

Report of the Immunization Practice Advisory Committee (IPAC) to SAGE

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6-8 November 2012



World Health
Organization

IPAC Overview

- 2012 Meetings
 - 17-18 April and 2-3 October
- Future meetings
 - 4-5 April 2013 (aligned with SAGE) and 8-10 October 2013

Key Topics Reviewed

- Programmatic Implications of Rotavirus age-limitations
- Hepatitis B birth dose implementation
- Controlled Temperature Chain for Meningococcal A vaccine (MenAfrivac®)
- Programmatic Considerations of Alternatives to Thiomersal-Containing Vaccines
- SAGE polio working group update
- Solar Refrigeration Systems
- Time Temperature Indicators



Programmatic Implications of Rotavirus vaccine age-limitations (April, 2012)

- Recommended that previously agreed upon rotavirus vaccine training case-scenarios be kept, but additional training scenarios be developed to address relaxation of age limitations, as concluded at April 2012 SAGE meeting

Hepatitis B birth dose implementation (April 2012)

- IPAC endorsed in principle the WHO document “*Practices to improve coverage of the hepatitis B birth dose vaccine*”
- Confirmed the document should be used as part of evidence-base for development of complementary operational materials on planning and implementation
- Noted that the document is an essential piece of the evidence base on hepatitis B birth dose practices, but not suitable in isolation as a basis to set policy direction

Controlled Temperature Chain (CTC) for Meningococcal A vaccine (MenAfrivac®) (April, October 2012)

- Provided detailed technical inputs into guidance document for using MenAfrivac® vaccine in a CTC during campaign
- Final guidance document to be field piloted in upcoming Men A campaign
- IPAC will review implementation issues in 2013

Controlled Temperature Chain (CTC) for Meningococcal A vaccine (MenAfrivac®) ⁽²⁾

- Pilot Guidance recommendations/clarifications:
 - There are two key decisions that need to be made at different levels (national and regional/district)
 - Integration of MenAfriVac® in a CTC with other activities (vaccines and other health interventions) should be avoided
 - Discard vaccines used in a CTC at the end of the four day CTC period, even if the VVM and threshold indicators are not expired (this will allow for worst-case scenario assessment of wastage, which should be reviewed after the pilot)
 - A strong evaluation plan for the pilot needs to be developed

Programmatic Considerations of Alternatives to Thiomersal-Containing Vaccines (April, Oct 2012)

- IPAC concluded the abrupt removal of thiomersal-containing vaccines would be extremely disruptive with disastrous consequences for vaccination programs and infant, child, and maternal health, likely resulting in increased mortality and morbidity.
- IPAC concluded it is essential that thiomersal-containing vaccines be exempt from global mercury-free treaty. IPAC noted that there are severe programmatic consequences of a shift away from thiomersal-containing vaccines, including vaccine supply interruption and dramatic increases in program costs and resource requirements for countries
- Although IPAC recognizes and supports global initiatives to reduce exposure to mercury, IPAC supports the position expressed by SAGE that thiomersal-containing vaccines are safe, essential, and irreplaceable components of immunization programs, especially in developing countries, and that removal of these products would disproportionately jeopardize the health and lives of the most disadvantaged children worldwide.

Programmatic Considerations of Alternatives to Thiomersal-Containing Vaccines ⁽²⁾

- IPAC called for intensified and unified effort at global and national levels to improve communication strategies to inform decision-makers and the wider public about the negative effects of a rapid transition away from thiomersal, using a wide set of partnerships beyond immunization and health sectors.
- IPAC recommended that WHO build upon the opportunity presented by the global initiative to remove mercury from the environment to heighten attention to improving vaccine formulations, presentations and packaging, logistics, program delivery, vaccine wastage, and waste disposal systems
- IPAC calls for an intensive research investment into programmatic improvements.
- As countries will come under increasing pressure to reduce environmental exposure to mercury, IPAC supports continued research into effective, feasible and affordable alternatives for new vaccine preservatives.

SAGE polio working group update (October 2012)

- IPAC members were requested to advise on the programmatic advantages and disadvantages of a routine dose of IPV given by the ID versus IM route, and highlight additional measures which programs should undertake in these scenarios.
- IPAC recommended further detailed review of existing literature and the relationship between quality of ID injections and vaccinator/health worker training.
 - Review BCG literature
 - Review ID injection errors

SAGE polio working group update ⁽²⁾

- IPAC noted the importance of GPEI developing feasible options for use of needle-free jet injection devices for ID application of IPV (e.g., availability, licensure, eventual cost).
- IPAC strongly recommended development of programmatic materials to address how IPV should be delivered including how to handle errors in administration (e.g., wrong dose or route), and cautioned against under-estimating the significant resources required to train health workers at all levels
- IPAC emphasised the need for GPEI to address negative perceptions of bifurcating the IPV supply market such that dose-sparing options (adjuvanted IM and fractional dose ID) are considered as viable choice only for low/lower middle income countries.

Solar Refrigeration Systems for EPI (Oct 2012)

- IPAC supports development of guideline documents regarding solar refrigeration and provided technical inputs into initial draft.
- Affirmed that evidence-based guidance needed for countries and implementing partners which outline best practices for planning, selection, procurement, installation, long-term maintenance and monitoring of solar refrigerators, as well as managing transition away from absorption units. Guidance should include cost estimation and innovative financing for both procurement and maintenance of the systems.
- IPAC recommends that WHO continue to promote and support the use of solar vaccine refrigeration through the building of local capacity and the provision of technical resources for countries

Time Temperature Indicators (Oct 2012)

Potential revision of the WHO Performance, Quality and Safety (PQS) standards for VVMs:

- IPAC encouraged WHO to seek ways to diversify the supplier base from one single source while keeping the basic design of the product the same.
- IPAC suggested WHO further scope the field on acceptability, comprehension and implementation of the current Vaccine Vial Monitor (VVM), before embarking on changes to the current technical specifications.
- IPAC suggested guiding principles; any change to the current VVM should not lead to programmatic disruption and confusion and should not require programmes to manage different devices or there would be a requirement for extensive re-training of personnel.

THANK YOU

