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EXTERNAL EVALUATION OF THE INTERNATIONAL COORDINATING GROUP ON VACCINE PROVISION (ICG) MECHANISM

Final Report

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ABBREVIATIONS

AMP	Agence de Médecine Préventive
BMGF	Bill and Melinda Gates Foundation
CDC	Centers for Disease Control and Prevention
DAC	Development Assistance Committee (OECD)
DRC	Democratic Republic of Congo
EMG	Evaluation Management Group
EYE	Eliminating Yellow Fever Epidemics
GTFCC	Global Taskforce on Cholera Control
ICG	International Coordinating Group on Vaccine Provision
IFRC	International Federation of the Red Cross and Red Crescent Societies
KII	Key Informant Interview
MSF	Médecins sans Frontières
OCV	Oral Cholera Vaccine
SC	Steering Committee
SIA	Special Immunization Activity
SOP	Standard Operating Procedure
UN	United Nations
UNEG	United Nations Evaluation Group
UNICEF PD	UNICEF Programme Division
UNICEF SD	UNICEF Supply Division
WHA	World Health Assembly
WHO	World Health Organization
YF	Yellow Fever

EXECUTIVE SUMMARY

The International Coordinating Group on Vaccine Provision (ICG) was established by four founding members (IFRC, MSF, UNICEF and WHO) in response to the 1996 outbreak of meningitis in Africa. Since its establishment, it underwent progressive changes. In 2001 yellow fever (YF) vaccine, and in 2013, oral cholera vaccine (OCV), were added to the ICG mandate. Its three guiding principles were in 2016 described as[1]:

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

The Gavi Alliance is currently the sole funding source for ICG stockpiles. Over the past years, stakeholders such as Gavi and UNICEF Supply Division (SD) have brought new dimensions to the ICG process, in particular related to market shaping, procurement and deployment of vaccines. Public interest in the ICG also increased, in particular following recent major outbreaks which also highlighted a weak link between outbreak responses and global disease control strategies. The work of the ICG is now followed more closely, including by the media. As such, transparency about decision-making, as well as accountability, was raised as an area deserving more scrutiny. Since 2015, stakeholders have highlighted a need to evaluate the functioning of the ICG mechanism. This is the context in which the evaluation of the ICG was commissioned.

Governance

International stakeholders who participated in the online survey consider that the mandate of the ICG to ensure timely, efficient, equitable and targeted deployment of vaccines is still to a large extent relevant. The evaluation team also considers the mandate relevant in the context where global vaccines supply for Meningitis, YF and Cholera do not meet fully demand and thus have to be rationed. Despite the fact that the ICG has a well-defined role, the responsibilities of the involved stakeholders are not clearly defined. From the social network analysis, it is clear that the ICG Secretariat plays a central and coordinating role in the entire ICG mechanism. Other stakeholders are involved in different aspects of the ICG mechanism (decision-making, forecasting, procurement and deployment of vaccines). The lack of a clear division of labour and responsibilities, and the lack of a formal governance structure is a weakness and strength at the same time. Having some level of informality and flexibility has been an asset of the ICG to ensure timely response to emergency outbreaks.

Practically all stakeholders agree that the ICG decision-making bodies have been effective in executing their task of allocating scarce vaccines to respond to outbreaks. Decisions are made in a short time, by consensus and based on the information which is available at the time. This process is largely in line with the 'no regrets' approach of decision-making. While this collective voice is a key strength because it protects the individual organisations from criticism, it raises issues of accountability as no single organisation can be held to account for the decisions made by the ICG.

The emerging single funding and procurement channels through Gavi and UNICEF SD have created a new situation. More organisations are involved in major components of the 'ICG response function' and can be held to account. In order to bind them into the ICG mechanism and assure a continued functioning of the entire process, a more formal and comprehensive governance structure and accountability mechanism is needed.

[1] WHO (2016). Review of the International Coordinating Group on Vaccine Provision (2006-2016) (No earlier reference to these guiding principles were found)

Recommendations:

- More clarity is needed on which actors and stakeholders are responsible for what part of the ICG mechanism, in particular on who is responsible for the decision-making, forecasting, procurement and deployment of the vaccines and which organisations are key contributors to these parts.
- Key performance indicators should be developed or existing ones adapted for each specific portion of the flow chart for which the ICG Secretariat, the Gavi Secretariat and UNICEF Supply Division are responsible.
- The decision-making role of the ICG has to function independently and no additional level of endorsement is needed as this would negatively impact on timeliness and independence. However, options could be explored to make the decision-making bodies more formally accountable to the respective global disease control initiatives through the establishment of an oversight body (see below), to review the composition of each of the three ICGs, and to adopt a stronger communication plan to clearly communicate the decisions made.
- Review the composition of each of the three decision-making bodies to make sure that the participating organisations can provide the most relevant technical and field expertise for the respective diseases.

Options for the future:

While the decision-making on country vaccine requests may best thrive as an independent body, a governance and accountability structure is required for the other functions of the ICG flowchart: forecasting, procuring, shipping, and monitoring of vaccine deployment.

For an oversight body, there are different options:

- A new body could be created for managerial oversight, consisting of senior staff of stakeholder organisations, including the GAVI secretariat, UNICEF SD and regional or rotating country representatives. It would be responsible to oversee the performance of each of the stakeholders and can hold organisations or countries to account. The advantage of creating a new body is that it will be tailored specifically to the ICG mechanism with clear oversight portfolio. The disadvantage is that it will require significant time and possibly also financial investment to make sure the oversight body is functional.
- Alternatively, an already existing body could be engaged to provide oversight. Or it could also be formed as a committee of the Gavi Alliance Board in which the majority of stakeholders are already represented. The advantage of using an already existing mechanism or sub-committee of an existing mechanism is that it may require less effort and investment; however, it is not clear at this point what type of oversight could be provided and whether all interests would be appropriately represented.

An oversight body should not interfere with the independence of the decision process, but rather assure that the decisions are executed optimally and transparently, and the financial donors to the Gavi Alliance receive the necessary reports to meet their own accountability needs.

If the Gavi Secretariat is involved in either of these oversight bodies as well as in the oversight bodies of the global disease control mechanisms, and *if* there is more clarity on how the respective ICG decision-making bodies will report to these oversight mechanisms, then Gavi secretariat observer role of the ICG decision process may no longer be necessary because it would receive sufficient information about the decision-making process.

Mechanisms and processes

The ICG has functioned well over the past 20 years and the majority of international and country-based stakeholders are appreciative of the ICG's performance. While criteria used during decision-making are publicly available, ICG members state that the criteria cannot be weighted because each outbreak is

different and the importance of certain criteria varies accordingly. The majority of key informants believe however that the decision-making process is sound, efficient and effective and the evaluation team confirms this. In almost all cases where the ICG has not met its own performance indicators, the causes were external and beyond the ICG control. This points to a problem in the scope and role definition of the ICG. Issues that were identified by the evaluation as requiring improvements include:

- An overlap of responsibilities within the ICG mechanism
- A lack of formalisation of ICG processes that may be appropriate for the decision-making group, but are not appropriate for the ICG Secretariat which has a number of clearly defined tasks for each stockpile vaccine request
- Weaknesses of the links between the ICG mechanism and global disease control mechanisms, with the perception by some stakeholders that allocation decisions focus too narrowly on responding to single outbreaks
- Lack of a wider strategy for meningitis coupled with the decreasing supply of polysaccharide vaccines is making an efficient response by the ICG difficult
- To effectively supply vaccines for emergency responses, manufacturers would like to have long-term contracts for each of the stockpile vaccines in order to guarantee timely supply and release of emergency vaccines.
- A perception by some country-based stakeholders that ICG allocation decisions are influenced by the engagement of ICG member organisations in their country.

Recommendations

- There is a need for a clear definition of roles and responsibilities among key actors in the ICG network, primarily the ICG Secretariat, UNICEF SD, and the Gavi Secretariat.
- Once the roles and responsibilities of the ICG Secretariat are well defined, it requires a set of functional SOPs to cover the functions for which it can be held to account.
- Similarly, once the roles and responsibilities of UNICEF SD are well defined, functional SOPs should be developed to standardize the process for vaccine procurement for each stockpile.
- The role and responsibilities of the country governments should also be formalised; promptness of the submission, resolving issues around licensing and customs, and ensuring an effective implementation of the campaign with adequate reporting.
- In order to address the dissatisfaction by country stakeholders on the transparency of the decisions and in particular the criteria used, the evaluation team recommends to also share a more standard response with the countries on how the criteria were applied during the decision-making.
- The evaluation team also recommends to more formally involve UNICEF SD during the decision-making process in order to ensure the decisions take the context of the global stockpile situation and production capacity better into account. This involvement can remain separate from the actual decision-making discussion
- WHO needs to step up to its mandate and develop a global strategy for meningitis control and a mechanism to implement it.
- The Gavi Alliance is an ideal partnership to improve the present and future availability of different meningitis serotype vaccines.
- To increase the timely and reliable availability of the meningitis vaccines in the short term we recommend to transfer the risk of wastage from the manufacturers to the international health community.

Funding

The funding of the three vaccine stockpiles has become more reliable and equitable since Gavi decided not to apply time limits to its financial commitment and to allow all countries to access the stockpiles. Remaining balances of previously established revolving funds for the three stockpiles that are administered by WHO still exist, and have in the last years proven useful as contingency funds when Gavi funding could for some reason not be used. Although these incidences should theoretically become rare, a contingency funding source is a safety mechanism that is widely supported by stakeholders.

Support for the operational costs of reactive immunisation campaigns in Gavi-eligible countries is provided by Gavi via WHO in an arrangement that is not within the scope of ICG responsibilities. Countries that are not eligible for Gavi support have to find alternate sources for vaccines and campaign financing. Tracking and reporting on the use of vaccines allocated through the ICG mechanism is variable but in general weak. It tends to be more complete when countries receive support for operational costs because the support is linked to monitoring and reporting requirements, or when specific support is provided by other initiatives, such as the Global Taskforce on Cholera Control (GTFCC).

Recommendations:

- Gavi funding of the vaccine stockpiles has had a positive effect on stabilising the availability of vaccines for outbreak responses and is widely supported. It should therefore be maintained.
- The need for a back-up mechanism to pre-finance urgent vaccine needs is also widely acknowledged. The recommendation is to create an ICG contingency fund:
    - By either using the balance of the current revolving funds with an annual call for replenishment, or through pre-financing any future contingency needs from the WHO Contingency Fund for Emergencies.
    - The conditions under which the contingency fund can be used should be clearly spelled out in SOPs in order to avoid confusion amongst stakeholders on its purpose and use. A decision should also be made whether these funds can be used to pre-finance operational costs for non-Gavi supported countries.
- Standardised, robust and enforceable reporting requirements should be established, and implemented by the ICG Secretariat which should be held accountable by the proposed oversight body. This will require additional investments either for technical support to the countries or in terms of human resources for the ICG Secretariat.

Communication and transparency

The stakeholders in the ICG mechanism have distinct information needs to facilitate their effective participation in outbreak responses and to account for their own investments and activities. There is currently no clear overview or strategy on public communication, nor about which stakeholder requires access to what type of information at what time. Lack of transparency was one of the most frequently voiced criticisms. Communication gaps have resulted in the circulation of unfounded rumours and in some reputational damage to the ICG.

ICG members want more and more detailed information about vaccine availability in the stockpiles in order to facilitate decision-making. Country applicants want a clearer and more comprehensive explanation of how allocation criteria were applied, and about the funding of the vaccines and operational costs. Besides the information it already receives, the Gavi Secretariat wants real-time access to information about vaccine deliveries. Financial donors to the Gavi Alliance and the ICG, and other extended partners, want more detailed information about vaccine allocations, reasons for rejections, and decisions about immunisation strategies that are sometimes part of the ICG decision on allocation volumes.

Recommendations:

- An assessment of the different information needs should be carried out, answering the question: *who needs what kind of information at which stage of the process?*
- Based on the outcome of the assessment a communication plan should be developed, outlining the information needs of all stakeholders with specific channels and instruments to support their role in the process for outbreak controls, as well as allowing them to fully meet their own accountability requirements.
- Recruit staff for the ICG Secretariat responsible for the implementation of this communication plan. While there is a need for a specialist to communicate technical information to a well-informed audience, the evaluation team also recommends considering a communications specialist capable of providing often sensitive messages to a broader audience that may be technically less informed.

- The implementation of the communication plan should also involve the definition and development of an appropriate platform for internal information-sharing between the different involved stakeholders. In addition, a similar platform could be developed for public information about the rationing of scarce vaccines.
- Gavi should also define more clearly how it communicates with the ICG members, with the ICG Secretariat and with the countries on its engagement with the ICG. There is an identified need to communicate clearly and consistently to countries the fact that Gavi is funding the three stockpiles and that all countries can access these but that non-Gavi supported countries should reimburse Gavi for the vaccines used and finance the operational costs themselves.
- The ICG Secretariat and UNICEF SD should invest time and resources in increasing their collaboration and information-sharing, for example through quarterly progress and management meetings outside of the annual ICG meetings.

Future role

The role of the ICG and the disease control mechanisms for yellow fever and cholera control like the Elimination of Yellow Fever Epidemics (EYE) and the Global Taskforce on Cholera Control (GTFCC) are distinct but interrelated. While they both promote the use of and make decisions on the allocation of scarce vaccines, the context in which they do this is different and requires a different approach. Nevertheless alignment and collaboration is necessary to ensure effective use of limited supply. The collaboration of the ICG Secretariat with EYE and GTFCC has improved, but several stakeholders consider that there is room for more collaboration and alignment. Most stakeholders do not support the option to fully transfer the mechanism for emergency vaccine deployment to EYE and GTFCC. Nevertheless, there is a belief that as global shortages of OCV and YF vaccine will become less acute the role of the ICG in managing emergency stockpiles of these vaccines will diminish. The situation is different for meningitis vaccines where there is no comprehensive global initiative and where vaccine shortages are a greater challenge.

There is wide agreement among stakeholders that the ICG Secretariat has acquired a competence in managing the process of rationing of scarce vaccines for emergency needs that can be applied to other vaccines, medicines and products. In each case, the members of the independent allocation committee need to be recruited according to criteria that assure the best decisions according to technical and global public health criteria, while preserving the political independence of the allocation process.

Recommendations:

- The sharing of information and collaboration between the EYE and the YF ICG should be formalised.
- At the next annual meeting of the YF ICG, the collaboration and information sharing between ICG and EYE should be a subject of a joint review.
- More formal and regular sharing of information with the GTFCC on the deployment and use of OCV in both emergency and non-emergency settings could improve knowledge management and overcome current hurdles in terms of licensing and importation of the vaccine.
- All vaccine requests for OCV and YF should be submitted to the respective global disease control mechanisms that will triage the requests and forward to the respective mechanism (ICG for emergency response, Gavi Secretariat for routine immunization and EYE or GTFCC secretariat for Special Immunization Activity (SIA). Given the lack of a global disease control initiative for meningitis, the requests for emergency vaccines will have to continue to be sent directly to the ICG Secretariat.

Options for the future:

- The ICG Secretariat has established a competence in managing emergency vaccine allocation requests which, according to most stakeholders, can be applied to other vaccines and products that are used for outbreak controls and that are globally in short supply. The precondition, however, is that it establishes a more formal definition of its remit and its procedures, as well as a formalised partnership with those responsible for procurement and financing.

- The ICG mechanism as such is also largely considered as a suitable mechanism for managing future vaccine-stockpiles for outbreak responses, such as Ebola and other new emerging infectious diseases for which there is limited supply. The composition of the ICG for each of the existing and new stockpiles should be open for changes. Members need to be recruited or trained according to criteria that assure the best decisions according to technical and global public health criteria while preserving the political independence of the allocation process.
- For those vaccines for which supply is increasing and for which functional global disease control mechanisms exist, the evaluation team recommends that stakeholders explore whether in the mid-term an effective assimilation of the ICG in the respective global disease control mechanism would provide a more efficient and effective control plan. This would improve general oversight and critical knowledge management, however it is critical to stress that with this assimilation the emergency response should not lose its independence and well established functionality.

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1 CONTEXT AND BACKGROUND

1.1 THE INTERNATIONAL COORDINATING GROUP ON VACCINE PROVISION (ICG)

The ICG was established as the *International Coordinating Group on Vaccine Provision for Epidemic Meningococcal Disease* in response to the 1996 outbreak of cerebrospinal meningococcal meningitis in Africa that affected primarily Nigeria and Burkina Faso with a total of 152,813 confirmed cases and 15,783 deaths. The actual incidence was likely considerably higher.

The first meeting of the ICG was held in January 1997 in Geneva. The primary focus of the ICG agreed in this meeting was to '*address the rational use of the limited amounts of vaccine available for 1997, to seek funds to ensure that as much vaccine as possible would be available to countries most in need, and to monitor and coordinate the distribution of vaccines which were procured through other sources, such as UNICEF or MSF*.'[2] Two groups were set up, the ICG and the ICG Executive Sub-Group, and terms of reference drafted. These further established that:

- The ICG meets each year in June and December. Membership is limited to those who agree to coordinated procurement and distribution of vaccine, including international organisations, NGOs, technical agencies, vaccine manufacturers, financial partners, and representatives from two countries within the meningitis belt plus one outside. World Health Organization (WHO) serves as secretariat.
- The Executive Sub-Group is the working arm of the ICG. The proposed composition includes one representative of each of the following organisations: CDC, IFRC, MSF, UNICEF, AMP, WHO Regional Offices (AFRO and EMRO), and WHO Headquarters. The Executive Sub-Group reviews requests for vaccine from emergency stocks and coordinates distribution through the following activities:
    - inventory of existing stocks in countries
    - review of vaccine availability from manufacturers
    - review vaccine requests and compare to criteria for vaccine distribution
    - identify missing information in vaccine requests and request as necessary
    - advise on the amount of vaccine to be distributed
    - monitor vaccine distribution by other mechanisms
    - review financial resources for procurement of vaccine

Since its establishment, the ICG underwent progressive changes. In 2003, the terms of reference were revised. The original objectives were maintained but the name of the 'Executive Sub-Group' was changed to 'ICG' and the four members IFRC, MSF, UNICEF and WHO were confirmed.[3] The remaining organisations, agencies and companies, later referred to 'ICG extended partners' were invited to participate in annual ICG meetings and in ad hoc working groups.[4]

In 2001, yellow fever (YF) vaccine, and in 2013, oral cholera vaccine (OCV) were added to the ICG mandate. The four members established separate partnership groups and annual meetings were organised for each of the three vaccine stockpiles. The terms of reference were not changed, but membership criteria were reformulated in 2012.[5] Eligible ICG members:

[2] International Coordinating Group on Vaccine Provision for Epidemic Meningitis Control. Summary Report. Geneva, Switzerland, 16-17 January 1997 WHO/EMC/ DIS/ICG/97.9

[3] Later communications variably refer to this group as 'ICG', 'ICG executive', or 'ICG core members'. In the presentation of the ICG to the Global Ebola Vaccine Implementation Team (GEVIT) Regional Workshop in 2016, WHO reverted to the name 'ICG Executive Sub-Group'

[4] International Coordinating Group on Vaccine Provision for Epidemic Meningitis Control. Report of the ninth meeting, Ouagadougou, Burkina Faso, 15–16 December 2003

[5] WHO Technical Working Group on creation of an oral choler vaccine stockpile. Meeting report Geneva, 26–27 April 2012

- must be an international public health agency or international non-governmental organisation
- must play an active role in outbreak response
- must show commitment
- must respect data ownership and confidentiality
- must be impartial

A call was issued for organisations seeking to join the ICG but no expressions of interest were received and the original four-member ICG was maintained for each vaccine group, as well as the Secretariat at WHO.

Separate standard operating procedures (SOPs) for the emergency stockpiles of meningitis and YF vaccine, but not for OCV, were drafted for vaccine applications, release, financing, replenishment, monitoring and reporting. In 2015, discussions started about an ICG mechanism for Ebola vaccine, and a first meeting of an ICG Ebola vaccine group was convened in December 2015.[6] This group is not yet operational and not included in this evaluation.

According to an internal review in 2016, the ICG has three guiding principles that have remained unchanged since its creation in 1997:[7]

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

In 1997, the ICG established the meningococcal revolving fund to pre-finance the purchase of meningococcal vaccine, vaccination supplies and antibiotics. Funds were raised through repeated appeals and reimbursements by countries.[8] According to the ICG Secretariat, the success of fundraising prior to 2007 was limited and only about 50 percent of costs were reimbursed.[9]

In 2002, the Gavi Alliance started to provide financial support for the procurement of YF vaccine for outbreak responses and preventive campaigns. Subsequently, nine separate funding decisions were taken related to the YF vaccine stockpile. For meningitis, Gavi involvement started in 2008 with the allocation of US$55.2 million to finance the stockpile of polysaccharide vaccines from 2009 to 2015. In 2016 a no-cost extension was granted and additional bridge funding of US$15 million was approved for 2017. In 2013, Gavi contributed US$15 million for the period of 2014 to 2018 to finance the global OCV stockpile for use in epidemic and endemic settings[10]. All these funding commitments were time-bound, and funds were held by UNICEF Supply Division (SD) and used to replenish the stockpiles of these vaccines.

In 2009/10 revolving funds were established for YF and meningitis (a 'new revolving fund' for meningitis) to ensure a source of funds if Gavi were not to extend its support beyond the original investment and to enable funding for non Gavi-supported countries. Donors to the funds included

[6] International Coordinating Group for Ebola Vaccine, 1st Meeting, 11 December 2015 – WHO Headquarters, Geneva, Switzerland

[7] WHO (2016). Review of the International Coordinating Group on Vaccine Provision (2006-2016) (No earlier reference to these guiding principles were found)

[8] WHO (2010). The ICG Meningococcal Meningitis Revolving Fund- Replenishment of Medical Supplies in ICG Stockpile and Recovery of Shipping Costs. Draft Standard Operating Procedures. SOP N° HSE/GAR/ERI-006

[9] International Coordinating Group for Vaccine Provision - Emergency Vaccine Stockpiles. Presentation to the Global Ebola Vaccine Implementation Team Regional Workshop, October 2016

[10] Gavi (2016) Annex F. Stockpile consultation meeting

the European Commission, the United Nations (UN) Central Emergency Revolving Fund, bilateral development agencies and ministries of health.[11] The funds were administered by WHO, and they created a possibility for the ICG Secretariat to use WHO procurement mechanisms for vaccines that could not be procured by UNICEF SD (see chapter 3.3). The funds were to be used to finance:

- Meningitis and YF vaccines
- Injection material and safety boxes
- Pharmaceuticals used for case management in YF or meningitis epidemics
- Storage, handling, freight, insurance and other expenditure associated with the shipment to destination [12]

Initially, all countries were expected to reimburse the cost of vaccines drawn from the stockpile, but in 2015 Gavi informed the ICG to stop requesting reimbursements from Gavi-eligible countries. In 2016, Gavi decided that investments in emergency vaccine stockpiles will no longer be time-bound and that non Gavi-supported countries could access doses from the three stockpiles, with a prior agreement that they reimburse the stockpile and Gavi would assume the financial risk of non-reimbursement. In this new context, and with all stockpile vaccines procured through UNICEF SD, the revolving funds are dormant, although they are still available for WHO procurement (e.g. for non-prequalified vaccines) or as a contingency fund.

Gavi provides funds to support the operational costs of emergency immunisation campaigns in Gavi-eligible countries. In 2016, the Gavi support for operational costs for emergency control of all three diseases was aligned at US$0.65 per vaccine dose. Gavi non-eligible countries need to seek funds for operational costs from other sources.[13]

Throughout the evolution of the ICG, the role of the Gavi Alliance as the main channel of international financial support for vaccine provision has increased. The Gavi Alliance is currently the sole funding source for emergency vaccine stockpiles as well as for the main proportion of operational costs of reactive immunisation strategies. In its 2016 meeting, the Gavi Alliance Board therefore requested that the Gavi Secretariat should *"observe ICG decision process on allocating doses to countries and participate in strategic decisions on epidemic response"*.[14] In May 2017, the ICG agreed to temporarily invite the Gavi Secretariat as observers to the ICG decision process, with a final decision to be reached in October after the discussion of the ICG evaluation.

[11] Standard Operating Procedures. Yellow Fever Emergency Stockpile (2011); and ICG. An explanation of the operation of the ICG meningococcal revolving fund and the ICG meningococcal stockpile. (2010)

[12] Internal WHO memo to Directors' Office, GAR (not dated). Use of the GAR-Based Revolving Funds Awards for Yellow Fever and Meningitis Vaccine

[13] Gavi (2016), Annex F: Stockpile Consultation Meeting Background Document and Meeting Report

[14] Gavi (2016). Minutes - Gavi Alliance Board Meeting, 7-8 December 2016

1.2 THE GLOBAL DISEASE CONTROL CONTEXT

The occurrence and response to outbreaks needs to be seen in the context of global disease control strategies. In many cases outbreaks are the consequence of insufficient coverage of routine immunisation systems and failure to compensate for that with effective special immunization activities, including campaigns. Other institutions and partnerships coordinate and support the control of cholera and YF, including through routine, preventive and reactive immunisation.

For cholera, the Global Taskforce on Cholera Control (GTFCC) was revitalised in 2011 following the World Health Assembly (WHA) 64.15 resolution. Its objective is to raise the visibility of cholera as a public health issue, facilitate sharing of evidence-based practices, and contribute to capacity development in all areas of cholera control. GTFCC can approve the allocation of OCV for prevention in hotspots or endemic areas as part of broader cholera disease control strategies that include water, sanitation and hygiene activities, treatment and social mobilisation. The GTFCC secretariat is hosted by WHO and a large number of organisations, including organisations that make up the ICG, participate in the different working groups of the GTFCC.[15]

Currently, there is only one OCV stockpile with a minimum of 2 million doses reserved for emergency response. Since 2013, 41 percent was used in humanitarian situations, 38 percent for outbreaks and 21 percent for endemic areas. The size of requests has increased from 200,000 (2013) to over 1 million doses (2017). The GTFCC plays a key role in supporting the implementation of the campaigns and provides support for monitoring and evaluation activities. During the 2017 annual OCV meeting, ICG and GTFCC discussed the need for one entry point for any OCV request which will be triaged and channelled to either the ICG or GTFCC. Annual reports for Gavi are prepared jointly by WHO and UNICEF and include an overview of OCV use for prevention and emergency campaigns.

The Yellow Fever Initiative was launched in 2006 as a joint collaboration of WHO and UNICEF, supported by Gavi. Key objectives were to support risk assessment and surveillance, to protect people through routine immunisation, mass prevention campaigns and emergency responses, to secure vaccine supply and to monitor the quality and effectiveness of vaccine use. Six million doses were reserved for emergency vaccination with the ICG responsible for its allocation. Remaining vaccines in the emergency stockpile could be used in preventive campaigns in endemic countries. This strategy ensured a minimum demand for vaccines and reduced the risk of wastage. Decisions on how and where to allocate left-over vaccines were made in the annual ICG meetings but were often not clear to external partners. Support for prevention campaigns can be requested from Gavi, initially by submitting a detailed risk assessment, and since 2011 directly through the Gavi new vaccine support application process. UNICEF SD is responsible for procuring and shipping vaccines based on the availability of the global stockpile and competing needs for outbreak control and routine immunisation.

