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Adverse events following pandemic influenza A (H1N1) 2009 monovalent and seasonal influenza vaccinations during the 2009–2010 season in the active component U.S. military and civilians aged 17–44 years reported to the Vaccine Adverse Event Reporting System

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ABSTRACT

Background: No comparative review of Vaccine Adverse Event Reporting System (VAERS) submissions following pandemic influenza A (H1N1) 2009 and seasonal influenza vaccinations during the pandemic season among U.S. military personnel has been published.
Methods: We compared military vs. civilian adverse event reporting rates. Adverse events (AEs) following vaccination were identified from VAERS for adults aged 17–44 years after pandemic (monovalent influenza [MIV], and seasonal (trivalent inactivated influenza [IIV3], live attenuated influenza [LAIV3]) vaccines. Military vaccination coverage was provided by the Department of Defense's Defense Medical Surveillance System. Civilian vaccination coverage was estimated using data from the National 2009 H1N1 Flu Survey and the Behavioral Risk Factor Surveillance System survey.
Results: Vaccination coverage was more than four times higher for MIV and more than twenty times higher for LAIV3 in the military than in the civilian population. The reporting rate of serious AE reports following MIV in service personnel (1.19 per 100,000) was about half that reported by the civilian population (2.45 per 100,000). Conversely, the rate of serious AE reports following LAIV3 among service personnel (1.32 per 100,000) was more than twice that of the civilian population. Although fewer military AEs following MIV were reported overall, the rate of Guillain–Barré Syndrome (GBS) (4.01 per million) was four times greater than that in the civilian population. (1.04 per million).
Conclusions: Despite higher vaccination coverage in service personnel, the rate of serious AEs following MIV was about half that in civilians. The rate of GBS reported following MIV was higher in the military.
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1. Introduction

In 2009, monovalent vaccines were rapidly developed and dispensed to prevent the spread of pandemic influenza A 2009 (H1N1) virus. In the United States, as the licensure and manufacturing processes for these novel vaccines were comparable to those of the seasonal vaccines for that year [1], similar vaccine safety profiles post licensure were anticipated. Subsequently, European studies which assessed safety among military personnel during the 2009–2010 influenza season found much higher reporting rates after MF59 and AS03 adjuvanted pandemic vaccines than after the seasonal trivalent inactivated influenza (IIV3) seasonal vaccines [2,3]. Similarly, an assessment of the adverse event (AE) profile in the U.S. civilian population following pandemic influenza A (H1N1) 2009 monovalent vaccine (MIV) using the Vaccine Adverse Event Reporting System (VAERS) was consistent with that of the seasonal influenza vaccines, although the reporting rate was higher [4]. In addition, one study assessing reporting rates to VAERS found reporting of hypersensitivity reactions following the pandemic influenza A (H1N1) 2009 vaccine to be elevated among adult civilian women compared with adult civilian men [5].

VAERS is a passive surveillance system for vaccine safety implemented in 1990 and is jointly administered by the Centers

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for Disease Control and Prevention and the Food and Drug Administration [6,7]. Healthcare providers are required to report vaccine AEs specified in the Vaccine Injury Table and manufacturers are required to report all AEs for licensed U.S. vaccines [8–10]. In addition, members of the public (vaccinees, parents of vaccine recipients, and others) may report suspected AEs to the system voluntarily. With the initiation of the national pandemic influenza A (H1N1) 2009 vaccination program, reporting to VAERS generally was enhanced by providing VAERS contact information on influenza vaccination record cards and advertising in medical journals. The military provided contact information for reporting to VAERS if there were problems after vaccination affecting its personnel [11]. Additionally, state vaccine safety coordinators were hired and trained on reporting requirements and more VAERS personnel were hired to code reports and obtain/review medical records. Finally, VAERS capacity to analyze additional reports was also improved so that potential safety signals could be rapidly identified.

To date, no comparative review of reports of AEs following pandemic influenza A (H1N1) 2009 and seasonal influenza vaccinations in the active component U.S. military in 2009–2010 influenza season has been published. It is also unclear whether elevated reporting rates to VAERS during the 2009–2010 influenza season found with the civilian vaccination program also affected the military population. The goals of this study were to identify potential differences between the U.S. military and civilian populations following pandemic influenza A (H1N1) 2009 and seasonal influenza vaccinations during the 2009–2010 influenza season related to: (1) vaccination coverage; (2) types of AEs reported to VAERS, and (3) a possible sex difference in hypersensitivity reactions reported following MIV among the military population.

