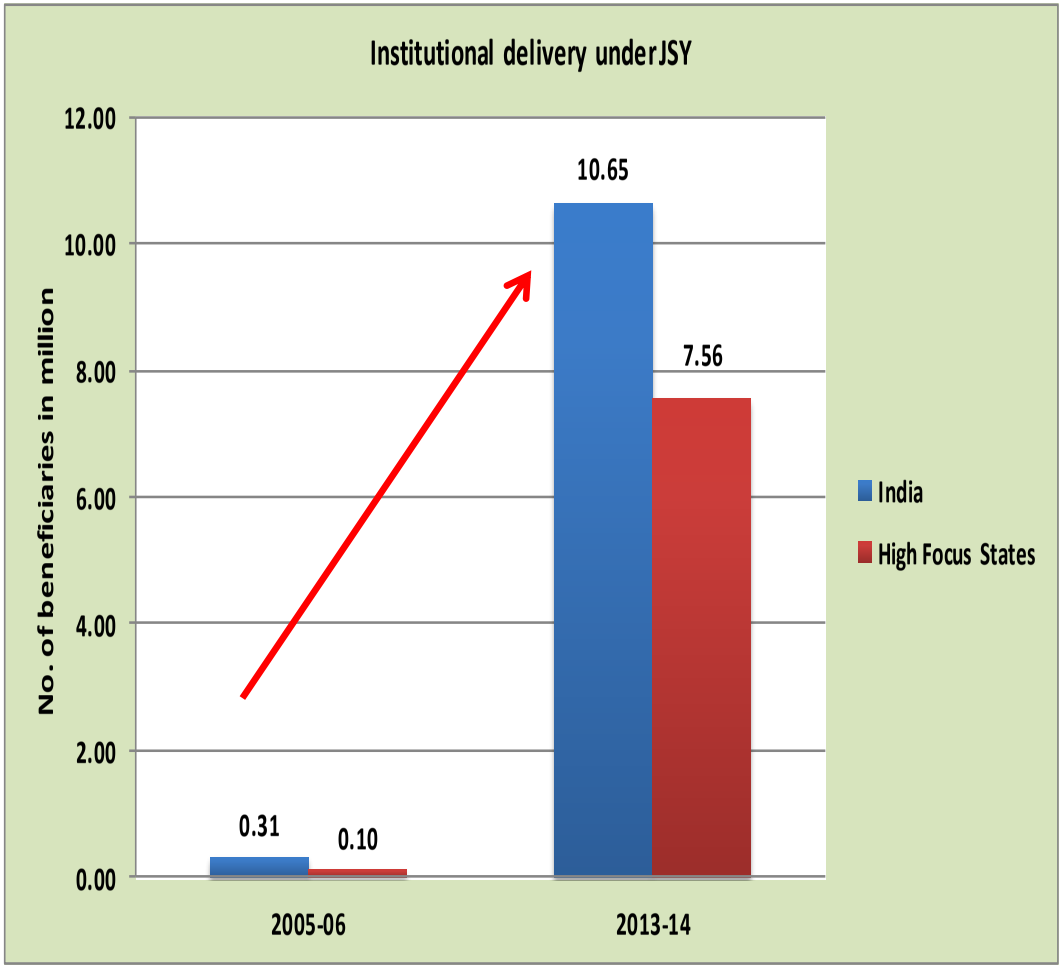
Percent DPT 3 & DPT Booster coverage, India



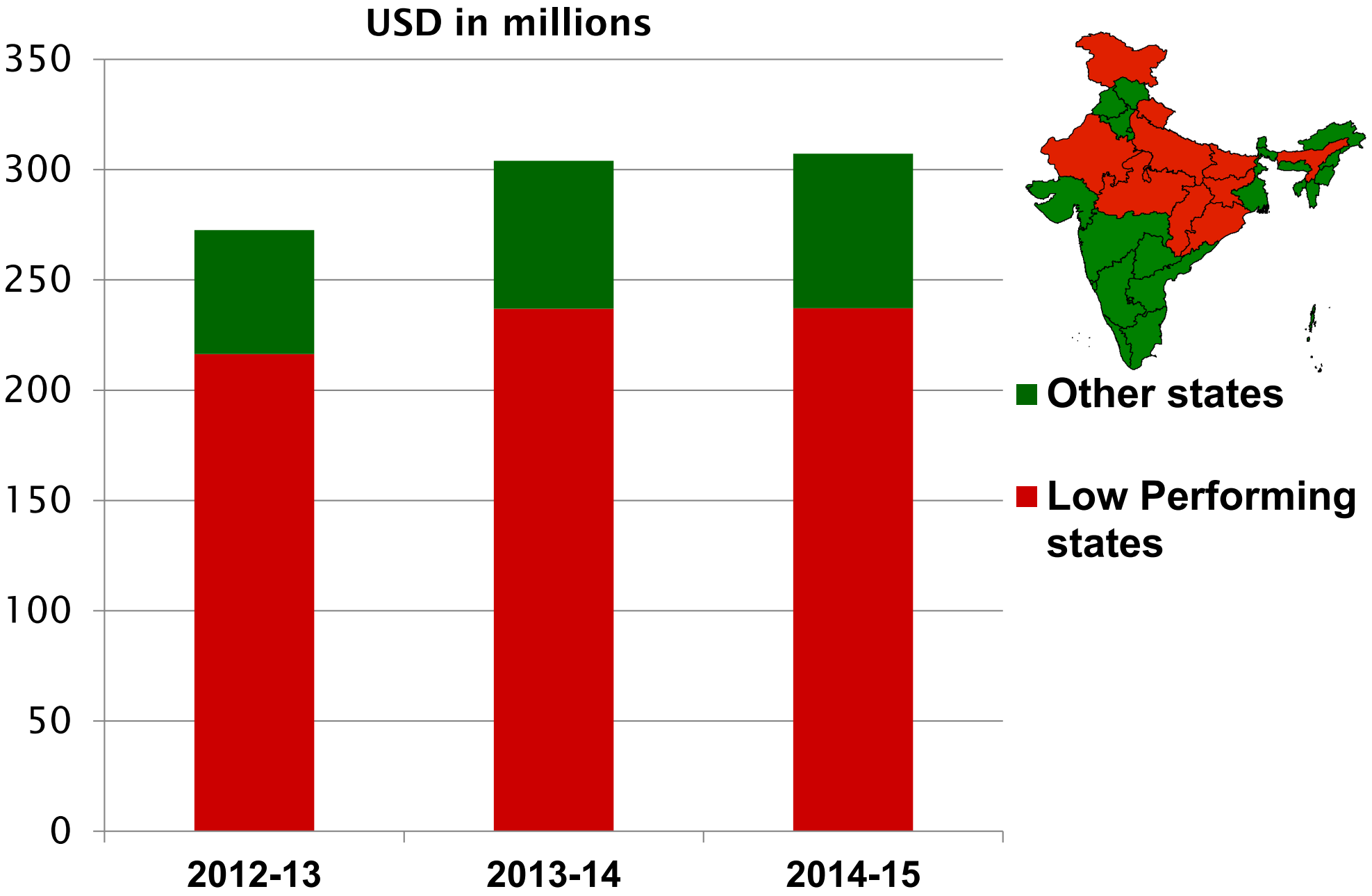
2. Promotion of hygienic birth at home or in health institutions under the NHM

Improving clean deliveries

- Janani Suraksha Yojana (JSY)
  - launched in 2005
  - conditional money transfer scheme to encourage pregnant women to give birth in health facility
- Janani Shishu Suraksha Karyakram (JSSK)-
  - launched in 2011
  - women delivering in health facilities received additional benefits
  - free drugs, consumables, diagnostics, blood, to and fro transport, and diet during stay
  - incentives to Accredited Social Health Activists (ASHA)



JSY Funding by GoI

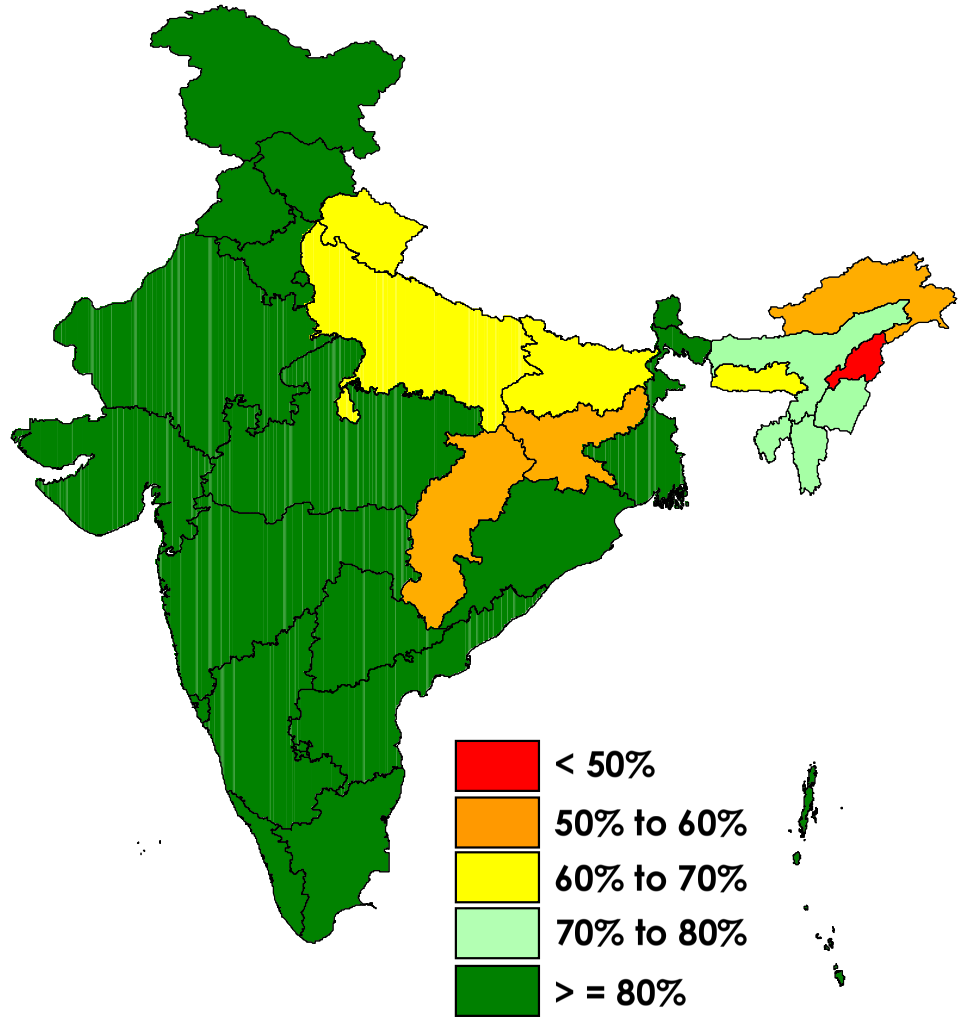


2. Promotion of hygienic birth at home or in health institutions under NHM (contd..)

Other interventions undertaken to improve clean deliveries:

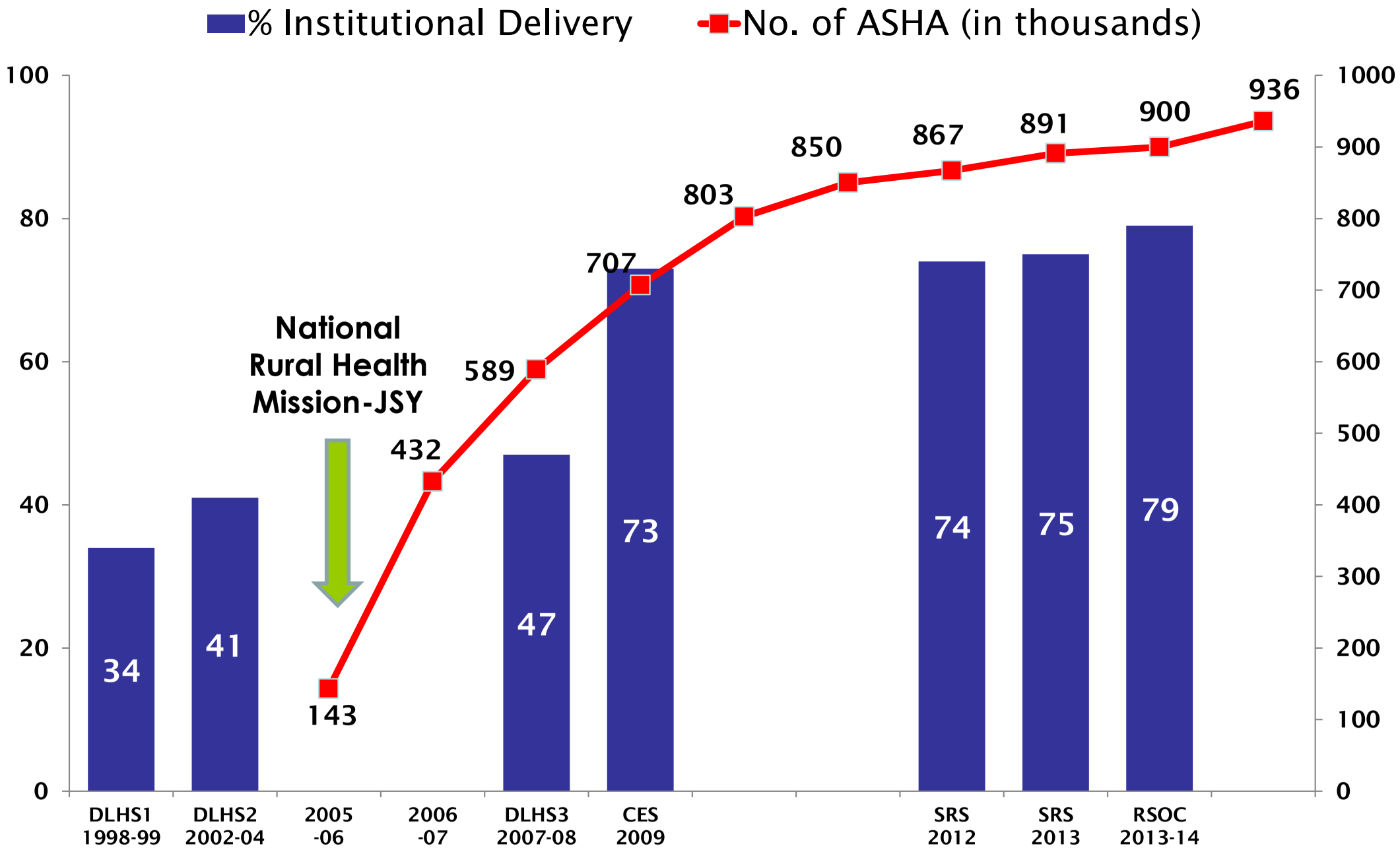
- Nearly **70,000 nursing personnel trained** and deployed
- More than **900,000 ASHAs** (community mobilizers) engaged
- Dial 108 Ambulance System introduced: **More than 20,000 ambulances supported** for timely access to public health facilities
- **Over 40 million Village Health & Nutrition Days (VHNDs) held**, with a range of ante-natal care and immunization services.

Skilled birth attendance as per most recent survey*, India

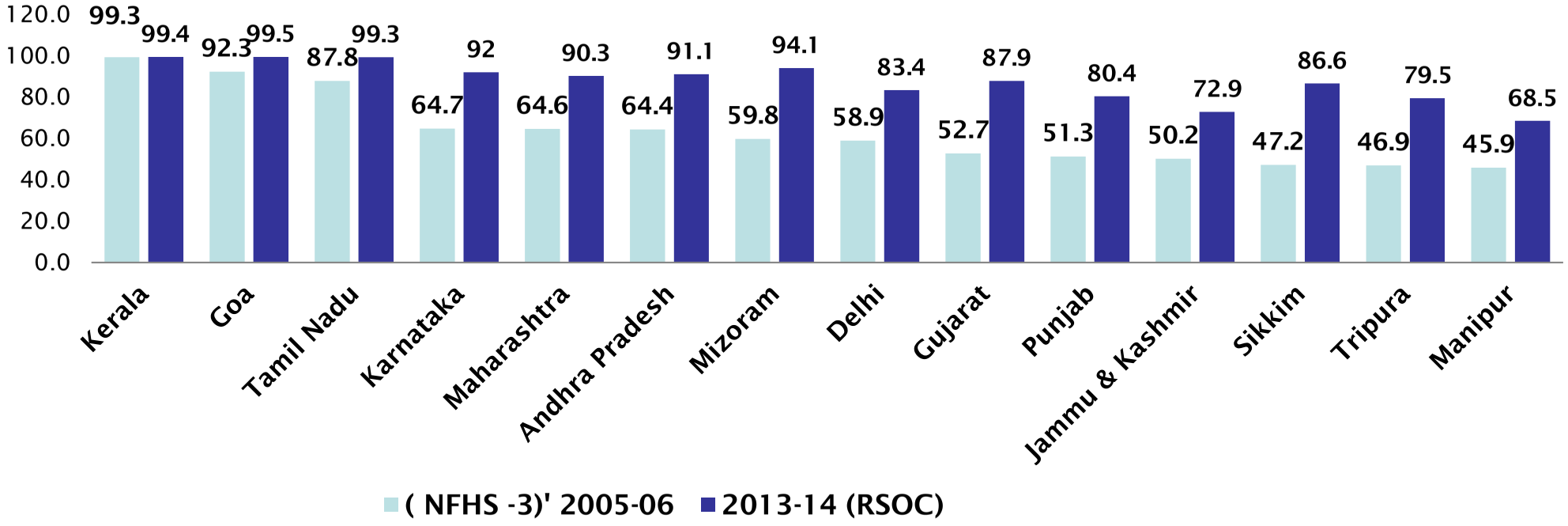


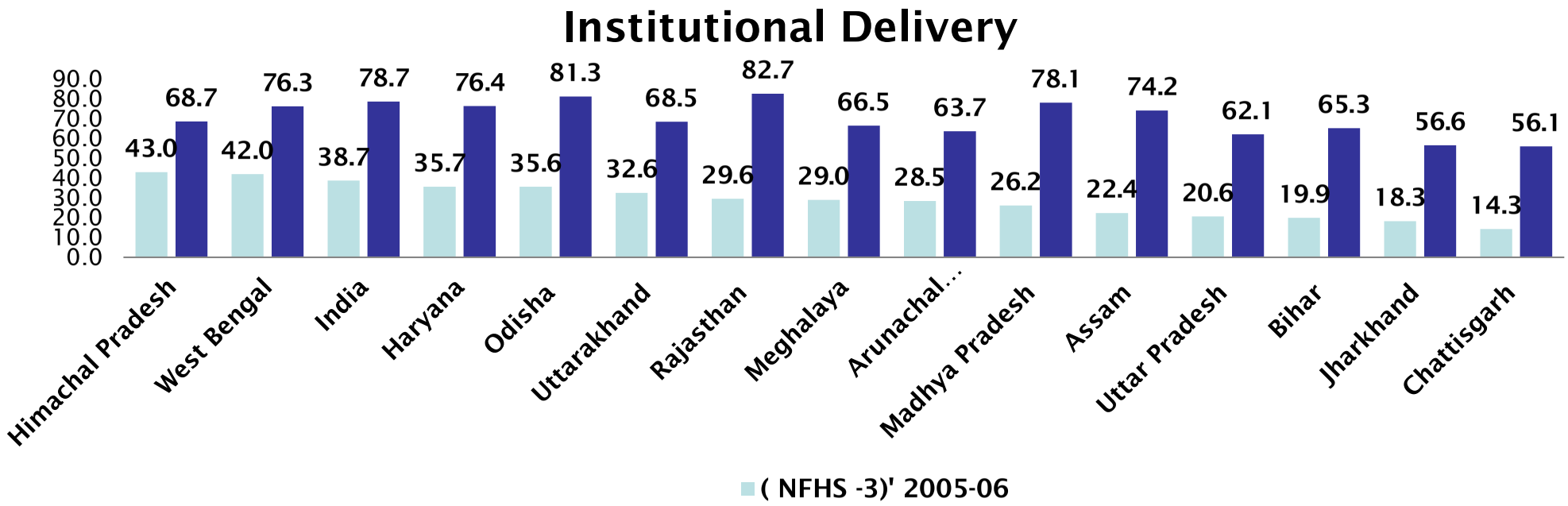
*** AHS : Annual Health Survey (2012-13); DLHS: District Level Household Survey (2012-13)**

ASHAs & Increase in institutional deliveries



Institutional Deliveries

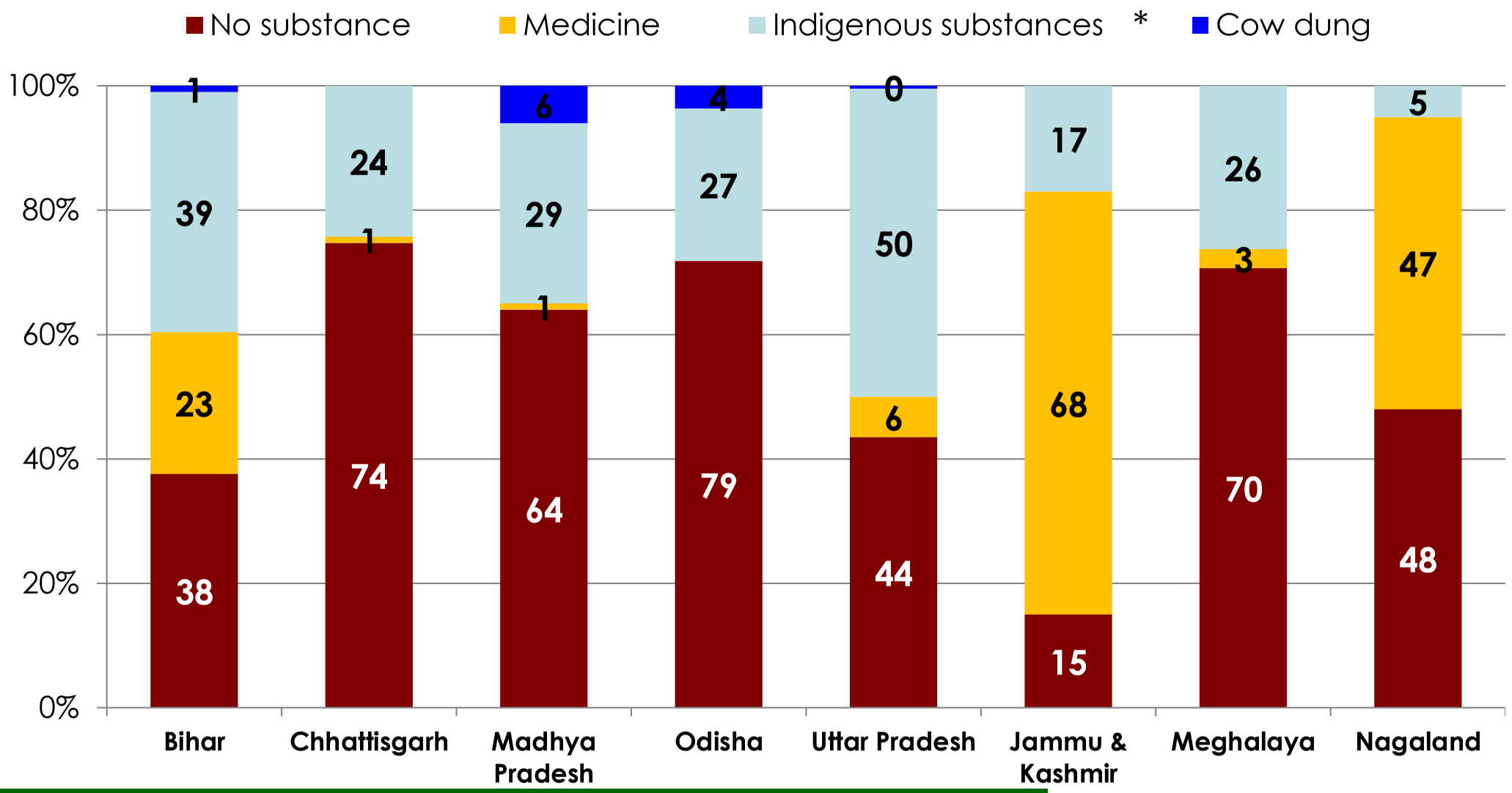




3. Intensive communication targeting communities to reduce harmful cord care practices

- Communication programme to reduce harmful cord care practices through ASHA, Anganwadi and female health workers
- ***Promotion of 5 "cleans" – hands, delivery surfaces, instruments for cutting cord, cord tie and caring of cord***

