

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 11 countries.

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 2003¹. 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, UNICEF² and WHO³. 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 cholera⁴, and in 2015 for the establishment of the Ebola ICG⁵:

- **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
	Conjugate A	Serum Institute of India	\$0.65	1,5 million	2012-2014
Conjugate ACYWY	Sanofi Pasteur	\$25	200 000	2015	
Yellow fever	17 D vaccine	Sanofi Pasteur	\$1.311*	59,7 million	2006-2016
		Bio-Manguinhos	\$1.05*		
		Institut Pasteur Dakar	\$1.189*		
		Chumakov	\$0.84*		
Cholera	OCV	Shantha	\$1.85	4,8 million	2014-2016

* Prices based on the 2016 deployments of vaccines

Coordination and communication between UNICEF SD and the ICG core members is critical to ensure that procurement strategies for vaccine fit the requested size and composition. Communication has sometimes proven challenging and differs from one stockpile to another.

For meningitis, the ICG Secretariat has found it difficult to know the status of the stockpile at any given time. During 2015 and 2016, questions were raised about procurement and whether the requested size and composition would be met, leading to insufficient quantities and delayed delivery of vaccines to Niger in 2015.

For yellow fever, during the epidemic in Angola and DRC in 2016, UNICEF SD and WHO regularly exchanged information on the four manufacturers' production figures, the number of vaccines deployable during any given week from the emergency stockpile and the number of doses available for routine immunization.

For cholera, given the unstable production of vaccine, WHO and UNICEF SD talk twice each month with manufacturers in order to know at any given time the status of the stockpile.

2.3 FINANCING

Initially, ICG members launched appeals with the purpose of raising funds to maintain the stockpile. The same approach was used in 2013 to establish the first OCV stockpile. In some instances, as with the trivalent vaccine for meningitis, core members contributed their own funds to establish a stockpile to be managed under the ICG mechanism.

In 2002 and 2009, Gavi provided time-limited funding for the yellow fever and meningitis stockpiles respectively on the basis of investment cases developed under WHO coordination. In 2009, Gavi communicated that it would stop its financing in 2010.

In 2010, with the aim of ensuring sustainability after the end of Gavi's investments, the ICG established a revolving fund, which Gavi approved. Countries and partners were asked to reimburse the cost of vaccines deployed by the ICG with the understanding that WHO would work with countries to raise the money needed to replenish the fund. This revolving fund is managed by the ICG Secretariat.

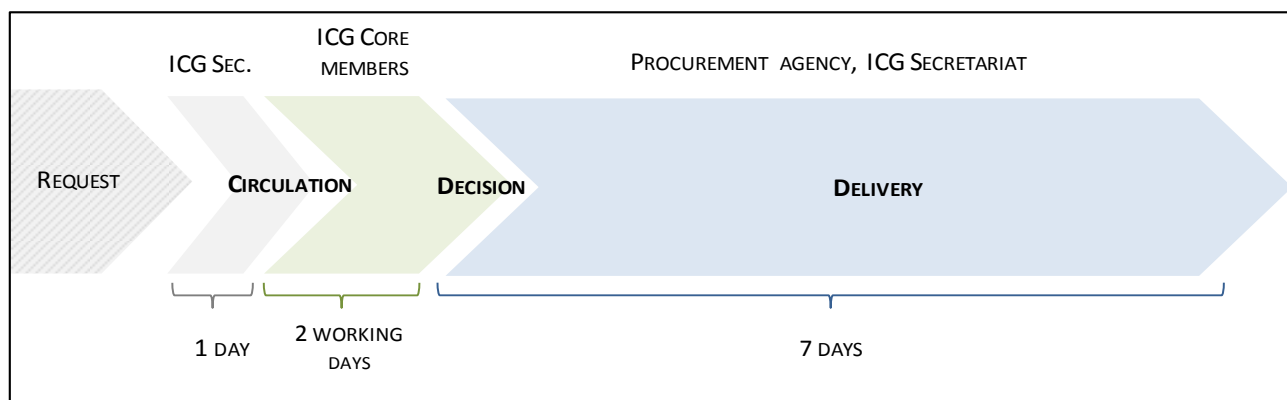
The revolving fund also serves as a contingency fund, enabling ICG to procure vaccine to respond to emergency situations, such as when Gavi and UNICEF SD funding/procurement mechanisms cannot be used to respond in a timely or appropriate fashion to a given country request, e.g. the use of funds to support Gavi non-eligible countries, or the possibility of advancing funds to affected countries while pledges by donors are being processed.

Recent examples include the procurement of non-prequalified meningitis C-containing vaccine to respond to a large outbreak in Niger and the procurement of yellow fever vaccine for Angola, a country that is not eligible for Gavi funding. This mechanism proved decisive in meeting the demand for vaccine.

3. REVIEW OF THE USE OF STOCKPILES DURING EMERGENCIES

Over the years, the request management process has been formalized to include steps/procedures (SOPs) and interactions among the ICG Secretariat, requestors (countries and/or organizations acting on behalf of countries), WHO disease expert focal points, ICG members and procurement channels (UNICEF SD or WHO). The goal is for vaccines to be delivered in country within 10 days from the time the ICG Secretariat receives a complete request (Graph 1).

Graph 1. Lead time for request reception to vaccine delivery



Performance indicators were set up for meningitis and applied to the other ICGs: one working day for request circulation, two working days for ICG core members to decide upon the completeness of the request, and seven days for vaccine to be delivered in country. Table 2 summarizes the performances of the ICG per disease over the past 10 years; more detailed information can be found in Annex 1.

