GLOBAL TASK FORCE ON
CHOLERA CONTROL

REPORT OF THE

6TH MEETING OF THE GTFCC WORKING GROUP ON ORAL CHOLERA VACCINE

3-4 DECEMBER 2019 | GENEVA, SWITZERLAND

Contents

List of acronyms and abbreviations 3
Note to the reader 4
Executive summary 5
Session 1: General Update from the GTFCC 6
Session 2: Overview of OCV campaigns in 2019 7
Session 3: Lessons learnt from the field on OCV campaigns 8
Session 4: Integration of OCV and WASH 10
Session 5: Optimising the use of OCV 13
Group 1: Prioritizing hotspots for vaccination 13
Group 2: Criteria for accessing the OCV stockpile 14
Group 3: Process 15
Session 6: Update on vaccine supply and development 17
Discussion 18
Session 7: Current research projects 19
Session 8: Defining research questions 21
The cholera research agenda 21
Results of the survey on priority research questions 21
Appendix 1: meeting agenda 24
List of participants 28

List of acronyms and abbreviations

BIBCOL	Bharat Immunologicals and Biologicals Corporation Limited
CATI	case-area targeted intervention
CORT	community outbreak response team
CTC	controlled temperature chain
DALY	disability-adjusted life year
DFID	UK Department for International Development
DRC	Democratic Republic of Congo
EMA	European Medicines Agency
EPI	Expanded Programme on Immunization
FAO	UN Food and Agriculture Organization
FDA	United States Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunization
GTFCC	Global Task Force on Cholera Control
icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh
ICG	WHO International Coordinating Group on vaccine provision for cholera
IDP	internally displaced population
IFRC	International Federation of Red Cross and Red Crescent Societies
IVI	International Vaccine Institute
MR	measles-rubella vaccine
MSF	Médecins sans Frontières
NCP	national cholera plan
OCV	oral cholera vaccine
OIC	Organisation of Islamic Countries
OPV	oral polio vaccine
PCR	polymerase chain reaction
RFP	request for proposals
SDGs	sustainable development goals
TCV	typhoid conjugate vaccine
THSTI	Translational Health Science and Technology Institute
UN	United Nations
UNICEF	UN International Children's Emergency Fund
US CDC	US Centers for Disease Control and Prevention
WASH	water, sanitation and hygiene
WHO	World Health Organization

Note to the reader

This report condenses discussions according to the subjects addressed, rather than attempting to provide a chronological summary. The summaries of the discussions and group work address the themes emerging from wide-ranging discussions among all speakers, and do not necessarily imply consensus.

Summaries of presentations and of points made in discussion are presented as the opinions expressed; no judgement is implied as to their accuracy or otherwise.

Executive summary

The sixth meeting of the Global Task Force for Cholera Control (GTFCC) Working Group on Oral Cholera Vaccines (OCV) took place in Geneva on 3-4 December 2020. The meeting objectives were as follows,

- To provide an update on the progress with *Ending Cholera—A Global Roadmap to 2030* ("the roadmap")
- To review the implementation of OCV campaigns globally
- To discuss mechanisms for accessing the OCV stockpile going forward
- To review the current and future supply of and demand for vaccines
- To refine and prioritize the OCV research agenda, including for the development of new vaccines

After assessing the achievements of the past year, discussing feedback from country representatives on their OCV campaigns, and hearing updates from partner agencies, vaccine developers, researchers and funders, the group defined a list of tasks to be addressed in the coming year. These included,

- Achieving consensus on the conditions and procedures for accessing the OCV stockpile
- Reviewing success stories of OCV implementation and using them to help support further campaigns
- Continuing work on the integration of OCV with provision of safe water, sanitation and hygiene (WASH)
- Strengthening cholera surveillance in countries and globally, and monitoring and evaluation of OCV campaigns
- Further development of the OCV research agenda in partnership with the Wellcome Trust, and identification of further opportunities to implement research

The presentations made at the meeting can be found here:

https://www.fondation-merieux.org/en/events/6th-gtfcc-working-group-on-oral-cholera-vaccine-meeting/

Session 1: General Update from the GTFCC

Speakers: ***Frew Benson****, GTFCC Chair;* ***Dominique Legros****, GTFCC Secretariat;* ***Kashmira Date****, OCV Working Group Chair*

The opening session was made up of a welcome from Frew Benson; an update on the work of the GTFCC Secretariat from Dominique Legros; and an update on the activities of the OCV working group from Kashmira Date.

Overall, there has been progress in the two years since *Ending Cholera—A Global Roadmap to 2030* was launched- more countries are declaring cholera and engaging in prevention and control, and cases and deaths have begun to fall—in many countries. Oral cholera vaccines (OCV) have played a major role in this - since the creation of the OCV stockpile, nearly 60 million doses have been delivered in 22 of the 48 countries that declared cholera in the same period. Six years ago, OCV was not considered a key intervention in the fight against cholera; today, it is used in every cholera outbreak, and successful examples of vaccine use include multiple endemic, epidemic and humanitarian emergency response situations, including recently after cyclone Idai in Mozambique and in Sudan. The OCV working group has played a key role through advocating for the use of OCV at the country, regional and global levels, developing clear, practical guidance for use in the field, and implementing critical research projects.

Oral cholera vaccines are still a relatively recent intervention about which there is still much to learn. Close collaboration, mutual trust and transparency will remain central to continued success. There is a great deal to do, not least in bringing down last year's figure of 3 000 preventable cholera deaths, responding to key research questions, ensuring equitable access to the OCV stockpile, and implementing campaigns. Remaining issues include the quality of reporting in many cholera affected countries, how to react when an outbreak occurs in the middle of implementing a long-term national cholera control strategy, how to improve data on incidence and sustainability, how to engage countries in preventive campaigns, and how to ensure that water, sanitation and hygiene (WASH) programmes are implemented after successful vaccination campaigns.

Since the last meeting, there have been important progress updates from vaccine manufacturers on package insert approvals and updates on use and production plans; the development of a framework for national cholera plans (NCPs) that includes OCV and monitoring and evaluation; production of draft technical guidance on integrating WASH and OCV (in collaboration with the WASH working group); initial prioritization of the research agenda and calls for proposals from the Wellcome Trust and the UK Department for International Development (DFID); and further progress in defining the Gavi – The Vaccine Alliance (GAVI) 2019-20 strategy for support and vaccine investment.

Despite the unreliability of epidemiological data, there is cause for cautious optimism. Reported cholera burden and deaths decreased in 2019 compared to 2018. However, many countries continue to report high incidence and mortality that need to see more progress. While it may not be possible to predict how the current progress will continue, the trends seem to be moving in the right direction. The way forward is to,

- advocate and engage countries not yet on board;
- develop the GTFCC operational model to provide better country support;
- ensure a strategic vaccine supply, tailored to needs, and use it in a strategic, preventive manner;

and

- support countries in implementing the cholera roadmap by reinforcing surveillance and targeting hotspots with multisectoral interventions, including OCV and sustainable longer-term WaSH and integrating/linking OCV and WaSH interventions.