Cord care practices - application of substances on umbilical stump



Reduction of harmful practices like cow dung

***Oil and clarified butter used for baby massage are the most common indigenous substances**

Data source: MNTE validation surveys 2014 & 2015

Improving Maternal & Child Health

- **RMNCH+A strategy under NHM:** 5X5 Matrix to focus on 184 high priority districts to address equity issue

5 X 5 Matrix for High Impact RMNCH+A Interventions

List of Minimum Essential Commodities

Reproductive Health

- FP commodities: Tubal Rings, IUCD 380-A, IUCD 375
- Oral Contraceptive Pills (OCPs) / (Mala-N), Condoms
- Emergency Contraceptive Pills (ECP) -(Levonorgestrel 1.5mg)
- Pregnancy Testing Kits (PTKs) - Nischay
- Tablet Mifepristone & Tab Misoprostol (Only at facilities conducting Safe Abortion Services)

Maternal Health

- Injection Oxytocin
- Tablet Misoprostol
- Inj. Magnesium Sulphate
- Inj. TT
- Tab. Methyldopa
- Tab. & Inj. Labetalol

Newborn Health

- Injection Vitamin K (1mg/ ml)
- Vaccines - BCG, Oral Polio (OPV), Hepatitis B
- Mucous extractor

Child Health

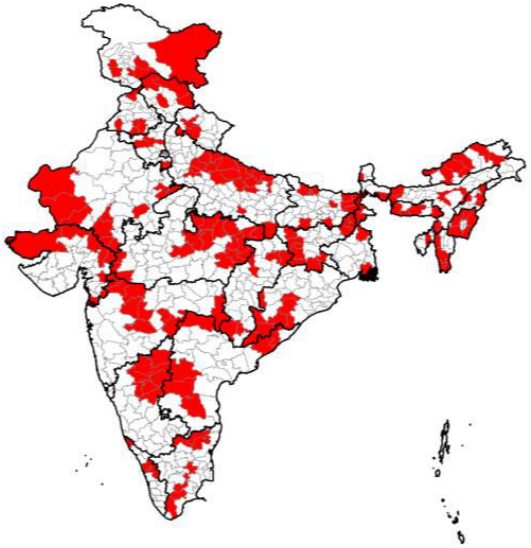
- Oral Rehydration Salt (ORS)
- Zinc Sulphate Dispersible Tablets (10 mg & 20 mg)
- Syrup Salbutamol & Salbutamol nebulising solution
- Vaccines - DPT, Measles, BCG, Hepatitis B, OPV, TT, JE (selected districts), Pentavalent vaccine (selected states)
- Syrup Vitamin A
- Syrup Albendazole

Adolescent Health

- Tablet Albendazole
- Tablet Dicyclomine
- RTI/ STI Kits

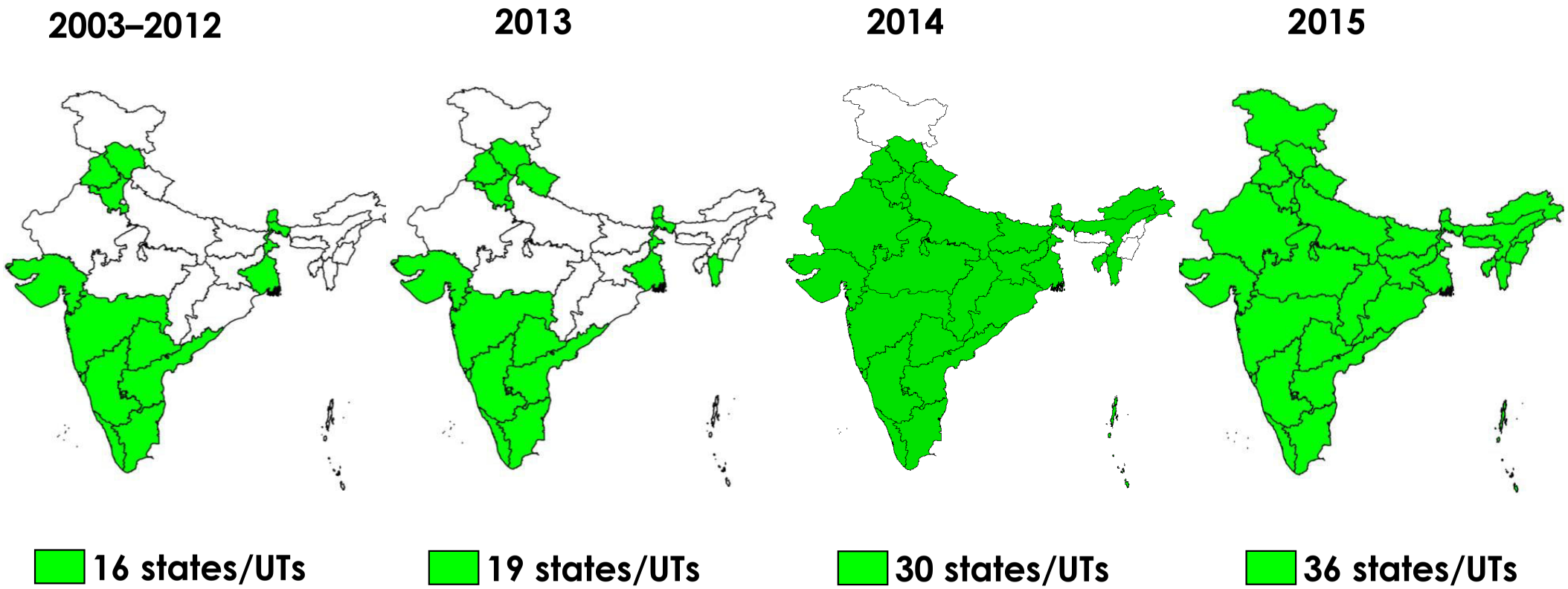
Cross cutting Commodities as per level of facility

- Iron & Folic Acid (IFA) Tablet, IFA small tablet, IFA syrup ĉ Dispenser, Folic Acid (400 µg)
- Antibiotics: Ampicillin, Metronidazole, Amoxicillin, Trimethoprim & Sulphamethoxazole, Inj. Gentamicin, Inj. Ceftriaxone (Syr. / Cap. / Tab. / Inj. as applicable)
- Miscellaneous: Paracetamol, Chloroquin and Inj. Dexamethasone (Syr. / Tab. / Inj. as applicable)
- Clinical /Digital Thermometer, Weighing machine, BP apparatus, Stop watch, Cold box, Vaccine carrier, Oxygen, Bag & Mask & MUAC (Mid Upper Arm Circumference) Tape
- Testing equipments for Haemoglobin, Urine and Blood Sugar, Hub cutter, Colour coded bins



High Priority districts

MNTE validation progress in India



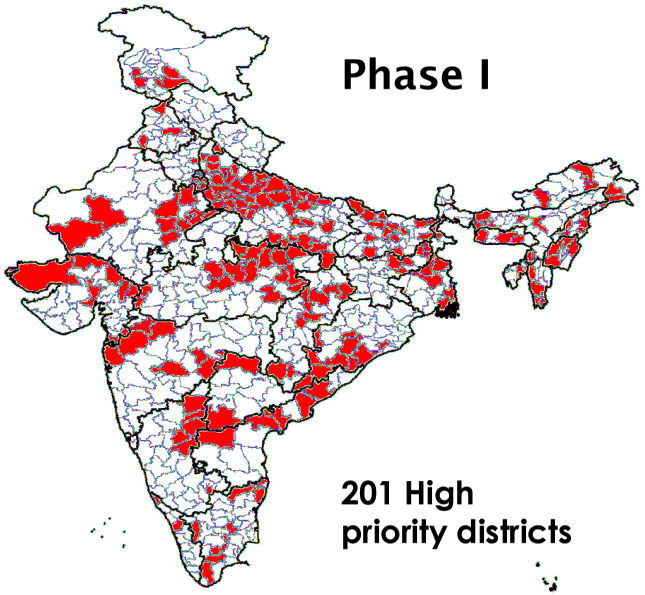
Validation through:

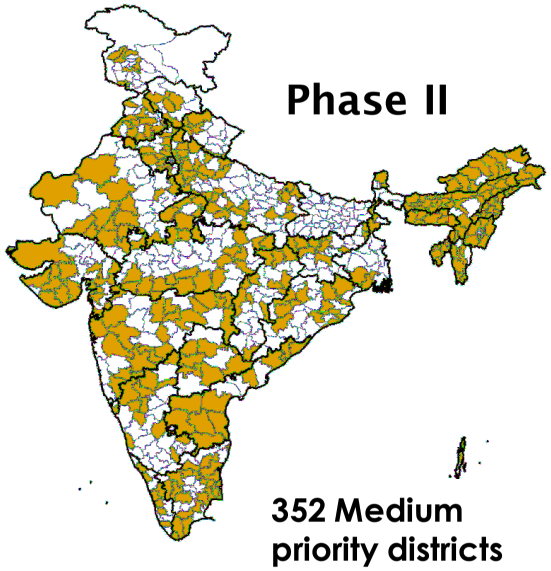
- LQAS in 25 large states, in high risk districts
- 30 x 7 cluster surveys in 4 medium sized states with hilly terrain
- Desk review of data in 7 small states, where quality data was available

Best practices for high quality validation

- **Application of lessons learnt from polio eradication**
  - Use of polio **microplans** to develop MNTE validation survey microplans
  - Intensive **training** of surveyors and supervisors
  - Daily evening **debriefings** at planning unit for corrective actions
  - Intensive supervision and monitoring with use of **real time data**
  - **Accountability** through district task forces for immunization
- **Pre-validation visits** including 30x7 cluster surveys in Uttar Pradesh and Bihar used to assess feasibility of validation
- Effective **partners**'x **support**: WHO-India-NPSP, WHO HQ and UNICEF & others

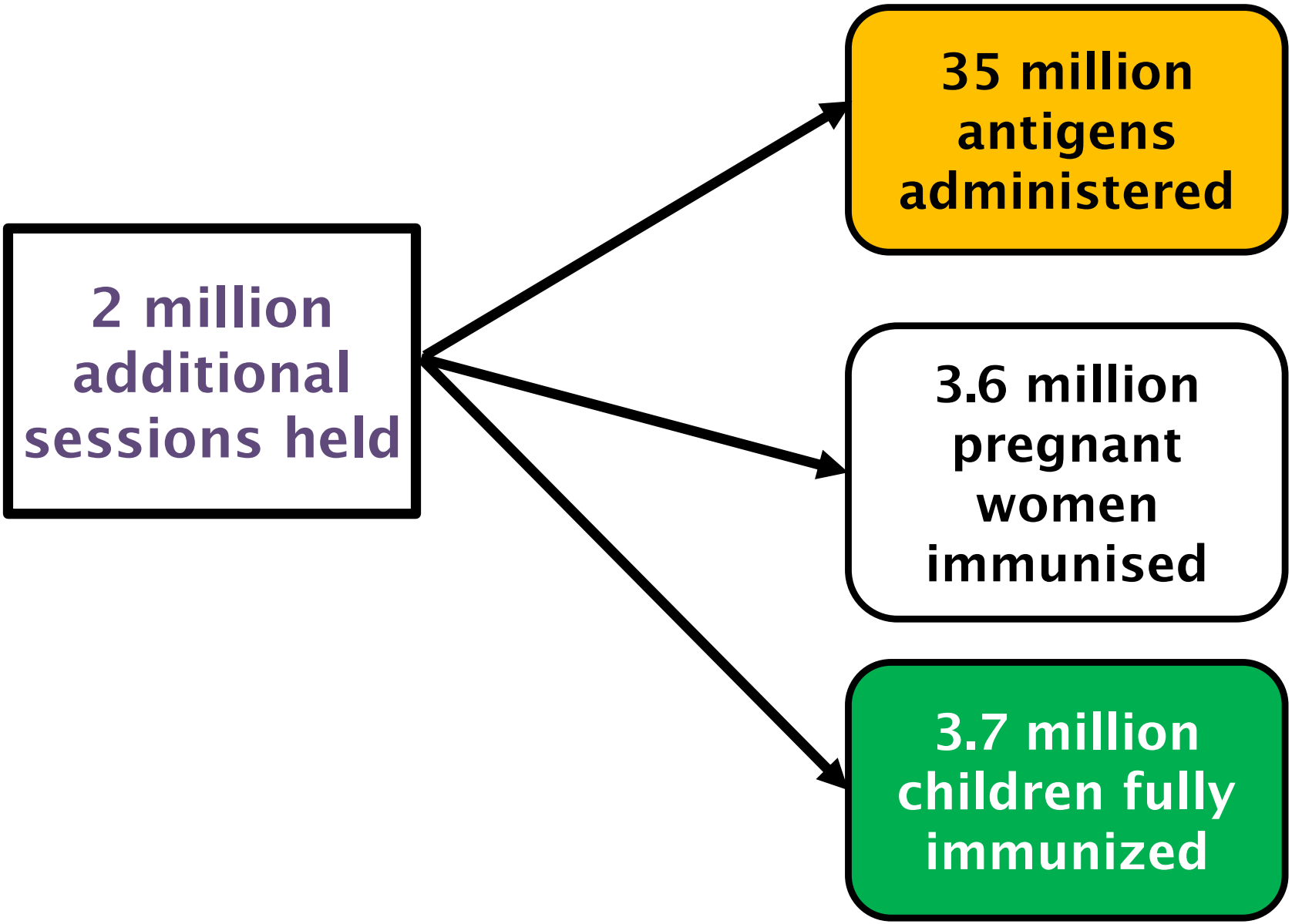
Strengthening RI - Mission Indradhanush





- **201 High priority districts & 352 Medium priority districts** with high left-outs & drop-outs in India
- **Catch up campaign** for low RI areas (vacant health center, migrant population, recent measles/diphtheria outbreaks)
- **7 days** each month for **4 months**
  - Phase 1 (April, May, June, July 2015)
  - Phase 2 (Oct,Nov,Dec2015 & Jan 2016)
- **Intensive** planning, training, monitoring, communication using polio network
- Active engagement of polio partners (WHO, UNICEF, Rotary)

Mission Indradhanush-Key Achievements



Laboratory backed VPD surveillance launched

- **Laboratory supported** diagnosis of Diphtheria & Pertussis
- Using polio surveillance as a **platform**
- Surveillance **launched** in Haryana and Kerala with support from WHO-India
- Plan to **expand** VPD surveillance to other states (Bihar & Rajasthan) in 2015

Lessons learnt ..1

- **Sharp reduction in MNT cases due to targeted interventions under Universal Immunization Programme**
  - Provision of TTCV during Ante natal care period
  - High coverage with TTCV sustained
  - High risk approach adopted for rapidly increasing protection at birth through targeted TT SIAs in weak performing states & districts

- **Systems strengthening measures leading to elimination of MNTE with positive MCH benefits and reduction in maternal & neonatal mortality**
  - Launch of National Health Mission in 2005
  - Rise in institutional births and skilled birth attendance
  - Innovate schemes such as Janani Suraksha Yojna & Janani Shishu Suraksha Karyakram
  - Engagement of ASHA and BCC initiatives have led to reduction in harmful cord practices

Lessons learnt ..2

- **Polio infrastructure and learnings leveraged to improve routine immunization**
  - Mission Indradhanush launched - Risk analysis and high risk approach
  - Emphasis on microplanning, capacity building and intensive monitoring
  - Engaging accountability mechanisms – task forces

- **Effective partners' support: WHO-NPSP, WHO HQ and UNICEF & others**

- **Polio learning on microplanning, training, supervision and data analysis utilized to conduct high quality MNT validation surveys**

Lessons learnt ..3

- **High TT coverage, institutional births, hygienic cord care practices with increasing TT coverage through life cycle approach will sustain MNT elimination**

- **Strengthening of VPD surveillance to detect cases of neonatal tetanus will further strengthen routine immunization**

India will continue to strive to ensure that our mothers & newborns remain Tetanus-free

Thank you

Critical operational challenges to achieving at least 80% Protection at Birth from MNT in high risk districts

SAGE WG on MNTE

Dr Jane Soepardi

Timeline of activities to Maternal and Neonatal Tetanus Elimination in Indonesia

- **1977** EPI started, 3 dose of DPT
- **1979** Introduction of 2 dose of TT for Pregnant women in EPI
- **1984** Introduction of 2 dose DT for school enters and 2 dose of TT for school leavers in EPI
- **1988** Safe motherhood program (village midwives)
- **1998** 5 dose TT schedule implemented, School Immunization Month
- **2000** Making Pregnancy Safer (social safety net)
- **2001** Community based NT Mortality Survey
- **2003** 2 rounds TT SIAs in high risk districts 2003 - 2009
- **2004** Introduction of DTP-HepB into EPI
- **2009** Joint WHO-UNICEF Reviews
- **2010**, **2011** Validation Surveys in phases, MNT eliminated in regions 1,2,3
- **2015**, **2016** UHC (delivery in health facility)
  District review in Papua, Region 4

Strategies to sustain MNT Elimination

EPI

- Increasing routine DTP coverage among infants and TT2+ among pregnant women
- Long term protection against tetanus through:
  - Booster doses:
    - DTP4 at 18 months (since 2013)
    - DT, Td for grade 1, 2 and 3 at elementary school (since 1984)
  - TT/Td vaccination among CBAW (incl. “brides to be” and pregnant women)
- Short term TT SIAs, in high risk districts only, targeting CBAW (15-39 years)

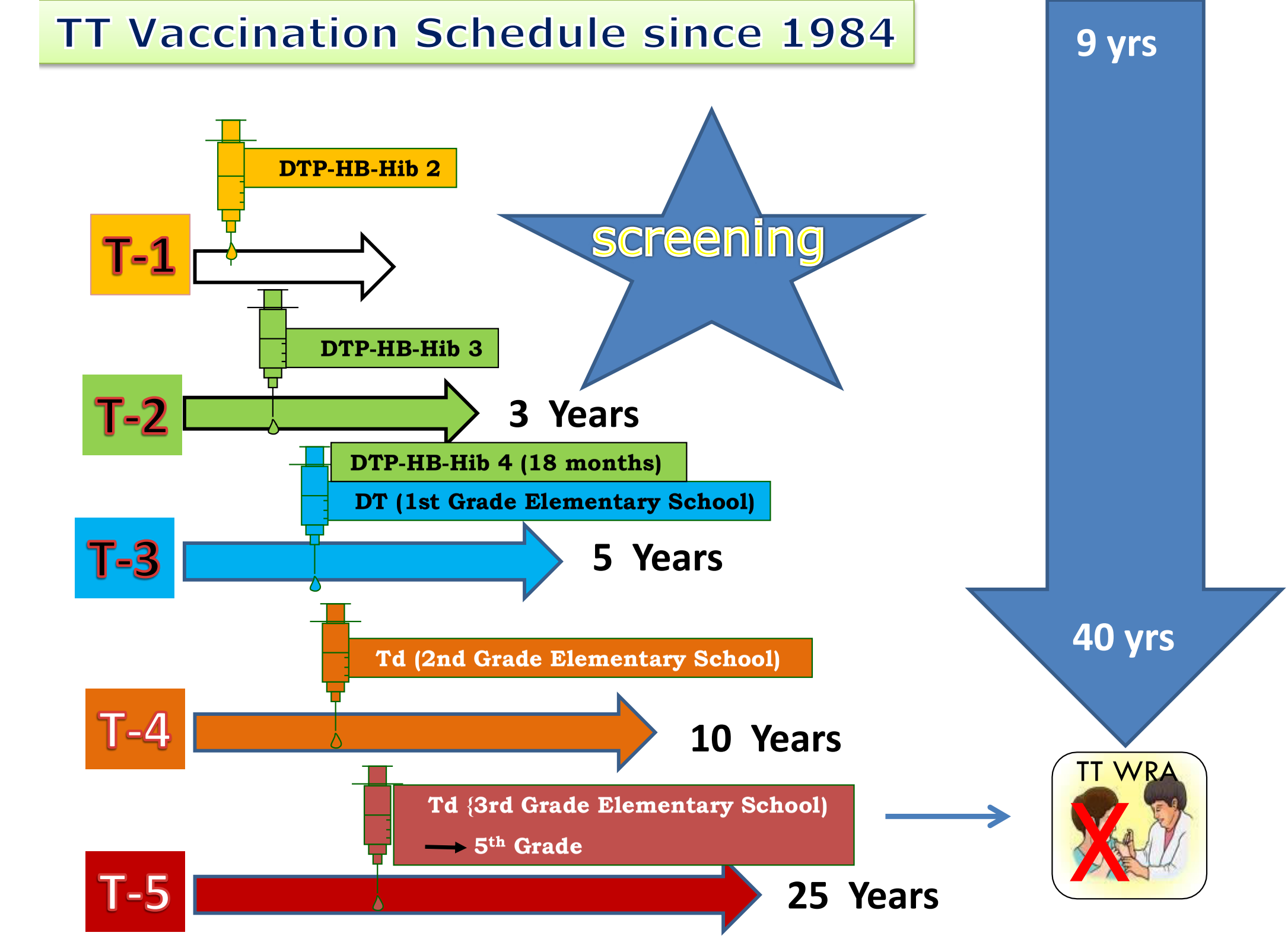
SURV

- Continued NT surveillance as part of VPD surveillance through improving sensitivity on NT cases in all districts incl. remote districts to monitor progress and identify areas at risk.

