

World Health Organization Study concludes risk of suffering Serious Injury due to COVID Vaccination is 339% higher than risk of being hospitalised with COVID-19

## **Description**

A new study endorsed by the World Health Organization has found that the risks of mRNA Covid-19 vaccination heavily outweigh the benefits, with scientists discovering a person is on average 339% more likely to suffer a serious adverse event such as cardiac arrest, stroke, or death due to the Pfizer Covid-19 injection than they are to be hospitalised with Covid-19.

# Serious Adverse Events of Special Interest Following mRNA Vaccination in Randomized Trials

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In 2020, prior to the Covid-19 vaccine rollout, the 'Coalition for Epidemic Preparedness Innovations' and 'Brighton Collaboration' created a priority list, **endorsed by the World Health Organization**, of potential adverse events relevant to COVID-19 vaccines.

The list comprised adverse events of special interest (AESIs), adverse events associated with prior vaccines in general, theoretical associations based on animal models, and Covid-19 specific immunopathogenesis; the process of disease development involving an immune response or components thereof.

The World Health Organization's Global Advisory Committee both endorsed and recommended the reporting of AESIs based on this priority list.

### Supplemental Table 1. Included and excluded SAE types across both trials

Included SAE types (matching AESI list): Abdominal pain, Abdominal pain upper, Abscess, Abscess intestinal, Acute coronary syndrome, Acute kidney injury, Acute left ventricular failure, Acute myocardial infarction, Acute respiratory failure, Anaemia, Anaphylactic reaction, Anaphylactic shock, Angina pectoris, Angina unstable, Angioedema, Aortic aneurysm, Aortic valve incompetence, Arrhythmia supraventricular, Arteriospasm coronary, Arthritis, Atrial fibrillation, Atrial flutter, Axillary vein thrombosis, Basal ganglia haemorrhage, Bile duct stone, Blood loss anaemia, Bradycardia, Brain abscess, Cardiac failure, Cardiac failure acute, Cardiac failure congestive, Cardiac stress test abnormal, Cardio-respiratory arrest, Cerebral infarction, Cerebrovascular accident, Chest pain, Cholecystitis, Cholecystitis acute, Cholelithiasis, Colitis, Coronary artery disease, Coronary artery dissection, Coronary artery occlusion, Coronary artery thrombosis, Deep vein thrombosis, Dermatitis bullous, Diabetic ketoacidosis, Diarrhoea, Diplegia, Dyspnoea, Embolic stroke, Empyema, Facial paralysis, Fluid retention, Gastroenteritis, Gastrointestinal haemorrhage, Haematoma, Haemorrhagic stroke, Hemiplegic migraine, Hepatic enzyme increased, Hyperglycaemia, Hyponatraemia, Hypoxia, Ischaemic stroke, Laryngeal oedema, Multiple sclerosis, Myocardial infarction, Noncardiac chest pain, Oedema peripheral, Pancreatitis, Pancreatitis acute, Pericarditis, Peripheral artery aneurysm, Peritoneal abscess, Pleuritic pain, Pneumothorax, Post procedural haematoma, Post procedural haemorrhage, Postoperative abscess, Procedural haemorrhage, Psychotic disorder, Pulmonary embolism, Rash, Rash vesicular, Respiratory failure, Retinal artery occlusion, Rhabdomyolysis, Rheumatoid arthritis, Schizoaffective disorder, Seizure, Subarachnoid haemorrhage, Subcapsular renal haematoma, Subdural haematoma, Tachyarrhythmia, Tachycardia, Thrombocytopenia, Thyroid disorder, Toxic encephalopathy, Transaminases increased, Transient ischaemic attack, Traumatic intracranial haemorrhage, Type 2 diabetes mellitus, Uraemic encephalopathy, Uterine haemorrhage, Vascular stent occlusion, Ventricular arrhythmia

Excluded SAE types (not matching AESI list): Abdominal adhesions, Abortion spontaneous, Abortion spontaneous incomplete, Accelerated hypertension, Adenocarcinoma gastric, Adrenal gland cancer, Alcohol abuse, Alcohol poisoning, Alcohol withdrawal syndrome, Animal bite, Ankle arthroplasty, Ankle fracture, Anxiety, Anxiety disorder, Aortic stenosis, Appendicitis, Appendicitis perforated, Arteriosclerosis, Asthma, Atelectasis, Autonomic nervous system imbalance, B-cell small lymphocytic lymphoma, Back injury, Back pain, Benign prostatic hyperplasia, Bipolar disorder, Breast cancer, Breast cancer stage I, Breast hyperplasia, Bronchitis, Cartilage injury, Cellulitis, Cervical radiculopathy, Cervical spinal stenosis. Cervical vertebral fracture. Choroidal neovascularisation. Chronic kidney disease, Chronic lymphocytic leukaemia, Chronic myeloid leukaemia, Chronic obstructive pulmonary disease, Clostridium difficile colitis, Clostridium difficile infection, Colon cancer stage III, Colon injury, Colorectal cancer, Completed suicide, Complicated appendicitis, Concussion, Confusional state, Constipation, Cough, Craniocerebral injury, Dehydration, Depression, Diplopia, Diverticular perforation, Diverticulitis, Dizziness, Drug hypersensitivity, Duodenal ulcer, Duodenal ulcer haemorrhage, Emphysema, Facial bones fracture, Fall, Feeling hot, Femoral neck fracture, Femur fracture, Fibromuscular dysplasia, Flail chest, Flank pain, Food poisoning, Foot fracture, Foot operation, Forearm fracture, Fracture nonunion, Gastric cancer, Gastric perforation, Gastrooesophageal reflux disease, Gout, Gun shot wound, Head injury, Heart disease congenital, Hepatic cancer metastatic, Hepatic mass, Hepatitis A, Hernia, Hiatus hernia, Hip arthroplasty, Hip fracture, Humerus fracture, Hypertension, Hypertensive emergency, Hypertensive urgency, Hypoglycaemia,

