## Case Series Drug Analysis Print Name: FOI 22 472 - Bolton - Pfizer COVID-19 Vaccine

 Report Run Date:
 09-Mar-2022

 Data Lock Date:
 08-Mar-2022 18:30:04

All UK spontaneous reports received up to and including 23/02/2022 for Pfizer COVID-19 vaccine where the reporter has concurrently provided a postal code that is located within Bolton.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

### Name: FOI 22 472 - Bolton - Pfizer COVID-19 Vaccine

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Reaction Name	Total	Fatal
Blood disorders		
Lymphatic system disorders NEC		
Lymph node pain	11	0
Lymphadenopathy	54	0
Blood disorders SOC TOTAL	65	0

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Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	17	0
Ischaemic coronary artery disorders		
Myocardial infarction	1	0
Noninfectious myocarditis		
Myocarditis	1	0
Noninfectious pericarditis		
Pericarditis	2	0
Rate and rhythm disorders NEC		
Arrhythmia	2	0
Cardiac flutter	2	0
Extrasystoles	1	0
Tachycardia	8	0
Supraventricular arrhythmias		
Atrial fibrillation	1	0
Supraventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	36	0

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear discomfort	1	0
Ear pain	5	0
Hearing losses		
Deafness	2	0
Deafness neurosensory	1	0
Hypoacusis	2	0
Sudden hearing loss	1	0
Inner ear signs and symptoms		
Tinnitus	12	0
Vertigo	10	0
Ear disorders SOC TOTAL	34	0

### Name: FOI 22 472 - Bolton - Pfizer COVID-19 Vaccine

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Reaction Name	Total	Fatal
Eye disorders		
Lacrimation disorders		
Lacrimation increased	1	0
Ocular disorders NEC		
Eye pain	3	0
Eye swelling	3	0
Ocular infections, inflammations and associated manifestations		
Eye pruritus	1	0
Ocular hyperaemia	1	0
Ocular nerve and muscle disorders		
Strabismus	1	0
Ocular sensation disorders		
Photophobia	1	0
Visual disorders NEC		
Diplopia	1	0
Photopsia	2	0
Vision blurred	9	0
Visual impairment and blindness (excl colour blindness)		
Blindness	1	0
Visual impairment	1	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	26	0

### Name: FOI 22 472 - Bolton - Pfizer COVID-19 Vaccine

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Colitis (excl infective)		
Crohn's disease	1	0
Diarrhoea (excl infective)		
Diarrhoea	26	0
Dyspeptic signs and symptoms		
Dyspepsia	1	0
Flatulence, bloating and distension		
Abdominal distension	1	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	6	0
Abdominal pain upper	12	0
Gastrointestinal pain	2	0
Gastrointestinal atonic and hypomotility disorders NEC		
Gastrooesophageal reflux disease	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	1	0
Dysphagia	2	0
Gastrointestinal spastic and hypermotility disorders		
Irritable bowel syndrome	1	0
Gingival disorders, signs and symptoms NEC		
Gingival swelling	1	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Haemorrhoids	1	0
Intestinal haemorrhages		
Rectal haemorrhage	1	0
Nausea and vomiting symptoms		
Nausea	72	0
Vomiting	20	0
Oral dryness and saliva altered	-	
Dry mouth	3	0
Oral soft tissue disorders NEC		-
Oral disorder	1	0
Oral soft tissue haemorrhages		-
Mouth haemorrhage	1	0
Oral soft tissue signs and symptoms		•
Hypoaesthesia oral	3	0
Oral discomfort	1	0
Oral pain	1	0
Paraesthesia oral	4	0
Oral soft tissue swelling and oedema		
Lip swelling	1	0
Mouth swelling	1	0
Stomatitis and ulceration		
Mouth ulceration	2	0
Tongue signs and symptoms		
Glossodynia	1	0
Swollen tongue	3	0
Gastrointestinal disorders SOC TOTAL	171	0