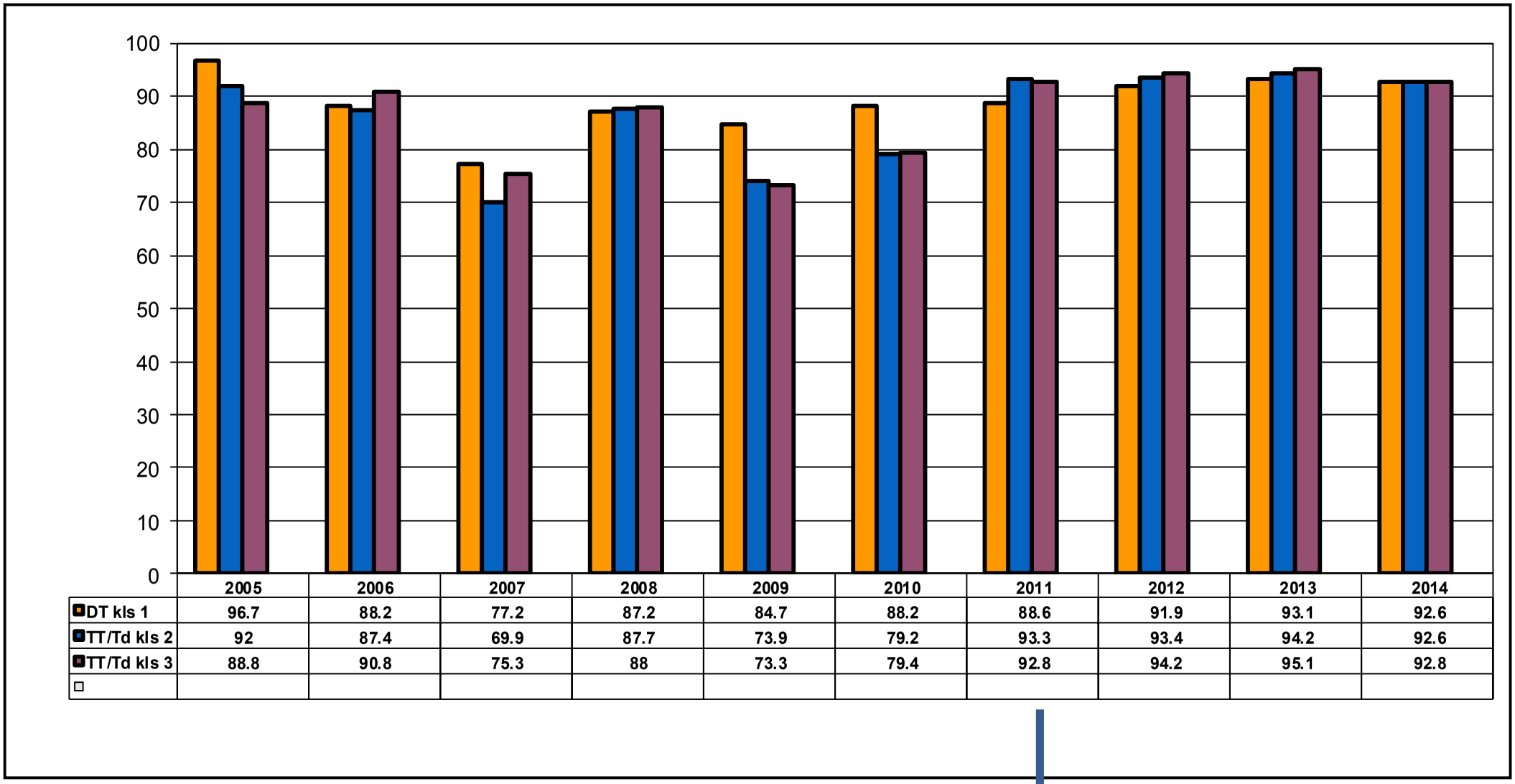
MCH

- Improving clean delivery and cord care practice
- Use of every opportunity during a child and mother’s contact in HF e.g. childhood treatment (IMCI), Malaria nets distribution, ANC screening for Malaria, HIV, etc.

TT Vaccination Schedule since 1984



School Based Immunization,
Td containing vaccines coverage, 2005-2014



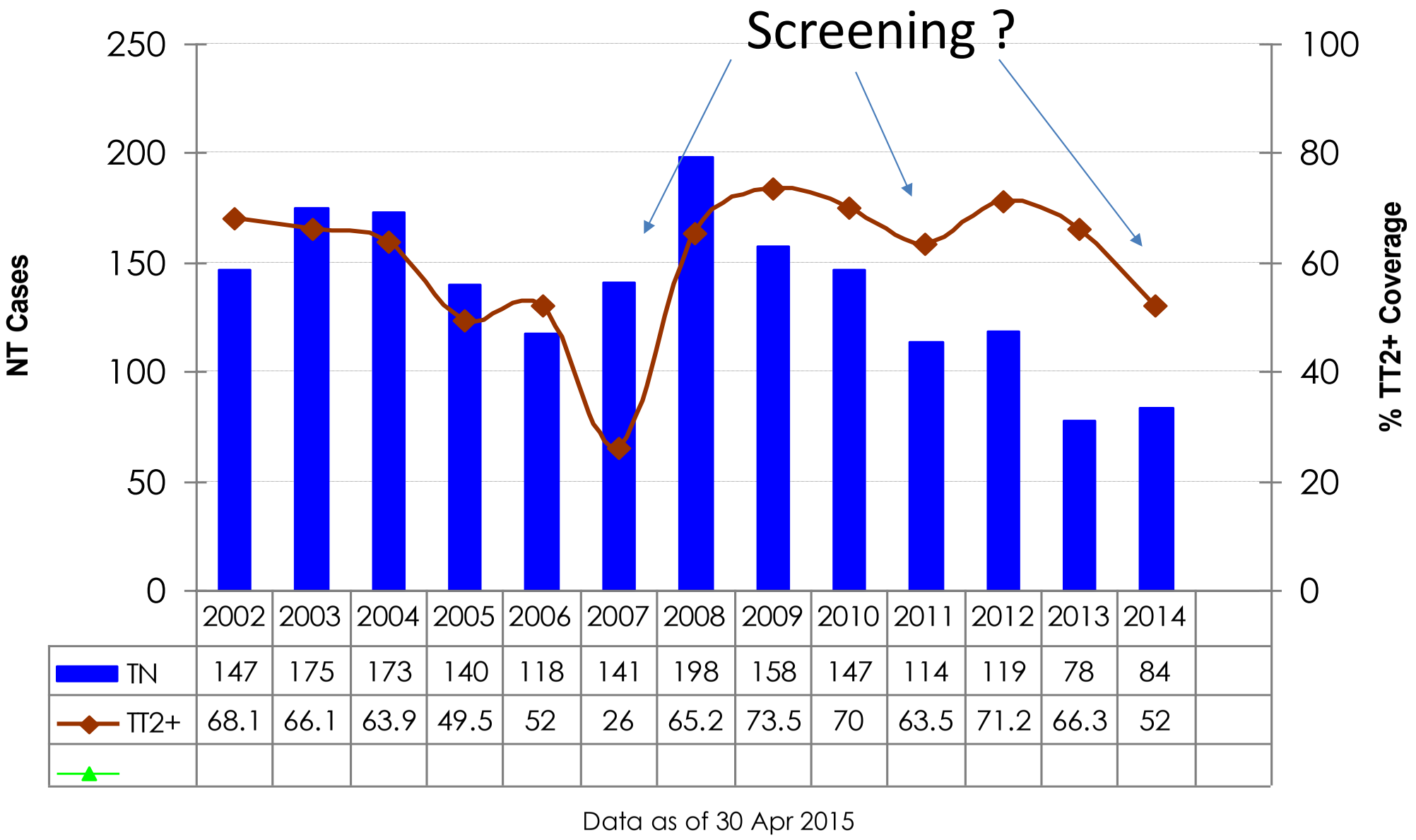
	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
DT kls 1	96.7	88.2	77.2	87.2	84.7	88.2	88.6	91.9	93.1	92.6
TT/Td kls 2	92	87.4	69.9	87.7	73.9	79.2	93.3	93.4	94.2	92.6
TT/Td kls 3	88.8	90.8	75.3	88	73.3	79.4	92.8	94.2	95.1	92.8

Td vaccine is used since 2011

Long term benefits of Vaccination through School based Immunization? Recording? Screening?

Picture was taken in 2014 during school based DT vaccination among first grade students at SD. YPPK St. Vincentius, Asologaima sub-district of Jayawijaya District, Papua - Indonesia

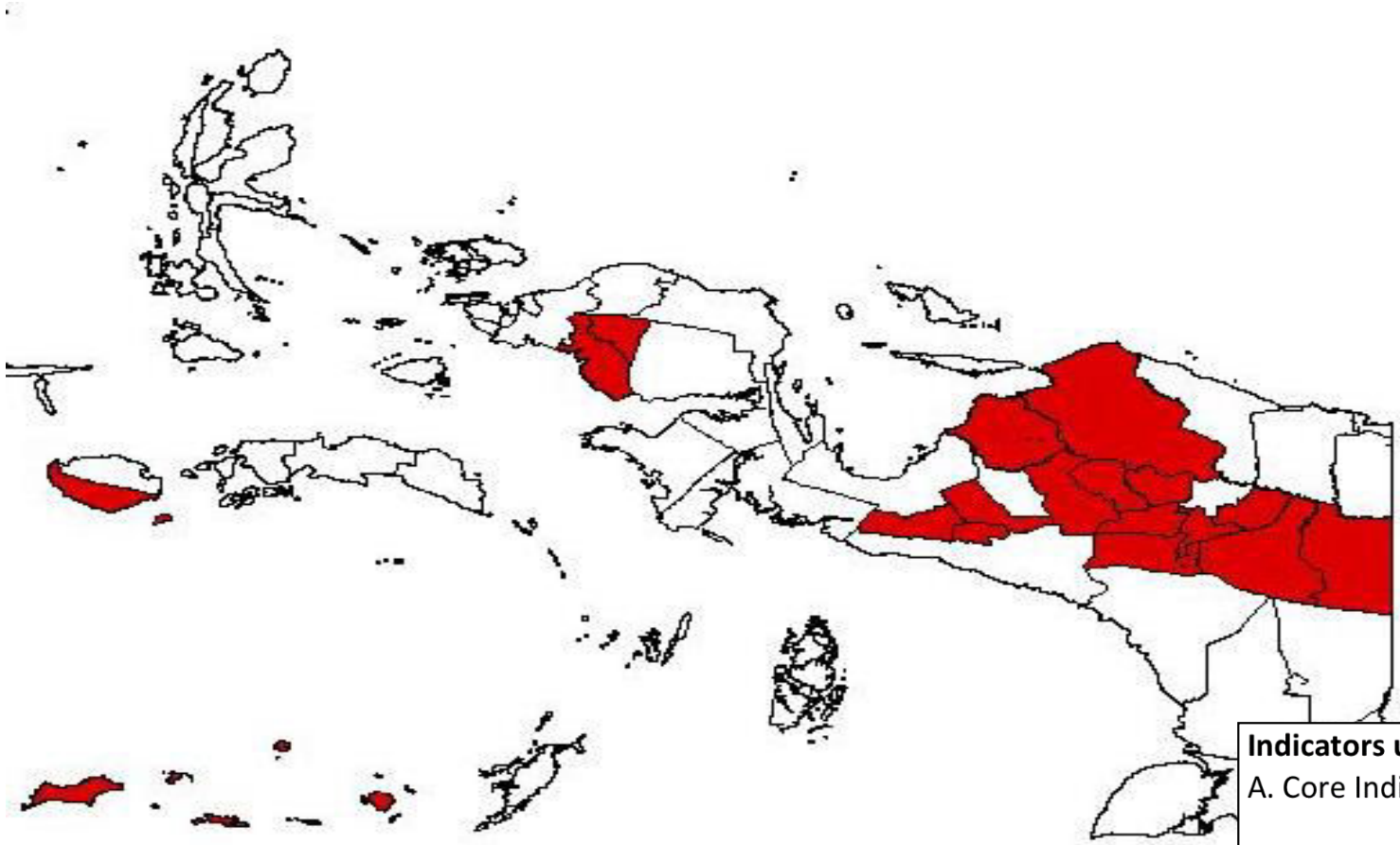
Neonatal Tetanus Cases and TT2+ (PW) Immunization Coverage, 2002 - 2014



	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
TN	147	175	173	140	118	141	198	158	147	114	119	78	84
TT2+	68.1	66.1	63.9	49.5	52	26	65.2	73.5	70	63.5	71.2	66.3	52

Data as of 30 Apr 2015

Selected 18 MNTE High Risk Districts



Indicators use for MNTE scoring system :

A. Core Indicators:

1 NT Rate/1.000LB
2 Skill Birth Attandance Rate
3 TT2+ Coverage
4 TT SIAs Coverage

B. Other Indicators:

1 ANC1
2 ANC4
3 Local Knowledge on Risk Status
4 DTP1 and DTP3 Coverage
5 School Based Immunization Coverage

Strategies to sustain MNT Elimination

EPI

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- Long term protection against tetanus through:
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    - DTP4 at 18 months (since 2013)
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  - TT/Td vaccination among CBAW (incl. “brides to be” and pregnant women)
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SURV

- Continued NT surveillance as part of VPD surveillance through improving sensitivity on NT cases in all districts incl. remote districts to monitor progress and identify areas at risk.

MCH

- Improving clean delivery and cord care practice
- Use of every opportunity during a child and mother’s contact in HF e.g. childhood treatment (IMCI), Malaria nets distribution, ANC screening for Malaria, HIV, etc.

Strategies to sustain MNT Elimination

- Increasing routine DTP coverage among infants and TT2+ among pregnant women

E

- Long term protection against tetanus through:
  - Booster doses:
    - DTP4 at 18 months (since 2013)
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  - TT/Td vaccination among CBAW (incl. “brides to be” and pregnant women)

P

I

- Short term TT SIAs, in high risk districts only, targeting CBAW (15-39 years)

S

U

R

V

- Continued NT surveillance as part of VPD surveillance through improving sensitivity on NT cases in all districts incl. remote districts to monitor progress and identify areas at risk.

- Improving clean delivery and cord care practice

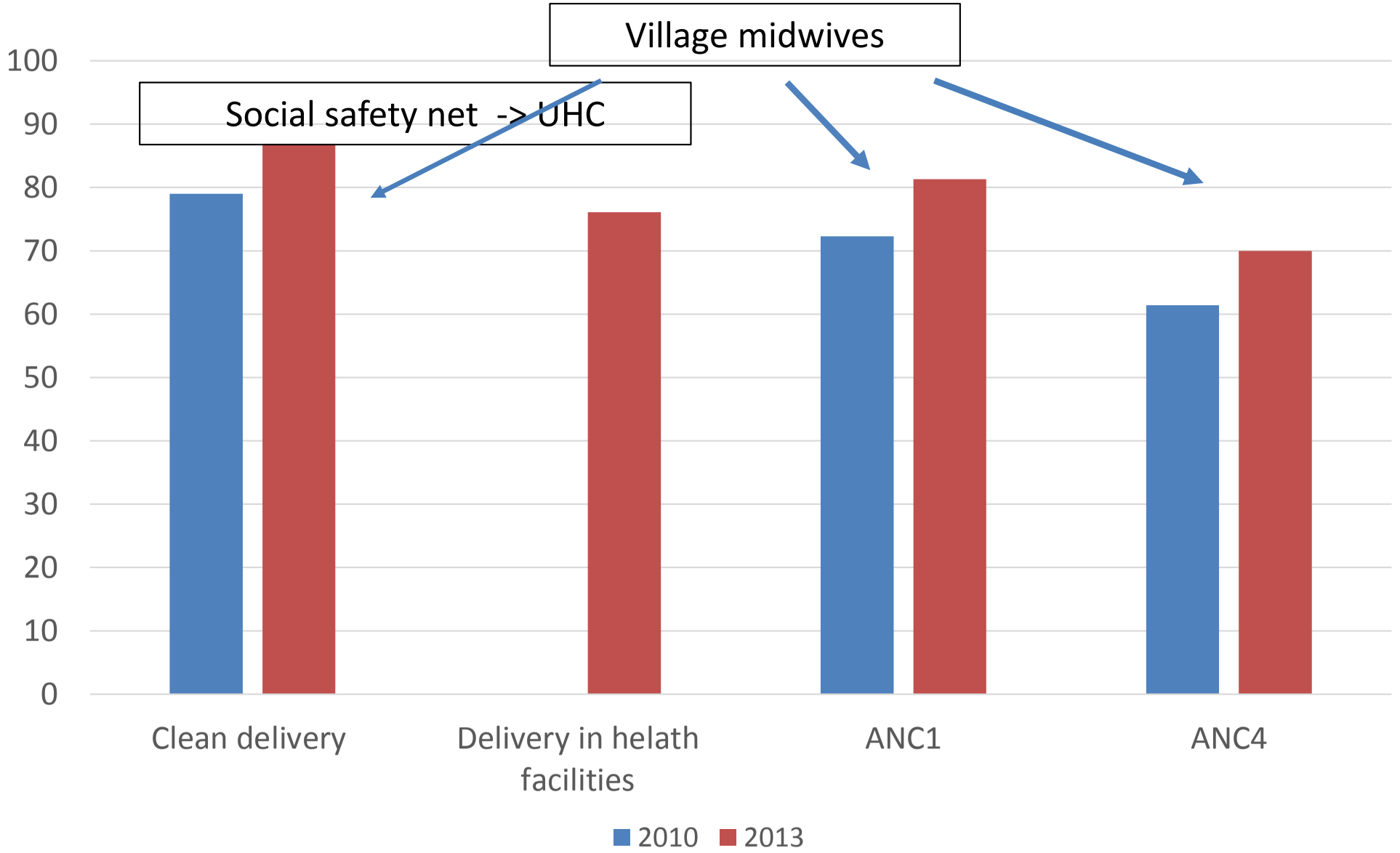
M

- Use of every opportunity during a child and mother’s contact in HF e.g. childhood treatment (IMCI), Malaria nets distribution, ANC screening for Malaria, HIV, etc.

C

H

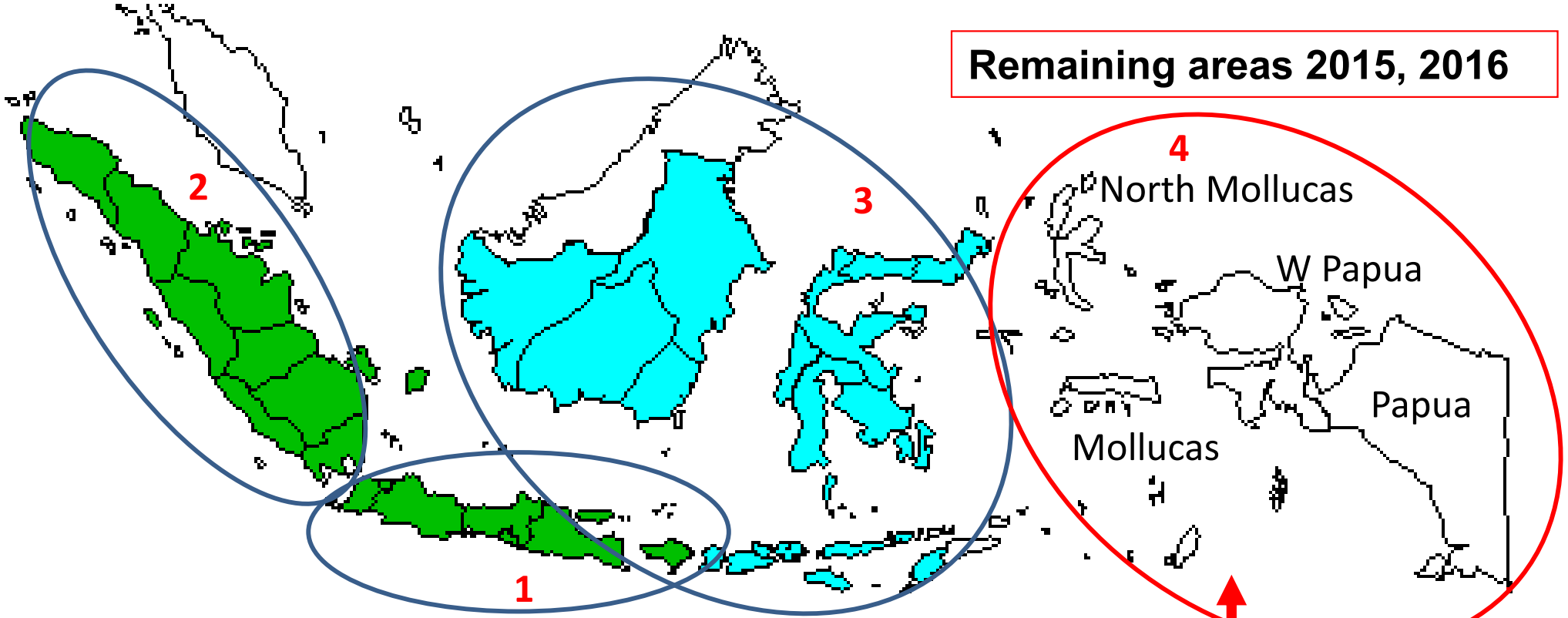
Progress on MCH in contributing to MNT elimination



Source: Basic Health Survery, 2010, 2013.

