



## Review

# Systematic review of reporting rates of adverse events following immunization: An international comparison of post-marketing surveillance programs with reference to China

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## ABSTRACT

**Background:** China is the most populous country in the world, with an annual birth cohort of approximately 16 million, requiring an average of 500 million vaccine doses administered annually. In China, over 30 domestic and less than 10 overseas vaccine manufacturers supply over 60 licensed vaccine products, representing a growing vaccine market mainly due to recent additions to the national immunization schedule, but data on post-marketing surveillance for adverse events following immunization (AEFI) are sparse.

**Objectives:** To compare reporting rates for various categories of AEFI from China with other routine post-marketing surveillance programs internationally.

**Methods:** Systematic review of published studies reporting rates of AEFI by vaccine, category of reaction and age from post-marketing surveillance systems in English and Chinese languages.

**Results:** Overall AEFI reporting rates (all vaccines, all ages) in Chinese studies were consistent with those from similar international studies elsewhere, but there was substantial heterogeneity in regional reporting rates in China (range 2.3–37.8/100,000 doses). The highest AEFI reporting rates were for diphtheria–tetanus–pertussis whole-cell (DTwP) and acellular (DTaP) vaccines (range 3.3–181.1/100,000 doses for DTwP; range 3.5–92.6/100,000 doses for DTaP), with higher median rates for DTwP than DTaP, and higher than expected rates for DTaP vaccine. Similar higher rates for DTwP and DTaP containing vaccines, and relatively lower rates for vaccines against hepatitis B virus, poliovirus, and Japanese encephalitis virus were found in China and elsewhere in the world.

**Conclusions:** Overall AEFI reporting rates in China were consistent with similar post-marketing surveillance systems in other countries. Sources of regional heterogeneity in AEFI reporting rates, and their relationships to differing vaccine manufacturers versus differing surveillance practices, require further exploration.

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**Abbreviations:** AEFI, adverse events following immunization; EPI, Expanded Program on Immunization; SAE, serious adverse events; WHO, World Health Organization; China CDC, Chinese Center of Disease Control and Prevention; NIP, National Immunization Program; MedDRA, Medical Dictionary for Regulatory Activities; HHE, hypotonic–hyporesponsive episodes; FDA, Food Drug Administration of the USA; COSTART, Coding Symbols for Thesaurus of Adverse Reaction Terms; DTwP, diphtheria–tetanus–pertussis whole-cell vaccine; DTaP, diphtheria–tetanus–pertussis acellular vaccine; DTP, diphtheria–tetanus–pertussis vaccine; BCG, Bacillus Calmette–Guerin vaccine; OPV, oral poliovirus vaccine; IPV, inactivated poliovirus vaccine; MV, measles virus vaccine; MM, measles and mumps virus vaccine; MMR, measles, mumps and rubella virus vaccine; MR, measles and rubella virus vaccine; HepB, hepatitis B virus vaccine; Td, tetanus–diphtheria vaccine; TT, tetanus toxic vaccine; MCV, measles virus containing vaccine; Hib, haemophilic influenza type b vaccine; JEV, Japanese encephalitis virus vaccine; Men, Meningococcal serogroup C vaccine; MenA, Meningococcal serogroup A vaccine; MenBC, Meningococcal serogroup B and C vaccine; AU, Australia; BR, Brazil; CN, China; CU, Cuba; FI, Finland; JS, Jiangsu; IS, Iceland; IT, Italy; NL, Netherland; OM, Oman; SK, Slovakia; SZ, Switzerland; US, USA; NSW, New South Wales; V, Veneto; J, Juiz de Fora; HB, Hebei; HN, Hainan; SH, Shanghai.

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## 1. Introduction

Vaccination programs in China started in the 1950s, initially delivered through rolling mass campaigns. From 1978, the National Expanded Program on Immunization (EPI) was initiated in China. Universal childhood immunization coverage goals of 85% were achieved at province level in 1988, county level in 1990 and township level in 1995 [1]. High vaccine coverage in China has led to striking reductions in vaccine preventable diseases, most notably poliomyelitis, measles and hepatitis B [1–5]. China has maintained the status of no indigenous wild virus poliomyelitis epidemics since September 1994 [6], reported measles incidence decreased to 2.9/100,000 population by 2010 following the nationwide supplementary immunization activities in September 2010 [2]. National serosurveys have documented that the prevalence of hepatitis B surface antigen in children aged under five years decreased by 90% in 2006 compared to 1992 [3]. By the end of 2007, the National Immunization Program was expanded to include vaccines targeting hepatitis A, Rubella, Mumps, Japanese encephalitis and Meningococcal meningitis [7].

