A report of the postmarketing spontaneous safety data over 24 years for GSK's measles-mumps-rubella (MMR) vaccine

Tina Singh, Giacomo Casabona, Remon Abu-Elyazeed, Volker Vetter, Fanny Hergibo

Presenter: Tina Singh
E-mail: tina.x.singh@gsk.com
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Background

GSK's MMR vaccine — Active immunization against MMR — Elicited robust immune responses, was well tolerated[2–4]

Live-attenuated MMR virus[1]

Individuals aged ≥12 months and older[1]

Licensed in >100 countries worldwide[5,6]

Monitoring the vaccine's real-world safety profile in the general population continues, and rapid collection of data on its real-world use is a strength of passive safety surveillance.

Objectives

We provide an overview of the postmarketing spontaneous safety data over 24 years for GSK's MMR vaccine.

Methods

GSK Global Safety Database
(4 Dec 1997–1 Mar 2022)

Patient exposure was estimated by number of DD.

Spontaneous AE reports
(following vaccination with GSK's MMR vaccine)

Analysis of annual reporting trends for AEs of clinical interest
(1998–2021)

- pyrexia
- rash
- febrile convulsions
- neurological conditions*

AE, adverse event; **DD**, doses distributed. *encephalitis and/or panencephalitis and/or meningitis and/or meningism; **meningism**, clinical syndrome of headache, neck stiffness, and photophobia, often with nausea and vomiting.

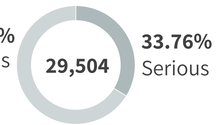
Results

DD and spontaneous AE reports retrieved
(4 Dec 1997–1 Mar 2022)

445,059,421 DD → **29,504 Spontaneous AE reports**

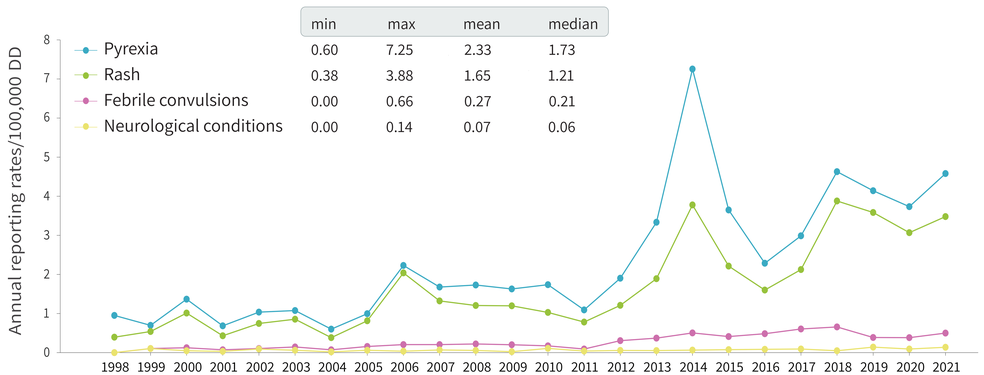
Reporting rate:
6.63 cases reported/100,000 DD

Seriousness of spontaneous AEs reported cumulatively



For the period analyzed, pyrexia, rash and febrile convulsions were amongst the frequently reported AEs following vaccination with GSK's MMR vaccine. The reporting rate for neurological conditions did not show an increasing trend over time.

Spontaneous AEs reported over 24 years (1998–2021), following vaccination with GSK's MMR vaccine



	min	max	mean	median
Pyrexia	0.60	7.25	2.33	1.73
Rash	0.38	3.88	1.65	1.21
Febrile convulsions	0.00	0.66	0.27	0.21
Neurological conditions	0.00	0.14	0.07	0.06

Note: Between Dec 2013–Apr 2015, a large number of AE notifications for several vaccines were received from one country's pharmacovigilance website, which is managed by their regulatory authority. This increased reporting was due to their initiative to improve information about vaccine safety with the aim of encouraging AE reporting by both physicians and patients. These reports did not constitute a safety concern.

Conclusion

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Post-licensure experience from spontaneous AE reporting for **GSK's MMR vaccine**

showed that its **safety profile** is **consistent** with that observed in clinical trials[4,11,12]

could help **reassure** the healthcare providers of the safety profile in **routine use**.

GSK continues monitoring the safety of its MMR vaccine worldwide.

Febrile convulsions. More than half of the reports of FC with known TTO, occurred from 6 to 11 days following MMR vaccination, aligned to several published articles.[7–10]

1,175 FC reported

Percentage of FC with TTO occurring from 6 to 11 days

FC, febrile convulsions; **TTO**, time to onset.

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