Following two connected largescale urban yellow fever outbreaks in Luanda (Angola) and Kinshasa (Democratic Republic of Congo - DRC) in 2016, a new strategic approach towards the Elimination of Yellow fever Epidemics (EYE) was developed. The objectives are not very different from those established previously but the strategy is more specific and comprehensive. It targets countries and regions that are most vulnerable and calls for building resilient urban centres, planning for urban readiness and strengthening the application of the International Health Regulation. It establishes a mechanism that automatically replenishes the emergency stockpile to ensure 6 million doses are available at all times. The current focus is on increasing immunity levels through mass vaccination, sustained by routine infant immunisation. The ICG remains responsible for rapid and independent decision-making on allocation of vaccines during emergencies. The EYE strategy has a governance

[15] http://www.who.int/cholera/task_force/en/

structure with a leadership group responsible for overall strategic direction, made up of senior management staff from WHO, UNICEF and the Gavi Secretariat, a coordinating secretariat hosted by WHO, and a Programme Management Group with technical staff from relevant organisations.[16]

For meningitis the situation is different and there is not one strategy that combines prevention, routine immunisation and emergency responses. There is currently sufficient supply of an affordable serogroup A meningococcal conjugate vaccine (MenAfriVac). Since 2010, 20 countries have conducted mass vaccination campaigns and 5 countries have introduced it as part of routine infant immunisation. This in combination with efforts by MenAfriNet and the WHO to improve preparedness and surveillance have led to a reduction in the number and severity of meningitis outbreaks in the countries of the African meningitis belt, however outbreaks are now dominated by other meningococcal serogroups for which there is currently not a sufficient supply of affordable conjugate vaccines.

In summary: The ICG mechanism has evolved throughout its existence, together with the evolution of its task. Its core mandate, to provide a mechanism for the rapid equitable allocation of scarce vaccines in response to epidemic outbreaks has not changed. Scarcity of vaccines continues to be a problem for all three epidemic diseases that were over time integrated in the ICG mandate, as well as a potential problem for other epidemic diseases for which an ICG mechanism is currently under discussion. However, the vaccine market dynamics and the approaches to creating and managing emergency stockpiles are distinct for each vaccine. Institutions or partnerships to coordinate and support the control of cholera and YF have emerged, including through routine, preventive and reactive immunisation. Comparable initiatives do not exist for meningococcal meningitis. The funding and procurement channels for emergency immunisation campaigns have become more streamlined. This is the context in which the evaluation of the ICG was commissioned.

1.3 The evaluation of the ICG

In order to strive for clarity the term ICG mechanism is used in this report to refer to the process of decision-making, forecasting, procurement and deployment of vaccines.

Since 2015, stakeholders involved with the ICG have highlighted a need to evaluate the functioning of the ICG mechanism because:

- For many years, the ICG was a relatively small mechanism working in the background. Larger organisations such as the Bill and Melinda Gates Foundation (BMGF) and Gavi have become more involved as the main funders of vaccine stockpiles and of international support to outbreak responses
- The increased number of stakeholders involved in outbreak responses and the complexity of vaccine supply market has made the management of emergency stockpiles more complex
- Transparency about decision-making was raised as an area deserving more scrutiny
- The role and responsibility of the ICG in managing the revolving fund is under discussion
- Effective coordination and communication between the ICG, the ICG Secretariat, UNICEF SD and the extended stakeholders is critical and has proven challenging
- The four founding organisations provide support to countries as part of their mandate outside of the ICG. This has created confusion among countries and partners about ICG's responsibilities

[16] WHO (2016) Global Strategy to Eliminate Yellow fever Epidemics (EYE)

- In the current context, questions are also raised on how ICG operates vis-à-vis broader global disease control strategies, and if the ICG's roles and responsibilities are still relevant and adequate.

The purpose of the evaluation is to inform decisions aimed at improving ICG's governance, its mechanism related to the management, composition and accessibility of disease-specific, emergency vaccine stockpiles, the transparency of decision-making processes as well as the ICG's internal and external communication.

The main objectives are to:

- highlight the strengths and weaknesses of ICG's governance; effectiveness, efficiency, and transparency of ICG decision-making; funding; and management and
- develop actionable options and recommendations for improving the functioning of the ICG and the ICG mechanism.

The scope of the evaluation did not include assessing whether the ICG mechanism is an appropriate and /or needed mechanism to respond to emergencies when vaccines are no longer in short supply. This was therefore not explicitly addressed by this evaluation.

Full terms of references are available in Annex 1.

2 METHODOLOGY

2.1 EVALUATION DESIGN AND DATA COLLECTION INSTRUMENTS

The detailed methodology of the evaluation is presented in Annex 10.

The ICG is not a programme, but rather a mechanism that supports outbreak control responses, together with other partners that may themselves have stronger or weaker links to the ICG. Preliminary interviews with members of the Evaluation Steering Committee (SC) documented that there are different views about the limits of the ICG mandate. The ICG does not have a formal outcome centred logical framework, but it has a structural framework and a flow diagram of processes that illustrate its functions (Annex 2). These are tested in the evaluation using a realist evaluation methodology[17] approach. Realist evaluations distinguish themselves from other theory-driven evaluation methodologies by their emphasis on collecting data and performing analyses on mechanisms and contexts of implementation.

The main focus of the evaluation was on the ICG governance structure, and on processes and mechanisms of each of the three vaccine stockpiles as outlined in the flow diagram. Data were collected in a matrix based on the evaluation questions that were adapted from the terms of reference and reviewed by the SC. Data were collected through:

- **Document reviews**: Documents were obtained from the ICG Secretariat, SC members and through internet searches. The document review included the review of data reported in two recent evaluations.[18]
- **Semi-structured key informant interviews with international stakeholders**: 48 interviews were conducted with international stakeholders. A list of key informants is provided in Annex 3
- **Semi-structured key informant interviews with country-based stakeholders**: 6 interviews were conducted with ministry of health and country-based technical partner staff who participated in six ICG requests for stockpile vaccines that were selected for in-depth analysis. A list of key informants is provided in Annex 3. The six requests were chosen by purposive sampling with input from SC members. (Annex 4)
- **On-line survey of international ICG stakeholders**: All international stakeholders were invited to participate in the survey which was only available in English (Annex 9). After sending one reminder the response rate was 29/54 (54%) and deemed appropriate for the analysis as over 60% of respondents invited of the four main stakeholder groups (funders, manufacturers, direct partners and ICG members) had responded. For further details on how this assessment was done, please consult Annex 8.
- **On-line survey of country-based stakeholders**: A separate online survey was developed for staff of ministries of health and lead technical partners who participated in at least one of 58 sampled vaccine stockpile requests in 28 countries and was available in French, English and Portuguese (Annex 9). Following a process to obtain recent contact details, a total of 62 people were actually invited to participate and after sending two reminders 36 responses were received (58% response rate), including 13 representatives of ministries of health.
- **Review of networking among ICG stakeholders**: Data on the number and types of communications between national and international stakeholders involved in the six ICG requests that were sampled for in-depth reviews were collected with the aid of a questionnaire and through analysis of the ICG Secretariat email folders for a social network

[17] Pawson, R., Tilley, N. (1997). *Realistic evaluation*. London, Sage.
[18] Dalberg (2016) Meningitis Outbreak Response Analytical Support: Evaluation of meningitis outbreak response; and WHO (2016) Review of the International Coordinating Group on Vaccine Provision (2006-2016)

analysis. The data was used to test a preliminary structure of the ICG network that is based on information provided by the 2016 internal review of the ICG.[19] It is presented in Annex 2.

The collected data were analysed using the relevant analytical approaches for each set of data (i.e. content analysis of reviewed documents and key informant interview (KII) responses; frequency analysis and comparative analysis by stakeholders of survey responses (see Annex 8 for more details) and social network analysis (see Annex 6 for more details)) and triangulated to answer the evaluation questions under the five evaluation objectives. The main questions and objectives are repeated under the headings of Section 3, and the full list is available in Annex 5.

2.2 LIMITATIONS

The support received by the ICG Evaluation Management Group (EMG), the SC and the ICG Secretariat greatly facilitated obtaining relevant information, reports, data and access to key informants. Some challenges were however identified during the evaluation.

- **Availability of key informants for the interviews:** The main sources of data for the evaluation were surveys and key informant interviews. This represented a challenge because the data collection period coincided with the summer months when respondents are known to be difficult to reach. The evaluation team followed up actively with key informants and survey participants to ensure adequate response rates. While the minimum pre-established threshold for response rates were achieved, some informants could not be reached. As such, we were not able to interview country stakeholders in Niger as part of the in-depth review. We were however able to obtain sufficient information from other sources.
- **Access to country based informants for the online survey:** We were not able to invite all the country stakeholders to the online survey due to a lack of valid contact details (in particular for ICG requests prior to 2014).
- **Gavi observer role:** A number of additional questions were asked to Gavi informants during interviews about its recent role as observer in the ICG decision-making process. The evaluation team also followed up with Gavi towards the end of the data collection phase in order to receive additional feedback, but due to time constraints it was not possible to obtain a response from Gavi. We were therefore not able to fully review the impact of Gavi's role as observer to the ICG decision-making process.

Despite the above-mentioned challenges, the evaluation team is confident that answers are provided to all the evaluation questions with a sufficient level of detail.

[19] WHO (2016) op.cit.

3 FINDINGS

3.1 GOVERNANCE

Objective: Assess whether the current governance structure of the ICG supports its effective, efficient and transparent functioning, and meets current demands for responding to outbreaks of the three diseases.

- To what extent are the roles and responsibilities of the ICG mechanism clearly defined and agreed by key stakeholders? Are they fit for purpose?
- To what extent does the current governance structure enable the ICG to achieve its objectives?
- To what extent are the original and the newly emerging stakeholders engaged?
- How effectively does the governance structure of the ICG assure that rational allocation decisions are made, that decision-making is transparent, and that the ICG is accountable for its decisions?
- Is the decision-making sufficiently transparent for all stakeholders to ensure accountability?
- To what extent are the 4 ICG core-member organisations accountable for a) timeliness of the response; b) effectiveness of the proposed outbreak control strategy and c) joint decisions made on stockpile management

Key findings:

- The role of the ICG is well defined in documents and also clearly articulated by the majority of stakeholders. The responsibilities, however, of the different stakeholders that participate in the ICG response are neither clearly defined nor documented. This is largely due to the fact that new stakeholders have emerged and the roles in the vaccine support of outbreak control have changed.
- The ICG was set up without a formal governance structure which is seen as a weakness, particularly by stakeholders who have recently taken an interest in the ICG mechanism.
- While there are calls for more formalisation, a number of stakeholders believe that the strength of the ICG is partly due to its informality and flexibility. Formalising the mechanism and governance structure too much may constrain the efficiency and timeliness of the decision-making.
- The ICG has been able to allocate vaccines based on technical and public health criteria in an equitable way, without political or financial considerations. This is a unique mechanism and the technical assessment and timely decision-making is very much valued.
- The decision-making process, however, is not sufficiently transparent. Decisions are made collectively and in confidentiality. This is at the same time a strength and a weakness, because no single organisation can be held accountable for the decisions made.
- There is no clear accountability mechanism because the division of labour and responsibilities have not been clarified.

The terms of reference for the ICG were developed during the first meeting in January 1997 and subsequently reviewed in 2003. Two groups are part of the mechanism: the ICG (made up of WHO, IFRC, MSF and UNICEF) who is responsible for decision-making and coordinating deployment of vaccine and the Extended partners (made up of international organisations, NGOs, technical agencies, vaccine manufacturers, financial partners and country stakeholders). The ICG Secretariat, hosted at the WHO, is a coordination hub which facilitates and implements the decisions made. In 2001, YF vaccine, and in 2013, OCV were added to the ICG mandate. The ICG established separate

partnership groups and organised annual meetings for each of the three vaccine stockpiles, and membership criteria were reformulated in 2012.

The objectives of the ICG remained largely the same for the past two decades and include:[20]

- To rapidly deliver vaccines to respond to disease outbreaks
- To provide equitable vaccine allocation through careful risk assessment, based on epidemiological and operational criteria
- To coordinate the use of limited amounts of vaccines and essential medicines
- To reduce wastage of vaccines and supplies
- To advocate for readily available, low-cost vaccines and medicines
- To work with manufacturers (through UNICEF and WHO) to guarantee the availability of vaccine emergency stock supplies at the global levels
- To follow standard operating procedures and establish financial mechanisms to purchase emergency vaccine supplies and ensure their sustainability.

While the ICG terms of references established the two groups of stakeholders (ICG members and extended partners) within the ICG, it did not formulate a formal governance structure and there are no binding contractual documents or memoranda of understanding. The four organisations work together and have a joint mandate, there are meetings and corresponding minutes, as well as standard operating procedures (many in draft form), but there is no clear governance structure or oversight mechanism.

This lack of a formal governance structure, and therefore a sense of informality and flexibility, is considered by a number of key informants as a major strength of the ICG, particularly for the decision-making. They expressed concerns that too much formalisation may reduce the ICG's ability to make rapid, technical decisions outside of political interference. In general, practically all interviewees agreed that the ability to make evidence-based or technical decisions in a timely way is a key asset of the ICG that should be safeguarded. It is also clear that this lack of a formal mechanism has not prevented the ICG from effectively allocating vaccines to respond to outbreaks in an equitable way over the past 10 years (see section 3.2).

Mandate

The international stakeholders who participated in the online survey consider that the mandate of the ICG to ensure timely, efficient, equitable and targeted deployment of vaccines for effective outbreak responses is to a large extent still relevant (average score of 4.14/5 - see data in Annex 8). The evaluation team also considers the mandate relevant in the context where global vaccines supply for Meningitis, YF and Cholera do not meet fully demand and thus have to be rationed. Stakeholders raised however two concerns: Is the ICG mechanism in fact ensuring timely and efficient deployment of vaccines and the fact that the allocation of vaccines for emergencies cannot be seen in isolation from a wider disease control response. These are further addressed in the report.

Roles and responsibilities

All key informants that were asked about the role and responsibilities of the ICG have a clear understanding that the role of the ICG is to ensure the equitable allocation of vaccines which are in limited supply during emergencies. However, different views exist about the responsibilities of the stakeholders that participate in the ICG mechanism. This is partly because there is a renewed interest in the ICG and its stakeholders, such as the Gavi alliance and its donors, the Gavi Secretariat and UNICEF SD, who have brought new dimensions to the ICG process, in particular related to market shaping, procurement and deployment of vaccines.

[20] http://www.who.int/csr/disease/icg/en/

From the social network analysis (see Annex 6), it is clear that the ICG Secretariat plays a central and coordinating role in the entire ICG mechanism. The other stakeholders are involved in different aspects of the ICG flowchart, as follows:

- The decision-making process is the exclusive responsibility of the ICG members, but since May 2017 with the Gavi Secretariat as observer.
- Forecasting of vaccines is to a large extent the responsibility of the ICG members but with increasing involvement of UNICEF SD and the Gavi Secretariat. Decisions on forecasting are usually made during the annual ICG meetings for YF, meningitis and OCV.
- Procurement of vaccines is to a large extent the responsibility of UNICEF SD but there has also been involvement by the ICG members and WHO procurement department in the past.
- Deployment of vaccines is mostly the responsibility of the UNICEF SD but there has also been involvement of the WHO logistics department.

For the decision-making process the same four organisations (WHO, IFRC, MSF and UNICEF) have been involved since 2003. While a call was issued in 2001 for organisations to join the ICG, no expressions of interest were received and the same four organisations make up the decision-making body for the three ICG stockpiles until today. When asked about the composition of stakeholders within the ICG decision-making bodies, two out of 7 informants had concerns about the added value of MSF and IFRC, while five others mentioned the composition was fine; they considered the ICG as a functional structure with two organisations coming from the UN system and two being independent civil society organisations. The technical expertise and field experience of both MSF and IFRC are also highly appreciated and respected by the other ICG members. Nevertheless, the majority of informants believe that the composition of organisations that make up the ICG for each of the stockpile could be reviewed.

There is, however, disagreement on whether the Gavi Secretariat should be involved in the ICG decision-making process. The majority of extended partners and some senior managers of the core organisations believe that Gavi because of its role as sole funder should more formally participate in the ICG mechanism. Given that there are currently no formal governance and accountability mechanisms (see below) they feel that the observer role allows for a better transparency and understanding of how ICG decisions are made. The majority of the ICG members, on the other hand, believe that the presence of Gavi during the decision-making does not have an added value and may even impact on the neutrality of the decisions made (see section 3.4 for more details). The evaluation team agrees that the observer role granted to Gavi is a useful temporary measure, however, when more formal governance and oversight mechanisms are put in place, the observer role may no longer be necessary. Additionally some countries or their partners stress the risk that the information used in the decision making process might influence the decision making process of Gavi support to these country negatively. Hence, some ICG members strongly advocate against Gavi as an observer to preserve the confidentiality of the proceedings.

The decision-making process has remained largely unchanged throughout the ICG existence and the roles and responsibilities of the members that represent each organisation and the ICG Secretariat are relatively clear. In the past, there was more confusion about the role of the WHO disease focal points and their involvement in the activities of the ICG Secretariat. With the restructuring of WHO in 2016, the ICG Secretariat was more formally separated from the technical disease teams in order to separate the function of decision-making from the operational responsibilities of the ICG Secretariat. The respective WHO disease focal point in the Infectious Hazard Management (IHM) department represents the WHO in the ICG and provides technical input for the decision-making. In some instances the WHO disease focal point is also involved in the preparation of the ICG request (see chapter 3.2). When necessary, the WHO disease focal point also consults with WHO colleagues of the Immunization, Vaccines and Biologicals (IVB) department and liaises with the WHO Country Offices

From the document analysis and also the social network analysis (see Annex 6) it is clear that Gavi and UNICEF SD have increasingly taken up key positions in financing, procuring and supplying of vaccines allocated by the ICG for emergency responses. This has led to some confusion about the different responsibilities and accountability with regards to forecasting, procurement and deployment of the vaccines (see chapter 3.2). UNICEF SD plays a key role in the procurement and deployment of the ICG vaccines, whereas the Gavi Alliance is the main funder and has tasked the Gavi Secretariat to be more actively informed about the functioning of the ICG mechanism. Both Gavi-secretariat and UNICEF SD are currently considered as extended partners.

Although UNICEF is a core member of the ICG, the majority of the interviewees believe that there are distinct roles for UNICEF Programme Division (PD) (member of the ICG decision-making body) and UNICEF SD (as a procurement service provider to execute the ICG decisions)[21].

Accountability

The majority of informants and respondents to the online survey consider the decision-making sound, in fact most informants do not question the decisions made. A number of donors and country stakeholders raised however concerns about the transparency of the process and whether the criteria applied are still relevant (see chapter 3.4). Decisions are made in a short time, by consensus and based on the information which is available at the time. This process is largely in line with the 'no regrets' approach of decision-making. This is a key strength of the ICG, because the collective voice protects the four individual organisations from criticism, but it raises issues of accountability.

At the individual level, the ICG members are accountable to their own organisations for the decisions made. However the ICG as a group cannot be held to account for the collective decision made because it is not a legal entity. Other stakeholders are now involved in the procurement and deployment of vaccines but the ICG (and therefore implicitly the four ICG members) are still held responsible for the timely deployment of vaccines. Furthermore, because there is no legal entity or clarity on who is accountable, public criticism of ICG decisions and effective deployment, for example for the supply of OCV to Yemen in 2017, have been directed at individual ICG member organisations, particularly WHO. This is probably also linked to the fact that WHO hosts the ICG Secretariat. In the past, the ICG has looked at options of rotating the ICG secretariat among the four members, however, this has not materialised.

In discussions with key informants, there was a strong call for a formal definition of the responsibilities of different stakeholders, so that they can be held to account for the parts of the process of vaccine mobilisation that are under their control. For example, can the ICG members be held to account for the timely delivery of vaccines? Or should this be UNICEF SD, or a combination of organisations? The governments that receive the vaccines should be included in this equation because they also have a responsibility to facilitate the importation and account for the use of the vaccines.

Oversight

There is no formal oversight body that can hold the ICG mechanism to account or monitor progress against the key performance indicators. At the annual meetings, the key performance indicators are presented and discussed, however there is no formal mechanism that can hold the ICG and its different stakeholders to account for poor performance. The emerging single funding and procurement channels through Gavi and UNICEF SD have created a new situation. More organisations are involved in major components of the 'ICG response function' and can be held to

[21] UNICEF is articulate that they are in fact only one organisation, however during the evaluation it became clear that the majority of stakeholders still view them as two separate entities. We have therefore treated them separately for the purpose of this evaluation.

account. In order to bind them into the ICG mechanism and assure a continued functioning of the entire process, a more formal and comprehensive governance structure and accountability mechanism is needed.

Over the past years, public interest in the ICG has increased, in particular following recent major disease outbreaks including Ebola in West Africa and yellow fever in Brazil, Angola and the DRC. The work of the ICG is followed more closely, including by the media. Furthermore, other global disease control initiatives were (re)launched and no formal coordination between these initiatives and the ICG are established as yet (see chapter 3.5). Not having a formal mechanism that outlines how the ICG and ICG Secretariat should relate to and coordinate with the extended partners as well as the global disease control initiatives is considered a weakness, in particular by the extended partners and some senior managers within the original four organisations.

3.2 Mechanisms and processes

Objective: Assess how well the ICG processes respond to outbreaks of yellow fever, meningitis and cholera, identify and propose areas of improvement.

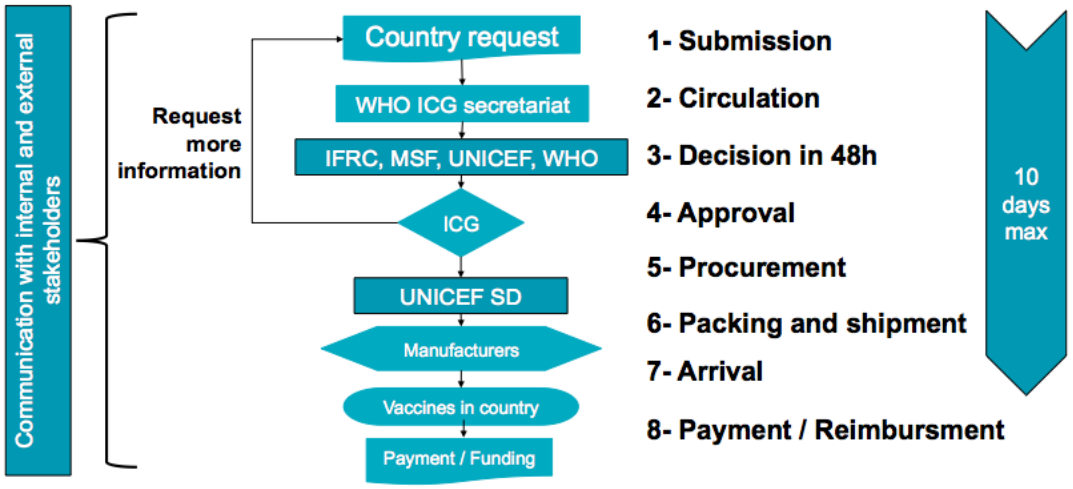
- In which ways are current arrangements (from submission of vaccine request to vaccine delivery) still adequate, efficient and fit for purpose? What could enhance its processes?
- To what extent are recipient countries satisfied with ICG response to emergency vaccine requests?
- What factors are most influential in ensuring an effective, efficient and equitable response to emergency outbreaks of the three diseases managed by the ICG?
- How adequate, effective and efficient are the existing SOPs for emergency response management? How do stakeholders perform against the procedures described in the SOPs?
- How adequate are existing vaccine stockpile composition, forecasting tools and procurement strategies to ensure that each stockpile size and composition is adequate to respond to outbreaks?
- To what extent are the stakeholders' roles and responsibilities for forecasting and managing stockpiles relevant and adequate to meet current demands? Are stakeholders acting according to their designated roles and responsibilities?

Key findings:

- The ICG response mechanism aims to deliver vaccines within 10 days. Over the past decade, this target was largely achieved for yellow fever and to some extent for meningitis. While the average for meningitis in the past 5 years was 13.3 days, improvements were observed for 2017. Delivery times for OCV largely exceed the target mostly related to issues of registration and customs clearance.
- The current arrangements from submission to delivery are adequate, however there are concerns about a potential conflict of interest when ICG members are directly involved in the preparation of a request. The decision-making is perceived as effective and efficient and generally decisions are taken within 48 hours. However there are concerns about the transparency of the decision-making process. UNICEF SD has been criticised in the past for not always conducting procurement and delivery in an emergency mode, however, the evaluation found no recent evidence to support this criticism.
- Country stakeholders are generally positive about the ICG response. They mostly appreciate the communication by the ICG Secretariat and the timeliness of the decisions; they are concerned however about the transparency of the decision-making and about the availability of support for the implementation of reactive immunisation campaigns.
- Factors that impact on an effective emergency response are ranked differently by international and country based stakeholders, however both believe the capacity to detect outbreaks is currently a major issue. Availability of funding is least important for international stakeholders, whereas country-based stakeholders are more concerned about the availability of funds for the operational costs of campaigns.
- SOPs for the stockpiles of meningitis and YF vaccines were established, but they are out-dated and not being used. SOPs for the stockpile of OCV have not been established.
- All stakeholders agree that it is difficult to forecast vaccine requirements for emergency outbreaks. It is, however, less of a problem for yellow fever and OCV, because left-over vaccines can be used for prevention and routine immunization (only yellow fever).
- Forecasting and procurement of vaccines is mostly an issue for the meningitis stockpile. A decrease in supply and perceived lack of flexibility by UNICEF SD to proactively secure sufficient supply has contributed to the current distrust between the ICG and UNICEF SD. Procurement of meningitis vaccines will remain an issue if no firm commitments are provided to manufacturers.

The ICG response mechanism

The ICG response mechanism aims to deliver vaccines within a maximum of 10 days after a request is received. The response is divided into steps that are summarised in the flow diagram below.



Adapted from http://www.who.int/csr/disease/icg/qa/en/

In the past 10 years, the target of 10 days from submission of the request to arrival of the vaccines was generally achieved for yellow fever vaccine (see Annex 8 for detailed tables). For meningitis vaccines, the average over the past 10 years was 11.7 days, however over the past 5 years the average time increased to 13.3 days, with the delivery taking on average 10.8 days. There is an improving trend in 2017 with 5 out of 9 requests for which vaccines were deployed achieving the target, which is better than the years before. For OCV, the target was missed most of the time, with the time between approval and delivery ranging from an average of 9 to over 25 days per country. Delays in delivery were mostly related to issues with licensing and customs clearance of the vaccine. The performance between 2006 and June 2017 is presented in the table. [22]

	Requests	Doses	Approvals (Countries)	Doses	Av. Days Circulation	Av. Days Decision	Av. Days Delivery
Meningitis	159	63,625,978	131 (18)	38,214,270	0.2	1.8	9.7
YF	60	79,401,831	52 (20)	63,163,637	n/a*	2.1	7.7
OCV	47	15,633,467	36 (16)	7,931,620	0.3	1.2	16.6

*For YF there is only data from 2016 on the days between submission and circulation

Key informants disagreed about whether the ICG can be held accountable for delays that occur after the request has been approved and the decision communicated to the procurement agent. As UNICEF SD is responsible for vaccine mobilisation process, the ICG members consider it is beyond their sphere of control. However, as it is currently still included among the ICG performance indicators, it is subject to the evaluation.

The preparation and submission of a request for vaccine is outside the remit of the ICG. However, late submissions or submission of incomplete application forms are a major source of delayed immunisation responses. The ministries of health are generally responsible for preparing and submitting requests, often with the support of technical partners. The in-depth review of six recent stockpile requests (see Annex 7) shows that the time between the detection of an outbreak to submitting a request to the ICG can take between nine and 37 days. Reasons for these delays

[22] Compilation by the evaluation team based on data received from the ICG Secretariat.

include limited national laboratory capacity, particularly for confirming meningitis outbreaks, as well as the complexity of the ICG request forms. Some countries receive support during the preparation of the request, from either country based technical partners or WHO disease focal points in Geneva. In these cases, the requests are only submitted to the ICG Secretariat once the technical partners believe it has sufficient quality.