China is the most populous country in the world, with an annual birth cohort of approximately 16 million, requiring an average of 500 million vaccine doses annually [8]. This necessitates both a fully functioning immunization service delivery system at village and township level, and an independent local vaccine industry to achieve and maintain continuous growth and expansion of the immunization program. There are over 60 vaccine products licensed in Chinese market, and over 80% of these vaccines currently administered in the National Immunization Program are made domestically. There are 16,100 vaccination sites in urban areas, and in rural areas there are 41,800 township vaccination sites and 186,400 village vaccination sites [8]. With the large number of locally made vaccines administered each year, and increasing attention on vaccine safety from the public and the media, China requires credible routine monitoring of adverse reactions and the capacity to rapidly respond to any newly emerging vaccine safety concerns.

A consistent adverse events following immunization (AEFI) surveillance system is needed for stable documentation of AEFI over time, and to provide a baseline for assessment of vaccine safety issues at the country and international level. Such systems have been long established in a number of countries including UK, USA, Australia and Brazil [9]. In China, although formal guidelines for the monitoring of vaccine safety issues from the China Ministry of Health have been in place since 1980 [10], moves to develop a national AEFI passive surveillance system did not occur until 2005, when a pilot system was implemented in 10 provinces; expanded in 2009 to the whole country [11]. However, no studies have reviewed regional and national average reporting rates of AEFI in China to enable comparison with those of passive AEFI surveillance systems

elsewhere. Reviews of the safety profile of specific vaccines [12–17] are frequently seen in the literature, but reviews of passive post-marketing surveillance systems are less common. We could identify only one review [18] comparing post-marketing surveillance programs among various countries, which focused on description of the characteristics and limitations of AEFI post-marketing surveillance systems in Australia, Brazil, Canada, European countries and USA. In this review, we identified all published reports of passive AEFI surveillance systems at the national and regional level in English and Chinese language, with a special focus on informing strategies to improve monitoring and reporting of AEFI in China.

## 2. Methods

A systematic review of population-based post-marketing surveillance studies was conducted following PRISMA guidelines [19] to identify all published reports on post-marketing surveillance of adverse events internationally with the aim of comparing their major characteristics and reporting rates with those from China.

### 2.1. Literature search

Medline, Embase and CINAHL were searched using the keyword terms “adverse event\*” or “adverse effect\*”, combined with “vaccine\*” or “immune\*”, and with “surveillance or post marketing stud\*” or “population stud\*”. Keyword searches were also conducted for specific vaccine categories including diphtheria–tetanus–pertussis (DTP), BCG (Bacillus Calmette-Guerin), Oral Poliomyelitis Vaccine (OPV), measles-containing vaccines (measles mumps, measles rubella, measles mumps rubella or MM, MR, MMR), hepatitis B vaccines (HepB) and Meningococcal vaccines. We then combined with the terms “adverse event\*” or “adverse effect\*”, and with “surveillance or post marketing stud\*” or “population stud\*”. Chinese studies were also identified from the Chinese Academic Journal (CAJ) database of Chinese National Knowledge Infrastructure (CNKI) from 2005 onwards (the period after which national AEFI surveillance systems were established) using the same search terms and strategy. CAJ is the most comprehensive, full-text database of Chinese journals in the world, which contains more than 7200 journals starting from 1915.

Diphtheria–tetanus–pertussis whole cell (DTwP) and acellular (DTaP) vaccines, Bacillus Calmette-Guerin (BCG), hepatitis B virus vaccine (HepB), oral poliovirus vaccine (OPV), inactivated poliovirus vaccine (IPV), Measles virus containing vaccines (MCV), Japanese encephalitis virus vaccine (JEV) and Meningococcal vaccines (Men) were included in the comparative analyses. These vaccines were selected because they are already incorporated into the national immunization schedule in China; or are vaccines

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