Session 2: Overview of OCV campaigns in 2019

Speakers: ***Malika Bouhenia****, GTFCC Secretariat;* ***Eduardo Vargas Garcia****, Secretariat of the WHO International Coordinating Group on vaccine provision for cholera (ICG);* ***Ruben Jamalyan****, UN International Children's Emergency Fund (UNICEF) Supply Division*

Ms Malika Bouhenia provided an overview of the OCV requests received and campaigns implemented in 2019. Requests for OCV have increased steadily over the years. OCV requests for preventive campaigns (via the GTFCC) in 2019 decreased and emergency requests through the WHO International Coordinating Group (ICG) markedly increased - 2019 saw an unusually high number and proportion of ICG requests.

About, 50% of dose requests were approved this year. Several requests were not approved for multiple reasons – 1) countries submitted requests too late in emergency contexts, 2) many requests were made through the wrong mechanisms, applying for ICG requests outside of emergency situations and 3) an insufficient number of vaccines in the stockpile to meet them all. The number of doses shipped per year is climbing steadily, and the stockpile "continues the virtuous cycle of increased supply, increased demand, increased use, increased supply." At the time of the meeting, 23.5 million doses had been shipped in 2019 (compared with 17,8 million in 2018).

Dr Eduardo Vargas Garcia provided more detail on ICG requests and Ruben Jamalyan gave an update on vaccine shipment by the UNICEF Supply Division. 2019 was the year with the highest number of ICG requests—18 in total at the time of meeting (compared to 12 in 2018). Only half the requested doses have been approved by the ICG: of the six rejected requests, four came too late, and two were judged to be low risk for cholera outbreaks. Partially approved requests were because of low vaccine supply in two cases, and once because of an excessively wastage rate. Shipping targets are not yet being met (with an average of 11.8 days instead of the targeted seven), for a range of reasons: countries taking time to be ready; rainy seasons delaying implementation; other emergencies (such as Ebola crises) removing resources; and those times when other vaccinations take precedence. UNICEF SD has the capacity to ship vaccines in 5-7 days. The capacity of countries to receive and stock vaccines is an important factor.

When there are not enough doses to meet demand, the ICG members may ask countries to target emergency populations, with the greatest need. Whole districts cannot be targets; it must be small parts of the population. Where operational costs are the barrier to implementation, advocacy is important—and where the country has emergency funds, these can be used as a stopgap. Another example of difficulties, from Cameroon, occurred when the UNICEF Supply Division shipped all 1.2 million doses of a request simultaneously, though only 600 000 were needed for the first round of the campaign and there was insufficient cold chain capacity to store them all. When the UNICEF Supply Division was informed about the capacity shortfall, shipments were adjusted—in this case, communication was the problem.

Strengthening focal points in countries can solve many of these issues—the capacity for rapid response to vaccine derived poliovirus is an example of how quickly systems can move when there are people on the job.

Data suggests that emergency use is probably not the best use of vaccine: it takes too long to request and implement: while GTFCC requests for preventive campaigns declined in 2019, they still represent the better use of the stockpile. And while there are different modalities of deployment, there is only one stock of vaccine, whether it is used for emergency outbreak or preventive campaigns. The mechanisms for requests and distribution should be adjusted to reflect this better.

There has been a significant increase in supply since 2013 (of 8 to 10 times); as of the time of the meeting, 23.5 million doses procured in 2019, representing a 32% increase in comparison to 2018 (17.83 million doses). Availability from suppliers is increasing, and from the point of view of the UNICEF Supply Division supply to emergency outbreak and preventive campaigns is managed as one task, with different modalities for deployment.

Session 3: Lessons learnt from the field on OCV campaigns

Facilitator: ***Myriam Henkens****, Médécins sans Frontières*
Speakers Panel 1: ***Nadège Taty Makuntima****, Programme National d'Élimination du Choléra et de lutte contre les autres Maladies Diarrhéiques (PNECHOL-MD), Democratic Republic of Congo;* ***James Onah****, National Primary Health Care Development Agency, Nigeria;* ***Awad Omer****, Federal Ministry of Health, Sudan*
Speakers Panel 2: ***Beyene Moges****, Ethiopian Public Health Institute;* ***José Paulo Langa****, Ministry of Health, Mozambique;* ***Tajul Bari****, icddr,b*

This session was composed of two panels. The first panel discussed timing of OCV campaigns, and the second looked at the benefits, constrains and duties associated with accessing the OCV stockpile. The six speakers explored examples of OCV campaigns from a number of different countries.

During the first panel, Nadège Taty Makuntima outlined the 2019 operational response to cholera in in Democratic Republic of Congo (DRC), and James Onah explained the OCV and WASH strategy in Nigeria, with particular focus on the identification of hotspots and the use of the vaccine throughout 2018-19. Awad Omer presented Sudan's experience of an OCV Campaign in the Blue Nile & Sennar States in 2019.

On the second panel, Beyene Moges described cholera vaccination in Ethiopia, where an outbreak that started in April 2019 had affected 61 districts by the time of the meeting. José Paulo Langa outlined the history of cholera, OCV use and WASH components in Mozambique; and Tajul Bari presented the experience of the pre-emptive OCV campaign to date, which prevented an epidemic of cholera in the humanitarian crisis unfolding at Cox's Bazar in Bangladesh. Across all of these experiences, a range of common challenges and responses were noted.

Resources, and human resources in particular, were highlight as key to roll out effective campaigns. The lack of sufficient and/or trained people can be a barrier in several areas of a campaign, especially at subnational level. It is important in the fieldwork of campaign administration and is also a factor in the development and signature of vaccine requests, which is a time-consuming process. Other issues include crowded programme calendars that leave little space for effective work, and domestic bureaucracy and infrastructure. Disbursement of funds for implementation can take too long, and logistics pose inevitable

problems, especially in isolated and/or insecure areas, with cold chain management a perennial problem. Sometimes the delay between vaccination rounds is too long, for a number of reasons, including problems with vaccine availability.

Surveillance remains an important issue. Decisions to request vaccines are based on the prevailing epidemiological situation in affected areas, and often the surveillance and the evidence are not strong. Demographic information is equally important: in the example of Ethiopia, planning was inaccurate due to a disparity between the estimated population and the actual population by the time the campaign was implemented: the process took so long that the population initially targeted was not the same when the campaign was conducted.

There are also issues around mapping hotspots—this is generally done at district level, but it is known that real hotspots are at sub-district levels, so there is a good chance that vaccine requests based on district level assessments are excessive. From a practical point of view, however, it can be hard to provide more granular information, either because of a weakness of systems or because of other dynamics—as in the example of Nigeria, where people will commonly travel to vaccination campaigns from other areas when they hear about an opportunity to access vaccines.

