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Report of the Annual Meeting

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List of abbreviations

| | |
|--------|--|
| AFRO | WHO Regional Office for Africa |
| CFR | Case fatality rate |
| Gavi | Gavi, the Vaccine Alliance |
| GTFCC | Global Task Force on Cholera Control |
| ICG | International Coordinating Group |
| IFRC | International Federation of Red Cross and Red Crescent Societies |
| IRC | Gavi Independent Review Committee |
| MSF | Médecins sans Frontières |
| OCV | Oral cholera vaccine |
| PAHO | Pan American Health Organization |
| SD | Supply Division of UNICEF |
| UNICEF | United Nations Children's Fund |
| VIS | Vaccine Investment Strategy |
| WASH | Water, sanitation and hygiene |
| WHO | World Health Organization |

Executive summary

The annual meeting of the International Coordinating Group (ICG) on Vaccine Provision for cholera was held on 11 September at the headquarters of the International Committee of the Red Cross in Geneva. The objectives of the meeting were to review the epidemiological situation during 2018–2019; discuss forecasts for vaccine demand over the coming years and options for increasing supply; to make a decision on present the size, composition and funding of the cholera vaccine supply for the coming year; and exchange information with the extended group of ICG partners and stakeholders, including vaccine manufacturers and country representatives.

The participants were updated on the epidemiological situation and vaccine shipments from the ICG cholera stockpile. The Pan American Health Organization (PAHO) gave an update on ongoing cholera prevention activities in the Americas, in Haiti in particular, and successes to date. The ICG Secretariat presented a review of its performance outcomes against its key indicators, followed by a review of emergency OCV campaigns (and missed opportunities) by WHO Headquarters. The meeting also involved country representatives, and the Ministry of Health of Mozambique outlined the challenges faced and lessons learned in implementing mass reactive campaigns following emergency vaccine requests to the ICG. After lunch, Gavi updated participants on its Supply and Demand Roadmap and work towards implementing its Vaccine Investment Strategy (VIS) for 2021–2025, after which UNICEF Supply Division (SD) presented its near-term projection of global cholera vaccine supply. Vaccine manufacturers then gave their production plans and forecasts for the coming years. Finally, the ICG partners, Gavi and UNICEF SD reached a decision on the required size of the cholera emergency stockpile for 2020.

During, 2018–2019 cholera outbreaks were reported in a number of countries including Zimbabwe, Niger, Mozambique, the Democratic Republic of Congo, Zambia, Ethiopia, Cameroon, in addition to the ongoing humanitarian crisis in Bangladesh. A total of 14 requests for 19,216,522 OCV doses were made between September 2018 and August 2019 inclusive, of which 10 were approved for a total of 10,668,532 doses. The ICG's key performance outcomes in 2019 were comparable with those from previous two years.

In 2019, ICG members and partners agreed that the targeted size of the ICG OCV stockpile is to remain the same for 2020 as recommended during the ICG meeting in 2018; 3 million OCV doses available at all times for use in emergency campaigns (as a lowest acceptable level).

Unlike in the case of other infectious diseases covered by the ICG mechanism, duration of protection offered by OCVs is relatively short, and use of OCVs alone is insufficient to achieve any notable reduction in the risk of cholera outbreaks. As in previous ICG meetings, there was significant emphasis on the role of long-term, multi-sectorial strategies integrating risk reduction measures (such as improved sanitation infrastructure) alongside preventive OCV campaigns—particularly in known “hotspots” where outbreaks are predictable and recur on a regular basis. Participants at the ICG meeting identified the need to give greater clarity on the roles of the GTFCC and Gavi IRC in reviewing and approving requests for OCV non-emergency campaigns.

In terms of emergency OCV requests, meeting participants agreed that further work is needed going forward on identifying countries' needs for technical assistance when making requests for OCVs for emergency and preventive campaigns, and on reviewing campaign implementation and use of vaccines on the ground. Concerns were also raised that OCV doses approved for release

by the ICG have been used in geographical areas other than those mentioned in the original request without the ICG's knowledge.

Since the conclusion of the external evaluation of the ICG in 2017, the new Governance and Oversight Committee (GOC) has held two meetings and approved the ICG Accountability Framework which sets out the actions and responsibilities of the ICG and each partner involved in the stockpile mechanism. It also sets out performance indicators for which each partner, including countries receiving vaccines, will be accountable. The ICG Secretariat reported on time from declaration of outbreaks to submission of emergency vaccine requests by countries for the first time. Work related to a proposal for an Ebola vaccine stockpile (ICG like mechanism) is also ongoing.

Introduction

Cholera is an acute diarrhoeal infection caused by the bacterium *Vibrio cholerae*. While control measures include treatment of cases with rehydration therapy, treatment with antibiotics and use of oral cholera vaccines (OCVs), improving water, sanitation and hygiene (WASH) conditions is essential for a sustained reduction in risk of outbreaks.

In 1997 more than 200,000 meningococcal meningitis cases and 20,000 deaths caused by *Neisseria meningitidis* serogroup A occurred across the meningitis belt. The International Coordinating Group on Vaccine Provision (ICG) was established the same year as an emergency mechanism to respond to outbreaks of epidemic meningitis. ICG groups and emergency vaccine stockpiles were established for yellow fever and cholera in 2001 and 2013 respectively.

The ICG brings together four founding agencies: The International Federation of Red Cross and Red Crescent Societies, Médecins Sans Frontières (MSF), the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO). It also consults with extended partners including technical experts and vaccine suppliers. Gavi, the Vaccine Alliance, is the principal funder of the three vaccine stockpiles.

The ICG's objectives are:

- To rapidly deliver vaccines in response to infectious disease outbreaks.
- To provide equitable vaccine allocation through careful and objective assessment of risk, based on epidemiological and operational criteria.
- To coordinate the deployment of limited quantities of vaccines and other essential medicines.
- To minimize wastage of vaccines and other supplies.
- To advocate for readily-available, low-cost vaccines and medicines.
- To work with manufacturers through UNICEF and WHO to guarantee availability of vaccine emergency stock supplies at the global level.
- To follow standard operating procedures and establish financial mechanisms to purchase emergency vaccine supplies and ensure the sustainability of stocks.