The two requests for OCV that were included in the in-depth review were both in countries with humanitarian crises (Iraq and South Sudan). The requests were prepared by the WHO humanitarian cluster lead in close consultation with WHO Regional Offices and Headquarters. The ministries of health were consulted but had little input in the process. At times, WHO Headquarters disease focal points provide direct on-site support for the preparation of a stockpile request, for instance for the OCV requests of Iraq and Mozambique, and for the YF vaccine request for Angola.

Some stakeholders believe that ICG members should not directly engage with countries prior to the submission of the request because of a potential conflict of interest. MSF stated that it recuses itself from the decision-process whenever the organisation is the requester.

Requests received by the ICG Secretariat that are judged to be complete are summarised and almost immediately circulated to the ICG members for decision-making. Since 2017, UNICEF SD and Gavi are also informed as soon as a request is received. Gavi receives the full summary sheet, whereas UNICEF SD receives information about the country, consignee details and number of doses/type of vaccine requested.

The ICG members have 48 hours to provide feedback on the request. The deadline is established by the ICG Secretariat and may be more than 48 hours for requests received on Friday. From the email review, it is clear that ICG members take this role seriously and detailed technical assessments are provided within the timeframe. When all four ICG members agree, the decision is taken by email, however when one member disagrees, it is further discussed over the phone. The decision is briefly summarised and shared with the applicant. Since 2017, the decisions including a brief explanation are also communicated in a summary sheet to Gavi.

In a large number of cases, more information is necessary and decisions are postponed until further information is received. Data on whether additional info was needed was collected for meningitis requests since 2014: of the 33 requests received since 2014, 12 (36%) were complete and 21 (64%) needed further information. The number of days between asking for and receiving the additional information was on average 3.4 days but included a range between 0 to 18 days. Of the 21 that required further information, four requests were eventually rejected.

The criteria used during decision-making differ among the three stockpiles and are publicly available.[23][24][25] According to the ICG members, the criteria cannot be weighted because each outbreak is different and the importance of certain criteria varies accordingly. The majority of key informants believe that the decision-making process is sound, efficient and effective. The evaluation team has also seen substantial evidence that decisions are made timely on technical grounds and by consensus based on the information available at the time. There is however a perception by some stakeholders that allocation decisions focus too narrowly on responding to single outbreaks without always taking the global epidemic context into consideration. There is also dissatisfaction on the transparency of the process and the criteria used. (see chapter 3.4 for further details) Furthermore, one country applicant believes that in the current context of limited access to vaccine for

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

[24] Yellow fever guidelines: http://www.who.int/csr/disease/icg/ICG-request-form-EN.pdf?ua=1.

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

prevention of meningitis outbreaks, the criteria that are used to decide on the allocation of meningitis vaccine, i.e. confirmation of an outbreak, are too rigid.

UNICEF SD is the sole procurement agent for Gavi funded vaccines for Routine Immunisation and Special Immunization Activities (SIA) like campaigns and "mob-up immunization". Given the fact that Gavi is now also the sole funder of the ICG stockpiles, UNICEF SD is currently the sole procurement agent for ICG stockpile vaccines. Since its involvement, UNICEF SD has been subject to criticism and concerns about its ability to operate and respond during emergencies. A number of informants mentioned UNICEF SD's non-availability over an Easter holiday to illustrate this. UNICEF SD emphasises however that its staff of the Rapid Response Team in the Vaccine Centre is always reachable and available. Moreover, the Rapid Response Team always coordinates ICG requests with colleagues of UNICEF SD's general emergency department which is on call 24/7. SD also recognises the need to improve its communications to create a better understanding among stakeholders about the obstacles it encounters during the procurement and deployment of ICG stockpile vaccines.

The procurement of vaccines is generally not an issue for yellow fever vaccine and OCV, except during the large yellow fever outbreaks in 2016. It is, however, a problem for meningitis vaccines (see section 3.2.2). Delays in the delivery of vaccine are due to a number of different factors, some of which are related to non-availability or late release of vaccines by the manufacturers (for example Nigeria meningitis 2016) and hence fall under the responsibility of UNICEF SD. The most common delays, however, are related to customs clearance and registration of vaccines at country level, in particular for OCV, and should be the responsibility of the country applicant.

Generally, country stakeholders are positive about the ICG response to requests for emergency vaccines. The online survey highlights that they are most appreciative of the communication by the ICG Secretariat, the established criteria for submitting a request and the timeliness of decisions. However, the transparency of the decision-making and the support provided to implement the outbreak response are least appreciated, although the latter is beyond the remit of the ICG. Respondents from countries that requested meningitis vaccines were overall least satisfied with the ICG response.

When asked to rank the factors that contribute to an effective outbreak response, international stakeholders indicated the in-country capacity to detect outbreaks, the availability of global stockpiles and the preparedness of countries to implement immunisation campaigns as most important for effective emergency responses. Financial capacity to pay for the vaccines as well as the country's capacity to monitor the campaign scored lower on the scale of importance. Opinions differed somewhat among the country-based stakeholders: the 12 government representatives found the adequateness of the outbreak response strategy and the capacity to detect an outbreak as most important and challenging and also consider the country capacity to pay for the vaccines an issue. The 19 representatives of technical partners in the countries ranked the availability of stockpile vaccine and of financial support for campaign costs as most important and challenging (see Annex 8).

There are a number of standard operating procedures (SOPs) to guide the work of the ICG Secretariat. The SOPs were drafted in 2011/2012 for meningitis and yellow fever and outline the process for how requests should be handled, how vaccines should be released, what the procedures are for financing, reimbursements, monitoring and reporting. No SOPs could be found for OCV, except for the detailed guidance document that describes the process and includes contact lists and templates for correspondence. The SOPs are out-dated; the guiding documents are more useful and relevant. While Secretariat staff generally follow the procedures outlined in the guiding documents, neither the SOPs nor the guidelines are used, and information about procedures is generally passed

on by word of mouth among staff members. It is apparent that there has not been a lot of staff turnover in the ICG Secretariat.

Forecasting and procurement strategies of stockpiles

The ICG core members decide on the size and composition of the emergency vaccine stockpiles during the annual meetings in a closed session. Recognising the critical role UNICEF SD and Gavi play, they are since 2016 invited to attend these sessions. UNICEF SD, however, has the impression that its forecasting expertise is not fully utilised by the ICG. In addition, the Gavi secretariat and manufacturers also expressed that they can contribute more.

Forecasting for OCV and yellow fever vaccine is not a critical issue because left-over vaccines from the emergency stockpile can be used for prevention and routine immunisation, and the stockpiles can more easily be replenished during the year. For yellow fever vaccine, a replenishment mechanism has been set up to ensure the availability of six million doses for emergencies at all times. Longer-term forecasts for YF vaccine and OCV are coordinated with the global disease control mechanisms (EYE and GTFCC). However, while this is the case the industry representatives would still like to receive a long-term contract for the release of emergency vaccines because these operations require more time and investment from the manufacturers.

There are more challenges with the forecast and procurement of meningitis vaccines because of the different serogroups and strains. (see textbox) Because of the difficulties related to meningitis strains and vaccines, the forecasting and procurement of these vaccines and in particular polysaccharide vaccines, have become increasingly difficult. Only in 2011 and 2013 UNICEF SD managed to procure sufficient vaccines to cater for all approved doses. In 2014, UNICEF SD could not procure 1.8 million requested doses of ACW vaccine because it was not allowed to procure a non-prequalified vaccine.

Vaccines for Meningococcal Meningitis

In 1997, the ICG was created to address the issue of vaccine shortages for reactive immunisation to combat seasonal epidemics of meningococcal meningitis in the Sahel and adjacent countries of the African meningitis belt. Immunisation with type-specific polysaccharide vaccine, when applied within four weeks of the start of the outbreak, was an effective intervention, the epidemics were largely caused by meningococci of the serotype A (NmA), and the vaccine was not costly. The vaccine, however, only conferred short-lasting immunity and there was practically no market beyond its use in African meningitis epidemics. The response of international public health agencies was to create the ICG to administer and ration a stockpile of polysaccharide NmA vaccine, bundled with one-way injection equipment and oily chloramphenicol, an antibiotic that did not have any use beyond the treatment of meningococcal meningitis and that has since been replaced by safer medicines.

This very practical and logical approach was, however, soon confronted with an increasingly complex situation. While meningitis outbreaks in Africa were dominated by NmA, other serotypes such as type C (NmC) and type W (NmW) were also circulating and gradually became more prominent. A programme to build a market and stimulate the production of a low-cost conjugate NmA vaccine, which confers longer-lasting immunity and herd immunity, came to fruition. Preventive immunisation with the new vaccine started in 2010. The number and severity of meningitis outbreaks decreased, and the proportion of outbreaks caused by NmA fell rapidly while NmW and NmC were increasingly responsible for new outbreaks.

Conjugate vaccines that confer protection against four meningococcal sero-types (ACWY) are too expensive for current use in mass immunisation or reactive immunisation campaigns in low-income countries. Furthermore, industrialised countries such as the UK and the Netherlands recently introduced routine immunisation with quadrivalent (ACWY) vaccine, which is likely to create further pressure on a tight vaccine market. A low-cost pentavalent conjugate vaccine (ACWYX) is under development but not expected to be on the market before 2022. Affordable polysaccharide vaccines that protect against two, three or four sero-types exist, but the number of manufacturers is limited, and they run a high risk that the vaccines they stockpile may not be of the type required and will have to be destroyed. Some manufacturers are withdrawing from the polysaccharide vaccine market.

Stockpile projections and management of meningitis vaccines has become very complex, with a growing risk of shortages of vaccines to control outbreaks of specific meningococcal serotypes, and a concomitant risk of wastage of unused and outdated stockpile vaccines.

The ICG decided to use the revolving fund to procure 500,000 doses. For the 2015 season, UNICEF SD was not able to secure sufficient vaccines at the start of the meningitis season. Remaining stock from 2014 covered the first vaccine request, and throughout 2015, vaccines became gradually available through reactive procurement by both the ICG Secretariat and UNICEF SD. For the 2016 season, UNICEF SD had issued a tender for 5 million doses of C- and W-containing vaccines, of which only a total of 1.2 million doses were offered by manufacturers. WHO's Procurement Office reserved another 1.5 million doses of ACW containing vaccine of which a total of 440.000 doses were delivered on behalf of the ICG, using the revolving fund.

This situation has contributed to a lack of trust between UNICEF SD and the ICG Secretariat, and explains why the Secretariat feels the need to continue lobbying manufacturers to increase their production. However, this has led to uncoordinated engagement and confusion among manufacturers. While on the one hand they have been convinced by the ICG to contribute to the vaccine stockpiles, they feel that they are running a high business risk because there is no assurance that the meningitis vaccines will be procured. To contribute to the emergency stockpile they need firmer commitments longer in advance in order to produce the forecasted supply. To address some of these issues, UNICEF SD has now issued a long-term tender (for four years) to allow manufacturers to plan their production, and is looking into possibilities to reduce wastage. Although the longer-term planning of UNICEF SD is welcome, risks remain high when there is no commitment for procurement or clarity on what happens with doses that are not used.

There is a strong call among all stakeholders, and also emphasized by industry representatives, to clearly define the roles and responsibilities of the different stakeholders that participate in the ICG mechanism, whether at decision-making, forecasting, procurement or deployment of the vaccines.

3.3 FUNDING

Objective: Identify the strengths and weaknesses of current funding arrangements to assure sufficient and sustainable financial support for vaccine responses to outbreaks

- To what extent are current funding mechanisms (including multi-year financial needs, sources and mix of funding) fit for purpose?
- What are the strengths and weaknesses of possible alternatives?
- How well are ICG funds being tracked?

Key findings:

- Current financing arrangements for vaccine stockpiles that are fully financed by Gavi and accessible to all countries contribute to stabilising the availability and assuring the equitable allocation of emergency stockpile vaccines.
- There have been few recent occasions when there was an urgent need to pre-finance vaccines that could not be procured with Gavi funds. An emergency fund that can be mobilised rapidly to cover any potential funding bottlenecks would therefore strengthen the capacity to respond to outbreaks.
- ICG revolving funds for vaccine procurement have served to meet urgent pre-financing needs in the past. However, any other emergency fund, such as the WHO Contingency Fund for Emergencies, could serve the same purpose if it can be mobilised rapidly.
- Support for operational costs of reactive immunisation campaigns in Gavi-eligible countries is provided by Gavi via WHO. Most countries that receive such support provide campaign reports to WHO, which in turn is accountable to Gavi for the use of the funds.
- Countries that are not eligible for Gavi-support have to find alternate sources to support vaccines and campaign costs. The frequency and quality of reports on the use of the emergency vaccines in these countries is mixed, and accountability for the use of stockpile vaccines is not systematically assured.

In the past, the emergency vaccine stockpiles were funded through revolving funds administered by WHO. In 1997, the ICG established the meningococcal revolving fund to pre-finance the purchase of meningococcal vaccine. Funds were raised through repeated appeals and reimbursements by countries. The Gavi Alliance started to contribute to the YF vaccine stockpile in 2002, and made a major contribution to the meningitis vaccine stockpile in 2008. Since then, it gradually became the main financing partner for emergency immunisation campaigns. Between 2006 and 2015, Gavi disbursed approximately US$89 million for the three vaccine stockpiles, including for the procurement of vaccines (86%), contribution towards operational funding for vaccination campaigns (13%), contribution towards personnel (two WHO disease focal points and two ICG Secretariat staff) and other activities related to stockpile management (1%).[26]

To ensure a source of funds if the Gavi Alliance were not to extend its support beyond the original investment and to enable funding for non Gavi-supported countries, revolving funds were established for YF and meningitis (a 'new revolving fund' for meningitis) in 2009/2010. Donors to the funds included the European Commission, the United Nations (UN) Central Emergency Revolving Fund, bilateral development agencies and ministries of health. The funds were administered by WHO, and allowed rapid disbursement for vaccine procurement, and were replenished by reimbursements from ministries of health or their international partners. Between

[26] Gavi (2016) Doc 13 – Gavi's support for emergency vaccines stockpiles

2010 and 2014, on average 50 percent of expenditures of the meningitis and yellow fever revolving funds were reimbursed (see Annex 8).

In December 2016, the Gavi Alliance Board approved new principles for investments in emergency vaccine stockpiles, including:

- Gavi investments for emergency vaccine stockpiles will no longer be time-bound
- Countries that are not eligible for Gavi support will have access to the three stockpiles and will be requested to reimburse the costs to Gavi. Gavi assumes the financial risk of non-reimbursement
- All Gavi-eligible countries (including those in accelerated transition) will have access to vaccines and operational costs without reimbursement. Support for operational (campaign) costs will be up to US$ 0.65 per targeted person per campaign for all three vaccines

With increasing engagement by Gavi, the ICG revolving funds lost their importance as a financing mechanism for vaccine procurement. Reimbursement rates fell rapidly after 2014 because the ICG Secretariat did not insist on reimbursement of vaccine costs from Gavi-eligible countries, and former donors to the funds discontinued their support because they channelled their monies directly to Gavi. Since January 2017, the funds are dormant waiting for a decision on further use. Although almost no funds were reimbursed in 2016, the revolving funds still functioned as a contingency fund throughout the year.

- In January 2016, the meningitis revolving fund was used to procure polysaccharide vaccines which were not yet WHO prequalified and could not be procured by UNICEF SD.
- In June 2016, the YF revolving fund was used to procure vaccines for the DRC when the Gavi funds available to UNICEF SD were temporarily exhausted.
- Throughout 2016, the YF revolving fund was used to pre-finance the procurement of vaccines for Angola based on a financial commitment of the World Bank to support the response to the outbreak.

In interviews, 17 key informants were asked about the advantages of the revolving funds. A majority (10/17) commented on the flexibility and the speed with which payments could be made. Two key informants believe that the revolving funds ensure sustainability of the ICG mechanism and encourage applicants to be more realistic in their application for stockpile vaccines since they have to reimburse the costs. One key informant also commented on the importance of the revolving fund to maintain the independence of the ICG. On the same question, 3/17 key informants (all donors to the Gavi Alliance) expressed their discontent with the revolving fund, mentioning lack of transparency and its impact on distorted engagement with manufacturers as key reasons. Respondents also indicated that communication to countries about the reimbursement has not been consistent, pointing to confusion amongst stakeholders. The annual reports to Gavi, produced jointly by WHO and UNICEF, provide an overview of the expenditures and receipts of the revolving funds, but it is unclear to what extent these details are shared with Gavi donors.

According to 'preliminary draft SOPs' for the meningitis vaccine revolving fund,[27] the ICG Secretariat administers the fund *'in accordance with WHO rules, regulations, procedures, policies and administration practices'*. It is unclear how the revolving funds are able to release payments quicker than other WHO funding mechanisms. In fact when the revolving fund was used to procure vaccines through UNICEF SD during the 2016 yellow fever outbreak, it was clear that the process was cumbersome as a number of WHO in-house procedures needed to be complied with which delayed the release of the funds.

[27] Document dated 21 Dec 2010. No updated or final version found

In interviews, 16/22 key informants thought it appropriate for all three stockpiles to be funded by a single donor, in particular since all countries will have access to the vaccines regardless of their eligibility for Gavi support. Not having to worry about the cost of vaccines removes some of the pressure in responding to a disease outbreak. However, 5/16 key informants also expressed the need for a flexible financing mechanism or contingency fund to ensure a timely response whenever Gavi funding is not available for some reason.

Among 15 factors to assure an effective outbreak response, the 31 country-based respondents to the on-line survey (12 government respondents and 19 technical partners) rated the availability of funds for campaign costs in third place. Gavi-eligible countries can submit a request for operational support as part of the application for stockpile vaccines to the ICG. Requests are reviewed by Gavi which can provide support up to US$0.65 per vaccine dose. This support is not expected to cover all operational costs, but it mitigates the risk that countries divert funds from routine immunisation programmes, or that outbreak responses are delayed or constrained by financial bottlenecks. The support is channelled via WHO to the national governments, which in turn submit campaign reports to WHO, either to the ICG Secretariat or to the technical disease focal points. WHO is accountable to Gavi for the proper use of the funds.

Countries that are not eligible for Gavi support are not entitled to apply for operational costs from Gavi and have to seek support elsewhere. Operational funding is often available from the emergency national budget line or from other donors. Key informants told the evaluation team that immunisation campaigns are never cancelled because of a shortage of funds for operational costs. The quality of the campaigns may however be affected and the implementation can be delayed as was the case in 2016 Angola yellow fever outbreaks.[28] When budgets are constrained, coverage surveys, supervision, monitoring and evaluation are often also the first activities to be reduced. As a consequence, despite request for reporting, these countries are less likely to provide quality campaign reports to the ICG, and accountability for the appropriate use of stockpile vaccines can therefore not be assured.

According to documents reviewed by the evaluation team, the reports of cholera immunisation campaigns were the most detailed and comprehensive. This may be related to the robust country support provided by the GTFCC team at WHO. Of the six outbreak responses reviewed in-depth, only one included support for operational costs from Gavi. It was also the only one that included details on the use of funds, while three more provided some level of reporting, and no campaign reports could be located for the remaining two.

The annual reports to Gavi on the funding of stockpile vaccines, do not provide a detailed breakdown of expenditures by campaign. Since 2015 only a summary financial statement is provided stating the expenditures for vaccines and logistics, and the balance of funds remaining.

[28] Angola is a non-eligible Gavi country and obtaining operational costs for the campaign took time. The ICG decided to approve the vaccine and WHO released the Emergency Contingency Funds to cover the operational costs. If no funding would have been provided for the operational costs, the delays in the vaccination campaign would have been longer.

3.4 COMMUNICATION AND TRANSPARENCY

Objective: Assess how well ICG partners and stakeholders are informed about the ICG mechanism and its response to outbreaks, and identify where and how improvements may be made.

- What is the quality and adequacy of the real-time data on stockpiles, procurement and delivery status available to the ICG and stakeholders?
- How well are ICG partners and stakeholders, particularly recipient countries, informed about the decision-making process governing the ICG's response to emergency disease outbreaks?
- How and where could improvements be made? (see section 5 options for the future)

Key findings:

- Data on stockpile availability has become more consistently available on the UNICEF SD website however the dashboard is rarely consulted by people outside of the ICG Secretariat and ICG members. It is unclear whether this information should be publicly available or shared more comprehensively with those that participate in decision-making.
- Adequate information on procurement is mostly an issue for the meningitis stockpile. Lack of performance in securing sufficient supply has contributed to a lack of trust between the ICG members, the ICG Secretariat and UNICEF SD. The ICG Secretariat continues to communicate directly with manufacturers, leading to confusion among the manufacturers and frustrations within UNICEF SD.
- Uncertainty about the delivery status has caused delays in implementation of vaccination campaigns. This is however not due to a lack of communication between UNICEF SD, the ICG Secretariat and the countries but rather do to factors often outside the control of UNICEF SD.
- There is no clarity as to which stakeholders should have access to what type of information at what time. There are clearly different expectations on needs and entitlement to information which require careful review.
- There is a high level of dissatisfaction by extended partners and country applicants on the transparency of how decisions are made, in particular on requests that are rejected or partially approved, but also on strategic decisions about the use of fractional doses or pre-emptive campaigns.
- Since 2017, the transparency and communication on the decision-making process has improved in particular towards Gavi, UNICEF SD and country stakeholders. However, it is still unclear to other extended stakeholders.
- Not having a short explanation available on why decisions are rejected or partially approved can harm the ICG because enquiries are made at different levels and contradicting messages circulate.

Communication on procurement, stockpiles and delivery status

Adequate and up to date information on stockpile availability is important for decision-making. In particular details on the quantity available for immediate shipment and their expiry date are needed but it is also important to know when the stockpile will be replenished, how the vaccines are presented (doses per vial) and in the case of meningitis also the type of vaccines available. In the past, the ICG Secretariat would obtain information on the number of vaccines awarded (i.e. doses made available by the manufacturers for the stockpile and confirmed by UNICEF SD in an award) at the start of the calendar year and would use this as a basis to inform the ICG members about the quantity of vaccines available in the stockpile when circulating the request. However, not

all vaccines awarded were always immediately available for shipment (for example Ethiopia Meningitis 2015) and clarity was required on vaccines awarded versus vaccines available. Following this request, UNICEF SD has developed an online dashboard on vaccine availability which is updated on a bi-weekly basis.

During the interviews 13 informants commented on the usefulness of the UNICEF SD dashboard. Of the six ICG members that provided feedback, three had used the dashboard and the other three were either not aware, or found it too difficult to access. Those who had accessed it, found it useful but two mentioned that it should include more information, such as the yearly evolution of the stockpile (from January to December), what vaccines come from which manufacturers, and in the case of meningitis also the prices and the vaccines in the stockpile. One ICG member is against sharing this information publicly because applicants should prepare their requests based on a justified need and not based on vaccine availability. Of the seven other stakeholders that commented, including three country stakeholders, none had accessed the dashboard and only one informant (a manufacturer) thought it could be useful.

Communication on procurement, in particular with manufacturers, is a concern. Difficulties in procuring the quantities requested (in particular for meningitis), has led to a lack of trust between the ICG and UNICEF SD. ICG members, especially from WHO, believe they have a role to play in terms of 'advocacy for increased supply', which requires direct contact with the manufacturers. Furthermore, when not enough vaccine was available, the ICG Secretariat procured directly from non-prequalified manufacturers. While this averted an acute vaccine shortage, it also, according to some manufacturers, created confusion due to conflicting messages being given by the ICG and UNICEF SD. During the Angola and DRC YF outbreaks, manufacturers commented that they were in constant contact with UNICEF SD but also had to deal with numerous requests from different WHO sources. Given UNICEF SD was responsible for procurement and delivery it is unclear why the WHO would reach out directly to the manufacturers. The situation is different for the OCV stockpile, where the ICG Secretariat, UNICEF SD and WHO disease focal points have joint regular teleconferences with the manufacturers to receive updates on supply, discuss past performance and provide updates on the epidemiological situation.[29]

Timely communication of shipment and delivery dates is important to ensure an effective outbreak response. Uncertainty about when countries will receive the vaccines has an impact on the countries' ability to plan for the implementation of the immunisation campaign. Effective communication of expected delivery dates is dependent on a number of issues such as availability of vaccines for immediate shipment at the manufacturer's warehouse, problems with labelling of the vaccines, delays in release from the warehouse, lack of license for use and/or importation (in particular for OCV vaccines), shipment method used, etc. In most instances UNICEF SD is responsible for communicating the delivery dates to the ICG Secretariat, who then informs the respective country stakeholders. From the review of the ICG Secretariat email folder it is clear that this communication flow between UNICEF SD, the ICG Secretariat and the countries is working well. Country stakeholders participating in the online survey were also satisfied with the communication provided during shipment and delivery. Only one of 31 country-based stakeholders complained that information was not received timely enough.

The communication flows related to procurement during outbreaks and delivery happens mostly between the ICG Secretariat, UNICEF SD, the manufacturers, country applicants and in some instances also the WHO Logistics department. Other stakeholders such as Gavi, donors to Gavi and the ICG and other technical partners are not routinely kept informed about procurement and expected arrival dates of vaccines. Some partners would like to receive more information, in particular real-time information on when vaccines will arrive in country. It may be necessary to

[29] Key informant interviews

review which partners need access to what type information at what time and also by whom. For example, should it be the ICG Secretariat or country applicant (ministry of health or technical partner) that communicates the expected arrival date to other technical partners in the country? Do donors to the ICG need access to information about the expected arrival date in real-time? The issue of need for information versus entitlement to information is not clearly defined.

Transparency of the decision-making process and ICG response

According to the interview and online survey data most stakeholders, including the country applicants, are least satisfied with the transparency of decision-making. All extended partners, including UNICEF SD, Gavi, donors and manufacturers, believe that the decision-making process is not sufficiently transparent. They want to have more information on why certain decisions were made, in particular when a request was rejected or not fully approved. There are also disagreements among stakeholders, particularly in relation to YF vaccine, about who should be involved in decisions beyond allocation of doses, for example on the use of fractional dosing (e.g. DRC YF 2016) and pre-emptive campaigns (e.g. Angola YF 2016). In the past the decisions of the ICG have depleted the stockpile and impacted on the availability of stock for preventive campaigns. Lack of transparency on these decisions has affected the trust of stakeholders in the ICG mechanism in recent years.

Country-based stakeholders consider transparency of decision-making a high priority. When asked to rank their level of satisfaction with different aspects of the ICG response during a recent stockpile request, transparency of decision-making was ranked the second lowest out of 11 factors that influence the response. Those applicants whose request was rejected or only partially approved were the least satisfied with the transparency of the decision-making process. Reasons for dissatisfaction included lack of understanding the criteria, lack of understanding how the criteria were applied, no clarity on why different vaccines as those requested were provided, differing assessments of the proposed strategy by the ICG and the country, and a perception of a conflict of interest by the decision-makers. One key informant mentioned that the decision-makers often represent organisations that also work in the field. If there are differences of opinion between the Government and these organisations at country level, it may influence the decision about vaccine allocations.

Since late 2016 transparency and communication on the ICG requests received and vaccines allocated has improved. The ICG Secretariat now prepares a summary sheet with information about requests received and decisions made (including the criteria used) and distributes it to the Gavi secretariat and WHO senior managers. The country applicants and the WHO regional and/or country office receive a brief summary of the decision made. These summaries, however, do not refer explicitly to the criteria used. UNICEF SD also receives a heads-up whenever a request is received by the ICG Secretariat so it can prepare for a possible decision to procure.