Table 2. ICG performance indicators for meningitis and yellow fever (2006-2016) and for cholera (2014-2016)

Stockpile	Requests		Approval			Performance indicators		
	# Received	# doses	# request	# countries	# doses	Circulation Av. (d.)	Decision Av. (wd.)	Delivery Av. (d.)
Meningitis	142	59 727 073	120	17	35 144 895	0	2.3	9.4
Yellow fever	57	73 101 831	49	20	59 654 292	n/a	2.2	7.7
Cholera	30	7 154 281	21	11	4 839 452	0.7	1.4	14.2

3.1 REQUEST SUBMISSION

Any request for vaccine from a stockpile during an emergency is prepared by the requesting country's Ministry of Health (MoH) or by an operational partner acting on behalf of the MoH. Request forms are on WHO's website. The forms ask for: an epidemiological description of the outbreak; laboratory confirmation that it is occurring; evidence that the country has the capacity to control the outbreak and carry out the vaccination; the identities of partners involved in the response; a description of the logistics and cold-chain capacity; plans for supervision, social mobilization and waste management; as well as supporting documents (vaccination plan, map of the affected areas, budget for operational costs, see Table 3).

The filled-in request is submitted to the ICG Secretariat, which reviews it and may seek additional information. Requests that are incomplete or contain contradictory information can delay the process. In those cases, the ICG Secretariat serves as an intermediary to get the required information as quickly as

possible. Once the request is finalized, the ICG Secretariat circulates it to the ICG core members for their decision.

Table3. List of documents to be provided for request completeness

Meningitis	Yellow fever	Cholera
1. Request form and annexes	1. Request form and annexes	1. Request form and annexes
2. Vaccination plan per district	2. Vaccination plan for the mass campaign	2. Vaccination plan
3. Spot map of affected areas	3. Outbreak investigation report	3. Map of areas to be vaccinated and of adjacent areas.
4. Budget for operational costs	4. Spot map of affected areas	4. Budget for operational costs
	5. Copy of the original regional laboratory results	
	6. Budget for operational costs	

3.2 REQUEST MANAGEMENT

The ICG Secretariat is in charge of managing requests, from submission to decision, and then follows up on vaccine delivery. It seeks to ensure timely communication with:

- **UNICEF SD or WHO Logistics** to inform that there is a request being considered and to inform manufacturers to be prepared to receive a purchase order
- **ICG core members** to coordinate email exchanges and telephone calls as needed to reach consensus
- **MoH and/or operational partners** to inform them of any decision and to discuss availability of vaccine and injection materials, estimated dates of arrivals, campaign plans
- the **disease expert focal point** and the logistic unit coordinating technical assistance, logistic cold chain, waste management, social mobilization, AEFI monitoring, supervision, post-vaccination monitoring, etc.
- **ICG partners** to inform them of the decision
- **UNICEF SD and all relevant agencies** (WHO Logistics) to approve the procurement and delivery in country

The ICG Secretariat usually circulates the request to the ICG members within one day of receipt and communicates the decision to countries and partners as soon as the decision has been made. The ICG Secretariat follows up requests and monitors performance for review at the annual meeting.

Since 2010, Standard Operating Procedures (SOPs) have been in place within the ICG Secretariat to ensure timely responses to requests. This has resulted in a more standardized and consistent process. Nevertheless, communication problems persist between ICG Secretariat and some partners -- in particular with UNICEF SD.

3.3 EMERGENCY DECISION ON VACCINE ALLOCATION

Decisions are made by consensus. The ICG Secretariat manages the email exchanges and teleconferences when they are needed. The details of these discussions are not publicly available. Confidentiality is critical because:

- ICG core members need to work free of external pressure (political, economic) to ensure that public health concerns are the sole basis for their decisions on allocation. As such, the ICG core members must be protected from undue influence.

- Countries often communicate sensitive information to ICG core members and may perceive its transmission to partners not participating in the decision making to be a breach of trust.
- Partners in the field may communicate unofficial information to the ICG with the proviso that the ICG will not share that information.

The ICG bases its decisions on pre-established criteria for the diseases as described in Table 4. The ICG core members assess all the information (official and non-official) provided against these criteria, weighing the public health needs and potential impact. The technical and operational expertise they have gained through years of such work complement their decisions.

Table4. Criteria for the release of the vaccine

Meningitis⁶	Yellow fever⁷	Cholera⁸
<ul style="list-style-type: none"> • Laboratory confirmation • Evidence of an ongoing outbreak based on the crossing of specific thresholds to declare an epidemic • Efficient case management in place • Availability of a mass vaccination campaign plan of action • Availability of standard storage conditions and material resources 	<ul style="list-style-type: none"> • Laboratory confirmation • Emergency situation: number of people at risk at a certain time and place • Risk of spread (risk of spread to other areas; vector density; non-immune people) • Efficient case management in place • Availability of a mass vaccination campaign plan of action • Availability of standard storage conditions and material resources 	<ul style="list-style-type: none"> • Laboratory confirmation • Severity (anticipated morbidity and mortality, risk of spread to a non-affected area) • Projected impact of vaccination: susceptibility and vulnerability of the population • Programmatic factors; local capacity to vaccinate; partners in the field • Other control measures in place (WASH) • Efficient case management in place • Availability of a mass vaccination campaign plan of action • Availability of standard storage conditions and material resources

Indicator of performance for decision making (two working days from the circulation of complete request or additional information) is available in Table 2 and in Annex 1.4. Over the past 10 years, the average decision time was 2.3 working days for meningitis, 2.2 for yellow fever and 1.4 for cholera.

Three types of decisions can be made: approval, partial approval (when the number of doses approved differs from the number of doses requested), or rejection. The ICG Secretariat summarizes the decision and the rationale behind it and communicates that to the country/requesting party and relevant partners. This happens generally on the same day the decision has been taken.

Over the years, processes for information sharing have evolved and become more standardized. Nevertheless, there is room for improvement, particularly around monitoring and IT tools (dashboard...), that would put in place more efficient, accessible and transparent communication mechanisms.

⁶ Meningitis guidelines: http://apps.who.int/iris/bitstream/10665/154595/1/WHO_HSE_GAR_ERI_2010.4_Rev1_eng.pdf?ua=1

⁷ Yellow fever guidelines: <http://www.who.int/csr/disease/icg/ICG-request-form-EN.pdf?ua=1>.

⁸ OCV guidelines: http://www.who.int/cholera/vaccines/Briefing_OCV_stockpile.pdf?ua=1

3.4 APPROVAL FOR PROCUREMENT AND DEPLOYMENT

The ICG Secretariat communicates to the procurement agency (UNICEF SD, in some instances WHO Logistics, MSF) the number of doses and, for meningitis, the type of vaccine (A, AC, ACW, ACWY; polysaccharide or conjugate) the ICG has approved. The ICG Secretariat also indicates the wastage /reserve factor, injection materials, vaccination cards and the type of transportation (air or sea freight) needed.

The procurement agency then orders the manufacturer to release the requested number of doses from the stockpile. In situations where the characteristics of the vaccines available do not match standards (e.g. short shelf life), or differ from the initial ICG request, the ICG Secretariat consults with partners and the procurement agency to advise on the option that best meets the public health need.

The manufacturer is responsible for conditioning the vaccine for shipment (packaging in cold boxes with ice/chill packs), and for issuing the required documentation and certificates for the release and shipment of the vaccine to the final destination (quality control certificates, packing lists, etc.).

Shipping is ensured primarily by UNICEF SD but can also be ensured by other partners (WHO, MSF) via freight forwarders that pick up vaccines from a manufacturer or a designated airport. UNICEF SD (or partners) informs the country of the date of arrival of the shipment.

The freight forwarder negotiates with the transport companies to find the quickest option and puts together the necessary documents (airway bill, invoices, packing list, and certificates) to obtain customs approvals.

Some countries delay delivery until their Ministry of Health has agreed to accept the vaccine. In other countries, the vaccine must be licensed or registered before being imported. In such cases, WHO engages with national regulatory agencies to identify the most appropriate emergency regulatory pathway to authorize the speedy delivery and use of the vaccine.

The ICG plays no leading role in this step, but follows-up with partners involved in procurement, shipping, prequalification, regulatory approvals and countries to make sure that the process is completed within the targeted times. When issues arise (not enough vaccine, difficulty in procurement) the ICG Secretariat is informed and steps in, if deemed necessary in consultation with the ICG core members.

3.5 REVIEW OF TECHNICAL SUPPORT FOR OPERATIONAL OUTBREAK RESPONSE

As described in this document, the role of the ICG mechanism is to ensure that vaccines are readily accessible and delivered in a timely manner to countries in need. Implementation of the campaign remains the responsibility of the country and the operational partner collaborating with the country. Although the provision of technical support would likely increase ICG performance and the quality of the campaigns, that is not per se the responsibility of the ICG mechanism. Instead, the provision of technical support is the responsibility of countries or implementing partners.

One component of mass vaccination campaigns that is often missing is the monitoring and evaluation of the use of vaccines once they have been delivered.

However, the ICG has always provided technical support when asked to do so by countries at any stage of their campaigns – request completion, risk assessment, implementation of campaigns, monitoring and evaluation. The organizations involved in the ICG mechanism provide support as part of their mandate, which has been a source of confusion among some countries and partners on where the responsibilities of the ICG end.

4. PROPOSAL FOR FURTHER EVALUATION OF KEY ELEMENTS

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 underscored the need to strengthen the ICG mechanisms to ensure that they can continue to carry out their mission.

Following discussions with stakeholders, including representatives of IFRC, MSF, UNICEF, Gavi, DFID, and BMGF, the members of the ICG are proposing to conduct an evaluation to review: (i) the ICG governance, (ii) the mechanisms related to the emergency stockpiles and their composition, and (iii) the internal and external communication procedures of the ICGs.

Proposed questions to be addressed are:

- Governance of the ICG mechanism:
 - Is the current structure fit for purpose?
 - What are the main roles and responsibilities among ICG members and partners that require clarification for i) stockpile management, ii) emergency response and iii) technical support?
 - Which decision processes require input from more partners?
 - How can internal and external communication be improved?
- Stockpile management:
 - Can additional tools and methods be used to improve multi-year and annual forecasting?
 - What financial mechanism can be put in place to maintain equity and timeliness in accessing the emergency stockpiles?
- Access to stockpiles during emergencies:
 - By disease, what are the key processes that contribute to the performance of the ICG during emergencies? How can they be improved?

The goal of this process is for the revised ToRs of the ICGs to be endorsed by the stakeholders and adopted by the ICGs' core members. The proposed process will be implemented in three phases:

- Phase 1: Complete the review of the ICG mechanisms and activities over the past 10 years that was initiated in September by the ICG Secretariat (preliminary draft to be shared with Gavi for the PPC);
- Phase 2: Based on the initial review, assess in detail the key processes defined previously, focusing on the review of options and solutions proposed for improving the functioning of the ICGs (weighing pros and cons for each suggested change);
- Phase 3: Gain the endorsement of stakeholders for the best options for revised ICG governance mechanisms and processes, and adoption of the new ToRs by the ICG core members.

Wide participation of stakeholders in this review will ensure that the problems identified are addressed and will lead to better understanding among all stakeholders of the strengths, limitations and challenges of the ICGs.

To do this, the ICG Secretariat, in consultation with the extended members, will set up a steering committee (SC) to oversee and monitor the process and to endorse the outcome.

The proposed composition of the steering committee includes representatives of the following partner communities: Member States (2-3), Gavi (1), donors (ECHO, DFID), vaccine manufacturers (1 public, 1 private), and ICG technical/operational partners (2).

