Malaria Vaccine Pilot Implementation and Long-term Supply

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World Health Organization

Lusitana
Vaccinated in Malawi on 23 April 2019

Abigail Blessing
Vaccinated in Ghana on 30 April 2019

Elian
Vaccinated in Kenya on 13 Sept 2019

Progress has stalled, new tools are needed

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Current prevention tools[1]

Insecticide-treated mosquito nets (ITNs)

- **45%** reduction in uncomplicated malaria
- **50%** population sleeping under an ITN

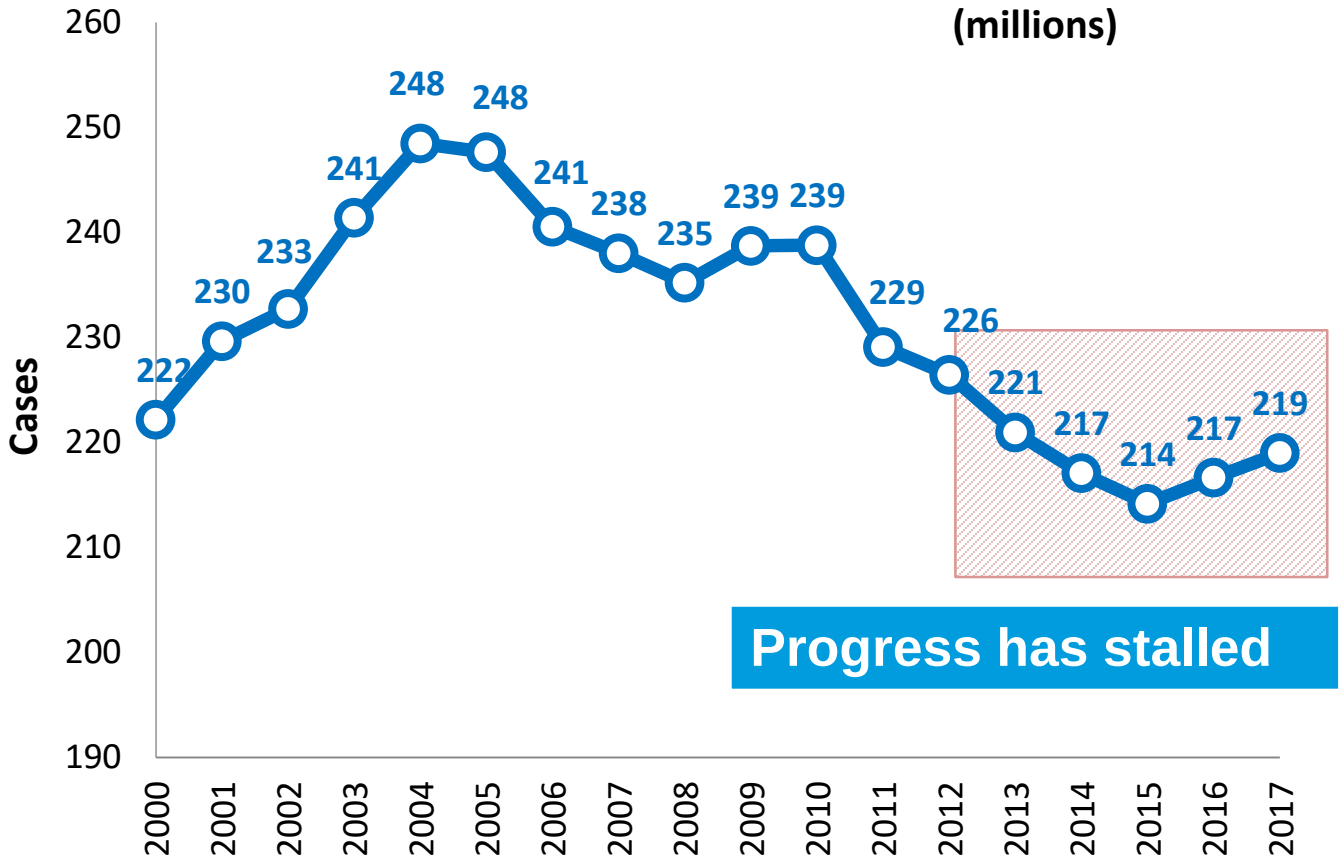
Indoor residual spraying

- **14%** reduction in uncomplicated malaria
- **6.6%** population at risk protected