Transparency has increased in other ways. The ICG Secretariat publishes summary information about each request on its website. This information includes the country, request number, date the ICG received the request, status of the request (i.e. approved, partially approved or rejected), the context (for OCV), target areas (for YF) or type of vaccine (for meningitis), the number of doses shipped, confirmed delivery date and date of the immunisation campaigns. In addition, Gavi was granted temporary observer status to the ICG deliberations on vaccine allocation in May 2017. Given the timing of this evaluation the impact of this measure could not be reviewed. At the time of the interview, the Gavi focal point had not yet participated in any decision round, only his deputy had participated in a single round. However, key informants outside of Gavi alluded to potential benefits and risks:

- On the one hand, it may increase the trust of the Gavi secretariat in the ICG decision and place it in a stronger position to defend the expenditures on emergency vaccine stockpiles to its Board and donors, while maintaining confidentiality of sensitive information.
- On the other hand, there is a risk that countries and the members of the ICG may no longer share all sensitive information, which may impact on the quality of decisions made. Furthermore, any increase in the number of participants and observers in confidential deliberations increases the risk of a breach of confidentiality.

While a number of key informants did not understand why the decision-making process should remain confidential, members of the ICG explained that they often receive non-official confidential information about disease outbreaks that is used in the decision process, but which cannot be discussed publicly as it may jeopardise the organisations or their staff in the field. Decisions are based on public and non-public information which is assessed using a high level of technical knowledge and field expertise, including feedback from the field personnel of the ICG member organisations. According to ICG members, this process is difficult to summarise in a short report or statement. Nevertheless, the fact that the ICG Secretariat did not provide more detailed information to wider stakeholders about partial approvals and rejections of recent requests, for instance for YF vaccine requested by Angola in 2016 or for OCV requested by Yemen in 2017, has resulted in some reputational damage to the ICG, as well as to the circulation of unfounded and contradictory rumours.

3.5 Potential future role

Objective: Identify options of what role the ICG could play in the future in terms of allocating and mobilising vaccines for additional disease outbreaks and/or in the context of broader strategies for the control of meningitis, cholera and yellow fever.

- What role does ICG play, and could it play in the future, vis-à-vis broader disease control strategies?
- How flexible is the ICG mechanism to accommodate new vaccine stockpiles, such as for the Ebola vaccine?

Key findings:

- The ICG is recognised by the global disease control strategies for Cholera (GTFCC) and YF (EYE) as the mechanism responsible for equitable and timely allocation of vaccines during emergencies.
- The majority of stakeholders do not think that the ICG should be further integrated with the existing global disease control mechanisms however further clarification is needed on the respective roles and responsibilities as well as communication and reporting lines.
- With increased supply of YF and OCV vaccines there will be a natural transition from vaccines allocated by the ICG to more vaccines being allocated by respective global disease control mechanisms. For meningitis there is no clear global strategy and pressing difficulties for ensuring sufficient supply of Meningococcal C/W/X vaccines.
- Provided issues on governance, communication and transparency are resolved, the ICG decision-making process is considered as appropriate to allocate and deploy other vaccines which are in short supply during emergencies.

The role of the ICG vis-à-vis other global disease control initiatives

Currently the ICG is recognised by the GTFCC and the EYE strategy as the body responsible for allocating vaccines for outbreak control in an equitable and timely manner. While the vaccine used may be the same for routine immunisation or SIAs and emergency response, there are differences in terms of scale, target population and planning cycles as well as in terms of procurement because vaccines need to be available in a very short timeframe.

While there is no formalised collaboration between the ICG and the GTFCC, many interactions happen at the level of individuals who participate in both mechanisms. The GTFCC Secretariat is based at the WHO and the WHO cholera disease focal points play an active role in both the GTFCC and the ICG. The GTFCC participates in the annual OCV meetings and other ICG members also participate in different working groups of the GTFCC.

The EYE mechanism is still being operationalised but the EYE Secretariat, also based at WHO, has made suggestions to ensure close collaboration with the ICG. These recommendations were presented at the annual ICG YF 2017 meeting and include:

- ICG Secretariat is invited to participate in the EYE programme management group
- ICG members are invited to participate in the EYE working group on vaccine supply and market shaping
- ICG decisions should be communicated to the EYE programme implementation and leadership group
- For requests larger than six million doses, the leadership group will decide on speed of stockpile replenishment based on current and overall risk in the short and medium term.

The ICG has not formally responded or accepted these suggestions but the ICG Secretariat already participates in the two-weekly programme management meetings.

There was little support by key informants in interviews and on-line surveys for a suggestion of further integration of the ICG with EYE and/or GTFCC. Among 19 key informants interviewed, 16 were of the opinion that the ICG should remain independent from the other mechanisms. The reasons differed among the 16 key informants: Four stressed that the ICG independence should be safeguarded to assure equitable vaccine allocations; two considered that the two global disease control strategies did not have the operational capacity or technical expertise to take over the ICG role; one informant mentioned that procurement and distribution of emergency vaccines requires a specific level and type of expertise that is best harnessed by one Secretariat that is specialised in this area. Another ten informants did not think that integration was necessary, but six were of the opinion that better alignment was needed, for example by creating triage points for all requests of OCV and YF vaccines, or by more regular and more formal communication. Another four informants, including industry representatives, wanted to have more clarity on the respective roles and responsibility of the ICG, the GTFCC and EYE. Only three key informants considered further integration possible, provided the global disease control strategies have the capacity to respond in a timely and equitable way. The online surveys responses were similar, with almost all respondents highlighting the need for a closer collaboration.

A number of key informants believe that a transition from the ICG to mechanisms such as GTFCC and EYE will happen 'naturally' once there is less shortage of the vaccine. Along these lines, one informant stated that "*more efforts should be directed towards addressing the root causes for unreliable availability of vaccines instead of finding ways to change and extend the life of the ICG*".

There is no current global coordinating mechanism for the control of meningococcal meningitis, so the question of integration of the ICG does not arise. The situation may change when an affordable penta-valent conjugate vaccine becomes available, but this is not expected before 2020.

How flexible is the ICG mechanism to accommodate new vaccine stockpiles?

The ICG mechanism was developed for meningitis and subsequently copied for YF and OCV. While decision-making about vaccine allocation for each of the three diseases requires distinct and specific technical expertise, the principles and procedures of the ICG mechanism can be applied to any epidemic disease for which vaccines and other medicines or products are available to control outbreaks, but are globally in short supply.

Most international stakeholders (20/29) believe the ICG can be used as a mechanism to ration scarce vaccines in order to assure an equitable allocation according to need and availability. Donors and manufacturers are less convinced. They believe the ICG is not the most appropriate mechanism, at least not in its current form, referring to issues of governance, communication and transparency. Gavi, UNICEF SD and manufacturers believe a centrally managed and funded mechanism for the allocation of vaccines during outbreak responses is important, however, some diseases such as Ebola, Zika, and Lassa Fever may require a differentiated approach for which the ICG as currently constructed is not well suited. For example some vaccines may be stockpiled at a pre-licensure stage which requires changes in terms of stockpile management.

Furthermore, if an ICG mechanism is developed for other vaccines, the membership of the ICG decision-making body would need to be reviewed. The current constellation of partners, developed in the context of a response to meningitis epidemics in the Sahel, was already questioned by some in terms of appropriateness for decision-making on YF vaccine and OCV. The experience and expertise of the ICG Secretariat as a coordinating body, on the other hand, was not questioned and was considered by most as a generic source of expertise that could be applied to other diseases.

Half of the country-based respondents also believe that the ICG could coordinate the equitable allocation of other scarce vaccines, medicines and commodities. Examples mentioned included an Ebola vaccine, typhoid vaccine, Ribavirin for Lassa fever, future vaccines for Rift Valley Fever and Hepatitis E, chlorine tables, personal protective equipment, PCR and other laboratory equipment. Of course, not all these commodities are in short supply warranting a rationing approach

4 Conclusions, Recommendations and Options for the Future

4.1 Governance

Key question: does the current ICG governance structure support its effective, efficient and transparent functioning, and does it meet current demands for responding to outbreaks of the three diseases?

Conclusion: Despite the fact that the ICG has a well-defined role, the responsibilities of the stakeholders involved in the mechanism are not clearly defined. The lack of a clear division of labour and responsibilities, and the lack of a formal governance structure is a weakness and strength at the same time. Having some level of informality and flexibility has been an asset of the ICG, allowing it to adapt to changing needs and to address new challenges such as the need to ration YF vaccines and OCV.

Without changing its principles and basic mode of operation, three distinct ICG mechanisms emerged and adapted their processes to the differing needs of allocating scarce vaccines to respond to emergencies of meningitis, yellow fever and cholera. Practically all stakeholders interviewed agreed that the ICG has been effective in executing this task and the evaluation team shares this opinion. A group like the current ICG of four partners with technical expertise, close links to the field, and dedication to respond rapidly at any time has proven its value. No single organisation can be held to account for the decisions made by the ICG which is in line with the 'no regrets' approach of decision-making.

There are three types of tasks for each of the ICG mechanisms: (1) decisions on allocations, (2) forecasting and procurement of vaccines, and (3) deployment of vaccines. While the ICG Secretariat functions as the central hub in all these tasks, in each task there are different stakeholders involved. New emerging stakeholders are taking over roles that were initially performed by the four ICG member organisations. The emerging single funding channel through the Gavi Alliance and the single procurement channel through UNICEF SD have created a new situation, because these organisations can be held to account for major components of the ICG mechanism as depicted in the flow diagram in Annex 2. While the task of decision-making should remain independent, the other tasks need a more formal accountability mechanism with clear key performance indicators.

Furthermore, the whole 'ICG network' needs a more comprehensive governance structure with clarity on how the different stakeholders within the ICG mechanism relate and report to each other, including with a potential oversight body, as well as how the three ICGs relate to other stakeholders such as the global disease control initiatives. This comprehensive governance framework and accountability mechanism is needed to assure a continued functioning of the process from vaccine application to delivery.

Recommendations:

- More clarity is needed on which actors and stakeholders are responsible for what part of the ICG mechanism, in particular on who is responsible for the decision-making, forecasting, procurement and deployment of the vaccines and which organisations are key contributors to these parts.
- Key performance indicators should be developed or existing ones adapted for each specific portion of the flow chart for which the ICG Secretariat, the Gavi Secretariat and UNICEF Supply Division are responsible.
- The decision-making role of the ICG has to function independently and no additional level of endorsement is needed as this would negatively impact on timeliness and independence. However, options could be explored to make the decision-making bodies more formally accountable to the respective global disease control initiatives through the establishment of

an oversight body (see below), to review the composition of each of the three ICGs, and to adopt a stronger communication plan to clearly communicate the decisions made.
- Review the composition of each of the three decision-making bodies to make sure that the participating organisations can provide the most relevant technical and field expertise for the respective diseases.

Options for the future:

While the decision-making on country vaccine requests may best thrive as an independent body, a governance and accountability structure is required for the other functions of the ICG flowchart: forecasting, procuring, shipping, and monitoring of vaccine deployment.

For an oversight body, there are different options:

- A new body could be created for managerial oversight, consisting of senior staff of stakeholder organisations, including the GAVI secretariat, UNICEF SD and regional or rotating country representatives. It would be responsible to oversee the performance of each of the stakeholders and can hold organisations or countries to account. The advantage of creating a new body is that it will be tailored specifically to the ICG mechanism with clear oversight portfolio. The disadvantage is that it will require significant time and possibly also financial investment to make sure the oversight body is functional.
- Alternatively, an already existing body could be engaged to provide oversight. Or it could also be formed as a committee of the Gavi Alliance Board in which the majority of stakeholders are already represented. The advantage of using an already existing mechanism or sub-committee of an existing mechanism is that it may require less effort and investment; however, it is not clear at this point what type of oversight could be provided and whether all interests would be appropriately represented.

An oversight body should not interfere with the independence of the decision process, but rather assure that the decisions are executed optimally and transparently, and the financial donors to the Gavi Alliance receive the necessary reports to meet their own accountability needs.

If the Gavi Secretariat is involved in either of these oversight bodies as well as in the oversight bodies of the global disease control mechanisms, and *if* there is more clarity on how the respective ICG decision-making bodies will report to these oversight mechanisms, then Gavi secretariat observer role of the ICG decision process may no longer be necessary because it would receive sufficient information about the decision-making process.

4.2 Mechanisms and procedures

Key question: How well do the ICG processes respond to outbreaks of yellow fever, meningitis and cholera, and what are potential areas for improvement?

Conclusion: The ICG has functioned well over the past 20 years and the majority of international and country-based stakeholders are appreciative of the ICG's performance. An analysis of the key performance indicators confirms this assessment. In almost all cases where the ICG has not met its own performance indicators, the causes were external and beyond the ICG control. This points to a problem in the scope and role definitions of the ICG (as elaborated above) and is also related to the different specificities of the approaches for yellow fever, meningitis and cholera.

The links of the ICG to the global disease control initiatives for cholera and yellow fever are already established. The WHO disease focal points and other ICG members have a pivotal role in this development, and personal relationships with staff of the ICG Secretariat have contributed to

improved collaboration. In fact, there are actually three ICGs operating each in a broader disease control context that has evolved differently over time. Particularly for meningitis, the ICG has assumed a different function considering a more challenging supply environment (forecasting, market shaping and procurement) as well as considering that a broader disease control strategy is not clearly articulated. The issue of meningitis vaccines is an area where the ICG runs the greatest risks of failing in its mandate to respond timely to urgent vaccine needs. This is a thorny issue, cannot be resolved by the ICG per se and requires a stronger and more concerted effort of the organisation jointly responsible for Global disease control.

There is a perception by some stakeholders that allocation decisions focus too narrowly on responding to single outbreaks without always taking the global epidemic context into consideration. There is also a perceived conflict of interest of ICG members whose organisations work at country level and there is dissatisfaction on the transparency of the process and the criteria used. According to the ICG members, the criteria cannot be weighted because each outbreak is different and the importance of criteria varies accordingly. The main criteria are however publicly available and the decision summary sheet shared with Gavi have also contributed to more insights on how criteria are being applied. This information, however, is currently only shared with the Gavi Secretariat.

Issues that were identified by the evaluation as requiring improvements include:

- An overlap of responsibilities within the wider network, for instance between the ICG Secretariat and UNICEF SD leading to tensions, inefficiencies and risks of errors through conflicting messaging
- A perception of a lack of transparency of the ICG decision processes (further addressed below in section 4.4)
- Lack of a wider strategy for meningitis coupled with the decreasing supply of polysaccharide vaccines is making an efficient response by the ICG difficult
- To effectively supply vaccines for emergency responses, manufacturers would like to have long-term contracts for each of the stockpile vaccines in order to guarantee timely supply and release of emergency vaccines. Long term contracts for the emergency stockpile have not been issued for OCV or YF
- A perception by some country-based stakeholders that ICG allocation decisions are influenced (positively or negatively) by the engagement of ICG member organisations in their country. In the view of the evaluation team, however, this is not a major issue, but rather a perception that has arisen on the basis of rumours because of the Secretariat's past lack of attention to communications. It should solve itself with the implementation of a more robust communication plan.

Recommendations

- There is a need for a clear definition of roles and responsibilities among key actors in the ICG network, primarily the ICG Secretariat, UNICEF SD, and the Gavi Secretariat.
- Once the roles and responsibilities of the ICG Secretariat are well defined, it requires a set of functional SOPs to cover the functions for which it can be held to account.
- Similarly, once the roles and responsibilities of UNICEF SD are well defined, functional SOPs should be developed to standardize the process for vaccine procurement for each stockpile.
- The role and responsibilities of the country governments should also be formalised; promptness of the submission, resolving issues around licensing and customs, and ensuring an effective implementation of the campaign with adequate reporting.
- In order to address the dissatisfaction by country stakeholders on the transparency of the decisions and in particular the criteria used, the evaluation team recommends to also share a

more standard response with the countries on how the criteria were applied during the decision-making.

- The evaluation team also recommends to more formally involve UNICEF SD during the decision-making process in order to ensure the decisions take the context of the global stockpile situation and production capacity better into account. This involvement can remain separate from the actual decision-making discussion
- WHO needs to step up to its mandate and develop a global strategy for meningitis control and a mechanism to implement it.
- The Gavi Alliance is an ideal partnership to improve the present and future availability of different meningitis serotype vaccines.
- To increase the timely and reliable availability of the meningitis vaccines in the short term we recommend to transfer the risk of wastage from the manufacturers to the international health community.

4.3 FUNDING

Key question: What are the strengths and weaknesses of current funding arrangements to assure sufficient and sustainable financial support for vaccine responses to outbreaks?

Conclusion: The funding of the three vaccine stockpiles has become more reliable and equitable since Gavi decided not to apply time limits to its financial commitment and to allow all countries to access the stockpiles. Remaining balances of previously established revolving funds for the three stockpiles that are administered by WHO still exist, and have in the last years proven useful as contingency funds when Gavi funding could for some reason not be used to procure stockpile vaccines. Although these incidences should theoretically become rare, a contingency funding source for vaccines is a safety mechanism that is widely supported by ICG stakeholders as long as its purpose and use is clearly defined.

Support for the operational costs of reactive immunisation campaigns in Gavi-supported countries is provided by Gavi via WHO in an arrangement that is not within the scope of ICG responsibilities as presented in the flow diagram. (See Annex 2) Countries that are not eligible for Gavi support have to find alternate sources for campaign financing.

The accountability by governments for vaccines mobilised through the ICG mechanism has not been systematically assured. Tracking and reporting on the use of vaccines is variable. It is generally more complete from countries that receive support for operational costs because the support is linked to a monitoring and reporting requirement. It is also more complete for OCV campaigns, presumably due to the strong technical support by the GTFCC to countries implementing reactive OCV immunisation, for which human and financial resources are available. All governments, regardless of whether they have to reimburse the cost of the vaccine or not, should be required to provide assurance that their allocation of a scarce resource has been used for the purpose for which it was granted. Having to pay for these scares vaccines does not obliterate anyone from proper reporting.

Recommendations

- Gavi funding of the vaccine stockpiles has had a positive effect on stabilising the availability of vaccines for outbreak responses and is widely supported. It should therefore be maintained.
- The need for a back-up mechanism to pre-finance urgent vaccine needs is also widely acknowledged. The recommendation is to create an ICG contingency fund:
    - By either using the balance of the current revolving funds with an annual call for replenishment, or through pre-financing any future contingency needs from the WHO Contingency Fund for Emergencies.

  - The conditions under which the contingency fund can be used should be clearly spelled out in SOPs in order to avoid confusion amongst stakeholders on its purpose and use. A decision should also be made whether these funds can be used to pre-finance operational costs for non-Gavi supported countries.
- Standardised, robust and enforceable reporting requirements should be established, and implemented by the ICG Secretariat which should be held accountable by the proposed oversight body. This will require additional investments either for technical support to the countries or in terms of human resources for the ICG Secretariat.

4.4 COMMUNICATION AND TRANSPARENCY

Key question: How well informed are ICG partners and stakeholders on the ICG mechanism and its response to emergency outbreaks? Where and how could improvements be made?

Conclusion: The confidentiality of the ICG decision process is understood by the majority of stakeholders and is not threatened by the call for greater transparency. The stakeholders in the ICG mechanism have distinct information needs to facilitate their effective participation in outbreak responses and to account for their own investments and activities. The ICG Secretariat and UNICEF SD have made recent efforts to streamline the flow of information between them and to provide more information that is accessible to wider stakeholders and to the public. But there is currently no clear overview or strategy on public communication, nor about which stakeholder requires access to what type of information at what time. Lack of transparency was one of the most frequently voiced criticism of the ICG by key informants. The different stakeholders have expressed a need for additional access to information as follows:

- ICG members want more and more detailed information about vaccine availability in the stockpiles in order to facilitate decision-making
- Country applicants want a clearer and more comprehensive explanation of how allocation criteria were applied, especially when applications were rejected or only partially approved, and they want clarity about the funding of the vaccines and operational costs
- Besides the information it already receives, the Gavi Secretariat wants real-time access to information about vaccine deliveries
- Financial donors to Gavi and the ICG, and other extended partners, want more detailed information about vaccine allocations, reasons for rejections, and decisions about immunisation strategies that are sometimes part of the ICG decision on allocation volumes

Communication gaps, for instance in relation to the OCV application from Yemen in 2017, have resulted in the circulation of unfounded rumours and in some reputational damage to the ICG. Stakeholders also identified some communication gaps at the level of extended partners. As such, it remained unclear how Gavi engaged with the ICG mechanism for some time, and to which extent funding of the stockpiles was guaranteed. Furthermore, UNICEF SD also recognises that its communication around the activities related to the ICG can be improved. Because the global disease control mechanisms like GTFCC and EYE have to a large extent representation of the same members, communication with the ICG is relatively well established and there are efforts underway to increase collaboration and information sharing between ICG and EYE.

Recommendations

- Further to the definition of clear roles and responsibilities of all stakeholders involved in the ICG mechanism, and further to laying these down into functional SOPs, An assessment of the different information needs should be carried out, answering the question: *who needs what kind of information at which stage of the process?*
- Based on the outcome of the assessment a communication plan should be developed, outlining the information needs of all stakeholders with specific channels and instruments to

support their role in the process for outbreak controls, as well as allowing them to fully meet their own accountability requirements.

- Recruit staff for the ICG Secretariat responsible for the implementation of this communication plan. While there is a need for a specialist to communicate technical information to a well-informed audience, the evaluation team also recommends considering a communications specialist capable of providing often sensitive messages to a broader audience that may be technically less informed.
- The implementation of the communication plan should also involve the definition and development of an appropriate platform for internal information-sharing between the different involved stakeholders. In addition, a similar platform could be developed for public information about the rationing of scarce vaccines.
- Gavi should also define more clearly how it communicates with the ICG members, with the ICG Secretariat and with the countries on its engagement with the ICG. There is an identified need to communicate clearly and consistently to countries the fact that Gavi is funding the three stockpiles and that all countries can access these but that non-Gavi supported countries should reimburse Gavi for the vaccines used and finance the operational costs themselves.
- The ICG Secretariat and UNICEF SD should invest time and resources in increasing their collaboration and information-sharing, for example through quarterly progress and management meetings outside of the annual ICG meetings.

4.5 Future role

Key question: What role should the ICG play in the future in terms of allocating and mobilising vaccines for additional disease outbreaks and in the context of broader strategies for the control of meningitis, cholera and yellow fever?

Conclusion: The role of the ICG and the respective disease control mechanisms for yellow fever and cholera control (EYE and GTFCC) are distinct but interrelated. While they both promote the use of and make decisions on the allocation of scarce vaccines, the context in which they do this is different and requires a different approach. Nevertheless alignment and collaboration is necessary to ensure effective use of limited supply. The collaboration of the ICG Secretariat with the global yellow fever and cholera control mechanisms (EYE and GTFCC) has strengthened but several stakeholders consider that there is room for improvement. The participation of ICG members, especially the WHO and UNICEF focal points, in these two mechanisms has strengthened the link but it is not formalised. Most stakeholders do not support the option to fully transfer the mechanism for emergency vaccine deployment to EYE and GTFCC because of a concern that specialised skills and experience for rapid vaccine mobilisation will be lost. Nevertheless, there is a belief that as global shortages of OCV and YF vaccine will become less acute the role of the ICG in managing emergency stockpiles of these vaccines will diminish.

The situation is different for meningitis vaccines where there is no comprehensive global initiative and where vaccine shortages are a greater challenge than for the other two diseases. There is wide agreement among stakeholders that the ICG Secretariat has acquired a competence in managing the rationing of scarce vaccines for emergency needs that can be applied to other vaccines, medicines and products for outbreak responses. In each case, the members of the independent allocation committee, i.e. the ICG, need to be recruited according to criteria that assure the best decisions according to technical and global public health criteria while preserving the political independence of the allocation process.

Recommendations

- The sharing of information and collaboration between the EYE and the YF ICG should be formalised.

- At the next annual meeting of the YF ICG, the collaboration and information sharing between ICG and EYE should be a subject of a joint review.
- More formal and regular sharing of information with the GTFCC on the deployment and use of OCV in both emergency and non-emergency settings could improve knowledge management and overcome current hurdles in terms of licensing and importation of the vaccine.
- All vaccine requests for OCV and YF should be submitted to the respective global disease control mechanisms that will triage the requests and forward to the respective mechanism (ICG for emergency response, Gavi Secretariat for routine immunization and EYE or GTFCC secretariat for Special Immunization Activity (SIA). Given the lack of a global disease control initiative for meningitis, the requests for emergency vaccines will have to continue to be sent directly to the ICG Secretariat.

Options for the future

- The ICG Secretariat has established a competence in managing emergency vaccine allocation requests which, according to most stakeholders, can be applied to other vaccines and products that are used for outbreak controls and that are globally in short supply. The precondition, however, is that it establishes a more formal definition of its remit and its procedures, as well as a formalised partnership with those responsible for procurement and financing.
- The ICG mechanism as such is also largely considered as a suitable mechanism for managing future vaccine-stockpiles for outbreak responses, such as Ebola and other new emerging infectious diseases for which there is limited supply. The composition of the ICG for each of the existing and new stockpiles should be open for changes. Members need to be recruited or trained according to criteria that assure the best decisions according to technical and global public health criteria while preserving the political independence of the allocation process.
- For those vaccines for which supply is increasing and for which functional global disease control mechanisms exist, the evaluation team recommends that stakeholders explore whether in the mid-term an effective assimilation of the ICG in the respective global disease control mechanism would provide a more efficient and effective control plan. This would improve general oversight and critical knowledge management, however it is critical to stress that with this assimilation the emergency response should not lose its independence and well established functionality.

ANNEXES

ANNEX 1: TERMS OF REFERENCE

Evaluation Purpose and Objectives

Discussions about the need for evaluating the ICG mechanism began in 2015 and in 2016, the ICG members decided to commission an external, independent evaluation. In preparation, a detailed review of the ICG mechanism and activities over the past 10 years (2006 to 2016) was completed in 2016 by the ICG Secretariat on behalf of the ICG's 4 core members, and is publicly available on the WHO website Review of the International Coordinating Group on Vaccine Provision /2006-2016), October 2016.

- The main purpose of this independent, external evaluation is to inform decisions aimed at improving ICG's governance, its mechanism related to the management and accessibility of disease-specific, emergency stockpiles and their composition, the transparency of decision-making processes as well as ICG internal and external communication.

Its main objectives are:

- To highlight the strengths and weaknesses of ICG's governance; effectiveness, efficiency, and transparency of ICG decision-making; funding; and management
- To develop actionable options and recommendations for improving the working of the ICG and ICG mechanism.

Scope and Focus

The ICG external evaluation will cover the period from 2006 to date. It will assess ICG's activities in relation to each of the ICG vaccine stockpiles (meningitis, yellow fever and cholera) as well as the overarching ICG governance, mechanism and processes – including communication and transparency.

With the exception of a possible visit to the UNICEF SD procurement offices based in Copenhagen, travel needs will be minimal. The vast majority of SC and ICG members are based in Geneva and/or can be easily accessed either for face-to-face meetings or virtually via electronic mechanisms.

Interviews should be conducted with representatives of both internal and external stakeholders, including high level executives and/or boards members. To a large degree, this would mean the SC members (since membership includes representatives of both, including 2-3 beneficiary countries) the ICG Secretariat and key staff of the UNICEF SD.

Evaluation Criteria

It is standard WHO policy for evaluations to use the five core evaluation criteria recommended by the OECD's Development Assistance Committee 2 (DAC) as and wherever appropriate. These are as follows:

- **Relevance**: The extent to which the objectives of an intervention are consistent with and useful to the needs of beneficiaries, country needs, global priorities and the policies of partner organisations and donors. Retrospectively, questions related to relevance may be used to evaluate whether the objectives of an intervention or its design are still appropriate given changed circumstances.
- **Effectiveness (or efficacy)**: Effectiveness measures the extent to which the intervention has attained its objectives. It is also used as an aggregate measure of (or judgement about) the merit of worth of an activity – i.e. the extent to which a programme has achieved, or is expected to achieve, its major relevant objectives and have a positive institutional impact.

