REVIEW OF THE INTERNATIONAL COORDINATING GROUP ON VACCINE PROVISION (2006-2016)

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Prepared by the ICG Secretariat, on behalf of the ICG core members:

- The International Federation of Red Cross and Red Crescent Societies (IFRC)
- Médecins Sans Frontières (MSF)
- The United Nations Children's Fund (UNICEF)
- The World Health Organization (WHO)

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BACKGROUND

Though outbreaks of meningitis, yellow fever and cholera are unpredictable events, they can each be controlled by the timely use of vaccine. Vaccine-preventable diseases typically affect people in vulnerable settings who have limited access to vaccines. But vaccines can take months to manufacture, and they are not always readily available in the amounts needed during emergencies. The resulting shortages have raised difficult issues about how limited supplies should be allocated during periods of high demand.

That is why, after public health organizations found themselves unprepared to respond in a timely manner to a large-scale outbreak of meningitis in Nigeria, a number of those agencies created in 1997 the International Coordinating Group (ICG) on vaccine provision. Comprising representatives of the International Federation of Red Cross and Red Crescent Societies (IFRC), Médecins Sans Frontières (MSF), the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO), the ICG has worked since then to manage stockpiles of vaccine for emergency use during outbreaks.

In order to avoid the "first-come, first-served" approach that had prevailed and that can result in inequitable distribution of vaccines, the ICG members move quickly to assess the needs and risks posed by outbreaks and then seek to allocate limited supplies of vaccine in an equitable manner.

The positive impact of the mechanism on subsequent meningitis outbreak responses led partners and advisors, including the Strategic Advisory Group of Experts on Immunization (SAGE), to recommend that stockpiles managed by the same ICG mechanism be created for yellow fever, cholera and Ebola. That happened in 2001, 2013 and 2015 respectively.

Working with countries, manufacturers and other partners, the ICGs have made available more than 35 million doses of meningitis vaccine to 17 countries, 60 million doses of yellow fever vaccine to 20 countries and nearly 5 million doses of Oral Cholera Vaccine (OCV) in 11countries.

Recent events show the important role the ICGs still have to play in stockpile management during emergencies:

- In 2014-2016, a shortage of polysaccharide serogroup C-containing vaccine for meningitis delayed epidemic control in Niger and Nigeria;
- In 2016, responses to the yellow fever outbreak in Angola and the Democratic Republic of the Congo (DRC) depleted the emergency stockpile twice, which led public health officials to divert vaccine that had been earmarked for routine use to be employed instead in the emergency response;
- In 2014-2015, competing requests for OCV in the aftermath of humanitarian crises and/or natural disasters (Haiti, South Sudan, Nepal, Iraq, and Ethiopia) and outbreaks (Ghana, Mozambique, the Democratic Republic of the Congo) underscored the critical need to prioritize requests.

The increased number of stakeholders involved in outbreak response and the complexity of the vaccine supply market have made the management of the emergency stockpiles more complex and made evident the need to strengthen the ICG mechanisms to ensure that they can continue to fulfil their mandate.

This document describes and reviews three major aspects of the ICG mechanism: its governance (1); management of emergency stockpiles (2); and the use of emergency stockpiles (3). It will be the basis for an evaluation of the ICG as proposed in the last part (4).

1. REVIEW OF THE GOVERNANCE OF THE ICG MECHANISM

1.1 GUIDING PRINCIPLES

Three principles guide the mechanism.

- **Equity:** distribution of vaccine based on public health priorities;
- **Rapid and timely access**: delivery of vaccine within a defined timeframe to control outbreaks;
- **Independence:** decisions made independent of any political or economic influences with the sole goal of improving public health.

1.2 MANDATE

The core mandate of the ICGs is to make available and ensure equitable access to vaccines for meningitis, yellow fever, and cholera during outbreaks. The ICG mechanism seeks to ensure timely and targeted deployment so that vaccines can be used as effective outbreak responses where they are most needed. The ICGs also manage the global emergency vaccine stockpiles and – working with manufacturers -- determine their size and composition with the goal of ensuring that adequate stocks of emergency supplies are accessible for emergency response.

1.3 STRUCTURE

The ICG was established through an informal agreement of the four founding agencies. There are no Memoranda of Understanding or any binding documents among the agencies. Its structure and governance does not fit into any of WHO's current advisory mechanisms. As a result, the mechanism is unique, relatively loose and flexible. These attributes have helped the ICG broaden its focus from meningitis alone to other vaccines and drug supplies (e.g. oily chloramphenicol, ceftriaxone) and to respond to non-emergency needs (yellow fever preventive campaigns) and humanitarian emergencies, (refugee or displaced populations). What remain unchanged are the commitment of the founding members and the guiding principles of the partnership.