Context specific barriers need to be assessed and countered. In some countries preventive campaigns will be needed in response to the geopolitical situation, as in Bangladesh, which saw a huge pre-emptive vaccination campaign prevent an epidemic of cholera in the humanitarian crisis among Rohingya refugees in Cox's Bazar: this was an emergency (ICG) request made before the cholera emergency had actually occurred (though a humanitarian emergency was certainly already happening). Other countries will need to consider the best time of year for implementation, to align with seasonal outbreaks where possible and to conclude second doses in targeted communities before the onset of the cholera season. In others, the difficulty will be in dealing with mobile populations, or confronting cultural barriers—for example, in Sudan the women in some target populations are not allowed to leave their homes to go to vaccination sites. Given the logistical difficulties of conducting two rounds of vaccination, particularly in unstable areas, it is inevitable that some people will only be vaccinated once. This is acceptable when the goal is to protect the entire population; and it is important not to use the lack of a first round dose as a reason to refuse anyone a second-round dose. Ideally, nobody who presents for vaccination should be refused.

Transparency and commitment from high levels of government provide a solid basis for domestic action, and also help focus the technical and financial support of the international community. A good team among all stakeholders—government and partners—is required for countries to prepare properly for campaign implementation in short time periods (especially relevant in outbreak responses). Support from national stakeholders outside health can be particularly helpful in reaching target populations.

Measures to improve the effectiveness of campaigns include systematic implementation of WASH activities—including risk communication—before, during and after vaccination, with a particular focus on high-risk areas; impact studies of vaccination in provinces already vaccinated; strengthening epidemiological and (especially) biological surveillance after vaccination; and promoting preventive vaccination in high risk areas. Advocacy is important, both to ensure adequate national vaccine stocks for preventive campaigns, and to strengthen WASH activities before, during and after vaccination.

Vaccination shortages can be exacerbated if an outbreak occurs. The use of doses allocated for preventive campaigns to respond to outbreaks in cholera hotspots is theoretically interesting if the country has the bandwidth to reallocate vaccinations in response to outbreaks; but it can be complicated politically if—for example—there are vaccination commitments to provinces that are then not fulfilled.

The Nigerian presentation contained a helpful list of strategic areas in which building capacity can increase the chances of success in controlling cholera. These were: leadership and coordination; epidemiological surveillance; laboratory surveillance; case management; social mobilization/risk communication; improvement in the supply of safe water, sanitation and hygiene; and the use of OCV.

Ultimately, a key part of the issue remains the fact that there are not enough vaccines in the stockpile, and all campaigns have to confront choices about how best to use those that are available. In this context, the shared role of the ICG and GTFCC is to ensure that the stocks requested are used where they will make a difference, and to refuse the requests that will not have an effect.

ICG requests must come early enough that it is possible for vaccination to make difference and for doses to be properly spaced—it is necessary to plan as often as possible for protection with two doses. Countries have to collaborate in maintaining these standards, ideally using vaccines where they are supposed to, and if not, then making sure that they inform the ICG/GTFCC of any use in a different situation.

Cholera is an epidemic-prone disease that is difficult to forecast. Hotspots can be identified, but it is still unpredictable, and a high level of flexibility is needed. There are too many emergency (ICG) requests and not enough GTFCC ones: this needs to change, because it makes predicting the need very difficult and greatly complicates the supply side of the equation. To support this flexibility, a high level of control over the stockpile is also needed, because the number of doses is limited and it is important to retain the capacity to react to unforeseen events. The examples shown demonstrate an ongoing struggle balancing the demands of maintaining the stockpile, responding to emergencies and managing other demanding situations.

Session 4: Integration of OCV and WASH

Speakers: ***Monica Ramos****, UNICEF;* ***Robert Fraser****, International Federation of Red Cross and Red Crescent Societies (IFRC);* ***Maurice Mwesawina****, Malawi Ministry of Health;* ***Abraham Mwanamwenge****, WHO Zambia*

Presentations in this session covered a range of topics, including an overview of the rationale for integration of OCV and WASH; the work of One WASH to promote a common approach to long-term sustainable WASH programmes among National Red Cross Red and Crescent Societies; prioritizing interventions in cholera hotspots; and country case studies from Zambia and Malawi.

Monica Ramos opened by presenting on the integration of WASH and OCV, addressing the rationale, the research, and a range of practical considerations for implementing and monitoring integration efforts.

OCVs can serve as an entry point for engaging communities around WASH, advocating for investment in WASH infrastructure, and getting people in the field to understand the complementarity of the two, in both endemic and epidemic settings.

A recent GTFCC desk review has shown limited reporting of WASH progress across countries. While some countries highlight the linkages between WASH and OCV as part of their campaigns, and most have detailed WASH plans, there is a lack of a systematic approaches across countries for planning, implementation and monitoring of integration of WASH with OCV. Actions for more systematic integration

might include: increasing the WASH detail required in the OCV request template; systematic reviews of integration after each campaign; regular reporting on progress or planning; mapping of WASH interventions in cholera hotspots; and setting baselines for WASH access and conditions in all cholera hotspots.

Integration in emergency campaigns is not easy, with funding, time pressure, and scarcity of human resources all posing challenges. To counter these, personnel for WASH and community engagement could be included in vaccination teams; local and national coordination are key; and monitoring is crucial.

Beyond the emergency context, medium and longer-term interventions and WASH investments in cholera hotspots should be informed by findings from WASH assessments, and linked to advocacy and fundraising efforts as part of national cholera plans.

Country experiences presented by Maurice Mwesawina (for Malawi) and Abraham Mwanamwenge (for Zambia) revealed a range of barriers to implementing WASH activities during OCV campaigns, including,

- inadequate human, material and financial resources;
- technical errors (like the example of poorly executed chlorination in emergency water supply tanks that discourage people from using the water);
- bureaucracy and poor coordination hampering collaboration between local and national authorities;
- failure to find sustainable solutions for particular contexts;
- difficulties dealing with mobile populations;
- seasonal flooding;
- cultural barriers inhibiting campaigns (such as the belief that cholera is due to witchcraft);
- resistance to behaviour change; and
- the fact that some hotspots have no WASH partners.

A number of solutions were presented and include,

- resource mobilization for WASH;
- intensified community engagement;
- enhanced coordination and collaboration with national partners (like using the military to clean up hotspots and unblock drains or working with the private sector to provide emergency infrastructure);
- provision of safe water points;
- enhancing sustainability through capacity building of community water point committees and workers who facilitate WASH in communities; and
- strengthening surveillance.

Most line ministries dealing with WASH will have a medium to long-term plan, and countries working towards the sustainable development goals (SDGs) should have all relevant stakeholders feeding in; but the situation can be complicated by an excess of external organizations bringing money and people into countries to do WASH activities. This is why national cholera control plans are important in laying out clear strategies for WASH integration.

Robert Fraser presented the One WASH project, which is implemented in cholera hotspots in difficult contexts and which aims to increase knowledge around OCV and WASH; decrease barriers to OCV; improve surveillance and response; and invest in long term sustainable WASH projects and infrastructure. It is currently the only existing major project that targets cholera hotspots with WASH activities.

