Malaria Vaccine Implementation Programme

Current status in the 3 pilot countries: Ghana, Kenya, Malawi

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SAGE meeting
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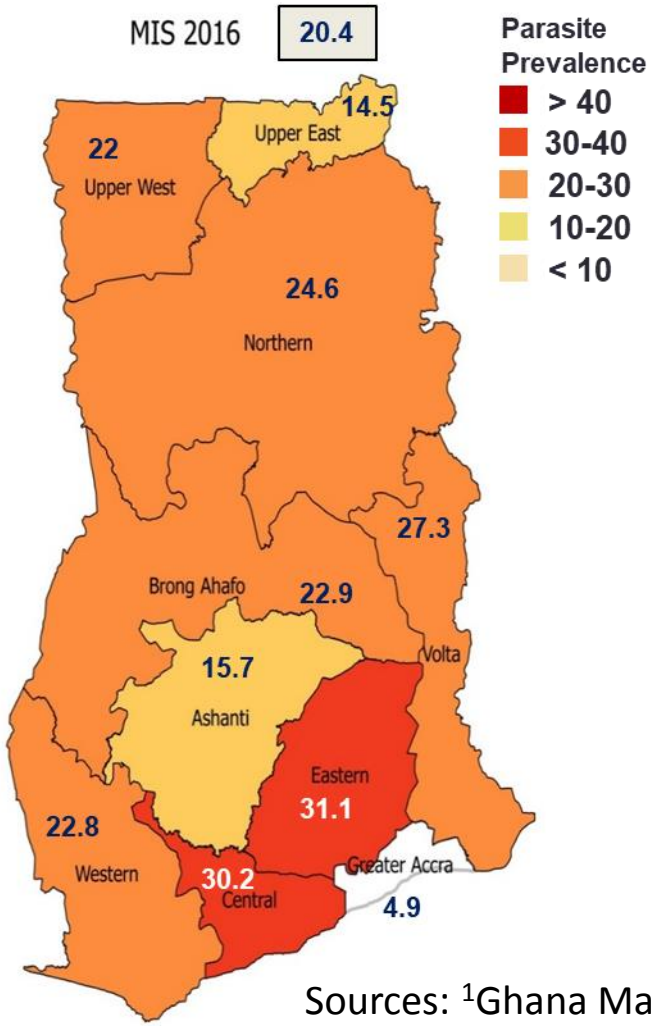
Outline

- Malaria burden
- Immunization and malaria programmes
- Progress of MVIP to date
- Next steps

