
THIRD FACE-TO-FACE MEETING BETWEEN THE GLOBAL
CERTIFICATION COMMISSION - CONTAINMENT WORKING GROUP
(GCC-CWG) AND NATIONAL AUTHORITIES FOR CONTAINMENT (NAC)
NOTE FOR THE RECORD

Wednesday 16 October

Geneva, Switzerland

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Wednesday 16 October 2019

Chair: J Partridge

SESSION 1: Introduction

Welcome and opening remarks

The Chair welcomed all participants to the 3rd Meeting of the National Authorities for Containment (NACs), with 20 NACs and 3 additional countries attending.

Introductions, objective of the meeting, and expected outcomes

D Moffett

The objective of this meeting is to facilitate robust discussions with the NACs on a) the progress of establishing containment within countries and b) the challenges that have arisen so far. The meeting will also allow GPEI to provide a programmatic update and outline the current priorities. The GPEI hope this is an opportunity to raise issues and solutions, and share amongst NACs how you have moved forward.

SESSION 2: Polio eradication, vaccine needs, and containment certification

Polio eradication: current situation, anticipated vaccine needs, programmatic next steps

M Zaffran

This presentation provided an update on the:

- Current outbreaks
- Stockpile and needs (IPV, mOPV2, nOPV)
- Implications and consequences for containment

Polio eradication was confirmed as a Public Health Emergency of International Concern (PHEIC) on 16 September 2019. There has been increased number of WPV1 paralytic cases in Pakistan and Afghanistan, from 33 cases in 2018 to 89 cases so far in 2019. In Pakistan, the programme has been off-track, facing political disruption and increased community resistance. In Afghanistan, ban on house-to-house campaigns has severely affected the ability of the program to reach children.

The program is currently battling many outbreaks of cVDPV2 in sub-Saharan Africa and risk of re-established poliovirus type 2 endemicity in this region. In 2019, there has also been detection of cVDPV2 outbreaks in Asia (China, Pakistan, Philippines). The limited supply of the mOPV2 vaccine, which is the only currently available tool to control these outbreaks, presents a serious concern. It is essential that there is an uninterrupted supply of mOPV2

available and an accelerated development of the more genetically stable OPV2 vaccine (the novel OPV2 vaccine (nOPV2)).

Discussion:

1. Inconsistent messaging for Polio Essential Facilities (PEFs).

It was raised that it is problematic for the NACs to provide inconsistent messaging and flexibility for different types of facilities/institutions: research labs, manufacturers and quality control laboratories. This undermines the accountability and authority of the NAC.

2. The CCS scheme and ICC requirements.

It was clarified that the Certificate of Participation (CP) is an entry into the CCS scheme, which all PEFs should obtain. The CP is then valid until April 2021 and then all active PEFs need to transition to a Certificate of Containment (CC) or Interim Certificate of Containment (ICC), if they want to continue to work with polioviruses after April 2021. The ICC and CC are similar; however, under an ICC you have known deviations from GAP III that have been approved. Therefore, the CP can provide a lot of flexibility in the short term and the ICC provides it in the medium term. The end goal is that all active PEFs will have a CC, however this might take 3-5 years.

3. Definition of Polio Essential Facilities and critical functions.

The NACs raised that it would be useful to have a WHO definition of essential facilities and critical functions, which incorporates the current programmatic priorities. This would provide some justification for any flexibility to certain PEFs (e.g. vaccine manufacturers). The NACs suggested that they should provide input into this definition.

4. Clarification of the secondary and tertiary safeguards for PEFs.

- Tertiary safeguards: Tertiary safeguards are only required by PEFs that are retaining wild poliovirus. These safeguards do not apply to Sabin polioviruses.
- Secondary safeguards: The Strategic Advisory Group of Experts (SAGE) recommended that there are immunisation requirements for the 100km area around the PEF. The NACs have reported challenges with implementation of this safeguard (IPV supply constraints, 100km goes over different countries). The WHO have asked an external company evaluate alternative options, including a risk-based approach. Once this analysis is complete with new proposals, it would need to go back to SAGE. WHO understand this secondary safeguard is a problem, and are actively seeking what is a better solution.