The standard approach follows two axes of intervention. Hotpots are likely to see more outbreaks and epidemics during the implementation period, so the first stage is to increase interaction with target populations and carry out community surveys to identify barriers to behavior change and OCV acceptance; to roll out rehydration kits and pushing the concept of oral rehydration salts; and to cover community cholera response as well as possible, working with community groups in the health system that can recognize cholera and react appropriately before international teams arrive. The second axis is the long-term one: conventional, developmental WASH delivery. It follows standard approaches: if a hotspot has WASH coverage of 50%, the goal is to raise it to minimum of 80%, using sustainable, proven WASH mechanisms that the project has already used to supply water to between 50 and 80 million people over recent years. For sustainability to be tenable, the recipient communities—even the poorest—have to be able to afford these services.

In partnership with the Organisation of Islamic Countries (OIC), One WASH has initiated a project cycle for a number of national interventions in OIC countries. Country proposals have been collected and analysed, with a view to completing more detailed project proposals by June 2020.

In reactive OCV campaigns, it is important that partners continue to ensure that WASH activities are implemented and supported in hotspots, and that attention is given to how WASH can support OCV. GTFCC is making progress in trying to identify the minimum package for linking WASH and OCV in emergency contexts, but this is not the solution: the required technology and approaches in the short term are very different to what is needed for the long term. Long term, sustainable WASH comes at a cost of about USD 45-50 per person.

At the end of the session, Dr Zeenat Patel from announced that GAVI is currently performing a funding policy review and considering removing all co-financing requirements, not only for cholera but also for all other campaigns. If this happens, it elevates the importance of the work of the OCV working group. The requirements exist in order to ensure that vaccines are used judiciously, and if the co-financing mechanism is judged to be too harsh, it will still be necessary for the group to make sure that vaccine eligible hotspots are clearly defined. The epidemiology working group has produced a good draft document on defining and identifying hotspots.

Session 5: Optimising the use of OCV

Group facilitators: ***Francisco Luquero****, Epicentre;* ***Dominique Legros****, GTFCC;* ***Imran Mirza****, UNICEF*

This was a group work session that explored how to target OCV and ways to achieve a more robust application process for accessing the stockpile. As an introduction, Dr Francisco Luquero presented the methodology used to identify cholera hotspots.

Cholera has two main epidemiological profiles: endemic areas and hotspot areas. Hotspots are "a geographically limited area (such as a city, administrative level or health district catchment area) in which environmental, cultural and/or socioeconomic conditions facilitate the transmission of cholera, and where it persists or re-appears regularly," and prioritizing interventions in hotspots is not easy.

Hotspots should be defined based on epidemiologic indicators alone (the two recommended indicators are the historical incidence of cases and the persistence of cholera in the area, with five years of data recommended for analysis), and prioritized and targeted by national cholera plans. The situation analysis and identification of priority areas for intervention should form part of a dynamic national process with an initial baseline assessment and annual monitoring and updating. The best information for prioritization can come from local teams in communities who interact regionally and then take information up to national level—it is arguably the best process for initial identification of hotspots, but it needs to be backed up with epidemiological data.

Identifying hotspots is complex work with a number of considerations. These include the use of a tool to identify hotspots and rank them in each of its categories according to incidence; building and ensuring the laboratory capacity required to underpin the process; identifying vulnerable areas and maintaining the equity principle (risk for cholera may affect areas with little cholera transmission but other factors that might precipitate its introduction or re-emergence, and it is important to include these areas in targeted interventions); and quantifying and planning for contextual factors such as inaccessible areas, displaced populations, and cross-border at-risk zones. All of this work will be affected by OCV supply constraints, and the fact that the populations of many current endemic areas exceed vaccine production capacity. By the next working group meeting, it is expected that countries will be reporting on their progress targeting hotspots in national plans.

Group 1: Prioritizing hotspots for vaccination

The group was led by Francisco Luquero and discussed questions such as the use of thresholds versus more contextual, country by country decision–making, and how to ensure equity between and within countries. The following key conclusions were reached.

- The key indicators for hotspots are high incidence and persistence of cholera.
- Additional criteria for OCV targeting include laboratory confirmation (which will soon be the norm) and use of a vulnerability index that considers factors such as displacement, poverty and proximity to other hotspots (especially those with cross border issues).
- Measures to help identify recommendations once a hotspot is identified, and to ensure supply, include:
    - analysis to help show whether hotspots fit with the figures; and
    - alignment of activities with those of the surveillance working group.
- In the longer term, it should not be possible to keep requesting vaccinations for places without

laboratory confirmations (though the time criteria for this requirement are unclear).

- Universal thresholds cannot be used. They often mean that those who do not meet their criteria are deemed unimportant, and this results in deaths. Very rarely will countries pay to address problems not considered "big enough."
- The ranking of need should be done in countries, and countries should decide how to ensure equity.
    - The OCV working group should avoid being prescriptive in this discussion and should instead provide guidance showing what it considers high, middle-high and middle-low need, to help countries understand where their health system fits in the global context.
    - Health systems analysis should be predicated on areas of high incidence and high persistence.
    - WHO should provide guidance on testing schemes to establish the burdens of disease in health systems.
- While it is not desirable for *guidance* to be prescriptive, funders, by contrast, must be prescriptive—so, for example, if ranges are ranked into high, middle and low, they might prioritise high range areas for support.
- Middle to lower range areas should really be focusing on WASH investments and other additional components of the response.
- Implementation criteria could also be used flexibly—for example, to allow for big requests from countries with very large at-risk populations that have good rationale for vaccination, proportional timing for implementation, and a feasible, equitable plan for doing it.

Group 2: Criteria for accessing the OCV stockpile

Participants in this group, which was led by Dominique Legros, felt principally that it is necessary to advocate for planned campaigns rather than emergency requests, and to have a clear series of criteria for campaigns and vetoes.

For planned vaccination requests, the following criteria should be considered:

- They should target highly endemic areas, with the presence of circulating *vibrio cholerae* in that area identified by culture or serosurveys
- Requests should be included as part of the national cholera plan (to ensure political will and engagement)
- Registration of vaccine in the country is a prerequisite.
- An official focal point should lead the request and remain in charge of following it up
- That focal point should ensure that other partners are engaged in the process

Vetoes for requests should be

- countries with no context for their request, and
- countries that do not officially report cholera

For emergency requests, criteria should be as follows

- Laboratory confirmation of cholera
- Risk factors review showing high risk in the target areas, based on conditions and historical data
- Weak capacity to implement control measures, meaning that outbreaks have to be prevented by vaccinating
- Engagement at the country level

Grounds for veto should include:

- Not officially reporting cholera;
- Inappropriate timing with regard to the outbreak; and
- A general lack of long-term cholera control planning (e.g. lots of emergency requests with no activity in between).

It might also be possible to have a cut-off based on the size of the request.

Work is commencing to estimate the proportion of emergency requests that have had successful impacts on outbreaks. Previous analysis in African countries shows that the median duration of an outbreak is three weeks—generally too short for vaccination to have much impact—and as previously noted, many emergency requests come too late.

