Vaccine 35 (2017) 2600–2604

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Assessment of sex-specific differences in adverse events following immunization reporting in Ontario, 2012–15

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ARTICLE INFO

Article history:
Received 1 February 2017
Received in revised form 8 March 2017
Accepted 10 March 2017
Available online 29 March 2017

Keywords:
Vaccine safety
Adverse events
Surveillance
Sex
Gender

ABSTRACT

We assessed sex-specific trends within passive vaccine safety surveillance in Ontario, Canada. AEFIs reported following vaccines administered between 2012 and 2015 were included. There were 2466 AEFI reports; 66.2% were female. Annualized reporting rates were 5.9 and 3.1 per 100,000 population, for females and males respectively. The female:male reporting rate ratio (RRR) was 1.9. Sex-specific differences by age group were greatest in adults 18–64 years (RRR 6.3); whereas there were no differences in children <10 years. Vaccine-specific RRRs were highest for vaccines recommended for routine use in adults or high risk populations. All event categories were female-predominant. The highest event-specific RRRs were for oculorespiratory syndrome (5.1), anaesthesia/paraesthesia (4.6) and anaphylaxis (3.0). Serious AEFIs (n = 113) were more evenly distributed (57.5% female, RRR 1.3) than non-serious (66.6% female, RRR 1.9). AEFI reporting among females was consistently elevated within the passive surveillance system in Ontario. Further study of the relationship between sex/gender and AEFI reporting is needed.

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1. Introduction

The sex differences in response to vaccination are likely multifactorial with both biological and behavioural influences [1]. There is growing evidence of sex-based biological differences in vaccine response. Higher immunogenicity and reactogenicity of vaccines in females has been consistently demonstrated [2–4] including evidence of more frequent and severe adverse reactions such as fever, injection site pain and inflammation, across a range of vaccines and ages [1,2,5].

Sex differences are also observed in passive reporting of adverse events following immunization (AEFIs), however it is often assumed that this reflects gender-based or behavioural differences, with females being more likely to report [1,6]. While several jurisdictions have noted female predominance in AEFI reports there are limited published analyses of AEFI surveillance data by sex to further explore these differences [7,8]. The goal of our analysis was to assess sex-specific trends in AEFI reporting within the passive provincial vaccine safety surveillance system in Ontario, Canada.

2. Methods

In Ontario, Canada's largest province (population 13.8 million; 2015), reporting of AEFIs by immunization providers is mandated by provincial public health legislation. In addition there is voluntary reporting from vaccine recipients or their caregivers. Reports of AEFIs are received by local public health units (PHUs) who investigate and enter information according to provincial surveillance guidelines into the integrated Public Health Information System (iPHIS), the electronic reporting system used in Ontario.

AEFIs reported following vaccines administered between January 1, 2012 and December 31, 2015 were extracted from iPHIS on May 1, 2016. AEFIs related to human papillomavirus vaccine were excluded as it was a female-only program during this time. Cases in which sex was not specified were excluded (n = 4). Adverse events were grouped by provincial surveillance definitions.[9] Annualized reporting rates were calculated using provincial population estimates as the denominator. Ages were grouped according to the provincial immunization schedule. Reporting rate ratios (RRRs) were calculated for comparison of reporting rates by sex and presented as ratios of the female to male reporting rate. Serious AEFIs were defined using the standard World Health Organization definition (i.e. an AEFI resulting in death, is life-threatening, requires in-patient hospitalization or prolongation of hospitalization, results in persistent or significant

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http://dx.doi.org/10.1016/j.vaccine.2017.03.035
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disability/incapacity, or a congenital anomaly/birth defect).[10] Analysis was performed using SAS version 9.3 and Microsoft Excel 2010. This project did not require review by the Public Health Ontario Ethics Review Board as it was considered as outside the scope of evidence generating initiatives requiring ethics review.

3. Results

In Ontario, there were 2466 AEFIs reported following vaccines administered over the four year period. The majority of AEFI reports (66.2%) were female. The annualized sex-specific reporting rates for females and males were 5.9 and 3.1 per 100,000 population, respectively and the overall female to male RRR was 1.9. No sex-specific trends over time were observed.

Although the age range of females and males was similar, females had a higher median age (33.7 years) compared to males (7.8 years). Female predominance was most pronounced in adults 18–64 years of age (RRR = 6.3), compared to adults 65 years and older (RRR = 1.8) and adolescents (RRR = 1.3). No sex differences were observed for children <11 years (all RRRs 1.0) (Fig. 1).

Within specific vaccines, the proportion of AEFI reports by sex varied (45.3% to 100.0% female). The highest female to male RRRs were observed for vaccines recommended for routine use in adults or high risk populations (Table 1). In contrast, only slight differences were observed for vaccines routinely administered to infants and children including three vaccines where male reporting rates were greater: diphtheria-tetanus-acellular pertussis-polio-*Haemophilus influenzae* type b, DTaP-IPV and pneumococcal conjugate vaccines.

