

Global Advisory Committee on Vaccine Safety (GACVS)



Report from the December 2017 meeting

Topics discussed in December



1. Pharmacovigilance readiness for malaria vaccine implementation
2. Harmonized approaches for the vigilance of interventions during pregnancy
3. Interrater reliability of causality assessment for serious adverse events following immunization
4. Rotavirus vaccine: safety update
5. Immunization and stress responses

Vaccine pharmacovigilance readiness for malaria vaccine implementation



- Pilot implementation planning in Kenya, Malawi and Ghana continue
 - Efforts underway to achieve adequate reporting rates, build capacity, establish national AEFI committees, clarify roles/responsibilities, develop data management systems, develop communication plans.
- Online meetings of the countries established 10 events as AESI to be monitored
 - Anaphylaxis, Thrombocytopenia, TSS, cellulitis, injection site pain (persistent), meningitis/encephalitis, AFP/GBS, SJS/TEN, allergic reactions, hepatic/renal failure

Conclusions/Recommendations

- GACVS endorsed 6 key indicators of readiness for vaccine pharmacovigilance
 - 10 reports/100,000 infants; AEFI committee; investigation teams; communication plans; focal point; method for active surveillance of AESI.
- GACVS recognized the challenges remaining in reaching PV readiness and AESI surveillance prior to RTS,S introduction
 - Short timelines to achieve targets to minimal capacity in PV and AESI reporting
 - Processing of data to allow comparisons between pilot areas
 - Ascertainment of vaccination history of AESIs

Harmonized approaches for the vigilance of interventions during pregnancy



- Stakeholders involved various aspects of “maternal interventions vigilance” met
 - Global applicability : clinical research, surveillance, registration systems
- It was proposed that harmonized sets of data be collected
 - Studies and evaluations of the health of pregnant women can be improved.
 - Data sets tailored to study characteristics, in settings of various infrastructure.
- There are plans for the GAIA terms and definitions to be considered by ICD 11
- A WHO task force will be established to address harmonization of coding and data systems
 - Part of developing a roadmap for improving maternal, neonatal and child health programmes and assessments of vaccine safety in pregnancy.

Conclusions/Recommendations

- With similar data needs for both clinical surveillance and public health vigilance, data coding and data systems should be usable for both purposes.
- Minimal data elements will need to be assessed for their availability in different settings and for different types of studies.

Interrater reliability of causality assessment for serious adverse events following immunization



- AEFI causality assessment methodology and tools endorsed in 2012.
 - Causality manual and AEFI assessment software developed
- Interrater study of tools was conducted in April 2017: evaluate the reliability of method and compare manual and electronic versions using serious AEFI cases
 - Good concordance of ratings with >80% agreement: experts and countries
- Concluded that electronic AEFI CA methodology was suitable at country level and for comparison of CA across countries.

Conclusions/Recommendations

- GACVS recommended systematic analysis of unclassifiable events
- Analysis of the questions posed on the checklist to evaluate interrater agreement regarding the responses provided;
- Updating of the AEFI causality assessment software
- The translation of the tools into additional UN languages

Rotavirus vaccine safety update



- GACVS reviewed recent evidence on
 - The impact of rotavirus vaccine
 - An updated Cochrane review on rotavirus vaccines and intussusception, and
 - Recent data from multicountry studies from sub-Saharan Africa and South Africa.
- Conflicting evidence between RCT and SCCS from different sources as to whether Rotarix or Rotateq was associated risk of intussusception.
 - In the African Intussusception Surveillance Network that uses Rotarix in 7 countries, no increased risk of was identified.
 - Post-market monitoring using SCCS in South Africa identified no risk overall or following the first dose. However there was a small risk (~2-fold) in the first 7 days following the second dose

Conclusions/Recommendations

- GACVS reassured that the benefit greater than the small potential risk of intussusception identified in most, but not all studies
 - Follow-up studies should continue to assess factors influencing intussusception.
 - As countries transition from OPV to IPV, studies evaluating both vaccine effectiveness and risk of intussusception should be considered
 - Countries should continue to assess risk of new vaccines as they are introduced

Immunization related stress

- GACVS convened an expert working group to explore anxiety-related reactions that have been reported as clusters and have affected immunization programs.
 - The output to be a guidance document

GACVS presented with a draft manual

- Includes concepts of anxiety, fear, immunization phobia, anxiety disorders including “needle phobias” and conversion disorders.
 - Complex syndromes that may have a stress component
- GACVS discussed the proposed terminologies and the classification.

GACVS recommended that the manual be circulated for consultation to stakeholders and that training materials be developed to accompany it.

The draft has undergone review by initial stakeholders

- Comments are under review by the working group

Additional reviews are planned and then a final draft to SAGE

Proposed topics for June, 2018

1. Further review of dengue vaccine safety
2. Continued review of guidance being developed related to immunization and stress reactions.
3. Further update on RTS,S pilot
4. Update on the Vaccine Safety Net and outcome of a VSN members meeting
5. Recent work of a new Vaccine Safety Communication working group
6. Update on the Global Vaccine Safety Initiative