International Coordinating Group on Vaccine Provision for Epidemic Meningitis Control

Annual meeting

7-8 July 2016

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Abbreviations

GAVI	The Global Vaccine Alliance
ICG	International Coordinating Group on Vaccine Provision for Epidemic Meningitis Control
KPIs	Key Performance Indicators
LTA	Long Term Agreement
Men	Meningococcal
M	million
NM	*Neisseria meningitidis*
PQ	Prequalified
SD	(UNICEF) Supply Division
SPn	*Streptococcus pneumoniae*
RCA	République Centrafricaine (Central African Republic)
RF	Revolving Fund
UNICEF	United Nation Children's Emergency Fund
WER	Weekly Epidemic Record
WHO	World Health Organization

Executive summary

On 7 and 8 July, the International Coordinating Group (ICG) on vaccine provision for meningitis held its annual meeting to define the vaccine and anti-biotic needs for 2017, as well as the composition of the 2017 Meningitis vaccine stockpile. Discussion focused on the Meningitis ICG mechanism, including the decision making process and criteria for vaccine release; the communication of the requests to countries and partners; the forecasting for 2017; the procurement strategy and processes (modus operandi); and the financing strategy. On the second day the focus of the discussion was on the vaccine demand and projected supply from the Meningitis vaccine manufacturers.

Disease experts anticipated a large *Neisseria meningitidis* (Nm) C outbreak, however mainly Nm W outbreaks were detected in 2016. The risk for Nm C outbreaks persists as the immunity is expected to be low. The need for heightened surveillance remains.

The stockpile consists of 5 million doses for the 2016 epidemic season. A total of 2,759,084 Meningococcal (Men) vaccines were requested, of which 1,217,560 doses were shipped to respond to six requests for vaccines. The average time between the ICG approving the request up to the vaccine arriving in the country was 13 days, which is longer than the seven days the ICG strives for. On average the vaccination started 6.5 days after reception of the vaccine within the country. Use of the Revolving Fund (RF) to cover costs of vaccines was requested and WHO's Procurement Office purchased 440,000 doses on behalf of the ICG using the RF.

The main challenges identified by the ICG during the meeting include:

1. Inadequate surveillance systems at country level with laboratory confirmation being the weakest part (section 1)
2. Delays in shipping and arrival of the vaccines after the ICG approval of the request (section 2)
3. Delay in the starting the vaccination campaign after arrival of the vaccine (Section 2)
4. Shortage of Meningococcal vaccines at global level to meet the countries' vaccine demands (both eligible and non-eligible GAVI countries) (section 6)
5. Lack of commitment (Long Term Agreements (LTA)) towards the manufacturers to secure stock for outbreak response by UNICEF SD (Section 6)
6. Feasibility of procuring Non-Prequalified (PQ) vaccines by UNICEF SD (section 7)
7. Reporting on Key Performance Indicators (KPIs) is ICG focussed and does not include partners' performance (section 7)
8. Vaccines not available at the beginning of the epidemic season to respond to outbreaks and unclarity about the quantity of vaccines secured (Section 7)
9. Vaccine threshold and the questioning of the benefits of delayed vaccine campaigns (section 7)

The ICG Members reached consensus that the forecast for 2017 will be five Million doses of Men vaccine containing C with a minimum of three Million doses vaccines containing CW, and a shelf life of two seasons.

The meeting concluded that a long-term strategy is required for three-five year forecasting of vaccine quantities to better discuss and negotiate with manufacturers. This strategic plan should be presented to GAVI. To improve the follow up on all incidents following the timeline of events, the Secretariat was advised to keep a logbook. A dashboard will be developed by UNICEF Supply Division on all ICG vaccine stockpiles accessible for the ICG members to follow on a weekly basis the vaccine availability and the status of the countries' request. In addition the procurement conditions of UNICEF SD and WHO need to be harmonized in situations when a vaccine is not prequalified.

1. Epidemiological update 2015-2016

In 2015, in Nigeria over 12,000 cases of meningitis were reported as well as the detection of the emergence of a new strain, *Neisseria meningitidis* (Nm) C, a unique clone genetically distinct from previous known disease strains. Disease experts anticipated a large Nm C outbreak for 2016 that, fortunately, did not occur. Mainly Nm W outbreaks were detected. This year (2016) the epidemic season started early with the peak at week 8 and finished early (around week 17). See Annex I for an overview of the pathogen distribution.