In order to ensure that each of the components is reviewed and options and recommendations are developed, broad participation from concerned partners will be ensured. One option is to establish working

Review of the International Coordination Group on Vaccine Provision (2006-2016)

groups composed of relevant partners and subject matter experts who will address the main issues identified by the steering committee. It will define the ToRs and composition of these working groups.

The process will be coordinated by the ICG Secretariat on behalf of the ICG. The ICG Secretariat will issue a call for consultants through relevant networks. The consultants will support the evaluation process, help organize and facilitate the working groups. They will be supervised by the ICG Secretariat and overseen by the steering committee.

The proposed timeline for carrying out the phases listed above goes from October 2016 to end of March 2017.

Proposed timeline for the ICG evaluation

<i>Abbreviations</i>			
<i>ICG Sec</i>	<i>ICG Secretariat</i>	<i>Consult</i>	<i>Consultant</i>
<i>ICG CG</i>	<i>ICG Core Group</i>	<i>WG</i>	<i>Working Group</i>
<i>SC</i>	<i>Steering Committee</i>		

Milestones	Activities	Who?	Due date	October	November	December	January	February	March
Approved evaluation process	Draft proposal for the evaluation process	ICG Sec.	15-Oct						
	ICG Core Group meeting to agree on : * Process and timeline * Composition of the SC *TORs for the SC	ICG CG	20-Oct						
Initiation of the evaluation	Initial meeting of the SC members to: *define working methodology * define TORs and composition for WG	SC	01-Nov						
	Selection of consultant(s) * Publication of the call for proposal *Review of applications *Selection of the consultant(s)	ICG Sec.	20-Nov						
Revised Terms of References of the ICG Mechanism	Evaluation process	Consult WG	10-Jan						
	Meeting of the SC to review interim results	SC	10-Jan						
	Evaluation process	Consult WG	28-Feb						
	Meeting of the SC to review final results	SC	05-Mar						
Endorsement and adoption of the revised ToRs	Endorsement of the revised ToRs: * Meeting with ICG members and other partners *Presentation of final results	Stake-holders	20-Mar						
	ICG CG formally adopt revised ToRs	ICG CG	25-Mar						

ANNEX 1. PERFORMANCE INDICATORS PER ICG

Note

- The period analysed below is from 01 January 2006 until 14 October 2016.
- ICG decision time is calculated in working days.
- Sources include archived requests, performance tracking sheets, and meeting reports of all ICGs.

ANNEX 1.1 MENINGITIS ICG

Table 5. Requests received, approved and doses shipped for meningitis vaccines.

Year	Requested			Approved			Shipped					
	# Req.	# Count	# doses	# Req.	# Count	# doses	Tot.	PS AC	PS ACW	PS ACWY	Conj. A	Conj. ACWY
2006	19	12	15,7	15	9	6,1	6,1	5,4	0.7	-	-	-
2007	22	6	10,4	20	5	7,1	7,1	6,9	0.2	-	-	-
2008	9	5	4,1	8	5	2,1	2	2	-	-	-	-
2009	34	3	13,1	34	3	11,4	11,4	9,7	1,7	-	-	-
2010	15	6	3,7	11	5	1,9	1,9	0.65	1,3	-	-	-
2011	6	3	2,4	4	2	1,3	1,3	1,2	0.05	-	-	-
2012	13	7	4,2	10	6	1,7	1,7	0.08	0.18	0.75	0.75	-
2013	2	2	0.26	2	2	0.26	0.26	-	0.06	-	0.2	-
2014	3	3	0.47	2	2	0.58	0.58	-	0.06	-	0.5	-
2015	11	3	2,7	8	3	1,6	1,6	-	0.6	0.8	-	0.2
2016	8	5	2,3	6	4	1,1	1,1	0.3	0.16	0.5	-	-
2006-2016	142	20	59,7	120	17	35,1	35,2	26,5	4,9	2.1	1,5	0.2

All doses in million. #: Number; Req.: Request; Count.: Countries; Tot.: Total.

Chart 2. Doses of meningitis vaccines requested to and shipped by the ICG (2006-2016)