- **Efficiency**: Measures the outputs - qualitative and quantitative - in relation to the inputs. It is an economic term which signifies that the aid uses the least costly resources possible in order to achieve the desired results. This generally requires comparing alternative approaches to achieving the same outputs, to see whether the most efficient process has been adopted.
- **Sustainability**: the likelihood of continued long-term benefits, and the resilience to risk of net benefit flows over time.
- **Equity**: Mainly used to refer to equal access for all population groups to a service without any discrimination.

Also, for the purposes of this evaluation, transparency should be applied as another criterion.

- Transparency: Transparency, in a business or governance context, refers to honesty and openness. Transparency and accountability are generally considered the two main pillars of good corporate governance. The implication of transparency is that an organisation's actions should be open to open scrutiny.

Key Evaluation Questions

There are four main evaluation questions that should guide the evaluation and these are listed below. Each includes a limited number of sub-questions. However, we anticipate that the main evaluation questions and sub-questions will be further developed by the evaluation team during the inception phase, after its initial desk research and information gathering exercise. The final questions and sub-questions will then be detailed in an evaluation matrix as part of the inception report.

It is recognised that the final evaluation questions will reflect the constraints of time, data availability and budget.

Q1. On Governance

- To what degree does the current governance structure of the ICG support its effective, efficient and transparent functioning? How relevant is it to meet today's demands?
- To what extent are the roles and responsibilities of the ICG clearly defined and agreed by key stakeholders? Are they fit for purpose?
- To what extent do ICG 4 core member organisations manage, oversee, and are accountable for joint decisions by the ICG?
- How effectively has the ICG evolved over the two decades to meet its objectives in an increasingly complex environment, including engagement of new and emerging stakeholders?
- How well does the ICGs' governance structure compare with current good practice? What are the strengths and weaknesses of current arrangements?
- What role does ICG play, and could it play in the future, vis-à-vis broader disease control strategies (e.g. how does the ICG mechanism for yellow fever fit in with the new global strategy on eliminating yellow fever epidemics – EYE strategy)?

Q2. On the ICG Mechanism and Processes

- How well do the ICG processes respond to the emergency outbreaks of yellow fever, meningitis and cholera? Where might improvements be made?
- In which ways are current arrangements still adequate, efficient and fit for purpose? What could enhance its processes?
- To what extent are recipient countries satisfied with ICG response to emergency vaccine requests?
- How adequate are existing vaccine stockpile composition and forecasting tools?

- What factors are most influential in ensuring an effective, efficient and equitable response to emergency outbreaks of the 3 core diseases managed by the ICG?
- How adequate, effective and efficient are the current mechanisms and processes between ICG emergency response and the individual ICGs' stockpiles being managed? Where and what kind of improvements should be made?
- How fit for purpose are current procurement strategies to ensure that stockpile size and composition are adequate to respond to outbreaks?
- To what degree are stakeholders acting according to their designated roles and responsibilities for forecasting and managing stockpiles? To what extent are those roles and responsibilities relevant and adequate to current demands?
- How flexible is the overall governance mechanism to accommodate new vaccine stockpiles, such as for the Ebola vaccine?

Q3. On Funding

- What are the strengths and weaknesses of current funding arrangements so as to assure sufficient and sustainable financial support of the ICG mechanism?
- To what degree are current funding mechanisms fit for purpose?
- How well are funds being tracked?
- How adequate are the current mechanisms for forecasting the financial needs for procurement?
- What mix of funding sources could be envisaged to improve current funding? What are the strengths and weaknesses of possible alternatives?

Q4. On Transparency and Communication

- How well informed are ICG partners and stakeholders on the ICG mechanism and its response to emergency outbreaks? Where and how could improvements be made?
- What is the quality and adequacy of the real-time data on stockpiles, procurement and delivery status available to the ICG and stakeholders? What could be done to improve the status quo?
- How well do ICG partners and stakeholders, particularly recipient countries, consider they are informed about the decision-making process governing the ICG's response to emergency disease outbreaks? How and where could improvements be made?

Evaluation Approach, Methodology and Methods

The evaluation will adopt a participatory approach to evaluate the past and current situation with a view to scoping the global mechanisms that are required now and in the future for global emergency stockpiles. A participatory approach has been shown to increase the engagement of stakeholders' interest and ownership of the evaluation results. As such, members of the evaluation's Steering Committee (SC) include representatives from a range of partners and stakeholders. In addition to acting as key informants during the evaluation process, SC members will also be consulted at different stages of the process such as the drafting stages of the terms of reference, inception note and evaluation report, and will have the opportunity to provide comments. However, since the evaluation is designed as an independent and objective exercise, in effect, the SC will serve an advisory role.

Individual knowledge experts can be called upon to support the evaluation team. Such individuals will provide subject knowledge input and guidance and may therefore include subject specialists external to the ICG. The SC members will provide the evaluation team with the names and details of such experts.

The innovation and creativity of the evaluation team in proposing its design is to be encouraged. Whilst the team is free to choose the methods most appropriate to responding to the evaluation questions a combination of qualitative and quantitative methods (mixed methods) is expected.

The methodology should demonstrate impartiality and lack of bias by relying on a cross-section of information sources (from various stakeholder groups) and by using mixed methods to ensure that the data is analysed through a variety of means (triangulation).

Evaluators should follow the principles set forth in the WHO Evaluation Practice Handbook, and the United Nations Evaluation Group (UNEG) norms and standards for evaluations and ethical guidelines.

Procedure

The evaluation team responding to the Call for Tender will propose a study design to include the following:

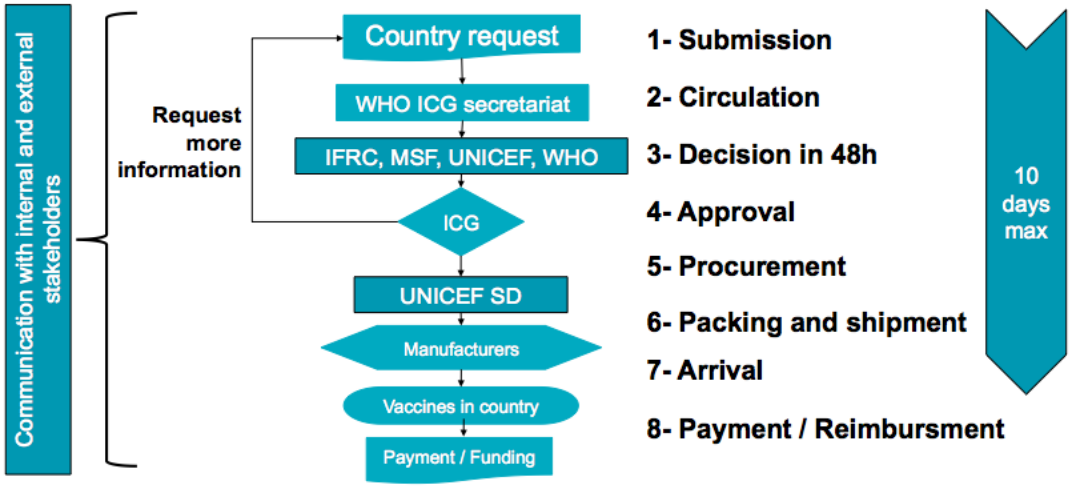
- A review and possible refinement of the evaluation objectives and questions in order to build on the initial ideas and identify their priorities and feasibility
- The data to be collected to respond to each of the key evaluation questions
- Details of the approach and methodology proposed
- A work schedule to illustrate the data collection process, timeline and deliverables

Interviews with the selected finalists will be arranged face-to-face or virtually.

The initial evaluation design will then be further developed by the contracted evaluation team within two weeks after contract start date, and presented in the form of an Inception Report. This will be based on an initial review of the available data and the results of consultations with key internal and external partners and stakeholders. (See section 3.8, page 48 in the WHO Evaluation Handbook for further guidance). It will also include the number and type of ad hoc subject expert groups that should be nominated by the SC to support the evaluation team.

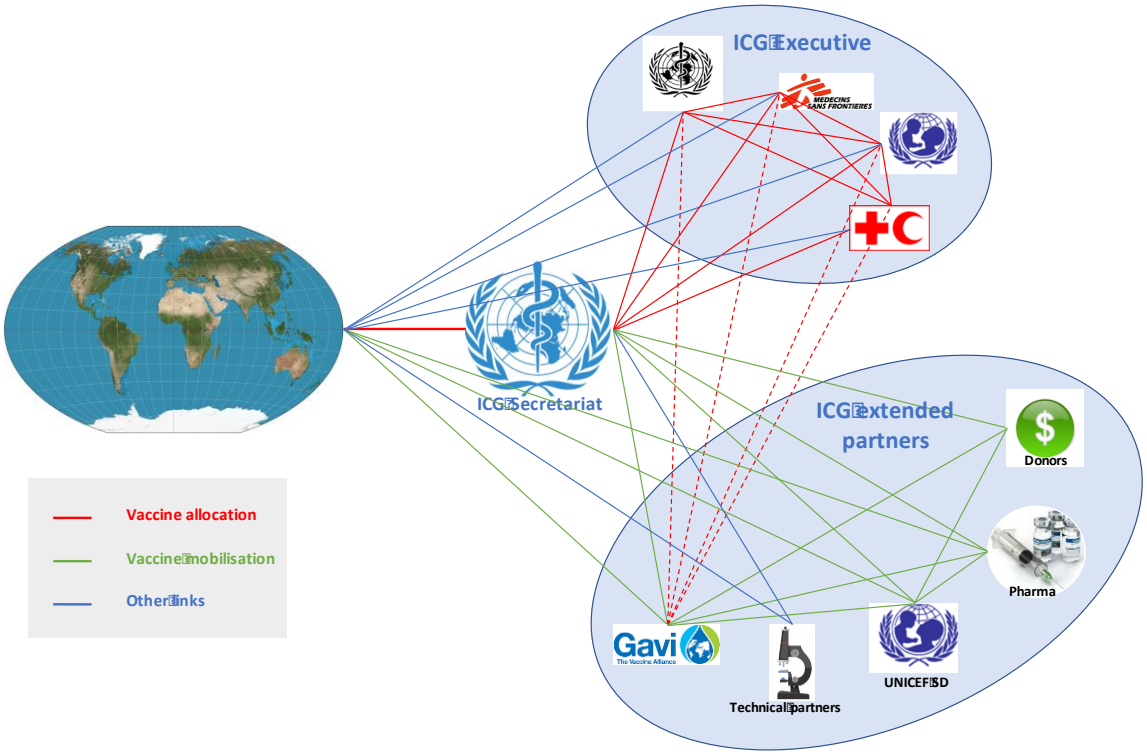
ANNEX 2: ICG FUNCTION AND NETWORK STRUCTURE

Flow diagram of ICG function



Adapted from http://www.who.int/csr/disease/icg/qa/en/

Preliminary ICG network structure (tested during the social network analysis)



ANNEX 3: LIST OF KEY INFORMANTS INTERVIEWED

The following people were interviewed as part of the external evaluation using a semi-structured interview approach. The ones **underlined and in bold** are members of the Steering Committee.

#	Name	Organisation	Key informant group
1	Amanda McClelland	IFRC	ICG Executive (Cholera, Meningitis, Yellow Fever)
2	**Panu Saaristo**	IFRC	ICG Executive (Cholera, Meningitis, Yellow Fever)
3	Myriam Henkins	MSF	ICG Executive (Cholera, Meningitis, Yellow Fever)
4	Michel van Herp	MSF	ICG Executive (Yellow Fever)
5	Miriam Alia	MSF	ICG Executive (Meningitis)
6	Imran Mirza	UNICEF	ICG Executive (Cholera, Meningitis)
7	Heather Papowitz	UNICEF	ICG Executive (Cholera)
8	Robert Kezaala	UNICEF	ICG Executive (Meningitis)
9	Yodith Sahlemariam	UNICEF	ICG Executive (Yellow Fever)
10	Dominique Legros	WHO	ICG Executive (Cholera)
11	Olivier Ronveaux	WHO	ICG Executive (Meningitis)
12	Sergio Yactayo	WHO	ICG Executive (Yellow Fever)
13	Alejandro Javier Costa	WHO	ICG Secretariat
14	Tim Nguyen	WHO	ICG Secretariat
15	**Vidhya Ganesh**	UNICEF	ICG Core Expert
16	**Robin Nandy**	UNICEF	ICG Core Expert
17	Pete Salama	WHO	ICG Core Expert
18	Gaya Manori Gamhewage	WHO	ICG Core Expert (Yellow Fever)
19	Katya Fernandez	WHO	ICG Core Expert (Meningitis)
20	Laurence Cibrelus and Asheena Khalakdina	WHO	ICG Core Expert (EYE Secretariat)
21	Lorenzo Pezzoli	WHO	ICG Core Expert (Cholera)
22	**Sylvie Briand**	WHO	ICG Core Expert
23	Mike Ryan	WHO	ICG Core Expert
24	Mamadou Djingarey	WHO AFRO	ICG Core Expert
25	**Greg Widmyer**	BMGF	Extended Partner
26	**Sonia Puglisi**	DCVMN	Extended Partner
27	**Jason Lane,** Alice Gilbert and Lawrie Harper-Simmonds	DFID	Extended Partner
28	**Ian Van Engelgem**	ECHO	Extended Partner
29	**Michael Thomas**	Gavi Secretariat	Extended Partner
30	Melissa Ko, Stephen Sosler and Wilson Mok	Gavi Secretariat	Extended Partner
31	Melissa Malhame	Gavi Secretariat	Extended Partner
32	Kathryn Alberti	Global Taskforce of Cholera Campaign	Extended Partner

33	Guillermo Gimeno	UNICEF SD	Extended Partner
34	Hans Christiansen	UNICEF SD	Extended Partner
35	Heather Deehan	UNICEF SD	Extended Partner
36	Ian Lewis	UNICEF SD	Extended Partner
37	Yalda Momeni	UNICEF SD	Extended Partner
38	Stéphane Arnaud	UNICEF SD	Extended Partner
39	Palle Skovgaard Madsens	UNICEF SD	Extended Partner
40	Jørgen Arnum Kofoeds	UNICEF SD	Extended Partner
41	Jean Christophe Aze	WHO (Logistics)	Extended Partner
42	Kamal Ait Ikhlef	WHO (Logistics)	Extended Partner
43	Ryan Novak	CDC (Meningitis) and MenAfriNet	Extended Partner
44	Kashmira Date	CDC (Cholera)	Extended Partner
45	John Roberts	Pfizer	Extended Partner (manufacturer)
46	Susan King	GSK	Extended Partner (manufacturer)
47	Amit Kumar, Francoise Griguer and Lynn Morgan	Sanofi-Pasteur	Extended Partner (manufacturer)
48	Yeongok Baik, Youngjin Lee and Rachel Park	EuBiologics (OCV)	Extended Partner (manufacturer)
49	Dr Hernando Agudelo	WHO Angola	In-country stakeholders
50	Dr Guylain Kaya Mutenda Sheria	Ministry of Health DRC	In-country stakeholders
51	Dr Wamala Joseph	WHO South-Sudan	In-country stakeholders
52	Dr Muntasir Elhassan	WHO Iraq	In-country stakeholders
53	Dr Clément Glèlè	Ministry of Health Benin	In-country stakeholders
54	Dr Lukusa Kakonku, Andre	WHO Benin	In-country stakeholders

ANNEX 4: SAMPLED ICG VACCINE STOCKPILE APPLICATIONS

Stockpile applications sampled for in-depth analysis

Country	Stockpile	Year	Month	Request	Approval	Gavi Funding
Angola	YF	2016	July	#10/2016	Fully	No
Benin	Meningitis	2017	April	#07/2017	Rejected	Yes
DRC	YF	2016	June	#7/2016	Partially	Yes
Iraq	OCV	2015	October	#12/2015	Fully	Yes
Niger	Meningitis	2017	April	#08/2017	Partially	Yes
South Sudan	OCV	2017	March	#2/2017	Fully	Yes

Stockpile applications sampled for on-line surveys[30]

Country	Stockpile	Year	Request	Approved doses	Approval	Gavi Funding
Angola	YF	2016	#10/2016	3,100,000	Fully	No
Angola	YF	2016	#8/2016	-	Rejected	-
Angola	YF	2016	#10bis/2016	1,906,060	Fully	No
Benin	Meningitis	2012	#11/2012	100,000	Partially	Yes
Benin	Meningitis	2017	#07/2017	-	Rejected	Yes
Benin	Meningitis	2017	#11/2017	-	Rejected	Yes
Brazil	YF	2017	#1/2017	3,504,542	Fully	No
Burkina Faso	Meningitis	2012	#10/2012	447,000	Partially	Yes
Cameroon	Meningitis	2017	#02/2017	7,079	Fully	yes
Cameroon	OCV	2015	#11/2015	116,344	Fully	Yes
Cameroon	YF	2013	#6/2012	177,805	Fully	Yes
CAR	Meningitis	2016	#8/2016	-	Rejected	-
Chad	YF	2012	#5/2012	1,129,198	Partially	Yes
Chad	Meningitis	2012	#9/2012	200,000	Fully	Yes
Chad	OCV	2012	#6/2014	-	Rejected	-
Côte d'Ivoire	Meningitis	2012	#1/2012	176,478	Partially	Yes
DRC	YF	2016	#11/2016	340,542	Fully	Yes
DRC	YF	2016	#7/2016	1,083,005	Partially	Yes
DRC	YF	2016	#9/2016	5,770,000	Fully	Yes
Ethiopia	Meningitis	2015	#11/2015	120,553	Partially	Yes
Ethiopia	OCV	2014	#2/2014	278,740	Fully	Yes
Ethiopia	OCV	2014	#5/2014	64,335	Fully	Yes

[30] Respondents from countries with multiple applications for the same stockpile were asked to choose only one

Country	Stockpile	Year	Request	Approved doses	Approval	Gavi Funding
Gambia	Meningitis	2012	#12/2012	-	Rejected	-
Ghana	Meningitis	2016	#5/2016	-	Rejected	-
Ghana	Meningitis	2012	#2/2012	105,720	Partially	Yes
Ghana	Meningitis	2016	#2/2016	161,111	Partially	Yes
Guinea	Meningitis	2013	#1/2013	63,075	Fully	Yes
Guinea	Meningitis	2014	#3/2014	521,048	Fully	Yes
Iraq	OCV	2015	#12/2015	510,000	Fully	Yes
Malawi	OCV	2017	#5/2017	240,000	Partially	Yes
Malawi	OCV	2016	#3/2016	40,000	Fully	Yes
Mozambique	OCV	2017	#4/2017	709,077	Fully	Yes
Mozambique	OCV	2015	#2/2015	-	Rejected	-
Nepal	OCV	2015	#6/2015	-	Rejected	-
Niger	Meningitis	2017	#08/2017	145,587	Partially	Yes
Niger	Meningitis	2016	#4/2016	156,719	Partially	Yes
Niger	OCV	2016	#1/2016	195,132	Fully	Yes
Nigeria	Meningitis	2017	#10/2017	694,065	Partially	Yes
Nigeria	Meningitis	2017	#06/2017	823,970	Fully	Yes
Nigeria	Meningitis	2017	#09/2017	189,233	Fully	Yes
Rep. Congo	YF	2012	#4/2012	38,805	Partially	Yes
Somalia	OCV	2017	#3bis/2017	264,600	Fully	Yes
Somalia	OCV	2017	#3/2017	907,202	Partially	Yes
South Sudan	OCV	2017	#2/2017	474,976	Fully	Yes
South Sudan	OCV	2017	#1/2017	68,967	Partially	Yes
South Sudan	OCV	2016	#8/2015	-	Rejected	-
Sudan	YF	2012	#3/2012	1,341,694	Partially	Yes
Sudan	Meningitis	2012	#13/2012	81,418	Fully	Yes
Tanzania	OCV	2015	#7/2015	254,582	Fully	Yes
Tanzania	OCV	2015	#4/2015	164,584	Fully	Yes
Togo	Meningitis	2017	#04/2017	120,000	Fully	Yes
Togo	Meningitis	2017	#01/2017	56,169	Fully	Yes
Togo	Meningitis	2016	#6/2016	93,280	Partially	Yes
Uganda	YF	2016	#4bis/2016	61,670	Fully	Yes
Uganda	Meningitis	2014	#1/2014	66,830	Fully	Yes
Uganda	YF	2016	#4/2016	714,579	Fully	Yes
Yemen	OCV	2017	#6/2017	1,000,000	Partially	Yes
Zambia	OCV	2016	#4/2016	598,131	Fully	Yes

ANNEX 5: DETAILED EVALUATION QUESTIONS

Based on the priority areas for the evaluation that the evaluation team gathered through preliminary interviews with members of the SC, and based on an analysis of evaluability and logical flow of questions, the detailed list of evaluation questions included in the ToR has been modified. We have also restructured the questions according to the domains of enquiry of the ToR, and added an additional domain, namely the future role of the ICG and its relation to existing broader disease control and outbreak response strategies and mechanisms.

Governance

Objective: Assess whether the current governance structure of the ICG supports its effective, efficient and transparent functioning, and meets current demands for responding to outbreaks of the three diseases.

a) To what extent are the roles and responsibilities of the ICG mechanism clearly defined and agreed by key stakeholders?
b) Are they fit for purpose?
c) To what extent does the current governance structure enable the ICG to achieve its objectives?
d) To what extent are the original and the newly emerging stakeholders engaged?
e) How effectively does the governance structure of the ICG assure that rational allocation decisions are made, that decision-making is transparent, and that the ICG is accountable for its decisions?
f) To what extent are the 4 ICG core-member organisations accountable for a) timeliness of the response; b) effectiveness of the proposed outbreak control strategy and c) joint decisions made on stockpile management
g) Is the decision-making sufficiently transparent for all stakeholders to ensure accountability?

Mechanisms and procedures

Objective: Assess how well the ICG processes respond to outbreaks of yellow fever, meningitis and cholera, identify and propose areas of improvement.

a) In which ways are current arrangements (from submission of vaccine request to vaccine delivery) still adequate, efficient and fit for purpose?
b) What could enhance its processes?
c) To what extent are recipient countries satisfied with ICG response to emergency vaccine requests?
d) What factors are most influential in ensuring an effective, efficient and equitable response to emergency outbreaks of the three diseases managed by the ICG?
e) How adequate, effective and efficient are the existing SOPs for emergency response management?
f) How do stakeholders perform against the procedures described in the SOPs?
g) How adequate are existing vaccine stockpile composition, forecasting tools and procurement strategies to ensure that each stockpile size and composition is adequate to respond to outbreaks?
h) To what extent are the stakeholders' roles and responsibilities for forecasting and managing stockpiles relevant and adequate to meet current demands?
i) Are stakeholders acting according to their designated roles and responsibilities?

Funding

Objective: Identify the strengths and weaknesses of current funding arrangements to assure sufficient and sustainable financial support for vaccine responses to outbreaks

a) To what extent are current funding mechanisms (including multi-year financial needs, sources and mix of funding) fit for purpose?
b) What are the strengths and weaknesses of possible alternatives?
c) How well are ICG funds being tracked?

Communication and transparency

Objective: Assess how well ICG partners and stakeholders are informed about the ICG mechanism and its response to outbreaks, and identify where and how improvements may be made.

a) What is the quality and adequacy of the real-time data on stockpiles, procurement and delivery status available to the ICG and stakeholders?
b) What could be done to improve the current status?
c) How well are ICG partners and stakeholders, particularly recipient countries, informed about the decision-making process governing the ICG's response to emergency disease outbreaks?
d) How and where could improvements be made?

Potential future role

Objective: Identify options of what role the ICG could play in the future in terms of allocating and mobilising vaccines for additional disease outbreaks and/or in the context of broader strategies for the control of meningitis, cholera and yellow fever;

a) What role does ICG play, and could it play in the future, vis-à-vis broader disease control strategies?
b) How flexible is the ICG mechanism to accommodate new vaccine stockpiles, such as for the Ebola vaccine?

ANNEX 6: SOCIAL NETWORK ANALYSIS

The ICG started in 1997 as an informal network of four international organisations supporting the response to meningitis outbreaks in the Sahel zone. Since then, it evolved into a more complex network with different nodes of decision-making for funding, stockpiling, procurement, and delivery of vaccines. New stakeholders joined the network, the boundaries of the ICG became less clearly defined, and the labels applied to distinct groups within the network changed several times. During the inception phase, we constructed a network model based on information provided in the 2016 internal ICG review. During the evaluation, we used the methodology of social network analysis (SNA) to test the model on the basis of documented and reported communications among stakeholders in the six stockpile applications that were sampled for in-depth reviews.

The method

SNA is the mapping and measuring of relationships and communications between individuals, groups and organisations. The nodes in the network are the organisations while the links show relationships or flows between them. SNA provides both a visual and a mathematical analysis of organisational relationships. To understand networks and their participants, the location of actors in the network are examined to provide insight into roles and groupings. The table provides a glossary of terms used in SNA. In the application column, the meaning of the terms in the context of this analysis are summarised. They are presented in subsequent paragraphs.

Term	Meaning	Application
Network	The relationship that exists between actors.	All organisations and individuals involved in mobilising emergency stockpile vaccines
Actors	Network members that are distinct individuals, collective units or entities	We identified 17 distinct actors, whereby some (e.g. the six ministries of health) were grouped and treated as single actors
Network metrics		
Network density Geodesic distance	Measures of the interconnectedness or strength of social networks. Networks in which all actors communicate directly with each other have a high density (measured from 0 to 1) and a low geodesic distance[31] (lowest possible value is 1).	These metrics are important for some analyses of social networks, but they have little application in this context where the objective is to examine the structure of the communication paths rather than their density
Actor metrics		
Degree centrality	The degree centrality of an actor is a count of the number of actors that are connected to it.	The ICG Secretariat has by far the highest degree and therefore position as a central information hub. There are, however, also several secondary hubs.
Betweenness centrality	The betweenness centrality of an actor is a metric of how many times he acts as a bridge along the shortest path between two other actors. The more actors an actor bridges, the higher his betweenness centrality	The ICG Secretariat has by far the highest betweenness centrality confirming its role as a main conduit of communications within the network.
Closeness centrality	This is the inverse of the sum of the distance between an actor and all other actors. The more central an actor is the lower its total distance from other actors, the higher its betweenness centrality.	A similar pattern is observed with the high centrality of the ICG Secretariat, followed by the WHO disease focal points, the UNICEF Programme and Supply Divisions, and the WHO Country Offices

[31] Geodesic distance is the distance between two vertices in a graph calculated by the number of edges in the shortest path

Data for the SNA were collected by asking key informants involved in the six sampled stockpile applications to complete a questionnaire estimating the number and type of communications with other actors in the context of this application, by additional information collected during key informant interviews and by an analysis of the ICG Secretariat email folders. Network actors included in the analysis were the applicants for stockpile vaccines (ministries of health and/or technical partners), the ICG Secretariat, the four ICG Members (MSF, WHO, IFRC and UNICEF Programme Division) and extended ICG partners such as the UNICEF Supply Division, Gavi, WHO and UNICEF Regional Offices, other disease control mechanisms (e.g. the GTFCC Secretariat), vaccine manufacturers and freight forwarders.

For WHO, a distinction was made between the WHO Country Offices, WHO Regional Offices, WHO disease focal points, WHO Logistics and WHO Headquarters (WHO staff that could not be allocated to the above groups). For UNICEF, a distinction was made between UNICEF Programme Division, UNICEF Supply Division, UNICEF Country Offices and UNICEF Regional Offices.

The breadth of the network is defined by the sample of the 6 outbreaks selected for the in-depth review and only includes those stakeholders for which evidence of communication and involvement was collected.

