Abstract

The popularization of vaccines is an important topic to prevent infectious diseases. Vaccine-associated adverse events occur but are generally rare. Most of the vaccine-prevented diseases have declined dramatically by vaccination, so surveillance of the vaccine-associated adverse events becomes more important for public health. This study focused on vaccine-associated adverse events which were reported for compensation in Taiwan. We analyzed the predisposing factors, onset time, vaccine types, *etc.* to know more about the vaccine-associated adverse events.

Materials and methods

Vaccine injury compensation program started from 1988. Totally, there are 199 cases reported by health providers during March 1988 and April 2004. By retrospective medical records review, we analyzed the vaccine types, age on vaccination, the interval between vaccination and disease onset, disease severity, clinical characteristics, prognosis, predisposing factors and the causal associations.

Results

Seventy-five persons died, 30 persons had handicap, 55 persons received autopsy and 99 persons got compensation. The male to female ratio of reported persons was 1.43:1. The proportions of persons in the age groups < 1 year, 1-6 years, 7-20 years, 20-64 years and 65 years were 67.3%, 17.1%, 8.1%, 2.0% and 5.5%, respectively. The maximal proportion was in the age group 2~4 month-old age (26.6%). The majority of events occurred within 3 days after vaccination (153/199, 76.9%). The duration between vaccination and disease onset was mostly occurred less than 24 hours (61.3%), followed by 24-72 hours (15.6%). Some events occurred more than one month after vaccination (5%), such as osteomyelitis due to BCG. The most commonly reported vaccine was DTP, which appeared in 56.3% of all reports, followed by OPV (53.3%), HBV (18.1%), JBE (8.5%), BCG (8.0%), influenza (7.5%) and MMR (7.5%). Ninety-four persons (47.2%) had fever, 63 persons (31.7%) had seizure, 48 persons (24.1%) presented as die on arrival, 26 persons (13.1%) had cellulites or abscess, and 19 patients (9,5%) had skin rash. Four persons got infection due to BCG, including 3 with osteomyelitis and one with systemic infection. Only 22 events were interpreted to have association with vaccination. The association could not be ruled out due to the time sequence in 70 cases. One hundred and seven events were dismissed.

Conclusion

Vaccine injury compensation occurred most commonly in persons received DTP and OPV. If the budget is affordable, DTaP and IPV or other combination vaccines may replace the DTP and OPV in the future. Since only severe complications were reported for compensation, the reported number must be much lower than the true incidence. Determining causal associations between vaccines and adverse events is difficult. The compensation system is built to help patients with vaccine-associated adverse events as well as health workers who provide vaccines. It is essential to detect new, unusual or rare vaccine adverse events, monitor number of complications, determine patient risk factors and

assess the safety of newly licensed vaccines.

Key words：vaccination, vaccine injury compensation, vaccine adverse event