Status of MNTE validation in INDONESIA

MNT has been eliminated in ± 88.7% cities/districts, 97.4% population



2010: Region 1 (Java & Bali); and region 2 (entire Sumatera)

2011: Region3 (entire Kalimantan, Sulawesi, NTT, NTB)

District Level data analysis:
- Using spreadsheet
- Series of indicators
- Classify MNT Status
- Classify routine performance

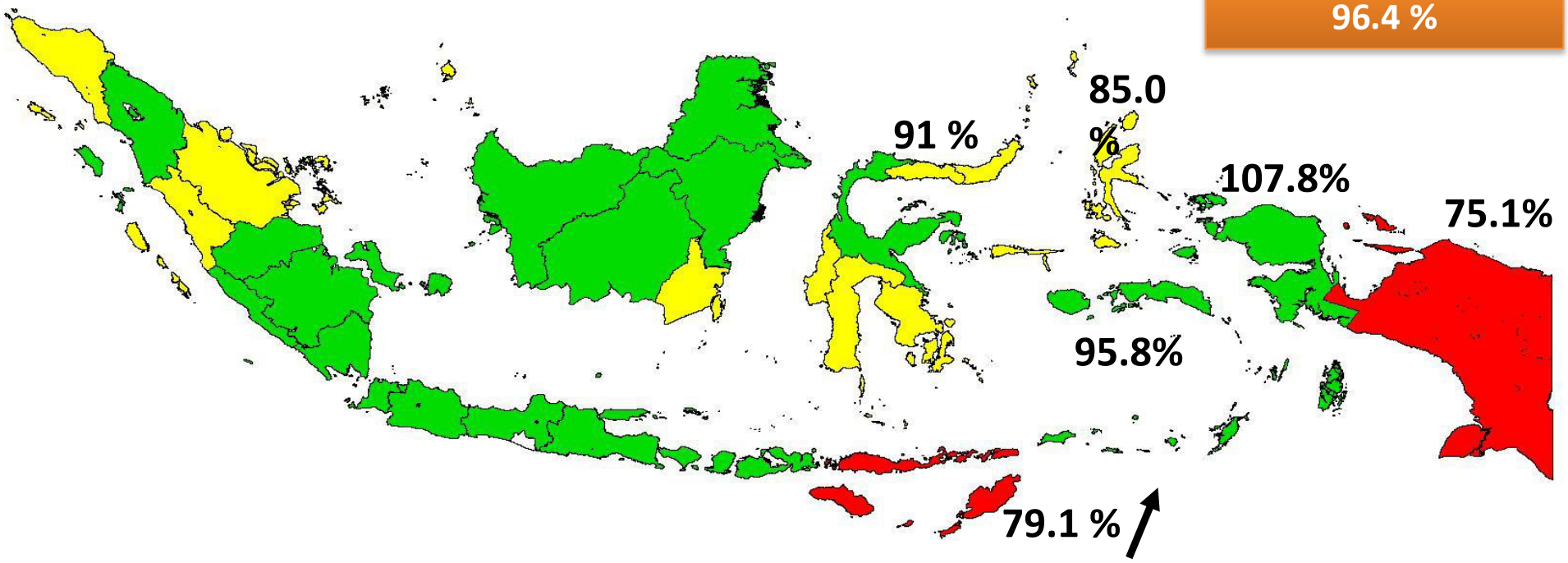
Challenges…….Denominator

- 7/14 districts in Papua are new, split from mother districts; high projected population estimates
- True/actual pop about 60% of political pop
- The real TT coverages are diluted or not reported

2016 Polio NIDs Coverage

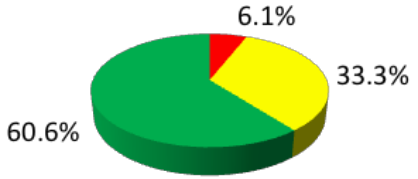
Discrepancy in use of target population between census and province/district (possible overestimation)

National Coverage: 96.4 %



Coverage <80%
Coverage ≥80% and <95%
Coverage ≥95%

Proportion of Province's Achievement



as of 29 March 2016

Coverage <80% Coverage ≥80% and <95% Coverage ≥95%

Logistic Challenge

- Papua: many highland districts with less developed or no road network, geographically very difficult to reach can only go by foot 1-3 days, security challenges

  196 HCs in 14 districts,

  only 9 % with electricity,

  only 50% refrigerator functioning (solar & electric)

- Mollucas: Remote islands, access and transport issues, high tides
- Small target population in very dispersed areas

TRANS PAPUA – August 2016

Socio-Cultural-Political Challenges

- Security concerns make it difficult for the health staff to do outreach activities (posyandu or pusling) and even for the population to access the health services in the facilities
- Bupati (Mayors) and DHO Heads support are key but variable in Papua
- Some tribes continue to practice the use of traditional methods in cutting the cord (sharp wood/bark as knot) and cord care (ash/herbs/bee's oil/etc)

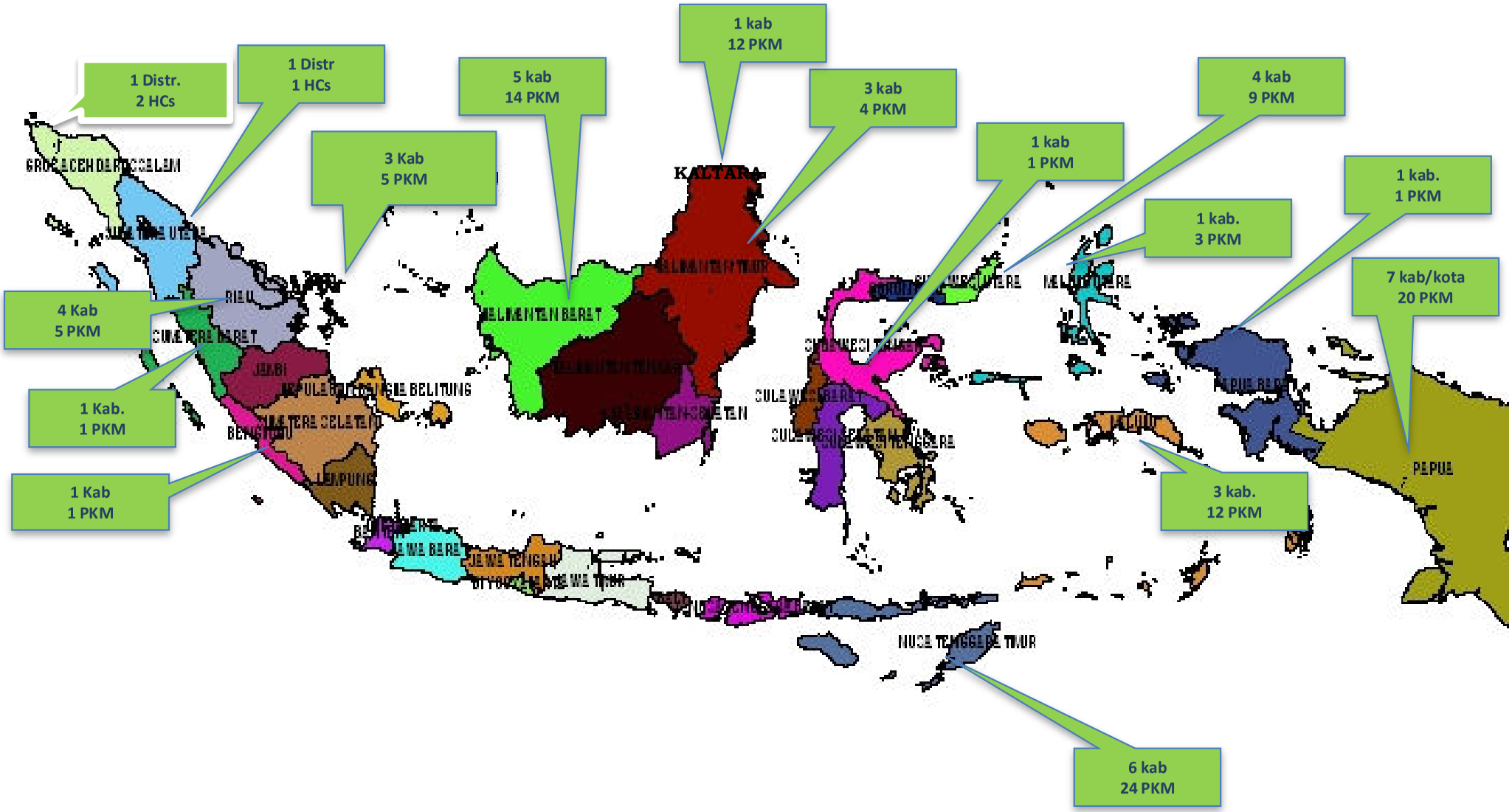
Health System Challenges

- Poor recording and reporting of accomplishments (underestimation)
- Lack of trained, motivated health staff
  - midwives and nurses in remote areas (<1 Doctor/10,000 pop)
  - Frequent staff turnover
  - Vaccinators have multiple tasks
- Healthcare Financing: difficulties in accessing government operational funds in Papua despite MoH directives

Team based health work force allocation

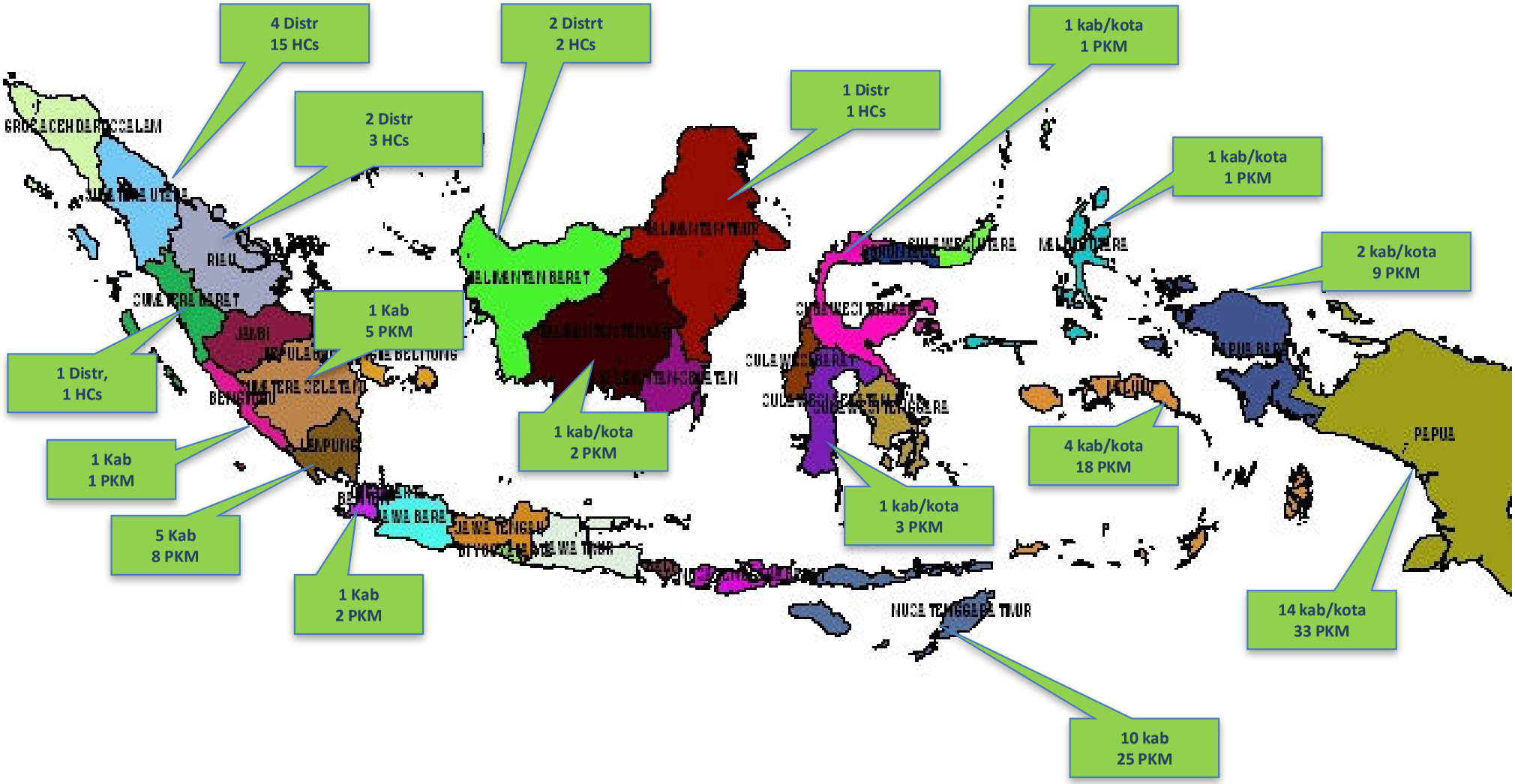
120 Remote Health Centers Year 2015

15 PROVINCES. 48 DISTRICTS



130 REMOTE HEALTH CENTRES YEAR 2016

16 PROVINCES, 51 DISTRICTS



What innovation are designed

- Priority to reach all WRA in the populated areas, Health centers with population >1500
- Prioritization based on accessibility and with a very detailed realistic / costed microplanning
- Adequate and timely availability of vaccine and logistics, enhanced supervision by Central and provincial level manager
- Assessments (RCA) undertaken to initiate appropriate action, especially in areas that are at highest risk with limited data,

WHO EXTERNAL MONITORING
15 March 2016

- Rapid Convenience Assessment (RCA) in House hold, Papua

  - Total Respondents : 1.401
  - Number of under 5s : 1.626
  - % under 5s immunized during NIDs : 89 %
  - Official Report : 79.1%

Polio NIDs : 8 – 15 March 2016

Innovative approach to provide TT

- Integrated service delivery, providing TT at all opportunity, Routine Immunization, MCH,
- Recent ORI after pertussis outbreak in one district , TT was also given to WRA
- Include TT Target for high risk districts as a pro-poor strategy
  - 1000 days agenda of Governor
- Optimizing Integration of TT with Polio End game strategies
  - Polio monitors also assisting in MNTE implementation
  - TT vaccine also given along with Polio NIDs in March specifically in very remote areas.

TT provided as part of Polio NIDs

Thank you

The saying ;

Eliminating MNT is simple and inexpensive…is not always correct ☺

World Health Organization

"New" Vaccination Platforms and Opportunities for TTCV Boosters

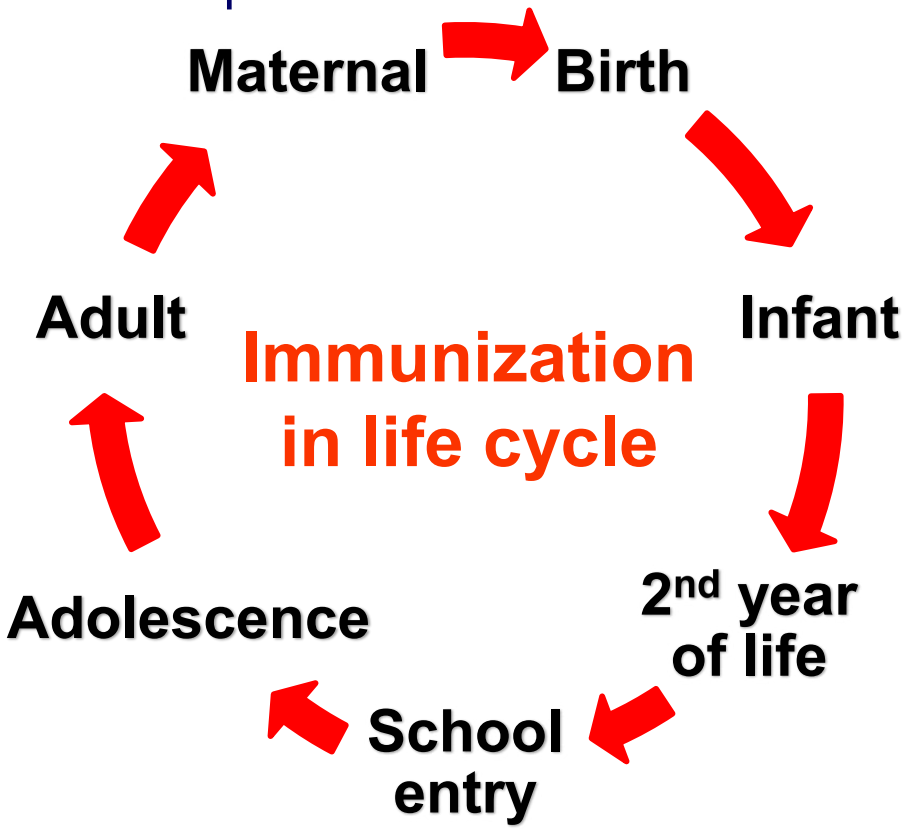
Tracey Goodman, EPI Team/HQ

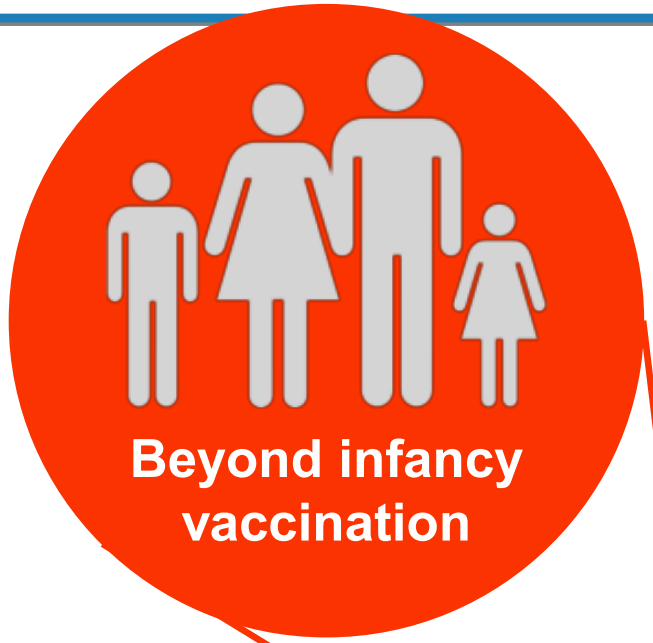
Presentation to the SAGE MNTE Working Group Meeting

Aug 17-19, 2016 (Geneva)

Vaccinating Older Age Groups

GVAP
ESTABLISH a life-course approach to immunization planning and implementation, including new strategies to ensure equity across the life span.





2YL Scheduled doses: WHO Recommendations

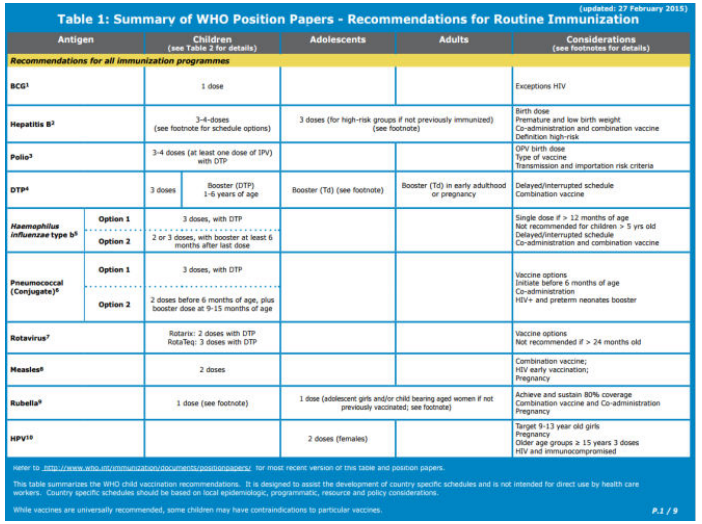
- DTP: Booster dose recommended 1-6 years (DTP-containing vaccine 4 or DTPCV4). For Pertussis-containing booster, it is recommended preferably during the second year of life.

- Measles-containing vaccine 2 (MCV2):
  - Where high-risk of measles mortality: recommended 15-18 months

- Men A routine dose: a 1-dose schedule, at 9–18 months of age based on local programmatic and epidemiologic considerations.

- Pneumococcal conjugate vaccine:
  - Alternative schedule (2p+1) with 2 doses before 6 months and booster given between 9 and 15 months.

- And catch-up of any missing/delayed doses!



(updated: 27 February 2015)

Table 1: Summary of WHO Position Papers - Recommendations for Routine Immunization

Antigen		Children (see Table 2 for details)		Adolescents	Adults	Considerations (see footnotes for details)
Recommendations for all immunization programmes						
BCG[1]		1 dose				Exceptions HIV
Hepatitis B[2]		3-4-doses (see footnote for schedule options)		3 doses (for high-risk groups if not previously immunized) (see footnote)		Birth dose Premature and low birth weight Co-administration and combination vaccine Definition high-risk
Polio[3]		3-4 doses (at least one dose of IPV) with DTP				OPV birth dose Type of vaccine Transmission and importation risk criteria
DTP[4]		3 doses	Booster (DTP) 1-6 years of age	Booster (Td) (see footnote)	Booster (Td) in early adulthood or pregnancy	Delayed/interrupted schedule Combination vaccine
Haemophilus influenzae type b[5]	Option 1	3 doses, with DTP				Single dose if > 12 months of age Not recommended for children > 5 yrs old Delayed/interrupted schedule Co-administration and combination vaccine
	Option 2	2 or 3 doses, with booster at least 6 months after last dose				
Pneumococcal (Conjugate)[6]	Option 1	3 doses, with DTP				Vaccine options Initiate before 6 months of age Co-administration HIV+ and preterm neonates booster
	Option 2	2 doses before 6 months of age, plus booster dose at 9-15 months of age				
Rotavirus[7]		Rotarix: 2 doses with DTP RotaTeq: 3 doses with DTP				Vaccine options Not recommended if > 24 months old
Measles[8]		2 doses				Combination vaccine; HIV early vaccination; Pregnancy
Rubella[9]		1 dose (see footnote)		1 dose (adolescent girls and/or child bearing aged women if not previously vaccinated; see footnote)		Achieve and sustain 80% coverage Combination vaccine and Co-administration Pregnancy
HPV[10]				2 doses (females)		Target 9-13 year old girls Pregnancy Older age groups ≥ 15 years 3 doses HIV and immunocompromised

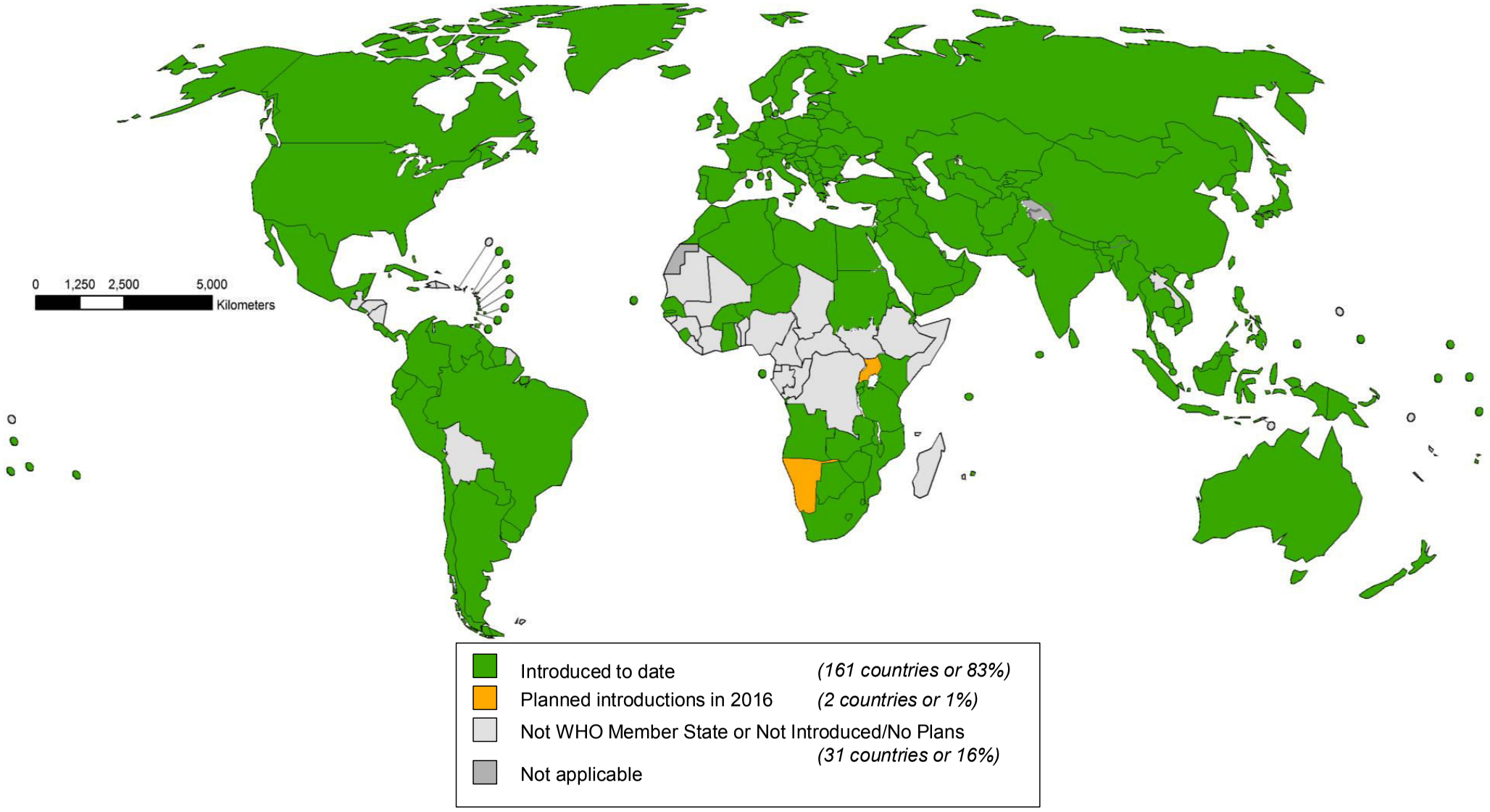
Refer to http://www.who.int/immunization/documents/positionpapers/ for most recent version of this table and position papers.