Sex differences were observed across a wide range of adverse events. Adverse event categories with the greatest female predominance were allergic events and injection site reactions (see Table 2). The highest event-specific RRR was for oculorespiratory syndrome (ORS), anaesthesia/paraesthesia, and infected abscess. There were higher reporting rates among males for Guillian-Barré syndrome (GBS), parotitis, syncope with injury and hypotonic-hyporesponsive episode.

Serious AEFIs (n = 113) were more evenly distributed between the sexes (57.5% female, RRR 1.3), with a median age of 3.2 years for females and 1.8 years for males. Serious reporting rate ratios were highest for those aged 18–64 and ≥65 years (RRR 5.6 and 1.9, respectively) followed by <1 and 1–3 years (RRR 1.1 and 1.5, respectively); whereas the 4–10 and 11–17 year categories were male-predominant (RRR 0.8 and 0.3, respectively).

AEFI-related health care utilization and outcome also varied by sex. The proportion of reports where medical care was sought was slightly lower for females than males (out-patient consultation: 73.2% vs. 77.7%; emergency department visit: 19.7% vs. 23.0%; and hospital admission: 4.2% vs. 5.7%, for females and males respectively). Among reported AEFIs, females were slightly less likely to be recovered at the time of reporting (65.8%) compared to males (71.0%), with a greater proportion of females than males not yet recovered (22.1% vs. 19.4%, respectively) or with residual effects (3.2% vs. 1.4%, respectively).

Although reports from both females and males were most likely to come from a health care provider (66.3% vs. 63.9%, respectively), females were twice as likely to self-report AEFIs compared to males (9.7% vs. 4.4%, respectively).

4. Discussion

Our analysis showed a predominance of female AEFI reports with a clear age-related trend in reporting by sex over a four-year period in Ontario. Sex-specific differences peaked in adults 18 to 64 years with the reporting rate for females almost 7 times higher than for males. In contrast, there were much smaller differences for older adults and adolescents and no sex-specific differences in children under 11 years. This has been seen in prior AEFI analyses in Ontario [11,12] and with passive vaccine safety surveillance in the United States (US) [7] and Australia [8]. Female predominance in reported adverse events across the lifespan has also been observed in vaccine safety studies, and it has been hypothesized that both biologic and social/behavioural factors may play a role [1,4,5,13].

The biological basis of sex differences in vaccine response is likely multi-factorial. While specific mechanisms are not fully understood, immunological, hormonal, genetic and microbiota factors have been proposed [1]. We found elevated rates of certain

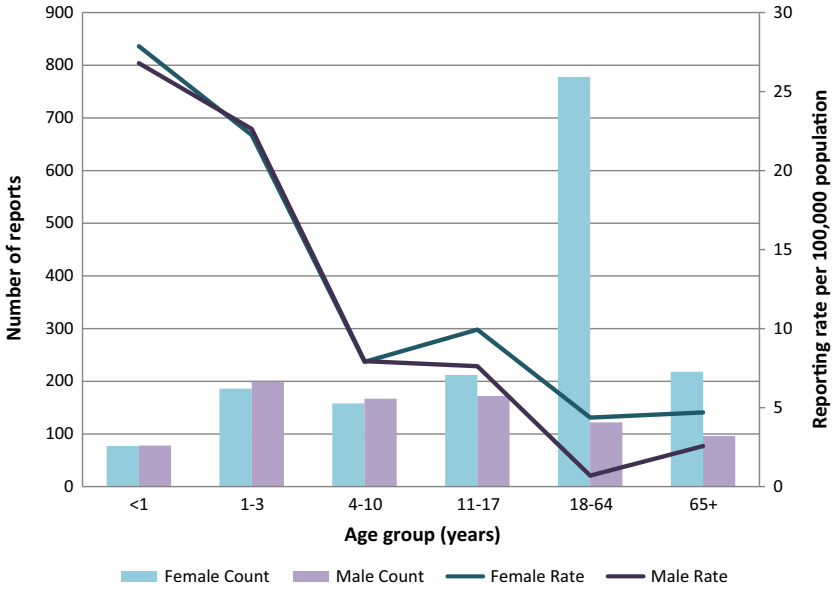

Fig. 1. Number of AEFI reports and reporting rates by age group and sex: Ontario, 2012–15 (n = 2459). **Ontario AEFI Reports:** integrated Public Health Information System database, extracted [2016/05/01]. **Ontario Population:** Population Estimates [2015], Statistics Canada, received [2014/07/03].
Notes: Three reports are excluded for unknown age and four are excluded for unspecified gender.

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