

Hepatitis B vaccine adverse events in China: Risk control and regulation

Li Meina^{1,*}, Liu Xiaodong², and Zhang Lulu^{1,*}

¹The Second Military Medical University; Faculty of Health Service; Institute of Military Health Management, PLA; Shanghai, China; ²Donghua University; Fashion and Art Design Institute; Shanghai, China

The death of 17 children raised public fears over infant hepatitis B vaccination in China. Though the relation between hepatitis B and children's death was denied after prudent investigation, the negative impact remained. In order to prevent or minimize adverse events after vaccination, special strategy including regulation and reimbursement should be developed.

The deaths of 17 children in China have been reported since November 2013 after receiving the hepatitis B inoculation produced by different companies, raising public fears over infant hepatitis B vaccination in the country. Food and drug regulators launched an investigation and ordered the country's 3 biggest hepatitis B vaccine makers to suspend production. After prudent investigation, The China Food and Drug Administration claimed that the babies' deaths were not related to the vaccine. The 17 deaths were due to various problems, including severe pneumonia, suffocation, kidney failure, severe diarrhea and congenital heart disease.

However, data from the National Health and Family Planning Commission showed that panic triggered by vaccine-related deaths in China led to a 30 percent drop in the hepatitis B vaccination rate in December 2013 compared with the same period in 2012, which poses a rising danger to newborns' health from infections. In line with recommendations by the World Health Organization, it is important to inoculate a newborn against hepatitis B within 24 hours of birth to achieve the intended preventative outcome.¹⁻³ WHO estimated that vaccination prevents the deaths of 2 to 3 million people annually. The immunization program in China

helped reduce the prevalence of hepatitis B below 1 percent among children under 5 years old, down from more than 9 percent before the introduction of the program in 2002. Accompany with the dramatic breakthrough in public health achievements from hepatitis B vaccine, there were also diverse adverse events following immunization reported by both media and academic journals.⁴⁻⁶ Though the causal relationship between hepatitis B vaccine and many diseases were denied, rare adverse events may still attract public attention and have negative impact on hepatitis B vaccination. Declined willingness of vaccination may result in lower vaccination rate which raise the susceptibility of hepatitis B.

As vaccine related reverse events cannot be completely avoided to some extent, special strategies from both technical and administrative level should be developed to prevent and control these reverse events. First, vaccination should be given priority as a state policy,⁷ and central, provincial, and municipal government should strengthen their supervision to assure the safety and efficiency of vaccine. Standardization and regulation of hepatitis B vaccine production, transportation, and utilization is of vital importance. It is necessary for government to announce the reverse incident rate and prevalence of hepatitis B without vaccination to let parents balance the benefit and risk of hepatitis B vaccination and make rational decision. Providing formal training to doctors in vaccine safety to address the questions of parents is also helpful.⁸ Second, reimbursement mechanism to aim directly at reverse event should be established, especially from the legislation level. To make up impairment, avoid the secondary damage and enable the victims

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*Correspondence to: Li Meina; Email: lijinhans53@126.com; Zhang Lulu; Email: zllrmit@aliyun.com

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get help timely, no-fault compensation system may be needed.⁹ Third, supervision on mass media is needed. Public media used the word of “deadly vaccine” to report this adverse event in China when investigation was going on. Furthermore, adverse news related to vaccine is usually reported by correspondent of social hot spot instead of scientific correspondent, which may result in unscientific or inexact report that mislead public attention and weaken public confidence in hepatitis B vaccine. On the whole, once vaccinated children are protected from regulatory, legal and technological level, similar tragedies related to hepatitis B vaccine will reduce gradually.

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