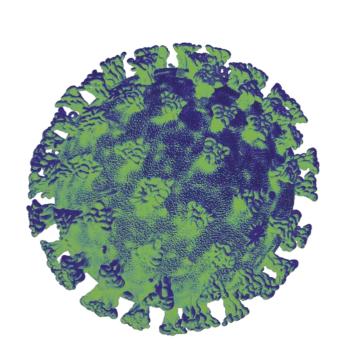
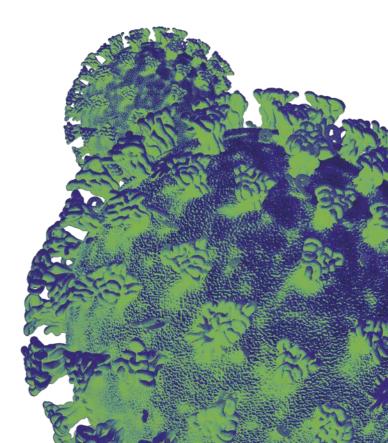


# **Technical Advisory Group**

# High-level findings of clotting in Wales and COVID-19 vaccination

19 March 2021





# High-level findings of clotting in Wales and COVID-19 vaccination

The European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Authority (MHRA) are investigating a small number of reports of clotting events in individuals who have received the AstraZeneca COVID-19 vaccine. These include cases of a rare clotting disorder of interest. No cases of this disorder have been identified in the 440,000 people who received a COVID-19 vaccination up until the end of January 2021.

A rapid evaluation of the Welsh healthcare data was undertaken on 16 March to respond to an urgent request for information on COVID vaccine-related blood clots. The focus of the analysis was to understand whether reports of a small number of rare blood clotting disorders (Cerebral venous sinus thrombosis) reported in Norway and Germany, had also been observed in vaccinated individuals in Wales.

Scientists at the <u>SAIL</u> (Secure Anonymised Information Linkage) databank in Swansea University along with Public Health Wales undertook the analysis using anonymised patient data in its secure databank.

Data was analysed for the period between 1 January 2019 and 31 January 2021 to determine whether there had been an increase in the numbers of the rare blood clotting disorder recorded during the initial vaccine roll-out. In the 25 month period, a total of 19 cases of the disorder were recorded. No new cases of cerebral venous sinus thrombosis were recorded in individuals who had received a vaccine in this period. Seven people with a previous diagnosis of this condition had been vaccinated by 31 January 2021.

Pathology reports for COVID-19 were also checked. None of the admissions reported in the Patient Episode Database for Wales (PEDW) for cerebral venous sinus thrombosis occurred after a positive test for COVID-19 (Polymerase Chain Reaction test; PCR test) in the Pathology Test Dataset.

Cerebral venous sinus thrombosis is a condition that is diagnosed in hospital. There is a delay in detailed coding of hospital records which is why the analysis was completed up until end of January 2021 but it will be updated going forward.

This condition is rare, with fewer than 1 person per month diagnosed in the Welsh population of 3.2 million people, 2.8 per million population annually.

Between 4 December 2020 and 31 January 2021, 440,000 people had at least one dose of the vaccine as recorded in the Welsh COVID Vaccine data. Of these, 180,000 people received the Oxford Astra Zeneca vaccine and 260,000 received the Pfizer Vaccine.

Work is ongoing in Wales to monitor the data from the vaccine programme using the linked data assets that we have in Wales.

#### **Additional Notes**

### Methods

Using PEDW (Patient Episode Database for Wales) data related to all hospitalisations in Wales, SAIL scientists searched for any admissions between 1 January 2019 and 31 January 2021 for clotting (using ICD-10 code I676).

Using the de-identified record linkage system in SAIL we were then able to investigate whether the 19 cases of cerebral venous sinus thrombosis had received at least a 1<sup>st</sup> dose of the vaccine as recorded in the CVVD (COVID Vaccination Data) before or after the condition had been identified.

The majority of episodes in the period studied have been coded under ICD-10, but this proportion will increase over time, so later analyses will have better overall capture of these events in both vaccinated and unvaccinated individuals.

# Databases used

**SAIL Databank** at Swansea University contains some of the richest populationscaled data in the world - some of which reaching back a quarter of a century or more.

Data linkage is way of harnessing this valuable resource by intelligently combining anonymised data from across multiple separate datasets based on commonly identifying information to create a new dataset for research analysis.

The SAIL Databank team have over 10 years' experience of producing pre-linked datasets according to researchers' requirements opening the doors to all researchers regardless of their own level of data linkage experience to use SAIL Databank as part of their important research.

The NHS Wales Informatics Service (NWIS) operate as a trusted third party to anonymise records and then match these records with non-personal event information that's used for research.

At NWIS, any personal information and the NHS number where present, are removed and replaced with an Anonymous Linking Field (ALF). This is an encrypted number unique to each person represented in the dataset, with no attributable meaning or currency outside the system.

NWIS maintains the Welsh Demographic Service register that acts as a proxy for a Welsh population demographic database and is used to match the ALFs with any corresponding non-identifiable data.

Reliable record matching is important to preserve record integrity and identity in the anonymised datasets in the SAIL Databank. Without this, the validity of subsequent research would be in serious question. The matching algorithm was devised at NWIS and we were able to make use of this for data coming to the Databank.

At SAIL Databank we re-encrypt the ALF to make it double encrypted (ALF-E). This ensures that neither SAIL nor NWIS can reverse engineer the anonymisation process to reveal identities.

More detailed information about privacy, anonymisation and record matching can be found here on the SAIL <u>Data Privacy and Security pages.</u>

Patient Episode Database for Wales (PEDW) consists of data from approximately 950,000 NHS admissions per year, collected since 1997. NHS Wales hospital admissions (inpatients and day cases) dataset comprising of attendance and clinical information for all hospital admissions: includes diagnoses and operations performed. The data are collected and coded at each hospital. Administrative information is collected from the central PAS (Patient Administrative System), such as specialty of care, admission and discharge dates. After the patient is discharged the hand written patient notes are transcribed by clinical coder into medical coding terminology (ICD10 and OPCS).

The data held in PEDW is of interest to public health services since it can provide information regarding both health service utilisation and also the incidence and prevalence of disease.

There are a number of different things that can be counted in PEDW e.g. individual episodes of care, admissions, discharges, periods of continuous care (group of episodes), patients or procedures.