This table summarizes the WHO child vaccination recommendations. It is designed to assist the development of country specific schedules and is not intended for direct use by health care workers. Country specific schedules should be based on local epidemiologic, programmatic, resource and policy considerations.

While vaccines are universally recommended, some children may have contraindications to particular vaccines.

P.1 / 9

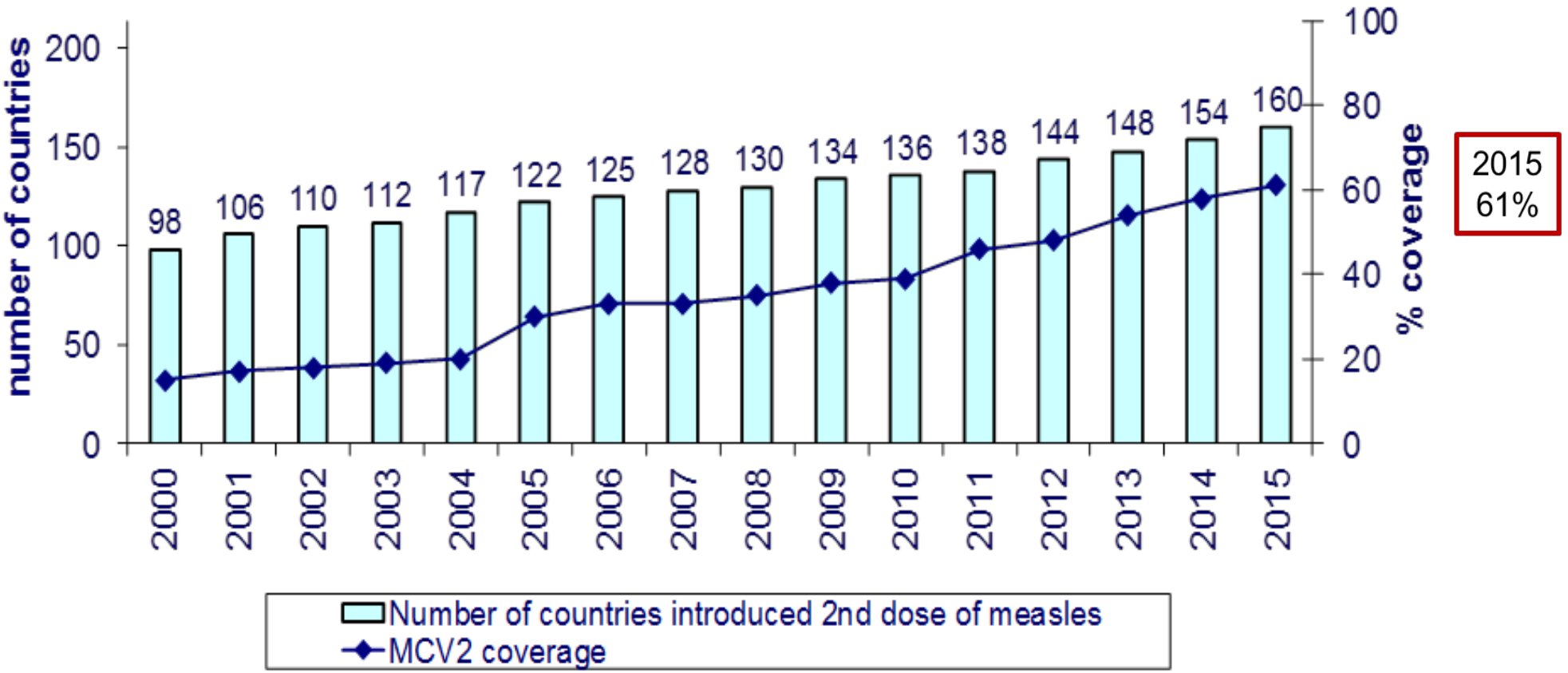
Majority of countries (161) have 2-dose measles schedule, 2015



Data source: WHO/IVB Database, as of 27 June 2016
Map production Immunization Vaccines and Biologicals (IVB), World Health Organization

WHO

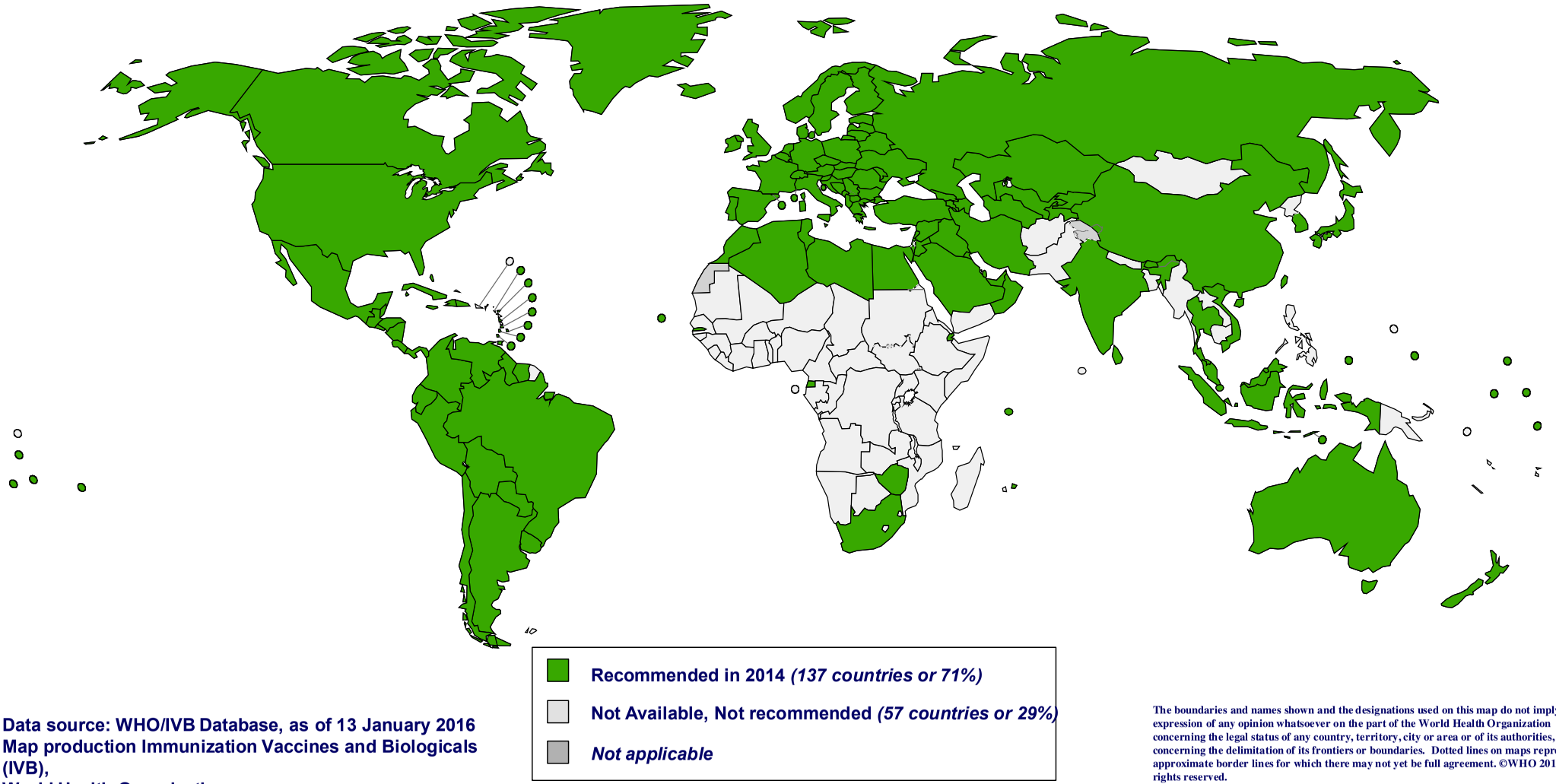
Steady Progress with MCV2, 1989-2015 Global Estimate (WUENIC)



Source: WHO/UNICEF coverage estimates 2015 revision. July 2016 and WHO database as at 25 July 2016
Immunization Vaccines and Biologicals, (IVB), World Health Organization.
194 WHO Member States. Date of slide: 25 July 2016.

World Health Organization

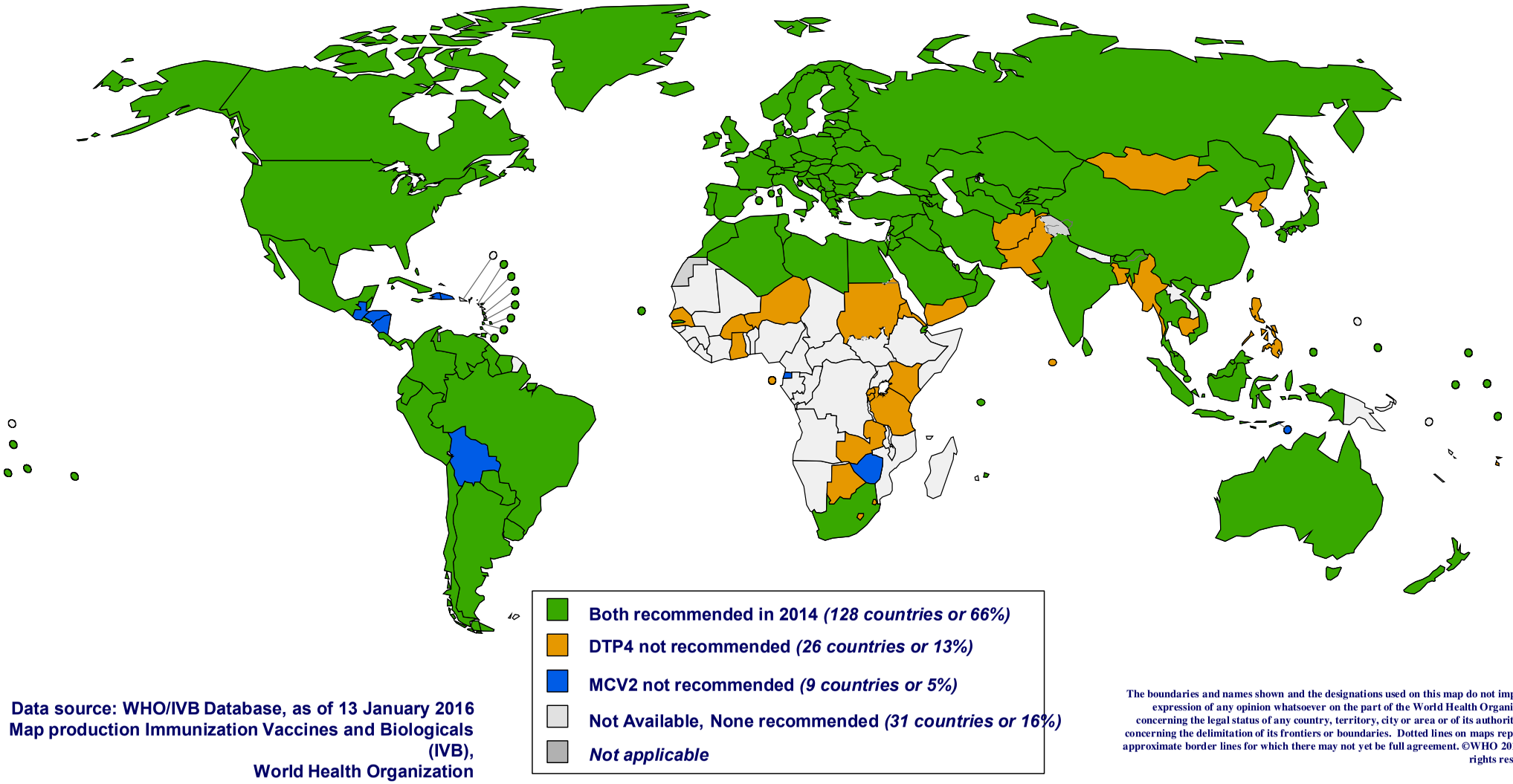
137 Countries recommending a 4th dose of DTP-containing vaccines (DTPCV4), 2014



Data source: WHO/IVB Database, as of 13 January 2016
Map production Immunization Vaccines and Biologicals (IVB),
World Health Organization

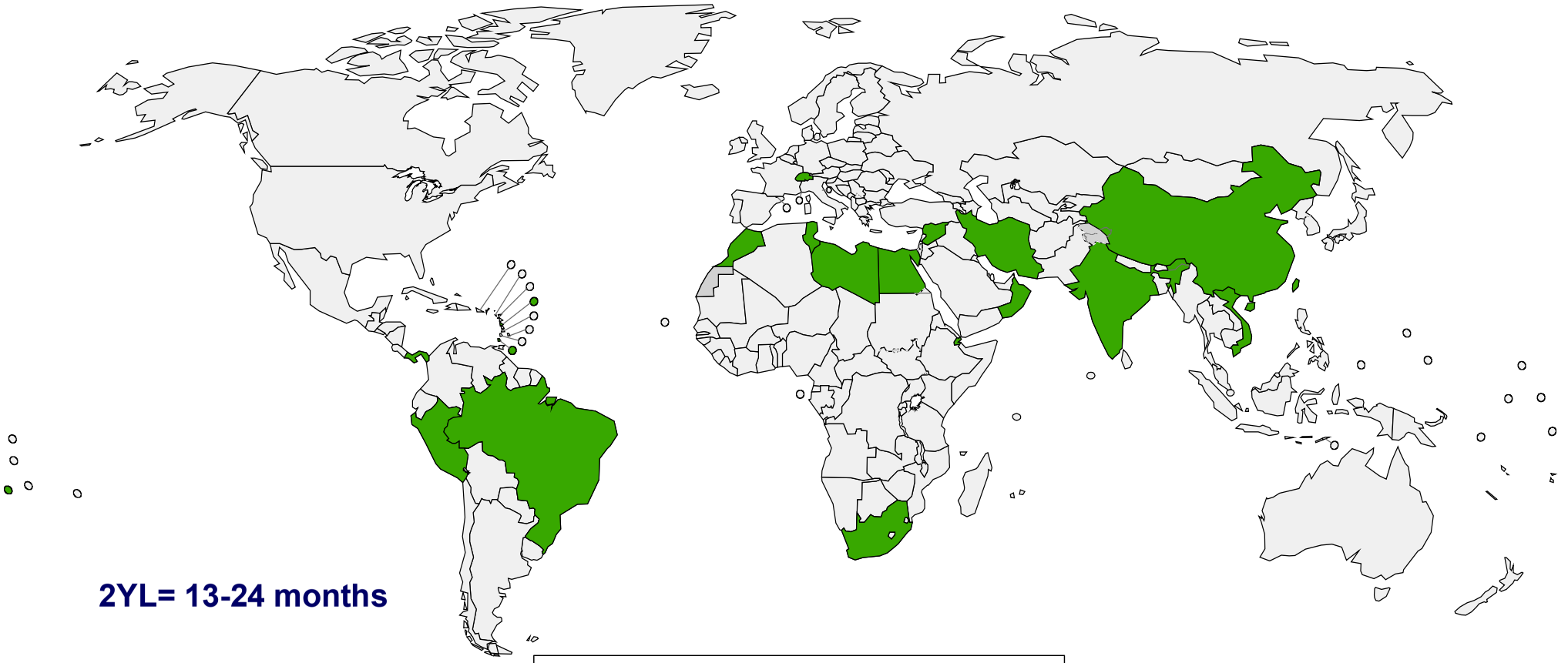
World Health Organization

128 Countries recommending both MCV2 and DTPCV4, 2014



Data source: WHO/IVB Database, as of 13 January 2016
Map production Immunization Vaccines and Biologicals (IVB),
World Health Organization

19 Countries recommending both DTPCV4 and MCV2 at the same age during 2YL, 2014



Data source: WHO/IVB Database, as of 13 January 2016
Map production Immunization Vaccines and Biologicals (IVB),
World Health Organization

Considerations: 2YL for TTCV Booster

- **Vaccine Supply**
  - For MCV2 same vaccine (wastage savings)
  - For TTCV booster needs to be different from primary series (Penta)
- **Demand creation among caregivers**
  - Need to improve communication with caregivers about need for 18 month visit (provision of immunization services to >1 year is new)
- **Data and Recording issues (Health staff training)**
  - Definitions
  - Recording and reporting issues – "how tally sheets influence behaviour"
  - Coverage calculations – "what denominator?"
- **Other IMPORTANT Influences**
  - Annual WHO/UNICEF Coverage Estimates (WUENIC) for MCV2
  - Funding support (Gavi for MCV2)

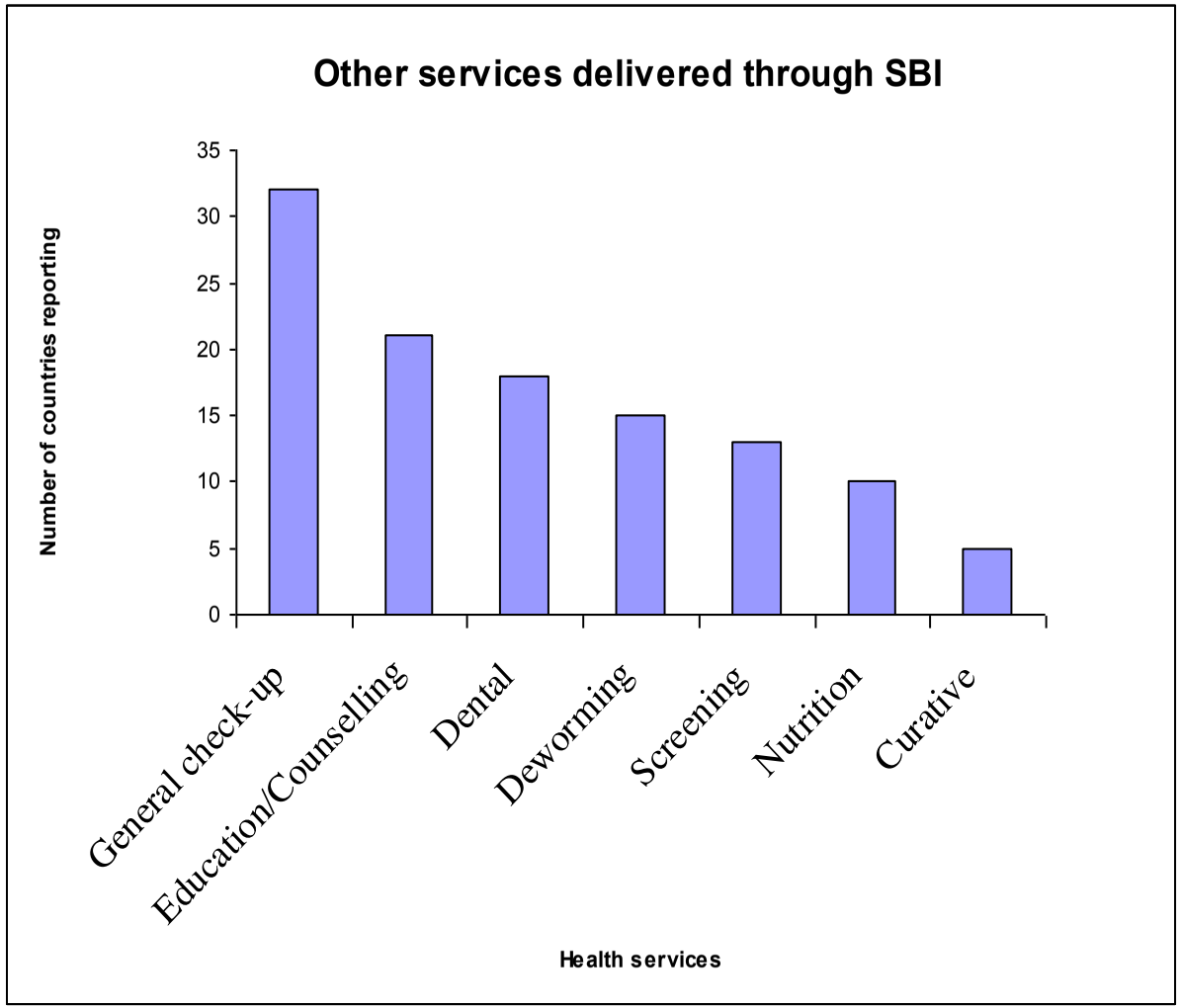
Routine Vaccination Provided in Schools, JRF 2015 data

School Vaccination				
Region	All Member states	LMIC		Total Member states
AMR	26	20		35
AFR	11	7		46
EMR	14	7		22
EUR	23	7		53
SEAR	4	4		11
WPR	17	12		27
Total	95	57		194
%	49%	60%		

School-based vaccination more frequent in LMICs (caution: SIAs?)

