CAG TC1 on showers
25 January 2018
Report

Abbreviations:
- BSC: Biological safety Cabinet
- CAG: Containment Advisory Group
- CAG1: First Meeting of the Containment Advisory Group, 19-20 June 2017
- CAG2: Second Meeting of the Containment Advisory Group, 28-30 November 2017
- TC1: First Teleconference of the Containment Advisory Group, 25 January 2018
- CCS: Containment Certification Scheme to support the Global Action Plan for Poliovirus Containment (GAPIII)
- GAPIII: Global Action Plan for Poliovirus Containment
- NAC: National authority for containment
- PEF: Poliovirus-essential facility
- TRS: Technical Report Series

Participants:
- CAG: Professor David Heymann (Chair), Dr Jagadish Deshpande, Dr Atef El-Gendy, Dr Vibeke Halkjær-Knudsen, Mr Neil Godden, Dr Janice Lo, Dr Mark Pallansch, Dr Åsa Szekely Björndal, Professor Shahina Tabassum and Mr Kenneth Ugwu.
- Excused: Professor George Griffin, Dr Bernard Fanget, Dr Stephen McAdam
- WHO: Jacqueline Fournier-Caruana, Roland Sutter, Nicoletta Previsani, Harpal Singh called in

Issue 1: The shower

Relevant GAPIII section
Annexes 2 and 3, Subelement 12.3.1 (g):
Controlled exit from the containment perimeter is via a walk-through exit shower. Showering out is mandatory except for facilities employing fully functional Class III BSCs or similar isolators (in such facilities, showering out is required in the event of an uncontrolled breach of the primary containment equipment).

History
Summary of requests to CAG1
Reconsider the need to install showers for use on exiting the containment perimeter, other than in the event of spill or other significant emergency.

CAG1 recommendation
Modify Subelement 12.3.1 (g) of Annexes 2 and 3 to read as follows:
Controlled exit from the containment perimeter is via a walk-through exit shower. Showering out is mandatory except for facilities employing closed systems demonstrating validated primary containment. Such systems may include contained lines for use in vaccine production and/or facilities employing fully functional Class III BSCs or similar isolators. For such facilities, showering out is not mandatory, other than in the event of an uncontrolled breach of the primary containment equipment.

CAG2 recommendation
The GAPIII requirements in Subelement 12.3.1 (g) of Annexes 2 and 3, as modified at the 1st CAG meeting, were not changed.

The CAG assigned a subgroup to the task to review the issue of mandatory showering, consider the information and evidence around the need/benefits of shower-out (including adherence to the precautionary principle to minimize the risk of release of poliovirus post eradication to as close as possible to zero), and evaluate whether or not a robust set of criteria could be developed for use in risk
assessments to justify the omission of routine showering-out. The CAG agreed to discuss this issue by teleconference in January 2018. Results of CAG discussions on this issue and associated CAG recommendations will be reported and published on the web.

Summary of CAG TC1 discussions and conclusions

a. The shower working group presented the flowchart ‘Should you shower out’.
b. The flowchart was discussed and suggestions for improvement were collected.
c. While not providing ‘a robust set of criteria for use in risk assessments to justify the omission of routine showering-out’, the CAG agreed on the need to obtain more information and convincing evidence from the field to indicate that showering is/is not effective and therefore should/should not be a required control. CAG will not develop a robust set of criteria.
d. The CAG was reminded of the urgency to provide comments on the shower to the TRS working group before the end of January and the fact many facilities are already designing/building showers to meet the requirement.

In conclusion, the Containment Certification Scheme (CCS) provides flexibility to PEFs and NACs in terms of installing/using showers until the declaration of global poliovirus eradication. CAG recommendations to the TRS drafting group will reflect these decisions.

Recommendations

The CAG recommended to further modify the GAPIII requirement in Subelement 12.3.1(g) of Annexes 2 and 3 modified at the 1st CAG meeting, to read as follows (text in colour is the GAPIII wording supported by the CAG; changes are shown in bold):

Controlled exit from the containment perimeter is via a walk-through exit shower. Showering out is mandatory except for facilities employing closed systems demonstrating validated primary containment. Such systems may include contained lines for use in vaccine production and/or facilities employing fully functional Class III BSCs or similar isolators. For such facilities, showering out is required as a precautionary measure, in the event of an uncontrolled breach of the primary containment equipment, during the period when further assessment of the effectiveness of showering is being undertaken.

For other facilities, the requirement for mandatory showering should be left to the discretion of the National Authority, after review of a risk assessment submitted by the PEF. Risk mitigation measures will be proposed by the PEF and approved by the National Authority for the interim period of at least two years during which evidence for-or-against-mandatory showering out will be generated.

The CAG urged the secretariat to commission a study to collect information on the use, effectiveness and risks associated with showering, including in facilities where showering is currently being used. The CAG will undertake further discussion on showers when the secretariat has collected the information necessary to make an evidence-based recommendation, or has shown that it is not feasible to collect such information.

CAG recommendations to the TRS drafting group will reflect these decisions.