The Terms of Reference (ToRs) of the ICG for meningitis were defined in 1997 and were revised annually until 2003[1]. Since then, they have not been changed. For the yellow fever and cholera ICGs, the ToRs have been based on those defined for the meningitis ICG. In 2015, the ToRs were extensively reviewed in the context of the establishment of the Ebola ICG. The roles and responsibilities within the ICG mechanism are as follows:

The **ICG core members** are composed of one main representative and one alternate each from IFRC, MSF, UNICEF[2] and WHO[3]. They decide each year on stockpile size and composition based on available data; manage the stockpiles; and decide within two working days of receiving a complete request on vaccine allocation for outbreaks and emergencies.

The **"extended" ICG partners** comprise a wide range of technical expert partners, operational organizations and donors involved in emergency response and vaccine/drug supply. They include vaccine

[1] Meningitis ICG meeting report 2003: The ICG Executive Sub Group refocused its activities on the original mandate: *"1.Ensuring optimal use of vaccines in the 1997 season through release of vaccine, drugs and injection material on a priority basis according to agreed criteria. 2. Setting up a mechanism with vaccine manufacturers to lessen the risk of a crisis in vaccine supply in future years. 3. Improving meningitis surveillance and control in countries at higher risk."*

[2] The UNICEF representative is from UNICEF Programme Division

[3] The WHO Representative is the disease focal point for the respective ICG

manufacturers and member states. Each partner contributes, according to its mandate, technical or procurement expertise, financial resources, operational support, etc.

The **ICG Secretariat** (WHO) ensures coordination of the group's day-to-day activities, receives requests for vaccine, verifies their completeness, disseminates information and facilitates discussions among the members to obtain consensus about how to respond – all within two working days. It also convenes meetings and teleconferences and reports annually on the epidemiological situation, on number of doses approved (or not) per country, on financial status, on status of the global stockpile, on supply and procurement decisions and on other ICG-related activities.

Each organization appoints its own representatives. ICG core members communicate regularly through teleconferences and emails and convene outside of scheduled meeting times whenever emergencies require their input. Each year, ICG core members and extended partners meet for two days to review the epidemic season's activities, procedures, criteria, supply and procurement issues, and to decide on stockpile composition and size for the following year.

1.3 MEMBERSHIP

The core members include the historic partners of the ICG. Core organizations have not changed since the first ICG was created. The criteria for membership were revised in 2013, during the establishment of the ICG for cholera[4], and in 2015 for the establishment of the Ebola ICG[5]:

- **Must be an 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.
- **Must play an active role in outbreak response**: agencies and organizations must participate in outbreak response and control interventions, including direct country field support.
- **Must show commitment:** ICG members must be available for emergency consultation at any time, at least through electronic means.
- **Must respect 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 purpose other than for evaluating an ICG request.
- **Must be impartial:** ICG members must have no financial involvement with the vaccine industry e.g. they must not perform consultancies for and/or receive funding from such manufacturers.

1.4 COMMUNICATION

Communication of the mechanism is coordinated by the ICG Secretariat, which maintains the WHO website; documents the annual meetings; reports to donors; and disseminates information to members and partners during regional and global forums. Some stakeholders have characterized these communications as insufficient. Specifically:

- While much information on the ICG is available on the WHO website, it is not all available on a single platform.

[4] Report from the Technical Working group on the creation of an OCV stockpile, WHO, 2012, (p.22). A call was issued for members seeking to join and meeting the criteria for eligibility for core membership. No expression of interest was received. ICG

[5] International Coordinating Group for Ebola Vaccine (EBOV), ToR for initiating ICG EBOV, 7 December 2015, WHO Headquarters, Switzerland

- Performance indicators for each ICG are analysed systematically and documented in annual reports but are not easily accessible.
- Information on the status of requests for vaccines from the stockpiles, the number of doses of vaccine the stockpiles contain at any given time, and how much vaccine has been sent where is not shared in real time outside of the ICG core members.

2. REVIEW OF STOCKPILE MANAGEMENT

The stockpile management describes the elements that are critical to ensuring that a global stock of vaccines is readily accessible to respond to an outbreak. Managing the emergency stockpiles is the responsibility of the ICG core members, with support from the ICG Secretariat. This includes deciding on vaccine release, use of doses close of expiry date, and release of remaining doses for routine or preventive campaigns.

2.1 DECISION MAKING ON STOCKPILE COMPOSITION

The ICG core members decide the size and composition of each stockpile of vaccines during the annual meeting, usually in closed session. In some cases, extended discussion and additional information/consultation are required to finalize a given forecast. Recognizing the critical role UNICEF SD plays as the single procurement agency for Gavi-supported countries, the ICG decided beginning in 2016 to invite the agency to observe the closed sessions of the ICG meetings.

The ICG core members base their decisions on the composition and size of the vaccine stockpiles on epidemiological trends of the disease and vaccine use in recent years, on the dynamics of the disease and on the experience on outbreak response accumulated during the past 20 years. Predicting the number of doses needed for a coming year is a public health decision that balances concerns about production excesses with concerns about ensuring that enough vaccine will be available to cover the anticipated needs.

Outbreaks are unpredictable. Modelling can inform long-term vaccine supply forecasting, but are not always accurate enough to guarantee that the anticipated number of doses and types of vaccines needed will prove sufficient. The unexpected yellow fever outbreak in Angola in 2016 and the emergence of an epidemiogenic meningitis strain (Nm C) responsible for large outbreaks in Niger and Nigeria in 2013-2014 illustrate well this problem.

In predicting how many doses will be needed to respond adequately to outbreaks during the following year, ICG members take into account various elements, including the epidemiological situation, characteristics of the vaccine, the estimated vaccine production capacity, discussion with vaccine manufacturers and countries, as well as vaccination strategies. Key to this work is maintaining open lines of communication with manufacturers and procurement agencies so that problems can be identified and addressed in a timely fashion.

For each stockpile, specific factors affect forecast decisions.

For meningitis, the ICG must take into account the dynamics of the outbreak (spread, intensity, etc.), and the serogroups and strains circulating during the epidemic season before deciding on the size and composition of the stockpile for the next year. It is critical to have an annual assessment of the vaccine needs, based on the latest trends, in order to minimize wastage, as the polysaccharide vaccines used for outbreak response cannot be rolled out for preventive campaigns. This exercise can take place only after the epidemic season.

For yellow fever, the ICG can more easily forecast how many doses may be needed for the next year's stockpile since concern about wastage is minimal -- any vaccine not required for emergency responses can be used for preventive campaigns.

For cholera, the OCV forecast has been determined mostly by production capacity and the relatively small demand for the vaccine outside the context of outbreaks or humanitarian use.

Although market shaping is not a function of the ICG, its decisions about stockpiling vaccines that have limited production and no market outside of emergency/outbreak use directly affect manufacturers' decisions and strategies.

2.2 PROCUREMENT AND MANAGEMENT OF EMERGENCY STOCKPILES

Procurement refers to the processes through which vaccine doses are stockpiled and deployed. In the past, procurement of vaccine was made by different members of the ICG since there were several ad-hoc sources of financing, including the ICG core members themselves.

Since Gavi took over the bulk of the financing for the stockpiles, UNICEF SD (in 2002 for yellow fever, 2009 for meningitis and 2016 for cholera) has been responsible for procuring the vaccine doses and types as defined by the ICG.

Procurement strategies differ from one disease/vaccine to another, depending on how quickly the vaccine may be needed, the vaccine market specificities and the number of manufacturers (see Table 1). However, in cases where UNICEF SD has not been able to meet the ICG's demand for vaccine, WHO has done its own procurement. Sometimes, WHO has also used its political influence with countries and manufacturers to obtain more vaccine and/or reprogrammed vaccine allocations to prioritize stockpiles for emergencies on behalf of the ICG.

Table 1. Vaccines and manufacturers per ICG stockpile

ICG	Type of vaccines	Manufacturers	Cost / dose	Total deployed	Year deployed
Meningitis	Polysaccharide AC	Sanofi Pasteur	$1.25	19,7 million	2006-2010; 2012; 2016
		Bio-Manguinhos		6,4 million	2009-2011
	Polysaccharide ACW	Finlay/Bio-Manguinhos	$1.5 -2.5	839 175	2013-2016
		GSK	$1.25	4,1 million	2006-2012
	Polysaccharide ACWY	GSK/Pfizer	$4	1,1 million	2015;2016
		Sanofi-Pasteur	$3.2 -5.8	1,1 million	2012;2015