Just some of the Serious Adverse Events included in the W.H.O endorsed list Source – Page 19 Scientists then sought to investigate the association between FDA-authorized mRNA COVID-19 vaccines and serious adverse events identified by the Brighton Collaboration, using data from the **still ongoing** phase III randomized, placebo-controlled clinical trials on which emergency authorisation was based.

Scientists discovered that in the Moderna trial, the excess risk of serious AESIs (15.1 per 10,000 participants) greatly surpassed the risk reduction for COVID-19 hospitalization relative to the placebo group (6.4 per 10,000 participants). This means recipients of the Modern injection were and are 140% more likely to suffer a serious adverse event than they are to be hospitalised with Covid-19.

In the Pfizer trial, the excess risk of serious AESIs (10.1 per 10,000) surpassed the risk reduction for COVID-19 hospitalisation relative to the placebo group (2.3 per 10,000 participants). This means recipients of the Pfizer injections were and are 339% more likely to suffer a serious adverse event than they are to be hospitalised with Covid-19.

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	Events <sup>a</sup>		Risk difference per 10,000 participants	Risk ratio (95% CI)
Trial	Vaccine	Placebo	(95% CI)	
All serious	adverse ev	ents <sup>b</sup>		1.00
Pfizer	127	93	18.0 (1.2 to 34.9)	1.36 (1.02 to 1.83)
Moderna	206	196	6.4 (-23.9 to 36.8)	1.05 (0.83 to 1.32)
Combined	333	289	12.9 (-0.4 to 29.3)	1.15 (0.96 to 1.38)
Serious adv	verse event	s of specia	I interest <sup>c</sup>	
Pfizer	52	33	10.1 (-0.4 to 20.6)	1.57 (0.98 to 2.54)
Moderna	87	64	15.1 (-3.6 to 33.8)	1.36 (0.93 to 1.99)
Combined	139	97	12.5 (2.1 to 22.9)	1.43 (1.07 to 1.92)

<sup>&</sup>lt;sup>a</sup> Denominators for Pfizer were 18,801 in the vaccine group and 18,785 in the placebo group, and for Moderna were 15,185 in the vaccine group and 15,166 in the placebo group.

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<sup>&</sup>lt;sup>b</sup> All SAEs are included in the calculations except for efficacy outcomes which were included in certain SAE tables: "COVID-19" and "COVID-19 pneumonia" (Moderna) and "SARS-CoV-2 test positive" (Pfizer). "All SAEs" for Moderna was calculated using the "Number of serious AEs" row in Moderna's submission to FDA.<sup>10</sup>

<sup>°</sup>Standard errors used to estimate 95% CIs were inflated by the factor √[#SAE]/[#patients with SAE] to account for multiple SAE within patients.

Combined, the mRNA vaccines were associated with an absolute risk increase of serious adverse events of special interest of 12.5 per 10,000 (95% CI 2.1 to 22.9).

The excess risk of serious adverse events of special interest surpassed the risk reduction for Covid-19 hospitalization relative to the placebo group in both Pfizer and Moderna trials (2.3 and 6.4 per 10,000 participants, respectively).

The combined risk reduction for Covid-19 hospitalisation equates to 4.35 per 10,000 participants. Therefore, recipients of mRNA Covid19 injections were and are on average 187% more likely to suffer a serious adverse event than they are to be hospitalised with Covid-19.

The scientists who conducted the study noted how when the FDA reviewed serious adverse events (SAEs) in relation to the Pfizer vaccine they concluded that SAEs were "balanced between treatment groups".

But in contrast to the FDA's questionable review, the scientists who conducted the W.H.O. endorsed study found an increased risk of all-cause serious adverse events in the Pfizer trial.

The full World Health Organization endorsed study can be viewed in full <a href="here">here</a>, but the scientists concluded that a systematic review and meta-analysis using individual participant data should be undertaken to address questions of harm-benefit in various demographic subgroups.

However, they note that to do this full transparency of the COVID-19 vaccine clinical trial data is needed to properly evaluate these questions. But unfortunately, well over a year after the widespread use of COVID-19 vaccines, participant-level data remain inaccessible. With the FDA attempting to delay the release of some of this data for 75 years.

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