

Global Advisory Committee on Vaccine Safety (GACVS)



Report from the June 2018 meeting



Topics discussed in June 2018



- Safety of dengue vaccine in the Philippines
- Vaccine safety net
- Pharmacovigilance in pilot use of malaria vaccine
- Progress in the Global Vaccine Safety Initiative
- Vaccine safety communication



Safety of dengue vaccine in the Philippines

- GACVS was presented the reanalysis of clinical trial data
 - Recommended that vaccine not be administered to individuals not previously infected with wild dengue virus.
 - Noted that no data available to allow analysis of risk according to the number of doses received by those seronegative at baseline
 - Recommendations were communicated to the SAGE WG (report was discussed at the April meeting)
 - SAGE advised countries considering CYD-TDV vaccination to include pre-vaccination screening
- The purposes of an update to the GACVS at this meeting were
 - to review reports on safety after the announcement and the updated safety profile of CYD-TDV
 - to review difficulties in determining if cases of severe dengue in those dengue-naïve were vaccine failures or immune enhancement



Safety of dengue vaccine in the Philippines

Conclusions/Recommendations

- In the absence of criteria for distinguishing vaccine failure from vaccine-related immune enhancement, individual cases cannot be attributed to one or the other.
 - As such cases should be classified as “indeterminate”, irrespective of the time since vaccination.
- GACVS also examined the possible risk of viscerotropic or neurotropic disease associated with the yellow fever backbone
 - Although this remains a theoretical possibility, non-clinical and clinical evaluations do not provide evidence of an association.
- As severe dengue may be accompanied by haemorrhagic systemic phenomena, a differential diagnosis can be made only if the vaccine strain is isolated.



Vaccine Safety Net

- The Vaccine Safety Net (VSN) was launched to identify trustworthy information on the Internet
 - GACVS provides advice and defined criteria for quality websites
 - Currently: 61 members, 29 countries, 16 languages, all regions.
- Members met in June 2018 in Veyrier-du-Lac to review the status of their activities, reflect on advances in social media and the Web and plan future growth
- Many challenges were identified through examples and experience. Suggestions were made. For example:
 - Web analytics to document patterns of web-searching on specific issues and monitor the effects of digital communication strategies in real time.
 - A digital toolkit or newsletter would provide updates, tips, lessons learnt and risk communication guidance and resources, based on VSN members' shared experience and other research



Vaccine safety net

Conclusions/Recommendations

- Mitigating challenges requires investment, partnerships/collaborations, research, advocacy, engagement of the young and the global and regional community.
- Building vaccine acceptance and addressing hesitancy is complex

GACVS welcomes the contribution of the VSN and supports the work presented.



Pharmacovigilance during pilot use of the RTS,S malaria vaccine - update

- Ghana, Kenya and Malawi have all granted special authorization for use of the RTS,S malaria vaccines.
- Safety data will be derived from follow up of
 - Surveillance in the pilot areas
 - Meningitis/cerebral malaria in sentinel hospitals/control areas
 - Active surveillance of AESI and passive AEFI surveillance
- Communications/data flows are being developed across partners
- Each country is continuing to strengthen their PV systems to meet criteria.



Pharmacovigilance during pilot use of RTS,S vaccine

Conclusions/Recommendations

- Countries to ensure training of teams on AEFI reporting as soon as possible
 - GACVS noted that barriers to reporting should be addressed
 - Also stressed the importance of ensuring the timely availability of individual data on AEFI in order that quality of reporting can be monitored regularly.
- For active surveillance, a manual of AEFI with case definitions was developed and adapted for each country
 - Each country will identify health care workers and health care facilities
 - Cases will be identified by regular review and data will be entered into a dedicated database
- GACVS agreed that development of country protocols, training and testing should proceed as soon as possible, concerned that a late start would miss initial pilot implementation



Progress in the Global Vaccine Safety Initiative: update for GACVS



- GACVS was updated in several key areas:
 - Progress made to Blueprint implementation since 2012 in achieving its objectives: systems and capacity indicators
 - The Global Vaccine Safety Observatory - a programme to strengthen global monitoring of vaccine safety
- The global vaccine safety strategy in the context of development of the Global Vaccine Action plan after 2020.



Progress in the Global Vaccine Safety Initiative



Conclusions/Recommendations

- GACVS has advocated for the GVSI and its objectives since inception
- Five of the 8 strategic objectives of the GVSI benefit directly from GACVS
 - AEFI monitoring, investigation, harmonized tools and methods, technical support platforms and expert advice.
- GACVS recommends continued close collaboration to ensure that the global vaccine safety strategy is well positioned in the new global approach to immunization
 - The Decade of Vaccines will be completed by 2020
 - A new strategy aligned with the WHO General Programme of Work 2019–2023, is being developed.



Vaccine safety communication

- A GACVS subcommittee on vaccine safety communication has been established
 - Integrate safety assessments with capacity to communicate
- A framework and templates for communication will be prepared
 - Mapping communication throughout the life cycle of products
 - Examining current vaccine safety communication tools
 - Identifying gaps, and proposing approaches to fill the gaps.
- The first task of the subcommittee was to prepare a detailed action plan, with case studies to illustrate how safety is communicated under various circumstances.



Vaccine safety communication

Conclusions/Recommendations

The Committee noted the extensive strategies and education resources already available for avoiding and mitigating crises in communicating vaccine safety.

Two were highlighted:

- The new Council for International Organizations of Medical Sciences (CIOMS) Guide to Vaccine Safety Communication
- The WHO Vaccination and Trust Library

GACVS considers that vaccine safety communication requires coordination among many stakeholders in multiple areas



Proposed topics for December, 2018

- Typhoid vaccines
- Immunization-related stress responses
- Blueprint Version II

