

COVID-19 vaccines and heavy menstrual bleeding: the impact of media attention on reporting to EudraVigilance

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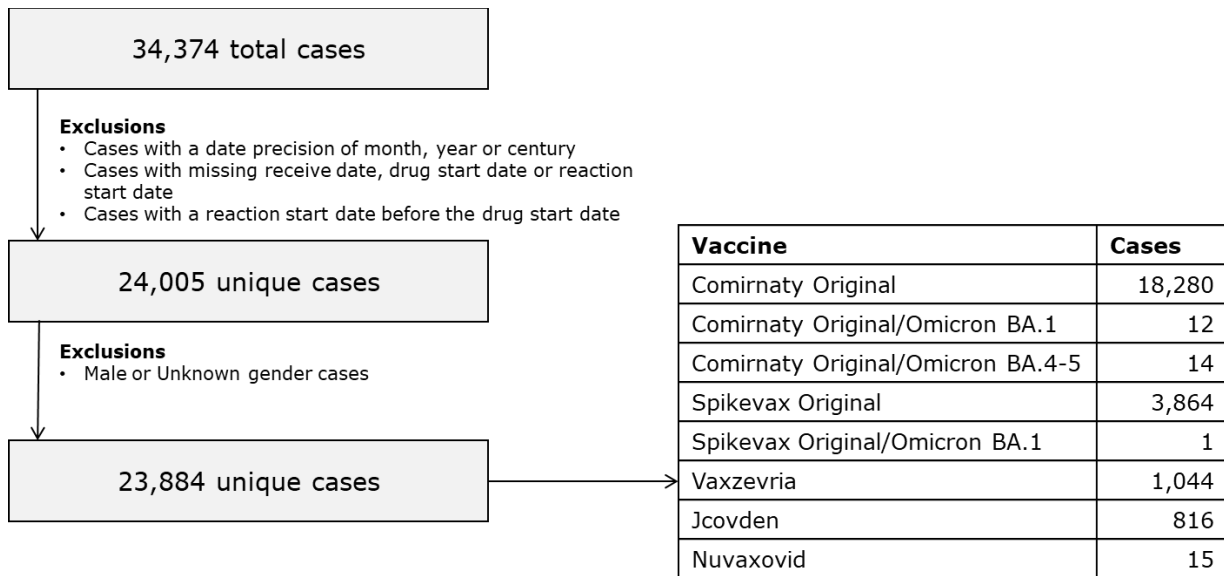
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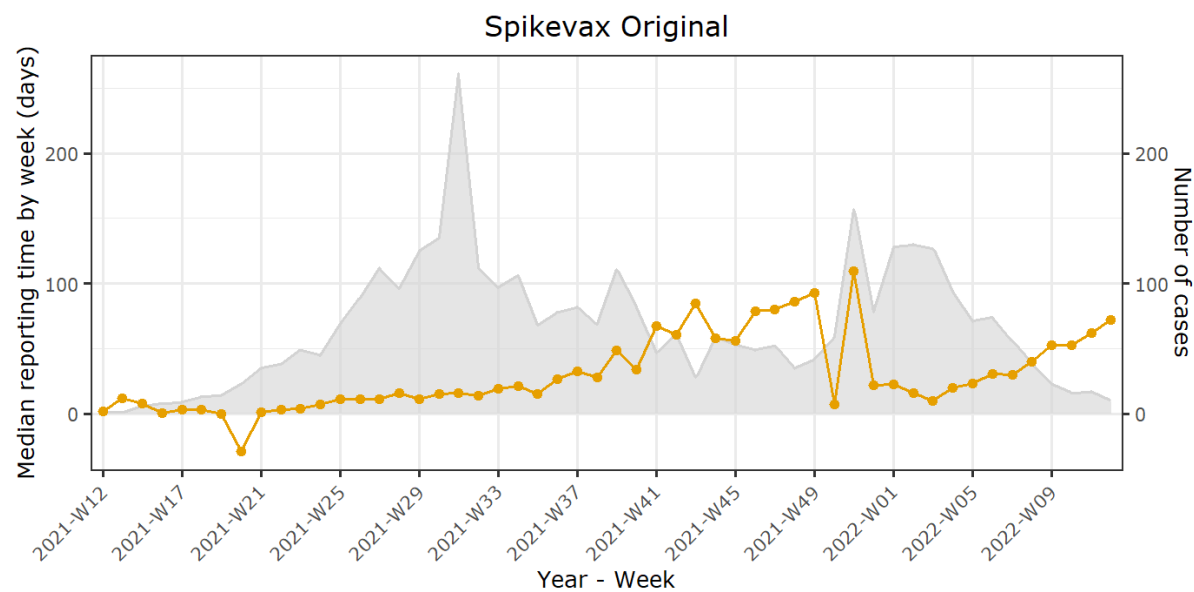
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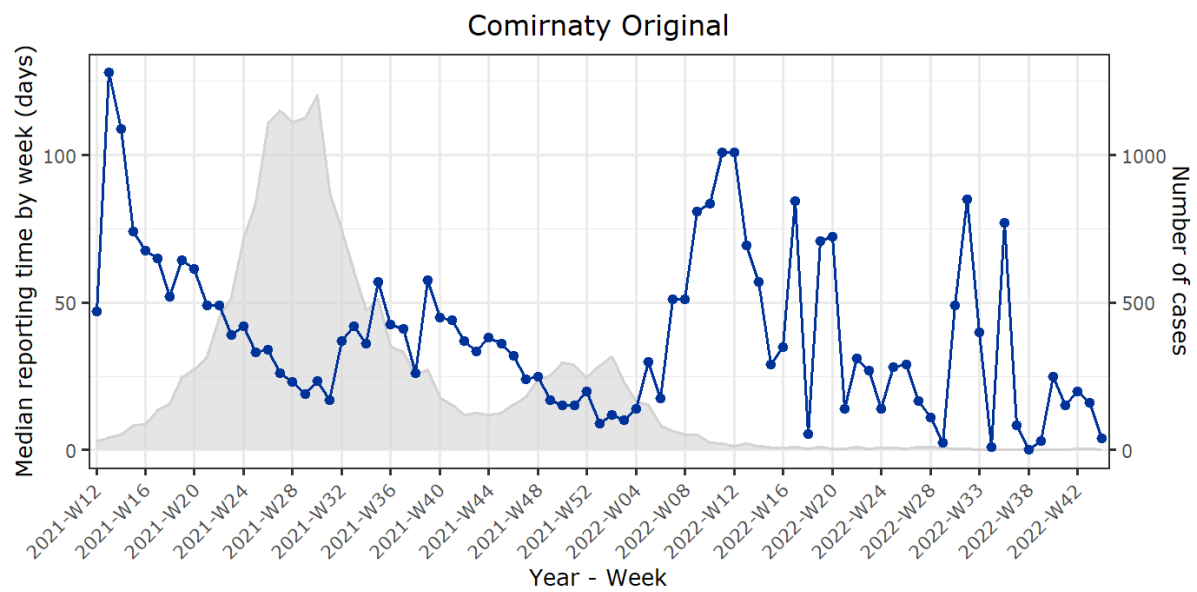