Intermittent preventive treatment (IPT)[2]

- **74%** reduction in uncomplicated malaria
- **12** countries implemented with 53% of eligible children treated

Number of malaria cases worldwide



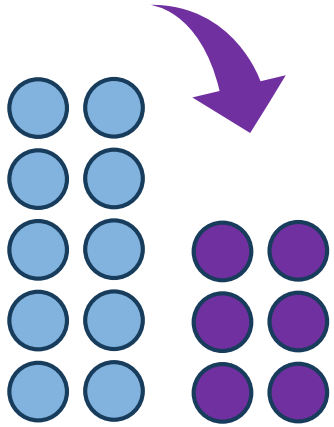
[1] Coverage numbers for Africa in 2017; [2] Numbers shown for Seasonal Malaria Chemoprevention, previously referred to as IPTc.
Source: World Health Organization. *World Malaria Report*, 2018; Cochrane Database Syst Rev. 2018;(11)CD000363; Cochrane Database Syst Rev. 2010;(4)CD006657; Cochrane Database Syst Rev. 2012;(2)CD003756; *The Lancet* 374.9700 (2009): 1533-1542

RTS,S/ AS01: proven efficacy, potential for high impact

Reduction of key outcomes in children receiving four doses of RTS,S, in comparison with those who did not receive RTS,S