The data were analysed using NodeXL Excel Template Version 1.0.1.386; Social Media Research Foundation (www.smrfoundation.org/).[32]

Network characteristics

The ICG is a multipartite network including different types of actors with distinct roles. The communication exchanges were considered to be non-directed because of the complexity of the interactions. With multiple emails and phone calls going in both directions, we deemed it inappropriate to allocate directions to the exchanges. The exchanges were not valued based on the usefulness participants allocated to them because not all participants answered questions on usefulness, and those who did scored all exchanges as 'very useful'.

The majority of exchanges (over 95%) were conducted via email, although also a number of phone calls took place (ca. 5%), in particular for making decisions.

The data collected spread across a period of three years (2015, 2016 and 2017) and three separate vaccine stockpiles (yellow fever, OCV and meningitis). Sub-analyses of the networks for each stockpile application show some differences. For instance, the network density was higher for yellow fever stockpile applications than for OCV and meningitis vaccine. The samples, however, are small (two applications per stockpile) and we therefore do not present any sub-analysis. Interactions that happen on a more regular basis (i.e. bi-weekly calls with the manufacturers for OCV) or on an ad hoc basis (i.e. consulting technical partners for advice, outside of the six sampled applications) are not reflected in the network analysis.

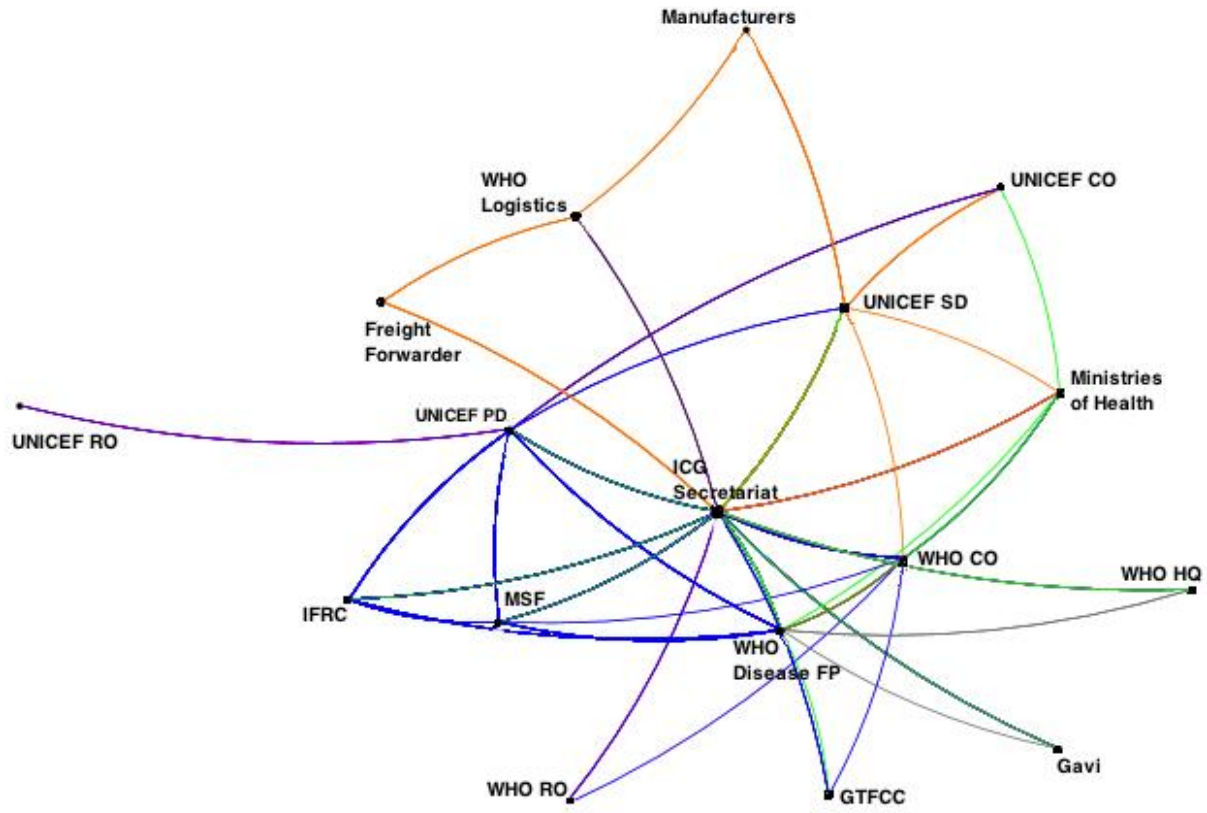
The total number of actors involved in the six stockpile applications was 17, with 351 exchanges, of which nine were unique (multiple email exchanges between two actors count as the same exchange). The network density - a measure of how many exchanges occurred in the network divided by the total number of exchanges that could exist if every actor had some interaction with every other actor- was 0.279. The maximum geodesic distance – largest number of exchanges required to interact with any other individual - was 3 and the average geodesic distance was 1.77.

[32] Smith MA, Shneiderman B, Milic-Frayling N, Mendes Rodrigues E, Barash V, Dunne C, Capone T, Perer A, Gleave E. Analyzing (social media) networks with NodeXL. Proceedings of the Fourth International Conference on Communities and Technology. 2009:255–264

These metrics indicate a network that is not very tight, however only data were on communications about a single issue over a relatively short time-period.

The structure of the ICG network is presented graphically using the Harel-Koren Fast Multiscale algorithm. It is based on the actor metrics calculated from information collected for the six stockpile applications and presented in the table below. The actors with the most exchanges are located in the centre of the graph, while those with fewer exchanges are found on the periphery. The distance between actors indicates how many exchanges they had (more exchanges equals shorter distance). The colours of the links indicate the content of the exchange (summarised as per the ICG flowchart):

- Lime = Preparation of the request
- Blue = Submission of request, circulation, decision-making
- Pink = Communication of decision
- Orange = Procurement, Shipment and Delivery
- Grey = Financing
- Green = Preparation of request *AND* financing
- Brown = Submission of request *AND* communication of decision *AND* shipment/delivery
- Purple = Circulation *AND* communication of decision



Actor	Degree Centrality	Betweenness Centrality	Closeness Centrality
ICG Secretariat	13	55,295	0,053
WHO Disease Focal Point	9	12,919	0,042
UNICEF Programme Division	7	21,569	0,040
WHO Country Office	7	6,386	0,038

Actor	Degree Centrality	Betweenness Centrality	Closeness Centrality
UNICEF Supply Division	6	13,802	0,038
Ministries of Health	5	3,995	0,036
MSF	5	0,833	0,036
IFRC	4	0,000	0,034
WHO Logistics	3	3,950	0,032
UNICEF Country Office	3	0,500	0,029
GTFCC	3	0,000	0,031
Manufacturers	2	0,750	0,026
WHO Head Quarter	2	0,000	0,030
Freight Forwarder	2	0,000	0,031
Gavi	2	0,000	0,030
WHO Regional Office	2	0,000	0,030
UNICEF Regional Office	1	0,000	0,025

Discussion

The analysis illustrates the central role of the ICG Secretariat in the entire stockpile mobilisation process from the application to vaccine delivery. The finding may be somewhat biased because only at the Secretariat did we obtain the email records to count exchanges. This would, however, only affect the distance to others in the network, and less likely the number of connections.

Among the ICG (the representatives of MSF, IFRC, UNICEF PD and WHO), only the WHO disease focal points and the representatives of UNICEF PD are extensively networked and close to the Secretariat. The representatives of IFRC and MSF are networked primarily within the ICG decision-making group and with the ICG Secretariat. The WHO disease focal points have the second largest number of contacts, both with the country level where their role would be mostly supportive, and with international actors where they provide an important link to international disease control initiatives. The representatives of UNICEF PD have a similarly active network, but their link to the country level is weaker.

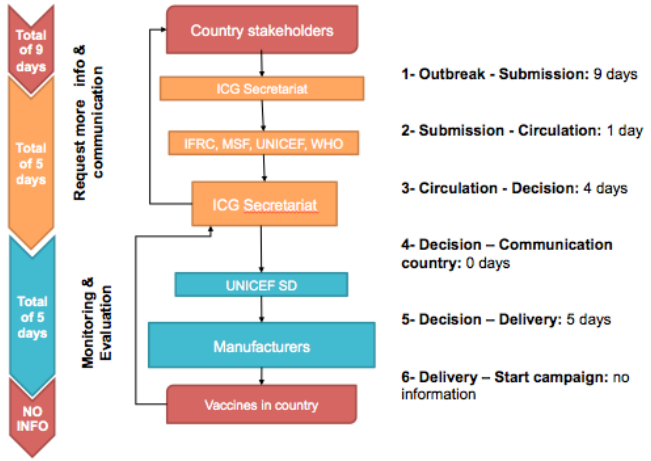
UNICEF SD serves as a hub in a smaller satellite network with country-level actors, manufacturers and the ICG Secretariat. The information links between UNICEF SD and the ICG Secretariat are strong. In at least five of the six stockpile applications, the ICG Secretariat kept UNICEF SD closely informed about upcoming requests and ICG decisions.

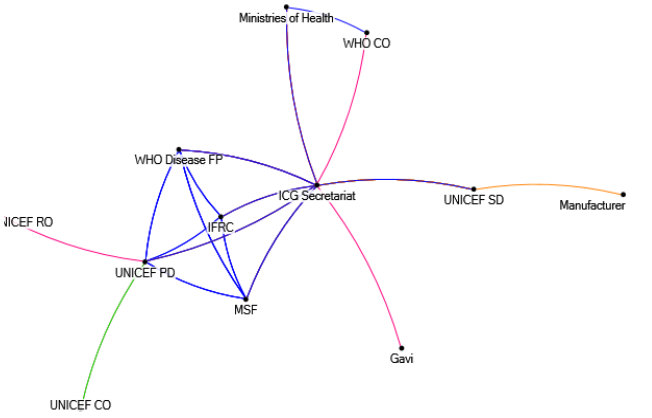
Gavi is quite peripheral to the network and only linked to the WHO Focal Points and the ICG Secretariat. But Gavi is also a relatively new actor in the network, and its contributions as the main financier of stockpile vaccines and outbreak control strategies are primarily contracted to WHO, removing Gavi one step from the campaign implementation level.

As initially hypothesised in the network structure we constructed prior to the evaluation (see Annex 2), the role of the ICG as a central hub is confirmed. The ICG (i.e. the ‘core group’ or the ‘executive’ as it is called in different documents) also appears as in the initial structure as a tight internal network that is more or less closely linked to the Secretariat. The main difference is the complexity of networking among the ‘extended partners’ who are not a homogenous group of organisations with similar roles and interests. This provides some useful information for the exploration of options that could potentially increase the efficiency of vaccine mobilisation for outbreak controls.

ANNEX 7: IN-DEPTH REVIEWS OF SELECTED OUTBREAKS

Niger – 2017/April – Request for 288,015 doses from Meningitis Stockpile – Partially approved





Legend: Preparation of the request; Submission of request, circulation, decision-making; Communication of decision; Procurement, Shipment and Delivery

This was the second request for meningitis vaccines in April by Niger. The first request was fully approved for 303,317 doses. The current request asked for a total 288,015 doses of the Men A/C polysaccharide vaccine. No coverage surveys were available for the previous campaign.

The request was submitted by Niger's ministry of health on April 19, and it was developed with technical support of partners like WHO, UNICEF and MSF, following the analysis of epidemiological and biological surveillance data.

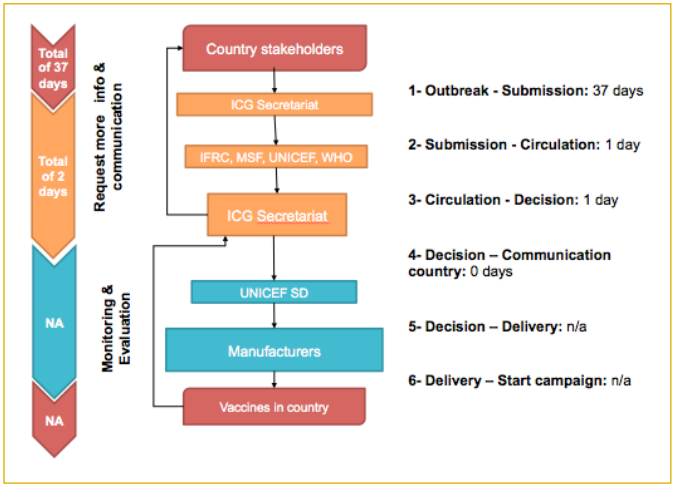
The request was circulated to ICG members on a Thursday afternoon (20 April), and a deadline was given for Monday afternoon (24 April), which is 48 hours not considering the weekend as working days. The deadline was respected. The request was partially approved (145,587 doses) for four districts because there was not sufficient evidence submitted for the other areas for which vaccines were requested, but additional doses could be approved upon receipt of new data, which Niger did not provide.

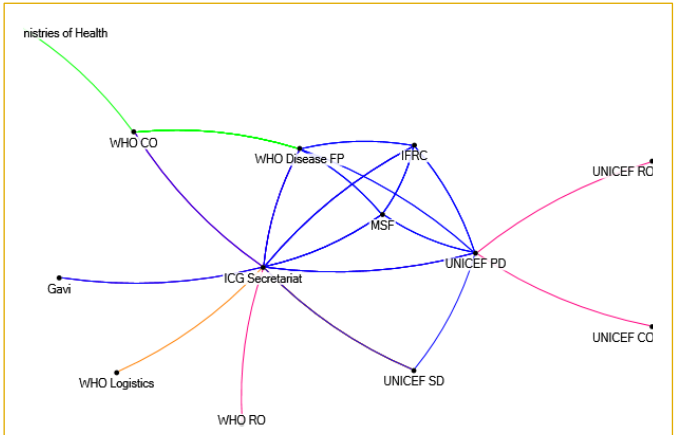
The ministry of health was informed on the same day the decision was made (24 April). The communication did not refer to the criteria used but included information on the number of doses approved, explanation that more doses can be sent if further information is provided, explanation that a part of the vaccines (47,800 doses) would expire by June 30, so the campaign should start soon. The reason for the inclusion of vaccine doses close to expiry date is because of the global shortage of meningitis vaccine and that further requests are expected before the end of the 2017 season. Gavi was also informed through the "Decision Summary Sheet" on the same day the decision was made, providing a short narrative explanation on the reasons for a partial approval.

It was agreed to use the 47,800 doses vaccines from the stockpile that were close to expiry, provided that UNICEF SD could supply them within 7 days. UNICEF SD confirmed that a quick delivery was possible and that it negotiated a favourable price. The vaccines arrived in Niger eventually on April 29, within five days after the decisions was made.

No report was received by the ICG Secretariat on the vaccination campaign.

Benin – 2017/April – Request for 448,813 doses from Meningitis Stockpile – Rejected





Legend: Preparation of the request; Submission of request, circulation, decision-making; Communication of decision; Procurement, Shipment and Delivery

Benin had started preventive vaccination due to outbreaks in neighbouring countries in March 2017 with available in-country stocks of vaccines. When there was an epidemic alert in April it submitted a request to the ICG because national stocks had depleted.

While the request was circulated to the ICG members on 19 April, the request was already submitted to the ICG Secretariat on 12 April, copying WHO technical members of the ICG. The technical members picked up the request and requested additional information and data from Benin. Only after about a week when the data was considered sufficiently complete, the WHO members asked the ICG Secretariat to circulate the request.

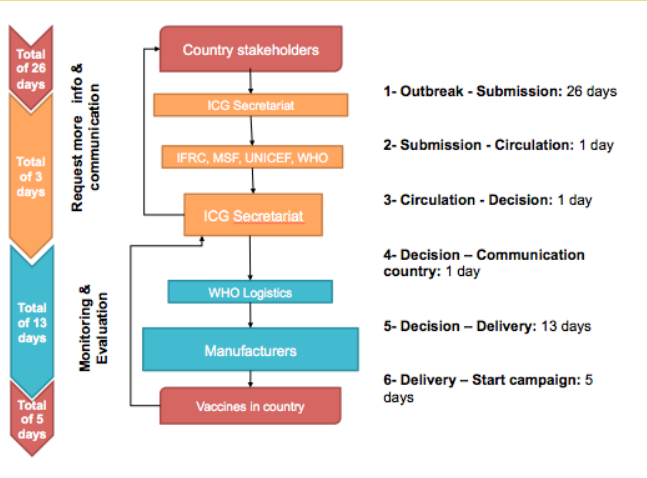
The number of doses of AS polysaccharide vaccine available in the stockpile that was mentioned when the request was circulated (583,000) appeared to be incorrect: UNICEF SD had updated the data on availability of vaccines on April 10 to 241,800 doses but this was not reflected.

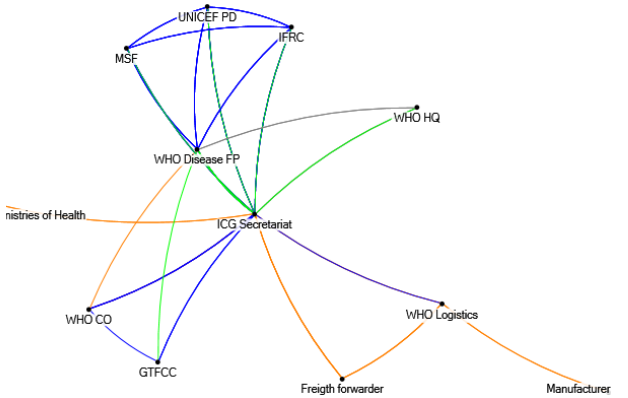
The request was rejected by the ICG because the epidemic threshold was not reached and there were too few confirmed cases. Furthermore, the request did not include a vaccination plan. The decision was made and communicated on July 20, but the ICG Secretariat had overlooked the request for ceftriaxone. On July 21 (Friday), ICG members were requested to review the request for ceftriaxone with a deadline given for July 24 (Monday), when ICG members approved the request for ceftriaxone. Part of the ceftriaxone was shipped from the stock in Geneva held at WHO until depletion of the stock. The remainder was procured by WHO at a manufacturer in Greece. The shipment from Geneva was rebooked and arrived on the 1st of May instead of 27 April. The shipment from Greece arrived on April 29.

Neither a report on the utilisation of the ceftriaxone, nor a reimbursement was requested and received from Benin. In the communication on the rejection to Benin, a suggestion was made to submit a revised request in case the epidemiological threshold was reached. Benin provided consequently additional data on May 5. The ICG Secretariat considered it a new request (#11), which was also rejected.

The decision summary sheet was only shared with Gavi on April 28.

Iraq – 2015/October – Request for 510,000 doses from OCV Stockpile – Approved





Legend: Preparation of the request; Submission of request, circulation, decision-making; Communication of decision; Procurement, Shipment and Delivery

The Iraqi Government declared a cholera outbreak on September 15 2015 with as of 1st of October 2015, 2,449 suspected cholera cases (777 confirmed) and 7 suspected deaths in 12 governorates.

The ICG Secretariat received a heads up on the upcoming request on September 30 through WHO technical experts (members of the GTFCC and of the OCV ICG), one of them actually being in Iraq to support the ministry of health with the preparation of the request and with responding to requests from the ICG for additional data. According to the focal person in the WHO Country Office, the requested data was challenging to obtain and much had to be based on assumptions.

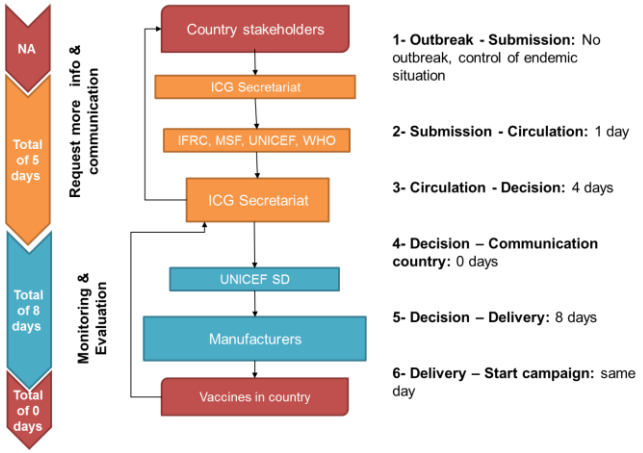
The request was officially submitted on October 4 and circulated with the ICG members on October 5. ICG members raised some concerns about the data and other information included in the request. A conference call was therefore set up, in which it was agreed to request additional data. Additional data was requested on October 7 and provided the next day by the WHO technical expert who was still in Iraq. Consequently, the ICG members approved the request on October 8. A number of concerns raised by the ICG members were communicated to the country on October 10.

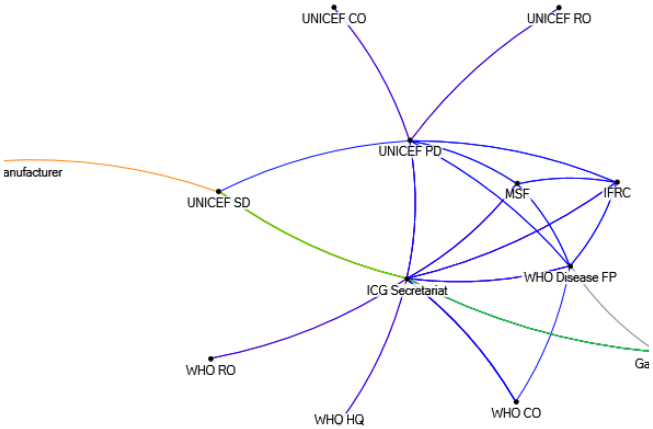
The procurement of the vaccines was done by WHO Procurement Office (UNICEF SD had not yet assumed the procurement role for the OCV stockpile at that time). Last minute, the shipment scheme had to be changed. The ministry of health did not agree that a part of the vaccines would go direct to Erbril. Instead, all had to go through Baghdad. Vaccines arrived in country in 2 shipments on October 22 and October 23.

The campaign started on October 31 and a campaign report was submitted after completion. The report was prepared by WHO Country Office with support of the ministry of health and CDC.

The government of Iraq claimed that it was not able to fund the vaccines. The vaccines, transport and operational costs were therefore funded through CERF.

South Sudan – 2017/Feb – Request for 474,976 doses from OCV Stockpile – Approved





Legend: **Heads up about the request**; **Circulation of request, decision-making;** **Procurement, Shipment and Delivery;** **Communication about decision-making;** **Financing**

This was the 2nd request from South Sudan in 2017 and the 4th in a period of 12 months. South Sudan experiences an ongoing cholera epidemic in the last years. Several OCV campaigns have been organized, all with support of ICG. At the same time, South Sudan is implementing an integrated approach for cholera control. The approach harnesses strategies for improving access to patient care, surveillance, social mobilisation, water, sanitation and hygiene, and use of OCV. In 2017, South Sudan requested OCV to complement the ongoing responses in areas with active cholera transmission. The planned OCV campaign was scheduled to take place in March 2017 in four selected counties with high active transmission and would use an existing stock of 38,583 OCV doses but also required an additional 474,976 to target a total of 2,237,488 people.

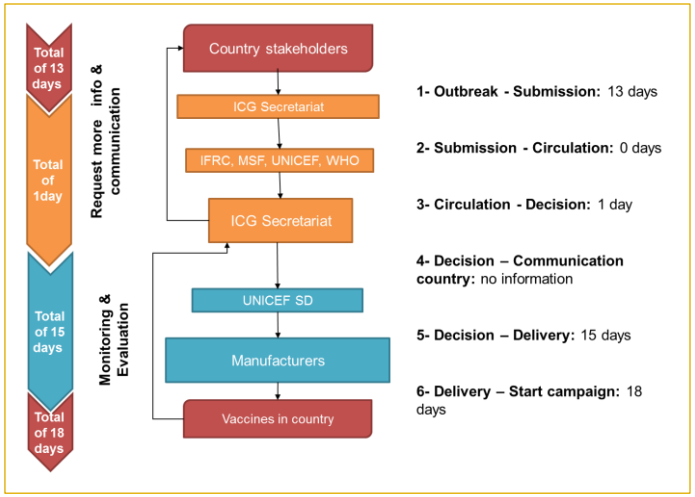
The request was submitted by the WHO, on behalf of the Ministry of Health, on March 2 and included a detailed micro plan and risk assessments. The ICG Secretariat circulated the request on Friday March 3 with deadline for responding by Tuesday March 7. Decision was made by email to approve the fully approve the request on March 7. The requester was informed the same day and the email made a number of recommendations, including the need for a longer term, comprehensive strategy, including WASH interventions, a better planning of the OCV campaigns and use of vaccine coverage surveys.

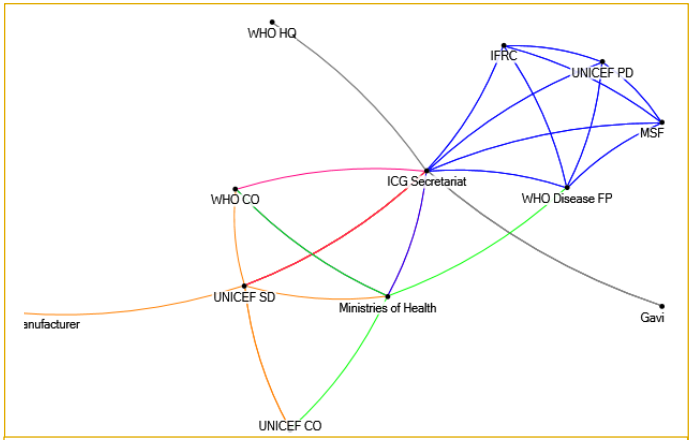
UNICEF SD received a heads up of the request on March 3 and the official procurement order on March 7. Vaccines were procured from Shanta and expected arrival date was March 15.

The campaign was implemented by WHO on behalf of the Minister of Health of South Sudan. MedAir provided support for Mingkaman district, IOM for Bentiu district and HLSS for Bor district. The plan was to administer the first doses between 15 and 18 March and second doses between 3 and 5 of April. It is however not clear to what extent the campaigns were realised on these dates. WHO does not provide specific response reports but provides ongoing reporting through the ERM website portal.

Gavi and senior staff within WHO IHM department were informed as soon as the request was received and also received the summary decisions sheet on March 7.

DRC – 2016/June – Request for 3,260,760 doses from YF Stockpile – Approved





Legend: **Preparation of request**; **Circulation of request, decision-making**; **Procurement, Shipment and Delivery**; **Communication about decision-making**; **Financing**

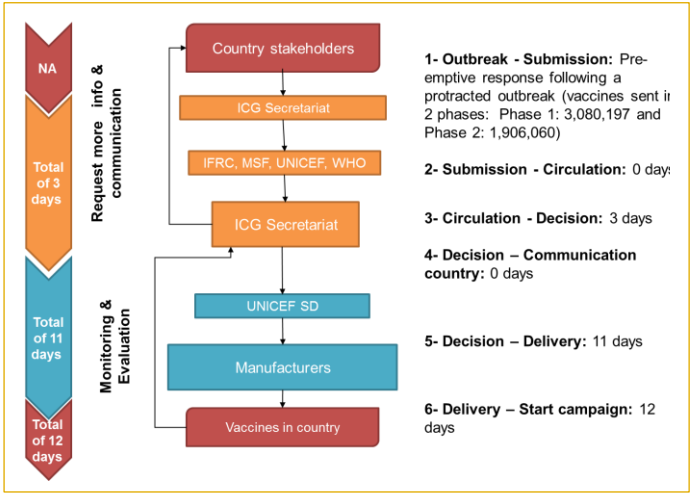
This was the 2nd request from DRC in 2016. The outbreak was largely in the south of the country, and was related to the YF outbreak in Angola and the frequent movement of people between the two countries, in particular with Kinshasa. Despite the vaccination campaigns that were conducted from 24 May to 4 June 2016, an autochthonous case was confirmed in the most populated commune of Kinshasa in June 2016. The vaccination campaign therefore planned to cover 8 health zones of Kinshasa and 3 health zones of Kwango in the border area.