2. Methods

2.1. Data sources

Military vaccination coverage among active duty personnel was determined using data from the Defense Medical Surveillance System (DMSS), an active surveillance system administered by the Department of Defense (DoD) to integrate data from medical treatment facilities, vaccination centers, and military personnel offices worldwide [12]. Data from DMSS also were used to validate active-duty military VAERS reports.

Civilian vaccination coverage was estimated using data from the National 2009 H1N1 Flu Survey (NHFS) and the Behavioral Risk Factor Surveillance System (BRFSS) survey [13–15]. Interview data collected for BRFSS and NHFS between November 2009 and June 2010 were used to measure pandemic influenza A (H1N1) 2009 vaccination coverage for October 2009 through May 2010. The population in each subgroup was estimated using the NHFS. Kaplan–Meier (KM) survival analysis was used to estimate the cumulative proportion of persons vaccinated separately for BRFSS and NHFS [15,16]. Monthly estimates from the two surveys were then combined in order to derive final monthly estimates of cumulative vaccination coverage [16].

2.2. Study design and population

We conducted a retrospective review of military and civilian VAERS reports to investigate possible differences in AE reporting rates for both the 2009 pandemic H1N1 and 2009–2010 seasonal influenza vaccines. The study population included all persons aged 17–44 years for whom a VAERS report was filed following either or both the pandemic (H1N1) 2009 or 2009–2010 seasonal influenza vaccines from August 1, 2009 through December 31, 2010. Service personnel were then identified if the VAERS report indicated that the vaccine (s) was administered in a military clinic and/or was purchased with military funds and included active personnel in the Army, Air Force, Marines and Navy.

2.3. Clinical review of reports

VAERS reports are classified as serious or non-serious. Reports are classified as serious based on the Code of Federal Regulations (21 CFR 600.80) if death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability or a congenital anomaly is reported. For serious reports from sources other than manufacturers, medical records are routinely requested. All VAERS reports were reviewed by a CDC medical officer who classified the AEs based on information in the text of the report and in medical records (when available) according to one of the following body system categories [4]: hypersensitivity (e.g., anaphylaxis, angioedema, dyspnea, urticaria, wheezing), cardiovascular (e.g., arrhythmia, hypertension, hypotension, myocarditis), ENT (ears, nose, throat), gastrointestinal (e.g., vomiting, diarrhea), local reaction (e.g., pain, tenderness, erythema), musculoskeletal (e.g., arthralgia, arthritis), neurologic (e.g., paresthesia, peripheral neuropathy, Bell's palsy, Guillain–Barré syndrome, convulsion), pregnancy-specific outcomes (e.g., spontaneous abortion, fetal death), psychiatric, respiratory (e.g., influenza-like illness, rhinorrhea, sore throat, cough), other infectious, other non-infectious conditions (e.g., diabetes, thrombocytopenia, multiple symptoms), and death. We used Brighton Collaboration criteria to verify the diagnosis for all reports suggestive of Guillain–Barré Syndrome (GBS) [17] and anaphylaxis [18]. We also considered GBS verified if medical records included a neurologist's diagnosis of GBS with no contradictory information and, for anaphylaxis, a documented physician's diagnosis of anaphylaxis within 24 h of vaccination. Cause of death was determined from the available autopsy report, death certificate, or medical record. Vaccine administration errors without an adverse health event and foreign reports were excluded.

2.4. Statistical analyses

We compared rates of AEs per doses administered following MIV, seasonal IIV3 and trivalent live attenuated influenza vaccine (LAIV3). To account for variability in the civilian estimation from the complex survey designs of NHFS and BRFSS in comparison with the data from the active military personnel, we used the delta method to calculate confidence intervals around the reporting rate ratios. We did not assess live attenuated monovalent vaccine (LAMV) further in our analysis as information on LAMV vaccination coverage for both military personnel and civilians was unavailable. We report descriptive analyses only consisting of the overall rates of AEs reported by the military and civilian populations. We could not perform statistical tests to assess reasons for the differences between the civilian and military populations because data for important confounding variables were unavailable.

Because VAERS is a routine surveillance program and does not meet the definition of research, it is not subject to Institutional Review Board (IRB) review and informed consent requirements. Similarly, NHFS was considered a non-research function and therefore not subject to IRB review.

3. Results

Of the total 434 military reports to VAERS for individuals who received MIV and/or seasonal influenza vaccine, 262 recipients were confirmed to be active component military in the DMSS; other reports denoted that the patient was a dependent or military

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