Types of Health Services Provided to School Children with Vaccination (2011)

- Services:
  - Deworming
  - General check up (vision, hearing, growth)
  - Dental
  - Screening (NCDs, nutritional status)
  - Education, awareness, mental health
  - Curative, referral
  - Nutrition (supplements, food)
- A few countries also report water & sanitation and hygiene

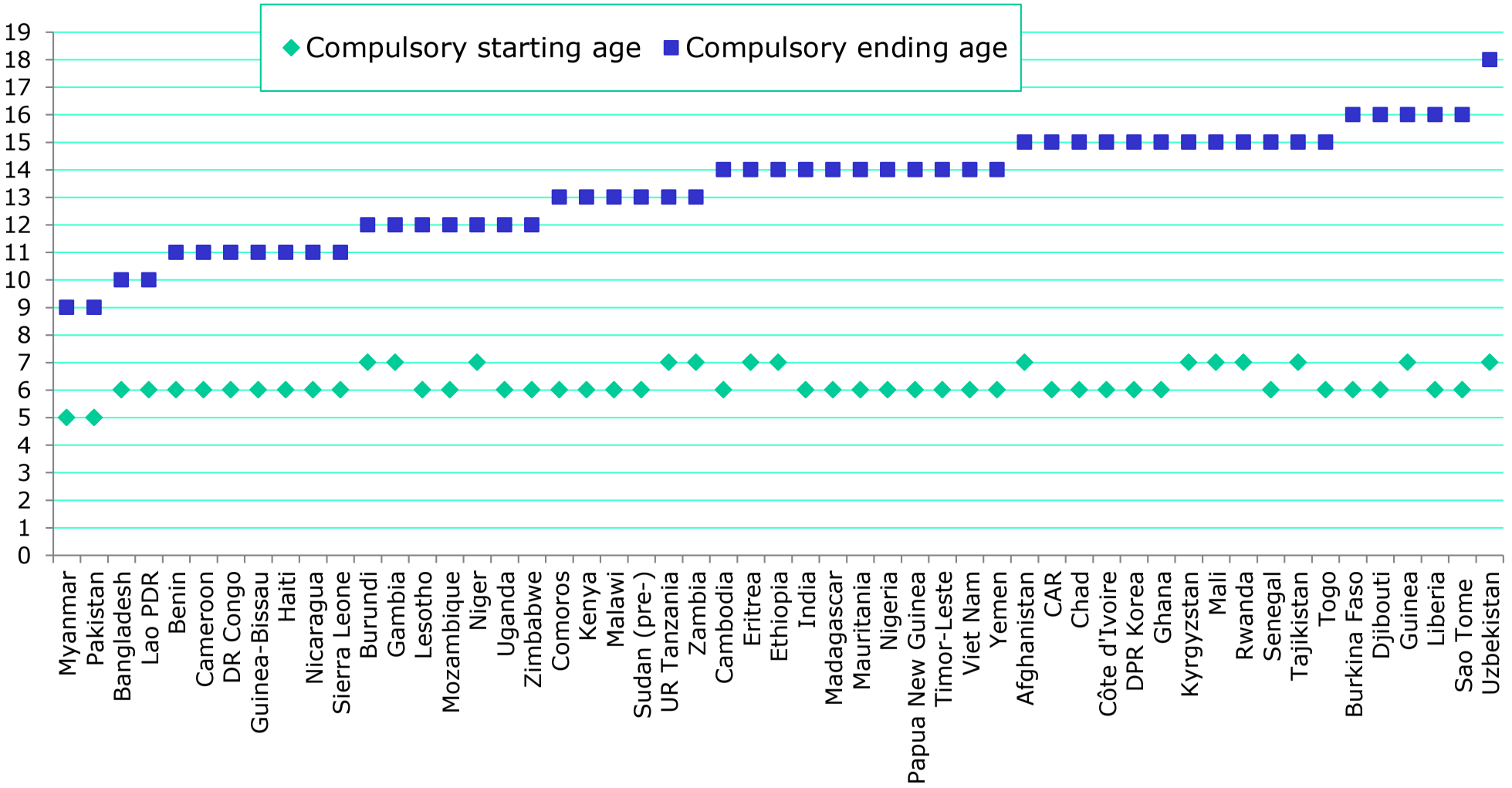


5 Country* Study 2009: Enabling factors for successful school vaccination

- **High enrolment** of school-age children, both genders
- **Strong primary healthcare system** with adequate network of health centres at lower levels
- Strong **central government support*** through vaccine supplies and equipment procurement
- **Collaboration between ministries**, especially MOH and MOE, and within department of MOH
- Standard of operations, **guidelines and training**
- **Cooperation of staff** from schools and healthcare workers
- **People's trust** in the public health and education system

*Indonesia, Malaysia, Sri Lanka, Syria, Tunsia

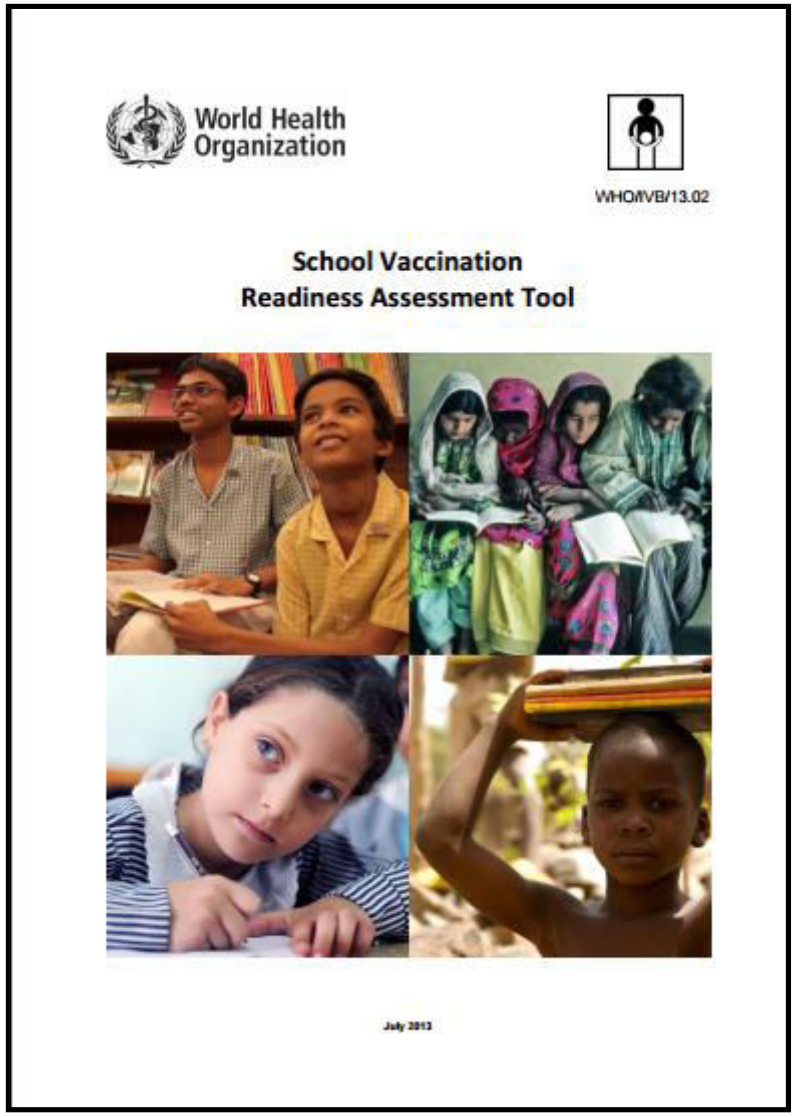
The opportunity of school health programs
Compulsory school age range



Source: UNESCO Institute for Statistics, 2012

S

School Vaccination: “Easy to say, difficult to do”



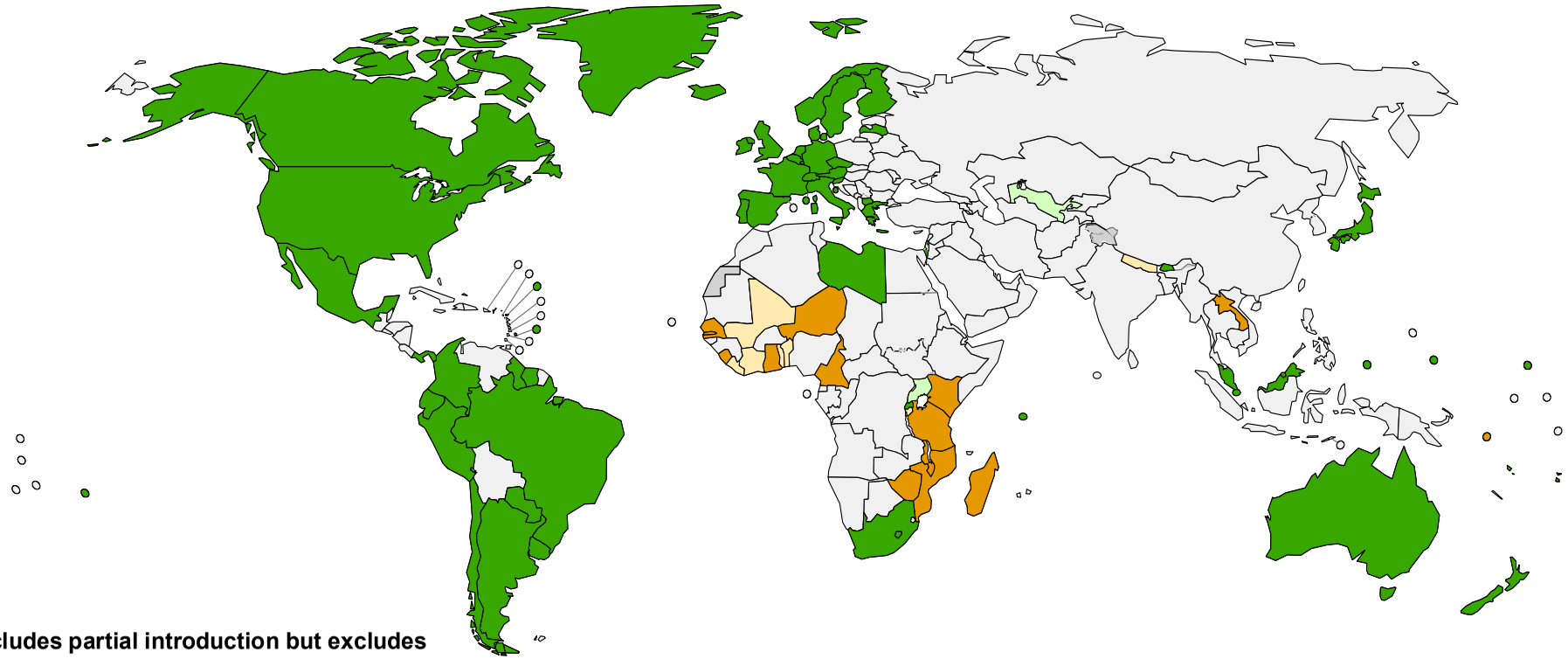
CONTENTS

1. **Overall readiness** - deals with the policy level support for school based vaccination
2. **School readiness** - deals with the school level infrastructure and processes
3. **Implementation readiness** - deals with the Health system readiness to administer in schools
4. How to develop an **improvement plan**
5. Bibliography

Global School Health Policies & Practices Surveillance (SHPPS)

- Build on the success of GSHS (optional component)
- Generate pop-based national data on the characteristics & quality of **school health policies** in schools (primary & secondary)
- 131 Questions in 5 topic areas:
  - Physical Education/Activity
  - Health Services (incl. vaccination)
  - Health Education
  - Nutrition Services
  - School Environment
- Country workshop July 2012 then piloting

Adolescent Vaccination Platform: HPV Vaccination



* Includes partial introduction but excludes countries where vaccination is temporarily interrupted

- Introduced* to date *(60 countries or 31%)*
- Gavi supported nationwide introduction *(2 countries or 1%)*
- Gavi Demo projects (started to date) *(14 countries or 7%)*
- Gavi Demo projects (starting 2015/16) *(9 countries or 4%)*
- Not Available, not Introduced / no plans *(111 countries or 57%)*
- *Not applicable*

0 875 1,750 3,500 Kilometers

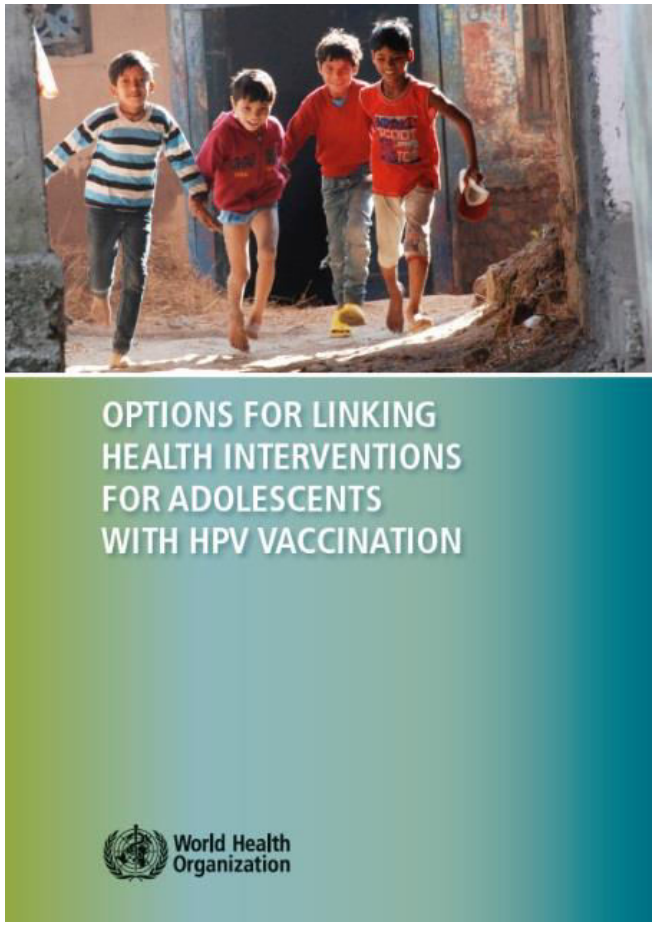
Data source: WHO/IVB Database, as of 30 January 2015
Map production Immunization Vaccines and Biologicals (IVB), World Health Organization

ADOLESCENT HEALTH

Integrating HPV vaccination with adolescent health interventions and programs

An opportunity for reaching girls and boys with additional health interventions.

TYPE	POSSIBLE HEALTH INTERVENTIONS
Screening	• Vision screening, if referral and glasses available and affordable
Commodities and treatment	• Anthelmintic treatment for schistosomiasis and soil-transmitted helminths (STH) • Insecticide-treated bednet for malaria prevention • Iron and folic acid supplementation
Information and life skills	• Promotion of physical activity • Prevention of mosquito-borne diseases • Menstrual hygiene education • Sexual and reproductive health education, HIV prevention and condom promotion
Other vaccines	• Td, Hep B, co-administration with other vaccines under investigation



Broutet et al. JAH, 2013; Hindin et al. JAH, 2015

Learning from HPV Vaccination

- School-based “campaign-style” = high coverage; found to be expensive ($3-$5/dose) and not sustainable
- Many adjusting delivery strategy to routine outreach/facility (coverage?)
- Strong communication effort needed (rumours/consent)
- Integration with other health interventions not easy/fast and boys left out
- Working with new partners takes time

In Summary

- No “ready made” platform exists for TTCV booster – BUT there are opportunities (will differ from country to country)
- Challenges for TTCV boosters likely to be similar (identifying target/denominators, demand, recording/reporting, training, rumours, etc…BUT at lot of learning from MCV2/2YL and HPV vaccine
- Funding support helps BUT countries have a lot to prioritize (financial sustainability is a concern for many)
- *“What gets counted, counts”* – need to produce WHO/UNICEF Coverage Estimates for TTCV boosters
- Engagement of new partners and stakeholders is key (particularly for adolescent platform and school vaccination)

World Health Organization

Thank you

HIV prevention through voluntary medical male circumcision and TTCV gaps for males

Liz Miller, Public Health England
Julia Samuelson
WHO Department of HIV/AIDS

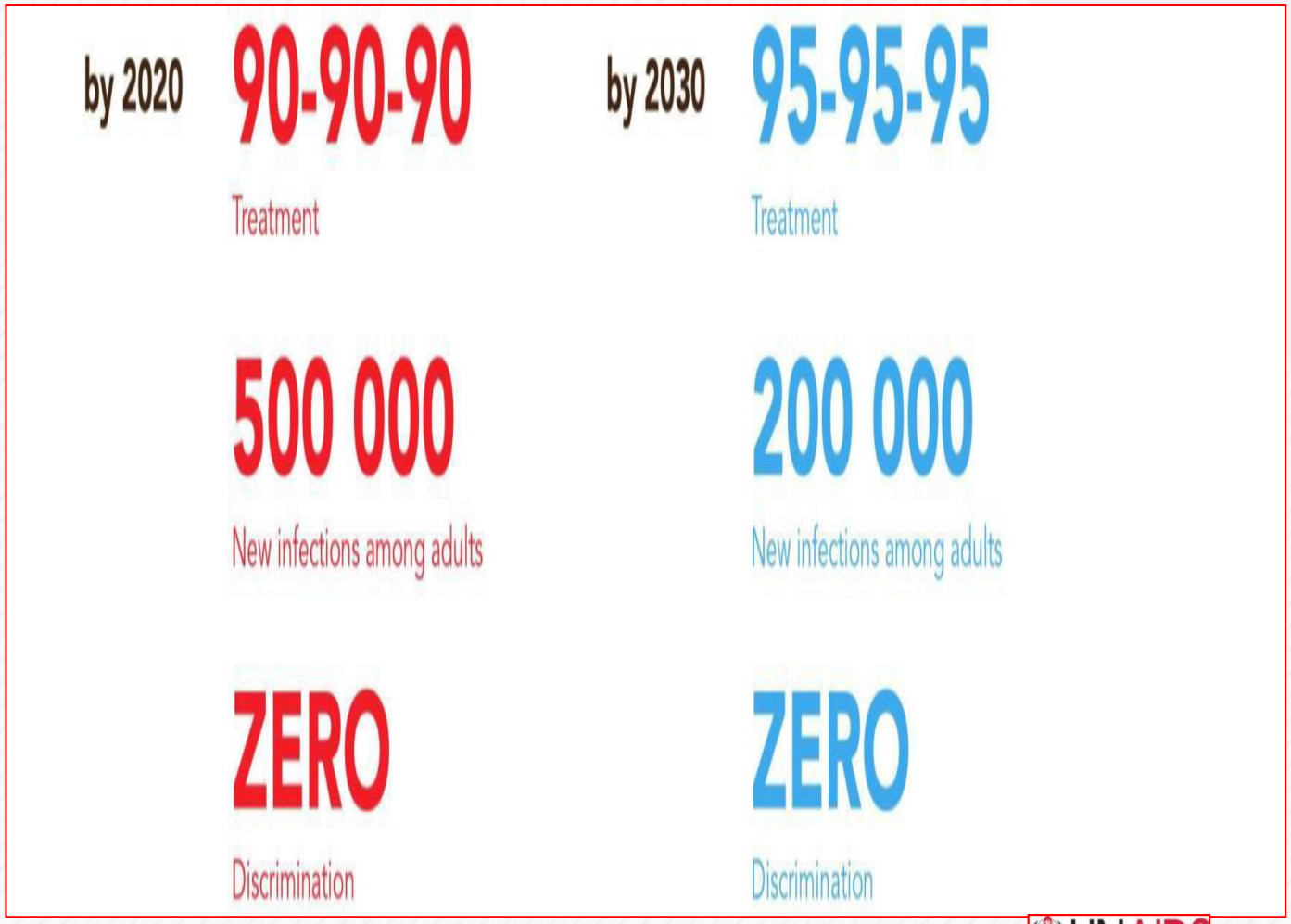
World Health Organization

2030 Agenda for Sustainable Development

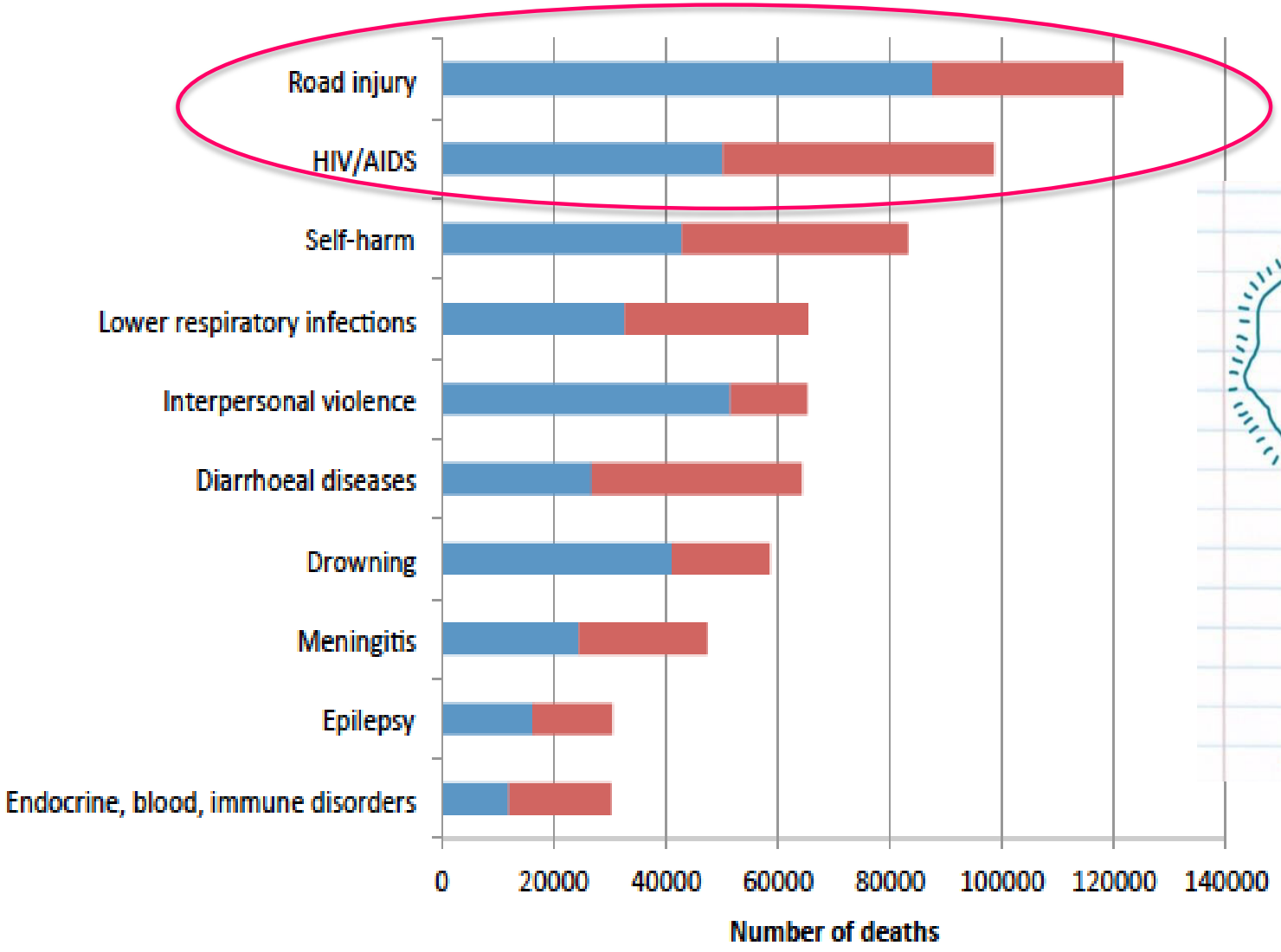
3.3 By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases

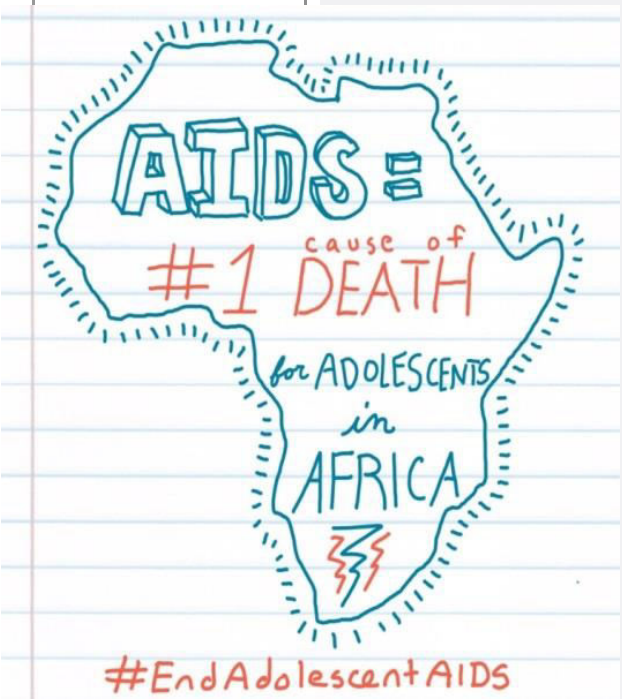
FAST-TRACK

ENDING THE AIDS EPIDEMIC BY 2030

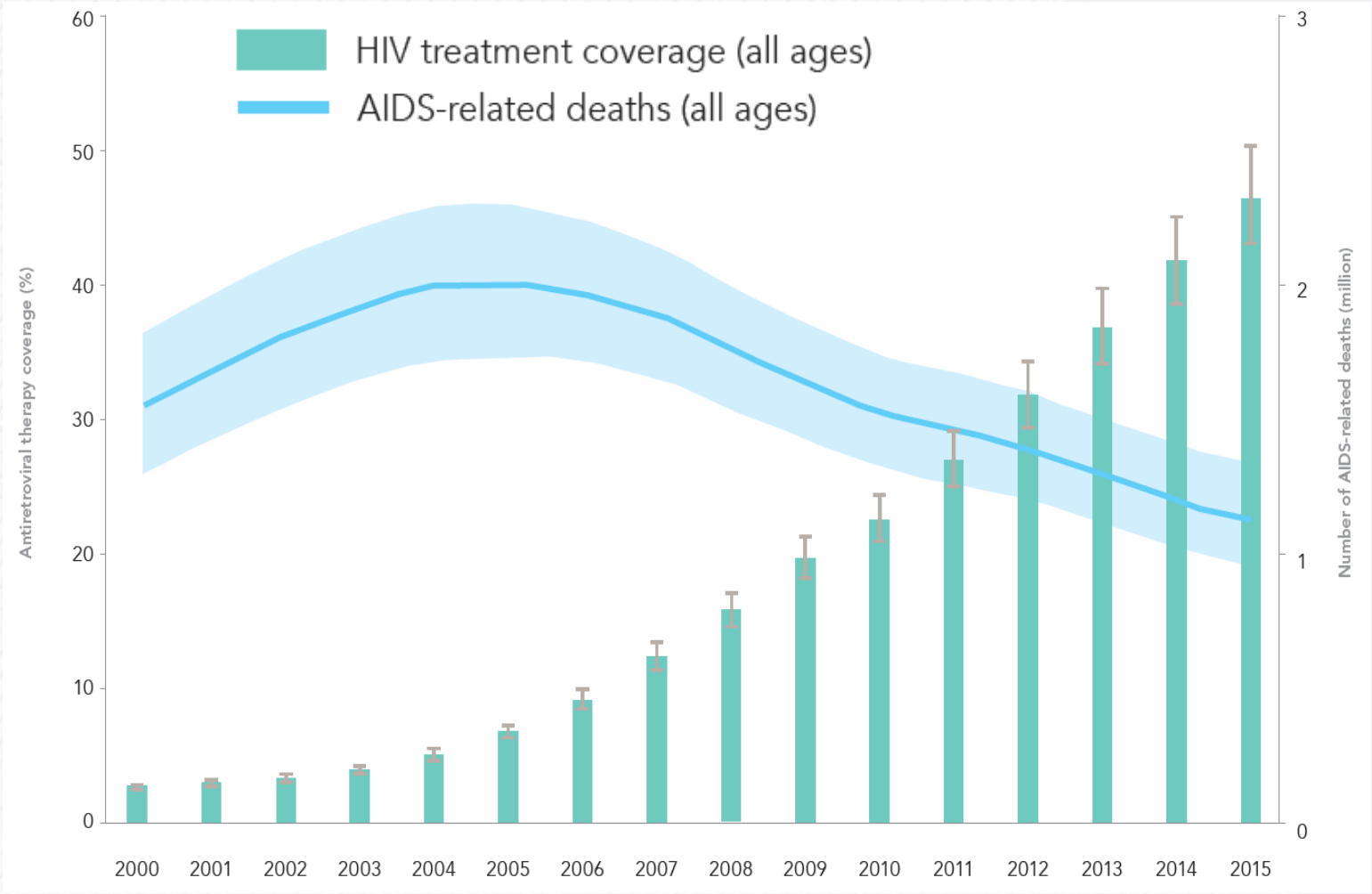


10 Leading Causes of Deaths in Adolesecents, Global, 2012

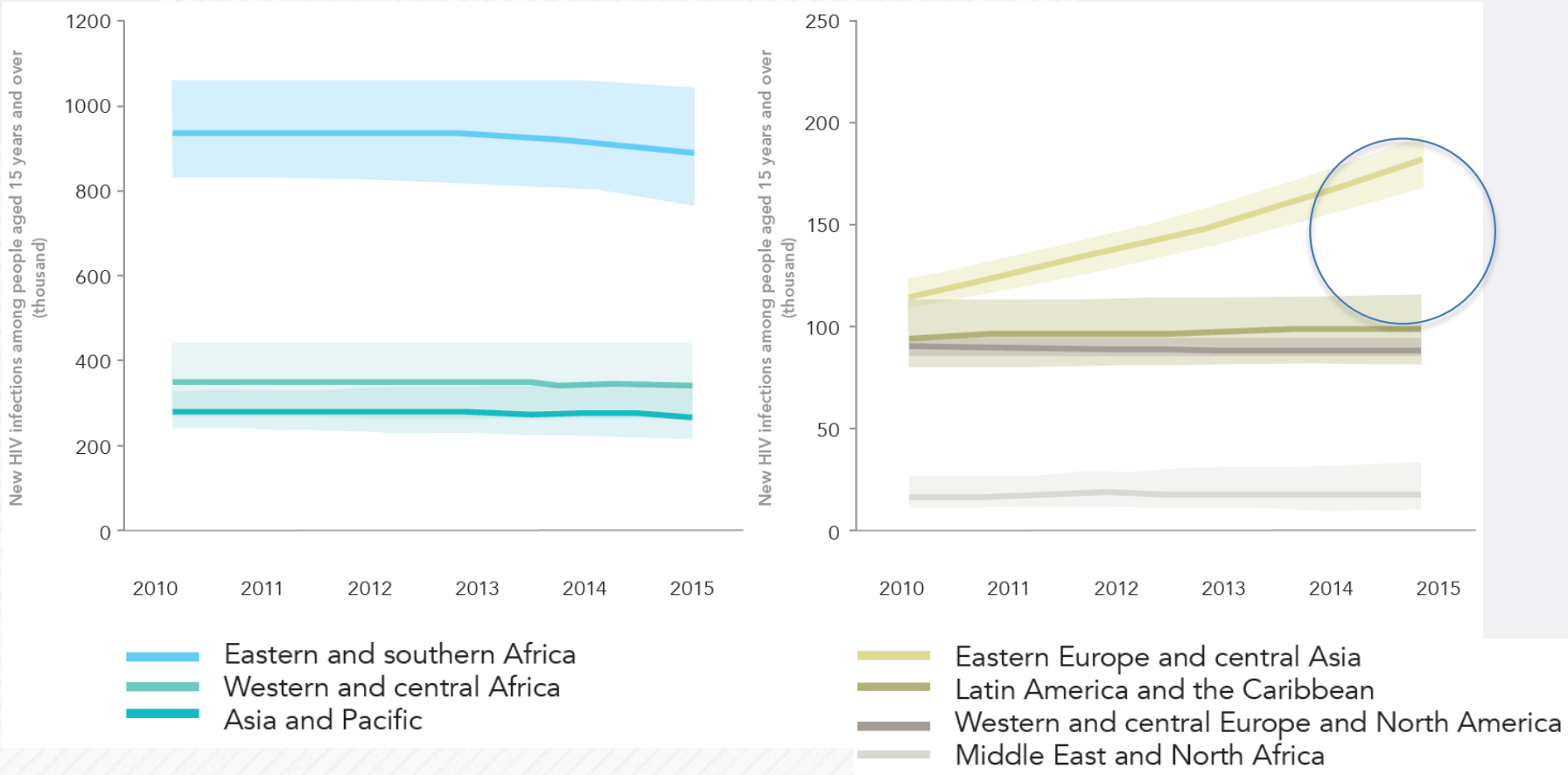




Antiretroviral therapy coverage and number of AIDS-related deaths, global, 2000–2015



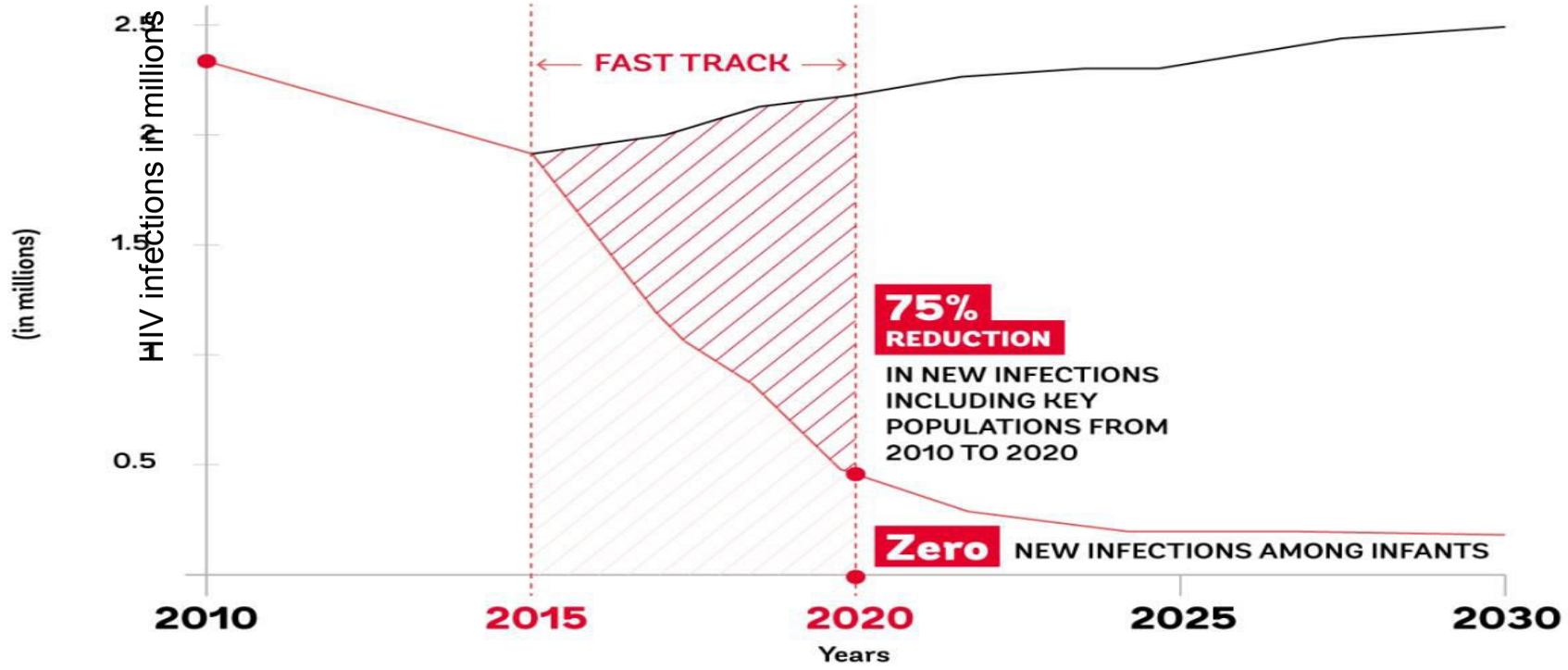
New HIV infections among people aged 15 years and over, by region, 2010–2015



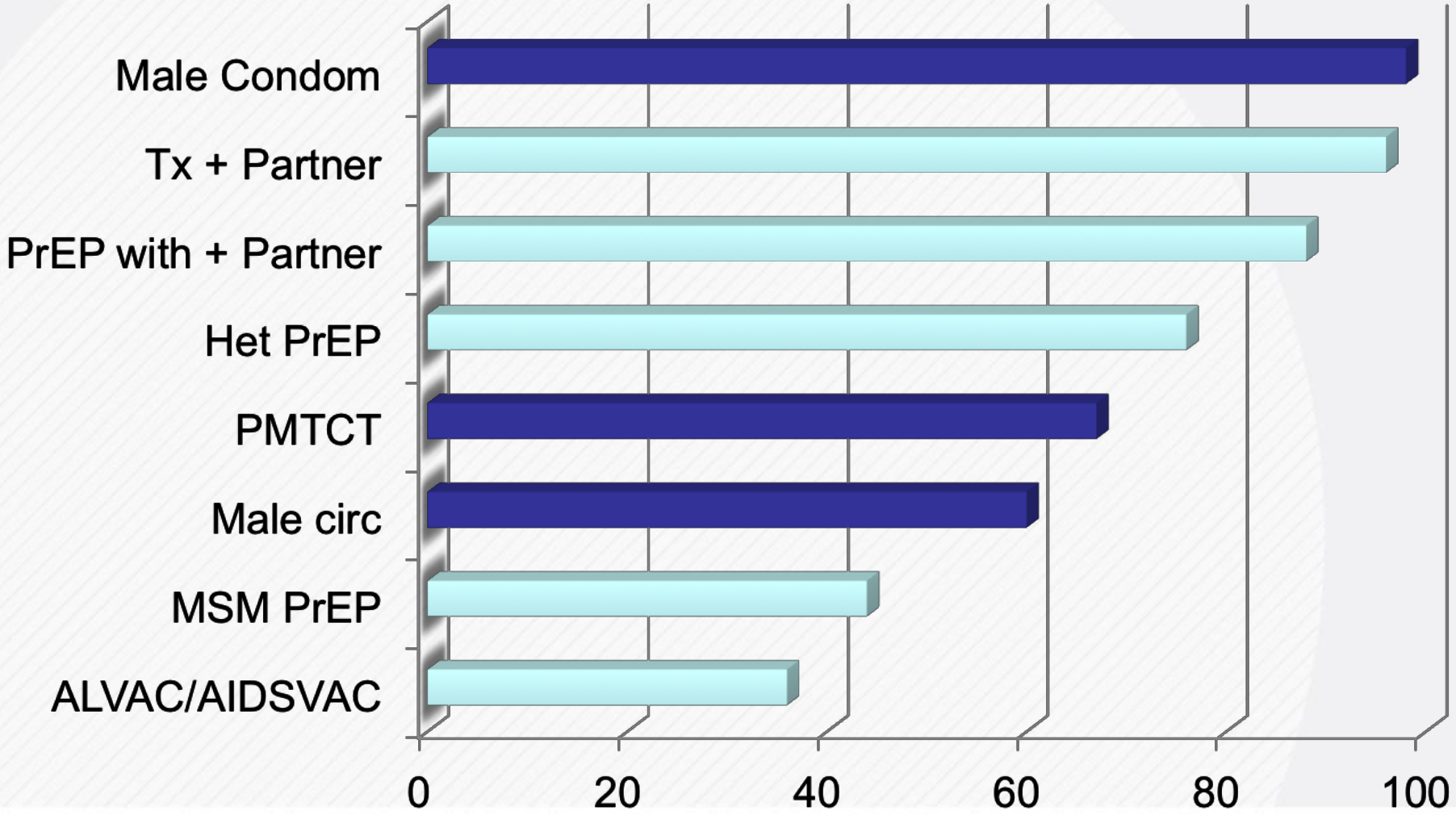
Source: UNAIDS 2016

HIV incidence is declining but very limited

HIV impact targets, maintaining coverage or fast track coverage



Efficacy in HIV Prevention Interventions (2013)



Medical male circumcision for HIV prevention

HIV prevention research:
- Observational data
- Global consensus to conduct RCTs

Implementation in priority countries of eastern & southern Africa

UNAIDS and WHO Global Recommendations

1989 | 2000 | 2005 - 2006 | 2007 | 2007 - today

Kenya, Uganda, South Africa randomized control trials

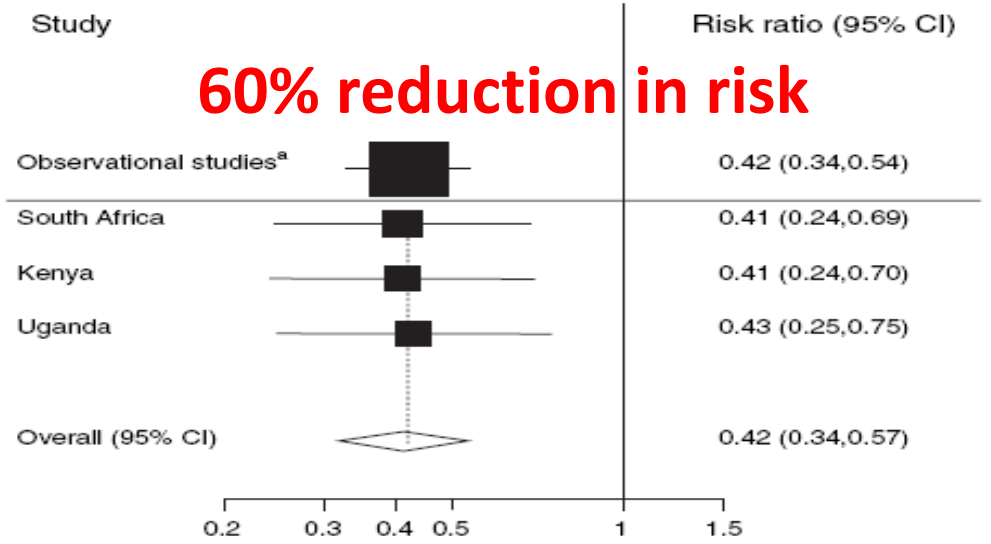
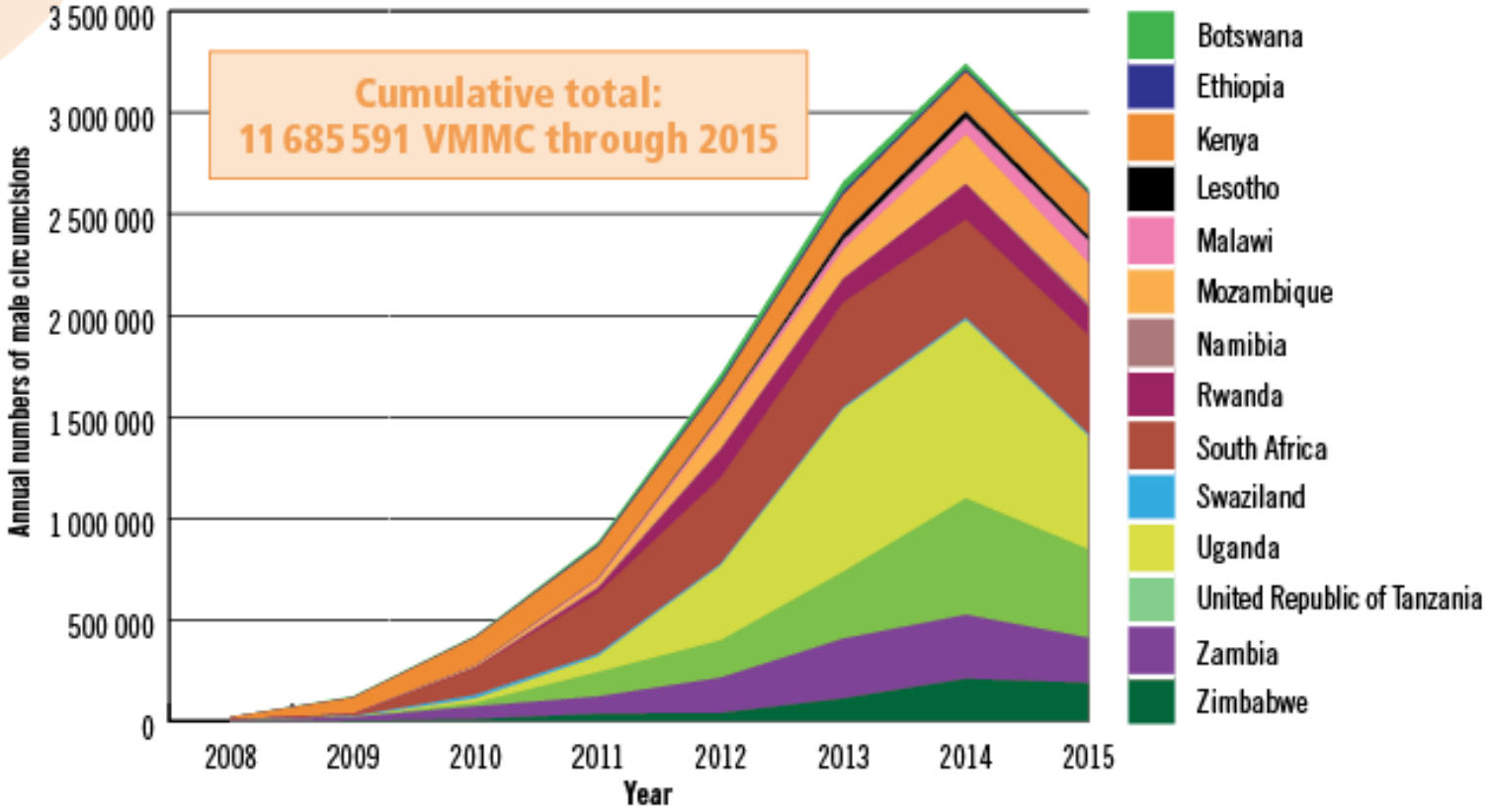


