Report from Gavi

Seth Berkley, CEO
Meeting of the Strategic Advisory Group of Experts on Immunization
October 2015
Delivering on Gavi’s strategy for 2016-2020
Gavi surpassed its 2011-15 introduction targets a year ahead of schedule.

Source: Gavi 2011-15 strategy key performance indicators; Gavi data
However, we are not on track to achieve our targets for coverage of new vaccines

- Slower roll-out in large countries
- Country readiness
- Slower roll-out in large countries
- Supply
- Country preference


= reasons for slow uptake
Average coverage across the Gavi 73 increased nearly 20 points in Gavi’s first decade...

% of children immunised in 73 Gavi countries

…but has plateaued in recent years

% of children immunised in 73 Gavi countries

Routine immunisation coverage has increased rapidly in many Gavi countries

<table>
<thead>
<tr>
<th>Coverage Level</th>
<th>Number of Countries</th>
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<tbody>
<tr>
<td>&lt;50%</td>
<td>17</td>
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<tr>
<td>50-59%</td>
<td>13</td>
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<tr>
<td>60-69%</td>
<td>4</td>
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<tr>
<td>70-79%</td>
<td>14</td>
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<td>80-89%</td>
<td>11</td>
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<tr>
<td>90%+</td>
<td>12</td>
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1999

- Afghanistan
- Angola
- Burkina Faso
- Chad
- Congo Rep.
- DR Congo
- Djibouti
- Ethiopia
- Guinea
- Guinea-Bissau
- Haiti
- Mali
- Niger
- Nigeria
- Sierra Leone
- Somalia

- Cambodia
- Cameroon
- Côte d’Ivoire
- DPR Korea
- India
- Lao PDR
- Liberia
- Madagascar
- Mauritania
- Pakistan
- Sudan
- Togo
- Uganda

- Mozambique
- Nepal
- Papua NG
- Senegal

- Azerbaijan
- Benin
- Bolivia
- Burundi
- Comoros
- Cambia
- Ghana
- Indonesia
- Kiribati
- Myanmar
- Nicaragua
- Sao Tome
- Tanzania
- Yemen

- Bangladesh
- Georgia
- Guyana
- Kenya
- Lesotho
- Malawi
- Rwanda
- Solomon Isl.
- Tajikistan
- Zambia
- Zimbabwe

- Armenia
- Bhutan
- Cuba
- Eritrea
- Honduras
- Kyrgyzstan
- Mongolia
- Moldova
- Sri Lanka
- Ukraine
- Uzbekistan
- Vietnam
Routine immunisation coverage has increased rapidly in many Gavi countries

### 2004

<table>
<thead>
<tr>
<th>Coverage Level</th>
<th>Countries</th>
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<tbody>
<tr>
<td>&lt;50%</td>
<td>8 countries</td>
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<tr>
<td>50-59%</td>
<td>5 countries</td>
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<tr>
<td>60-69%</td>
<td>13 countries</td>
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<tr>
<td>70-79%</td>
<td>15 countries</td>
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<td>80-89%</td>
<td>15 countries</td>
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<tr>
<td>90%+</td>
<td>16 countries</td>
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</table>

- Angola, Chad, Ethiopia, Lao PDR, Niger, Nigeria, Somalia
- Afghanistan, Cent Afr Rep., DR Congo, Haiti, Timor-Leste
- Congo Rep., Côte d’Ivoire, Djibouti, Guinea, Guinea-Bissau, India, Kiribati, Mali, Pakistan, Papua NG, Sierra Leone, Uganda, Zimbabwe
- Azerbaijan, Benin, Burkina Faso, Cameroon, Comoros, DPR Korea, Georgia, Indonesia, Kenya, Madagascar, Mauritania, Nicaragua, Sudan, Togo, Yemen
- Bhutan, Bolivia, Burundi, Cambodia, Cuba, Gambia, Ghana, Malawi, Mozambique, Myanmar, Nepal, Rwanda, Senegal, Tajikistan, Zambia
- Armenia, Bangladesh, Eritrea, Guyana, Honduras, Kyrgyzstan, Lesotho, Moldova, Mongolia, Sao Tome, Solomon Isl., Sri Lanka, Ukraine, Uzbekistan, Vietnam
Routine immunisation coverage has increased rapidly in many Gavi countries