Malaria burden - Ghana

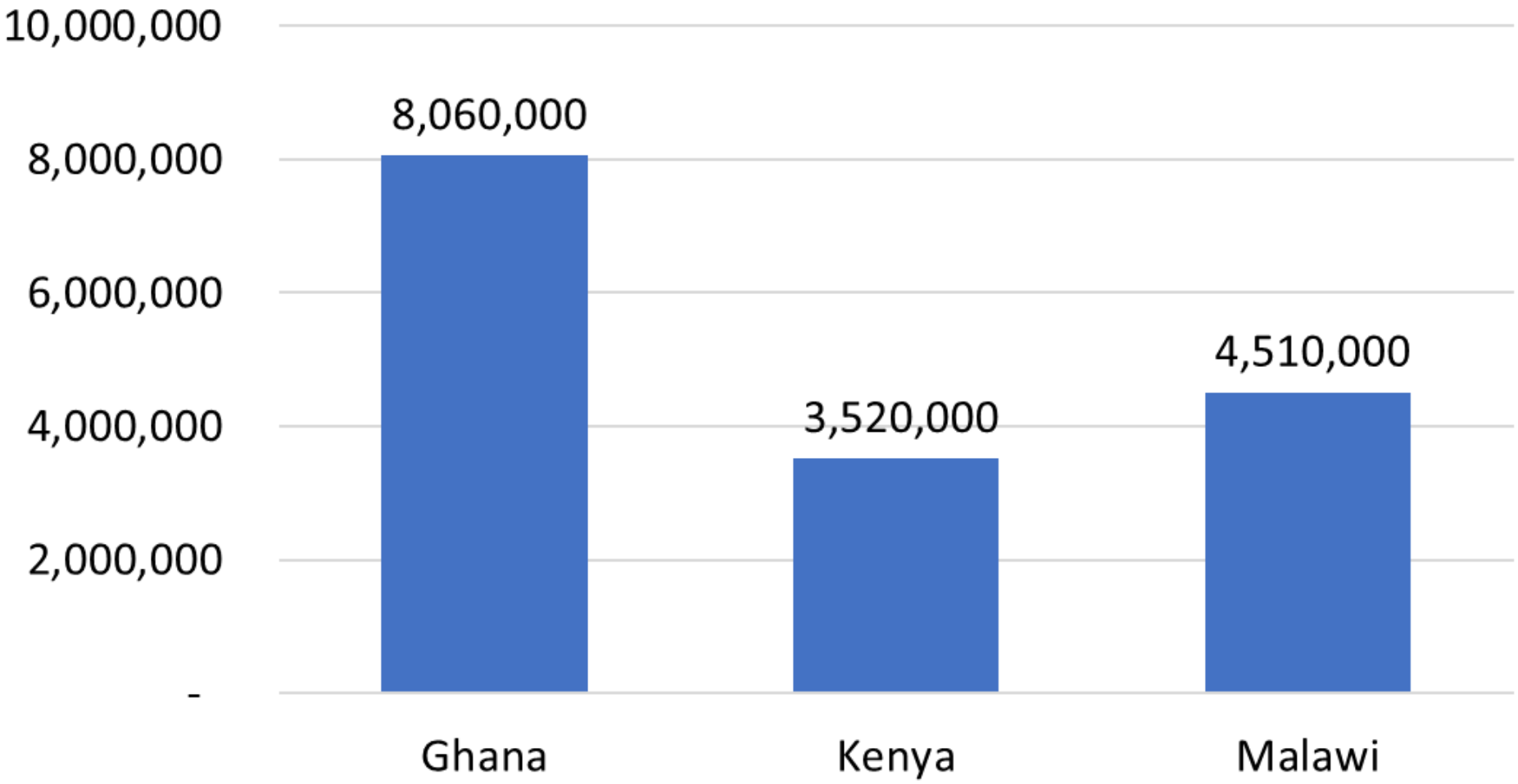
Malaria Parasite Prevalence among children 6-59 months in Ghana 2016[1]



- Progress has been made, but parasite prevalence remains high (20.4% in 2016)[1]
- Estimated 8 million malaria cases and >12,000 deaths in 2016[2]
- Major cause of hospital attendance, contributing to an estimated 30% of admissions[3]

