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Post-marketing surveillance of BCG vaccination

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Bacille Calmette-Guerin (BCG) is a vaccine for preventing childhood tuberculosis (TB), especially military and meningeal TB. Approximately 100 million newborn children receive BCG annually. Taiwan has an annual TB incidence rate of approximately 50 cases/100,000 persons. Moreover, the risk of developing childhood extrapulmonary TB without lung involvement is highest among children <5 years of age. The National Immunization Program has included neonatal BCG vaccination since 1965. Although BCG is effective in preventing progressive primary TB, adverse reactions to the vaccine do occur. A laboratory-based surveillance program to differentiate *Mycobacterium bovis* BCG from other species of the *M. tuberculosis* complex was established to monitor adverse events among vaccinated children since 2003. A policy of enhanced childhood TB surveillance was implemented in 2007 and clinicians were advised to send clinical specimens to the Centers for Disease Control in Taiwan for differential diagnosis of *M. bovis* BCG for patients <5 years of age. According to an international survey, the estimated rate of osteitis/osteomyelitis is 1-700/1,000,000 vaccinated newborns or infants with different strain-derived BCG. In Taiwan, the estimated incidence of BCG osteitis/osteomyelitis increased from 3.68 cases per million vaccinations during 2002-2006 to 30.1 per million during 2008-2012. We found no association between cases and vaccine batches, inoculation age, underlying disease or *Salmonella* spp. infection. The increased number of cases resulted mainly from multidisciplinary management, including enhanced laboratory diagnosis. Once BCG-related infection is confirmed, medical treatment has to be consistent.

Biography

Ruwen Jou has completed her PhD from The Ohio State University. She is the Director of Tuberculosis Research Center at Centers for Disease Control, Taiwan and the Adjunct Professor at National Yang-Ming University. Her research interest is mainly focused on diagnosis and genomics of *Mycobacterium tuberculosis* complex and *Mycobacterium leprae*, molecular epidemiology of tuberculosis and leprosy. She has published more than 50 papers in reputed journals.

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