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Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site pain	1	
Asthenic conditions		
Asthenia	9	
Fatigue	110	
Malaise	16	
Febrile disorders	70	
Pyrexia	70	
Feelings and sensations NEC		
Chills	40	
Feeling abnormal	10	
Feeling cold	5	
Feeling hot	6	
Hangover	1	
Hunger	1	
Temperature intolerance	1	
Thirst	2	
Gait disturbances		
Gait disturbance	1	
General signs and symptoms NEC		
Condition aggravated	2	
Crying	1	
Energy increased	1	
Illness	7	
Influenza like illness	12	
Peripheral swelling	15	
Secretion discharge	1	
Swelling	16	
Swelling face	7	
Inflammations		
Inflammation	2	
Injection site reactions		
Injection site bruising	1	
Injection site erythema	1	
Injection site joint pain	1	
Injection site mass	4	
Injection site pain	11	
Injection site pruritus	1	
Mass conditions NEC		
Mass	1	
Oedema NEC		
Face oedema	1	
Oedema peripheral	1	
Pain and discomfort NEC		
Axillary pain	16	
Chest discomfort	7	
Chest pain	22	
Discomfort	1	
Non-cardiac chest pain	1	
Pain	44	
Tenderness	3	
Vaccination site reactions		
Vaccination site induration	1	

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site mass	2	0
Vaccination site pain	4	0
Vaccination site swelling	2	0
Vaccination site warmth	2	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
General disorders SOC TOTAL	465	0

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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	4	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	1	0
Atopic disorders		
Seasonal allergy	1	0
Immune and associated conditions NEC		
Immune system disorder	1	0
Immune system disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Infections		
Coronavirus infections		
COVID-19	4	0
COVID-19 pneumonia	1	1
Suspected COVID-19	2	0
Ear infections		
Ear infection	1	0
Herpes viral infections		
Herpes simplex	1	0
Herpes zoster	2	0
Influenza viral infections		
Influenza	7	0
Lower respiratory tract and lung infections		
Lower respiratory tract infection	1	0
Muscle and soft tissue infections		
Psoas abscess	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Neutropenic sepsis	1	0
Skin structures and soft tissue infections		
Vaccination site pustule	1	0
Trypanosomal infections		
African trypanosomiasis	1	0
Upper respiratory tract infections		
Nasopharyngitis	5	0
Sinusitis	1	0
Urinary tract infections		
Kidney infection	1	0
Urinary tract infection	1	0
Viral infections NEC		
Sweating fever	2	0
Infections SOC TOTAL	33	1

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Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Maternal exposure during breast feeding	3	0
Maternal exposure during pregnancy	3	0
Muscle, tendon and ligament injuries		
Tendon injury	1	0
Non-site specific injuries NEC		
Fall	1	0
Radiation injuries		
Sunburn	1	0
Site specific injuries NEC		
Head injury	1	0
Limb injury	1	0
Skin injuries NEC		
Contusion	2	0
Skin injury	1	0
Injuries SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Investigations		
Blood gas and acid base analyses		
Oxygen saturation decreased	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	1	0
Heart rate and pulse investigations		
Heart rate	1	0
Heart rate decreased	1	0
Heart rate increased	4	0
Heart rate irregular	1	0
Investigations NEC		
Blood test	1	0
Physical examination procedures and organ system status		
Body temperature	1	0
Body temperature increased	2	0
Weight decreased	1	0
Weight increased	1	0
Urinalysis NEC		
Blood urine present	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure increased	2	0
Investigations SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	5	0
Increased appetite	1	0
Diabetes mellitus (incl subtypes)		
Diabetes mellitus	1	0
Disorders of purine metabolism		
Gout	2	0
General nutritional disorders NEC		
Abnormal weight gain	1	0
Feeding disorder	1	0
Poor feeding infant	1	0
Total fluid volume decreased		
Dehydration	1	0
Total fluid volume increased		
Fluid retention	1	0
Metabolic disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	1	C
Bone related signs and symptoms		
Bone pain	3	C
Pain in jaw	2	C
Joint related disorders NEC		
Periarthritis	1	C C
Joint related signs and symptoms		
Arthralgia	43	C
Joint swelling	2	C
Muscle infections and inflammations		
Myositis	1	C
Muscle pains		
Fibromyalgia	1	C
Myalgia	43	C
Myofascial pain syndrome	1	
Muscle related signs and symptoms NEC		
Muscle fatigue	1	C
Muscle spasms	4	C
Muscle twitching	1	
Muscle tone abnormalities		
Muscle rigidity	1	L C
Nuchal rigidity	1	Ċ
Muscle weakness conditions		
Muscular weakness	2	C
Musculoskeletal and connective tissue conditions NEC		
Mobility decreased	2	C
Musculoskeletal stiffness	6	C
Musculoskeletal and connective tissue pain and discomfort	3	
Back pain	12	C
Flank pain	1	C
Limb discomfort	4	C
Musculoskeletal pain	1	C
Neck pain	8	C
Pain in extremity	52	C
Soft tissue disorders NEC	02	
Groin pain	2	C
Neck mass	2	Ċ
Synovial disorders	2	
Synovitis	1	C
Tendon disorders		
Tendonitis	1	
	200	
Iuscle & tissue disorders SOC TOTAL	200	