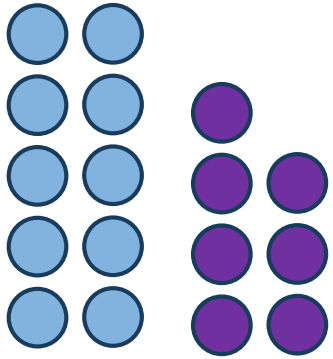
Clinical malaria

39% reduction



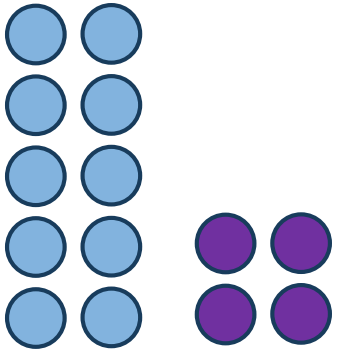
Severe malaria

29% reduction



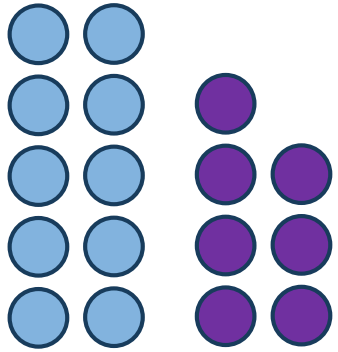
Severe malaria anaemia

61% reduction



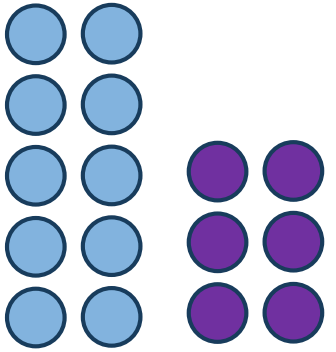
Need for blood transfusion

29% reduction



Malaria hospitalization

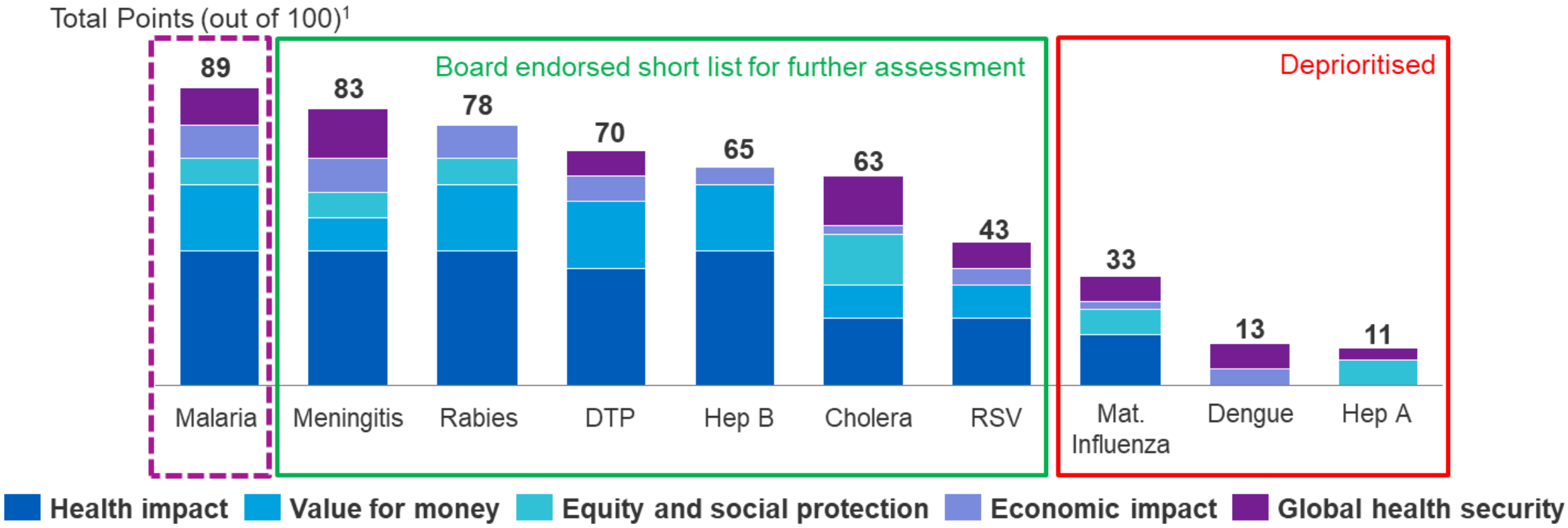
37% reduction



Source: RTS,S Clinical Trials Partnership. Efficacy and safety of RTS, S/AS01 malaria vaccine with or without a booster dose in infants and children in Africa: final results of a phase 3, individually randomised, controlled trial. *The Lancet*. 2015 Jul 4;386(9988):31-45.

Malaria vaccine ranked highly in Gavi's 2018 VIS assessment

In 2018, six VIS candidates shortlisted for investment case development; malaria used as a comparator