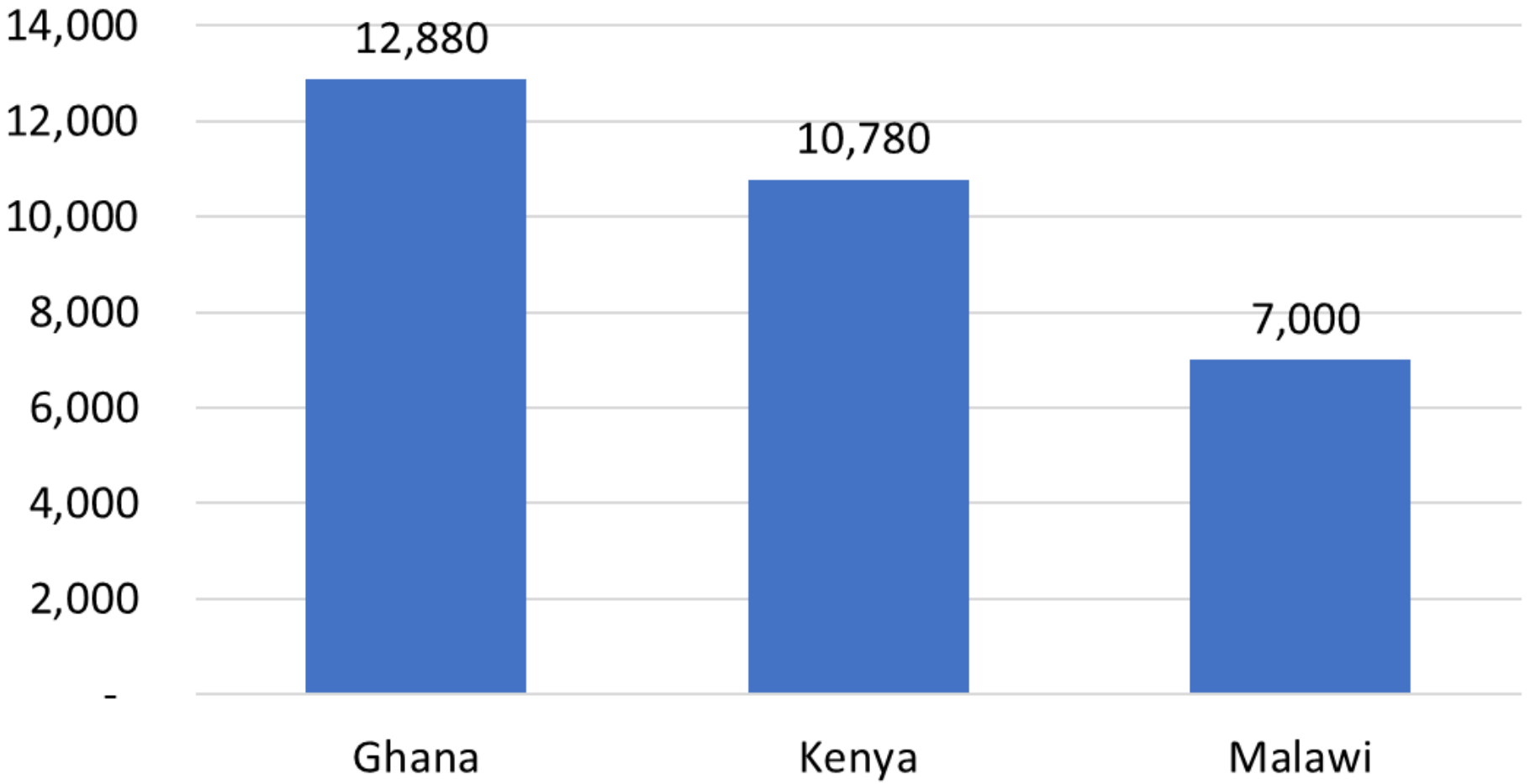
Sources: [1]Ghana Malaria Indicator Survey 2016; [2]World Malaria Report 2017; [3]Ghana DHIMS2, 2015

