Meningococcal Vaccine
ICG stockpile 2016

The Meningitis Vaccine Project - Closure Conference
Addis Ababa 22-23 February 2016

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World Health Organization
International Coordinating Group (ICG) for vaccine provision
Background
International Coordination Group

- Raison d’être of ICG: relative shortage of vaccines in comparison with potential needs

- Creation of ICG(s)
  - ICG meningitis: 1997
  - ICG yellow fever: 2000
  - ICG cholera: 2012

- Financially supported by GAVI since 2009 for meningitis plus the revolving fund
Objectives of ICG for meningitis

For meningitis (from WHO website)

– to ensure the availability and rational distribution of emergency supplies of meningococcal vaccine to countries experiencing epidemic meningococcal meningitis

– to ensure timely availability of vaccine in countries experiencing epidemics;

– to coordinate international efforts in preparing for, and responding to, epidemic meningitis.
ICG and expert networks

Although originally set up to ensure vaccine availability, the ICG may also serve as a forum for technical discussions among all relevant partners, to improve cooperation and coordination of epidemic preparedness and response.

Expert meetings are organized according to needs (eg for Men C last October)
ICG-Member organizations: IFRC, MSF, UNICEF-PD, WHO

Criteria for membership:

1. **International public health agency or international non-governmental organization** whose mandate is the provision of support to countries on health matters irrespective of race, religion, gender or political affiliation.

2. **Active role in DISEASE response**: agencies and organizations must participate in DISEASE response and control interventions. Active presence in response to countries – direct country field support.

3. **Commitment and daily availability**: ICG members must be available for emergency consultation at any time, at least through electronic means.

4. **Respect of data ownership and confidentiality**: agencies must commit to respect the confidentiality of country data received for ICG decision-making purposes and seek approval from the country sending the request prior to sharing or using the information for any other purpose than for evaluating an ICG request.

5. **Lack of conflict of interest**: ICG members must not have any involvement with the vaccine industry e.g. perform consultancies for and/or receive funding from such manufacturers.
Decision criteria

- Decisions are based on the information provided on the request looking mainly at:
  - the epidemiological situation,
  - intervention strategy (treatment, other interventions, capacity to implement vaccination campaign, etc.)
  - pre-existing stocks in the country,
  - country capacity, local coordination of the epidemic response and operational aspects of the response (treatment, other measures, etc.)

- Decision is taken in 2 working days by ICG members
ICG Timelines (ideal)

<table>
<thead>
<tr>
<th>Country</th>
<th>WHO ICG Sec.</th>
<th>ICG</th>
<th>WHO-ARO/KL; UNICEF SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICG request preparation</td>
<td>Circulation to ICG members</td>
<td>Decision</td>
<td>Shipping P.O</td>
</tr>
<tr>
<td>2 days</td>
<td>1 day</td>
<td>1-2 days</td>
<td>Packing &amp; shipment</td>
</tr>
<tr>
<td>(10 days)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5 days (2+3)</td>
</tr>
</tbody>
</table>
ICG Timelines 2015 (real-life)

ICG performance indicators AVERAGE (days)

<table>
<thead>
<tr>
<th></th>
<th>Reception to Circulation</th>
<th>Additional info submitted</th>
<th>Decision</th>
<th>Decision to Reception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>0.9</td>
<td>1.3</td>
<td>1.85</td>
<td>9.7*</td>
</tr>
</tbody>
</table>

Time between arrival of the vaccines in the country and the start of the vaccination AVERAGE (days)

<table>
<thead>
<tr>
<th></th>
<th>Vaccination starts (after reception)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>7*</td>
</tr>
</tbody>
</table>

*Average calculated using the dates of the 1st shipment for the request #5:
- 4 days from the decision to the reception.
- 2 days from reception to the start of the vaccination
Number of meningitis vaccine doses released by ICG

- 57,805,334 doses
- 1,500,000 doses
- MenA conjugate
What could ICG improve?

