Review of Adverse Events Following Immunization (AEFI) Reports after 2011–12 Seasonal Influenza Vaccination in Taiwan

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Declaration

The Taiwan National Adverse Drug Reaction Reporting Center, operated under Taiwan Drug Relief Foundation, is designated and funded by Taiwan Food and Drug Administration, Department of Health, Taiwan.

Background

Taiwan National Adverse Drug Reaction Reporting System was put in place to collect and analyze spontaneous AEFI reports to ensure safety of seasonal influenza vaccination since 2010.

Objective

To identify potential safety concerns that warrant further evaluation after 2011–12 seasonal influenza vaccination.

Methods

All AEFI reports received from October 1, 2011 through February 8, 2012 following 2011–12 seasonal influenza vaccination were reviewed. Reported adverse events were categorized according to MedDRA System Organ Class. Reports of death and certain medically important conditions were followed up by medical charts review. We calculated age-specific AEFI reporting rates for serious and non-serious reports.

Results

We received 151 reports after 2,572,037 doses of 2011–12 seasonal influenza vaccines administered (reporting rate 5.87 per 100,000 doses administered); 53 (35.1%) reports were classified as serious, including 1 report of death. 87 (35.1%) reported events were related to general disorders and administration site conditions, followed by 38 (15.3%) events of nervous system disorders and 37 (14.9%) events of skin and subcutaneous tissue disorders. The reporting rate of serious reports was the highest among the age group of <7 years (3.25 per 100,000 doses administered). Medical charts review of death reports and other medically significant events revealed no common epidemiologic patterns. Among serious reports, one case of Stevens-Johnson syndrome (SJS) and one case of toxic epidermal necrolysis (TEN) were received. Upon medical charts review we noted the individual developed TEN after influenza vaccination had concomitant *Mycoplasma* infection whereas the SJS case had no other identifiable etiologies attributable.

Conclusions

On our review of adverse events following 2011–12 seasonal influenza vaccination, no potential safety concerns were recognized. Nevertheless, reports of SJS following seasonal influenza immunization shall be carefully monitored because of its high morbidity and mortality. Package Insert was suggested to be added with related information to warn health care professionals and the public on this potential risk.

Table 1. Demographics of reports

Characteristics	Age group, years				
	<7	7-12	13-64	≥65	Total (%)
No. of Doses Administered	**399,450**	**646,326**	**491,318**	**1,034,943**	**2,572,037**
Seriousness *					
Serious	**13**	**11**	**11**	**18**	**53(35.1)**
Death	0	0	0	1	1(0.7)
Life-threatening	0	4	0	2	6(4.0)
Hospitalization (initial or prolonged)	8	7	7	10	32(21.2)
Other medically important event	5	0	4	5	14(9.3)
Non-Serious	**24**	**44**	**20**	**10**	**98(64.9)**
Reporting Rate §					
for Serious Reports	3.25	1.70	2.24	1.74	2.06
for Non-Serious Reports	6.01	6.81	4.07	0.97	3.81
for All Reports	9.26	8.51	6.31	2.71	5.87

§ Number of reports per 100,000 doses of 2011-12 seasonal influenza vaccine administered

*An AEFI is classified as serious when the patient outcome is death, life-threatening, hospitalization (initial or prolonged), disability or permanent damage, congenital anomaly/birth defect and other medically important event.

Table 2. Reported Events (by MedDRA System Organ Class)