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Reaction Name	Total	Fatal
Neoplasms		
Metastases to specified sites		
Metastases to lymph nodes	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebral haemorrhage	1	
Cerebrovascular accident	1	(
Subarachnoid haemorrhage	1	
Coordination and balance disturbances		
Balance disorder	2	(
Dysstasia	1	(
Disturbances in consciousness NEC		
Lethargy	14	(
Loss of consciousness	5	(
Somnolence	7	(
Syncope	6	(
Dyskinesias and movement disorders NEC		
Psychomotor hyperactivity	1	(
Facial cranial nerve disorders		
Facial nerve disorder	1	(
Facial paralysis	2	(
Facial paresis	1	(
Headaches NEC		
Cluster headache	2	(
Headache	124	(
Sinus headache	1	(
Tension headache	3	(
Vascular headache	1	(
Memory loss (excl dementia)		,
Amnesia	1	(
Memory impairment	1	(
Mental impairment (excl dementia and memory loss)	1	
Disturbance in attention	1	(
Migraine headaches	1	
Migraine	12	(
Migraine with aura	3	(
Mononeuropathies	5	,
Peroneal nerve palsy	1	(
Muscle tone abnormal		,
	1	(
Drop attacks	1	L L
Narcolepsy and hypersomnia	1	(
Hypersomnia	1	(
Neurological signs and symptoms NEC Dizziness	FG	(
	56	
Dizziness postural Head discomfort	3	(
	1	
Olfactory nerve disorders	1	
Parosmia	1	
Paraesthesias and dysaesthesias	0	
Burning sensation	2	
Dysaesthesia		
Formication		
Hypoaesthesia	7	
Paraesthesia	15	
Seizures and seizure disorders NEC		
Seizure	1	
Sensory abnormalities NEC		

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Reaction Name	Total	Fatal
Nervous system disordersus system disorders cont'd		
Ageusia	2	0
Dysgeusia	8	0
Electric shock sensation	1	0
Neuralgia	2	0
Sensory loss	1	0
Speech and language abnormalities		
Dysarthria	1	0
Tremor (excl congenital)		
Tremor	6	0
Nervous system disorders SOC TOTAL	304	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	2	0
Pregnancy conditions SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
Anxiety symptoms		
Anxiety	6	
Nervousness	1	
Stress	1	
Tension	1	
Confusion and disorientation		
Confusional state	6	
Depressive disorders		
Depression	2	
Disturbances in initiating and maintaining sleep		
Insomnia	6	
Fear symptoms and phobic disorders (incl social phobia)		
Fear of falling	1	
Fluctuating mood symptoms		
Mood swings	1	
Hallucinations (excl sleep-related)		
Hallucination	2	
Hallucination, tactile	1	
Mood alterations with depressive symptoms		
Depressed mood	4	
Panic attacks and disorders		
Panic attack	1	
Panic reaction	1	
Parasomnias		
Abnormal dreams	2	
Nightmare	2	
Psychiatric elimination disorders		
Enuresis	1	
Psychiatric symptoms NEC		
Psychiatric symptom	1	
Psychotic disorder NEC		
Psychotic disorder	1	
Sleep disorders NEC		
Sleep disorder	1	
Stereotypies and automatisms		
Bruxism	1	
Psychiatric disorders SOC TOTAL	43	

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Pollakiuria	1	0
Renal disorders NEC		
Renal disorder	1	0
Urinary abnormalities		
Haematuria	1	0
Renal & urinary disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Breast disorders NEC		
Breast mass	2	0
Breast signs and symptoms		
Breast pain	6	0
Erection and ejaculation conditions and disorders		
Erectile dysfunction	1	0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	8	0
Intermenstrual bleeding	5	0
Menstrual disorder	10	0
Menstruation irregular	24	0
Premenstrual pain	1	0
Menstruation with decreased bleeding		
Hypomenorrhoea	4	0
Menstruation delayed	20	0
Oligomenorrhoea	1	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	25	0
Polymenorrhoea	2	0
Testicular and epididymal disorders NEC		
Testicular pain	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	9	0
Reproductive & breast disorders SOC TOTAL	119	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	15	0
Bronchospasm and obstruction		
Asthma	1	0
Chronic obstructive pulmonary disease	1	0
Conditions associated with abnormal gas exchange		
Asphyxia	1	0
Coughing and associated symptoms		
Cough	8	0
Haemoptysis	1	0
Productive cough	1	0
Sputum discoloured	1	0
Nasal congestion and inflammations		
Nasal congestion	2	0
Nasal disorders NEC		
Epistaxis	2	0
Nasal pruritus	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Tonsillar hypertrophy	1	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	1	1
Upper respiratory tract signs and symptoms		
Aphonia	1	0
Dry throat	1	0
Dysphonia	4	0
Oropharyngeal pain	17	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	3	0
Sneezing	5	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	69	1

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Reaction Name	Total	<u>Fatal</u>
Skin disorders		
Alopecias		
Alopecia	1	
Alopecia areata	1	
Angioedemas		
Angioedema	1	
Apocrine and eccrine gland disorders		
Cold sweat	3	
Hyperhidrosis	14	
Night sweats	3	
Dermal and epidermal conditions NEC		
Dry skin	3	
Pain of skin	1	
Papule	2	
Skin sensitisation	2	
Skin swelling	2	
Skin warm	1	
Dermatitis and eczema		
Dermatitis	1	
Dermatitis allergic	1	
Dermatitis contact	1	
Eczema	1	
Skin irritation	1	
Erythemas		
Erythema	10	
Exfoliative conditions		
Skin exfoliation	1	
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	1	
Pruritus NEC		
Pruritus	28	
Psoriatic conditions	20	
Psoriasis	1	
Purpura and related conditions		
Petechiae	1	
Rashes, eruptions and exanthems NEC		
Rash	24	
Rash erythematous	9	
Rash macular	3	
Rash papular	4	
	3	
Rash pruritic	3	
Urticarias		
	11	
kin disorders SOC TOTAL	135	

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Immunisations		
COVID-19 immunisation	2	0
Orbit and globe therapeutic procedures		
Strabismus correction	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	1	0
Surgical & medical procedures SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Vascular disorders		
Circulatory collapse and shock		
Circulatory collapse	1	0
Haemorrhages NEC		
Haemorrhage	3	0
Lymphoedemas		
Lymphoedema	1	0
Non-site specific embolism and thrombosis		
Embolism	1	0
Thrombosis	6	0
Peripheral embolism and thrombosis		
Deep vein thrombosis	3	0
Peripheral vascular disorders NEC		
Hot flush	7	0
Site specific vascular disorders NEC		
Pallor	2	0
Vascular hypertensive disorders NEC	-	-
Hypertension	3	0
Vascular disorders SOC TOTAL	27	0
TOTAL REACTIONS FOR DRUG	1790	3
TOTAL REPORTS	597	
TOTAL FATAL OUTCOME REPORTS	397	3