- Improve stock availability through discussions with & pressure on manufacturers – knowing that outbreak responses is a risky business (losses always possible)

- Smart pressure on manufacturers – we want also to keep them in the loop

- Highlight the main problems in functioning – the stockpile has not been made available in a timely manner
Meningococcal Vaccine Availability for the ICG stockpile 2016
1. Yearly ICG request procurement to have a minimum doses of vaccines ready to ship for outbreak responses

2. Based on the best “guesstimate” of the needs and external expert consultations

3. Discussed with manufacturers around June / July for the following year

4. Procurement agents in charge of negotiation with manufacturers (LTA, etc.) – UNICEF SD mainly because of GAVI financing – WHO procurement exceptionally
ICG Stockpile 2016 - requirements

- 1,500,000 doses of Men A conjugate vaccine

- 5,000,000 doses of multivalent C-W containing vaccines
  - Men AC, ACW and ACWY PS + Men C conjugate
  - One to one discussion with manufacturers (WHO UNICEF SD)
  - ICG to agree on a mix of different vaccines for UNICEF SD to issue the tender in early September

- Ceftriaxone
  - 7000 5 days treatments (2 g per day per adult so 70 000 vials) in stock for the beginning of the season – including a small stock in Geneva
Expert opinion on Men C containing conjugate vaccines

- Meningococcal multivalent conjugate vaccines are preferable, but not available.

- Limited stocks of meningococcal C conjugate (1,3 md) vaccine should be used for outbreak rather preventive.

- Any combination of Men C-W containing polysaccharide should be considered for the stockpile.
## Consultation with the manufacturers

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Supplier</th>
<th>Vaccine</th>
<th>Composition</th>
<th>Quantity confirmed (doses)</th>
<th>Extra quantity possible (doses)</th>
<th>Price/dose</th>
<th>Production 2016 (doses)</th>
<th>WHO PQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSK</td>
<td>Pfizer</td>
<td>Nimenrix</td>
<td>ACWY conjugate – TT</td>
<td>Not available</td>
<td>Not available</td>
<td>$80-100</td>
<td>3,000,000</td>
<td>No</td>
</tr>
<tr>
<td>GSK</td>
<td>Pfizer</td>
<td>Mencevax</td>
<td>ACWY polysaccharide</td>
<td>700,000</td>
<td>0</td>
<td>$4</td>
<td>3,800,000</td>
<td>No</td>
</tr>
<tr>
<td>GSK</td>
<td>GSK</td>
<td>MenHibrix</td>
<td>CY + Hib conjugate – TT</td>
<td>Not available</td>
<td>Not available</td>
<td>$20-40</td>
<td>Very limited</td>
<td>No</td>
</tr>
<tr>
<td>GSK</td>
<td>GSK</td>
<td>Menitorix</td>
<td>C + Hib conjugate – TT</td>
<td>Not available</td>
<td>Not available</td>
<td>$20-40</td>
<td>Very limited</td>
<td>No</td>
</tr>
<tr>
<td>Novartis</td>
<td>GSK</td>
<td>Meneo</td>
<td>ACWY conjugate-CRM 197</td>
<td>Not available</td>
<td>Not available</td>
<td>$80-100</td>
<td>7,000,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Novartis</td>
<td>GSK</td>
<td>Menjugate-C</td>
<td>C conjugate-CRM 197</td>
<td>0</td>
<td>0</td>
<td>$15-18</td>
<td>3,000,000</td>
<td>No</td>
</tr>
<tr>
<td>Baxter</td>
<td>Pfizer</td>
<td>NeisVac-C</td>
<td>C conjugate – TT</td>
<td>300,000</td>
<td>0</td>
<td>donation</td>
<td>1,500,000</td>
<td>No</td>
</tr>
<tr>
<td>Wyeth</td>
<td>Pfizer</td>
<td>Meningitec</td>
<td>C conjugate – CRM 197</td>
<td>0</td>
<td>0</td>
<td>Recalled</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>Sanofi-Pasteur</td>
<td>Sanofi-Pasteur</td>
<td>Menomune</td>
<td>ACWY polysaccharide</td>
<td>Not available</td>
<td>360,000</td>
<td>$5,8</td>
<td>3,000,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Sanofi-Pasteur</td>
<td>Sanofi-Pasteur</td>
<td>Menactra</td>
<td>ACWY conjugate – DT</td>
<td>0</td>
<td>220,000</td>
<td>$25</td>
<td>5,000,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Sanofi-Pasteur</td>
<td>Sanofi-Pasteur</td>
<td>Men AC</td>
<td>AC polysaccharide</td>
<td>500,000</td>
<td>0</td>
<td>$1.25</td>
<td>3,500,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Finlay</td>
<td>Bio-Manguinhos</td>
<td>MenVax ACW</td>
<td>ACW polysaccharide</td>
<td>440,000</td>
<td>0</td>
<td>$2.5</td>
<td>3,000,000</td>
<td>No</td>
</tr>
<tr>
<td>Finlay</td>
<td>Finlay</td>
<td>Men BC</td>
<td>BC polysaccharide</td>
<td>0</td>
<td>1,000,000</td>
<td>?</td>
<td>1,500,000</td>
<td>No</td>
</tr>
<tr>
<td>Baxter</td>
<td>UK Government</td>
<td>NeisVac-C</td>
<td>C conjugate - TT</td>
<td>800,000</td>
<td>200,000</td>
<td>$0</td>
<td>?</td>
<td>No</td>
</tr>
</tbody>
</table>
Vaccine procurement: ICG stockpile 2016