The 2019 annual meeting of the ICG on Vaccine Provision for cholera was held on 11 September at the headquarters of the International Committee of the Red Cross in Geneva. Participants included representatives of the World Health Organization (WHO) headquarters (HQ), including ICG Secretariat, the WHO Regional Office for Africa (AFRO), WHO Nigeria and Burkina Faso country offices, the Pan American Health Organization (PAHO), United Nations Children's Fund (UNICEF), with participants both from HQ and the Supply Division (SD), Médecins sans Frontières, the International Federation of Red Cross and Red Crescent Societies (IFRC), the Ministry of Health of Mozambique, Bill and Melinda Gates Foundation, and Gavi, the Vaccine Alliance. Representatives from vaccine manufacturers were also in attendance.

The primary objectives of the meeting were to review the epidemiological situation of cholera worldwide for 2018–2019, review the emergency requests for OCV over the same period and provide a brief summary of the related OCV campaigns; discuss current vaccine demand forecasts; discuss the size of the ICG OCV stockpile; and discuss vaccine supply and future development plans with the manufacturers.

The meeting follows on from that of the previous year, which took place on 19 September 2018. At that meeting it was decided that the stockpile would be increased from a size of 2 million doses to 3 million; available at all times for response to emergency requests. It was also emphasized that there was a need to clarify mechanisms and procedures to access vaccines via both the ICG and GTFCC mechanisms (for emergency and longer-term preventive campaigns respectively), in addition to the establishment of standard mechanisms for large multiyear requests. Reducing time needed for delivery of vaccines to countries following approval of emergency requests was identified as an important area for improvement. Finally, participants discussed work on the establishment of the new Governance and Oversight committee for the ICG mechanism, and the implementation of its new Accountability Framework.

1. Epidemiological update 2019

Background

Cholera outbreaks occur in all WHO regions, and researchers have estimated that every year, there are 1.3 to 4.0 million cases of cholera, and 21 000 to 143 000 deaths worldwide due to the infection worldwide¹. While significant progress has been made in the Americas towards reducing cholera cases, mortality and the threat of outbreaks through improvements in detection, case management and sanitation infrastructure, areas of high incidence remain in the AFRO and SEARO Region. Forecasting the time and severity of individual outbreaks also remains a major challenge.

Emergencies requiring large-scale deployment of OCVs can take the form of acute outbreaks or humanitarian crises. OCVs are administered as two doses at a minimum two-week interval, and this poses a challenge for planning and execution of emergency response campaigns. One course of vaccination provides protection for around three years, although this can be shorter in infants under five years. While high priority is placed on containing outbreaks through reactive OCV campaigns, vaccination should be employed alongside other interventions with the aim of both prevention and risk reduction. OCV is less effective in the longer term, and only improvements in WASH can secure a long-term reduction in cases and the threat of outbreaks.

The epidemiological situation in 2018/2019

A number of significant outbreaks and humanitarian crises were reported from September 2018 to August 2019. In **Bangladesh**, there was transmission of cholera among the Rohingya refugee population in October 2018. Three culture-confirmed cases were reported from refugee camps in the country June 2019, but no further cases were reported. In **Niger** there were a total of 3,823 cases and 78 deaths reported (CFR 2.0%) from July to November 2018. The highest intensity of cholera transmission occurred in August and September, and it is suspected that these cases were linked to outbreaks in Katsina and Zamfara States in **Nigeria**. In the Maradi Region, there were 3,443 cases and 60 deaths (CFR 1.7%), or 90% of the national total. Of these, 2,641 cases and 42 deaths (CFR 1.5%) reported from Madarounfa Department.

Cameroon also reported 1,429 cases and 82 deaths among both hospital and community cases (CFR 5.7%) in North and Far North Regions from May 2018 to September 2019. In the North Region there were two peaks of cholera transmission in late 2018 and mid-2019. Meanwhile, in the Far North Region, there were a reported 175 cases and 8 deaths (CFR 4.6%) since June 2019. **Chad** reported 51 cases and 2 deaths (CFR 3.9%) from 1 July to 1 September 2019. Both outbreaks in Cameroon and Chad were related to an outbreak in **Nigeria's** Borno State, and areas in Cameroon's the Far North region and Chad which reported cases are situated along the principal transport corridor between Maiduguri (capital of Borno State) and N'Djamena in Chad.

Cholera transmission has continued in **Zimbabwe** since the previous ICG meeting in September 2018. From 4 September 2018 to 12 January 2019 there were a reported 10,671 cases and 69 deaths (CFR 0.65%), and, of these, 9,971 cases and 46 deaths (CFR 0.5%) were reported from Harare. Most cases were localized to specific neighbourhoods, and 7,326 (73.5% of cases in Harare) were from Glenview and Budiriro districts.

¹ https://www.who.int/health-topics/cholera#tab=tab_1. Accessed 27 March 2020.

In **Mozambique** there were two cholera outbreaks during 2019. The first occurred in Sofala Province in early 2019, with a reported 6,768 cases and 8 deaths (CFR 0.12%). The second outbreak in Cabo Delgado took place from 1 May to 19 June 2019 in the wake of Cyclone Edi. A total of 283 cases and 0 deaths were reported, and its scale was limited by a timely OCV response campaign after the ICG approved an emergency vaccine request.

