

107. New Vaccine and New Vaccination Method for BCG in France: Safety Considerations.

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Background: In France, BCG vaccination is mandatory for day-care, school attendance children and adults at risk. At the end of December 2005, the multiple-puncture, percutaneous method, Monovax® (Sanofi Pasteur) production was stopped leading to a unique method (intra dermal route) and strain: BCG SSI® (Danish strain, 1331). In January 2006, a rapid increase of spontaneous reporting of adverse local reactions was observed and became a particular concern. A national pharmacovigilance survey started then, being conducted by Saint-Etienne Pharmacovigilance Centre.

Objective/aim: the purpose of this study is to present the first results of this inquiry.

Methods: all spontaneous notifications registered by French pharmacovigilance network or by Company (Sanofi Pasteur MSD) were reviewed from beginning of the launch up to the end of May 2006. Expected reactions following vaccination were excluded from this study.

Results: 203 locoregional adverse effects (LAE) were reported: 164 abscesses, 35 local adverse reactions (inflammation, induration, erythema, subcutaneous nodule), and 5 suppurative lymphadenitis. Abscesses could be severe, painful, associated with large ulceration (up to 4 cm). Bacteriological cultures were positive for mycobacterium in 8 cases, 94% of abscesses occurred during the 2 first months post vaccination. No case of disseminated BCG infection was reported at the end of May 2006.

24% of LAE were considered as serious, because of hospitalisation or required surgical intervention. Misuse was associated in 41% of the cases: overdosage, wrong route (subcutaneous) or wrong site of administration (forearm, thigh, buttock, internal face of the arm), inappropriate schedule of vaccine administration. Practitioners mentioned difficulties performing this vaccination in many cases. Comparison with prescription data indicated that children between 1 month and 12 months were mainly at risk. During the period of the survey, 231 297 vials were sold.

Discussion: Even though these adverse effects are already well described with this vaccine, this survey indicated an excess of cases with misuse, and in the age group between 1 and 12 months. Practitioners are insufficiently trained in the correct procedures of administration of this new vaccine. Afssaps requested a Risk Management Plan to minimise the risk. A Dear Doctor Letter was sent in July 2006 to all vaccinators with a special document about injection technique.

Conclusion: Transition from percutaneous multi-puncture BCG vaccination to intradermal vaccine induced many new problems in France. This may modify acceptability of this vaccine. Information, education and training may contribute to minimise the risk.