

Covid-19 vaccine side-effect reporting systems: public knowledge, attitudes, experience, and 'hesitancy' in 3 European countries

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Project - topic

‘the benefits outweigh the risks’: public reassurance?

How are such assessments constructed?

How are reports are sorted, classified and analysed?

To explore:

- (a) the structures/processes through which data on adverse events thought to be due to a Covid-19 vaccine are gathered;
- (b) processes of data-categorization and analysis; formulation of risk assessments;
- (c) popular awareness of procedures for reporting symptoms and experiences of them.

Project - methods

- UK, Netherlands, Italy – different systems
- Small pilot study - qualitative methods:
policy and regulators' documents and data; social media;
+interviews with professionals/experts; + inquiries with
members of public.
- Medical sociology/Science & Technology Studies (STS)
- -> UK case; background

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Coronavirus Yellow Card reporting site

Report suspected side effects to medicines, vaccines, medical device and test kit incidents used in coronavirus testing and treatment to the Medicines and Healthcare products Regulatory Agency to ensure safe and effective use

Find the medicine / vaccine / device you wish to report.

Start report

Sample of social media posts

MHRA's 'Yellow Card' reporting':

- “Son had bad reactions after both XXXX jabs. We told him to yellow card them. Dont think he bothered. ”
- “my husband read his (leaflet) so I wasn't totally irresponsible & already knew about the yellow card”
- “I received an automatic email inviting me to complete after my vaccine - many others I know did not and ...knew nothing about it”
- “I found the app too complicated and confusing”

So – issues of communications; family relations; technology, etc

(From Twitter, summer 2021)

‘Lay epidemiology’/ ‘practical reasoning’

How data can be construed, interpreted, shared:

“I..discovered a .. community of people linking Covid19 vaccs and menstrual horror stories” (*Twitter, 2021*)

Postmenopausal haemorrhage	82	0
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	6	0
Abnormal withdrawal bleeding	1	0
Dysmenorrhoea	2489	0
Intermenstrual bleeding	935	0
Menstrual discomfort	23	0
Menstrual disorder	1529	0
Menstruation irregular	2744	0
Premenstrual dysphoric disorder	9	0
Premenstrual headache	7	0
Premenstrual pain	97	0
Premenstrual syndrome	101	0
Retrograde menstruation	1	0

Having made a report

“Thank you very much for completing a Yellow Card report for a suspected side effect to a COVID-19 vaccine. **Your report supports the MHRA’s ability to continuously monitor the safe and effective use of vaccines in this pandemic.**

Vaccines are the most effective way to prevent infectious diseases and they save millions of lives worldwide. Like all medicines, vaccines can cause side effects. Some side effects can come to light when given to a larger number of people than took part in clinical trials however, most are mild and short-term, and not everyone gets them. The known safety profile of COVID-19 vaccines is available on the Coronavirus Yellow Card reporting site.”

Etc.

(MHRA, 2021)

MHRA/Regulator's data, e.g.

COVID-19 mRNA Pfizer-BioNTech Vaccine Analysis Print

Report Run Date: 07-Oct-2021
Data Lock Date: 06-Oct-2021 18:31:55

All UK spontaneous reports received between 09/12/20 and 06/10/21 for mRNA Pfizer/BioNTech vaccine.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

“Spontaneous reports..continual review”

Pharmacovigilance process – how are data analysed?

Exertional headache	8	0
External compression headache	2	0
Headache	22539	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	10	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	7	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	42	3
Cerebral venous thrombosis	6	0
Superior sagittal sinus thrombosis	4	0
Transverse sinus thrombosis	1	0

Pharmacovigilance/side-effects analysis: assembling expertise

 Medicines & Healthcare products Regulatory Agency

Research and analysis

Report of the Commission on Human Medicines Expert Working Group on COVID-19 vaccine safety surveillance

Published 5 February 2021

“MHRA seeks independent expert advice from the Commission on Human Medicines (CHM). In May 2020, the CHM established an Expert Working Group (EWG), consisting of experts in medicine, infectious disease, pharmacoepidemiology and data analytics”

Pharmacovigilance/side-effects analysis: methodologies (of knowledge production)

'Four main strands' in MHRA strategy:

(First 3 'signal detection/strengthening')

1. Enhanced passive surveillance – 'observed vs expected' analysis (i.e. Yellow Card for Covid)

2. Rapid Cycle Analysis and Ecological analysis
(analysing 'pre-defined events' from GP practice and select population data)

3. Targeted active monitoring – Yellow Card Vaccine Monitor

<https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance>. Feb 2021

Concluding - questions

- How reports from multiple sources in multiple vocabularies are aggregated?
 - Transparency of data and analysis systems
 - Regulators' public communication/ Vaccine PR?
 - attempted legitimation via 'public health' population-level discourse
 - 'practical reasoning' in publics' reporting (and discussion)
- > implications for public trust, confidence, 'hesitancy'?

Thank you

Blume T & Mezza, M (2021) COVID-19 vaccines and the fear of side effects. *Culturico*, April 11.

<https://culturico.com/2021/04/11/covid-19-vaccines-and-the-fear-of-side-effects/>

Horlick-Jones, T. (2005) Informal logics of risk: contingency and modes of practical reasoning. *Journal of Risk Research* 9(3): 253-272.