<table>
<thead>
<tr>
<th>Coverage (%)</th>
<th>Number of Countries</th>
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<tbody>
<tr>
<td>&lt;50%</td>
<td>3 countries</td>
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<tr>
<td>50-59%</td>
<td>2 countries</td>
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<tr>
<td>60-69%</td>
<td>6 countries</td>
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<tr>
<td>70-79%</td>
<td>16 countries</td>
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<tr>
<td>80-89%</td>
<td>17 countries</td>
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<tr>
<td>90%+</td>
<td>28 countries</td>
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</table>

- Chad
- Somalia
- Ethiopia
- Guinea
- Afghanistan
- Haiti
- Lao PDR
- Mauritania
- Nigeria
- Papua NG
- Angola
- Benin
- Congo Rep.
- DR Congo
- India
- Indonesia
- Madagascar
- Mali
- Mozambique
- Niger
- Pakistan
- Timor-Leste
- Togo
- Uganda
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- Azerbaijan
- Cameroon
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- Côte d’Ivoire
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- Guinea-Bissau
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- Liberia
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- Sierra Leone
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- DPR Korea
- Eritrea
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- Guyana
- Honduras
- Kyrgyzstan
- Lesotho
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- Myanmar
- Nicaragua
- Rwanda
- Sao Tome
- Solomon Is
- Sri Lanka
- Tajikistan
- Uzbekistan
- Vietnam
- Zambia
Routine immunisation coverage has increased rapidly in many Gavi countries

<table>
<thead>
<tr>
<th>Coverage Level</th>
<th>&lt;50% 5 countries</th>
<th>50-59% 2 countries</th>
<th>60-69% 4 countries</th>
<th>70-79% 14 countries</th>
<th>80-89% 16 countries</th>
<th>90%+ 32 countries</th>
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<td>Countries</td>
<td>Cent Afr Rep.</td>
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<td>Yemen</td>
<td>Angola</td>
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10 countries <50%
As coverage increases, countries are encountering a “ceiling” effect

Average percentage point change in 5 year period by baseline coverage level, third dose of DTP-containing vaccine

1999-2014 trend observations from 53 countries divided into three five-year groups (2000-2004, 2005-2009, 2010-2014) with prior year serving as baseline
Immunisation coverage in 73 Gavi-supported countries
A closer look... 81%
A closer look...
A closer look...
In addition, significant inequities persist in many countries

Immunisation inequities by population characteristics, Madagascar, 2011

Source: UNICEF
Gavi 2016-20 strategy focused on accelerating progress on coverage & equity and sustainability

Gavi’s four strategic goals 2016-20

1. Accelerate equitable uptake and coverage of vaccines

2. Increase effectiveness and efficiency of immunisation delivery as an integrated part of strengthened health systems

3. Improve sustainability of national immunisation programmes

4. Shape markets for vaccines and other immunisation products

Source: Gavi 2016-20 strategy
How will Gavi measure coverage & equity?

2016-20 strategy indicators

Reach of RI coverage
- 3rd dose of pentavalent vaccine
- First dose of measles vaccine

Breadth of protection
- Average coverage across all Gavi supported vaccines

Equity of RI coverage
- Difference in penta3 coverage by
  - Geography (by district)
  - Wealth
  - Education status of mother / female caregiver

Recommended 2016-20 targets

- +5 percentage points (Reach of RI coverage)
- +32 points (Breadth of protection)
- +10 percentage points (Equity of RI coverage)

Gavi 2016-20 strategy targets to be approved by Board in December
Coverage target will require 50% acceleration in rate of coverage growth for each country strata.

Average percentage point change in 5 year period by baseline coverage level, third dose of DTP-containing vaccine.

1999-2014 trend observations from 68 countries divided into three five-year groups (2000-2004, 2005-2009, 2010-2014) with prior year serving as baseline.
Continued focus on new vaccine introductions to address inequities in access between countries

Introductions per year

Source: Vaccine Implementation data; data as of 15 September 2015 (SDFv11). Unconstrained introduction dates were used for all vaccines except yellow fever and rotavirus vaccines.
Four key elements of new approach to strengthen coverage and equity

1. More proactive and country-tailored grant management
   - Direct funding support review
   - GAMR (incl. JAs and HLRP)
   - Translation of strategy into frontline actions (& linkage to Gavi support)

2. New ways of working with Partners
   - Partners’ Engagement Framework (incl. RFI for expanded partners)

3. Transformational engagement in SFAs
   - Supply chain
   - Data
   - Sustainability
   - Demand promotion
   - Political will
   - Leadership, mngmt & coord.