In the **Democratic Republic of Congo**, a total of 17,271 cases (averaging 600–700 per week) and 311 deaths (CFR 1.8%) were reported between 1 January and 25 August 2019. An outbreak occurred in North Kivu Province over February to August of 2019, with a reported 3,620 cases and 37 deaths (CFR 1.0%). Areas around Goma, Karisimbi and Nyiragongo in the south of the province were most severely affected. Nationally, cholera transmission peaked in Week 34 of 2019 with a total of 712 cases. Of these, 633 (88.9%) occurred in North Kivu, South Kivu and Tanganyika Provinces. It was noted that, compared with 2018, there has been a shift in the distribution of new cases away from “epidemic regions” in the west of the country which have been considered lower-risk but have experienced significant outbreaks in recent years, to “endemic regions”, mostly in eastern provinces, which have traditionally been considered high-risk. Two outbreaks were reported in the north-east of **Zambia** in areas adjacent to the Democratic Republic of Congo. While 253 cases and 6 deaths (CFR 2.4%) were reported in Mupulungu District from 3 April to 22 May 2019, there were reported 13 cases and 0 deaths reported during 16–31 August in Nsama District. **Ethiopia** reported 1,097 cases and 11 deaths (CFR: 1.0%) between 1 January and 18 August 2019, with nearly half of these (45.6%) occurring in the Oromia Region. A significant number of cases were reported in the Tigray Region and along its border with Amhara Region.

PAHO Region update

The Dominican Republic and Haiti are the only countries in the PAHO Region to have experienced significant transmission of cholera in recent years. The **Dominican Republic** reported its last suspected cholera case in December 2018. There, the number of suspected cases and deaths had been falling annually from 20,851 cases and 336 deaths in 2011 (CFR: 1.6%) to 118 cases and 1 death by 2018 (CFR: 0.9%)².

By comparison, in neighbouring **Haiti**, according to the country’s Ministry of Health there were a reported 352,033 suspected cases and 2,927 deaths (CFR: 0.8%) in 2011, falling to 3,777 cases and 41 deaths (CFR: 1.1%) by 2018³. In 2019 the country reported 530 suspected cases and 3 deaths (CFR: 0.6%) over Weeks 1–33. Suspected cases during 2019 occurred primarily in the Departments of Centre, Artibonite and Ouest (home to the capital Port-au-Prince), with confirmed cases occurring only in Artibonite and Ouest.

Cholera control efforts in Haiti as part of the Ministry of Health’s national plan for cholera elimination have included preventive campaigns since 2013, pre-emptive vaccination campaigns in high risk areas (for example, in Saint-Michel de l’Attalaye in April 2018), improved case management and laboratory confirmation capacity. These have met with significant success. Efforts have focussed on vaccination and prevention of outbreaks in 12 communes identified as hotspots. Around 1.4 million people in Haiti (out of a total population of approximately 12 million) received at least one OCV dose from 2013 to 2018, and this has contributed to the rapid decline in cholera-associated deaths. The national plan recognizes the need for a mechanism for rapid reaction to emerging national outbreaks to facilitate their rapid containment. There has also been

² World Health Organization. Cholera, 2018. Weekly Epidemiological Record 2019; 94(48): 561–567. <https://extranet.who.int/iris/restricted/bitstream/handle/10665/330003/WER9448-eng-fre.pdf?ua=1>. Accessed 16 December 2019.

³ Ministère de la santé publique et de la population (MSPP). Rapport du Réseau National de Surveillance: Choléra (33ème semaine épidémiologique 2019). <http://mspp.gouv.ht/site/downloads/Profil%20statistique%20Cholera%20Pour%20la%2033SE%202019.pdf>. Accessed 15 December 2019.

scale-up of laboratory capacity across the entire country with the establishment of six regional laboratories for confirmation of cholera cases and detection of other infectious diseases. During 2019, 98% of the cholera suspected cases have been sampled by the Haitian Ministry of Public Health and Population cholera surveillance system. Haiti will continue to refine its outbreak alert and response mechanism at the national and subnational levels, and develop outbreak contingency plans. Although significant progress has been made to date, the risk of a large scale cholera outbreak in the country remains.

2. ICG response and performance outcomes

From September 2018 to August 2019 the ICG received 14 requests for 19,216,522 doses following eight humanitarian crises and six outbreak emergencies (Table 1). Of these, as of 11 September, 10 were approved or partially approved by the ICG for a total of 10,668,532 doses, (or 55% of doses requested excluding one pending request). Just over one-third of approved doses were dispatched to Mozambique, and another fifth each to Zimbabwe and the Democratic Republic of Congo.

Table 1. Summary of emergency requests to the ICG for cholera vaccines, 2018 and 2019

| Request number and country | Request date | Days for request circulation | Days for additional information | Days decision time ¹ | Approval | Days delivery time | Days to campaign start | Vaccine doses requested |
|----------------------------|--------------|------------------------------|---------------------------------|---------------------------------|--------------|--------------------|------------------------|-------------------------|
| #11 (2018) Zimbabwe | 19/09/2018 | same day | N/A | same day | Approved | 9 days | 7 days | 2,763,358 |
| #12 Niger | 28/09/2018 | same day | 5 days | same day | Approved | 8 days | 53 days | 2,293,776 |
| #13 (H)* Bangladesh | 16/10/2018 | same day | 1 day | 2 days | Approved | 13 days | 2 days | 164,278* |
| #1 (2019) Mozambique | 21/03/2019 | same day | N/A | 1 day | Approved | 11 days | 1 day | 1,769,906 |
| #2 Zimbabwe | 01/04/2019 | same day | N/A | 2 days | Approved | 11 days | 2 days | 975,646 |
| #3 Cameroon | 04/04/2019 | 1 day | 7 days | 1 day | Approved | 46 days | 62 days | 1,361,898 |
| #4 (H) DRC | 05/04/2019 | same day | 7 days | 1 day | Not approved | N/A | N/A | 1,776,890 |
| #5 DRC | 06/04/2019 | same day | 6 days | 1 day | Approved | 8 days | 34 days | 2,119,078 |
| #6 Zambia | 10/04/2019 | same day | 13 days | same day | Approved | 6 days | 22 days | 136,834 |
| #7 (H) Ethiopia | 12/04/2019 | same day | N/A | 2 days | Not approved | N/A | N/A | 1,324,444 |
| #8 (H) Mozambique | 30/04/2019 | same day | N/A | 2 days | Approved | 9 days | 5 days | 1,854,444 |
| #9 (H) Ethiopia | 02/05/2019 | same day | 7 days | 1 day | Approved | 7 days | N/A | 1,557,532 |
| #10 (H) Iran | 28/05/2019 | same day | N/A | 1 day | Not approved | N/A | N/A | 280,664 |
| #11 (H) Sierra Leone | 22/08/2019 | same day | N/A** | N/A | N/A | N/A | N/A | 1,002,052 |

N/A: not applicable; (H): humanitarian crisis; *single-dose campaign; **cancelled by the requestor; ¹working days.

