Adverse events following vaccination of older people may be under-reported

Hazel J Clothier[1,2], Nigel W Crawford[1,2], Melissa Russell[2], Jim P Buttery[1,3,4]

Adverse events following immunisation (AEFIs) in Australia are monitored by diverse jurisdictional passive surveillance systems that report to the national database, established primarily for detecting safety problems with childhood vaccinations. Supplementary, active AEFI surveillance systems, such as AusVaxSafety (operated by the National Centre for Immunisation

Adverse events following immunisation (AEFIs) reported to SAEFVIC, July 2007 – June 2016, by age group

	Age at vaccination				
	60–69 years	70–79 years	80–89 years	≥ 90 years	Total
AEFI reports	345	244	51	5	645
Sex (women)	252 (73%)*	158 (65%)	33 (65%)	4 (80%)	447 (69%)
Reactions†					
Localised	240 (70%)	169 (69%)	27 (53%)	3 (60%)	439 (68%)
Systemic‡	66 (19%)	28 (11%)	9 (18%)	1 (20%)	104 (16%)
Fever	53 (15%)	28 (11%)	6 (12%)	0	87 (13%)
Gastrointestinal	50 (14%)	31 (13%)	5 (10%)	0	86 (13%)
Musculoskeletal	41 (12%)	33 (14%)	1 (2%)	2 (40%)	76 (12%)
Allergic	28 (8%)	30 (12%)	2 (4%)	1 (20%)	61 (9%)
Headache	30 (9%)	15 (6%)	1 (2%)	0	46 (7%)
Inflammatory/immune	21 (6%)	8 (3%)	1 (2%)	1 (20%)	31 (5%)
Respiratory	14 (4%)	3 (1%)	3 (6%)	1 (20%)	21 (3%)
Cardiac	9 (3%)	7 (3%)	0	0	16 (2%)
Neurological	8 (2%)	4 (2%)	1 (2%)	0	13 (2%)
Other§	54 (16%)	36 (15%)	13 (25%)	1 (20%)	104 (16%)
Total	614	386	74	8	1082
Serious AEFIs, number	38	28	5	0	71
Proportion (95% CI)	11.0% (7.9–15%)	11.5% (7.7–16%)	9.8% (3.2–21%)		11.0% (8.7–14%)
Visited emergency department	18	16	0	0	34
Proportion (95% CI)	5.2% (3.1–8.1%)	6.6% (3.8–10%)	—	—	5.3% (3.8–7.3%)
Admitted to hospital, number	14	18	3	0	35
Proportion (95% CI)	4.1% (2.2–6.7%)	7.4% (4.4–11%)	5.9% (1.2–16%)	—	5.4% (3.8–7.5%)
Attended clinic, number	12	5	0	0	17
Proportion (95% CI)	3.5% (1.8–6.0%)	2.0% (0.7–4.7%)	—	—	2.6% (1.5–4.2%)
Vaccines†					
Influenza	210 (61%)	121	31 (61%)	3 (60%)	365 (57%)
Pneumococcal	166 (48%)	145	18 (35%)	3 (60%)	332 (51%)
Diphtheria/tetanus/pertussis booster	45 (13%)	21	3 (6%)	0	69 (11%)
Zoster	0	0	1 (2%)	0	1 (2%)
Other	16 (5%)	10	1 (2%)	0	27 (4%)
Total	437	297	54	6	794

SAEFVIC = Surveillance of Adverse Events Following Vaccination In the Community. * In one case, sex was not reported. † Multiple responses possible. ‡ Includes lethargy and malaise. § Includes drug administration errors (21 cases). ◆

[1] SAEFVIC, Murdoch Children's Research Institute, Melbourne, VIC. [2] University of Melbourne, Melbourne, VIC. [3] Monash Children's Hospital, Melbourne, VIC. [4] Monash Centre for Health Research and Implementation, Monash University, Melbourne, VIC. ✉ hazel.clothier@mcri.edu.au • doi: 10.5694/mja16.01371

Research and Surveillance) request AEFI information by automated SMS and email messages after selected vaccinations. Understanding AEFI reporting patterns for older people is important for identifying safety problems in this group, particularly following the introduction of a zoster vaccine program targeting 70–79-year-old people in November 2016.[1]

During July 2007 – June 2016, the Victorian enhanced passive AEFI surveillance service, Surveillance of Adverse Events Following Vaccination In the Community (SAEFVIC),[2] received 645 reports for people aged 60 or more (6.5% of all reports), a mean of 72 reports per year; 69% concerned women, and pneumococcal or influenza vaccines were the most frequently implicated vaccines (697 of 794 [88%]). The most frequent AEFIs were localised reactions (40.6% of all reactions; 95% confidence interval [CI], 37.6–43.6%); serious AEFIs were reported in 11% of cases (95% CI, 8.7–14%), and 5.4% of reported patients (95% CI, 3.8–7.5%) were hospitalised. Increasing age was not associated with higher frequencies of serious AEFIs or seeking medical attention (Box).

Two deaths were reported, unlikely to have been vaccine-related: a single vehicle accident after an uneventful influenza vaccination, and a post-vaccination diagnosis of acute disseminated encephalomyelitis. As a result of high annual influenza vaccination coverage in this population, coupled with age-related baseline mortality rates, deaths coincident with vaccination are likely to be more frequent in older people; robust investigation and causality assessment are therefore critical.[3]

Given that each year an estimated 75% of Australians aged 65 or more receive influenza vaccine, and many also receive pneumococcal vaccine, AEFI reporting for older people was less frequent than anticipated. In 2013, fewer AEFIs per influenza vaccine dose were reported for Australians over 65 than for those aged 18–65 years.[4] Despite having more comorbidities, older Australians also reported fewer serious AEFIs in an earlier study of all age groups.[5] The apparent under-reporting may reflect adverse events being perceived as normal in older people and therefore not linked with recent vaccinations, a higher threshold for reporting, or reduced access to reporting channels.

Analysing hospital admissions may increase case ascertainment, particularly for serious AEFIs. The expansion of AusVaxSafety in 2017 to include all age groups may also increase reporting by prompting associating events with recent vaccination,[6] but surveillance via mobile phone messaging in this age group may be unreliable.

Other methods of detection may be needed for AEFIs in older people. Improving case ascertainment and using vaccination data from the Australian Immunisation Register, which has recorded vaccinations for all age groups since 2016, will enable more sensitive and reliable surveillance, maintaining the overall safety of the National Immunisation Program.

As new vaccine programs are introduced for older people, vaccine pharmacovigilance in this age group must be improved. AusVaxSafety active surveillance is an important first step.

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