1. **UNICEF SD Procurement**: issued a tender for 5 million doses of Men AC/ACW/ACWY PS vaccines

2. **WHO Procurement**: on behalf of the ICG with the Revolving Fund reserved 1.5 million doses of Men ACW from Finlay/Cuba

3. **Vaccine donation** from UK and Pfizer
<table>
<thead>
<tr>
<th>Meningococcal Vaccines</th>
<th>Manufacturer</th>
<th>February</th>
<th>March</th>
<th>April</th>
<th>May</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men AC PS</td>
<td>Sanofi-Pasteur</td>
<td>500,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MenVax ACW PS</td>
<td>Bio-Manguinhos/Finlay</td>
<td>160,000</td>
<td></td>
<td>280,000</td>
<td></td>
</tr>
<tr>
<td>Mencevax AGWY PS</td>
<td>GSK/Pfizer</td>
<td>570,000</td>
<td></td>
<td>130,000</td>
<td></td>
</tr>
<tr>
<td>Men ACWY PS</td>
<td>Hualan Biological</td>
<td>150,000</td>
<td></td>
<td>300,000</td>
<td>300,000</td>
</tr>
<tr>
<td>Menomune - Men ACWY PS</td>
<td>Sanofi-Pasteur</td>
<td></td>
<td></td>
<td>360,000</td>
<td></td>
</tr>
<tr>
<td>Neis-Vac C - Men C conjugate</td>
<td>Pfizer</td>
<td>300,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neis-Vac C - Men C conjugate</td>
<td>UK-Pfizer</td>
<td>800,000</td>
<td></td>
<td>400,000</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>2,480,000</td>
<td>1,470,000</td>
<td>300,000</td>
<td></td>
</tr>
</tbody>
</table>
NeisVac –C (Men C conjugate)

- Donation to WHO: Pfizer 300,000 doses + UK 1,000,000 doses = 1,300,000 doses
  - It is not licensed in African countries
  - It is not WHO prequalified
  - Mono-dose, prefilled syringes
  - Very stable: up to 25°C, 9 months
  - Storage in Dubai
  - Operational costs: increase of transport and storage costs
ICG demand will of 5 million doses of C/W135 containing vaccines will not be met

ICG Revolving Fund secured 440,000 doses of MenVax ACW

WHO is negotiating donations for 1.3 million doses of Men C conjugate

UNICEF tender Men polysaccharide vaccines
  - 1,450,000 doses of Men ACWY
  - 500,000 doses of Men AC

Total = 4,25 million doses till May 2016 (Men AC, ACW, ACWY and Men C conjugate)
The MVP has made the difference, but the fight is not over!