High malaria burden in 3 pilot countries, Estimated malaria cases, 2016



Source: World Malaria Report 2017

High malaria burden in 3 pilot countries, Estimated malaria deaths, 2016



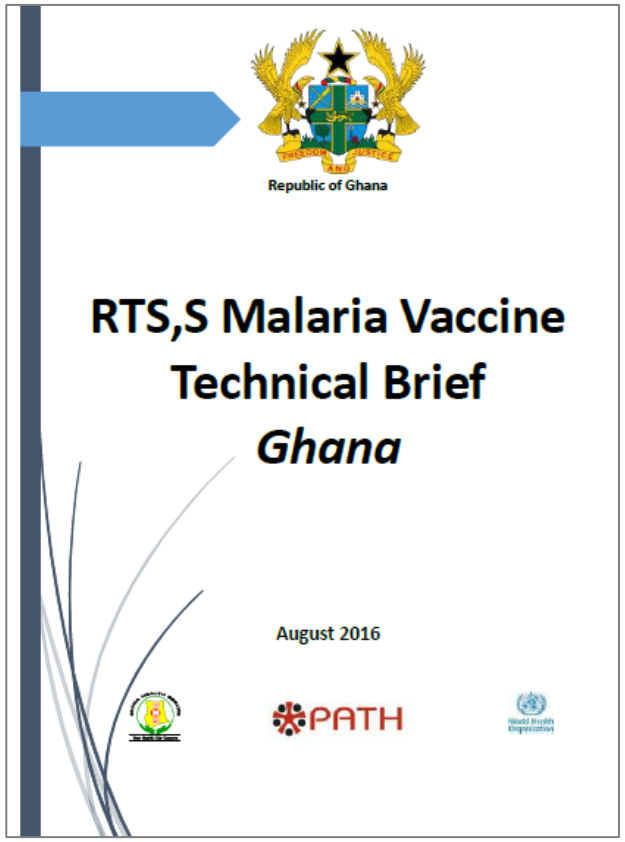
Source: World Malaria Report 2017

In the setting of good malaria control efforts and strong programmes

Indicator	Ghana[1]	Kenya[2]	Malawi[3]
Insecticide-treated mosquito nets: % of children under 5 who slept under an ITN last night	52%	54%	68%
Chemoprevention: % of pregnant women who have access to and receive three or more doses of intermittent preventive treatment (IPTp)	60%	38%	43%
Indoor Residual Spraying: % of households sprayed by IRS within last 12 months	90% in selected districts	98% in Migori county	N/A

Sources: [1]Ghana Malaria Indicator Survey 2016 and Post-spray survey report 2017; [2]Kenya MIS 2015 and Post-spray survey report 2017, [3]Malawi MIS 2017

Country decision-making to take part in MVIP



- **2009:** Malaria Vaccine Technical Working Group (TWG) established
- **2015/2016:** RTS,S/AS01 malaria vaccine technical brief prepared by TWG, summarizing data and information to support informed decision-making for participation in the MVIP based on EMA positive opinion & WHO position
- **January 2016:** MOH submitted an expression of interest to participate in MVIP
- **April 2017:** Country selection announcements made

Ghana Technical Brief is accessible at:
http://www.ghanahealthservice.org/malaria/category.php?nmcpcid=86

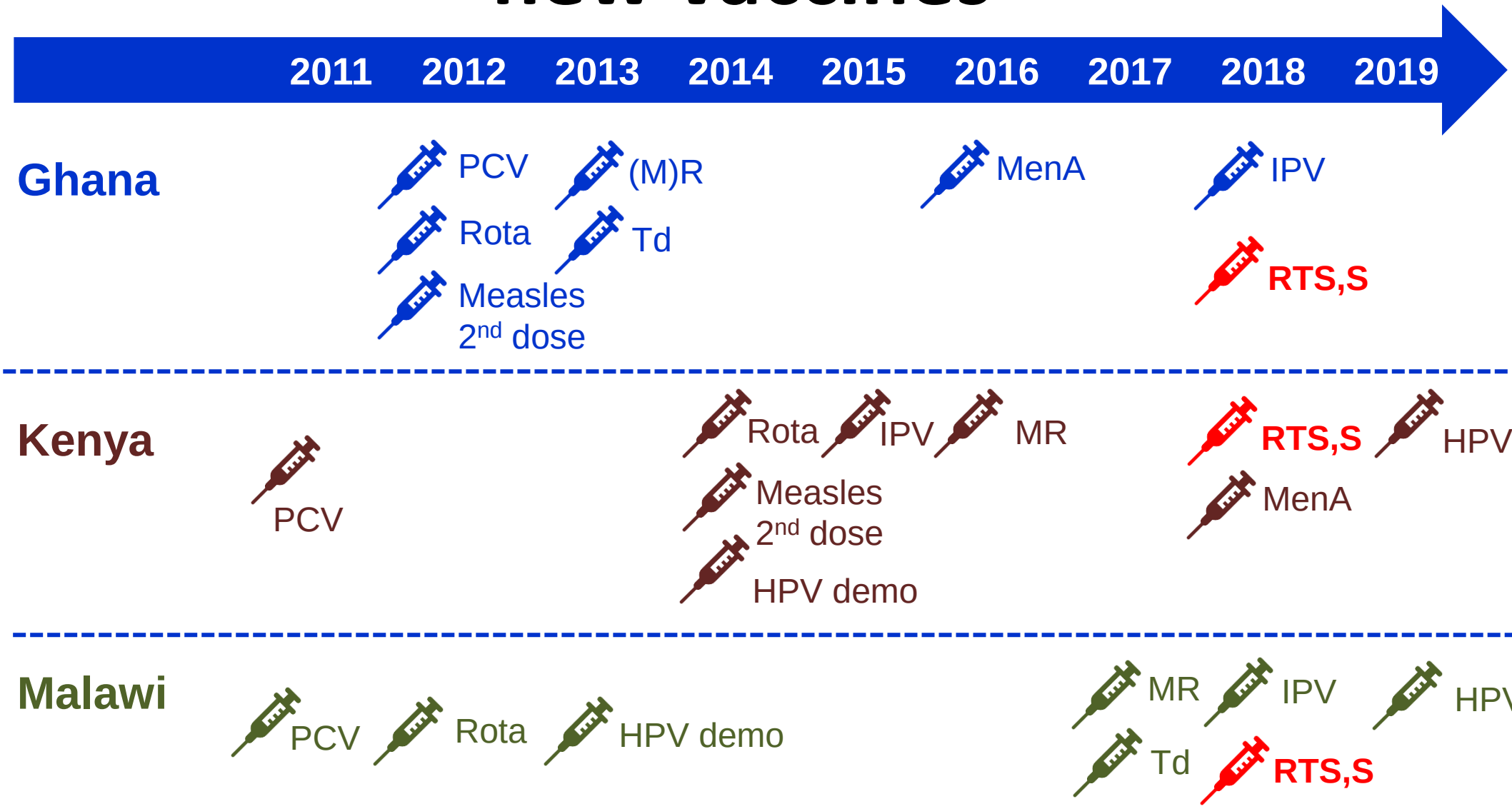
Building on strong immunization programmes…