4. Differentiated approach prioritizing 20 countries
   - Focus on 20 priority countries
   - Intensified engagement with countries (‘C&E approach’)
   - Country-specific strategies (e.g. India)

Sustainable coverage & equity
A new country-centric process to design, monitor and review grants

Integrated package of support to meet country needs
- New and under-used vaccines
- Health system strengthening
- Country-driven technical assistance
- Transition planning

Routine monitoring
- Country-driven joint appraisals
- Performance frameworks
- Country level KPIs for partners

High Level Review Panel (HRLP)

Impact evaluation
- Small area estimations
- Grant evaluation

Design support, with country lens

Review & evaluate support
A new Partners’ Engagement Framework to provide targeted technical support

1. **Targeted country assistance:**
   - Country-driven assistance plan
   - Prioritisation of countries
   - Assistance to include management support

2. **Special investments in strategic focus areas:**
   - Supply chain
   - Data
   - Demand generation
   - Sustainability
   - Political will
   - Leadership, management and coordination

3. **Foundational support:**
   - Long-term funding for core partners (WHO, UNICEF, World Bank, CDC, CSO) for coordination in key programmatic areas
Six “Strategic Focus Areas” identified as first priorities for transformational work

- Supply chain
- Data
- Demand generation
- Leadership, Management & Coordination
- Political will
- Sustainability
SFA example: Supply Chain
Three objectives of CCE Optimisation platform

CCE available everywhere it’s needed
Vision: Equip 90,000 facilities with upgraded equipment and extend CCE to 45,000 unequipped facilities over the next 5-7 years

Right technology for each facility
• Incentivise manufacturers to develop higher performing / lower cost technologies
• Help countries to choose the right technology for their needs

Facilities impacted by Platform¹, #

<table>
<thead>
<tr>
<th>Facility extension</th>
<th>Facility upgrade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently Equipped</td>
<td>90</td>
</tr>
<tr>
<td>Country Plans</td>
<td>90</td>
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<tr>
<td>Potential Impact</td>
<td>15</td>
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<td>45</td>
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Total cost of ownership², USD

<table>
<thead>
<tr>
<th>Absorption</th>
<th>SDD</th>
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<tr>
<td>4.990</td>
<td>2.850</td>
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</table>

Reliable and robust equipment performance
Improve technology design to mitigate common failures (e.g., voltage regulators) and enhance CCE maintenance

Source:
1: Estimations for 55 countries eligible for platform funding based on Board presentation (excluding India)
2: Based on Board presentation assuming a Dometic RCW 50EG (24L) as absorption and a BFRV15 (15L) as SDD

**SFA example: Data**

What the Alliance aims to achieve in data by 2020

**Focus areas**

- **Immunisation Delivery, Coverage & Equity (DCE)**
- VPD surveillance
- Vaccine safety

**Goals for 2020**

- **ImmunisationDelivery, Coverage & Equity (DCE)**: Measurable improvements in availability, quality, use and transparency of data to **improve immunisation coverage and equity**

- **VPD surveillance**: Quality and timely data on VPD to **strengthen programme management, inform decisions** and provide **evidence** for measurement of impact and risk

- **Vaccine safety**: Ability to **identify and investigate** signals of severe AEFIs, **respond** efficiently and effectively and **address public concerns** on safety
Critical to accelerate progress in selected large and fragile countries

- ~75% of under-immunised children* in Gavi countries are in 10 large or fragile states
- Accelerating progress in these countries critical to drive global improvement in coverage

* Based on children receiving three doses of a DTP-containing vaccine

20 countries have been prioritised for more intensified engagement and tailored support.