Figure. Annual number of voluntary medical male circumcisions performed for HIV prevention in 14 countries in East and Southern Africa, 2008–2015



Impact

- these 11.7 million MC estimated to avert 335 000 HIV infections by 2025; half a million by 2030
- in HIV incidence reduction shown in Rakai Uganda and Orange Farm South Africa

Table. Key features of 15 cases of tetanus after voluntary medical male circumcision reported to the World Health Organization from 2012 to 2016

Procedure date	Country	Procedure method	Age, years	Days to symptoms	Days to diagnosis	Days to death	Circumcision wound	Unclean substance applied to wound	Alternate exposure route on body
May 2016	Rwanda	Device	18	9	10	18	Clean	No	Possibly
Mar 2016	Rwanda	Device	34	8	11	12	Clean	Unknown	No
Sep 2015	Rwanda	Device	39	Unk	14	n/a	Clean	Unconfirmed	Yes
Sep 2015	U.R. Tanzania	Surgery	13	7	15	tbc	Unk	Yes	Yes
Mar 2015	Uganda	Surgery	19	10	12	Unknown	Clean	Unknown	No
Mar 2015	Uganda	Surgery	11	7	10	12	Septic	Yes	No
Nov 2014	United Republic of Tanzania	Surgery	18	11	16	35	Septic	Yes	Unknown
Sep 2014	Uganda	Device	32	7	8	14	Septic	Unknown	Unknown
Sep 2014	Uganda	Surgery	11	11	12	17	Septic	Yes	Yes
Aug 2014	Kenya	Surgery	15	11	11	13	Septic	Yes	No
Aug 2014	Uganda	Device	19	11	12	14	Septic	Unknown	Unknown
May 2014	Rwanda	Device	47	12	12	n/a	Clean	Unconfirmed	Yes
Jun 2013	Uganda	Surgery	18	8	15	n/a	Clean	Unknown	Yes
Dec 2012	Zambia	Surgery	12	5	8	9	Septic	Yes	No
Apr 2012	Zambia	Surgery	16	12	12	n/a	Septic	Unknown	No

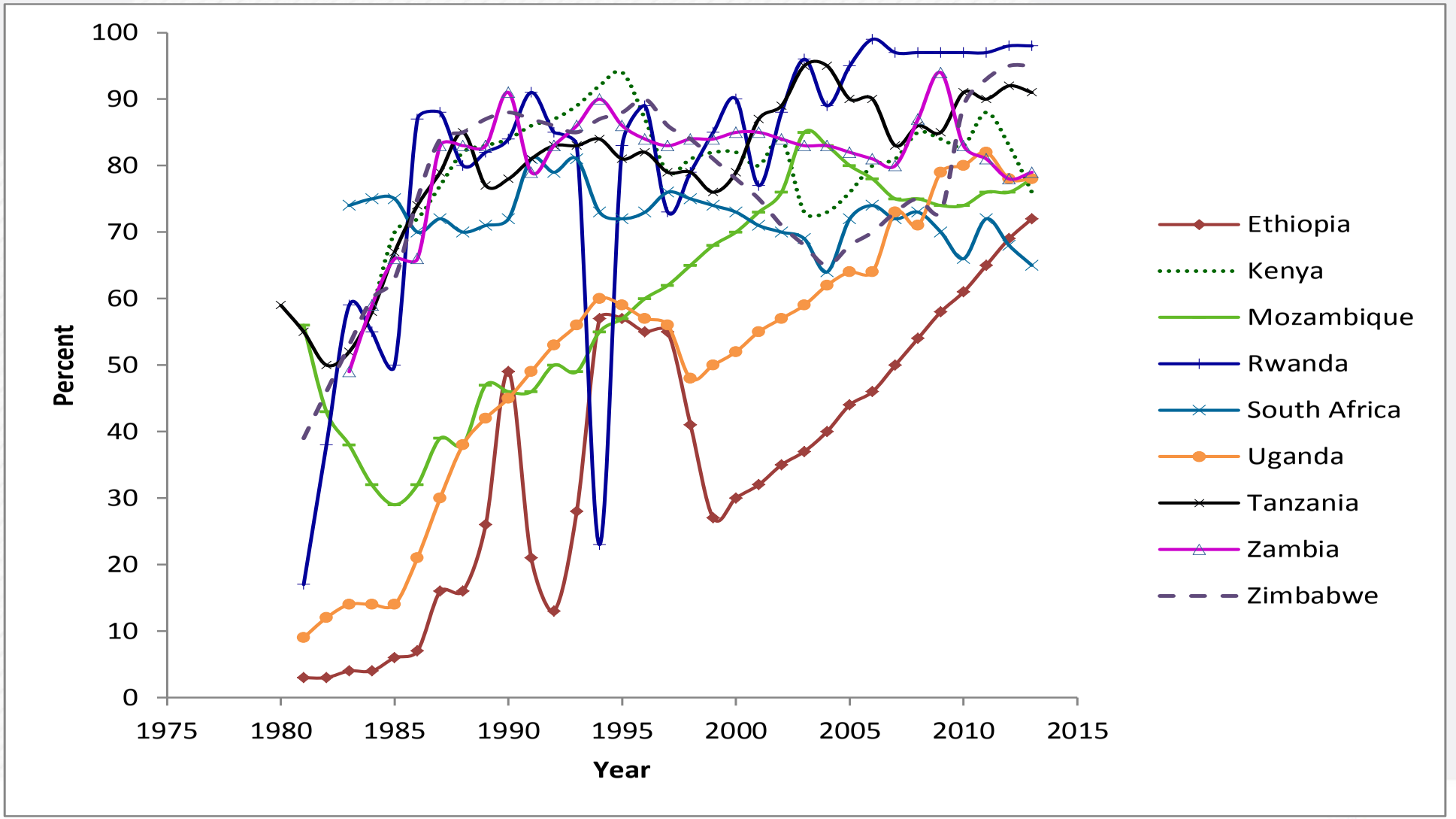
Additional points -- Uganda, Indonesia

- Background rates
  - Inpatient non-neonatal rate of 3 / 100 000 males
  - Outpatient NN rate of 8.6 / 100 000 males
    - risk of tetanus following circumcision is restricted to an approximate one month period
    - the relevant background comparison is tetanus incidence per month, not year, or 0.25 inpatient cases / 100 000 months, 0.71 outpatient cases /100 000 months
    - Method differences
- Zziwa, 2009: St Francis Hospital Buluba Uganda, record review
  - 154 cases during 2005-2008: 66% males, 66% > 5 years, CFR 47%
  - Among 71 cases in 2007-8:
    - 87% lower extremity wounds
    - Cause 17% jiggers – unknown 52%
- HCMC VietNam, 80% admissions males
- Papua Indonesia interested in VMMC, TTCV rates appear low

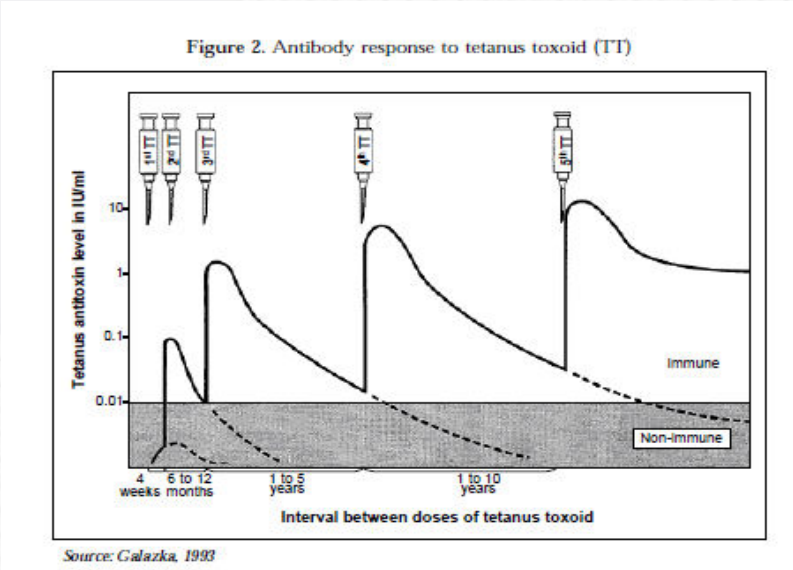
Summary of hospital studies of non-neonatal tetanus in sub-Saharan Africa published 2003-2014 – 71% males, 32.7 years

Year	Author	Country	Study Period	Population	Sample Size	Mean/Median Age (yrs)	Male (%)	Case Fatality Rate (%)
2014	Sawe et al.[24]	Tanzania	2009-2011	ICU admissions at 4 tertiary hospitals	5627			71
2013	Muteya et al.[25]	DR Congo	2005-2009	All tetanus admissions		39.38	95.5	52.4
2013	Traore et al.[26]	Guinea	2001-2012	Tetanus cases all hospitals in Conakry	8,649		73	75
2012	Oshinaike et al.[27]	Nigeria	2006-2011	Tetanus admissions >10 years	176		75	56.2
2012	Bankole et al.[28]	Nigeria	2000 -2009	Adult tetanus admissions	78,009	30.4	75	16.3
2012	Amare et al.[29]	Ethiopia	2001-2009	Tetanus admissions ≥13 years	68	33.8	77.9	35.3
2012	Minta et al.[30]	Mali	2004-2009	Tetanus admissions ≥15 years	1,839			46.2
2012	Aba et al.[31]	Cote d'Ivoire	2003-2008	Surgical tetanus cases	29	36		45
2011	Amare et al.[32]	Ethiopia	1996-2009	Tetanus admissions ≥13 years	171	33	75.4	38
2011	Ugwu & Ugwu[33]	Nigeria	1999-2008	Children after intramuscular injection	175		60	80
2010	Akhuwa et al.[34]	Nigeria	2005-2008	Post-neonatal tetanus cases	18	5.83	77	5.9
2010	Fawibe et al.[35]	Nigeria		Adult tetanus admissions	35	33		57
2009	Tadesse et al.[36]	Ethiopia	2003-2008	Adult tetanus admissions	29	35	65.5	41.4
2009	Dao et al.[37]	Mali	2001-2004	All tetanus admissions	54	39	69	38.9
2009	Zziwa et al.[38]	Uganda	2005-2008	All tetanus admissions	25,118	13.5	66	47
2009	Chukwubike et al.[39]	Nigeria	1996-2005	Tetanus admissions ≥16 years	86		58.1	42.9
2009	Ajose & Odusanya[40]	Nigeria		Adult tetanus admissions	164			70.1
2008	Towey and Ojara[41]	Uganda	2005-2006	All ICU admissions	218			47
2008	Soumare et al.[42]	Senegal	1999-2006	Post-circumcision tetanus at ID clinic	1,291	9	NA	7.4
2008	Onwuekwe et al.[43]	Nigeria	1999-2003	All tetanus admissions	12	29	58	0
2007	Komolafe et al.[44]	Nigeria	1995-2004	Adult tetanus admissions	79		70. 9	45
2007	Sanya et al.[45]	Nigeria	1990-2001	Adult tetanus admissions	202	36	68	64
2006	Melaku et al.[46]	Ethiopia	1985-2000	All tetanus admissions	3,548	37.1	58.3	
2005	Ndour et al.[47]	Senegal	1999-2002	Tetanus after intramuscular injection	46	34.5		60.8
2005	Amsalu et al.[48]	Ethiopia	1989-1998	Children with tetanus diagnosis	113	9		31.4
2005	Soumare et al.[49]	Senegal	Mar-Sept 2002	Children aged 1-15 with tetanus	40	8.8	75	8
2005	Soumare et al.[50]	Senegal	Sept-Dec 2002	Tetanus admissions >4 years	30	36	70	26.7
2005	Ojini & Danesi[51]	Nigeria	1990-1999	Tetanus admissions ≥10 years	349	29.8	66	36.96
2005	Seydi et al.[52]	Senegal	2001-2003	Tetanus admissions >28 days old	410	20	70.7	22
2005	Mchembe & Mwafongo[53]	Tanzania	2004	Tetanus admissions		20-40	91	72.7
2004	Tanon et al.[54]	Cote d'Ivoire	1985-1998	All tetanus admissions	1,870	28	71	31.9
2003	Hesse et al.[55]	Ghana	1994-2001	All tetanus admissions	158	32.7	76.6	50

Diphtheria-Tetanus-Pertussis dose 3 (DTP3) immunization coverage in 9 of the African countries implementing voluntary medical male circumcision



Generation of short term protection (relevant for recommendations pre-male circumcision)



- Booster response in a primed individual (at least one dose in past)
  - Time since last dose not relevant as booster response is elicited many decades after last dose (common feature of inactivated vaccines)
  - Age (adolescent versus adult) not relevant
  - Kinetics suggest booster dose should be given at least 7 days before procedure but ideally 14 days before
  - One booster dose sufficient
- Primary response in a vaccine-naïve individual
  - Single priming dose inadequate
  - Two doses 4 weeks apart needed
- No herd immunity

Natural immunity to tetanus?

- Recovery from disease does not reliably produce protective antibodies
- Some claim natural immunity can be acquired via asymptomatic colonisation of gut to explain antibodies detected in unvaccinated individuals but
  - lack of prior vaccination not confirmed in these individuals or
  - Non-specific in vitro assay used
- Safer to assume that there is no background of naturally-acquired immunity
- Also no herd immunity as infection is not spread human to human

Quote from tetanus module 3 2006

- *Studies in African schoolchildren (Rey, 1981), Indian military recruits (Menon et al. 1976), persons taking care of horses (Lahiri, 1939), pregnant women in New Guinea (MacLennan et al. 1965), and healthy persons in Upper Volta (Breman et al. 1981), have demonstrated that populations in developing countries with a high level of exposure to tetanus spores usually lack tetanus neutralizing antitoxins. Even if asymptomatic colonization and infection of the intestine with tetanus organisms occurs in some areas of the developing world, natural immunity is not thought to have any practical importance in controlling tetanus.*

Recommendations from consultation in 2015 and 2016

A dual approach: TTCV and clean care

- **For conventional surgical methods of male circumcision, the experts recommended that no modification** the strategies used will depend on the country's TTCV schedule and practices, and its tetanus burden. Ministries of health are advised to develop and phase in effective and practical delivery strategies for providing at least one dose of TTCV at the time of voluntary medical male circumcision (VMMC), unless an individual has documented evidence of protection through receipt of the necessary number of doses of TTCV.
- **For circumcision with a device method that requires that the foreskin remains in situ for several days before it is removed, the June 2016 consultation updated its previous advice:** should only be undertaken if the client is adequately protected against tetanus by immunization with TTCV. Based on WHO 2006 recommended vaccination schedule
  - two TTCV doses at least 4 weeks apart, with the second dose at least 2 weeks before device placement; or
  - b) if a client has previously received three infant doses, or one dose during adolescence or adulthood, a booster at the time of device placement (this must be given at least 2 weeks before placement); or
  - c) a series of five doses of TTCV.
- Need to strengthen efforts to **better educate** all MC clients, their parents/care givers (in case of adolescents), communities, traditional healers **on importance of avoiding harmful wound-care practices**. This applies to all male circumcision methods.
- Principles of IPC for skin preparation must be applied for all methods.
- Work closely with immunization programmes

Rapid (point of care) antibody test

- Marketed as ProTetanus in UK, TQS in rest of Europe and SD BIOLINE Tetanus in Korea
- Detection threshold 0.1 IU/mL for serum or 0.2 IU/mL if whole blood

http://webarchive.nationalarchives.gov.uk/20141205150130/http://www.mhra.gov.uk/Publications/Postersandleaflets/CON008382

MHRA guidelines on point of care testing

http://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CCEQFjAA&url=http%3A%2F%2Fnhscep.usecnnect.co.uk%2FShowDocument.ashx%3Fid%3D451%26i%3Dtrue&ei=ogP-VJWJNMPiU9eqgqgP&usg=AFQjCNF5e7H1cyUcJwj-O-juThCXMUme3Q&bvm=bv.87611401,d.bGQ

- Reviewed by NHS Purchasing and Supply Agency in 2010 (report at above web address) for assessing need for HTIG and booster dose in A&E
- Potential use in relation to MC
  - Serosurveys of susceptibility in target population (high specificity and sensitivity needed to produce meaningful results)
  - Pre-MC screening (high specificity needed to avoid false positives)

Test performance: conclusions of NHS review

- More effective at determining a patient's immune status than history
- Specificity high (estimates ranged from 94-100% using ELISA at 0.1IU/mL as "gold standard")
- Sensitivity low (estimates ranged from 55-83%)

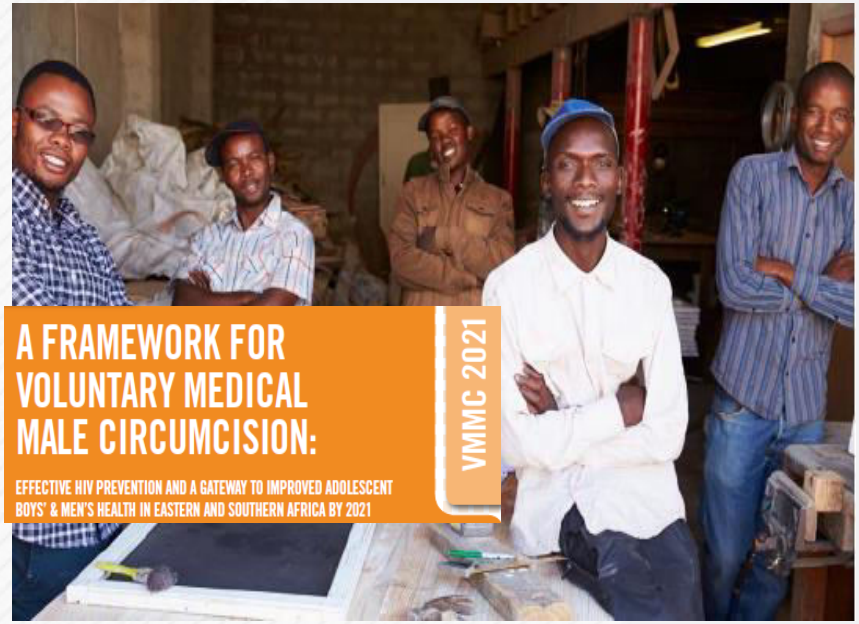
Thus, test could be useful for identifying non-immune subjects but not useful for serosurveys.

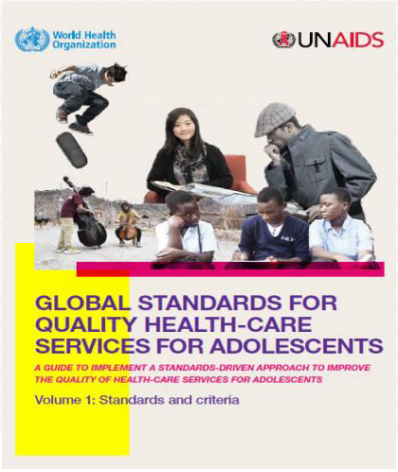
Key issues on implementation in the 14 countries of ESA

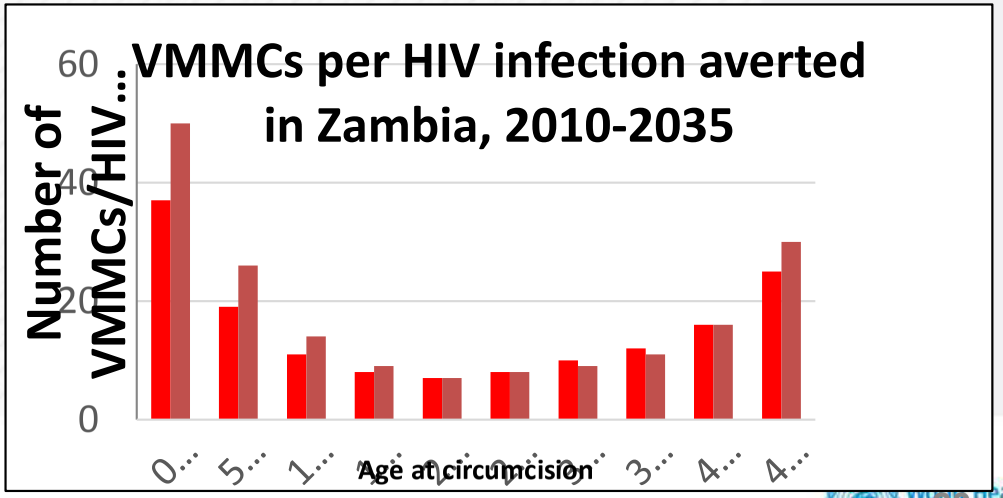
- Vaccination policy:
  - Policy for boys and men after infancy limited
    - reported policy to provide booster doses only in South Africa (6 and 12 years); Zimbabwe (18 months)
- Practice: coverage of school and booster age unknown
- Reporting tetanus
  - Only Uganda reports non-neonatal tetanus – reporting accuacy?
  - Safety monitoring within VMMC / programmes
- Resources
  - Reported stock out in Rakai Uganda during pilot to implement 2 doses
  - Funding – HIV or vaccine programmes?
- Other options: use of POC ?
- Immediate and longer term perspectives:
  - VMMC platform, routine vaccination for adolescents

Adolescents are in need of multiple services_ HIV/AIDS, vaccination (HPV, TTCV), other

Source: UNICEF AllIn To end Adolescent AIDS







Strategies and synergies by providing multiple services

- Gender gap in TTCV for males
- VMMC Platform – reaching adolescent and adult men
  - Short term – dual approach to protection
    - Clean care – skin prep and wound care -- especially adolescents?
    - Surgical, phase in one dose at time of MC, country context
    - Compression device method: 2 doses of TTCV unless evidence of vaccination
  - Role for POC, uniject?
- Longer term
  - Routinize 5 - 7 year dose
  - School and adolescents doses for boys and girls
  - Adolescents in need of integrated package of relevant services