Group 3: Process

The original idea was for this group, led by Imran Mirza, to discuss which request mechanism—the ICG or the GTFCC—to keep. The message emerging from this discussion was again the need to advocate for more planned campaigns rather than emergency requests; and if this is to be done effectively, there cannot be two entry points. There must instead be a single point of contact for requests, with countries using a single form, and as much as possible of the burden of the application being shifted from the countries to the GTFCC.

This was not, however, a unanimous conclusion. Some participants felt that the current logic is simple, change is unnecessary, and the systems should be left as they are, with improved guidance on their use.

Either way, it remains important that countries understand different types of vaccine use. Ultimately, the roadmap is country-driven, and vaccination should be a government-led part of national cholera plans, with requests based on strong capacity and good information. Rather than spend the entirety of the session discussing a completely new process for vaccine requests, this group, led by Imran Mirza, considered how best to refine the existing mechanisms, emerging with the following observations and conclusions.

- There are currently two mechanisms for OCV access, the ICG and the GTFCC. Many countries submit requests to inappropriate mechanisms (primarily the ICG), resulting in rejected requests that would have been accepted if the appropriate mechanism had been used. This situation is exacerbated by excessively lengthy timelines for processing GTFCC requests, making decisions and shipping vaccines. A revamped process is needed to encourage the shift of supply and programme implementation to planned/preventive OCV use—i.e. more GTFCC requests and fewer ICG ones.
- ICG and GTFCC application requirements and supporting documentation are currently different, and the criteria for which way the request should go are not always clear in the field. They need to be explained very clearly to all stakeholders, making sure that people know how things should be differentiated.
- It is important to determine what information is needed by the GTFCC Secretariat in order to advise countries on which mechanism to use, making sure that information requirements are not burdensome. Documentation requirements cannot be allowed to slow the process in outbreaks that require a rapid OCV response. (This approach was not unanimously supported within the group, as it was also emphasized that capacity and criteria should ideally be developed for

determination at country level).

- WHO country offices play an important triage role for countries, and in this regard should be more closely linked with the GTFCC Secretariat.
- Current guidance for ICG versus GTFCC requests is not clear enough and should be refined, including by clarifying that when countries apply for OCV through either mechanism, support is not guaranteed.
- A flow chart or decision tree would be helpful to determine ICG versus GTFCC requests: the existing decision tree document must be available on the ICG and GTFCC websites, supplemented with dissemination and awareness building at regional and country levels to ensure it is actively applied.

The overarching distinction between the two types of request is the distinction between emergency and non-emergency contexts. Mirroring and complementing the work of the previous group, criteria to determine the appropriate mechanism were defined to include:

- whether cholera transmission is ongoing, with laboratory-confirmed cases;
- the need for a contextually appropriate definition of an outbreak, including an excess of cases above background/ongoing incidence;
- whether cases are increasing or decreasing;
- whether suspected cases are still being recorded in the fortnight prior to the request; and
- whether there is a humanitarian situation or emergency with high risk of a cholera outbreak.

If all these criteria were to be met the country would be advised to develop an ICG request; if only some were met, a GTFCC request would be more appropriate.

Session 6: Update on vaccine supply and development

Speakers: ***Amit Kumar****, Shantha Biotec;* ***Julia Lynch****, International Vaccine Institute (IVI);* ***Gill Davinder****, Hilleman;* ***Juan Barriga****, Emergent BioSolutions*

In this session, the working group received an update on the current status of OCV supply. Participants were given information on the numbers of doses shipped and projections on future shipments, and a number of technical updates on improvements to current vaccines and development of new ones. Work is ongoing to commercialize processes designed to give a higher yield of vaccines.

Amit Kumar gave an update on vaccine production at Shantha Biotec (which produces Shanchol); while Gill Davinder did the same for Hilleman (Hillchol). Julia Lynch then presented the work of the International Vaccine Institute (IVI). IVI is vaccine developer and as part of its Cholera Programme—developed some vaccines and entered collaborations to increase supply, including through reformulation. The programme's goals are to ensure OCV supply by supporting manufacturers and creating new supply; to improve cholera vaccines; and to support vaccine introduction and use. On the supply front, IVI has two technology transfer projects working to increase vaccine production. The first, Cholvax, is predicated on technology transfer to Incepta. Phase 3 has met the primary end-point of non-inferiority to Shanchol, but technical issues have delayed registration in Bangladesh and application for registration is now not expected until 2020. Initial capacity for the vaccine is expected to be 4-6 million doses per year. The second project will, if successful, result in India having its own OCV manufacturing facility in a 3-5 year timeframe, producing 2-4 million doses per year. The goal is to build this capacity by transferring manufacturing technology to Bharat Immunologicals and Biologicals Corporation Limited (BIBCOL); to transfer technology and know-how to the Translational Health Science and Technology Institute (THSTI) to support clinical development and registration of the OCV in India; and to provide support for pre-clinical and clinical studies for OCV registration in India. While this number of annual doses will not meet all of India's needs, it is a starting point: companies that have not previously made vaccines need to learn process, control and quality management systems to build a foundation for later expansion.

IVI has also received a Gates grant to look at a simplified vaccine formulation that, if effective, could reduce OCV costs by 25% while increasing production capacity by 38%. This is the start of a three-year project with the potential to yield a new registered product at the end; IVI's intent would be to share the results with any manufacturer.

Work is also ongoing on a new cholera vaccine—currently, the predevelopment of cholera conjugate vaccine. This has the potential to be single dose injectable and might have a more durable response and increased protection in the age groups where OCV is weakest. It is combinable with other antigens and potentially complementary to OCV for use in mass vaccination campaigns. The technology for this vaccine is being transferred to Eubiologics as a manufacturing partner. Trial material is expected to be available for 2021 for the first human study of novel conjugate vaccine.

Juan Barriga of Emergent BioSolutions presented another option currently in development: VAXCHORA (cholera vaccine, live, oral). This vaccine has been approved by the US Food and Drug Administration (FDA) and is under registration in Europe, but is not yet approved by the European Medicines Agency (EMA). The effectiveness of VAXCHORA has not been established in people living in cholera-affected areas. Its

potential role in global control is unclear. It is currently focussed on travellers, but in the future will probably be available for younger children. The fact that the live vaccine organism is shed for seven days after administration raises questions about risk in endemic countries, in health care settings and around immunosuppressed patients. It is also worth noting that the FDA-approved vaccine was approved for maintenance in frozen conditions; it is currently in submission to FDA and EMA for management at higher temperatures.

Discussion

A wide range of points was raised in discussion.

