Timing of COVID-19 vaccination a decisive factor in the number of reported side effects

A comprehensive analysis of reported suspected side effects after COVID-19 vaccination in relation to the reporting time shows a strong link between the number of reports and the time when the individual COVID-19 vaccine batches were used in the vaccination programme.

The analysis in brief

Since the Danish COVID-19 vaccination programme was rolled out in end-December 2020, the Danish Medicines Agency (DKMA) has received more than 71,000 reports of suspected side effects involving the four vaccines used in Denmark.

The DKMA has analysed the relationship between the time the individual vaccine batches were used and the number of reports on suspected side effects received by the DKMA from the start of the Danish COVID-19 vaccination programme until June 2023.

The DKMA received a high number of reports especially at the start of vaccination programme in 2021 when both healthcare professionals and the general public were particularly attentive to side effects.

It is important to make clear that the number of reported suspected side effects is *not* the same as the number of side effects having actually occurred. We know that not all side effects are reported, but also that suspected side effect symptoms not considered vaccination-related are.

The COVID-19 vaccines have been produced in batches on an ongoing basis – and during the vaccination programme, different vaccine batches have been rolled out in step with their production. As indicated by the figures below, different batch sizes have been used over time. At the start of the vaccination programme, the batches were relatively small, but later, both larger and smaller batches were used.

Timing affects the number of reports

Our analysis investigates, on the one hand, the side effect reports received by the DKMA and, on the other, the vaccine batches related to those reports.

Our analysis shows that the number of reports of suspected side effects after COVID-19 vaccination is highly related to the timing of the individual vaccine batch used in the vaccination programme.

In brief, the number of reports per 100 doses is higher for the batches used early in the vaccination programme.

The pattern is the same for the two mRNA vaccines, Comirnaty and Spikevax, used in the Danish vaccination programme.

The two previously used vector vaccines, Vaxzevria and Jcovden, were used significantly less, in terms of quantity and time, so their vaccine data are of lesser importance to the overall analysis.

No difference in the safety of the vaccines

Our analysis concludes that the number of reported suspected side effects was highest in the beginning of the vaccination programme, coinciding with the time of strong awareness about side effect reporting and vaccine side effects in general.

The analysis raises no suspicion that the safety of the various COVID-19 vaccine batches used in the Danish vaccination programme has been different. The only difference observed is that significantly more side effects were reported at the start of the vaccination programme. During this period, especially the quite common and non-serious side effects were reported. Later in the vaccination programme, during the booster rounds, significantly fewer side effects were reported per vaccine dose administered.

Read more

Reference is also made to an analysis by the German Paul-Ehrlich-Institut, which has asked the public about their state of health.

The study includes more than one million vaccinations from 400 different vaccine batches and concludes that there are no batch-specific differences in the number of reported symptoms.

Read more: Positions of the Paul-Ehrlich-Institut - Statement from the Paul-Ehrlich-Institut: No batch-specific increases of reports of suspected vaccine side effects after COVID-19 vaccinations with Comirnaty - Paul- Ehrlich-Institut (pei.de)

