Review of Adverse Events Following Immunization (AEFI) Reports After 2010-11 Seasonal Influenza Vaccination in Taiwan, October 1, 2010 January 16, 2011

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Declaration

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Background

Safety concerns regarding influenza vaccines had risen in Taiwan after the mass immunization campaign against 2009 pandemic influenza A (H1N1) (pH1N1). During the 2010–11 influenza season, Taiwan National Adverse Drug Reaction Reporting System collected and analyzed spontaneous AEFI reports after seasonal influenza vaccination.

Objective

To review AEFI reports after 2010–11 seasonal influenza vaccination and to identify potential safety concerns that warrants further evaluation.

Methods

All AEFI reports received from October 1, 2010 through January 16, 2011 following 2010–11 seasonal influenza vaccination were reviewed. We compared the MedDRA® High Level Term proportional reporting ratio (PRR) for AEFIs after 2010–11 seasonal influenza vaccines with pH1N1 vaccines by age groups (<7, 7–12, 13–64, and ≥65 years). Signal of disproportionate reporting (SDR) was defined as an adverse event with PRR ≥2, chi-square ≥4, and the number of reports (n) ≥3.

Results

We received 132 reports after 2,782,138 doses of 2010–11 seasonal influenza vaccines administered (reporting rate 4.74 per 100,000 doses administered); 43 (33%) reports were classified as serious, including 6 reports of death. Medical review did not indicate that vaccinations were associated with these deaths. Among serious events, 19 (23%) were related to the nervous system disorders. SDRs were observed for "injection site reactions" for the 7–12 years (PRR=3.92, chi-square=8.90, n=7) and "febrile disorders" for the ≥65 years (PRR=3.13, chi-square=6.77, n=9). All events of "injection site reactions" for the 7–12 years were from non-serious reports of different vaccine brands and batches. Clinical review of reports for "febrile disorders" in the group of ≥65 years revealed no common epidemiologic patterns.

Conclusions

Our review of adverse events following 2010–11 seasonal influenza vaccination did not recognized any new safety concerns. This near-real time AEFI surveillance will be routinely conducted during influenza seasons to serve as groundwork of vaccine safety monitoring in Taiwan.

Table 1. Demographics of reports

Characteristics	No. of reports (%) n=132	No. of doses administered n=2,782,138	Rate§
Gender			
Male	67 (50.8)	-	-
Female	65 (49.2)	-	-
Age group, years			
Total	132 (100.0)	2,782,138	4.74
<7	26 (19.7)	312,595	8.32
7-12	45 (34.1)	976,543	4.61
13-64	25 (18.9)	583,603	4.28
≥65	36 (27.3)	909,397	3.96
Seriousness			
Serious*	43 (32.6)	-	-
Death	6 (4.5)	-	-
Life-threatening	1 (0.8)	-	-
Hospitalization (initial or prolonged)	36 (27.3)	-	-
Non-Serious	89 (67.4)	-	-

§ Number of reports per 100,000 doses of 2010-11 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)

System Organ Class	Non-Serious Events No. of events (%)	Serious Events No. of events (%)
Blood and lymphatic system disorders	1 (0.6)	1 (1.2)
Ear and labyrinth disorders	1 (0.6)	1 (1.2)
Endocrine disorders	0 (0.0)	2 (2.4)
Eye disorders	5 (3.2)	1 (1.2)
Gastrointestinal disorders	17 (10.8)	9 (10.8)
General disorders and administration site conditions	49 (31.2)	17 (20.5)
Immune system disorders	1 (0.6)	1 (1.2)
Infections and infestations	3 (1.9)	9 (10.8)
Investigations	0 (0.0)	1 (1.2)
Metabolism and nutrition disorders	1 (0.6)	0 (0.0)
Musculoskeletal and connective tissue disorders	10 (6.4)	3 (3.6)
Nervous system disorders	28 (17.8)	19 (22.9)
Renal and urinary disorders	0 (0.0)	5 (6.0)
Respiratory, thoracic and mediastinal disorders	10 (6.4)	6 (7.2)
Skin and subcutaneous tissue disorders	31 (19.7)	6 (7.2)
Vascular disorders	0 (0.0)	2 (2.4)
Total	157 (100.0)	83 (100.0)

Table 3. SDRs Observed

Age group, years	SDR (MedDRA HLT)	No. of events	PRR	95% CI	Chi square
7-12	Injection site reactions	7	3.92	1.70-9.01	8.90
≥65	Febrile disorders	9	3.13	1.43-6.84	6.77