Three requests were approved in 2018 (**#11, #12 and #13 2018**) after that year's ICG meeting to respond to ongoing cholera transmission in **Zimbabwe**, an outbreak emergency in **Niger** in areas bordering Nigeria, and the continuing humanitarian crisis in **Bangladesh**.

During 2019 the ICG approved two requests from **Mozambique (#1 and #8 2019)** in response to an outbreak emergency in Sofala Province and a humanitarian crisis in Cabo Delgado after damage caused by Cyclone Edi. In both cases, rapid decision-making by the ICG, delivery of vaccines to the country, and implementation of campaigns significantly to the effectiveness of vaccination campaigns. In Cabo Delgado there was a rapid decline in cholera transmission in response to the campaign, the outbreak was effectively contained, and no deaths due to cholera were reported.

An additional request for an additional 975,646 doses for **Zimbabwe (#2)** was fully approved following previous campaigns in the country after ongoing cholera transmission in and around Harare.

Implementation of emergency response campaigns in **Cameroon (#3)** were delayed over two months after arrival of vaccines in-country following approval of release of 1,361,898 OCV doses by the ICG. Some doses delivered to the country were diverted to the Far North Region where new cases were reported after the initial request. Campaign implementation in the in Far North Region faced several challenges including the deteriorating security situation, the remoteness of areas covered by campaigns, clashes with other routine campaigns scheduled at the same time, and issues related to reaching populations during Ramadan.

A request from the **Democratic Republic of Congo (#4)** in response to a humanitarian crisis in Lumbubashi in the south of the country was not approved by the ICG as the request came too late for any emergency vaccination campaign to effectively prevent further cases. A subsequent request (**#5**) was approved for over 1.67 million doses. Of the approved doses, 1.6 million were deployed in North Kivu, where the first round of the campaign started in late May and achieved 94% vaccination coverage. Ebola cases in Goma affected the implementation of second round of the campaign, however. A request for 136,834 doses from **Zambia (#6)** was approved to respond to an outbreak in areas bordering the Democratic Republic of Congo.

While a request from **Ethiopia (#7)** for just over 1.3 million doses was not approved by the ICG, another for 778,766 doses to respond to a humanitarian crisis (**#9**) was fully approved. ICG members noted that these vaccines were not used as agreed in the original operational plan included in the emergency request, and that they were used for other purposes without approval from the ICG.

A request from **Iran (#10)** was not approved. As of 11 September 2019 a request for OCV vaccines had been submitted by **Sierra Leone (#11)**, and the ICG was awaiting further information from the country to support the request. But additional information was not available from the country and eventually the request has been cancelled.

Almost no adverse events following immunization were reported during 2019, and 15 suspected events reported following campaigns in Zambia were considered by the country's Ministry of Health unlikely to be vaccine-related.

ICG performance outcomes in 2019

The ICG's key time performance indicators were calculated for October 2018 to September 2019, and separately for October to December 2018 and January to September 2019 (Table 2). Performance outcomes for the latter period are reported below for ease of comparison with previous years.

During January to September 2019 the mean decision time for the 10 requests made over January to September 2019 (excluding the pending request made by Sierra Leone, #11) was 1.2 days (range: 0–2). Mean delivery time for the seven approved requests for which vaccines were released was 14.4 days (range: 7–46), and this average was substantially increased by the delay in delivery of vaccines to Cameroon (#3). Mean time to campaign start in-country was 21.0 days (range: 1–62). By comparison, in the same period during 2018, there were 10 requests of which nine were approved by the ICG. Mean decision time was 1.3 days (range: 0–4), mean time for delivery of vaccines was 10.9 days (range: 5–16), and mean time until the start of vaccination campaigns was 10.0 days (range: 6–31).

As of 2019 the ICG Secretariat has collected data on time taken for countries to complete preparation of requests (time from declaration of an outbreak to submission of a request to the ICG). Mean time for request preparation for the five requests submitted for response to outbreak emergencies during January to September 2019 was 56.8 days, with a range of 7 days (#1 and #6) to 185 days (#3). After arrival of vaccines in-country, mean time between first round and second rounds of immunization was 58 days (range: 18–112).

Table 2. Summary of ICG performance indicators for emergency oral cholera vaccine requests, October 2018–September 2019

| Period | Number of requests | Number additional information requested (%) | Number approved (%) [*] | Mean days decision time (range) [*] | Mean days delivery time (range) ^{**} | Mean days request preparation (range) ^{***} | Mean days reception to campaign start (range) ^{****} |
|--------------------|--------------------|---|----------------------------------|--|---|--|---|
| Oct–Dec 2018 | 3 | 2 (67%) | 3 (100%) | 0.7 (0–2) | 10.0 (8–13) | 48.0 (11–85) | 20.7 (2–53) |
| Jan–Sept 2019 | 11 | 6 (55%) | 7 (70%) | 1.2 (0–2) | 14 (6–46) | 56.8 (7–185) | 21.0 (1–62) |
| Oct 2018–Sept 2019 | 14 | 8 (57%) | 6 (100%) | 1.1 (0–2) | 12.8 (6–46) | 52.7 (7–185) | 20.9 (1–62) |

^{*}Requests for which full information had been received by the ICG as of 12/09/2019; ^{**}Approved requests; ^{***}Emergency vaccine requests in response to cholera outbreaks only, excluding humanitarian crises (7 requests, non-H in Table 1); ^{****}Approved requests for which campaigns had not started by 12/09/2019.

The ICG currently has three key performance targets: requests are circulated to ICG members within one working day; the ICG decision-making body reaches a decision on approval of requests within two working days; and UNICEF SD delivers approved vaccines to the requesting country within seven days.