SESSION 3: Poliovirus containment communications

Tools and information: results of the NAC survey and progress on the NAC platform.

H Singh

The results of the NAC survey were presented. In response to survey feedback, GAP III is currently undergoing revision with the aim to clarify issues and challenges that have been raised so far through its implementation. The revised GAP III will be sent out for public consultation in 2020.

The NACs requested an online communication platform, which has been developed and will be available at the end of 2019. In response to feedback that NACs should be able to speak with one another without WHO involvement, the platform will not be monitored by WHO.

SESSION 4: Containment certification update

Polio containment: where are we now and future direction?

L Boualam + A King + N Previsani

This presentation covered:

- Progress with CPs, ICCs, CCs
- Expected timelines, deadlines for submissions, validity
- Results of NAC data call
- Next steps: moving towards ICC/CC; who, how, and when

As requested by the NACs, Arlene King, chair of the GCC-CWG, presented the trends from the received CP applications and outlined elements where the GCC-CWG have requested more data. This comprised five incompleteness elements and five clarity elements.

Incompleteness elements:

- i. Rationale for retaining poliovirus materials. This area often required more discussion and it was not always clear what was the essential research.
- ii. Timeline action plan (time to achieve ICC or CC). The application needs to state what you want to achieve, e.g. are you planning on going on to a CC or ICC (which might change).
- iii. Current containment conditions during the validity of the CP. Some NACs have outlined their adequate current containment conditions during CP validity, which is very useful.
- iv. Secondary safeguards. There has been very detailed information from several applications e.g. seroprevalence area, sub national/municipality vaccination coverage in the commuting distance of PEF. However, we are unlikely to reject the application if you can't provide coverage data.

- v. Evidence of tertiary safeguards.

Clarity elements:

- i. A sense of financial and human resources to address requirements in future
- ii. An awareness of immunity in area around PEF (e.g. are there any religious groups?)
- iii. Specimen container transport - detail how specimen gets transported from one area to another within the PEF.
- iv. Description of facility – be clear about describing/mapping the PEF layout.
- v. Insure all workers in facility are appropriately immunised.

Discussion:

1. The December 2019 deadline is for submission of all CP applications for facilities retaining PV2 to the relevant NACs. The NACs then need to submit this application to CWG, which we expect would largely be in Q1 2020, however there is not a set deadline for this.
2. For the CWG application review, there are two primary reviewers selected from the CWG. The CWG Chair then provides the final decision and condenses the reviewer's comments into a few paragraphs to provide to the NAC with the decision.
3. It was asked when a facility can begin/resume working with poliovirus along the CCS scheme. It was stated that after a PEF has submitted the CP application and been awarded a CP it can continue working with the virus.
4. There was discussion over the size of a PEF (e.g. one building, one site or one organisation) and how many CPs should be required for a facility.

Action point (1): Develop a framework to define what is classified as single or multiple PEFs and CP applications.

Action point (2): Have NACs present at the next meeting their own experience of submitting CP applications.

Structured Afternoon Discussion

Training

The GPEI have organised training over the past few years (e.g. GAP III training, CCS training, basic/general trainings). It would be good to understand the demand for training from NACs: what type of training and the timeline (incorporating the change/rotation of people in the NAC – interest in receiving regular training). There were various individual preferences raised by NACs for face to face or online training courses.

Action point (3): Conduct a NAC survey to identify the specific trainings required and the style of training (in person or online).

Auditor Qualification

The main problems identified were the lack of lead auditors (only one lead auditor globally) and the shortage of possibilities to obtain required training hours to qualify auditors. The constraints raised by NACs included: PEFs do not want to provide training to auditors; lack of a lead auditor in the country to monitor training; there are not enough PEFs in country/region obtain the required training hours; the investment of money and time from country is substantial when they only have one or very few PEFs.

