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Covid-19 vaccination and the risk of developing SLE. Additionally, we identified moderate quality and consistent evidence to suggest no association with SLE flares.

- We found only one study, of moderate quality, suggesting an association between vaccination with the Pfizer Covid-19 vaccine and the risk of fibromyalgia in elderly people. More research is needed to elucidate this potential association.
- We identified moderate-high quality evidence, suggesting that there is no association between Covid-19 vaccines and the risk of Graves' disease.
- We only found poor quality studies on the association between Covid-19 vaccines and the risk of depression. Good quality studies should be conducted to understand this.
- We found evidence of a possible association between Covid-19 vaccines and the risk of POTS. However, the overall risk is low, and much lower than that seen following Covid-19 infection in unvaccinated people.
- We identified moderate quality data and inconsistent studies on a potential association between Covid-19 vaccination and the risk of optic neuritis.
- The data identified on the association between Covid-19 vaccines and heart failure suggested a reduced risk among vaccinated compared to unvaccinated individuals.

Introduction

5.117. I, as lead author, have received and read the evidence submitted to the Inquiry by vaccine injured and bereaved groups. This includes multiple case reports and patient and carer experiences from people who suffered other suspected adverse effects of vaccination.

5.118. Many of these conditions are rare or have multiple contributing causes, which makes it challenging to investigate them and establish the requisite degree of causation so as to permit the conclusion they are directly related to the Covid-19 vaccines. A systematic literature review on their association with the Covid-19 vaccines or the conducting of epidemiological studies would be resource-intensive and is beyond the scope of this report. However, the co-authors and I have conducted a high-level literature review in order to identify those potential ADRs where there is some evidence to suggest the need for further research in the form of a formal systematic review of the literature and/or bespoke good quality epidemiological studies. In the following subsections, we summarise the methods used for our literature review, and then compile the knowledge we extracted from the published studies deemed of sufficient quality at the time of writing this report (November 2024). I make a recommendation at the end of this report to the effect that the MHRA should consider whether any of the ADRs raised by Material Providers warrant further examination by way of systematic reviews and/or epidemiological studies.

Methods for our rapid literature review

5.119. We started our literature review with a long list of conditions and health outcomes distilled from relevant witness statements. These were: Acquired Amegakaryocytic Thrombocytopenia, Acute kidney Injury, Acute onset Reactive Arthritis, Acute onset Autoimmune Hepatitis, Acute Necrotising Pancreatitis, Alopecia, Atrial fibrillation, Autonomic Nervous System Dysfunction, Brain haemorrhage, Bullous Pemphigoid, Cancer,

Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP), Chronic Mononeuritis Multiplex, Chronic Obstructive Pulmonary Disease, Chronic Pain Syndrome, Connective Tissue Disorders, Depression, Dorsal Root Ganglionopathy, Dysautonomia, Dystonia, Erythromelalgia, Exacerbation of Hemicrania Continua, Essential tremor, Fibromyalgia, Gastroparesis, Giant Cell Arteritis, Graves Disease, Heart Failure, Hemiplegic Migraine, Hyperacusis, Hypothyroidism Myxedema, Hyper immune response to Covid 19 vaccination, Hypoaldosteronism, Hyperprolactinaemia, Inappropriate Sinus Tachycardia, Intracranial Hypertension, Lupus, Mast Cell Activation Syndrome (MCAS), Medical Post Traumatic Stress Disorder, Mastocytosis, Motor Neurone Disease, Migraines with Aura, Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, Neurogenic Bladder, Nodular Paniculitis, Non-Hodgkin's Lymphoma, Nystagmus, Optic Neuritis, Pericardial Effusion, Peripheral Neuropathy, Pernicious Anaemia, Polymyositis, Postural Orthostatic Tachycardia Syndrome (POTS), Post Traumatic Stress, Post-Vaccination Syndrome, Pneumonitis, Progressive Bulbar Palsy, Psychosis, Pulmonary Sarcoidosis, Pudendal Neuralgia, Rapid Onset Glioblastoma, Reactivated Epstein Barr Virus, Reactivated Lyme Disease, Reactivated Shingles, Rheumatoid Arthritis, Secondary Hypogonadism, Scleroderma, Seizures, Sjogren's Syndrome, Shoulder Injury Related to Vaccine Administration (SIRVA), Small Fibre Neuropathy, Stevens-Johnson Syndrome, T-Cell Lymphoma, Thyrotoxicosis, Tinnitus, Trigeminal Neuralgia, Uveitis, Vaccine-induced Raynaud's Syndrome, Ventricular Tachycardia, Vasculitis, and Vestibulopathy.

5.120. For each of these, we conducted a query in the largest repository of medical research, the PubMed library. The literature search focussed on at least moderate quality studies on the association between Covid-19 vaccination and the risk of developing each of the events listed above. We restricted the search to large spontaneous report database analyses (e.g. US VAERS), case-control, self-controlled-case series and cohort studies, considered in this report as at least moderate quality evidence on vaccine safety. We also limited our search to studies mentioning each of the potential ADRs in the study title or abstract. We did not limit our search by language or date of publication. With all this in mind, the five co-authors of this report worked using a consistent and reproducible search query and a structured form for the extraction of findings. These, together with the list of identified manuscripts, are available as an Appendix (INQ000474569) alongside this report.

5.121. The following subsections summarise the findings obtained for the potential ADRs where we found at least moderate quality studies on the association with Covid-19 vaccines, regardless of their results. The potential ADRs to which this applied were the following 14: Chronic Obstructive Pulmonary Disease (COPD), Varicella-zoster-virus (VZV) reactivation / Shingles, Seizures, Shoulder Injury Related to Vaccine Administration (SIRVA), Tinnitus, Autoimmune connective tissue disease and alopecia, Rheumatoid Arthritis (RA), Systemic Lupus Erythematosus, Fibromyalgia, Graves' disease, Depression, Postural Orthostatic Tachycardia Syndrome (POTS), Optic Neuritis, and heart failure. For all other events listed above, we did not find any moderate or high-quality evidence in the literature search we conducted. This does not mean that there is no association, it just means that we did not find published studies demonstrating such a link.

Chronic Obstructive Pulmonary Disease (COPD)

5.122. We only found one study that would pass our inclusion criteria on the association between Covid-19 vaccination and the risk of developing COPD (Huh et al., 2024). This retrospective cohort study utilised a combined database of nationwide healthcare claims data, Covid-19