Figures

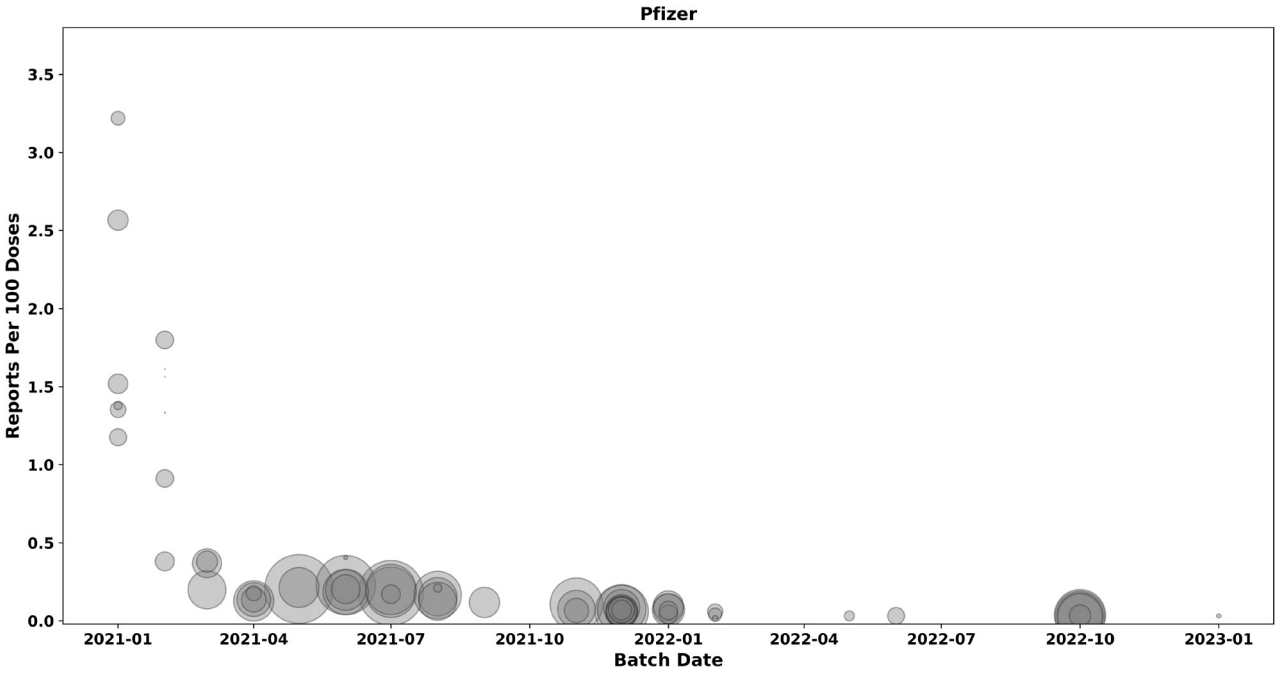

Figure 1– Pfizer/BioNTech (Comirnaty): A grey dot shows the Comirnaty batches used, and the size of the dot corresponds to the relative size of that specific batch. The x axis is time, and the y axis is the number of reports per 100 vaccine doses.

The figure shows that the number of reports of suspected side effects per 100 doses is relatively high in the first months of 2021 when the supplied batches were relatively small.

As 2021 progresses, we see that considerably larger batches give rise to much fewer reports per 100 doses. Further into 2021 and in 2022, we also see small batches giving rise to the same number of reports per 100 doses as the larger batches.

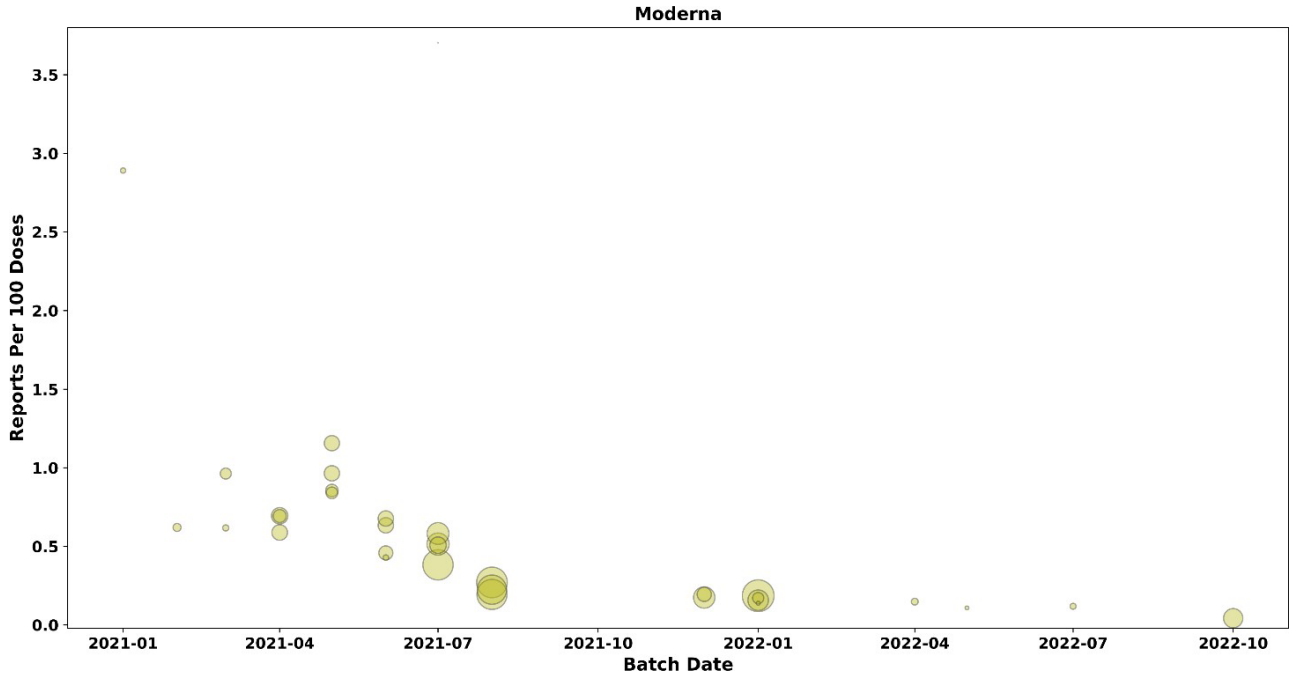

Figure 2 – Moderna (Spikevax): A yellow dot shows the Moderna batches used, and the size of the dot corresponds to the relative size of that specific batch. It is shown that the number of reports per 100 doses is relatively high in the first half of 2021 when the supplied batches were relatively small.

As 2022 progresses, we see the same scenario of smaller batches giving rise to a lower number of reports per 100 doses compared to the first half of 2021.

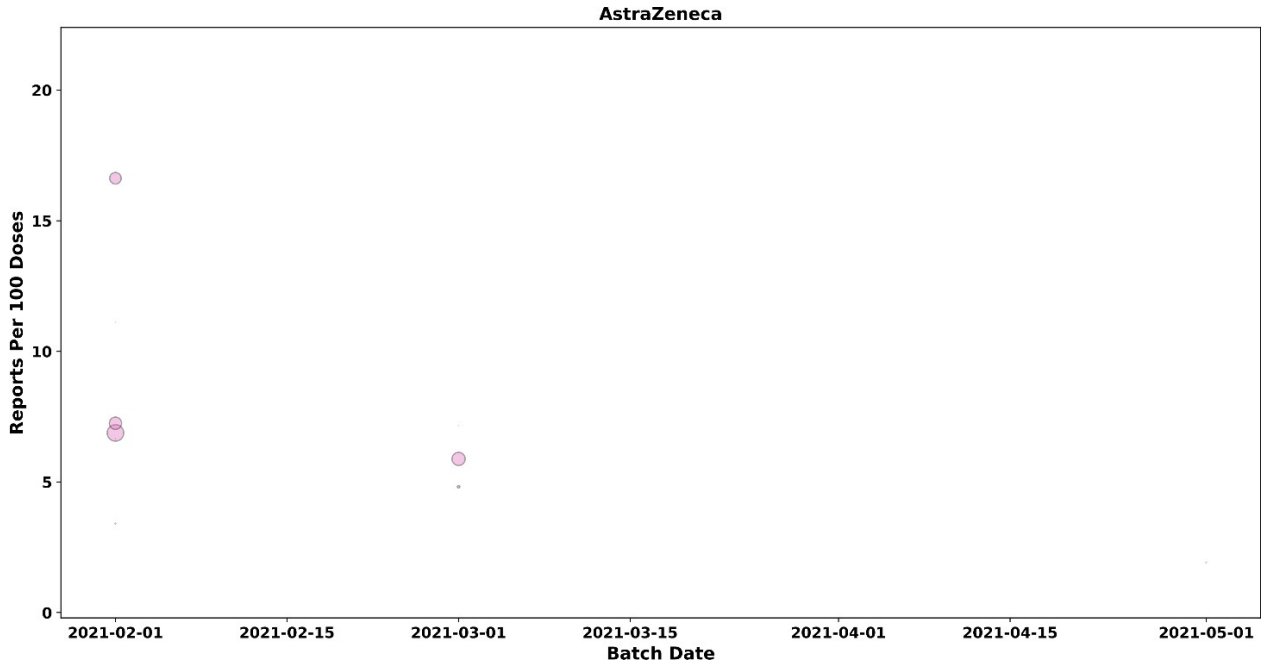

Figure 3 – AstraZeneca (Vaxzevria): A pink dot shows the AstraZeneca batches used, and the size of the dot corresponds to the relative size of that specific batch.

Note that the scales of both the x and y axes of this figure are different from the x and y axes of Figure 1 and Figure 2. The x axis is different because Vaxzevria was taken out of the Danish vaccination programme in March 2021. Consequently, there are no new Danish batch data after this date.

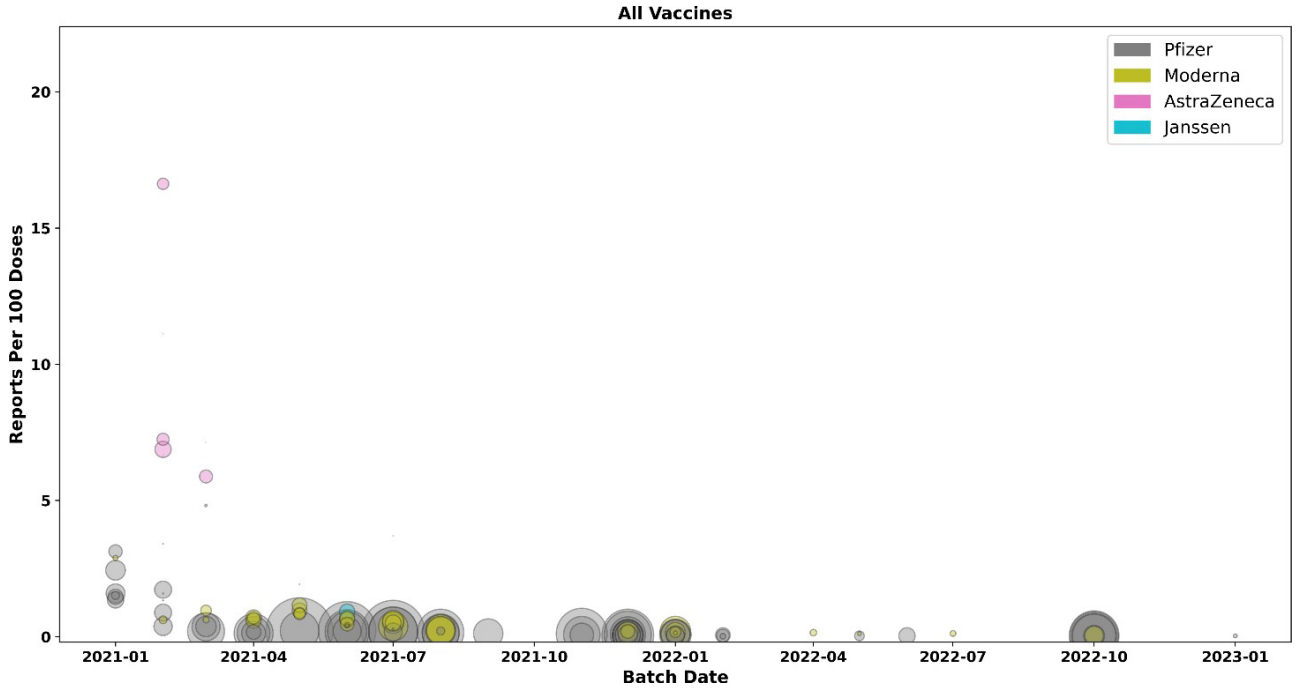

Figure 4 – Individual batches for all four vaccines used: Note that Vaxzevria (AstraZeneca), with relatively few batches over a relatively short period of time, accounted for a relatively large share of COVID-19 vaccine side effect reports. Note: The y axis is different from the y axis in Figure 1 and Figure 2.