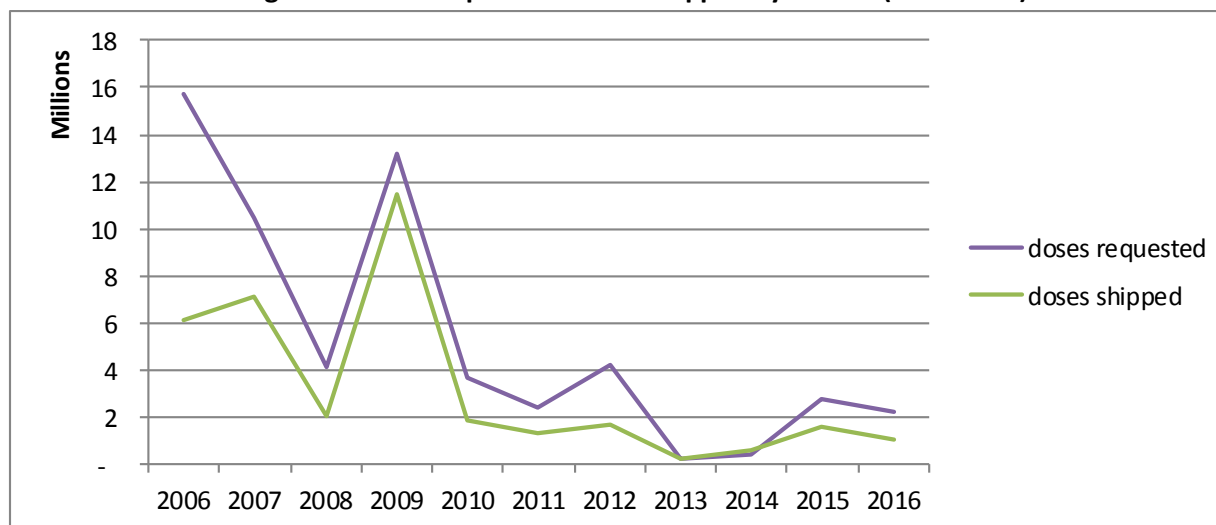
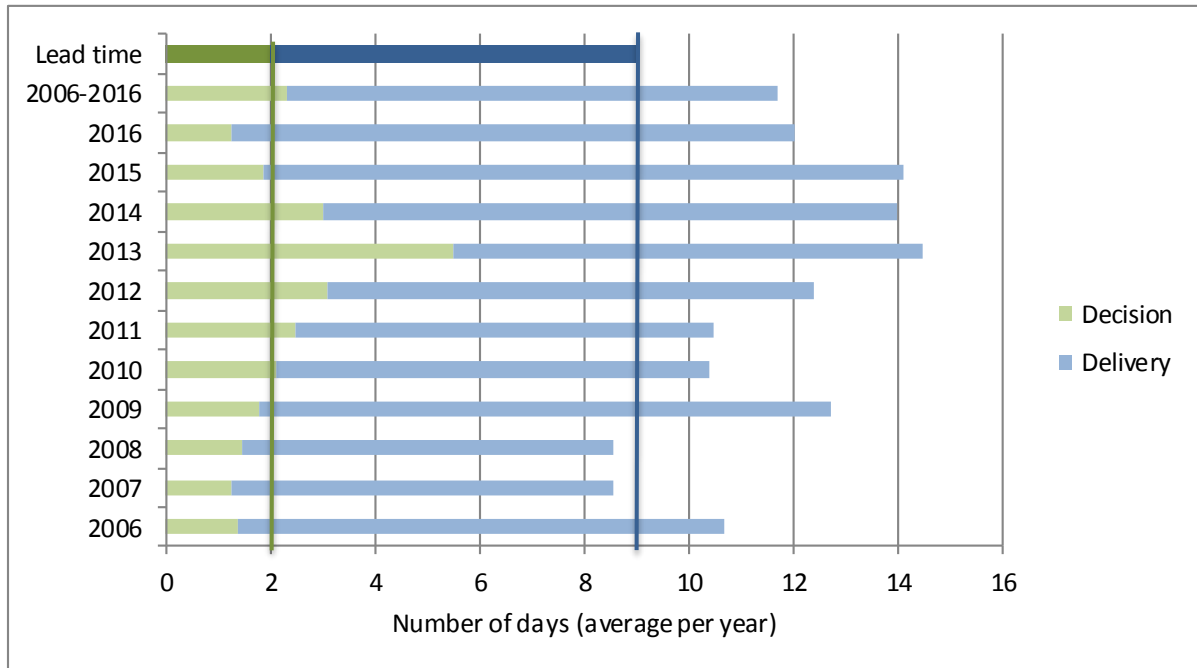


Chart 3. Performance of the ICG Meningitis for decision and delivery (2006-2016) compared to lead time



Discussion

Background on meningococcal epidemics⁹

Epidemics due to the Nm A, the main cause of epidemics in Africa until 2010, have almost disappeared, following the progressive introduction of mass vaccination with the serogroup A meningococcal conjugate vaccine since 2010. Epidemics continue to occur from other serogroups, mainly Nm W (in 2010, 2012 and 2016) and more recently Nm C, which emerged in North West Nigeria in 2013 and since has expanded, causing unprecedented large-scale outbreaks in Nigeria and Niger in 2015 and smaller ones in 2016.

The unpredictability of the outbreaks and of vaccine supply makes procuring vaccine for all type of serogroups challenging. Since 2011, vaccine manufacturers have started phasing out production of affordable polysaccharide PS vaccine (GSK/Pfizer in 2015, Sanofi date to be announced) in favour of conjugate vaccines. While three quadrivalent conjugate vaccines (A, C, W, Y) are licensed, their cost and restricted availability have limited their use for the outbreak response stockpile.

The constrained vaccine supply resulted in vaccine shortages and procurement delays in 2012, 2015 and 2016 (see Graph 2). Vaccine allocation had to be restricted to those areas and age groups that were most vulnerable.

Performance of the meningitis ICG¹⁰

Keeping the entire process from request to delivery less than 10 days is a goal not always meet. However, in more than 80% cases, vaccines are delivered in 15 days or less. Information below details some issues.

- In 2009, only 20% of vaccine shipments were delivered within the target 7-day lead time. This was mainly due to the enormous number of shipments (35 in three months), the new procurement

⁹ Meningitis outbreak response: the continuing need for a global meningococcal vaccine stockpile, WHO, 2016

¹⁰ Sources: reports of the annual ICG meeting and monitoring of requests

mechanism, as well as lack of Gavi funds at the start of the season. Another difficulty was that Bio-Manguinhos vaccine could not be delivered to Nigeria, for lack of registration and licensing.

- In 2011, one shipment was delayed due to problems with customs in Dubai, where the stockpile was held.
- In 2012, the decision time was generally closer to 3 days. This was due to the complexity of the requests: NmW135 epidemics in a context of limited availability and expensive prices of tetravalent vaccines, and NmA epidemics in countries introducing Conjugate Men A vaccine. In delivery, some of the delay occurred because vaccines from Sanofi in the USA were not ready at the time of the request and because of logistical problems in Chad (20 days for one shipment).
- In 2013, the ICG decision time for one request was 5 days, which include 3 days spent clarifying and completing missing information. The delay in delivery is explained by difficulties in shipping the vaccines to Juba, South Sudan.
- In 2014, delivery in Uganda was delayed because the vaccine was not licensed in Uganda and a waiver from the government was needed.
- Since 2010 and the introduction of Men A vaccine, the requests have concerned either less typical outbreaks (e.g. meningitis C in Nigeria) or come from countries with less experience in managing meningitis outbreaks and completing their requests.