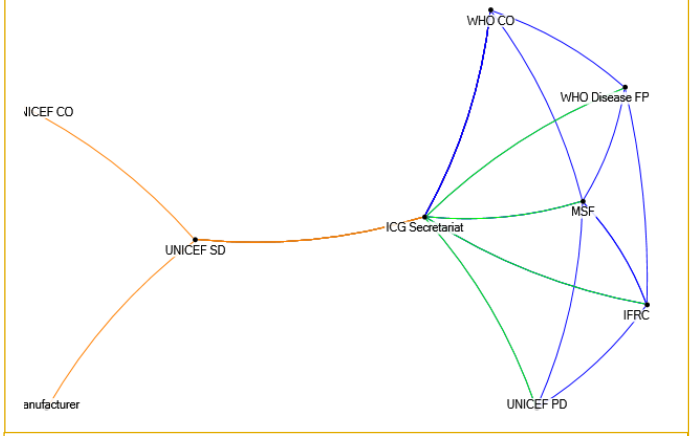
The request for 3,260,760 doses was prepared by the Ministry of Health, with support provided by the WHO and UNICEF country offices and included a detailed operational budget for a total of $2,937,615. It was submitted to the ICG Secretariat on June 14. The ICG Secretariat circulated the request to the ICG members on the same day. The email provided a comprehensive and detailed summary of the request and investigation reports, including the cost of the request and the number of doses (5.7 million) available in the stockpile at that time.

WHO and MSF requested more information, in particular for the case reported in Kinshasa. Additional information was received on June 17 and a teleconference organised the same day. During decision making, the epidemiological situation, in particular the seriousness of the confirmed cases and results of previous vaccination campaigns were taken into account. Subsequently a decision was made to partially approve the request for a total of 1,083,005 YF vaccine doses with 564,485 doses for 3 health zones in Kwango and 518,520 doses for Kinshasa. This was later reduced to 1,083,000 in line with the manufacturer's packaging conditions. It is not clear when and how this information was communicated to the Ministry of Health, as no email could be retrieved. Gavi was not kept informed about the request or the decision made.

UNICEF SD received the official procurement order on June 17. As UNICEF SD had exhausted the Gavi funding for vaccine procurement, the revolving fund was used to procure the vaccine through UNICEF SD. Vaccines were procured from Sanofi Pasteur who received the procurement order on June 29. Vaccines arrived in country on 2nd of July and the campaign started on July 20. The campaign was coordinated by the ministry of health with support of WHO and lasted for 10 days. A total of 995,859 people were reached, an administrative coverage rate of 102%. A comprehensive report was received in early October including information on strategy used, administrative coverage rate, strengths and weaknesses, and a financial overview. No coverage survey was conducted. At the end of October, the ICG Secretariat formally requested Gavi to reimburse the cost of the vaccines to the revolving fund. Various staff from WHO headquarters were involved in this communication but the request was eventually rejected as no prior approval had been sought from Gavi.

Angola – 2016/July – Request for 4,986,260 doses from YF Stockpile – Approved in 2 phases





Legend: **Preparation of the request**; **Submission of request, circulation, decision-making;** **Procurement, Shipment and Delivery**

This was the 6th request from Angola in 2016. Thus far, Angola had received 15 million doses of the 17.7 million it had requested. This request aimed to pre-emptively vaccinate the districts that were sources of local transmission and had not yet been vaccinated and districts across the border with DRC to prevent additional cross-border spread. The start of the next rainy season was another reason to continue with a pre-emptive vaccination. The request was submitted by the Yellow Fever incident manager on July 19 and included an explanation on why target areas approved in the previous request had changed and an overview of vaccines received to date.

The ministry of health of Angola officially stated that it would cover all vaccination costs, including operational costs, which are not covered by the international community. At the time of making the request WHO and MoH were expecting a declaration from GAVI relative to their commitment to contribute to 50% of costs.

The ICG email inbox is missing a number of exchanges regarding the circulation and approval of this specific request. Upon further enquiry, the ICG secretariat confirmed that the decision was made via teleconference within 48 hours. ICG members, asked independently, corroborate this. The request was approved conditionally in 2 phases, with a first batch of 3,080,197 to be released immediately. Since there was still a balance of 1.4 million doses missing and under verification, the remaining doses would be released after receiving a vaccination campaign report and verification of total amount of vaccine in stock in-country. The WHO country office was informed about this decision on July 21; the communication included calculations on the number of vaccines approved and which districts should be prioritised.

UNICEF SD received the procurement order on July 22 and vaccines were received in country in two shipments. The first was arrived on August 2nd with 2 million doses from Sanofi Pasteur; the second one arrived on August 4th with 1.8 million doses from the Institute Paris-Dakar.

The campaign with the first 3.1 million of vaccines started on 16 of August and lasted for 12 days. It reached 2,673,584 people with an administrative coverage rate of 90%. The report of phase 1 was submitted on 30th of Augustus with the request to release the remaining 1.9 million doses. This decision was made the same day and the remaining vaccines arrived in the country in 3 shipments (28 September, 5 October and 7 October). No report of the second phase was found. Gavi was not kept informed about the request received and/or decisions made.

ANNEX 8: DATA SUPPORTING THE FINDINGS

This annex presents a frequency analysis of data collected by the online surveys and additional overviews collected from the available documents. The information is organised per thematic sub-area and starts with an overview on who participated in the two online surveys. The data collected through key informant interviews is summarised in the body of the report.

PARTICIPATION IN THE ONLINE SURVEYS

A total of 54 stakeholders were invited to participate in the online survey for international stakeholders. After sending one reminder, a total of 29 respondents from five major stakeholder groups had responded as follows:

Type of stakeholder	Total # invited	# Responded	# did not participate
Core member staff (not involved in decision-making)	15	4	11
Extended technical partner	3	0	3
Funders to the Gavi Alliance	5	4	1
ICG member (involved in decision-making)	13	10	3
Manufacturer	8	5	3
Direct partners (including UNICEF SD and Gavi Secretariat)	8	6	2
Total	**54**	29	25

In the group of 'core member staff' five senior staff from the respective core organisations were invited and because all of them had provided valuable input during the interviews, we decided not to follow up further for the online survey. The three representatives of an extended technical partner commented that the questions were too detailed for them given that they had not been closely involved with the ICG, so this group was excluded from the stakeholder analysis. With the exception of these two stakeholder groups, more than 60% of the respondents invited for the other four types of stakeholders responded. Hence the sample was deemed appropriate to conduct a frequency and comparative analysis by stakeholder group.

A total of 31 country based stakeholders participated in the online survey with 12 representatives from the Ministry of Health and 19 representatives from technical organisations. The respondents provided details on the ICG response for the following countries and outbreaks:

Countries	Cholera	Meningitis	Yellow Fever	Total
Angola			2	2
Benin		3		3
Brazil			1	1
Central Africa Republic		1		1
Chad			1	1
Congo Republic			1	1
Democratic Republic of Congo			1	1
Ethiopia	2			2
Ghana		1		1
Guinea		1		1
Iraq	1			1
Nepal	2			2
Niger		1		1
Nigeria		2		2

Somalia	2			2
South Sudan	2			2
Sudan			1	1
Tanzania	3			3
Uganda			1	1
Zambia	2			2
Total	**14**	**9**	**8**	**31**

Result of the requests	Cholera	Meningitis	Yellow Fever	Total
Rejected	2	3		5
Partially approved	1	5	2	8
Fully approved	10	1	6	17
NA	1			1
Total	**14**	**9**	**8**	**31**

GOVERNANCE

Is the mandate of the ICG still relevant?

Analysis of mean, standard deviation and variance by international stakeholders (scores out of 5 with 1 = not at all relevant and 5 = extremely relevant)

Stakeholders	Mean	Standard deviation	Variance
EQUITY			
Funders	2,50	1,91	3,67[33]
Direct partners	4,17	0,98	0,97
ICG members	4,40	0,97	0,93
Manufacturers	4,40	0,55	0,30
Core member staff	5,00	0,00	0,00
Total	**4,14**	**1,21**	**1,46**

To what extent has the ICG lived up to its principles of equity, rapid access and independence in decision-making?

Analysis of mean, standard deviation and variance by international stakeholders (scores out of 6 with 1 = strongly disagree and 6 = strongly agree)

Stakeholders	Mean	Standard deviation	Variance
EQUITY			
Funders	3,50	1,91	3,67[34]
Direct partners	4,00	1,00	1,00
Manufacturers	4,40	0,89	0,80
Core member staff	5,33	0,58	0,33
ICG members	5,78	0,44	0,19
Total	**4,83**	**1,27**	**1,62**
RAPID AND TIMELY ACCESS TO VACCINES			
Funders	4,00	1,41	2,00[35]
Manufacturers	4,00	1,00	1,00
Direct partners	4,20	1,30	1,70
ICG members	4,80	0,92	0,84
Core member staff	5,00	0,00	0,00
Total	**4,46**	**1,04**	**1,07**
INDEPENDENCE OF DECISION-MAKING			
Direct partners	3,75	0,96	0,92
Funders	4,00	1,83	3,33[36]

[33] The variance ranges from not at all relevant (1) to extremely relevant (5)

[34] The variance ranges from disagree (2) to strongly agree (6)

[35] The variance ranges from disagree (2) to agree (5)

Manufacturers	4,60	0,55	0,30
Core member staff	5,50	0,58	0,33
ICG members	5,78	0,44	0,19
Total	**4,92**	**1,16**	**1,35**

Is there an adequate balance in membership of ICG?

Analysis of mean, standard deviation and variance by international stakeholders (scores out of 5 with 1 = strongly disagree and 5 = strongly agree)

Stakeholders	Mean	Standard deviation	Variance
Funders	2,00	1,41	2,00[37]
Direct partners	2,50	1,29	1,67[38]
Manufacturers	3,20	0,84	0,70
Core member staff	3,33	1,15	1,33
ICG members	3,67	0,87	0,75
Total	**3,08**	**1,15**	**1,33**

Is the ICG held adequately to account for decisions made?

Analysis of mean, standard deviation and variance by international stakeholders (scores out of 5 with 1 = strongly disagree and 5 = strongly agree)

Stakeholders	Mean	Standard deviation	Variance
Funders	1,50	1,00	1,00[39]
Direct partners	2,17	0,75	0,57
Manufacturers	3,20	0,84	0,70
Core member staff	4,25	0,50	0,25
ICG members	4,25	0,46	0,21
Total	**3,19**	**1,27**	**1,62**

Is the role of UNICEF SD clearly defined?

Analysis of mean, standard deviation and variance by international stakeholders (scores out of 5 with 1 = strongly disagree and 5 = strongly agree)

Stakeholders	Mean	Standard deviation	Variance
Direct partners	2,50	1,05	1,10[40]
Funders	2,75	0,96	0,92
Manufacturers	3,40	0,55	0,30
ICG members	3,50	0,71	0,50
Core member staff	3,75	1,26	1,58[41]
Total	**3,21**	**0,94**	**0,88**

[36] The variance ranges from disagree (2) to strongly agree (6)

[37] The variance ranges from strongly disagree (1) to agree (4)

[38] The variance ranges from strongly disagree (1) to agree (4)

[39] The variance ranges from strongly disagree (1) to most of the times (3)

[40] The variance ranges from strongly disagree (1) to agree (4). UNICEF SD opinions range from disagree (2) to agree (4).

[41] The variance ranges from disagree (2) to strongly agree (5)

Are changes to the governance structure needed?

Analysis of mean by international stakeholders (0 = No; 1 = Yes)

Stakeholders	Mean
Core member staff	0,25
ICG members	0,29
Direct partners	0,42
Manufacturers	0,67
Funders	0,75
Total	**0,44**

MECHANISMS AND PROCESSES

Do the current processes allow for rapid deployment of vaccines?

Analysis of mean by international stakeholders (scores out of 6 with 1 = never and 6 = always)

Stakeholder type	Mean for Yellow fever	Mean for Meningitis	Mean for Cholera
Technical partner	3.83	3.83	3.5
Manufacturer	4.33	2	3.6
Funder	4.67	4	3
Executive group member	4.67	4.28	4.5
Core member staff	5.00	5.5	5
Total	**4.46**	**4**	**3.95**

Key performance indicators for Yellow Fever from 2006 to 2017[42]

Presented by country

Countries	# of outbreaks	Total Doses requested (as per initial request)	Total Doses Shipped	Mean # of days for Circulation	Mean # of days for Decision	Mean # of days for Delivery
Angola	7	24,392,414	20,031,860	0.1	0.7	6.2
Brazil	2	10,300,000	7,504,607	1.0	0.5	8.0
Burkina Faso	1	412,560	388,000		1.0	No info
Cameroon	10	3,582,127	3,269,300		3.3	8.3
CAR	6	5,542,484	4,566,800		1.6	7.0
Chad	1	1,604,908	1,129,200		2.0	6.0
Congo	2	119,117	119,200		5.5	6.5
Côte d'Ivoire	3	3,328,771	3,332,000		2.7	7.7
DRC	7	12,339,968	10,025,500	0.3	2.1	10.7
DRC	1	559,876	560,000		2.0	8.0
Ethiopia	1	762,752	585,900		3.0	4.0
Ghana	1	260,941	260,100		2.0	7.0
Guinea	3	554,507	541,800		1.7	6.0
Liberia	4	1,076,376	593,200		2.3	10.5
Paraguay	1	2,000,000	2,000,000		2.0	2.0
Senegal	2	159,626	160,000		9.0	12.0
Sierra Leone	2	580,776	580,000		2.0	2.0
Sudan	2	4,891,517	3,760,700		2.0	6.5
Togo	1	5,166,794	1,983,000		1.0	No info
Uganda	3	1,766,317	1,772,470	0.0	0.3	7.3
Total	**60**	**79,401,831**	**63,163,637**	**0.2**	**2.1**	**7.7**

[42] Compiled from the source documents on key performance indicators for each of the stockpiles and with new data until July 2017.

Presented by year

Year	# outbreak request	Total Doses requested (as per initial request)	Total Doses Shipped	Mean # of days for Circulation	Mean # of days for Decision	Mean # of days for Delivery
2006	1	856,786	860,000		2	4
2007	2	5,313,504	2,129,800		3	No Info
2008	10	10,466,847	10,058,600		1	8
2009	8	2,875,630	1,115,800		4	8
2010	8	5,228,172	4,616,600		3	6
2011	5	1,624,655	2,594,100		3	10
2012	5	6,796,171	5,188,800		2	6
2013	6	2,644,545	2,331,900		3	8
2014	1	559,876	560,000		2	8
2016	13	36,735,645	30,203,430	0	1	9
2017	1	6,300,000	3,504,607	1	-	8
Total	**60**	**79,401,831**	**63,163,637**	**0**	**2.13**	**7.73**

Key performance indicators for Meningitis from 2006 to 2017[43]

Presented by country

Countries	# of outbreaks	Total Doses requested (as per initial request)	Total Doses Shipped	Mean # of days for Circulation	Mean # of days for Decision	Mean # of days for Delivery
Benin	3	1,338,621	100,000	-	3	6
Burkina Faso	8	12,249,800	8,220,190	0	2	7
Cameroon	3	154,068	7,200	-	4	10
Central African Republic	2	263,677	40,000	-	1	7
Chad	22	6,001,771	3,576,262	-	2	10
Côte d'Ivoire	2	356,663	234,788	-	3	8
DRC	2	317,351	288,200	1	1	6
Eritrea	1	1,000,000	-	NA	No info	NA
Ethiopia	2	840,266	120,560	-	-	22
Gambia	1	320,970	-	NA	2	NA
Ghana	7	1,096,271	487,121	-	1	8
Guinea	4	553,614	784,123	-	4	9
Kenya	1	216,000	216,000	-	1	12
Mali	2	6,202,744	800,000	-	1	12
Niger	30	9,556,777	7,468,522	1	2	9
Nigeria	38	14,113,651	10,442,285	0	2	11
South Sudan	1	198,770	198,770	No info	2	11
Sudan	17	5,617,243	2,718,394	0	2	9
Togo	6	1,515,048	727,200	-	1	13
Uganda	7	1,712,673	1,784,655	0	1	8
Total	**159**	**63,625,978**	**38,214,270**	**0.2**	**1.9**	**9.7**

[43] Compiled from the source documents on key performance indicators for each of the stockpiles and with new data until July 2017.

Presented by year

Year	# outbreak request	Total Doses requested (as per initial request)	Total Doses Shipped	Mean # of days for Circulation	Mean # of days for Decision	Mean # of days for Delivery
2006	20	15,720,456	6,120,990	-	1	9
2007	22	10,493,399	7,124,331	0	1	7
2008	9	4,165,851	2,053,095	-	1	7
2009	35	13,185,009	11,430,900	-	2	11
2010	19	3,403,258	1,914,835	No info	2	8
2011	6	2,423,059	1,338,805	No info	3	8
2012	13	4,279,489	1,747,091	No info	3	9
2013	2	261,845	261,845	No info	6	9
2014	3	475,619	587,878	-	3	11
2015	11	2,770,670	1,660,010	1	2	12
2016	8	2,238,818	1,097,000	-	1	11
2017	11	4,208,505	2,877,490	-	2	11
Total	**159**	**63,625,978**	**38,214,270**	**0.2**	**1.9**	**9.7**

Key performance indicators for Cholera from 2013 to 2017[44]

Presented by country

Countries	# of outbreaks	Total Doses requested (as per initial request)	Total Doses Shipped	Mean # of days for Circulation	Mean # of days for Decision	Mean # of days for Delivery
Bangladesh	1	200,000	200,025	Loan	Loan	Loan
Cameroon	1	116,344	116,375	1	-	11
Chad	1	320,000	*Redirected to GTFCC*	1	3	-
DRC	2	800,740	800,750	-	1	11
Ethiopia	2	343,067	343,075	1	2	No info
Guinea Conakry	1	284,702	284,725	Loan	Loan	Loan
Haiti	2	1,200,000	636,215	Loan	Loan	Loan
Iraq	1	510,000	510,020	2	1	14
Malawi	5	830,000	530,025	0	1	14
Mozambique	3	1,316,059	780,040	-	2	28
Nepal	5	845,421	36,295	2	2	13
Niger	1	195,132	195,160	-	2	12
Somalia	4	1,252,642	718,200	-	1	17
South Sudan	12	2,485,755	1,469,650	1	2	14
Sudan	1	212,605	*Rejected*	1	1	-
United Rep of Tanzania	2	329,166	419,195	-	1	9
Yemen	1	3,500,000	-	-	-	81
Zambia	2	891,834	891,870	1	2	10
Total	**47**	**15,633,467**	**7,931,620**	**0.5**	**1.3**	**16.6**

[44] Compiled from the source documents on key performance indicators for each of the stockpiles and with new data until July 2017.

Presented by year

Year	# outbreak request	Total Doses requested (as per initial request)	Total Doses Shipped	Mean # of days for Circulation	Mean # of days for Decision	Mean # of days for Delivery
2013	1	120,000	120,000			
2014	10	1,842,485	1,366,215	1	2	17
2015	17	4,371,732	2,242,800	1	1	12
2016	10	2,818,457	2,465,745	0	1	16
2017	9	6,480,793	1,736,860	-	1	23
Total	**47**	**15,633,467**	**7,931,620**	**0.5**	**1.3**	**16.6**

Satisfaction rate with the ICG response by country respondents presented by stockpile and decision made (fully approved, partially approved and rejected)

Analysis of mean, standard deviation and variance for all requests (scores out of 5 with 1 = not at all and 5 = to great extent)

Stockpile	Mean	Standard deviation	Variance
Cholera	4,31	1,49	2,23
Meningitis	3,56	1,59	2,53
Yellow Fever	4,88	0,35	0,13
Total	**4,23**	**1,38**	**1,91**

Analysis of mean, standard deviation and variance for fully approved requests (scores out of 5 with 1 = not at all and 5 = to great extent)

Stockpile	Mean	Standard deviation	Variance
Cholera	5,00	0,00	0,00
Meningitis	5,00	NA	NA
Yellow Fever	4,83	0,41	0,17
Total	**4,94**	**0,24**	**0,06**

Analysis of mean, standard deviation and variance for partially approved requests (scores out of 5 with 1 = not at all and 5 = to great extent)

Stockpile	Mean	Standard deviation	Variance
Cholera	4,00	NA	NA
Meningitis	4,20	0,84	0,70
Yellow Fever	5,00	0,00	0,00
Total	**4,38**	**0,74**	**0,55**

Analysis of mean, standard deviation and variance for rejected requests (scores out of 5 with 1 = not at all and 5 = to great extent)

Stockpile	Mean	Standard deviation	Variance
Cholera	1,00	0,00	0,00
Meningitis	2,00	1,73	3,00
Total	**1,60**	**1,34**	**1,80**

Overall rating of the ICG response process by country-based respondents

Analysis of mean by stockpile for all requests (scores out of 5 with 1 = very poor and 5 = very good)

Factors that impact on ICG response	Cholera	Meningitis	Yellow Fever	Total
Support for implementing outbreak response	3,86	3,11	4,25	3,74
Transparency of the decision-making	3,93	3,78	3,50	3,77
Availability of technical assistance during request preparation	4,00	3,78	3,63	3,84
Timeliness of vaccine delivery	4,14	3,56	3,75	3,87
Follow up after conclusion of the vaccination campaign	3,93	3,22	4,50	3,87
Adequateness of the vaccine supply	4,07	3,33	4,25	3,90
User-friendliness of request	4,00	3,56	4,25	3,94
Follow up during shipment and delivery	4,00	3,67	4,13	3,94
Timeliness of the decision-making	4,14	3,89	3,88	4,00
Appropriateness of request criteria	4,14	3,78	4,25	4,06
Communication by ICG	4,43	4,44	4,25	4,39

Analysis of mean by stockpile for all fully or partially approved requests (scores out of 5 with 1 = very poor and 5 = very good)

Factors that impact on ICG response	Cholera	Meningitis	Yellow Fever	Total
Support for implementing outbreak response	3,77	3,11	4,25	3,70
Transparency of the decision-making	3,85	3,78	3,50	3,73
Availability of technical assistance during request preparation	3,92	3,78	3,63	3,80
Timeliness of vaccine delivery	4,08	3,56	3,75	3,83
Follow up after conclusion of the vaccination campaign	3,85	3,22	4,50	3,83
Adequateness of the vaccine supply	4,00	3,33	4,25	3,87
User-friendliness of request	3,92	3,56	4,25	3,90
Follow up during shipment and delivery	3,92	3,67	4,13	3,90
Appropriateness of request criteria	4,08	3,78	4,25	4,03
Timeliness of the decision-making	4,46	3,89	3,88	4,13
Communication by ICG	4,38	4,44	4,25	4,37

Ranking of factors according to the importance in the ICG response process by international and country-bases stakeholders

Analysis of mean by international stakeholders (scores out of 4 with 1 = unimportant and 4 = very important)

Factors that impact on ICG response	Funder	Manuf.	Core member	ICG member	Direct partner	Total
In-country detection capacity	4,0	3,8	4,0	4,0	3,7	3,9
Availability of stockpiles	4,0	3,8	3,5	3,9	4,0	3,9
Country preparedness for vaccination	3,8	4,0	3,5	3,7	3,7	3,7
Technical capacity for evaluating request	3,3	3,4	4,0	3,9	3,7	3,7
Equitable distribution	3,8	3,8	4,0	3,5	3,5	3,7
Rapid release and shipment	3,3	3,6	3,8	3,5	3,7	3,6
Adequacy of response strategy	3,0	3,4	3,5	3,6	3,7	3,5
Funding for operational costs	3,3	3,2	3,8	3,4	3,5	3,4
Timeliness of decision-making	3,0	3,0	3,3	3,8	3,5	3,4
Technical capacity for implementation	3,5	3,4	3,5	3,3	3,3	3,4
Technical capacity request preparation	2,7	3,4	4,0	3,4	3,0	3,3
Transparency of decision-making	3,8	3,4	3,5	2,9	3,5	3,3
Completeness request	2,3	3,4	3,8	3,4	3,0	3,3
Monitoring and evaluation	3,8	2,8	3,3	3,2	2,7	3,1
Financial capacity to pay for vaccines	1,8	2,2	2,5	2,3	1,6	2,1

Analysis of mean by country-based stakeholders (scores out of 4 with 1 = unimportant and 4 = very important)

Factors that impact on ICG response	Technical partner	Government	Total
In-country detection capacity	3,8	4,0	3,9
Adequacy of response strategy	3,8	4,0	3,9
Availability funding for operational costs	3,9	3,8	3,9
Technical capacity for preparation request	3,8	3,9	3,8
Availability of stockpiles	3,9	3,7	3,8
Country preparedness for vaccination	3,8	3,8	3,8
Technical capacity for implementation	3,8	3,8	3,8
Monitoring and evaluation	3,7	3,8	3,7
Completeness request	3,7	3,8	3,7
Transparency of decision-making	3,7	3,8	3,7
Technical capacity for evaluating request	3,6	3,8	3,7
Timeliness of decision-making	3,6	3,8	3,7
Equitable distribution	3,5	3,8	3,6
Rapid release and shipment	3,2	3,8	3,4
Financial capacity to pay for vaccines	2,9	3,1	3,0

Forecast of stockpiles versus number of doses approved for past 3 years[45]

Year	OCV		YF		Meningitis	
	Forecast	**Doses approved**	**Forecast**	**Doses approved**	**Forecast**	**Doses approved**
2015	2 million	1.6 million	6 million	7.8 million*	3.2 million	2.2 million
2016	2 million	1 million	6 million	30.2 million**	6.5 million	1.2 million
2017	2 million	3 million	6 million	3.5 million	5 million	2.9 million

** These doses came largely from the remaining 2014 stockpile*

*** For the first 6 million doses, funds from the 2015 stockpile were used since the stockpile had not been accessed in 2015. It is a rolling revolving stockpile: the stockpile is immediately replenished after use, thus permitting management of large urban outbreaks, which was the case in Angola and DRC*

FUNDING

Summary of yellow fever and meningitis revolving funds[46]

	Cost estimates	Amount Replenished	% reimbursed	Donors
YELLOW FEVER				
2009/10	$5.218.237	$1.735.363	33%	CERF, ECHO
2011	$1.787.846	$1.878.125	105%	UNICEF Liberia, ECHO, CERF
2012	$5.838.787	$4.397.255	75%	ECHO
2013	$3.032.945	$1.666.291	55%	CERF
2014	$788.910	$451.687	57%	MoH DRC
2015	$0	$0		Not necessary
2016	$24.344.654	$3.833.738	16%	CERF, In-kind donation
TOTAL	**$41.011.379**	**$13.962.459**	**34%**	(Excluding $5.4 million pending from the WB)
MENINGITS				
2010	$2.202.415	$1.188.772	54%	ECHO, MSF France, MSF Holland, WHO Sudan, UNDP
2011	$1.362.595	$1.281.691	94%	CERF, MSF, WHO/MoH Sudan
2012	$3.485.615	$3.224.779	93%	ECHO, CERF
2013	$294.884	$283.525	96%	ECHO
2014	$179.973	$178.458	99%	UNICEF
2015	$10.166.590	$2.445.708	24%	MSF, UNICEF, ECHO
2016	$3.769.909	$314.652	8%	Pending
TOTAL	**$21.461.981**	**$8.917.585**	**42%**	

[45] Sources: Reports of annual meetings of OCV, YF and meningitis stockpiles 2014, 2015, 2016 and 2017(draft)

[46] Sources: Overview of revolving funds (until 2014); annual reports to Gavi; summary overview prepared by the ICG secretariat for the Meningitis annual meeting in 2017.