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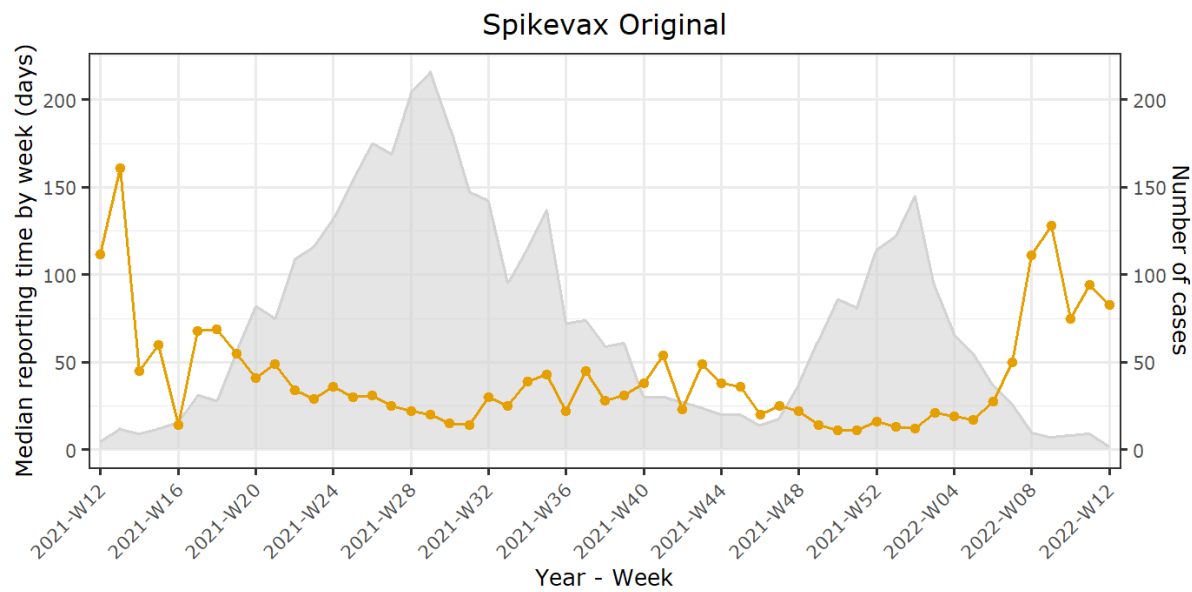
Supplementary Figure 1. Attrition diagram of the case identification strategy in EV during the study period (from 1 January 2021 to 13 December 2022) Due to heterogeneous vaccination schemes a case may have been retrieved for more than one vaccine.