Vaccine coverage estimates for 2016 (2015)*

	Ghana	Kenya	Malawi
DTP-HepB-Hib *First dose, at 6 weeks*	**94%** (97%)	**96%** (96%)	**89%** (93%)
DTP-HepB-Hib *Third dose, at 14 weeks*	**93%** (88%)	**89%** (89%)	**84%** (88%)
Measles *First dose, at 9 months*	**89%** (89%)	**75%** (75%)	**81%** (87%)
Measles *Second dose, at 15-18 months*	**75%** (63%)	**32%** (28%)	**61%** (8%)

*according to WHO/UNICEF coverage estimates, as of 15 July 2017

…with experience introducing new vaccines



Malaria Vaccine Implementation Programme Scope

- Approximately 120,000 children per year in each country will have the opportunity to receive RTS,S with vaccination continuing for at least 30 months
  - ➢ Vaccine introduction led by the immunization programmes
- Introduction will be accompanied by evaluations to determine the public health role of the vaccine:
  - Operational feasibility of administering 4 vaccine doses in the context of health service delivery
  - Impact on severe malaria and mortality
  - Consolidate safety profile, with emphasis on meningitis and cerebral malaria
  - ➢ Evaluations led by independent evaluation partners

Progress to date

- **Joint regulatory review by national regulatory authorities facilitated by AVAREF in Feb 2018**
  - Response on authorization for use expected by May 2018
- **Development of vaccine introduction plans, led by EPI in collaboration with malaria control programme and partners, focussing on:**
  - Vaccine supply, logistics, cold chain, …
  - Service delivery, schedule, training, …
  - Monitoring, reporting tools, …
  - Advocacy, social mobilization and communications, …
  - Strengthening of AEFI reporting and monitoring, …

Progress to date

- **Country-based evaluation partners identified by WHO through Request for Proposal process**
  - Master protocol approved by WHO Research Ethics Review Committee in Feb 2018
  - Country-specific protocols to be developed by evaluation partners in coming months
  - Identification of 6-8 sentinel hospitals per country to capture data on potential safety signals and impact on severe malaria ongoing
- **Evaluation partners for qualitative dynamics of health care utilization study (led by PATH) identified**

Integrating RTS,S into the EPI schedule

WHO position[1]: A 4-dose schedule is required, with the first dose given as soon as possible after 5 months of age, doses 2 and 3 given at monthly intervals, and the fourth dose given 15–18 months after the third dose .

Example: Ghana vaccination schedule

Age / Vaccine	Birth	6 weeks	10 weeks	14 weeks	5 mo	6 mo	7 mo	9 mo	12 mo	18 mo	22 mo	24 mo
BCG	X											
OPV	X											
DPT-HepB-Hib (penta)		X	X	X								
Pneumococcal CV		X	X	X								
Rotavirus		X	X									
Inactivated Polio				X								
MenA										X		
Measles-Rubella								X		X*		
Yellow Fever								X				
Vitamin A						X			X	X		X
RTS,S Ghana						X	X	X				X
RTS,S Kenya						X	X	X				X
RTS,S Malawi					X	X	X				X	

Opportunities

- Additional visits for RTS,S in the first and second year of life present opportunities to catch up children who missed earlier EPI vaccine doses, including those administered in second year of life (including second measles dose)
- Additional visits may also present opportunities to reach children and caregivers with other health interventions (such as Vitamin A, growth monitoring, deworming, etc.)

Status of countries PV readiness (GACVS recommended indicators)

As of April 2018

Criteria	Ghana	Kenya	Malawi
AEFI surveillance indicator (min 10 AEFI reports per 100,000 surviving infants)	✓	●	✓
Functional AEFI review committee	✓	●	✓
Trained and resourced AEFI investigation teams	▲	●	▲
Safety communication plans evaluated and tested	✓	▲	▲
Focal person for vaccine safety within EPI	✓	✓	✓
Active AESI surveillance in place	●	●	●

Communication – a high priority

- Information on vaccine benefits and risks
- Partial protection
  - A child who receives the vaccine may still get malaria
  - Need to continue to use other malaria control measures and seek health care promptly in case of fever
- Importance of child receiving all 4 doses
- Initial introduction of vaccine will be only in a sub-set of high burden areas
- Communication plans, engagement strategies and IEC materials currently being developed

Next steps

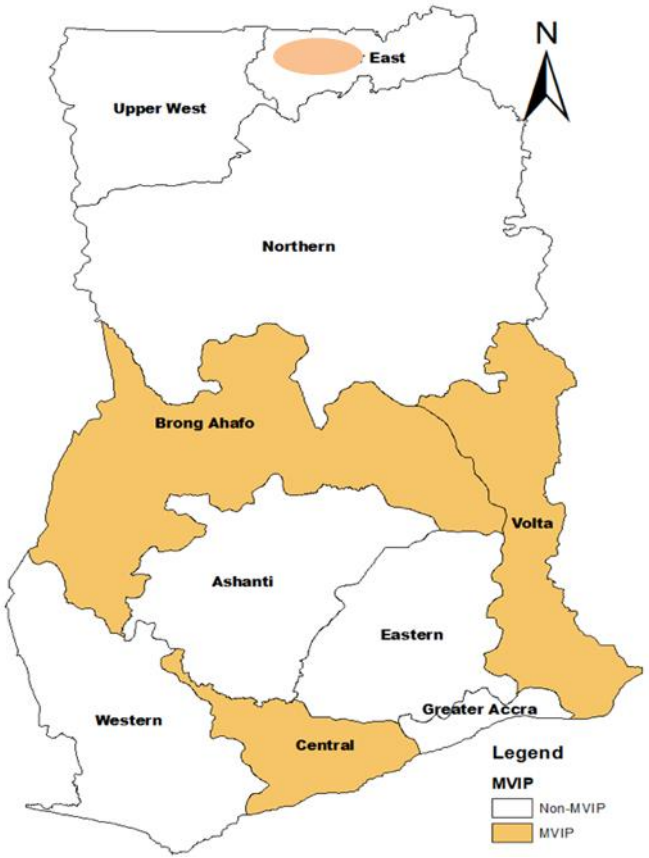
- Random assignment of areas where vaccine will be introduced vs. comparator areas
- Implementation of introduction plan activities:
  - Finalize communication plans
  - Finalize IEC materials, continue stakeholder sensitization and engagement
  - Training of health workers
  - Modify monitoring and supervisory tools to include RTS,S
  - Upgrade cold chain, where necessary
  - Continue to strengthen pharmacovigilance
  - Evaluation partners to develop protocols, standard operating procedures and training materials
- Launch vaccine introduction – late 2018

THANK YOU

Back-up

Selection of pilot areas within each country

Driven by national processes



Considerations:

- Malaria parasite prevalence > 20% (high burden despite good use of malaria control interventions)
- Vaccination and malaria control programme performance
- High infant / child mortality
- Respresentation of different malaria ecological zones / Rural - urban mix
- Number of districts/sub-counties (to serve as unit of randomization)