ANNEX 1.2 YELLOW FEVER ICG

Table6. Requests received, approved and doses shipped for yellow fever vaccines.

Year	Requested			Approved			Shipped
	# Req.	# Countries	# doses	# Req.	# Countries	# doses	#doses
2006	1	1	856 786	1	1	856 786	860 000
2007	2	2	5 313 504	2	2	2 129 710	2 129 800
2008	10	8	10 466 847	10	8	10 058 745	10 058 600
2009	8	6	2 875 630	6	5	1 115 516	1 115 800
2010	8	5	5 228 172	5	4	4 616 227	4 616 600
2011	5	5	1 624 655	4	4	2 593 626	2 594 100
2012	5	4	6 796 171	5	4	5 189 627	5 188 800
2013	6	3	2 644 545	5	3	2 330 749	2 331 900
2014	1	1	559 876	1	1	559 876	560 000
2016	11	3	36 735 645	10	3	30 203 430	30 203 430
2006-2016	57	20	73 101 831	49	20	59 654 292	59 659 030

#: Number; Req.: Request.

Chart4. Doses of yellow fever vaccines requested from and shipped by the ICG (2006-2016)

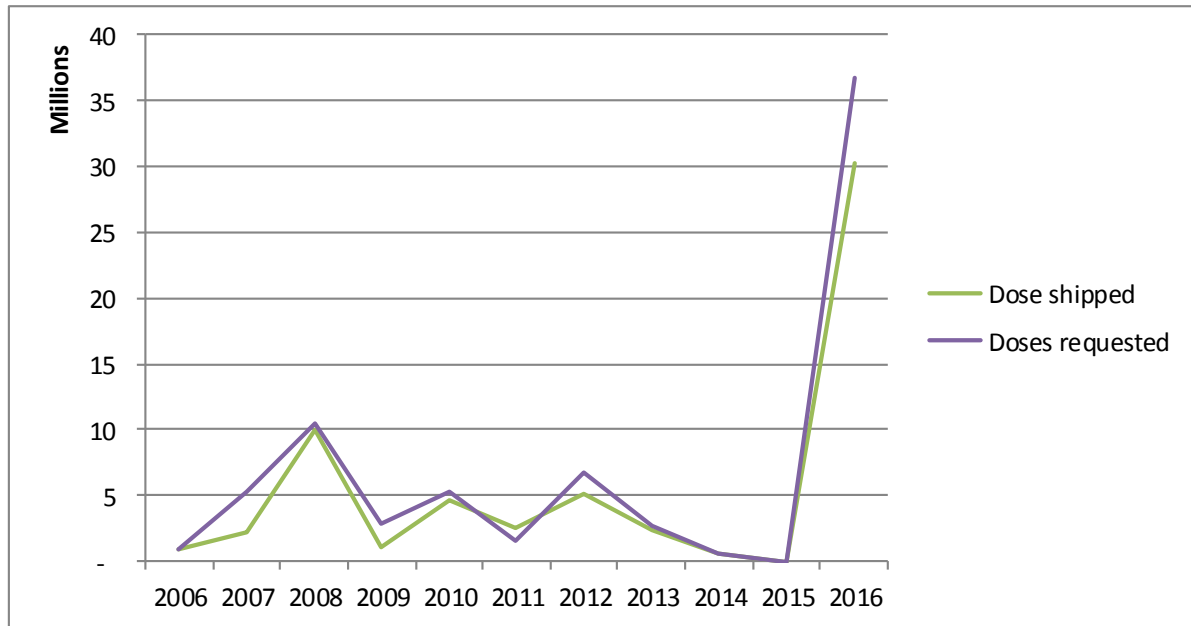
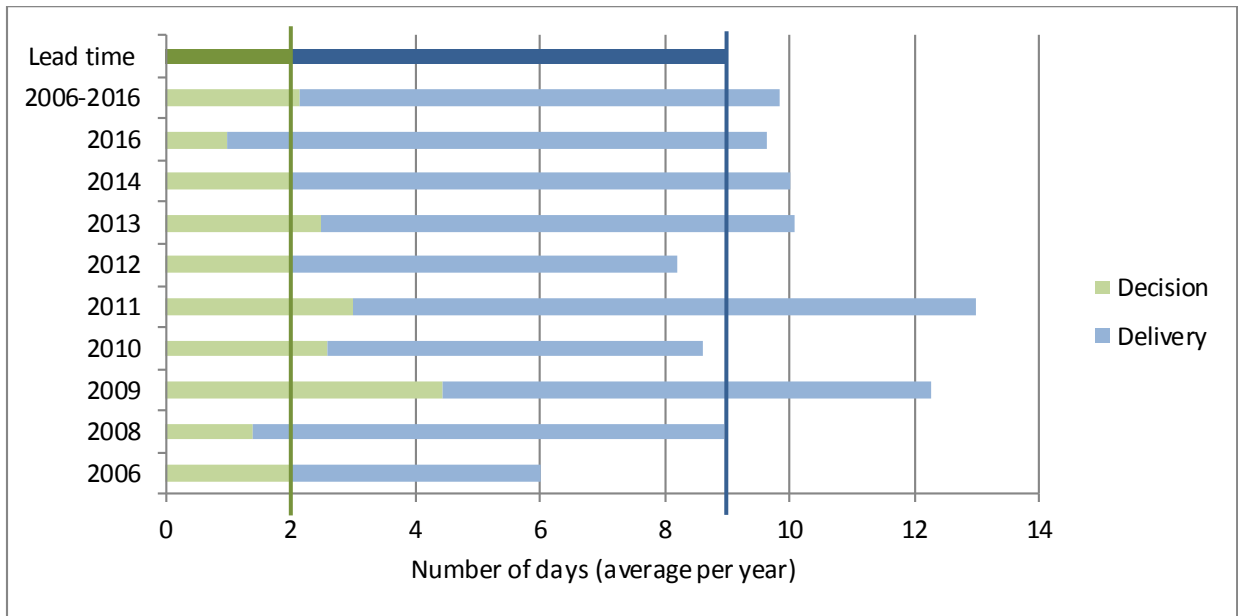


Chart5. Performance of the ICG yellow fever for decision and delivery (2006-2016) compared to lead time



Discussion¹¹

On average, performance indicators for the yellow fever ICG are close to the target lead times. Status of completion of requests at the time they are circulated to the ICG core members is not well documented. This is likely to explain the long decision time in 2009 and 2010 and 2013.