Supplementary Figure 2. Median reporting time (days) and number of cases per receive week for Spikevax Original. The median reporting time is calculated by receive date minus reaction start date and indicated in orange. The weekly number of cases based on the receive date is indicated by the right-axis and shown by the grey area.



Supplementary Figure 3. Median reporting time (days) and number of cases per reaction start week for Comirnaty. The median reporting time is calculated by receive date minus reaction start date and indicated in blue. The weekly number of cases based on the receive date is indicated by the right-axis and shown by the grey area.



Supplementary Figure 4. Median reporting time (days) and number of cases per reaction start week for Spikevax Original. The median reporting time is calculated by receive date minus reaction start date and indicated in blue. The weekly number of cases based on the receive date is indicated by the right-axis and shown by the grey area.

Supplementary Table 1. Number of EEA cases reported to EudraVigilance during the study period (from 1 January 2021 to 13 December 2022) by country and vaccine brand. Due to confidentiality issues, countries with 10 or less cases were not included.

Country	Vaccine brand	Number of cases reported to EV
Netherlands	Comirnaty Original	5308
Germany	Comirnaty Original	4535
France	Comirnaty Original	2418
Norway	Comirnaty Original	1876
Germany	Spikevax Original	1005
Netherlands	Spikevax Original	807
Sweden	Comirnaty Original	775
Denmark	Comirnaty Original	639
Norway	Spikevax Original	626
Spain	Comirnaty Original	587
Finland	Comirnaty Original	578
France	Spikevax Original	511
Netherlands	Jcovden	466
Germany	Vaxzevria	346
Belgium	Comirnaty Original	334
Austria	Comirnaty Original	286
Italy	Comirnaty Original	285
Ireland	Comirnaty Original	231
Germany	Jcovden	185
Spain	Spikevax Original	179
Netherlands	Vaxzevria	171
Sweden	Spikevax Original	153
Iceland	Comirnaty Original	135
Denmark	Spikevax Original	133
Belgium	Spikevax Original	110
Spain	Vaxzevria	99
Finland	Spikevax Original	94
Italy	Spikevax Original	92
Czech Republic	Comirnaty Original	82
Norway	Vaxzevria	70
Iceland	Jcovden	58
Italy	Vaxzevria	53
Ireland	Vaxzevria	51
Denmark	Vaxzevria	47
Croatia	Comirnaty Original	45
Belgium	Vaxzevria	40
Austria	Vaxzevria	39
Iceland	Spikevax Original	38
Ireland	Spikevax Original	38
Sweden	Vaxzevria	34
Austria	Spikevax Original	32
France	Vaxzevria	32
Portugal	Comirnaty Original	32