- Influenza vaccine takes just a few months to get to market; it was suggested that OCV stakeholders might assess what it would require in regulatory terms to adopt a similar approach for cholera.
- Caution is required when changing formulations: studies have shown that some recent Ogawa strains are significantly different immunologically from the vaccine strain, for reasons that are not understood. If formulations are to be changed, ensured strains should be used.
- In streamlining the regulatory process, trying to lower costs and expand vaccine production quickly, it is necessary to be reductionist—taking things out, not putting new ones in.
- If new vaccines are to become available in 2-5 years, consumer countries are likely to have a number of questions around the future. They have already had "a long journey" regarding the use of current vaccines and will need to know clearly the added value and difference between vaccines. Questions that need to be looked at now include whether they will be prequalified by WHO and supported by GAVI and how much they will cost— "2-5 years is not far off." It is important to "agree the most stable one… that should be used as the new generation of cholera vaccine."
- There is a well-established system of the expanded programme on immunization (EPI) in countries that incorporate vaccines as they become available and recommended for use; OCV integration with EPI should be considered. This is an opportune time: WHO is working on a new immunization agenda, along with GAVI and the US Centers for Disease Control and Prevention (US CDC), and "[EPI] could be a strong collaboration that would make this whole movement much easier." The counterargument is that full integration would be hard; OCV requires targeted interventions in limited areas, not covering entire countries, and this makes the EPI connection challenging but should be considered in the context of different immunization platforms.
- Opportunities to link with other immunization platforms should also be considered. There are a number of ways to maximize such opportunities: coordinating risk assessments with EPI and doing combined assessments for polio, measles etc.; integrating OCV and measles vaccination campaigns; merging supply chains and logistics with other campaigns; using the EPI tool to assess cold chain capacity; and more. If these things can be coordinated there are big opportunities for cholera vaccines to achieve wider coverage and better equity.

Session 7: Current research projects

Speakers: ***Andrew Azman****, John Hopkins University;* ***Vittal Mogasale****, IVI;* ***Francisco Luquero****, Epicentre;* ***Firdausi Qadri****, International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b);* ***Kashmira Date****, US CDC*

Andrew Azman then presented the work of John Hopkins University, where a large group is addressing a range of areas related to OCV, improving understanding of the epidemiology, the genetics, the dynamics and how to use interventions better. A global database is being built up with data from across the world—maps, burden projections, impact of control, etc.—and should be accessible in 2020. Other work includes: study of global cholera epidemiology and burden (updating incidence maps with data through to 2019, building time-space maps in Africa, and estimating seasonality in sub-Saharan Africa); mapping cholera with cross-sectional serology; examining case studies to inform future interventions; modelling potential impacts of OCV; examining whether OCV can be used to eliminate cholera; combining genomic and epidemiological data to show a number of introductions into Africa from South Asia, illuminating how epidemics are linked; working to bring sequencing closer to the source, having genomic data generated in the field by the people who want it and enabling heightened precision in decision making around acute watery diarrhoea (is this cholera; if so, what type?") and how to target interventions to particular cholera types; doing dose-interval studies in Zambia and Cameroon; and evaluating a number of different diagnostics.

The IVI, presented in this session by Vittal Mogasale, is working on an evaluation of the impact and cost-effectiveness of the road map; a field based economic evaluation of OCV use in Malawi and Mozambique; and the development of Excel-based tools for costing OCV delivery and cholera treatment. For cost effectiveness analysis, stopcholera.org has the VICE calculator, a simple Excel-based tool that estimates the cost-effectiveness of oral cholera vaccination in various settings and under various implementation strategies, including mass and targeted vaccination campaigns. The calculator compares Disability Adjusted Life Years (DALYs) against the costs and health outcomes of cholera vaccination campaigns and is a useful planning tool: "not perfect, but it does a job."

Francisco Luquero explained Epicentre's work to finalize ongoing projects on controlled temperature chains (CTC) and self-administration of OCV, looking at vaccine coverage and effectiveness in Malawi; delayed second doses (looking at coverage surveys in Zambia and Malawi and immunogenicity data for eight-month delayed second doses in DRC); and indirect vaccine protection (examining absence of clustering of cholera cases in vaccinated areas of Lusaka). Ongoing projects include the UrgEpi project on rapid identification responses to measles and cholera outbreaks in ex-Katanga DRC; a performance study of three promising rapid diagnostic tests (Crystal VC O1, Cholkit O1 and SD Bioline O1/O139); a Wellcome-funded Project in DRC to measure the impact of OCV on hotspot settings, using clinical and serological surveillance to understand how transmission is modified in hotspots after vaccination; and ongoing collaborations with Institut Pasteur and Johns Hopkins University on molecular testing (polymerase chain reaction/PCR and whole genome sequencing) and serosurveillance methods.

With regard to second doses and the push for countries to reduce the time between doses, a balance must be struck. From an immunological perspective, delaying a second dose might—if anything—be a good thing, and would not decrease immune response. The pertinent issue is that delaying the second dose heightens the likelihood of dropout between doses and increases risk in the population: where there is transmission, incidence rises, especially in young children. But it is not well understood how fast the

second dose can be administered, and funders are unlikely to have a great appetite for big studies to clarify this.
Kashmira Date explained how the US CDC has been working on various areas of cholera prevention and control between different groups at CDC, including surveillance (epidemiology and laboratory),outbreak investigations, emergency response, WaSH, and OCV research, monitoring and evaluation. Regarding vaccines, there is an ongoing study of the safety and immunogenicity of Oral Polio Vaccine (OPV) and OCV when co-administered, which is showing good preliminary results for both safety and immunogenicity. Proposed future research includes leveraging the polio programme in selected countries to enhance cholera surveillance, and a coadministration study of OCV, measles/rubella (MR) and typhoid conjugate (TCV) vaccines looking at safety, immunogenicity and feasibility.

There is a need for evaluation studies to incorporate environmental surveillance data. Long term transmission cycles related to contaminated environments have been well described in Asia, but very poorly in Africa. There is a need for deeper understanding of how household environments affect transmission (through flooding, contamination of wells, cross environmental contamination, contamination of reservoirs and so on); there is some effort in this area with regard to typhoid, and it would be helpful to leverage the resultant opportunities. That said, detection of cholera in the environment is not easy. In 2013, for example, IVI was involved in a small (unpublished) environmental survey study of cholera in northeast India that found “very few” positives in samples from lakes, pumps and other water sources despite the fact that it focused on areas where cholera cases were found. If limited funds are available to measure the impact of OCV, environmental surveillance might not be the best way in which to spend it. The most important goal remains the lowering of incidence.

Firdausi Qadri presented Bangladesh’s recent cholera prevention efforts and plans to implement OCV and control cholera in the coming years. The presentation covered a number of research elements including recent OCV studies on feasibility and effectiveness in urban endemic settings; efficacy of a single dose regimen; efficacy of vaccine stored at elevated temperatures; and emergency deployment of OCV to populations of Rohingya refugees. One challenge in measuring impact is always the need for a place with a counterfactual, and Bangladesh is one of those places—there is always cholera, and phased implementation provides many opportunities to measure impact. Expanded surveillance in Bangladesh could help capitalize on this huge incidence. With regard to the vaccination choice for the country’s cholera control plan, it was mentioned that Hillchol could be fill-finished by a local producer in Bangladesh.

Session 8: Defining research questions

The cholera research agenda

Helen Groves *and* ***Elizabeth Klemm****, Wellcome Trust*

The Wellcome Trust is well placed to assist the GTFCC in coordinating research and to help ensure that the evidence needs of the cholera community are identified and met, and that there is better, more evidence-based use of OCV. Part of this work has been the process, starting in 2018, of developing a research agenda aligned with the roadmap. Successful implementation of the roadmap will mean identifying evidence gaps and prioritizing (and communicating) research to fill those gaps in order to guide researchers and funders; helping policy-makers incorporate research into their National Cholera Control Plans; improving the interim research agenda; helping ensure greater involvement of researchers with the GTFCC working groups; and incorporating the evidence needs of implementation specialists and policy makers into research.

There are several activities in the research prioritisation process, including defining the objectives of the activity; developing strong partnerships with stakeholders, including the GTFCC Working Groups; engaging with stakeholders; identifying research questions (where the GTFCC will have an important role); defining the assessment criteria for each research question; ranking the research questions; and, finally, reaching a consensus on the research priorities—again, a point at which the GTFCC working groups will have critical input.

The next steps in this process are for the Wellcome Trust to visit the GTFCC working groups to spread awareness and encourage engagement with the development of the research agenda, and to identify individuals outside the GTFCC communities with whom to engage. For the GTFCC, the tasks are to identify research questions for each area; engage policy makers and implementers with the development process; and engage with third-party groups.

Results of the survey on priority research questions

A number of previous meetings and consultations have already helped refine the research agenda topics, including the GTFCC OCV Working Group Meeting in 2017; a stakeholder consultation on preferred product characteristics for cholera vaccines in 2017; a Wellcome Trust/DFID GTFCC research agenda scoping meeting in 2018; and a range of ongoing consultations with countries and partners. Known current knowledge gaps include questions around the impact of vaccination on disease transmission and trends; vaccine characteristics (including among children aged 1-5); OCV integration, both with WASH and with other immunization programmes; and the economics of OCV, including costing and cost-effectiveness in different settings and around delivery strategies.

A short survey of GTFCC members on priority research questions asked two simple questions—

- Please list the top three short term research questions (in the next 1-3 years)
- Please list the top three medium term research questions (in the next 3-5 years)

—and the preliminary results were as follows.

- Vaccine effectiveness and duration of protection was the most popular short-term research topic. Particular research areas noted in this sphere included:
    - understanding of dose interval strategies;
    - the level of protection of breastfeeding infants in mothers who have received OCV;
    - duration of protection at community level following mass vaccination campaigns in different settings;
    - understanding when to use a single dose rather than two; and
    - opportunities for one-dose rather than two-dose vaccination schedules.
- OCV and WASH integration was the next most popular area, with questions including:
    - barriers to WASH investment at scale to compliment OCV use; and
    - the added value of WASH interventions at time of OCV administration.
- Other topics included:
    - comparative effectiveness of CATI (case-area targeted intervention) versus OCV;
    - what strategies are effective for OCV in emergency and insecure contexts;
    - whether seroepidemiology can be used to define hotspots in countries with poor microbiological surveillance capacity;
    - maximizing the efficiency and benefits using of CTC with OCV out of the cold chain;
    - vaccine market research and price-determining factors;
    - what OCV does *not* deliver in long-term cholera elimination;
    - cultural and contextual barriers to OCV acceptance;
    - different delivery approaches; and
    - whether seroepidemiology can be used to define hotspots in countries with poor microbiological surveillance capacity.

After a long period of discussion of the areas above, and the draft Wellcome Trust agenda, the priority research areas were further clarified by the working group as follows:

- Vaccine effectiveness and duration of protection
    - Vaccine effectiveness and scheduling in children
    - Factors influencing vaccine effectiveness in infants and children
    - The use of single dose regimes (a) in children and (b) at different endemicity levels
- Social science: defining barriers to OCV acceptance
- Alternative vaccine strategies—e.g. through health care workers, CTC and self administration
- Vaccine impact
    - As part of CATI, community outreach response teams (CORT) and/or delivered by rapid response teams
    - Outbreak response versus longer term campaigns
- Cost effectiveness
- Administration and integration
    - Integration with other interventions, including for malaria (provision of prophylaxis and bednets), measles, polio and WASH packages
    - Integration with programmes for refugees, internally displaced populations (IDPs) and nomadic and other special populations—including screening components for refugees
- Targeting
    - Better mapping
    - Study of natural immunity
    - Use of seroepidemiology and new surveillance models
    - Level of protection of vaccines
- CTC benefits and costs
- Dosing intervals and boosters

Closing session and agenda of work

Before closing the meeting, a brief agenda of work was presented to the group. The main tasks for the working group in the coming year will be as follows:

- To clarify the conditions around accessing the OCV stockpile
- To disseminate appropriate guidance on hotspot identification and prioritization
- To clarify the criteria and process for OCV requests and review of the requests
- To review success stories of OCV implementation, identify the lessons contained therein, and support in ensuring timely implementation of OCV campaigns
- To continue work on the integration of OCV and WASH, with appropriate priority also given to strengthening surveillance (the WASH working group will meet in March 2020 and the OCV group should be prepared to work with them on this)
- To strengthen the monitoring and evaluation of OCV campaigns
- To continue to develop the OCV research agenda, in partnership with the Wellcome Trust, taking forward the issues identified in this meeting and supporting the Trust in responding to them
- As OCV campaigns are implemented to continue robust M & E and identify opportunities to implement research (especially through impact studies)
- To develop advocacy material for OCV use in countries.

Dominique Legros closed the meeting with his thanks to the participants and more broadly to the partners of the GTFCC. He acknowledged the strong dedication and close collaboration of countries and partners that made possible the progress accomplished over the last few years. He pointed out that there is still a lot of work to do but it is achievable.

Appendix 1: meeting agenda

GLOBAL TASK FORCE ON CHOLERA CONTROL

Sixth Meeting of the Global Task Force for Cholera Control (GTFCC) Working Group on Oral Cholera Vaccines

3-4 December 2019

PRELIMINARY ANNOTATED AGENDA

TUESDAY 3 December

Session	Content
8.30-9.00	**Welcome and Registration**
9.00-9.30	**Session 1: General Update from the GTFCC** *During this session the GTFCC secretariat and the chair of the working group will present the progress made since the last meeting of the working group as well as the key issues at stake that will be discussed during the meeting.* • Intro Chair GTFCC and ADG WHO – welcome participants • Presentation by GTFCC secretariat – Dominique Legros • Presentation by OCV WG Chair – Kashmira Date
9.30-10.30	**Session 2: Overview of OCV campaigns in 2019** *The first part of this session will take stock of the OCV campaigns that took place in 2019* • Overview of the OCV campaigns in 2019 – Malika Bouhenia • Update on 2019 ICG requests – Eduardo Vargas Garcia • Update on vaccines shipment – Ruben Jamalyan
10.30-11.00	**Coffee Break**
11.00-12.30	**Session 3: Lessons learnt from the field on OCV campaigns**