Excluding the pending request made by Sierra Leone (#11), nine out of 10 requests in 2019 (90%) were circulated to ICG members the same day and another the following working day. Decisions were reached within two days all of the ten requests (100%) after all necessary information had been received (additional information was requested from countries for five of 10 requests). Delivery time was within seven days for two of the seven approved requests (29%).

These three performance outcomes for 2019, measured against the ICG's key performance targets, compare with 100%, 91%, and 0% respectively in 2016, and 100%, 87% and 18% in 2017, and 80%, 90% and 14% in 2018. Although mean time to delivery in 2019 (12.8 days) compares unfavourably with that in 2018 (10.9 days), the proportion of approved requests in 2019 for which vaccines were delivered to countries following approval of requests was higher than in the previous three years.

During the period from September 2018 to August 2019, OCV requests from countries mostly applied systematic approaches to compiling the necessary information for decision-making by the ICG. However, more information was needed for the majority of requests before a definite decision on approval could be reached. Specifically, ICG members identified insufficient quality of laboratory evidence confirming outbreaks, submission of requests without maps showing geographic ranges of outbreaks, and the need for greater precision in outlining campaign plans as the primary challenges.

As in previous years, time taken to deliver vaccines from manufacturers to requesting countries continues to represent a major area for improvement. A major constraint on timeliness of delivery is the need to secure approval for importation of vaccines from national customs authorities. Although there has been some reduction in time needed to secure customs approval and some countries have shown greater flexibility, others' approval processes remain relatively rigid.

Participants agreed that the ICG should intensify its work on reviewing campaign implementation and use of vaccines on the ground, as campaign monitoring and evaluation were reported to be limited in quality and scope in some countries. While these activities have included monitoring of administrative coverage and cost effectiveness, the majority of campaigns during 2019 did not report WASH coverage. ICG members also stressed that vaccines must be deployed as specified in the original campaign plan included as part of ICG requests. It was noted that three campaigns (in Zambia, Ethiopia and Cameroon) campaigns were not implemented as planned, and the ICG was not given sufficient notification of these changes.

Challenges for emergency vaccine response and lessons learned in 2019

The timely and effective response to outbreak emergencies in Mozambique during 2019 was achieved through the combined efforts by national personnel, the ICG and UNICEF SD. The country ensured rapid preparation of emergency requests and implementation of vaccination campaigns through effective mobilization of Ministry of Health staff and health workers, some of whom were requested to work during evenings. During campaigns in Cabo Delgado following the country's second request (#8 2018) which took place during Ramadan, vaccinations were administered during evenings to more effectively reach the predominantly Muslim population. This successful experience could be applied to other Muslim-majority countries or regions should an outbreak of cholera (or other vaccine-preventable disease) occur during Ramadan.

Although the Democratic Republic of Congo is currently pursuing a multi-year national plan for cholera prevention, the country is simultaneously facing multiple disease threats, and, as a result, there is severe competition for limited resources. As a result, implementation of emergency response campaigns (#5 2019) were hampered, and there has been poor integration of campaigns with WASH as authorities have been preoccupied with "firefighting" as opposed to long-term risk reduction. The ICG members and partners identified the need to provide a greater degree of technical support and guidance to the country.

Any delay in starting campaigns after arrival of vaccines in-country may represent an opportunity cost as vaccine doses could have been used in other outbreaks. In some countries, both emergency and preventive campaigns OCV campaigns may be ongoing simultaneously, and scheduling of cholera campaigns may clash with those for other infectious diseases such as Polio. Although these countries may face competing priorities, this may also represent an opportunity to administer OCV with other vaccines as has been successfully applied in Bangladesh. This may not be applicable in some instances, however, where acceptability for combining campaigns may be low; in such cases additional efforts may be needed to engage local stakeholders ahead of campaigns.

Meeting participants also noted the reluctance on the part of some countries to request technical assistance in making emergency vaccine requests, and emphasized that ministries of health should be made aware that this may be available from the ICG. It was suggested that WHO country offices could also play a role to play in assisting in preparation of emergency requests. Some countries, such as Nigeria and Kenya, did not make requests for stockpiled OCVs from the ICG despite their availability; this represents a missed opportunity to provide at-risk populations protection from developing cholera outbreaks.

3. Vaccine supply, procurement, forecasting and deployment

During the 2018 annual meeting, the ICG and partners agreed that the targeted size of the ICG OCV stockpile is to remain the same for 2020 as recommended during the ICG meeting in 2018; 3 million OCV doses available at all times for use in emergency campaigns (as a lowest acceptable level).

During 2019 size of the cholera ICG vaccine stockpile has been maintained at over 3 million doses.

The primary constraint preventing the achievement of this target is the limited global supply of WHO-prequalified OCVs. UNICEF SD reported that, despite the notable increase in global OCV supply over the past decade, demand for both emergency and non-emergency use has continued to increase. As a result, the gap between supply and demand for OCVs has yet to be narrowed.

UNICEF SD is engaging with manufacturers to secure long-term supply agreements, and it is expected that multi-year tenders will be issued once the terms of financial support from Gavi are finalized. UNICEF SD has noted that current suppliers to the ICG stockpile are making investments in increased production capacity, and this has facilitated greater frequency and volumes of vaccine deliveries in response to emergency requests. Manufacturers have also shown flexibility, and have maintained or improved timeliness in mobilizing stockpiled doses once emergency requests have been approved. One positive development for both UNICEF SD and manufacturers is that early communication with vaccine suppliers and freight forwarders as soon as ICG requests are received, to allow advanced preparation for vaccine release, has become more routine. Operational challenges for emergency OCV use remain, however. These include the fact that OCV requires a two dose schedule of the same vaccine type. Although preferable to dispatch both shipments together, these may be sent as two separate shipments if vaccine supply is constrained or logistic bottlenecks exist.

OCV use

The use of OCV in both emergency and non-emergency campaigns has increased markedly over the past 20 years. In the past six years (since 2013), GTFCC and Gavi data indicate that closer to 58 million doses have been used for emergency and preventive campaigns.