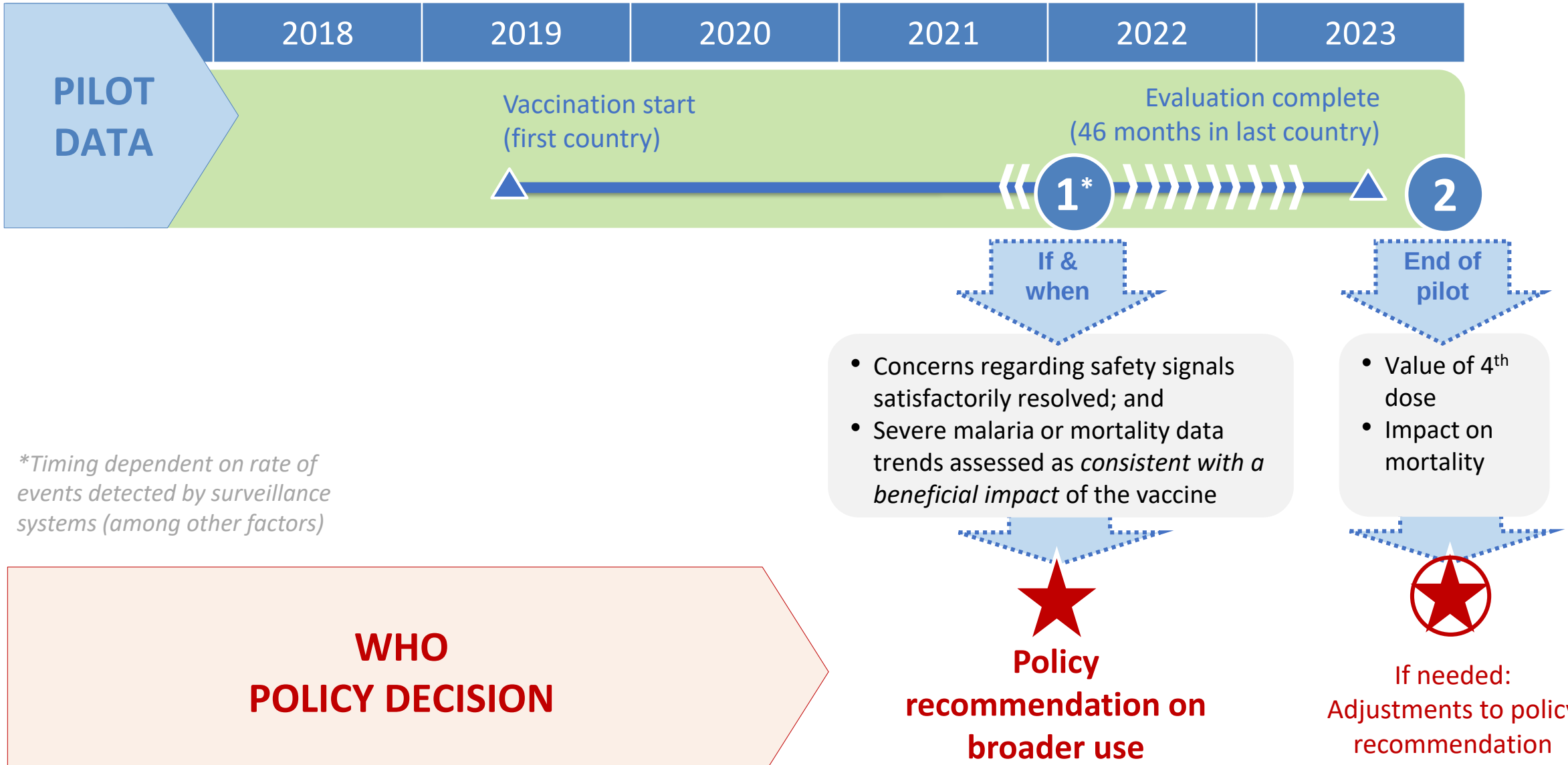
1. Maximum 40pts for health impact (30pts for total deaths averted, 10pts for deaths averted per 100k), 20pts for value for money (cost per death averted), 15pts for equity and social protection impact, 10pts for economic impact and 15pts for global health security
Note: Malaria not up for investment decision. Used as comparator with Health impact and economic impact based on high-level estimates

Evolving Evidence Base for the Malaria Vaccine

New findings since 2016 that informed the Framework for Policy Decision on RTS,S Malaria Vaccine

- **Results from extended (7 year) follow-up of phase 3 trial**
  - **Impact gained during first 4 years, when children are at highest risk of malaria illness and death, was not lost** during subsequent years
  - **Reassuring on rebound.** Rebound not seen after 4 vaccine doses, and limited after 3 doses: no excess of severe malaria
- **Policy decision need not be predicated on attaining high coverage**
- **New safety analysis and data reassuring.** Pooled analysis of all phase 2 trial data, and an ongoing phase 3 trial, have not replicated safety signals in phase 3 trial
- **Modelling suggests value of 4th dose may have been over-estimated in phase 3 trial.** 4th dose may provide minimal incremental benefit. This is in contrast to the clinical trial data (26% incremental benefit)

Step-wise approach to policy recommendation



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Thank you