	Panel members will discuss important matters related to the implementation of OCV campaigns such as the time to implementation, type of requests submitted as well as the availability of OCV doses. Facilitator: Myriam Henkens **Panel 1: Timing of campaigns** • Nadège Taty Makuntima, DRC • James Onah, Nigeria • Awad Omer, Sudan **Panel 2: Accessing the OCV stockpile: benefits, constrains and duties** • Beyene Moges, Ethiopia • José Paulo Langa, Mozambique • Firdaudi Qadri, icddr,b
12.30-13.30	**Lunch Break**
13.30-14.30	**Session 4: Integration of OCV and WASH** *During this session participants will reflect on how the OCV campaigns can be used to trigger WASH investments and medium to long term WASH planning in cholera hotspots.* • Integration of WASH and OCV during emergency campaigns – concept note and desk review - Monica Ramos • One WASH – Robert Fraser, IFRC • Example of WASH activity implementation during an OCV campaign – Maurice Mwesawina, Malawi • Example of WASH activity implementation during an OCV campaign – Zambia
14.30-15.00	**Coffee Break**
15.00-17.30	**Session 5: Optimising the use of OCV** *Taking stock of the discussions and presentations, this group work session will aim at further defining how OCV is targeted and outlining a more robust application process for accessing the stockpile.* Group work (2 hours): - Hotspots prioritization – Facilitator: Francisco Luquero - Criteria for accessing the stockpile - Facilitator: Dominique Legros - Process - Facilitator: Imran Mirza

	Feedback from the group work in plenary (30 minutes)
17.30	**End of Day 1**

WEDNESDAY 4 December

9.00-9.30	**Summary of Day 1**
9.30-10.45	**Session 6: Forecast demand and supply of OCV** *This session will provide an update on the current status of OCV supply and present a tool developed to forecast OCV demand.* • Update on vaccines production – Julia Lynch, IVI • Update on vaccines production – Amit Kumar, Shantha Biotec • Update on new vaccines – Gill Davinder, Hilleman • Update on new vaccines - Juan Barriga, PaxVax
10.45-11.15	**Coffee Break**
11.15-12.45	**Session 7: Current Research projects** *During this session, research studies that contribute to advancing the agenda of the OCV working group will be presented.* • Andrew Azman, John Hopkins University • Vittal Mogasale, IVI • Francisco Luquero, Epicentre • Tajul Bari, icddr,b • Kashmira Date, US CDC
12.45-14.00	**Lunch Break**
14.00-16.00	**Session 8: Defining research questions** *During this session, participants will review the results of a short survey on research priorities for the OCV working group and agree upon next steps for moving forward the OCV research agenda.* • Cholera Research Agenda – Wellcome Trust • Presentation of the results of the survey on priority research questions Discussion
16.00-16.30	**Coffee Break**

16.30-17.00	**Agenda of work** **Closing**

List of participants

CHAIRMAN OF THE GTFCC

Frew Benson, Chief Executive Director, National Department of Health, South Africa

REPRESENTATIVES FROM COUNTRIES

Cameroon

Adidja Amani, Director of Vaccination, Ministry of Public Health

Democratic Republic of Congo

Dr Nadège Taty Makuntima, PNECHOL-MD, Ministry of Health

Ethiopia

Beyene Moges Agizie, Deputy Director General, Ethiopian Public Health Institute

Malawi

Maurice M'Ban'Ombe, Disease Surveillance Officer, Ministry of Health

Mozambique

Jose Paulo Langa, Head of Surveillance Department, National Institute of Health

Nigeria

James Onah, Head, Outbreak & Response Unit, Department of Disease Control & Immunization, National Primary Health Care Development Agency

Philippines

Theodora Cecile Magturo, Medical Specialist-IV, Food and Waterborne Disease Program Manager, Department of Health

Sudan

Awad Omer Mohamed, National EPI Manager, Federal Ministry of Health

GTFCC PARTNER INSTITUTIONS AND DONOR AGENCIES

Bill and Melinda Gates Foundation

Tanya Shewchuk, Senior Program Officer

US Centers for Disease Control and Prevention

Kashmira Date, Cholera and Typhoid Vaccines Lead

Emergent Biosolutions

Juan Jose Barriga-Garcia, Director, Medical Affairs Europe

EPICENTRE

Francisco Luquero, Deputy Director, Intervention Epidemiology

Fondation Mérieux

Cindy Grasso, Conference Organizer

Valentina Picot, Clinical Research Manager & Conference Manager

GAVI

Zeenat Patel, Head Vaccine Implementation
Adam Soble, Programme Manager
Margarita Xydia Charmanta, Senior Manager, Market Shaping

Hilleman Labs

Gill Davinder, Chief Executive Officer

United Nations High Commissioner for Regugees

Allen Maina, Senior Public Health Officer

Institut Pasteur

Marie-Laure Quilici, Head of the French National Reference Center for Vibrios and Cholera

International Centre for Diarrhoeal Disease Research, Bangladesh

Iqbal Hossain, Senior Scientist, Hospitals, Nutrition and Clinical Services Division
Tajul Islam Bari, Consultant
Firdausi Qadri, Senior Scientist, Enteric and Respiratory Infections, Infectious Diseases Division

International Federation of Red Cross and Red Crescent Societies

Robert Fraser, Senior Officer Water and Sanitation
Gwenn Eamer, Senior Officer, Public Health in Emergencies

International Rescue Committee

Michelle Gayer, Director Emergency Health

International Vaccine Institute

Jacqueline Lim, Research Scientist
Julia Lynch, Deputy Director General
Vittal Mogasale, Head Policy and Economic Research

Johns Hopkins University

Andrew Azman, Assistant Scientist
David Sack, Professor

Mass General Hospital Center for Global Health

Louise Ivers, Executive Director

Médecins Sans Frontières

Myriam Henkens, International Medical Coordinator

PATH

Simpson Evan, Senior Program Officer

SANOFI

Benjamin Merle, Product Planner

Shantha Biotechnics Private Limited

Amit Kumar, Senior General Manager-Commercial Operations

UNICEF Headquarters

Imran Mirza, Health Specialist
Monica Ramos, Coordinator, GTFCC WASH Working Group

UNICEF Supply Division

Ruben Jamalyan, Procurement Associate, Supply Division

UNIVERSITY OF GOTHENBURG

Jan Holmgen, Professor

WELLCOME TRUST

Helen Groves, Project Support Office
Elizabeth Klemm, Postdoctoral Fellow

WORLD HEALTH ORGANISATION

Zambia Country Office

Abrahams Mwanamwenge, Cholera Focal Point

Regional Office for Africa

Linda Haj Omar, Epidemiologist

Pan American Health Organization

Andrea Vicari, Advisor

Regional Office for the Eastern Mediterranean

Sherein Elnossery, Consultant

GTFCC Secretariat

Kathryn Alberti, Technical Officer
Malika Bouhenia, Technical Officer
Dominique Legros, Team leader
Margot Nauleau, Technical Officer
David Olson, Technical Officer

ICG Secretariat

Eduardo Vargas, Medical Officer

Immunization, Vaccines and Biologicals (IVB)

Maricel Castro, Technical Officer

Brian Atuhaire, Consultant

OTHERS

Mark Nunn, Rapporteur

* * *