Vaccines are released for use via these two complimentary mechanisms. The ICG mechanism is optimized for specific emergency situations such as outbreaks and humanitarian crises where the opportunity for other interventions is limited and rapid response is vital for preventing further disease transmission. In general, one request corresponds to one campaign in response to a specific outbreak or humanitarian crisis situation in a defined geographic area (for example following recent cyclones affecting Mozambique in early 2019). The GTFCC mechanism, by contrast, is adapted for long-term vaccination plans in non-emergency scenarios, and most often applicable for countries with known “hotspots” with recurrent outbreaks. The GTFCC mechanism requires requesting countries to go beyond vaccination and to implement long-term, multi-sectorial strategies as part of a national cholera control plan. Gavi funds vaccines (and other materials) and operational costs for Gavi-eligible countries applying for vaccines under both mechanisms; non-Gavi-eligible countries may access vaccines but are required to reimburse costs borne by Gavi. In October 2017, 35 GTFCC partners endorsed a declaration on ending

cholera through implementation of a new global roadmap. Its overarching objective is to end cholera as a public health threat in 20 countries and reduce deaths by 90% by 2030. Efforts towards meeting this objective have been bolstered by the adoption of a resolution on cholera prevention at the 71st World Health Assembly in May 2018

Currently, inadequate WASH results in periodic, recurrent outbreaks which place pressure on the ICG stockpile. The GTFCC 2030 Roadmap emphasizes a transition from outbreak preparedness and response to prevention and control. The GTFCC will support countries to devise realistic targets for cholera control, to coordinate vaccination campaigns with long-term, systematic cholera control plans at the national level (with an emphasis on known cholera hotspots), and to make firm commitments to go beyond vaccination and implement WASH interventions. It is hoped that long-term reliance on OCV campaigns will gradually be reduced as WASH scales up. In relation to the ICG stockpile, the GTFCC mechanism provides an avenue for the allocation of stockpiled doses to preventive mass vaccination programmes as they approach expiry. These priorities are complemented by Gavi's long-term commitment to invest in OCVs; this allows for multi-year planning of preventive campaigns, and to optimize integration of vaccination campaigns with national cholera control strategies encompassing WASH and other multi-sectoral approaches.

Around 20 countries are known to have hotspots and could be eligible to make a request for vaccines for preventive use under the GTFCC mechanism. Lack of clarity on vaccine availability over the medium term and procedures for applying for OCVs for large-scale preventive use currently inhibit the implementation of the type of multi-year plans called for by the GTFCC 2030 Roadmap.

Meeting participants agreed that further discussions between Gavi and the ICG are needed to clarify the roles of the GTFCC and Gavi Independent Review Committee (IRC) in reviewing and approving requests for OCV preventive campaigns, and how these groups can collaborate to ensure a rigorous but timely review process. It was also highlighted that many ministries of health do not consider prevention as an initial approach to confronting the risk of cholera outbreaks, and that the ICG and its partners can play a role in advocating for comprehensive risk reduction strategies, and in providing support for preparation of requests for OCV campaigns under both the ICG and GTFCC mechanisms.

Demand forecasting and the Gavi Vaccine Investment Strategy

In December 2018, Gavi endorsed the selection of six high-priority diseases, including cholera, for development of an investment case based on expected health impact, value for money, equity and social protection impact, economic impact and global health security impact.

As part of the Vaccine Investment Strategy (VIS), Gavi developed six plausible ten-year demand scenarios (2019–2028) ranging from “very high” to “very low”, to allow consideration of multiple possible trajectories of vaccine demand based on different assumptions. These forecasts are based on anticipated demand from 40 Gavi-eligible countries (excluding India), and account for how improvements in WASH in different countries may influence the risk of outbreaks and subsequent OCV demand.

Based on the “medium–high scenario”, which is used as a Gavi's Supply and Procurement Roadmap 2018 base case demand scenario, demand rise from just over 30 million doses annually from 2019 to nearly 80 million doses by 2022 onwards. There is expected to be a gradual decline in demand to under 70 million doses by 2027 (of which 27 million doses are expected from deployment of stockpiled vaccines under the ICG and GTFCC mechanisms).

Regarding the current state of the vaccine market, the forecast shows that global demand is unlikely to be fully met despite increasing OCV supply. There is currently no buffer capacity to meet additional demand in the event of multiple large outbreaks occurring simultaneously. Although current vaccine suppliers have shown a high degree of reliability in meeting their production targets and have experienced no licensing issues in recent years, their performance at significantly higher levels of OCV output remains untested. Although current OCV prices are relatively affordable, market competition remains insufficient with a single manufacturer providing for 70% of the market. However, Gavi anticipates that two to four new WHO-prequalified OCVs will be made available between 2021 and 2023. A Bangladeshi manufacturer, Incepta, is expected to launch a new product (“Cholvax”) which could eventually meet all domestic needs. While current suppliers are continuing to invest in innovations in their OCV product lines, further progress is needed to address the three major challenges encountered in OCV use: the need for two doses, the relatively short duration of protection (three years) necessitating re-vaccination of at-risk populations, and lower efficacy in infants.

Gavi’s market shaping targets include the provision of at least 48 million doses to 39 Gavi-eligible countries (excluding India and Bangladesh) by 2021, the entry of one new supplier to the OCV market by 2021 and another by 2023, and the emergence of new vaccine candidates targeting protection of 10 years or more by 2023.

The strategy’s long-term funding commitments will give greater predictability, both for manufacturers in terms of their future production schedules and for planning for future OCV campaigns. Gavi has confirmed that it will continue to invest in the use of OCV in endemic settings (alongside emergency use and) through bridge funding for 2020 to cover the period before Gavi’s next five-year funding cycle begins. In 2018 the Gavi Board agreed in principle to re-orientate its OCV programme to emphasize cholera prevention, subject to funding, from 2021 onwards. Gavi has completed its guidelines for targeted non-emergency use of OCV in defined hotspots, and the Gavi IRC will begin reviewing applications for OCV campaigns in such endemic areas from 2021.