COMMUNICATION AND TRANSPARENCY[47]

Is the decision-making sufficiently transparent?

Analysis of mean, standard deviation and variance by international stakeholder (scores out of 5 with 1 = strongly disagree and 5 = strongly agree)

Stakeholders	Mean	Standard deviation	Variance
Funders	1,25	0,50	0,25
Direct partners	2,00	1,10	1,20[48]
Manufacturers	2,80	0,45	0,20
Core member staff	3,50	1,29	1,67[49]
ICG members	4,20	0,42	0,18
Total	**3,00**	**1,31**	**1,71**

POTENTIAL FUTURE ROLE

Could the ICG cater for new vaccine stockpiles?

Analysis of mean, standard deviation and variance by international stakeholder (0 = No and 1 = Yes)

Stakeholders	Mean	Standard Deviation	Variance
Funder	0,50	0,58	0,33[50]
Manufacturer	0,67	0,58	0,33[51]
Technical partner	1,00	0,00	0,00
Core member staff	1,00	0,00	0,00
Executive group member	1,00	0,00	0,00
Total	**0,86**	**0,35**	**0,12**

Should the ICG include other vaccines or commodities?

Analysis of mean, standard deviation and variance by country-based stakeholders (0 = No and 1 = Yes)

Stakeholders	Mean	Standard Deviation	Variance
Country applicant	0,63	0,50	0,25
In-country technical partner	0,42	0,51	0,27
Total	**0,55**	**0,51**	**0,26**

[47] See also annex 6 for social network analysis

[48] The variance ranges from strongly disagree (1) to agree (4)

[49] The variance ranges from disagree (2) to strongly agree (5)

[50] Two participants said No and two said Yes

[51] Three out of 5 participants responded with 1 saying No and two Yes

ANNEX 9: ONLINE SURVEY QUESTIONNAIRES

FOR COUNTRY-BASED RESPONDENTS

The respondents for the survey are the key contact persons for epidemic outbreak control in the ministries of health who are informed about the processes and outcomes of at least one recent ICG request, as well as key contact persons of any lead technical partner(s) who have provided support to the MOH during the application process in-country.

Ministries of health will be asked to complete only one questionnaire for each stockpile request (meningitis, yellow fever or cholera vaccines). Countries that applied for several types of vaccines should therefore complete one questionnaire for each type. In order to allow better correlation and aggregation of data, responses should refer to a single identified application.

Introduction

The aim of this survey is to obtain a full picture of the ICG role in outbreak responses, including the opinions from a wider group of country based stakeholders on the functioning of the ICG during a disease outbreak and future role of the ICG mechanism in a wider context.

The survey addresses country-based stakeholders (representatives of the Ministry of Health or representatives of technical partners in the country) that have participated in epidemic outbreak responses and for which email addresses were obtained from the ICG Steering Committee.

The survey was kept deliberately short and should only take XX minutes of your time. Please complete the survey as soon as possible and before August XXX.

For any question, please contact Marieke Devillé (marieke@hera.eu)

Identification[52]

1. Name of respondent
2. *Name of the organisation, institution or network
3. *Position of respondent
4. Email address
5. *Country
6. *Level of involvement with the ICG mechanism *(drop down menu: Country Applicant (for ICG stockpile), In-Country Technical Partner, Other – please specify)*
7. *Involvement with ICG has been for the following applications for vaccines (drop down list of disease type and year – select all outbreaks in which you participated)
8. *Select only one outbreak on which most of your answers to this questionnaire are based

All identifying information from this survey will be removed for analysis.

9. Please confirm you agree to participate in this survey as part of the external and independent evaluation of the ICG. *(drop down menu: yes, no)*

ICG Mechanism

10. *To what extent were you satisfied with the ICG response to the application for stockpile vaccines for the control of the outbreak you selected? *(5-point Likert scale ranging from "not at all" to "a great deal"; with option of NA and text box for additional clarifications)*

[52] Questions marked with a (*) are mandatory

11. *Please rate each of the ICG arrangements (from submission of request to delivery) according to the following criteria: (*5-point Likert scale ranging from "very poor" to "very good"; with "very poor" scoring 1 and "very good" 5 points; add NA option; and text box for additional clarifications)*

    - Submission *(15 points)*
        - Appropriateness of the submission request requirements
        - User-friendliness of the submission process
        - Availability of technical assistance for support with request forms
    - Decision-making *(15 points)*
        - Timeliness of the decision-making
        - Transparency of the decision-making criteria
        - Communication by the ICG secretariat
    - Procurement and delivery *(15 points)*
        - Appropriateness of the vaccines supply
        - Timeliness of the vaccine delivery
        - Follow up by the ICG Secretariat after delivery
    - Implementation *(10 points)*
        - Support for the implementation of the disease control strategy
        - Follow up by the ICG Secretariat after implementation

12. *What factors are most influential in ensuring an appropriate response to emergency outbreaks of the 3 core diseases managed by the ICG? *(relative ranking of factors from a list that includes factors related to effectiveness, efficiency and equity)*

    - Adequacy of the identified disease control strategy
    - Technical capacity of the people preparing the submission
    - Completeness of the submission
    - Technical capacity of the core members evaluating the request
    - Availability of the core members to evaluate the request
    - Transparency of the decision-making
    - Availability of sufficient stockpiles
    - Equitable distribution of vaccines among disease outbreaks
    - Availability of adequate stockpiles
    - Responsiveness of the manufacturer to prepare/ship the vaccines
    - Preparedness of the country to receive the vaccines and implement the disease control strategy
    - Technical capacity to implement the disease control strategy
    - Monitoring and evaluation of the disease control strategy
    - Financial capacity to implement the disease control strategy
    - Financial capacity to pay for the vaccines
    - Other (please specify)

13. From the same list as above, identify up to 3 factors that are the most challenging and impact on the effectiveness of the ICG response mechanism? *(multiple choice table with ability to choose up to 3 options; and text box for additional clarifications)*

14. How can the ICG response mechanism be improved in terms of:

    - Effectiveness *(open-ended question)*
    - Efficiency *(open-ended question)*
    - Equity *(open-ended question)*

Future role of the ICG

15. What future do you see for the ICG, especially taking into consideration existing global disease control strategies such as EYE, Taskforce on Cholera, etc? *(open-ended question)*
16. Should the ICG accommodate new vaccine stockpiles? If yes, which ones and how? *(drop down menu: yes, no; If yes, which ones?)*

Additional questions or comments

17. Do you have any further comments you would like to share? *(open-ended question)*

FOR INTERNATIONAL STAKEHOLDERS

The respondents for the survey are international stakeholders with knowledge about and involvement in the management, mobilisation or use of emergency stockpile vaccines for meningococcal meningitis, yellow fever and cholera through the ICG mechanism.

Introduction

The aim of this survey is to obtain a full picture of the ICG role in outbreak responses, including the opinions from a wider group of international stakeholders on the current and future role of the ICG mechanism in a wider context.

The survey addresses international stakeholders that have participated in epidemic outbreak responses and for which email addresses were obtained from the Evaluation Steering Committee.

The survey was kept deliberately short and should only take XX minutes of your time. Please complete the survey as soon as possible and before August XXX.

For any question, please contact Marieke Devillé (marieke@hera.eu)

Identification[53]

1. Name of respondent
2. *Name of the organisation, institution or network
3. *Position of respondent
4. Email address
5. *Level of involvement with the ICG mechanism (drop down menu: ICG Secretariat, staff of ICG Core member organisation, Donor to the ICG, manufacturer for the ICG, ICG extended partner, other – please specify)
6. *Involved with the ICG since (provide year)

All identifying information from this survey will be removed for analysis.

7. Please confirm you agree to participate in this survey as part of the external and independent evaluation of the ICG. *(drop down menu: yes, no)*

[53] Questions marked with a (*) are mandatory

ICG Governance

8. *To what extent is the mandate of the ICG still relevant in the current context? *(5-point Likert scale ranging from "not at all" to "a great deal", with NA option; and text box for additional clarifications)*
9. *To what extent has the ICG mechanism lived up to its guiding principles of … *(5-point Likert scale ranging from "not at all" to "a great deal" for each of the 3 options; and text box for additional clarifications)*

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

10. *Is there an adequate balance between the original core members and other stakeholders that have emerged along the years? *(5-point Likert scale ranging from "not at all" to "a great deal", with NA option; and text box for additional clarifications)*
11. *Is the decision-making of the ICG sufficiently transparent to ensure accountability? If not, how can it be improved? *(5-point Likert scale ranging from "not at all" to "a great deal"; and text box for additional clarifications/suggestions)*

ICG Mechanism

12. *Does the current ICG arrangements (from submission of request to delivery) allow for an effective emergency response to …? (specify type of outbreak from drop-down – allow multiple choices) *(5-point Likert scale ranging from "not at all" to "a great deal"; and text box for additional clarifications)*
13. ***What factors are most influential in ensuring an appropriate response to emergency outbreaks of the 3 core diseases managed by the ICG?** *(relative ranking of factors from a list that includes factors related to effectiveness, efficiency and equity*

    - Adequacy of the identified disease control strategy
    - Technical capacity of the people preparing the submission
    - Completeness of the submission
    - Technical capacity of the core members evaluating the request
    - Availability of the core members to evaluate the request
    - Transparency of the decision-making
    - Availability of sufficient stockpiles
    - Equitable distribution of vaccines among disease outbreaks
    - Availability of adequate stockpiles
    - Responsiveness of the manufacturer to prepare/ship the vaccines
    - Preparedness of the country to receive the vaccines and implement the disease control strategy
    - Technical capacity to implement the disease control strategy
    - Monitoring and evaluation of the disease control strategy
    - Financial capacity to implement the disease control strategy
    - Financial capacity to pay for the vaccines

- Other (please specify)

14. From the same list as above, identify up to 3 factors that are the most challenging and impact on the effectiveness of the ICG response mechanism? *(multiple choice table with ability to choose up to 3 options; and text box for additional clarifications)*
15. How can the ICG response mechanism be improved in terms of:

    - Effectiveness *(open-ended question)*
    - Efficiency *(open-ended question)*
    - Equity (open-ended question)

Future role of the ICG

16. What future do you see for the ICG, especially taking into consideration existing global disease control strategies such as EYE, Taskforce on Cholera, etc? *(open-ended question)*
17. Should the ICG accommodate new vaccine stockpiles? If yes, which ones? *(drop down menu: yes, no; If yes, which ones?)*

Additional questions or comments

18. Do you have any further comments you would like to share? *(open-ended question)*

ANNEX 10: METHODOLOGY

The paradigmatic approach to the evaluation is inspired by the realist evaluation methodology.[54] The ICG is not a programme, but rather a mechanism that supports outbreak control responses, together with other partners that may themselves have stronger or weaker links to the ICG. There are different views of the demarcation of what is considered part of the ICG mandate and what is outside its remit, an issue that will be explored by the evaluation. The ICG does not have a formal outcome centred logical framework, but it has a structural framework and a flow diagram of processes that illustrate its functions. These will be tested in the evaluation using the realist perspective on the 'how' of functioning in different contexts.

We will explore what works, for whom, how, and in what situation. In order to evaluate this, the OECD/DAC criteria will be used: relevance, effectiveness, efficiency, sustainability and equity. Transparency will be added as a further criterion of evaluation.

We will evaluate the ICG mechanism using a matrix based on the evaluation questions that have been adapted from the terms of reference. We will use the following methods for data collection and analysis:

Data collection

- Document reviews
- Semi-structured key informant interviews
- In-depth study of a sample of six stockpile requests
- On-line survey of international ICG stakeholders
- On-line survey of ICG applicants for a sample of outbreak responses over the past 5 years

Data analysis

- Content analysis of documents and interview responses
- Social network analysis
- Comparative rating by stakeholders

Document review

Documentation about the functioning of the ICG mechanism over the past 10 years have been assembled by the ICG Secretariat and provided to the evaluation team. Additional documentation will be requested from the Secretariat and from stakeholders as we proceed with the evaluation. For the review of (confidential) e-mail communication and documents, specific confidentiality measures have been agreed. In addition to the documents received from key stakeholders, we will conduct on-line searches to identify and access published papers and other relevant publicly available documents.

Key informant interviews (KII)

The main data collection method for the qualitative aspect of the evaluation will be KIIs. Five groups of stakeholders were identified for whom interview guides have been developed. The questions and topics to be explored with each group are not identical (and even within groups there are different sub-sets). The majority of the interviews will be conducted via Skype or telephone. In addition, evaluation team members attended the 2017 annual meetings of the ICGs on meningitis, yellow fever and cholera vaccines, and used this occasion to contact stakeholders and set preliminary interview dates. A site visit of the UNICEF SD in Copenhagen for face-to-face

[54] Pawson, R., Tilley, N. (1997). *Realistic evaluation*. London, Sage.

interviews will also be conducted. Each interview will be conducted by two members of the evaluation team.

On-line surveys

We will conduct two on-line surveys to collect data from a wider group of stakeholders. The aim of the surveys is to complement the information collected through KIIs and document reviews.

The **survey of international stakeholders** in outbreak responses will focus on the current and future role of the ICG mechanism in a wider context. The survey of **country-based stakeholders** will collect information about the process of one recent request for vaccines from each stockpile submitted by countries. This survey will be addressed to the ministry of health staff in charge of submitting the request and to in-country staff of the lead partner(s) who supported the preparation of the submission. Recent requests were chosen for this survey because of concerns expressed by the SC at the time of the kick-off meeting in Geneva that ministry of health and partner agency staff are highly mobile, and it would be difficult to contact informants who were leading in earlier requests.

Both surveys will be developed on the SurveyMonkey platform.[55] The survey for international partners will be available in English, and the survey for country-based stakeholders in English, French and Portuguese.

In-depth reviews of selected outbreaks

To assess the effectiveness, efficiency and transparency of the ICG response management, a selection of six stockpile requests will be analysed in-depth through a review of all communications related to the application and response, as well as KIIs with applicants and stakeholders who were involved in responses to the six outbreaks. This review will include a detailed analysis of e-mail traffic and documented communication exchanges associated with the stockpile request, as well as the relationships of the stakeholders involved in decisions and tasks related to the responses. For this purpose, an excel data tool was developed for the social network analysis (see below) to be completed by the most relevant person in each organisation that participated in the selected outbreak responses.

The six stockpile requests were selected by purposive sampling. The sampling criteria were:

- Include two requests for each of the three stockpiles
- Include at least one request that was refused (10/58)
- Include at least two requests for which only partial allocations were made (18/58)
- Include at least one stockpile allocation that was not funded by Gavi (3/48)
- Take into consideration the recommendation for inclusion provided in writing by the SC

Content analysis of documents and key informant interview responses

While the data collected through KIIs and on-line surveys will be focused on ICG responses to outbreaks during the last five years (2012-2017), the desk review will address broader ICG governance issues over a period of 10 years (2007-2017).

The interview responses will be summarised in a searchable matrix for the performance of a content analysis. The content analysis will compare responses for each of the evaluation questions, tabulate frequencies of similar responses, and triangulate the responses with information obtained through the desk review and online surveys.

[55] www.surveymonkey.net

Social network analysis[56]

Social network analysis will be used to document the relationships of the stakeholders involved in decisions and tasks related to the selected outbreak responses. The social network analysis will explore whether the information flow and the decision-making processes that occur within this network are organised in a way that assures transparency and accountability, while living up to the established principles of equity, timeliness and independence. We have constructed a preliminary network structure based on information provided in the 2016 internal review of the ICG.[57] This will be tested with data collected from the in-depth review of six outbreaks, as well as additional information provided in KIIs.

Evaluation matrix and evaluation questions

A detailed evaluation matrix, based on the evaluation questions, is developed. It includes an assignment of indicators to each evaluation question, and correlates these with the relevant OECD/DAC evaluation criteria. It also presents the sources of data and the type of analysis that will be used to answer each question.

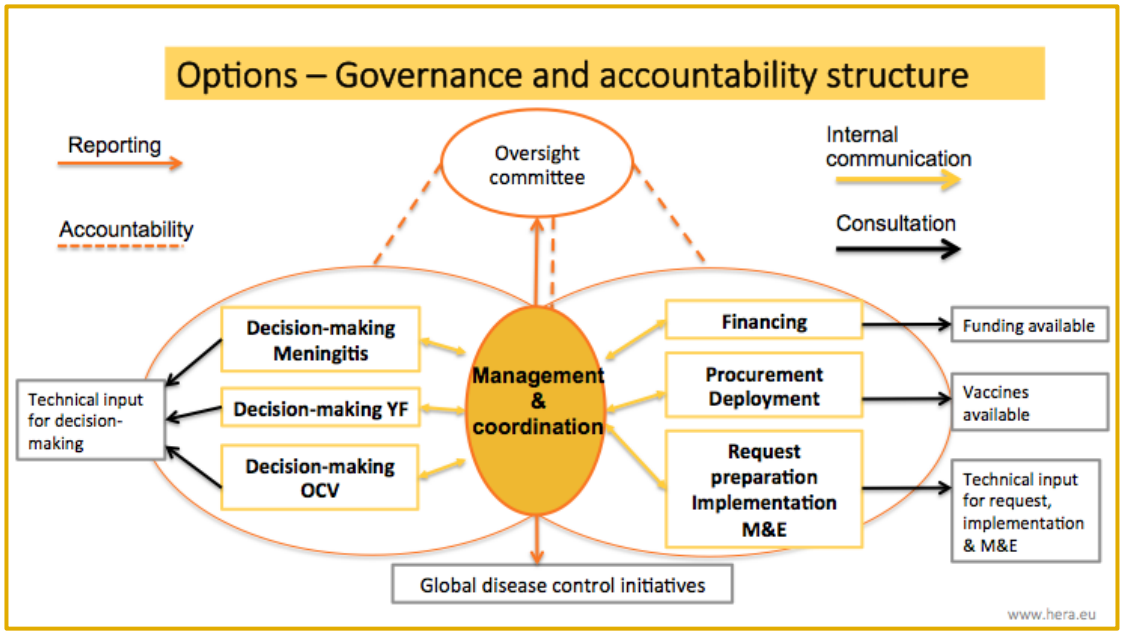
Based on the priority areas for the evaluation that the evaluation team gathered through preliminary interviews with members of the SC, and based on an analysis of evaluability and logical flow of questions, the list of evaluation questions included in the ToR has been modified. We have also restructured the questions according to the domains of enquiry of the ToR, and added an additional domain, namely the future role of the ICG and its relation to existing broader disease control and outbreak response strategies and mechanisms. The table lists the evaluation questions and relates them to those included in the ToR.

[56] Drew, R.S., Aggleton, P., Chalmers, H. and Wood, K. (2011) Using Social Network Analysis to Evaluate a Complex Policy Network; Evaluation 17(4) 383-394

[57] WHO (2016) Review of the International Coordinating Group on Vaccine Provision (2006-2016)

ANNEX 11: OPTIONS FOR GOVERNANCE AND ACCOUNTABILITY STRUCTURE

The following graphic is a representation of how the governance and accountability structure could be considered:

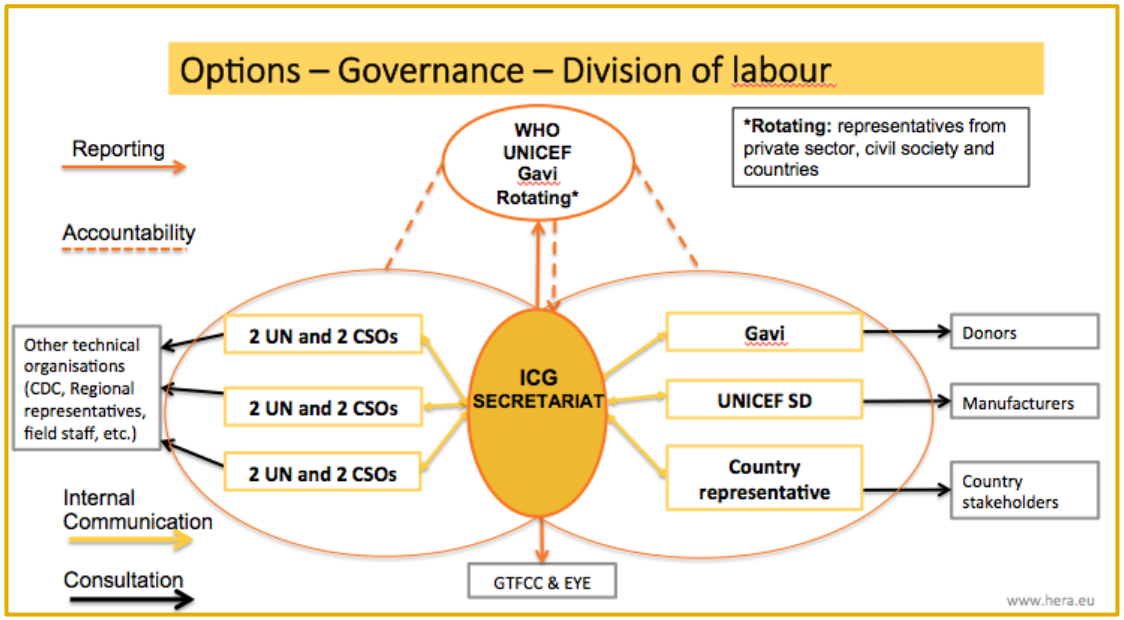


The key activities of the ICG are represented in the circles on the left and right side: they comprise on the one hand the independent decision-making process on requests submitted for the three stockpiles (left hand circle) and on the other hand the operationalisation of requests (right hand circle): preparation by the countries, securing funding to pay for the vaccines, procurement and deployment of the vaccines, and implementation of the campaign, including reporting. Management and coordination of the requests takes place centrally through a Management and Coordination cell, who communicates actively with the involved stakeholders in the decision-making and operationalisation of requests, considered as internal communication. In addition to internal communication, external communication and/or consultation takes place as well. The decision-makers can call upon technical input, while the stakeholders responsible for financing liaise with funders, the stakeholders responsible for procurement and deployment liaise with the manufacturers and countries, and the stakeholders involved in the preparation of the request, with the implementation of campaigns and with post-campaign reporting liaise with country stakeholders.

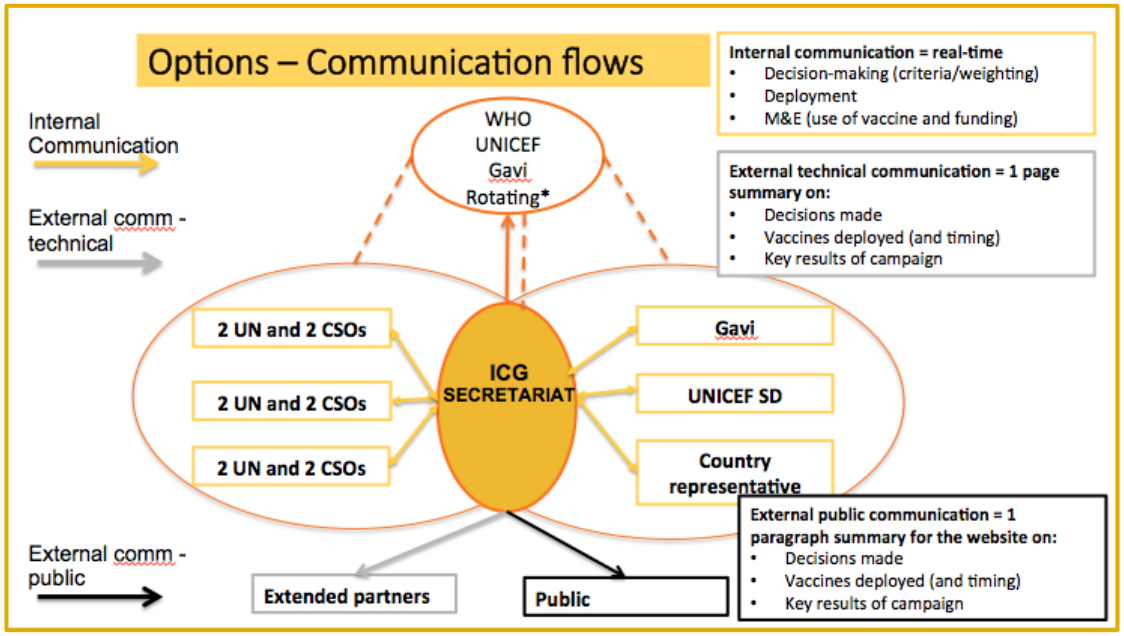
Reporting lines are proposed from the Management and Coordination cell to an oversight committee. At the same time, and considering the strengthening of the links with the global disease control initiatives, the Management and Coordination cell should also report to those initiatives.

The oversight committee can hold the Management and Coordination cell to account, but it can also hold the involved stakeholders in the operationalisation to account through Key Performance Indicators (e.g. completeness and timeliness of requests, procurement lead time, in-country distribution, availability of operational costs, post-campaign reporting, etc.). While the decision-making in itself should remain independent, the oversight committee can also hold the decision-makers to account by applying a Key Performance Indicator on timeliness of the decision, as well as on the criteria used during decision-making.

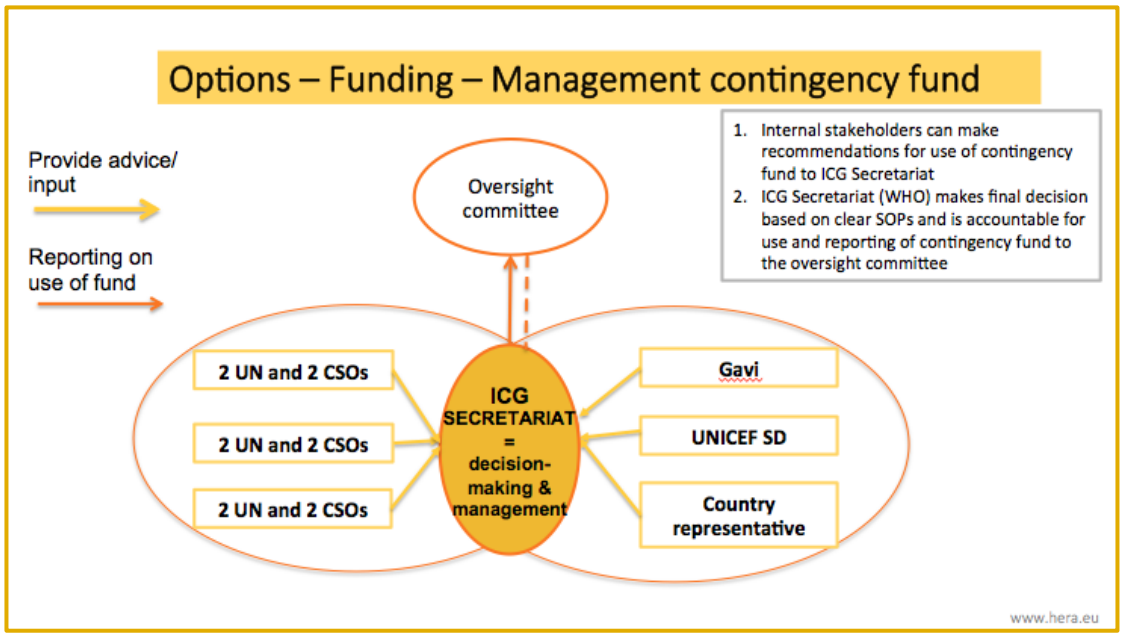
The following graphic is a representation of how the composition of the ICG including the governance and accountability structure could be considered:



In terms of Communication, the following graphic provides a consideration for satisfying the information needs of all involved stakeholders:



In terms of Funding, the following graphic demonstrates an option particularly on the roles management mechanism for the use of the proposed contingency fund:



Lastly, the following graphics provide an overview on how the ICG could possibly work in the future for other products in short supply, and how a transition from the ICG to a global disease initiative (for example yellow fever) could work: