

Medically invisible women. Also for the European Medicines Agency with regard to the serious blood clotting disorders caused by covid19 vaccines. By Mercedes Pérez- Fernández & Juan Gérvas.

Being invisible, being a woman.

“Imagine a world where your phone is too big for your hand, where your doctor prescribes a drug that is wrong for your body, where in a car accident you are 47% more likely to be seriously injured, where every week the countless hours of work you do are not recognised or valued. If any of this sounds familiar, chances are that you’re a woman” (1).

What can be done to tackle a problem potentially so silent and systemic? The first solution: collect sex-aggregated medical data. This means data are collected and analysed separately on both males and females (2).

Aim.

To assess how women are made invisible by the European Medicines Agency in the case of severe blood clotting disorders as adverse effects of genetic covid19 vaccines.

Janssen, the Johnson-Johnson (J&J) vaccine. The USA agencies versus de European Union agency.

1 The USA.

The FDA, said in a press briefing on April 23: “The health agencies have confirmed 15 reported cases of the blood clotting disorder, ALL in women ages 18 to 59 who had received the J&J vaccine.

Three of the cases were fatal; seven women remain hospitalized.

To date, more than 8 million doses of the J&J vaccine have been administered in the U.S.

Risk of rare blood clots from J&J vaccine:

Overall: 1.9 cases per 1 million people.

Women ages 18 to 49: 7 cases per 1 million people.

Women 50+: 0.9 cases per 1 million people” (3).

2 The European Union.

“At its meeting of 20 April 2021, the European Medicines Agency (EMA)’s safety committee (PRAC) concluded that a warning about unusual blood clots with low blood platelets should be added to the product information for COVID-19 Vaccine Janssen.

As of 13 April 2021, over 7 million people had received Janssen’s vaccine in the United States. All cases occurred in people under 60 years of age within three weeks after vaccination, the MAJORITY in women” (4).

Summary.

In the European Union, no additional data. Women are invisible.

AstraZeneca vaccine. European Union.

With more than 222 cases updated 4 April, the European Medicines Agency (EMA) was able to provide data on the risk of serious adverse effects of blood clotting by age group and infection rate, BUT NOT BY SEX («There were insufficient data available from across the EU to provide further context on benefits and risks with regard to sex») on 26 April (5,6).

“EMA’s human medicines committee (CHMP) has further analysed available data to put the risk of these very rare blood clots in the context of the vaccine’s benefits for different age groups and different rates of infection.

The Committee analysed the vaccine’s benefits and the risk of unusual blood clots with low platelets in different age groups in the context of the monthly infection rates: low (55 per 100,000 people), medium (401 per 100,000 people) and high (886 per 100,000 people).

The analysis looked at prevention of hospitalisations, ICU admissions and deaths due to COVID-19, based on different assumptions of vaccine effectiveness to contextualise the occurrence of these unusual blood clots. It showed that the benefits of vaccination increase with increasing age and infection rates.

There were insufficient data available from across the EU to provide further context on benefits and risks with regard to sex” (6).

Summary.

In the European Union, no additional data. Women are invisible.

More on the AstraZeneca vaccine.

From what has been published, outside the European Medicines Agency, we know:

In Austria-Germany there were 9 women cases out of a total of 11. Deaths, 6 (on 7 March) (7).

In Norway there were 4 women cases out of a total of 5. Deaths, 3 (on 20 March) (8).

In the UK there were 120 women cases out of a total of 209. Deaths 41 (24 females, 17 males). On 21 April (9).

Global summary.

It could be that the higher frequency of adverse effects in women is due to the fact that they are the first and most vaccinated because they belong to groups at risk, such as health professionals and the social and healthcare sector.

But in any case the European Medicines Agency makes women invisible with regard to the serious alterations in blood coagulation caused by covid19 vaccines.

No sex-disaggregated data are provided, even though the problem predominantly affects women, in terms of frequency and lethality.

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References

1 Invisible women

<https://carolinecriadoperez.com/book/invisible-women/>

2 Medically invisible women part one: Caroline Criado-Perez at Digital Health Rewired

<https://practicebusiness.co.uk/medically-invisible-women-part-one-caroline-criado-perez-at-digital-health-rewired>

3 U.S. Resumes Use of Johnson & Johnson COVID-19 Vaccine

<https://www.aarp.org/health/conditions-treatments/info-2021/johnson-and-johnson-vaccine-resumes.html>

4 COVID-19 Vaccine Janssen: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets

<https://www.ema.europa.eu/en/news/covid-19-vaccine-janssen-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood>

5 AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets. News 07/04/2022

<https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood>

6 AstraZeneca's COVID-19 vaccine: benefits and risks in context

<https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-benefits-risks-context>

7 Greinacher A, Thiele T, Warkentin TE, Weisser K, Kyrle PA,

Eichinger S. Thrombotic Thrombocytopenia after ChAd0x1 nCov-19 Vaccination. N Engl J Med. 2021 Apr 9. doi: 10.1056/NEJMoa2104840. Epub ahead of print. PMID: 33835769.

8 Schultz NH, Sørvoll IH, Michelsen AE, Munthe LA, Lund-Johansen F, Ahlen MT, Wiedmann M, Aamodt AH, Skattør TH, Tjønnfjord GE, Holme PA. Thrombosis and Thrombocytopenia after ChAd0x1 nCoV-19 Vaccination. N Engl J Med. 2021 Apr 9. doi: 10.1056/NEJMoa2104882. Epub ahead of print. PMID: 33835768.

9 Coronavirus vaccine – weekly summary of Yellow Card reporting Updated 29 April 2021

<https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting>