

WORLD HEALTH ORGANIZATION
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ORGANISATION MONDIALE DE LA SANTÉ
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ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

Recommendations of the European Technical Advisory Group of Experts on Immunization

The European Technical Advisory Group of Experts on Immunization (ETAGE) provides independent review and expert technical input to the WHO Regional Office for Europe immunization programme, with the objective of facilitating and accelerating achievements of the regional targets specified in the “Health21” strategy, relating to the reduction in burden of vaccine preventable disease.

**The European Technical Advisory Group of Experts (ETAGE) recommendations
on Rubella vaccine use during supplementary immunization activities (SIA) in the
WHO European Region, September 2003**

The substantial body of information that is available has not identified a foetus that has been damaged by the immunization of a woman with rubella vaccine either during pregnancy or within one month prior to conception; however, there is still insufficient data to unequivocally state there is no risk to the foetus when a pregnant woman receives the vaccine near the time of conception.

Therefore, ETAGE recommends that:

- Rubella vaccination of women known to be pregnant should be delayed until immediately after delivery;
- In view of the apparent absence of any risk of foetal abnormality following infection with rubella vaccine virus, inadvertent rubella vaccination during pregnancy or immediately before pregnancy should not represent a reason for interrupting pregnancy; and there is no need for further counselling;
- WHO European Regional Office should work with Member States to increase available data on the outcome of foetal exposures to vaccination, and on the frequency of congenital rubella; and
- WHO European Regional Office should make available to interested professional groups and organizations the current information on the risks associated with foetal exposure to natural rubella virus and to rubella vaccine virus.

The European Technical Advisory Group of Experts (ETAGE) recommendations on safety of MMR and hepatitis B vaccines, March 2004

Technical session 2: Vaccine safety

WHO global concept, policies and activities

Dr Philippe Duclos gave a presentation on the WHO global concept, policies and activities on vaccine safety. It was emphasised that vaccine safety involves far more than dealing with the technical requirements to ensure the greatest achievable levels of safety, but also involves educating both governments and the general public on levels of risk and appropriate risk assessments. It also involves providing responses in support of immunization programmes when inappropriate or inaccurate risk associations or risk assessments are applied.

WHO has been actively pursuing improvements in vaccine safety on a number of fronts, including ensuring manufacture of safe vaccines, safe delivery of vaccines, and establishing surveillance for vaccine-associated adverse events. To provide a strong scientific and technical basis to its vaccine safety programme, in 1999 WHO established a Global Advisory Committee on Vaccine Safety (GACVS), an advisory body that can respond promptly, independently and with scientific rigor to vaccine safety issues of global importance. This committee provides an assessment of the evidence for relationships between vaccines and events attributed to them, and can review the latest knowledge on vaccines and vaccine safety in collaboration with all interested parties.

Safety of MMR vaccine

Dr John Spika gave a presentation addressing recent questions over the safety of MMR vaccine. Concerns over a possible link between vaccination with MMR and autism were raised in the late 1990s, following publication of studies claiming an association between natural and vaccine strains of measles virus and inflammatory bowel diseases, and separately, MMR vaccine, bowel disease and autism. Based on the extensive scientific information reviewed and studies conducted, the Global Advisory Committee on Vaccine Safety (GACVS) concluded that no evidence exists of a causal association between MMR vaccine and autism or autistic disorders. In addition, there is no evidence to support the routine use of monovalent measles, mumps and rubella vaccines over the combined vaccine, and there should be no change in current vaccination practices using MMR.

Safety of Hepatitis B vaccines and birth dose

Dr Pierre Van Damme provided a presentation on the safety of hepatitis B vaccine. Over recent years there have been reports of adverse events following receipt of hepatitis B vaccine. However, there is no evidence from sound epidemiological studies and analyses that suggests a triggering association or a causal link between hepatitis B vaccination and the onset or relapse of multiple sclerosis (MS) or any other demyelinating disease. A hypothetical link between vaccination and acute lymphoblastic leukaemia (ALL) has been suggested, but there are no other scientific data supporting such an association and studies are ongoing.

Hepatitis B vaccine remains one of the safest and most effective vaccines in use, protecting people of all ages against hepatitis B virus infection and the wide spectrum of liver diseases infection can cause. The scientifically proven benefits of hepatitis B vaccination far outweigh any suggested risk. Perinatal transmission is one of the most efficient and devastating transmission modes of hepatitis B virus. If the first dose of hepatitis B vaccine is offered at birth

(preferably within 12-24 hours after delivery), it is effective in preventing perinatal infection. There is at present no evidence to suggest that countries should make changes to existing hepatitis B immunization programmes, or delay introduction of programmes to protect populations at risk.

ETAGE discussed the importance of vaccine safety in general, to ensure continued confidence and public trust in immunization programmes, through provision of relevant, accurate, scientific and evidence based information to the professionals and public. Discussions continued on the safety of MMR and Hepatitis B vaccine to finalize the specific recommendations of ETAGE.

Recommendations

1. ETAGE notes the conclusion of the GACVS that no evidence exists of a causal association between MMR vaccine and autism or autistic disorders, and encourages Member States to continue the use of MMR in childhood immunization programmes.
2. Hep B vaccine safety recommendations:
 - ETAGE endorses the continued use hepatitis B vaccination in national immunization programmes, including administration of thiomersal containing and thimerosal-free vaccines to newborns for prevention of perinatal transmission.
 - ETAGE agrees that the hepatitis B vaccine is one of the highly safe vaccines in preventing hepatitis B infection because there is no scientific data supporting the existence of as causal link between the vaccine and severe adverse events with the exception of very rare anaphylactic reaction.
 - ETAGE recommends that the Regional Office:
 - Encourages and assists Member States in achieving and maintaining high immunization coverage with hepatitis B vaccine
 - Assists Member States in conveying information on the safety and efficacy on hepatitis B vaccine to the general public and medical community through clear, consistent and powerful messages.