Overall, the Non-A Nm outbreaks persist and remain unpredictable. The risk for Nm C expansion could still be high since there is low immunity against Nm C. The need for highly efficient surveillance continues, with laboratory confirmation currently being the weakest part of meningitis control. Nineteen countries are under meningitis surveillance with most reporting well. One of the main challenges in communicating with the communities is the fact that several types of meningitis exist. It remains important to communicate during the Meningitis A vaccination campaigns that other forms of Meningitis (C and W) exist that require vaccination with a different vaccine.

In 2015 a *Streptococcus pneumoniae* (Spn) outbreak occurred in Ghana whilst no guidelines were available to advise the country on its response. A preliminary guidance was developed based on an informal consultation and published in the WHO Weekly Epidemic Record (WER) No 23 10 June 2016[1]. A 5-7 day treatment was given to the affected population. However the evidence, if this is effective, is not conclusive and more studies are needed to evaluate if shorter courses are more beneficial compared to longer courses (10 days) during Sp meningitis outbreak response.

[1] http://www.who.int/wer/2016/wer9123/en/

2. ICG response and Performance

A total of 2,759,084 Men vaccines were requested of which 1,217,560 doses were shipped, as can be seen in table 1 below.

Country	Date received	Vaccines requested by country	Approval (total/partial)	Quantity shipped*
Ethiopia #11	24/11/2015	520,266	120,553	120 560
Togo # 1	10/02/2016	227,980	227,980	228,100
Ghana # 2	25/02/2016	196,564	161,111	160,000
Togo # 3	26/02/2016	502,297	229,658	229,600
Niger # 4	02/03/2016	544,685	156,719	198,400
Ghana # 5	09/03/2016	137,529	Not approved	0
Togo # 6	24/03/2016	222,325	93,280	93,500
Nigeria # 7	25/03/2016	220,761	187,338	187,400
RCA # 8	04/04/2016	186,677	Not approved	0
Total shipped		2,759,084	1,176,639	1,217,560

*shipped quantities vary from approved quantities due to packaging

Table 1: vaccines requested and shipped

The main reasons for refusal of requested vaccines include:

- Ghana (#5): only two cases were confirmed in the affected area and the rainy season had started so the vaccine was no longer needed (epidemic threshold is 10/100,000)
- République Centrafricaine (#8): once the request was received it was too late to start the vaccination campaign

Partial approval was provided based on epidemic data and scarcity of the vaccine:

- Ethiopia(#11): prioritization of the affected refugee population and the communities around the refugee camps
- Togo ((#3): prioritization of the areas most affected and a continued increase in the number of cases
- Niger (#4): prioritization of the most affected areas, areas not vaccinated in 2015 or with low coverage and areas adjacent to epidemic areas.

	Reception to Circulation to ICG Members	**Additional info submitted**	**Decision by ICG**	**Decision to Reception**
Average	Same day	4.14	1.42	13

Table 2: Average days of ICG performance indicators

The average time between the ICG approving the request up to the vaccine arriving in the country was 13 days, which is longer than the seven days the ICG strives for (see Annex II). These delays have implications at country level for the launching of the reactive vaccination campaign. In several instances, the campaign started only ten days after the arrival of the vaccine. On average the vaccination started 6.5 days after reception of the vaccine within the country.

Reasons for delays in shipment include:

1) Ethiopia: for unknown reasons the vaccines were not ready for shipment and no alternative existed
2) Togo: due to a discrepancy in the content of the vials of GSK/Pfizer ACYW vaccine - the vaccine and the diluent were labelled as a 10 dose vial, however, they contained 8 doses and had already obtained the Belgium NRA approval), . Delays were due to obtaining a technical advice from the PQ team by UNICEF SD. In addition, the Nigerian request was incomplete and obtaining the additional needed information took more than two weeks, resulting in a delay of approval and arrival of the vaccine in the Nigeria.

The time between the decision (approval) and arrival of the vaccines needs to be improved and quickly confirmed to countries/requesters so that the country can start implementing the vaccine campaign within two days after arrival of the vaccine.

3. Stockpile update

3.1 Vaccines

UNICEF SD had issued a tender for 5 million doses of Meningococcal C- and W-containing vaccines on 8 October 2015. A total of 1,240,000 d was offered by suppliers: made available for the 2016 epidemic season : 500,000 doses of Men AC (Sanofi-Pasteur) and 740.000 doses of Men ACWY (GSK/Pfizer). WHO's Procurement Office had reserved 1,5M doses of Men ACW from Bio Manguinhos/Finlay of which a total of 440.000 doses were delivered on behalf of the ICG, using funds from the RF. In addition, potential 700-800 k doses of Men C conjugated vaccines were donated by the Government of the United Kingdom – however, not available for