<table>
<thead>
<tr>
<th>10 countries with most under-immunised children</th>
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<tbody>
<tr>
<td>Afghanistan</td>
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<td>Chad</td>
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<td>DR Congo</td>
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<td>Ethiopia</td>
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<td>India</td>
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<td>Nigeria</td>
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<td>Uganda</td>
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<table>
<thead>
<tr>
<th>10 countries with high inequities(^1) or conflict</th>
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</thead>
<tbody>
<tr>
<td>Central African Republic</td>
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<td>Haiti</td>
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<td>Madagascar</td>
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<td>Mozambique</td>
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<td>Myanmar</td>
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<td>Niger</td>
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<td>Papua New Guinea</td>
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<td>Somalia</td>
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<td>South Sudan</td>
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<td>Yemen</td>
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</table>

20 prioritised countries account for >80% of under-immunised children in Gavi 73

\(^1\) High inequity is defined as >20% coverage difference between highest and lowest wealth quintile in DHS surveys after 2010.
Progress in India critical to global coverage and equity agenda

1. Coverage and equity
   Increase immunisation coverage and equity in India through targeted support to strengthen the routine immunisation system

2. New vaccines
   Maximise health impact by accelerating adoption of new vaccines in India

3. Market shaping
   Maximise procurement savings and vaccine supply security by sharing information, coordinating tactics and building a long-term strategy that strengthens local public and private sector manufacturers

4. Sustainability
   Ensure that vaccine programmes in India will be sustainable beyond 2021 by supporting the government to plan for the transition and advocating for increased domestic spending on immunisation
24 countries in accelerated transition phase, 4 set to become fully self-financing from 2016

Note: Cuba and the Ukraine are no longer receiving Gavi vaccine support.
Key updates on programmes
Measles and rubella: Global control and eradication efforts off track

Number of Reported Measles Cases with onset date from Mar 2015 to Aug 2015 (6M period)

Data source: surveillance DEF file
Data as of 5 October 2015
Measles and rubella: Gavi’s current support fragmented and limited in scope and time

Past: Gavi-IFFIm provided US$ 176M to M&RI in 2004-2008

Current direct support ($1.3 Billion Programmed):

<table>
<thead>
<tr>
<th>Routine measles second dose (duration of 5 years)</th>
<th>Measles-Rubella campaigns (below 15 years) before start of routine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles SIA 6 high risk countries for population below 5 years of age</td>
<td>Outbreak response fund to Measles - Rubella Initiative (US$ 55m through to 2017)</td>
</tr>
</tbody>
</table>

Indirect support:
- Performance-based funding with measles coverage indicator, as part of HSS
Strengthened measles control critical as first step before focusing on elimination

What is realistic foundation for eliminating measles…

…90% routine MCV1 coverage for 3 years?

Gavi 73 countries

- MCV1 <90% in past 3 years
- MCV1 >90% for past 3 years

3 regions targeting elimination in 2015

Number of countries in each region with MCV1 coverage >90% for past 3 years:

- **EURO**: 42 out of 53 (79%)
- **EMRO**: 12 out of 21 (57%)
- **WPRO**: 19 out of 27 (70%)
Measles and rubella: Gavi Board to consider enhanced engagement (up to $800M for 2016-20)

<table>
<thead>
<tr>
<th>Current Gavi support</th>
<th>Proposed changes</th>
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<tbody>
<tr>
<td><strong>Routine Measles second dose</strong> for 5 years</td>
<td>Routine Measles 2\textsuperscript{nd} dose and MR as normal co-financed vaccines</td>
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<tr>
<td><strong>Measles SIAs</strong> in 6 high risk countries for under-5s</td>
<td>Extend support to all Gavi countries that need measles SIA before introducing MR</td>
</tr>
<tr>
<td><strong>MR campaigns</strong> for under-15s before routine introduction</td>
<td>Support follow-up campaigns where required</td>
</tr>
<tr>
<td><strong>Outbreak response fund</strong> to MRI until 2017</td>
<td>Continue to support outbreak response beyond 2017</td>
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</table>

**Key conditions of Gavi support:**
- Countries develop 5-year M and R plan as part of national RI plan
- Countries finance routine first dose of measles vaccine or equivalent
- Better use of data and independent monitoring to target and strengthen SIAs

NOTE: Gavi already projected to invest ~US $600M in measles and rubella 2016-20
Ebola: Gavi supporting recovery of routine immunisation and health systems