In the shorter-term, Gavi will update its demand forecast based on new information; put in place its learning agenda for evaluation of impacts of OCV use in different contexts; develop application guidelines, requirements and decision criteria for requests for targeted non-emergency use of OCV in defined hotspots; and disseminate these guidelines to countries and partners involved in request preparation.

5. Governance, accountability and transparency

Over 2016–2017 a formal, independent evaluation of the ICG's structure and its activities was carried out by the consultancy Hera, and its results were presented to the ICG Secretariat in October 2017. The evaluation report highlighted the need for improved accountability, transparency and oversight of the ICG mechanism. Specifically, the evaluation noted that responsibilities of different parties within the ICG mechanism overlapped, and that it lacked an oversight mechanism to ensure that the ICG decision-making groups are accountable to both their stakeholders and the organizations they represent.

In response to these recommendations, the ICG Governance Oversight Committee (GOC) was established in February 2018 to provide overall oversight and strategic direction to the ICG mechanism; review performance of the process against agreed performance indicators; ensure alignment of the mechanism with ICG's founding principles; and to advise on linkages with wider disease control initiatives (such as the Defeating Meningitis by 2030 strategy). To ensure its independence, committee members will not be directly involved in the work of the ICG mechanism and will comprise senior staff drawn from the WHO, IFRC, MSF, UNICEF and Gavi.

The GOC held its first meeting in September 2018, where agreement was reached on its composition and procedures. During the second meeting of the GOC on 12 July 2019, its members approved the ICG Accountability Framework, which sets out the roles and responsibilities of the ICG and each of its partners involved in the mechanism in relation to five key functional areas: general oversight and management; emergency stockpile requests and decision-making; vaccine deployment and follow-up; sustainable funding of vaccination campaigns and campaign implementation; and vaccine demand and supply environment.

During the last GOC meeting, UNICEF suggested that the role of the GOC should include both strengthening collaboration between the ICG, its partners and wider disease control initiatives, and ensuring that the ICG's work should be complimentary to achieving their objectives. The GOC holds a unique position to view the ICG's work from a strategic perspective and to work with other global health actors on advocacy (for example, in calling for the development of new vaccine products based on known needs and operational challenges faced by the ICG and partners). GOC members were requested to advise on specific aspects of the Accountability Framework including terms of reimbursement for vaccines by non-Gavi-eligible countries, vaccine allocation criteria for emergency requests, and estimation of operational budgets for vaccination campaigns.

The Gavi Secretariat was accorded temporary observership at ICG deliberations in 2017, and its observership status was made permanent at the GOC meeting in July 2019.

As agreed in the Accountability Framework, the range of key performance indicators (KPIs), reflecting the responsibilities of each ICG partner, will be significantly expanded. These will be systematically reported in future ICG publications. The range of KPIs included in the Accountability Framework are now attached to a wider range of partners and not all are specific to the ICG alone. The responsibilities of individual countries in relation to request preparation, implementation of vaccination campaigns, campaign monitoring and evaluation, and financial reporting on vaccination campaigns has also been recognized. However, any appraisal of countries' performance against the KPIs should account for their unique challenges and the degree of support they require in preparing emergency vaccine requests.

Proposal for an Ebola vaccine stockpile

It is expected that, following efforts to expedite the development of Ebola vaccines in the wake of the 2014–2015 West African Ebola epidemic and recent outbreak in the Democratic Republic of Congo, the first Ebola vaccine will be licensed by 2020. Gavi has proposed an ICG-like mechanism for Ebola vaccines once these are available, and participants at the second meeting of the GOC in July 2019 were supportive of the proposal. While Gavi agreed an initial funding window from 2014 to 2020 to explore possibilities for the establishment of such a mechanism, the Gavi Board will deliberate on a new funding window to continue this work at its next meeting in December 2019.

An Ebola-specific stockpile mechanism would likely differ from that of existing ICG stockpiles, and would likely involve allocation of vaccines for both preventive campaigns and emergency response. Specific vaccination strategies, which would likely involve ring vaccination as opposed to mass vaccination strategies used for other infectious diseases currently covered by the ICG mechanism. The stockpile's size, composition, decision-making criteria for release of stockpiled vaccines, and strategies for vaccine deployment, will require revisiting periodically as the epidemic situation on the ground evolves. Further technical input from SAGE and UNICEF SD will also likely be needed. While there is recognition of the value of establishing an ICG-like mechanism for Ebola, the ICG's effectiveness in timely and equitable decision-making on vaccine allocation, and recent improvements in its transparency and accountability, given the complexity of Ebola response it is likely that an even wider range of stakeholders and technical experts may need to be engaged.

5. Discussion

The most significant development since the 2018 ICG meeting has been the expansion of the stockpile from 2 million to 3 million doses. Although the increase in the size of the stockpile will, in time, encourage more proactive use of OCV for both emergency and preventive campaigns, the challenge remains as to how to meet this new demand. This challenge can only be tackled through further market shaping efforts by Gavi, investments in new production capacity by manufacturers, and an emphasis on innovation to find solutions to the major challenges encountered in OCV use (such as the need for two doses and their relatively short duration of protection).

Most countries endemic for cholera also experience outbreaks or humanitarian crises. The epidemiological characteristics of cholera necessitate a mix of frameworks for accessing OCVs, and flexibility for when situations change. One challenge within countries is that GTFCC and ICG requests may be prepared by different agencies, and meeting participants discussed how the GTFCC OCV Working Group can provide countries direct support, and how the ICG, its Secretariat and the GTFCC can better coordinate their activities. Another outstanding question identified by the ICG and partners is how to catalyse investment in WaSH and preventive OCV campaigns.

Many countries face competing priorities, including the need to respond to other diseases such as measles, polio and Ebola, and limited cold chain capacity shared across multiple vaccination campaigns. Further efforts by countries, with technical support from the ICG partners, are needed to connect the dots between different programmes. Opportunities exist to leverage complementarities between different disease control programmes, and MSF has emphasized that OCV campaigns have successfully been combined with measles campaigns in the past.

