Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

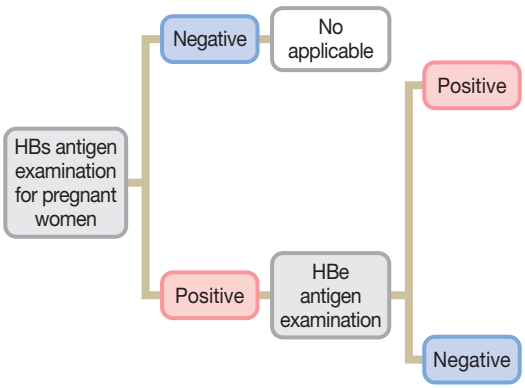
No.49, December 2010

Failure to implement measures to prevent mother-to-child transmission of Hepatitis B

Six cases where anti-HBs human immunoglobulin (HBIG) was administered to a infant immediately after birth, whose mother was an Hepatitis B carrier, but Hepatitis B vaccine (HB vaccine) was not given, have been reported (information collection period: from January 1, 2007 to October 31, 2010; the information is partly included in “Individual Theme Review” in the 20th Quarterly Report).

Cases where measures to prevent mother-to-child transmission for infants whose mothers were Hepatitis B carriers, were not carried out according to protocol, have been reported.

Schedule of the protocol to prevent mother-to-child transmission of Hepatitis B



(Prepared based on “About Hepatitis B (General Q&A)” by the Ministry of Health, Labour and Welfare)

Schedule of infant

	Month	At birth	1st month	2nd month	3rd month	4th month	5th month	6th month
Immunization	HB vaccine			●	●		●	
	HBIG	●		●				
Examination	HBs antigen		●					●
	HBs antibody							●

	Month	At birth	1st month	2nd month	3rd month	4th month	5th month	6th month
Immunization	HB vaccine			●	●		●	
	HBIG	●		●*				
Examination	HBs antigen			●*				●
	HBs antibody							●

* can be omitted.

● shows immunization ● shows examination

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Case

The obstetrician asked the pediatrician to administer HBIG for a infant whose mother was a Hepatitis B carrier, on the day after birth. The obstetrician made a reservation for only a regular one-month checkup, instead of making a reservation for a regular one-month checkup with the pediatric specialized digestive outpatient department which is in charge of the HB vaccination. Because of this, the infant only underwent a regular one-month check-up. One year later, the infant's mother saw a pamphlet in another hospital, began to have doubt about measures to prevent mother-to-child transmission of hepatitis B. Then she contacted to the outpatient pediatric department of this hospital with some questions. Upon checking, it was discovered that the HB vaccination was not administered according the protocol.

The Ministry of Health, Labour and Welfare has issued notification regarding measures to prevent mother-to-child transmission Hepatitis B.

Issued by the Employment, Children and Families Bureau Maternal and Child Health Division, No. 0427001, April 27, 2004
Issued by the Administrative notice of Maternal and Child Health Division, Equal Employment, Children and Families Bureau, Ministry of Health, Labour and Welfare, on December 4, 2009
Issued by the About Hepatitis B (General Q&A) revised in April 2008,Third Revision, the Ministry of Health, Labour and Welfare
http//www.mhlw.go.jp/bunya/kenkou/kekkaku-kansenshou09/documents/faq_HepatitisB.pdf

Preventive measures taken at the medical institution in which the event occurred.

- **Information of the newborn infants is to be shared and coordinated, not only with the obstetrician who was in charge of the delivery, but also with the pediatrician involved with the infant.**
- **Prepare documents on regarding measures to prevent mother-to-child transmission of Hepatitis B, and provide a sufficient explanation to the mother before delivery.**

* As part of the Project to Collect Medical Near-Miss/Adverse Event Information (a Ministry of Health, Labour and Welfare grant project), this medical safety information was prepared based on the cases collected in the Project as well as on opinions of "Comprehensive Evaluation Panel" to prevent occurrence and recurrence of medical adverse events. See quarterly reports and annual reports posted on the Japan Council for Quality Health Care website for details of the Project. http://www.med-safe.jp/

* Accuracy of information was ensured at the time of preparation but can not be guaranteed in the future.

* This information is neither for limiting the discretion of healthcare providers nor for imposing certain obligations or responsibilities on them.

J C Q H C

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