• Immediate restoration of EPI services:
  • Catch-up and strengthen vaccination campaigns (US$ 12,561,015 approved and disbursed; several DTP3, MCV1, MenA, Measles & Polio campaigns conducted in 2015)
  • Restore population confidence in health systems via engagement with CSOs (US$ 500,000 of which 275,000 has been disbursed)
  • Fast-track reprogramming of existing HSS grants (US$ 3M in total)
  • Rapid recruitment & training of healthcare workers
  • Plans for upgrade of supply chain have been initiated

• Medium/long-term recovery of health system:
  • HSS proposals with doubled ceilings as per Dec 2014 Board decision. Preparation of HSS proposals will start as of Q1 2016
  • Ensure complementarity of support across agencies
Ebola vaccine – critical priorities today for use

- Availability of doses in case of resurgence or new outbreak
- Emergency Use Authorisation Listing pathway
- Manufacturer commitment to pursue full licensure
- Continue product development towards improved vaccine profile

Gavi to procure doses for stockpile after licensure and WHO recommendation
Gavi’s growing role in outbreak preparedness and response

Yellow fever vaccine stockpile

Meningitis ACWY-containing vaccine stockpiles

Oral cholera vaccine stockpile

Ebola?

Others?
IPV: Significant delays in introduction due to supply constraints

- 25 IPV introductions in Gavi countries to date

- 28 IPV introductions in Gavi supported countries delayed to 2016 due to supply constraints, 8 delayed after the switch
  - Delays in manufacturer production scale-up
  - Increased use of IPV in campaigns

- Gavi engaged in polio legacy discussions to support strategic integration of relevant assets into RI
Malaria: Preparing for recommendation from SAGE/MPAC; Close collaboration with Global Fund

- RTS,S among shortlisted vaccines analysed in Vaccine Investment Strategy 2013
- Board deferred decision until after finalisation of trials and WHO recommendation
- Timeline for Gavi review:
  - 12 November: Programme and Policy Committee guidance
  - 2/3 December: Board guidance on potential Gavi engagement
- Close collaboration with Global Fund

Malaria vaccine: How good is good enough?

By Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance, and Dr Mark Dybul, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria

How effective does a vaccine have to be before it should make available? This is far from straightforward. Clearly, it needs to be capable of preventing disease, but to what extent? None are 100% effective. So in the cold light of day, for most countries it comes down to a complex calculation based on the cost effectiveness it saves. Illness avoided and the availability of other effective interventions. For highly effective vaccines – ones which offer a high level of immunity – this normally proves uncontroversial, but what about ones that are less effective? How much protection do they need to provide in order to justify their use?

Such is the question World Health Organisation (WHO) experts will now be preparing to ask themselves as they consider whether or not to recommend the world’s first malaria vaccine for use in affected countries in Africa. That’s because today the European Medicines Agency effectively gave the GlaxoSmithKline vaccine – called Mosquirix – a green light, meaning that the 250,000-page application has now passed every regulatory bar required of it for WHO to consider it. Its decision is expected in October.

With nearly 200 million cases of malaria every year, resulting in the death of around 1,200 children every day, this may seem like a no-brainer. However, the decision is a complex one. Clinical trial data suggests that Mosquirix offers only partial protection, preventing one-in-three cases of clinical malaria, a relatively low success rate compared to other approved vaccines. What’s more, the clinical trials were carried out with the vaccine used in conjunction with high use of other interventions, such as long-lasting insecticide treated bednets and antimalarial drugs.

So we don’t really know how effective the vaccine is by itself or how well it would perform outside the controlled setting of a clinical trial. In fact, there are still many unknowns. We don’t know, for example, if the vaccine will give people a false sense of security, and lead to a reduction in the use of bednets and other interventions. Given the progress that has been made since 2000 in halving the number of malaria deaths, that would be tragic.

Similarly, the effectiveness is very much dependent upon infants receiving an additional booster shot, after an initial three doses. Without this protection starts to wane significantly from 36% efficacy with the booster to around 23% in older infants, the equivalent of preventing one-in-four cases and even fewer in younger children. The obvious answer is to make sure everyone gets that booster, but that’s easier said than done. With vaccinations half the challenge is making sure everyone gets the full course. That’s all very well in the controlled setting of clinical trials but in practice what sort of dropout rate can we expect for that booster shot, particularly since this will be given outside of the normal childhood immunisation schedule?
THANK YOU