

Executive summary

- The GACVS sub-committee appreciated the efforts made by the first 2 initial use countries to implement AEFI and AESI surveillance
- The data were preliminary with notable variability in reporting
- From the analyses presented of the limited data, there were no safety “red flags” or clusters observed
- At this point, the data are not sufficient to reassure the members from a safety perspective to move to wider use
- The members are hopeful that the quantity and quality of the safety data will improve by July, allowing for a more comprehensive analysis and review

Specific concerns raised include

- The pressure / burden on countries to creating an additional safety monitoring system
- The marked variability in reporting. Some examples were:
 - Only 1 of 6 states reported AEFI using the forms
 - Clarification is still pending for 11 AESI indeterminate cases
 - Anaphylaxis was deemed by the causality committee as not relevant to nOPV2. However it was highlighted that although rare, a few cases of anaphylaxis have been reported from other countries.
 - Uncertainty of whether the 6month retrospective case search was actually conducted and if so, the pending outcomes of this search
- Missing data
 - The need to better analyze what data are missing (eg completeness, timeliness, biased reporting from only few centers etc.) in order to identify any biases
- Training
 - More attention is required to address gaps in safety surveillance. There is a need for robust training on safety surveillance, causality assessment
 - The 6month retrospective case search is a significant undertaking and it could be asked whether this is productive or is creating confusion for countries. If this is a requirement from the nOPV2 WG, the need for training on how to conduct such searches and what to look for and where to look for in this regard needs to be better clarified

Points for consideration for the nOPV2 WG to prepare for the meeting in July

- Ensure that timely and necessary trainings take place in initial use countries to cover general safety surveillance and its applicability in nOPV2 safety surveillance. Training should cover AEFI, AESI, causality assessment, and, the 6/12 retrospective case search (if this is a requirement by the nOPV2 WG)
- Develop a more structured reporting template to be shared with countries. This might be helpful to better organize safety data and ensure consistency in data collection
- Documentation / tabulation to summarize what data are missing - by dates and regions, in order to identify any biases
- Presentation of key polio AFP surveillance indicators (including GBS and TM), would be helpful. Given the gaps in AESI and AEFI surveillance, AFP surveillance can also be drawn on as a proxy for strength of safety surveillance

- Presentation of the follow up of all indeterminate cases using a documentation process for causality assessment
- Presentation of the outcomes of further genetic analyses of isolates from AFP and ES
- Presentation of SIA completeness