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BRIEF REPORT

MMR Vaccine Adverse Drug Reactions Reports in the CDC WONDER System, 1989-2019

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Abstract

Introduction: From January 1 to June 20, 2019, 1,077 individual cases of measles have been confirmed in 28 states. This is the greatest number of cases reported in the U.S. since measles was declared eliminated in 2000.

Methods: We retrieved data from the Vaccine Adverse Event Reporting System (VAERS) database, a national post-licensure vaccine safety surveillance system, through the CDC WONDER interface for reports of children aged 12 months to 6 years vaccinated with the MMR vaccine in the U.S. between January 1, 1989 and January 1, 2019. Specific ADRs evaluated in this analysis included anaphylaxis, febrile seizures, encephalitis, and orchitis. Disproportionate reporting of ADRs was assessed using proportional reporting ratios (PRRs) to identify possible new vaccine safety signals.

Results: A total of 158,602 ADR reports were identified for the MMR vaccine (all manufactures) and 329,379 reports for all other vaccines. No disproportionate reporting of any AE was found, except for orchitis, even though we might expect to see a higher proportion of these ADRs with the MMR vaccine than for all other vaccines.

Conclusion: The findings of this analysis appear to be reassuring as we found no disproportionate reporting of ADRs historically associated with the MMR vaccine as compared to all other vaccines over a period of 30 years. Although vaccine safety may be a well-known fact for healthcare providers, the use of the CDC WONDER interface and PRRs is an easy and quick way to reassure clinicians and patients regarding vaccine safety.

Keywords

Vaccine, Safety, Measles, Mumps, Rubella, Adverse reactions, Adverse events, VAERS, Reporting system

Abbreviations

VAERS: Vaccine Adverse Event Reporting System; CDC: Centers for Disease Control and Prevention; MMR: Measles, Mumps and Rubella vaccine; ADRs: Adverse Drug Reactions; AE: Adverse Events; PRRs: Proportional Reporting Ratios

Introduction

From January 1 to June 20, 2019, 1,077 individual cases of measles were confirmed in 28 states [1]. This is the greatest number of cases reported in the U.S. since measles was declared eliminated in 2000 [1]. Concerns about vaccine safety is a common reason parents express for refusing vaccinations for their children [2]. The CDC Wide-ranging Online Data for Epidemiologic

Table 1: CDC WONDER reports retrieved. Anaphylaxis included anaphylactic reaction (122 MMR vaccine reports; 187 all other vaccines) and anaphylactic shock (8 MMR vaccine reports; 10 all other vaccines). ITP, idiopathic thrombocytopenic purpura; ADR, adverse drug reactions.

	MMR vaccine	All other vaccines
Anaphylaxis	130	197
Febrile Seizures	1390	2446
Encephalitis	86	123
Orchitis	25	16
Severe Orchitis	1	2
ITP	60	83
All ADR	158,602	329,379
All severe ADR	22,002	41,344

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Table 2: Proportional Reporting Ratios (PRR) analysis. Evans, et al. criteria for signal detection: PRR ≥ 2, the χ^2 ≥ 4, and the number of individual cases ≥ 3.4 ITP, idiopathic thrombocytopenic purpura.

	PRR (CI 95%)	χ^2 with Yates correction	#Individual cases	Meets Evans, et al. criteria?
Anaphylaxis	1.372 (1.099-1.712)	7.550	130	No
Febrile Seizures	1.182 (1.106-1.263)	24.401	1390	No
Encephalitis	1.441 (1.094-1.897)	6.459	86	No
Orchitis	3.375 (1.811-6.292)	15.240	26	Yes
Severe Orchitis	0.940 (0.085-10.362)	0.000	1	No
ITP	1.501 (1.077-2.093)	5.407	60	No

Research (CDC WONDER) is a system developed to promote information-driven decision making and provide access to detailed public health information to healthcare providers [3]. This study aims to evaluate reports submitted to the VAERS system of children exposed to the MMR vaccine and the speed, simplicity, and versatility of the CDC WONDER web interface.

Methods

We retrieved data from the Vaccine Adverse Event Reporting System (VAERS) database, a national post-licensure vaccine safety surveillance system, through the CDC WONDER interface for reports of children aged 12 months to 6 years vaccinated with the MMR vaccine in the U.S. between January 1, 1989 and January 1, 2019. Specific ADRs evaluated in this analysis included anaphylaxis, febrile seizures, encephalitis, orchitis, and idiopathic thrombocytopenic purpura. Disproportionate reporting of ADRs was assessed using proportional reporting ratios (PRRs) to identify possible new vaccine safety signals. This is a statistical aid to signal generation based on the proportionate approach and the stability of a large database. It involves the calculation of the proportions of specified reactions or groups of reactions of drugs of interest where the comparator is all other drugs in the database [4]. The result is the PRR where the PRR is a/(a + c) divided by b/(b + d) in a two by two table [4].

Results

A total of 158,602 ADR reports were identified for the MMR vaccine (all manufactures) and 329,379 reports for all other vaccines (Table 1). ADRs terms with disproportionately higher reporting after MMR vaccine compared to all other vaccines were assessed using the criteria of Evans, et al. (PRR ≥ 2, the χ^2 ≥ 4 with Yates correction, and the number of individual cases ≥ 3) [4]. No disproportionate reporting of any AE was found, except for orchitis (Table 2), even though we might expect to see a higher proportion of these ADRs with the MMR vaccine than for all other vaccines. We further evaluated disproportionate reporting of severe orchitis (defined as orchitis that resulted in death, permanent disability, life threatening, hospitalized, existing hospitalization prolonged, congenital anomaly or birth defect, as specified by the CDC WONDER "Serious" tab selection) and no disproportionate reporting was found.

Conclusion

Measles virus is highly infectious and, before the introduction of vaccines > 90% individuals were infected by age 10 [5]. The findings of this analysis appear to be reassuring as we found no disproportionate reporting of ADRs historically associated with the MMR vaccine as compared to all other vaccines over a period of 30 years [6]. Although vaccine safety may be a well-known fact for healthcare providers, the use of the CDC WONDER interface and PRRs is an easy and quick way to reassure clinicians and patients regarding vaccine safety.

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All the listed authors contributed to the design and implementation of the research, to the analysis of the results and to the writing of the manuscript.

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