COVID-19 vaccine safety signals in adverse event reports

Vibeke Manniche
MD, PhD in Public Health
LIVA
Denmark



The rest of the scientific team

Tomáš Fürst PhD



Assistant Professor
Palacký University, Czech Republic

Max Schmeling



Independent Data Scientist
Innometric
Denmark

Jonathan Gilthorpe PhD



Assoc. Prof. in Neuroscience
Umeå Univeristy, Sweden

Peter Riis Hansen MD PhD



Professor of Cardiology
Copenhagen University Hospital
Univeristy of Copenhagen
Denmark

Pfizer quote

"We flew the aeroplane while we were still building it"

Kathrin Jansen (former Senior Vice President/Pfizer, Manager for Vaccine Research & Development)

Interview in *Nature Reviews Drug Discovery*, November 2022

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RESEARCH LETTER

Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine

Max Schmeling[1] | **Vibeke Manniche**[2] | **Peter Riis Hansen**[3]

[1]Innometric, Skørping, Denmark

[2]LIVA, Copenhagen, Denmark

[3]Department of Cardiology, Kobenhavns Universitet, Copenhagen, Denmark

Correspondence

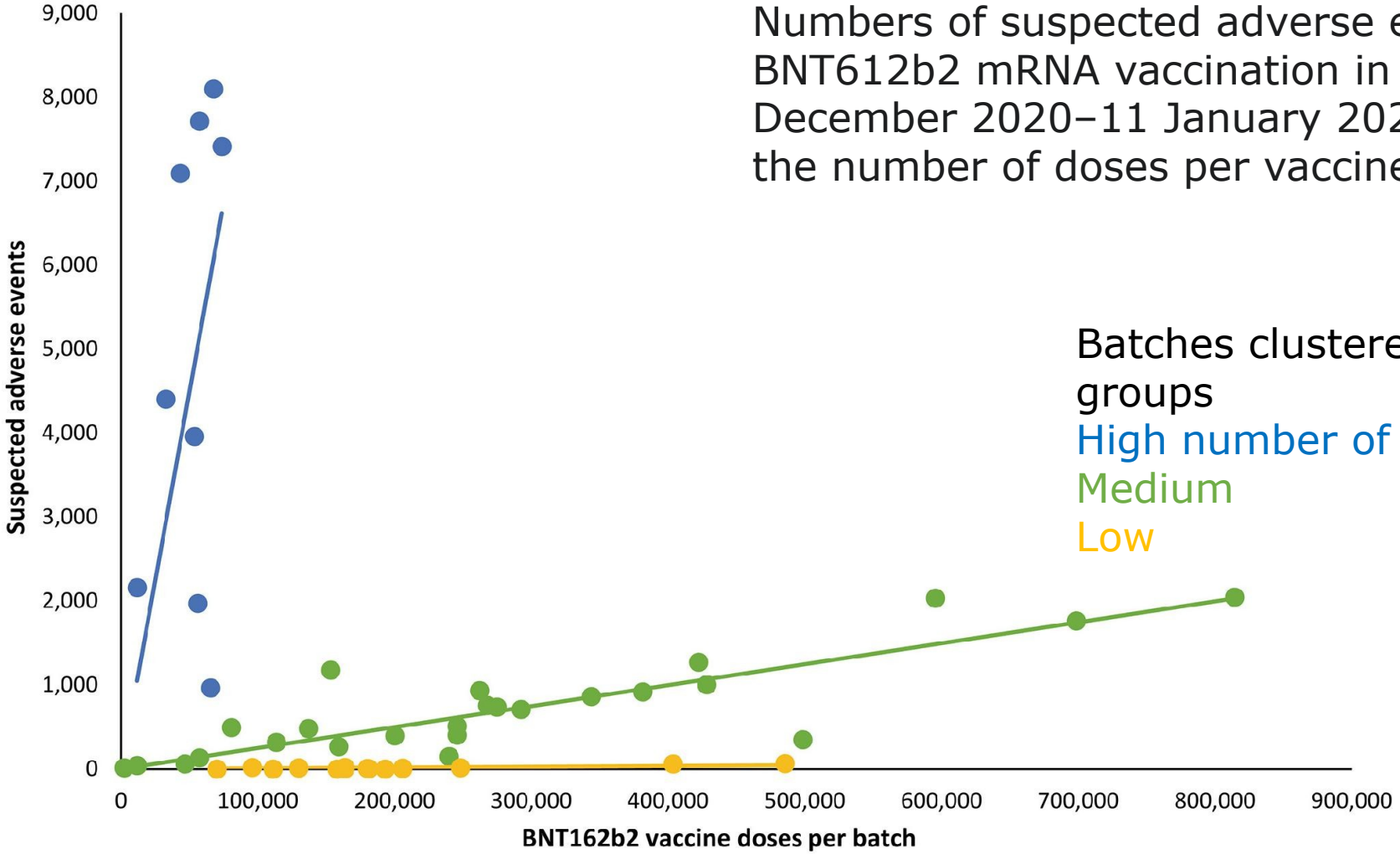
Peter Riis Hansen, Department of Cardiology, Kobenhavns Universitet, Copenhagen, Denmark.

Email: prha@sund.ku.dk

Batch dependent safety of the BNT162b2 mRNA COVID 19 vaccine

- https://doi.org/10.1111/eci.13998
- Study period 27 dec. 2020 to 11 jan. 2022
- 52 different BNT162b2 vaccine batches were administered
- 10.793.766 doses were administered to 4.026.575 persons
- 43,496 Adverse reactions were registered in 13,635 persons
- The study did not include a backlog of 49,794 adverse reactions, which at the time was not yet processed by the Danish Medicines Agency and to which we could not gain access.

Batch-dependent differences in SAE reports Denmark



Numbers of suspected adverse events (SAEs) after BNT612b2 mRNA vaccination in Denmark (27 December 2020–11 January 2022) according to the number of doses per vaccine batch.

Batches clustered into 3 different groups

High number of reported SAEs

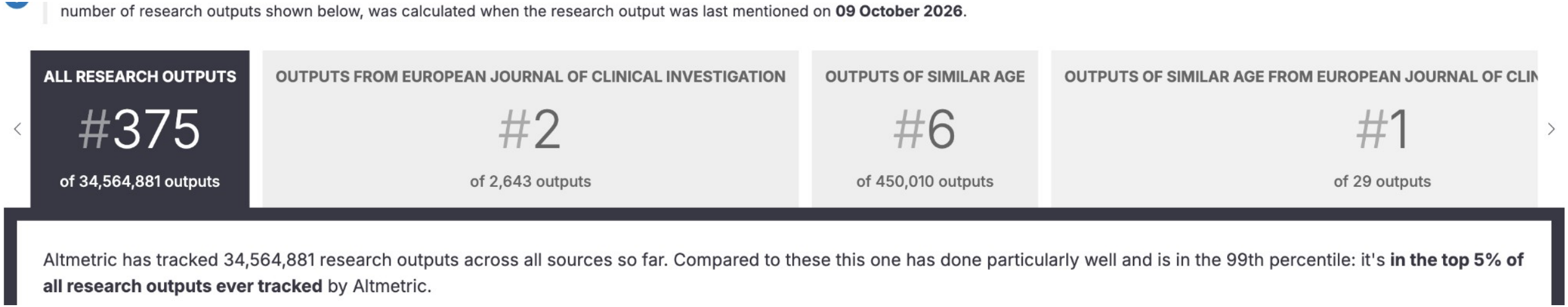
Medium

Low

Schmeling *et al*. (2023) - Main conclusions

- *Russian roulette…*
- *”Five out of six scientists have proven that Russian roulette is harmless.” – Robert Malone*

Without any press coverage…



Batch dependent safety of the BNT162b2 mRNA COVID 19 vaccine

- https://doi.org/10.3390/medicina60081343
- Study period 27 dec. 2020 to 11 jan. 2022
- 52/112 different BNT162b2 vaccine batches were administered
- In Denmark 93,245 Adverse reactions were registered in 34,410 persons.
- In Sweden 219,731 Adverse reactions were registered in 56,784 persons.
- At this time only a few hundred reports had not been processed in both Denmark and Sweden

medicina

https://www.mdpi.com/1648-9144/60/8/1343

MDPI

Article

Reports of Batch-Dependent Suspected Adverse Events of the BNT162b2 mRNA COVID-19 Vaccine: Comparison of Results from Denmark and Sweden

Vibeke Manniche [1], Max Schmeling [2], Jonathan D. Gilthorpe [3] and Peter Riis Hansen [4,5,*]

1 LIVA, Rosenvængets Allé 6A, DK-2100 Copenhagen, Denmark; vibeke@vibekemanniche.dk
2 Innometric, Bavnehøjvej 5, Hellum, DK-9520 Skørping, Denmark; max@schmeling.dk
3 Department of Medical and Translational Biology, Umeå University, 901 87 Umeå, Sweden; jonathan.gilthorpe@umu.se
4 Department of Cardiology, Copenhagen University Hospital—Herlev and Gentofte, Gentofte Hospitalsvej 1, DK-2900 Hellerup, Denmark
5 Department of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Blegdamsvej 3B, DK-2200 Copenhagen, Denmark
* Correspondence: peter.riis.hansen@regionh.dk; Tel.: +45-31-31-18-31

Batch-dependent differences in SAE reports Denmark and Sweden

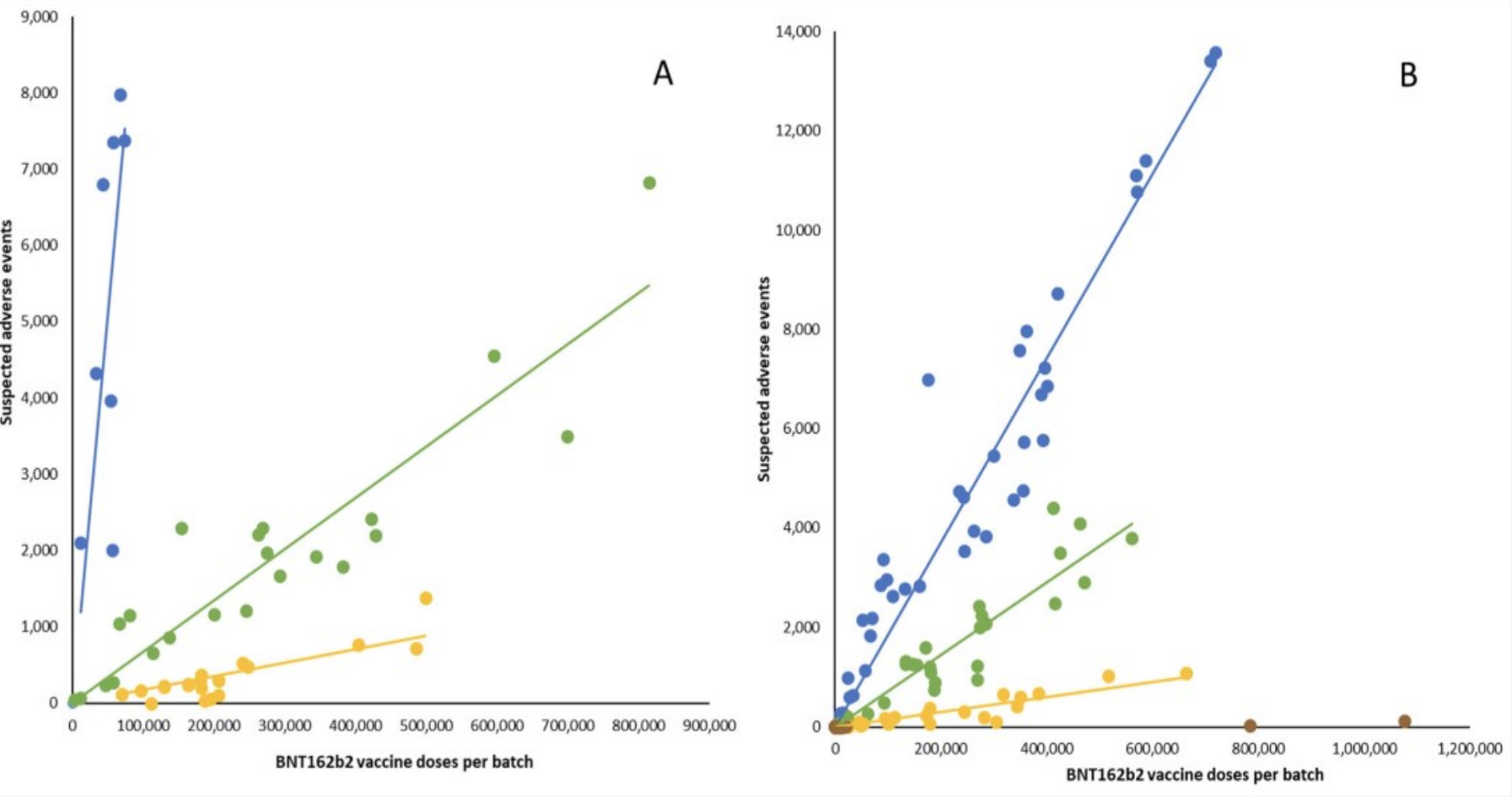
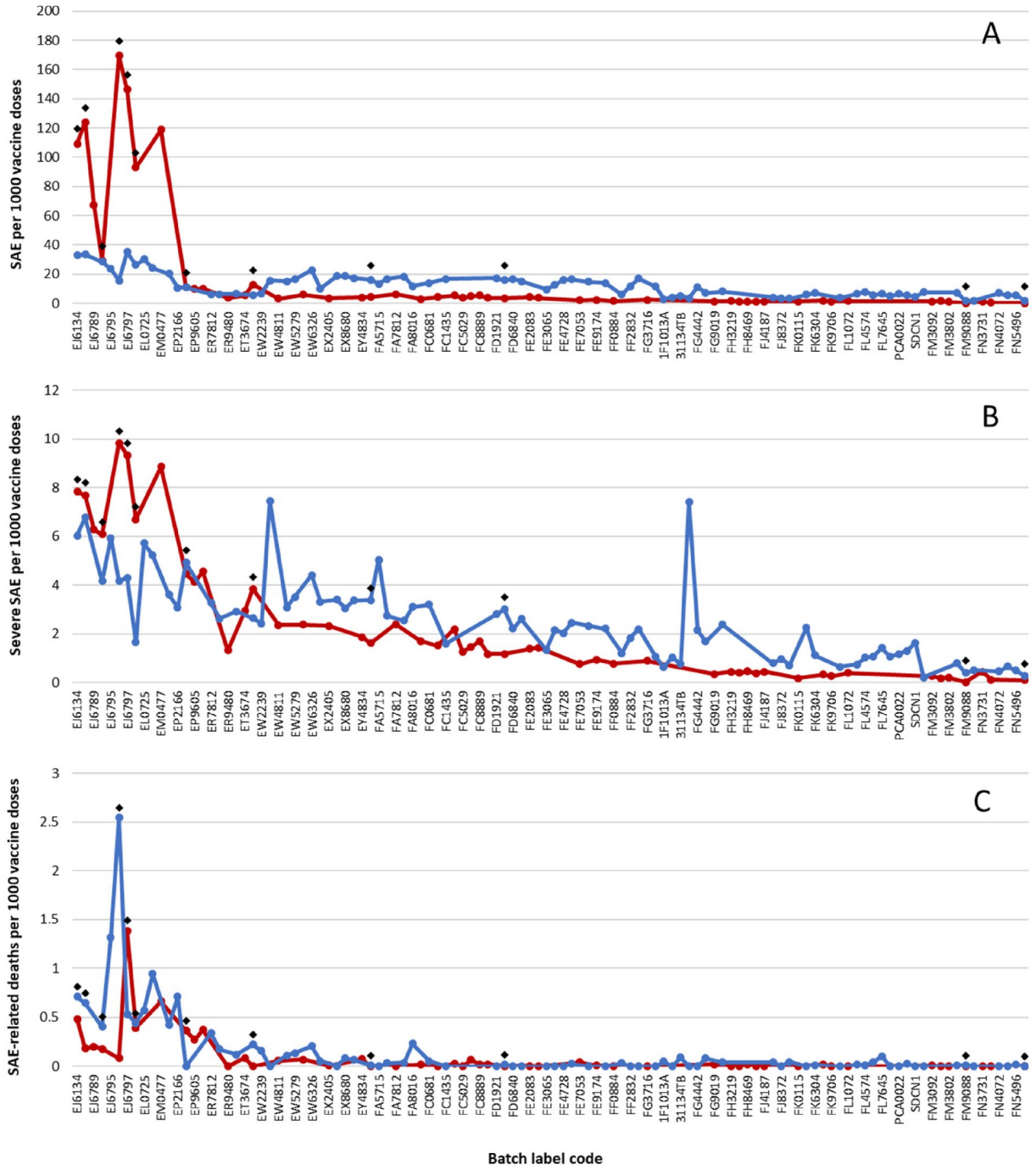


Figure 1. Number of suspected adverse events after BNT162b2 mRNA vaccination in Denmark in the period from 27 December 2020 to 11 January 2022 (**A**) and in Sweden in the period from 27 December 2020 to 19 January 2024 (**B**)

Batch-Dependent SAE Rates for Vaccine Batches Shared between Denmark and Sweden



SAEs) per 1000 doses per batch:

Denmark (red)

Sweden (blue)

Manniche *et al*. (2023) - Main conclusions

- Wide variation in the risk of side effects after COVID-19 vaccination.
- Some people who received Pfizer/BioNTech's COVID-19 vaccine had a significantly higher risk of reported side effects than others.
- Replication of the Danish study from April 2023.
- 75% of SAE were from women – not only explained by bleeding aso. Should be scrutinised by authorities
- Underreporting – even more than the usual 85% underreporting. Here much less doctors reporting than usual.
- Confirmation of a major safety issue with Pfizer's COVID-19 vaccine.
- Not just a phenomenon in Denmark and likely to be a widespread problem.
- Would normally have led to safety reviews and product recalls.
- Precautionary principle set aside

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Mary Ann Liebert
A Part of Sage

Batch-dependent safety signal: Nationwide analysis of suspected adverse events following COVID-19 vaccination in Germany

Vibeke Manniche[1], Vít Karásek[2], Max Schmeling[3], Jonathan D. Gilthorpe[4], Tomáš Fürst[5], and Peter Riis Hansen[6,7]

Abstract

Background: Preliminary reports have suggested a batch-dependent safety signal for COVID-19 vaccines. It is important to establish if these findings can be replicated.

Methods: We used publicly available nationwide data from Germany spanning the first 3.5 years of the vaccination campaign to calculate weekly rates of spontaneously reported suspected adverse events (SAEs) per 1000 administered vaccine doses.

Results: SAE rates ranged between 2.2 and 22.8 per 1000 doses and women accounted for 72% of all SAEs. Crucially, SAE rates for Comirnaty (Pfizer-BioNTech), Spikevax (Moderna), and Vaxzevria (AstraZeneca) were very high in the initial phase of vaccination rollout and hereafter declined precipitously. For example, SAE rates in weeks 1–4 of 2021 were 8.2, 50.8, and 620.9 per 1000 doses of Comirnaty, Spikevax, and Vaxzevria, respectively, but fell to 4.4, 11.6, and 7.4 per 1000 doses in weeks 12–16 of 2021.

Conclusions: SAE rates in Germany were highly elevated in the initial phase of COVID-19 vaccination rollout and then fell precipitously, a pattern compatible with a batch-dependent safety signal. Furthermore, there was a considerable overrepresentation of women with SAEs. These preliminary results call for more definitive studies of batch-dependent COVID-19 vaccine safety.

Findings Germany

- SAE rangede from 2.2 - 22.8 pr 1000 doses
- 72% of reports where from women
- SAE rates were very high for Pfizer, Moderna and Astrazeneca in the initial phase of the roll out and declined rapidly here after
- The batch-dependency were NOT only a problem for Pfizer

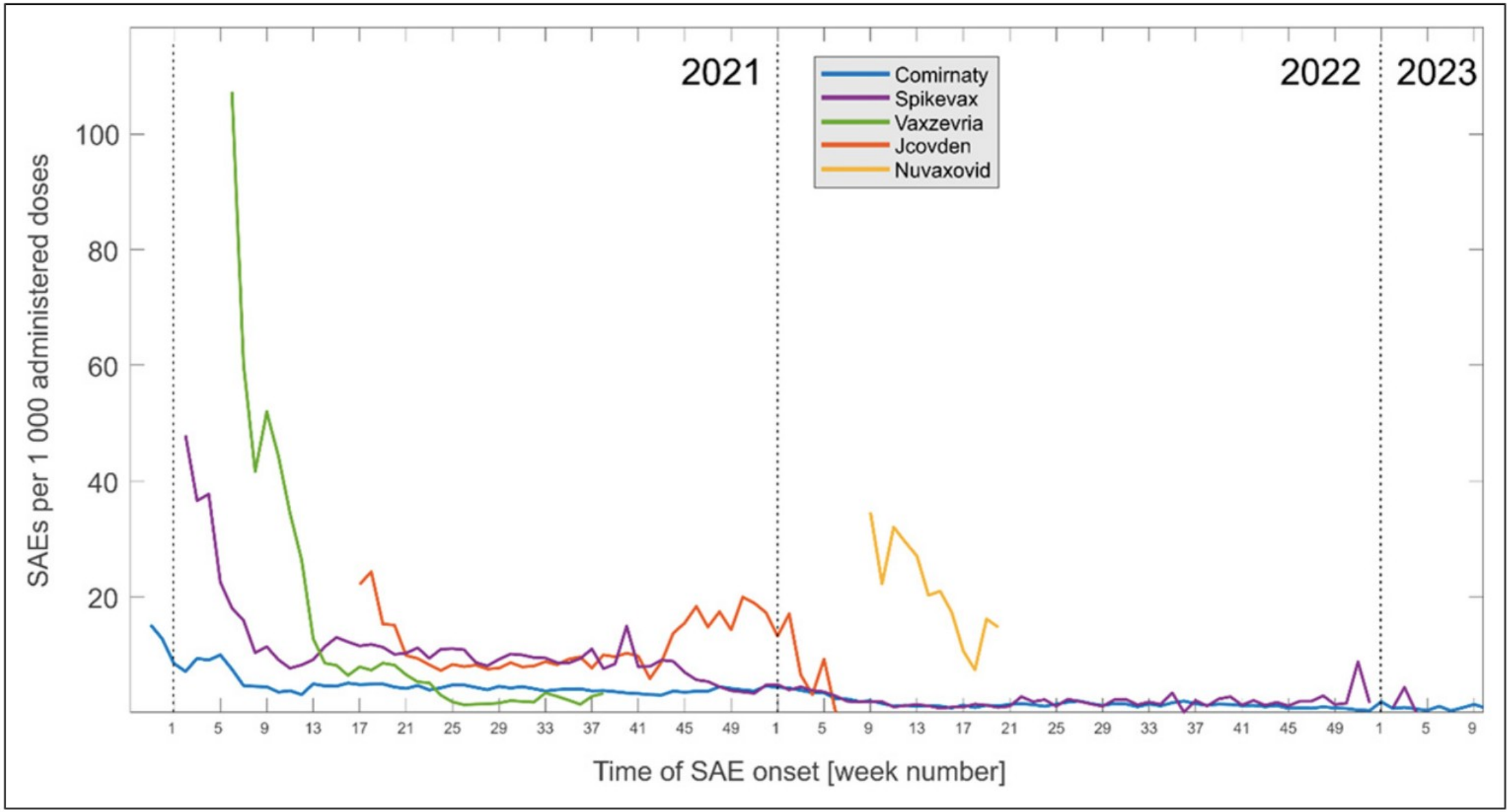
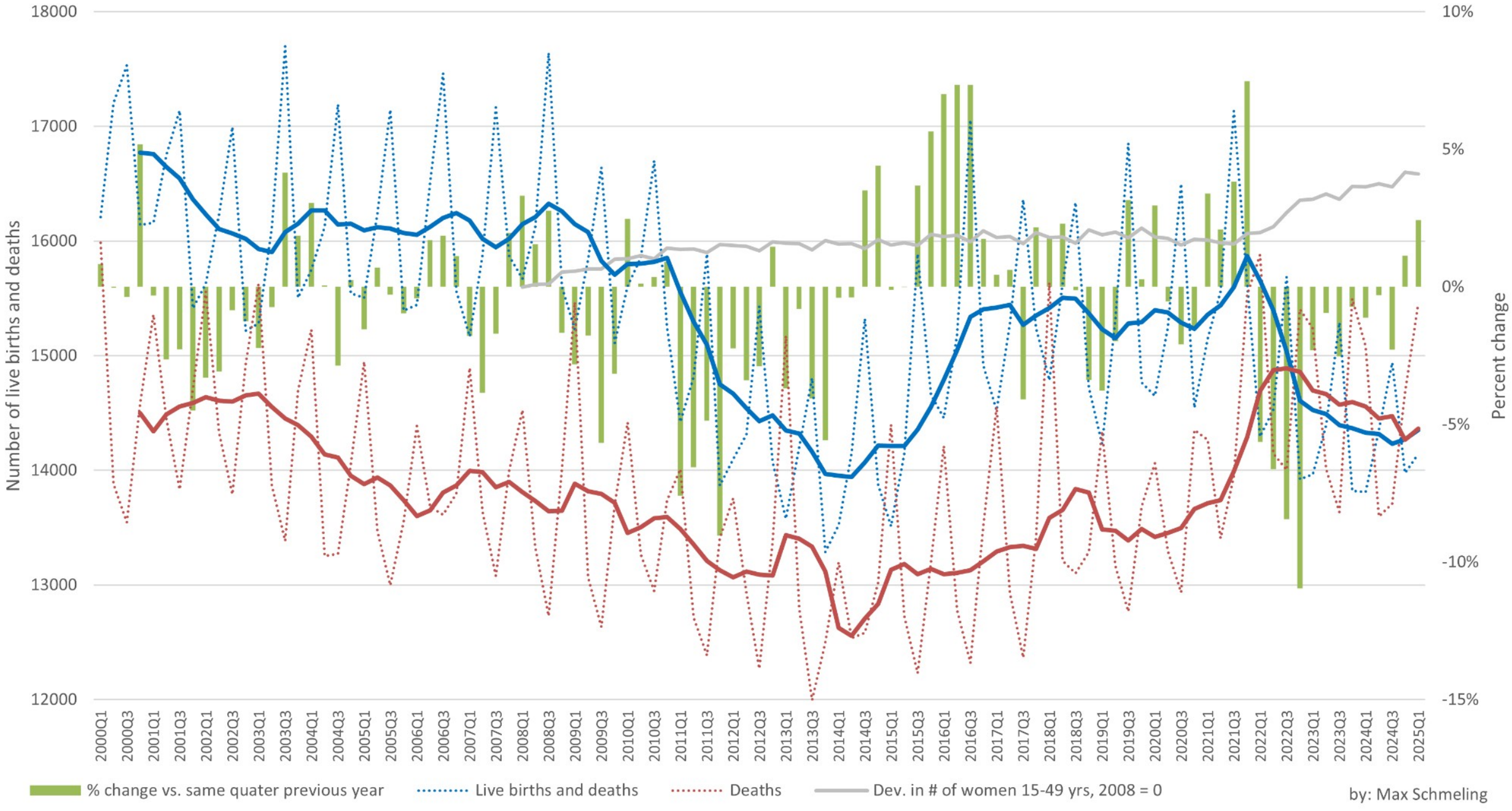


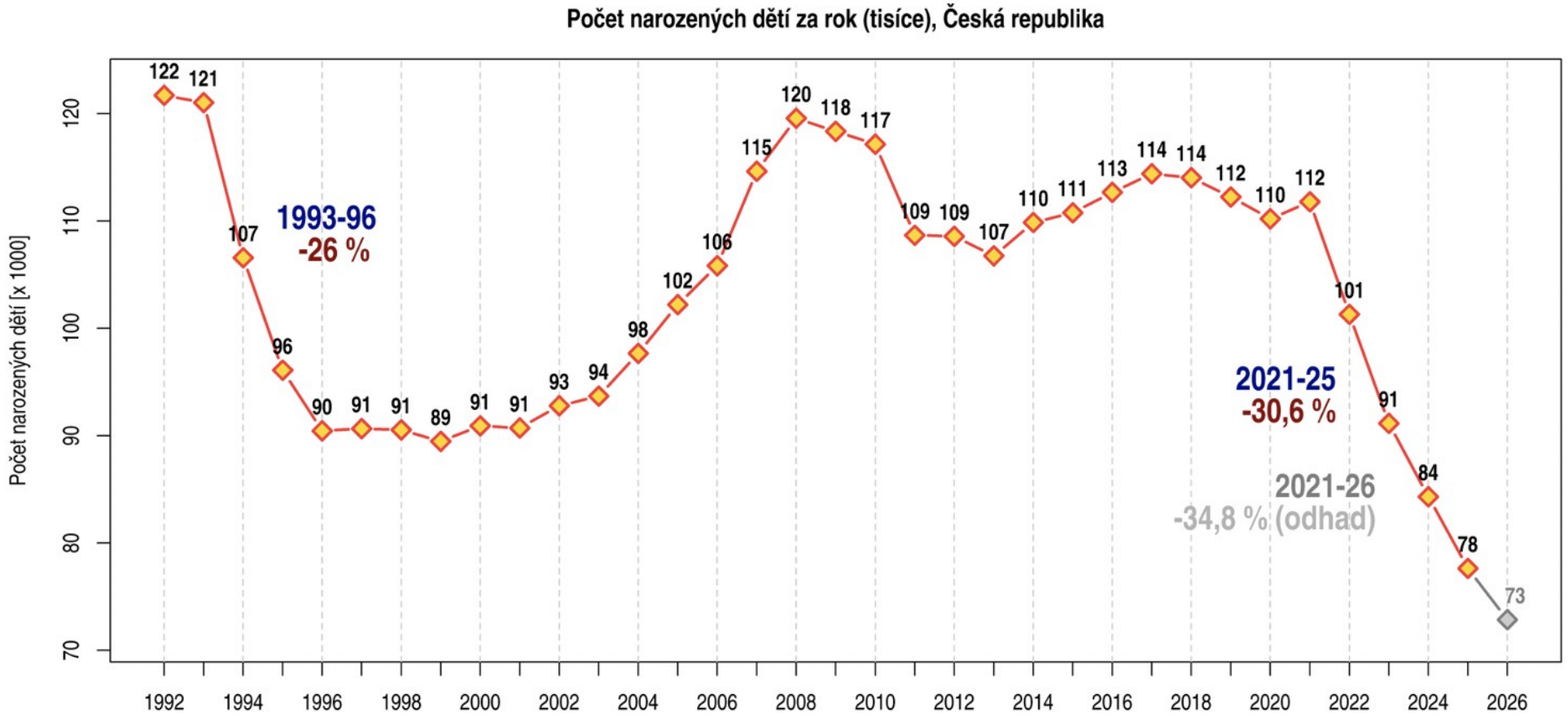
Figure 1. Weekly rates of reported suspected adverse events (SAEs)[1]. [1]Weeks in which <100 doses of a given vaccine type were administered are not shown.

Live births and deaths in Denmark



by: Max Schmeling

Počet narozených dětí za rok (ČR, 1992–2026)



A. Komárek, data ČSÚ, poslední aktualizace byla 11.9.2026

Conclusion

- Batch dependent safety signals were apparent with Pfizer/BioNTech’s vaccine at an early stage.
- Our latest study from Germany shows that Moderna and Astrazeneca had same problem
- This has been confirmed in Czech Republic (Fürst, 2024) and USA (Jablonski and Hooker, 2024) data
- 3 out of 4 reported SAE were from women
- Now submitted study showing **All Cause Mortality linked to batches** - replicating the findings
- We have been denied access to data from SSI and lack of transparency is a major problem
- Czech national data shows a safety signal related to pregnancy – needs to be followed up with record level data in more countries.
- Deaths from the COVID19- injection may contribute to the excess mortality

Why batch-dependency?

- Product quality issues (rapid upscaling)
- Too much mRNA
- DNA-contamination
- Too much of whatever…
- Storage - issues
- Transportation- issues
- Administration into the arm

Questions

If the risk of SAE changed along the way - and got less - then what about **efficacy**? Did it end up just being saline?

Why did authorities from early on ignore the severe signals of batch-dependency, myocarditis aso

Next step

- CDC/NIH/Fauci certainly obviously set aside the basic precautionary principles and misled the public and politicians
  - Which the rest of the world copied 1:1
- People all over the world where misled by their authorities and politicians
- People in charge should be held responsible for the morbidity and mortality
- We need batch-studies of specific diseases - ex breast cancer, myocarditis, arrhythmia aso
- We need many more studies - and transparency
- Transparent access to public data
- Access to stored vials from previous batches

Manniche quote

"They certainly flew the aeroplane while they were still building it - and the plane crashed"

Vibeke Manniche (MD, PhD, scientist)

Presentation at the Parliament of the Czech Republic october 12 2026

https://journals.sagepub.com/doi/10.1177/09246479251353384

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Brief Report

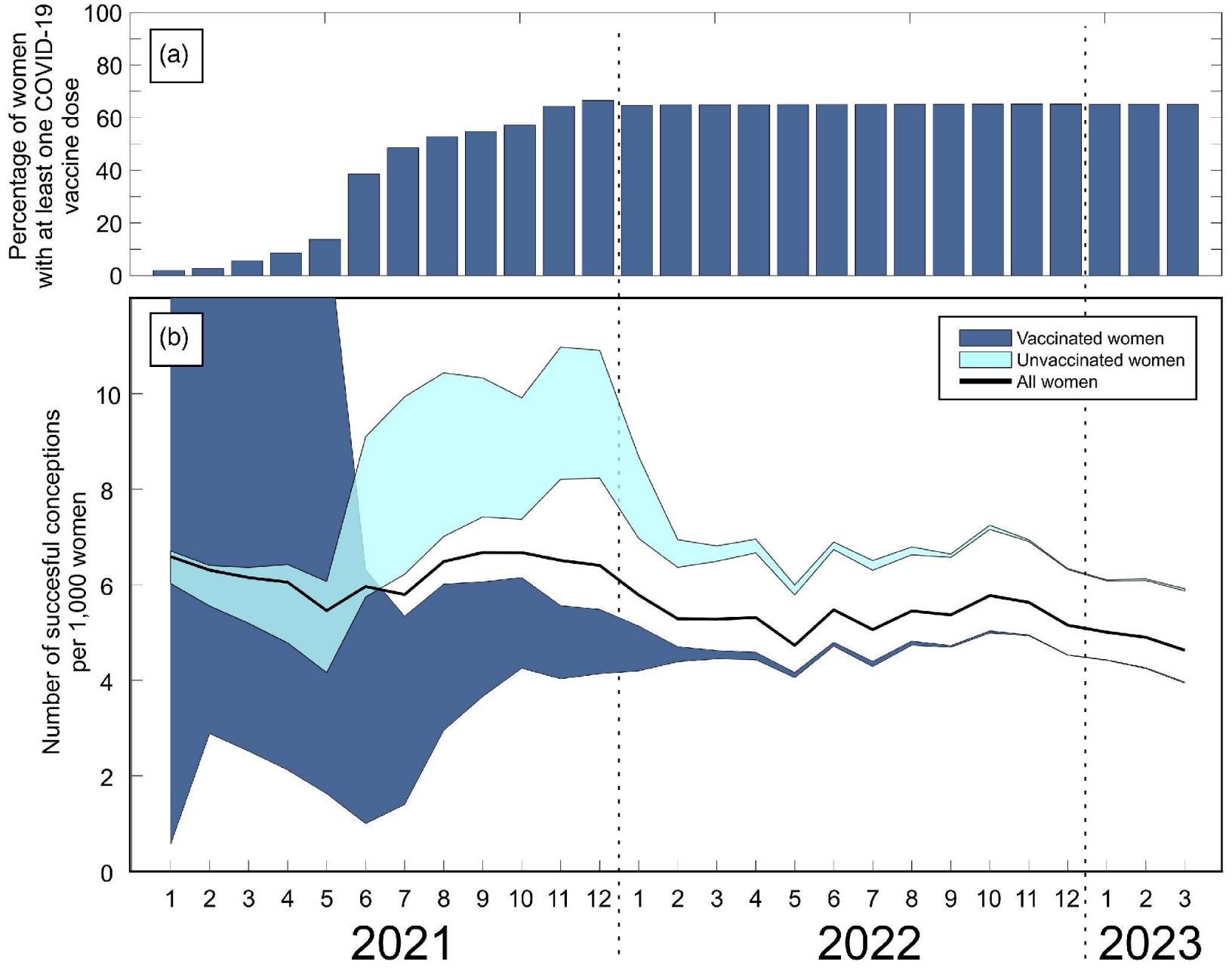
Rates of successful conceptions according to COVID-19 vaccination status: Data from the Czech Republic

Vibeke Manniche[1], Tomáš Fürst [2], Max Schmeling [3], Jonathan D Gilthorpe [4], and Peter Riis Hansen [5,6]

Total views and downloads: 86321 - most read last 6 months

Czech Republic 1.2 million cases

- Successful conceptions amongst unvaccinated and vaccinated women



Total Fertility Rate (TFR)

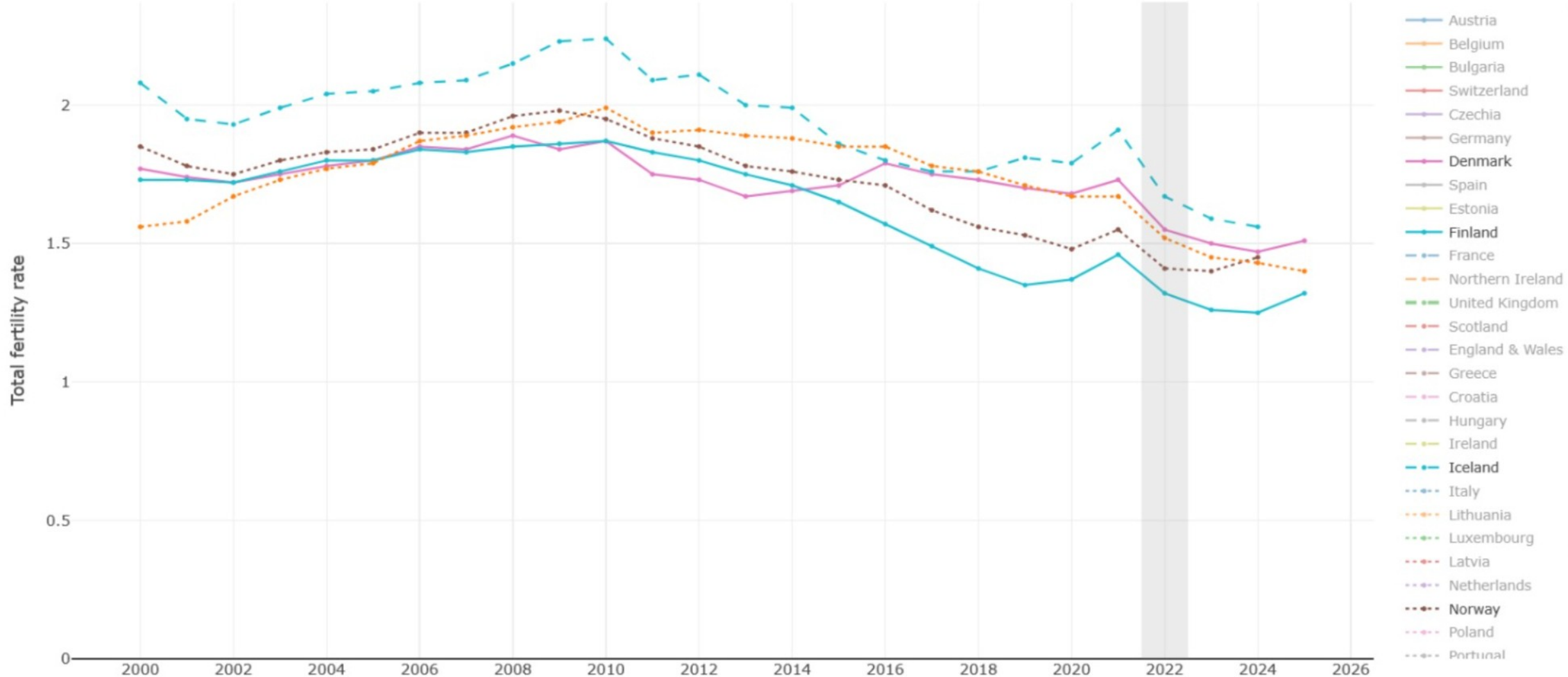
The **Total Fertility Rate (TFR)** is the average number of children that would be born to a woman over her lifetime if she were to experience the exact age-specific fertility rates recorded in a given population during a specific calendar year

*A TFR of roughly **2.1 children per woman** is considered the replacement level in developed nations—the rate required for a population to replace itself from one generation to the next without migration*

Total fertility rate in European countries, 2000-2025

Source: Human Fertility Database, STFF (stff.xlsx). Hover for values (unified by year); click a legend entry to hide it, double-click to isolate it. The shaded band marks 2022.

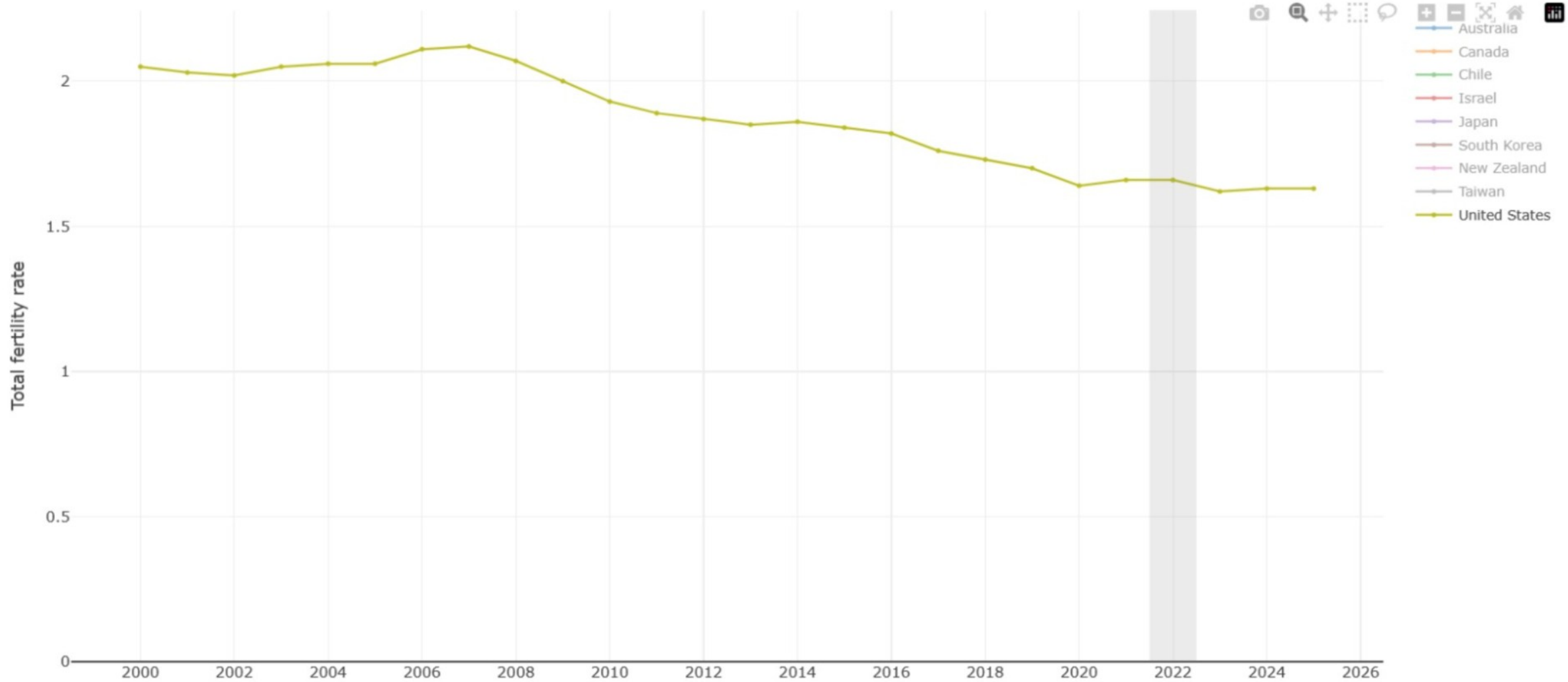
Show all | Hide all | Central Europe | Nordic | South | West/Central | Baltic & East



Total fertility rate in non-European countries, 2000-2025

Source: Human Fertility Database, STFF (stff.xlsx). Hover for values (unified by year); click a legend entry to hide it, double-click to isolate it. The shaded band marks 2022.

Show all | Hide all | Asia | Americas | Oceania



Total Fertility Rate (TFR) US

- TFR in USA is at all time low.
- There has been a marked decrease in 2020 (probably due to the pandemic disruption).
- Then a slight rebound in 21 and 22 (but not return to 2019 numbers).
- In 2023 further decrease to all time low
- In 2024 it was about the same as 2023.
- TFR for 2014 was 1.64 TFR for 2025 was 1.59.

Why is this important…

- Unique
- First nationwide study analyzing births in relation C19 vaccination
- Data set is limited – can’t analyse potential confounders
- It shows a signal – which must be followed up in record level data
- A very common reported side effect is menstrual disturbances


Thanks for listening!