In 2011, it took 13 days for the ICG to approve a request from Senegal, as it was difficult to identify the population at risk because of migration. The ICG had to request supplementary information from the country.

In 2011, vaccine stockpiles were more limited than expected. Vaccine manufacturers supplied less than the quantity they had promised in their procurement agreements with UNICEF SD. This shortage affected emergency and routine vaccination programmes.

Other challenges include:

- Yellow fever case detection is often challenging, leading to delayed completion of request for vaccines. This is due, in part, to limited capacities for laboratory confirmation.
- With the advent of mass preventive campaigns in some countries, interpretation of serology results has become difficult and can delay decision-making.

¹¹ Sources: reports of the annual ICG meeting and monitoring of requests

ANNEX 1.3 CHOLERA ICG

Table7. Requests received, approved and doses shipped for OCV and loans requested and shipped

Year	Requested			Approved			Shipped	Loan	
	# Req.	# Count.	# Doses	# Req.	# Count.	# Doses	# Doses	Requested	Shipped
2014	6	4	1 043 765	4	3	567 390	567 390	918 720	918 825
2015	14	8	3 292 059	9	5	1 806 440	1 806 560	107 9673	436 240
2016	10	6	2 818 457	8	6	2 465 622	2 465 745	-	-
2014-2016	30	13	7 154 281	21	11	4 839 452	4 839 695	1 998 393	1 355 065

#: Number; Req : Request; Count.: countries

Chart6. Doses of OCV requested and shipped for emergencies and loans requested and shipped (2014-2016)

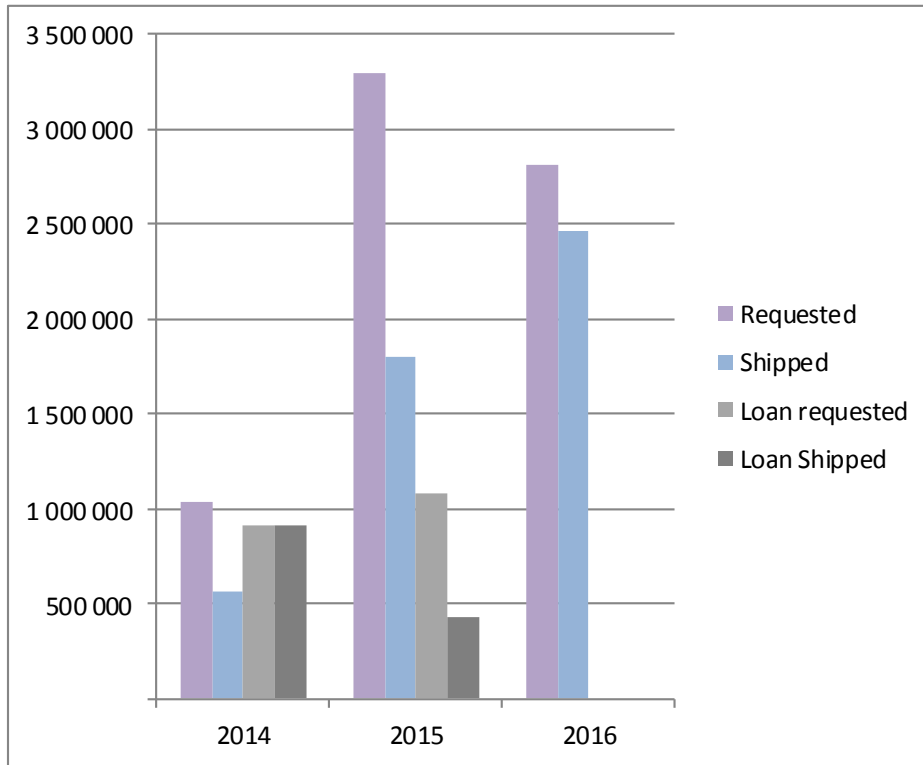
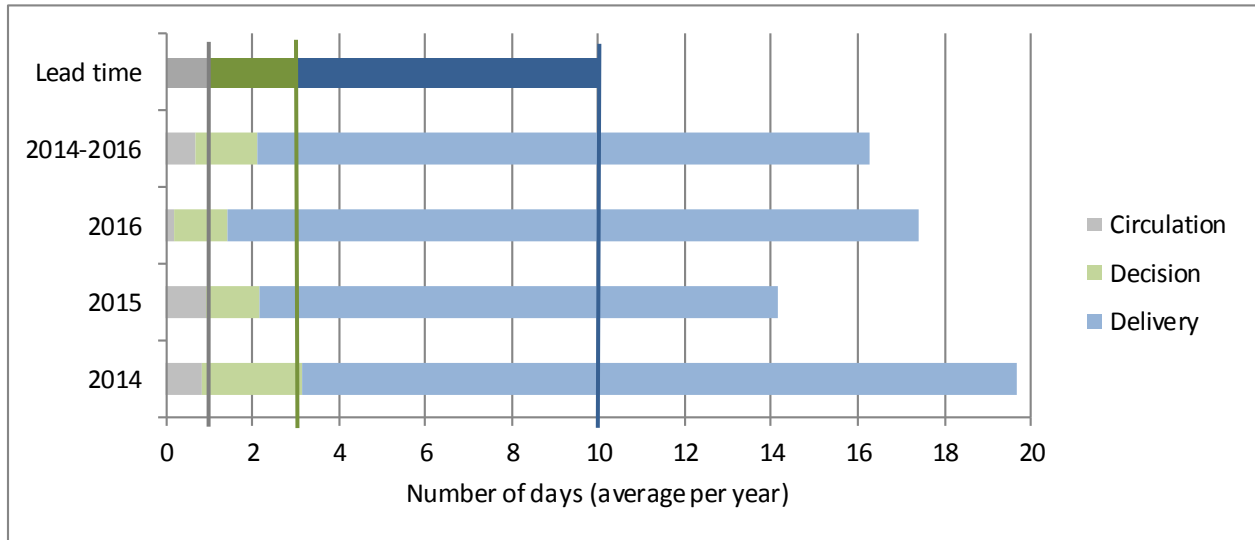


Chart7. Performance of the ICG cholera for circulation, decision and delivery (2014-2016) compared to lead time



Discussion¹²

The OCV ICG, on average, meets lead time target for circulation and decision.

Delivery to country is more challenging. This is partly explained because the OCV is a relatively new vaccine and regulatory issues have arisen in some countries. For example:

- In 2014, OCV was not licensed in Ethiopia and approval was needed from the National Regulatory Authority. As a result, it took 17 days to deliver the vaccine.
- In 2015, a similar delay occurred due to lack of registration of the vaccine in Tanzania.

In terms of vaccine availability, the manufacturers have not met the production goals requested by the ICG, and supply does not meet demand.

From 2013 to 2015, the entire supply of OCV was allocated to the emergency stockpile. On occasions, the ICG granted “loans” (see Chart 6.) on the basis of strong justification for the decision to release OCV from the stockpile outside of the emergency or outbreak context.

The prequalification in December 2015 of Euvichol, a vaccine from EUBiologics, is expected to ease supply concerns.

¹² Sources: reports of the annual ICG meeting and monitoring of requests

ANNEX 1.4 SUMMARY TABLE OF PERFORMANCE INDICATORS PER ICG

Year	Circul.	Decision		Delivery		Total			
	Av. (d.)	Av. (d.)	%≤ 2 wd	Av. (d.)	%≤ 7 d.	Av. (d.)	%≤10 d.	10<%≤13 d.	%>13 d.
Meningitis									
2006	0	1.4	88%	9.3	31%	10.6	47%	35%	18%
2007	0.3	1.3	91%	7.3	64%	8.9	79%	14%	7%
2008	0	1.4	89%	7.1	63%	8.5	75%	13%	13%
2009	n/a	1.8	91%	10.9	23%	12.7	43%	20%	37%
2010	n/a	2.1	79%	8.3	31%	9.9	55%	45%	0%
2011	n/a	2.5	50%	8.0	50%	10.5	50%	50%	0%
2012	n/a	3.1	46%	9.3	56%	12	44%	33%	22%
2013	n/a	5.5	50%	9.0	50%	14.5	0%	50%	50%
2014	0	3.0	33%	11.0	0%	13.5	0%	50%	50%
2015	0.9	1.9	75%	12.3	13%	15	38%	0%	63%
2016	0	1.3	88%	10.8	20%	12.2	40%	20%	40%
2006-2016	0.2	2.3	80%	9.4	35%	11.4	50%	25%	25%
Yellow fever									
2006	n/a	2.0	100%	4	100%	6	100%	0%	0%
2007	n/a	2.5	50%	n/a	n/a	n/a	n/a	n/a	n/a
2008	n/a	1.4	90%	7.6	57%	9.4	71%	0%	29%
2009	n/a	4.4	43%	7.8	50%	11.6	50%	17%	33%
2010	n/a	2.6	60%	6.0	75%	8	75%	25%	0%
2011	n/a	3.0	50%	10.0	50%	13	50%	0%	50%
2012	n/a	2.0	100%	6.2	80%	8.2	75%	25%	0%
2013	n/a	2.5	50%	7.6	20%	10.2	60%	20%	20%
2014	n/a	2.0	100%	8.0	0%	10	100%	0%	0%
2016	n/a	1.0	85%	8.6	55%	10	64%	18%	18%
2006-2016		2.2	72%	7.7	53%	9.9	63%	15%	22%
Cholera									
2014	0.8	2.3	50%	16.5	0%	19.5	0%	0%	100%
2015	0.9	1.2	86%	12.0	11%	13.8	11%	22%	67%
2016	0.2	1.2	100%	16.0	0%	17.4	0%	43%	57%
2014-2016	0.6	1.4	83%	14.1	5%	15.9	6%	28%	67%

Circul.: Circulation; Av.: Average; d.: day; wd: working days; n/a: not available

ANNEX 2. ACRONYMS

AEFI	Adverse Events Following Immunization
BMGF	Bill and Melinda Gates Foundation
DFID	Department for International Development
DRC	Democratic Republic of the Congo
Gavi	Global Alliance for Vaccines and Immunization
ICG	International Coordinating Group on vaccine provision
IFRC	International Federation of the Red Cross and Red Crescent Societies
MoH	Ministry of Health
MSF	Médecins Sans Frontières
OCV	Oral Cholera Vaccine
PPC	Programme and Policy Committee
SAGE	Strategic Advisory Group of Experts on Immunization
SC	Steering Committee
SOP	Standard Operating Procedures
ToR	Terms of Reference
UNICEF	United Nations Children's Fund
UNICEF SD	United Nations Children's Fund Supply Division
WASH	Water, Sanitation and Hygiene
WHO	World Health Organization

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Archived country requests

SOPs and step-by-step documents