Individual countries face a number of responsibilities, including submission emergency vaccine requests to the ICG after confirmation of cholera outbreaks, delivery of vaccines to affected areas after arrival in-country, and campaign monitoring and evaluation. The responsibility for preventing outbreaks in the first place through provision of effective WASH infrastructure and other long-term interventions also ultimately rests on countries. As the experience in Haiti has shown, concerted efforts at the country level in collaboration with partners such as PAHO are key to sustained reductions in the risk of cholera outbreaks.

The ICG has established its new Governance Oversight committee and is moving forward with the implementation of the Accountability Framework. These developments will improve the transparency of the ICG mechanism and ensuring the ICG and partners, including requesting countries, are accountable for meeting their responsibilities. Work related to a proposal for an Ebola vaccine stockpile is also ongoing.

6. Meeting decision and action points

The following decisions were taken by the members of ICG to the cholera vaccine stockpile:

- The targeted size of the ICG OCV stockpile is to remain the same for 2020 as recommended during the ICG meeting in 2018; 3 million OCV doses available at all times for use in emergency campaigns (as a lowest acceptable level).
- The ICG Secretariat is to raise concerns with individual countries and WHO country offices that OCV doses approved for release by the ICG are being used in geographical areas other than those mentioned in the original request without the ICG's knowledge.

The ICG for cholera identified the following action points:

- Technical assistance is to be offered to individual countries via WHO country office to develop OCV vaccine requests for emergency campaigns.
- The ICG is to intensify its work on reviewing campaign implementation and use of vaccines on the ground.

Common issues were also raised over the three consecutive days of ICG meetings.

Action points identified from all three meetings included:

- The ICG Secretariat is to follow up by email to formulate specific KPIs for countries submitting emergency requests to which they will be accountable within the ICG Accountability Framework. These will reflect countries' areas of responsibility, including timeliness of request submission and campaign implementation, and give consideration to countries' capacity to implement these effectively. Following these discussions, the ICG and GOC are to define, compile data on, and report on consistent indicators for all ICG stockpiles.
- The ICG and UNICEF SD are to continue their work on identifying and evaluate specific bottlenecks in the procurement and delivery process with a view to improving vaccine delivery lead times.

Participants agreed on the action points by consensus and expressed their commitment to moving forward with their implementation over the coming year.

7. Progress since 2018

- **Action point:** The ICG is to include time from declaration of outbreaks to submission of emergency vaccine requests and time required for laboratory confirmation of cases as performance indicators in future years. The ICG will report on this indicator annually going forward.

▶ **Result:** The ICG Secretariat has started to collect data on time from declaration of outbreaks to submission of emergency vaccine requests since the beginning of the 2019 epidemic season, and this indicator will be reported in future ICG reports and publications. As part of ongoing work to implement the ICG Accountability Framework, it is expected that data on time to confirmation of cases and declaration of outbreaks will be gathered in future years.
- **Action point:** The cholera stockpile is to be expanded from its current level of 2 million doses. The expanded revolving stockpile is to comprise a total of 3 million doses exclusively for ICG emergency requests.

▶ **Result:** The ICG stockpile has expanded to a total of 3 million doses. There remains the need to intensify efforts towards securing the necessary vaccine supplies to meet the targeted stockpile size.
- **Action point:** Further efforts are to be made for improving demand forecasting for cholera vaccines.

▶ **Result:** Gavi will continue to refine and update its OCV demand forecasts for its six demand scenarios as new information becomes available to better inform its Vaccine Investment Strategy. The ICG Accountability Framework explicitly sets out the responsibility of the ICG technical expert partners (WHO, UNICEF, IFRC, MSF) for vaccine demand forecasting with input from Gavi.
- **Action point:** The need for greater representation of countries at future ICG meetings was identified.

▶ **Result:** Staff from the WHO Nigeria and Burkina Faso country offices attended the 2019 ICG meeting.

Annex 1. Meeting agenda

ICG OCV Annual Meeting

IFRC, Geneva

11 September 2019, Auditorium B

Agenda

Objectives

- Review the epidemiological situation in 2018-2019
- Review the outbreaks and campaigns supported by ICG during 2018-2019
- Discuss the vaccine demand forecast
- Present the vaccine supply and future development plans with the manufacturers
- Discuss the stockpile size (global and emergency)

Chair: Frank Mahoney

| Time | Topic | Presenter |
|--|--|----------------|
| 08:45 – 09:00 | Arrival and welcome of participants | |
| Session 1: Epidemics, campaigns | | |
| 09:00 – 10:30 | Cholera epidemiological situation in 2018-2019 (ICG requests) | WHO HQ |
| | Cholera in the Americas: Current situation and vaccination plans | WHO PAHO |
| | Vaccine shipments, 2018-2019 | UNICEF SD |
| 10:30 – 10:45 | Coffee break | |
| 10:45 – 12:00 | ICG performance – review of key indicators | ICG Sec. |
| | Review of campaigns with OCV in 2018/2019 (ICG related) and missed opportunities | WHO HQ |
| | Reactive campaigns in Mozambique: challenges, lessons learned | MOH Mozambique |

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|---|--|--|
| 12:00 – 13:00 | Lunch | |
| Session 2: Vaccine supply | | |
| 13:00 – 15:00 | Vaccine demand forecast and roadmap – VIS update | Gavi |
| | Vaccine supply: current and short-term projections. | UNICEF SD |
| | Manufacturers production plans and future vaccine developments 2019-2022 | Sanofi-Shantha EuBiologics Hillman labs VaBiotech PaxVax Incepta Shanghai Biotechnology |
| 15:00 – 15:30 | Coffee break | |
| Session 3: Stockpile size (closed session) | | |
| 15:30 – 16:30 | Discussion: Stockpile size requirements (global and emergency) | IFRC, MSF, UNICEF PD, WHO, UNICEF SD, Gavi (only) |
| 16:30 – 17:00 | Conclusions – wrap up | All participants |
| 17:00 – 19:00 | Reception | All participants |

Annex 2. List of participants

**International Coordination Group (ICG) for Vaccine Provision
Annual Meeting for Oral Cholera Vaccine
11 September 2019
IFRC, Geneva, Switzerland
Auditorium B**

Provisional List of Participants

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