Country	Vaccine brand	Number of cases reported to EV
Hungary	Comirnaty Original	31
Romania	Comirnaty Original	25
Spain	Jcovden	25
Greece	Comirnaty Original	22
Ireland	Jcovden	15
Lithuania	Comirnaty Original	15
Poland	Comirnaty Original	14
Belgium	Jcovden	12

Supplementary Note 1. ROR calculation

The calculation of the ROR is based on two-by-two contingency table and was performed as described in the EMA guideline for Screening of adverse drug reactions in EV¹⁷:

COVID-19 vaccine/Event	Heavy menstrual bleeding	Other events
COVID-19 vaccine	a	b
Other medicinal product	c	d

Where:

- ‘a’ indicates the number of individual cases that list the COVID-19 vaccine and the adverse event “Heavy menstrual bleeding”;
- ‘b’ indicates the number of individual cases that list the COVID-19 vaccine but not the adverse event “Heavy menstrual bleeding”;
- ‘c’ indicates the number of individual cases that list the adverse event “Heavy menstrual bleeding” but not the COVID-19 vaccine;
- ‘d’ indicates the number of individual cases that do not list the adverse event “Heavy menstrual bleeding” or the COVID-19 vaccine.

Supplementary Note 2. Keywords used in the media search.

(("Covid*" OR "coronavirus" OR "corona*" OR "mRNA*" OR "kórón*" OR "koron*" OR "Κορωνοϊός" OR "Κορωνοϊός" OR "Ιός Κόβιντ" OR "covidvaccinering" OR "κορονα*") AND ("vaccin*" OR "vaccination" OR "vaccinering" OR "vakc*" OR "rokot*" OR "vaccina*" OR "cjepiv*" OR "cepiv*" OR "vacuna*" OR "szczepi*" OR "vaksin*" OR "impf*" OR "bólusetningu" OR "bóluefni" OR "védóoltás" OR "Εμβόλιο" OR "Εμβόλια" OR "ο*kov*" OR "вакцина*") AND (("men*tru*" OR "menstruáció" OR "менструац*" OR "цикъл" OR "miesiączka" OR "mens" OR "ciclu menstrual" OR "menstruație") AND ("bleeding" OR "blutung*" OR "krv*ca*" OR "krv*ce*" OR "bloeding*" OR "saignemen*" OR "bløt*" OR "blödning*" OR "blød*" OR "vérzés" OR "кървене")) OR "menstruatiebloeding" OR "menstruationsblödning*" OR "mensrubb*" OR "kuukautisten vuoto" OR "kuukautisvuoto" OR "menstruationsblødning" OR "menstruasjonsblødning" OR "sangrado menstrual" OR "sanguinamento mestruale" OR "sangramento menstrual" OR "menstrualno krvarenje" OR "menstrualne krvavitve" OR "krwawienie miesiāczkowe" OR "krwawienie okres*" OR "kuukautisten verenvuoto" OR "τίδαβλæðingar" OR "Menstruationsblutung" OR "менструално кървене" OR "εμμηνόρροια" OR "έμμηνος ρύση" OR "έμμηνος κύκλος" OR "εμμηνορροϊκή αιμορραγία" OR "menstruációs vérzés" OR "menstruaalverejooks" OR "fsada menstruwali" OR "menstruālā asiņošana" OR "menstruasjonsforstyrrelser" OR "тежък цикъл" OR "sângerare menstruală") NOT ("Maskenpflicht" OR "akupressur" OR "homici*" OR "Kina" OR "fertilitetsbehandling" OR "Wimbledon" OR "Natasha Brock" OR "feminist*" OR "Eric Clapton"))