It was suggested that as a priority, the GPEI should develop a process to qualify at least 5-10 lead auditors globally within the next 12 months. There were two suggestions of possible processes:

- A. WHO to identify and hire a pool of 10-20 international people who can become lead auditors.
- B. Develop a streamlined training process for immediate lead auditors.
 - NACs need to identify if there is a person that could potentially be a GAP III lead auditor.
 - Global lead auditor (Paul) needs to assess capability of the identified persons (e.g. go to facility together and conduct audit).
 - There needs to be an agreement between CAG/WHO that this process is suitable given the situation.

Additional points/limitations raised to this process:

- The identified person would need to be available and be a trained GAP III auditor.
- Consideration of whose scheme they would be qualified under (different for each countries).
- Country specific language restrictions (Japan).
- Country specific restrictions where there is only single PEF in the region (South Africa).

Action point (4): Develop a process to qualify at least 5-10 lead auditors globally within the next 12 months.

- i. Develop a landscape of country-specific requirements, restrictions and approaches. Then the GPEI can review and try develop some options for auditor training.
- ii. Identify facilities that would be willing to host auditor training through mock audits. WHO will continue talking with countries to try and identify any such facilities.
- iii. Suggestion for the Netherlands NACs to write up their strategy for training auditors and circulate to other NACs.

Costs and sponsors

The NAC costing exercise. The Bill and Melinda Gates Foundation funded PATH to evaluate the estimated cost for a NAC to perform its duties and for a facility to become a PEF, through to the ICC. PATH selected some NACs and PEFs across all regions to evaluate. However, the results did not provide much insight into specific costs, because, the situation is very different for each individual PEF and NAC. The results will be published and the report shared with all the NACs

Action point (5): Circulate the results of the NAC costing exercise conducted by PATH.

Contracts

During the auditing process the respective PEF and NAC will enter a contract. It was suggested that NACs should share amongst themselves any draft contracts or guidance on what should be included in the contracts, recognising that regulations will be country-specific.

The Netherlands NAC shared the outline of the contract they have developed, which included: the overall goal of the contract; the contractual duties of the NAC; the contractual duties of the PEF; the total cost (stating that the PEF will be responsible for the financial resources); and standard confidentiality statements.

SESSION 5: Regulatory considerations and essential roles of different national authorities

Collaboration between NACs and NRAs

- Expected NRA/NAC coordination
- TRS1016, GAPIII, CCS

End of day discussions

1. The NACs emphasised that it would be useful to have some guidance from the CWG for what will be required for the ICC/CC applications.

Action point (6): Follow up on request of the NACs for CWG guidance on ICC/CC application process.

2. The CP and ICC/CC application is required to be submitted in English, however there are not always financial and human resources to translate all documents into English. This is a problem for NACs and PEFs where English is not the native language, with a capacity difference for large manufacturers and small research labs.

Action point (7): Follow up on language requirements for documentation and the limitations of translation capacity.

3. Potentially Infectious Materials (PIM) guidance.

Action point (8): Schedule a teleconference call to discuss PIM guidance.

4. The options for labs or QC labs.

Action point (9): Circulate the relevant CAG recommendation.

5. Communication to PEFs on the declaration of wild poliovirus type 3 (WPV3) eradication. There is a high-level communications statement regarding WPV3 available on the GPEI website.

Action point (10): WHO to develop additional communication points on WPV3 eradication for NACs to use in discussion with PEFs.

6. GAP III revisions should not lead to additional auditing requirements, as the purpose of the revisions is to clarify GAPIII, rather than to create more work.
7. Update on the draft exposure guidelines. The draft guidelines have been closed for public comments. The final version of this document will be available on the GPEI website in the next few months.
8. NACs raised that the reporting and communication strategy for breach in containment needed to be clearer.

Action point (11): Clarify the breach reporting process.

Closing meeting

The Chair stated that it is very clear that we need platforms for communication and support between NACs. The online platform will be available soon, but other ways have been suggested (regional meetings, teleconference) that we can implement.

The main priority raised from this meeting is to develop a plan for how we are going to have lead auditors in place this time next year. The first step will be to make a landscape for each country for their specific requirements and develop a range of options for how we are going to manage the auditor training.

All participants were thanked for coming.

