

Case Series Drug Analysis Print

Name: FOI 22/404: Pneumococcal Polysaccharide Vaccine Adverse Reactions.

Report Run Date: 14-Feb-2022
Data Lock Date: 02-Feb-2022 18:30:04
Earliest Reaction Date: 23-Nov-1979
MedDRA Version: MedDRA 24.1

FOI 22/404: All UK spontaneous suspected adverse reactions
Pneumococcal associated with Pneumococcal Polysaccharide
Polysaccharide Vaccine.
Vaccine Adverse
Reactions.:

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	3	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
Coombs positive haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Coagulopathies</i>		
Factor VIII inhibition	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	2	0
<i>Haemolyses NEC</i>		
Haemolysis	2	0
<i>Leukocytoses NEC</i>		
Neutrophilia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	4	0
Lymphadenitis	3	0
Lymphadenopathy	48	0
Lymphadenopathy mediastinal	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
Pancytopenia	1	0
<i>Neutropenias</i>		
Agranulocytosis	1	0
Febrile neutropenia	1	0
Neutropenia	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	3	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	3	0
Blood disorders SOC TOTAL	84	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	13	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	1	0
Coronary artery thrombosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure acute	1	1
Ventricular failure	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	2	0
Angina pectoris	3	0
Myocardial infarction	5	3
Myocardial ischaemia	4	1
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<i>Myocardial disorders NEC</i>		
Myocardial fibrosis	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Pericardial disorders NEC</i>		
Cardiac tamponade	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Bradycardia	3	0
Cardiac flutter	1	0
Tachycardia	17	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	3	0
Sinus tachycardia	1	0
Supraventricular tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Ventricular extrasystoles	1	0
Ventricular fibrillation	1	0
Cardiac disorders SOC TOTAL	68	5

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Ventricular septal defect	1	0
<i>Haemoglobinopathies congenital</i>		
Sickle cell anaemia	1	0
<i>Renal and urinary tract disorders congenital NEC</i>		
Urinary tract malformation	1	0
Congenital disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	2	0
Ear disorder	1	0
Ear pain	8	0
<i>Eustachian tube disorders</i>		
Eustachian tube dysfunction	1	0
<i>Hearing losses</i>		
Deafness	2	0
Deafness neurosensory	1	0
Deafness unilateral	1	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	10	0
Vertigo	12	0
Ear disorders SOC TOTAL	39	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	2	0
Endocrine disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	2	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dacryostenosis acquired	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye oedema	1	0
Eye pain	3	0
Eye swelling	2	0
Periorbital oedema	2	0
Vitreous disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye irritation	1	0
Eye pruritus	1	0
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	2	0
<i>Ocular sensation disorders</i>		
Photophobia	11	0
<i>Orbital structural change, deposit and degeneration</i>		
Orbital oedema	1	0
<i>Pupil disorders</i>		
Mydriasis	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Necrotising retinitis	1	0
<i>Scleral infections, irritations and inflammations</i>		
Scleritis	1	0
<i>Visual disorders NEC</i>		
Diplopia	2	0
Photopsia	2	0
Vision blurred	8	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Visual acuity reduced	2	0
Visual impairment	2	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	56	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	1
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	52	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	3	0
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	12	0
Abdominal pain lower	2	0
Abdominal pain upper	10	0
Abdominal tenderness	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Duodenogastric reflux	1	0
Gastrooesophageal reflux disease	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	11	0
Anal incontinence	1	0
Dysphagia	4	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	2	0
Irritable bowel syndrome	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	204	0
Retching	1	0
Vomiting	122	0
Vomiting projectile	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
Salivary hypersecretion	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	2	0
Lip erythema	1	0
Lip pain	1	0
Oral mucosal blistering	1	0
Oral pain	2	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	5	0
Mouth swelling	1	0
Palatal oedema	1	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Retroperitoneal haematoma	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	5	0
Stomatitis	2	0
<i>Tongue disorders</i>		
Glossitis	1	0
Tongue ulceration	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	3	0
Tongue blistering	2	0
Tongue oedema	1	0
Gastrointestinal disorders SOC TOTAL	482	1

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site pain	1	0
Administration site rash	1	0
Administration site swelling	1	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	75	0
Chronic fatigue syndrome	2	0
Fatigue	149	0
Malaise	289	0
<i>Body temperature altered</i>		
Hypothermia	1	0
<i>Death and sudden death</i>		
Death	3	3
Sudden death	1	1
<i>Febrile disorders</i>		
Pyrexia	502	0
<i>Feelings and sensations NEC</i>		
Chills	200	0
Feeling abnormal	17	0
Feeling cold	31	0
Feeling drunk	1	0
Feeling hot	70	0
Feeling of body temperature change	17	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	9	0
Gait inability	2	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	12	0
Foaming at mouth	1	0
Illness	18	0
Induration	14	0
Influenza like illness	112	0
Local reaction	177	0
Multiple organ dysfunction syndrome	1	1
Peripheral swelling	376	0
Screaming	1	0
Swelling	116	0
Swelling face	7	0
<i>Inflamations</i>		
Inflammation	71	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	7	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	10	0
Injection site abscess sterile	1	0
Injection site atrophy	1	0
Injection site bruising	2	0
Injection site discharge	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site discolouration	3	0
Injection site erythema	87	0
Injection site haematoma	2	0
Injection site haemorrhage	1	0
Injection site hypersensitivity	1	0
Injection site induration	9	0
Injection site inflammation	73	0
Injection site joint swelling	1	0
Injection site joint warmth	1	0
Injection site mass	12	0
Injection site movement impairment	3	0
Injection site necrosis	3	0
Injection site oedema	4	0
Injection site pain	105	0
Injection site pruritus	9	0
Injection site rash	20	0
Injection site reaction	118	0
Injection site scar	3	0
Injection site swelling	76	0
Injection site ulcer	3	0
Injection site urticaria	3	0
Injection site vesicles	3	0
Injection site warmth	25	0
Interactions		
Drug interaction	4	0
Inhibitory drug interaction	1	0
Mass conditions NEC		
Mass	6	0
Nodule	1	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Localised oedema	9	0
Oedema	13	0
Oedema peripheral	14	0
Pain and discomfort NEC		
Axillary pain	19	0
Chest discomfort	25	0
Chest pain	31	0
Discomfort	10	0
Facial pain	4	0
Non-cardiac chest pain	1	0
Pain	214	0
Tenderness	34	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	13	0
Adverse event	1	0
Drug ineffective	9	0
Therapeutic response decreased	1	0
Therapy non-responder	6	0
Vaccination failure	10	0
Ulcers NEC		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Ulcer	2	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	3	0
Shoulder injury related to vaccine administration	3	0
Vaccination site bruising	6	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site erythema	89	0
Vaccination site haematoma	1	0
Vaccination site induration	17	0
Vaccination site inflammation	19	0
Vaccination site irritation	3	0
Vaccination site joint effusion	1	0
Vaccination site joint movement impairment	5	0
Vaccination site joint pain	2	0
Vaccination site joint swelling	1	0
Vaccination site mass	9	0
Vaccination site movement impairment	23	0
Vaccination site necrosis	1	0
Vaccination site oedema	1	0
Vaccination site pain	171	0
Vaccination site phlebitis	1	0
Vaccination site pruritus	7	0
Vaccination site rash	22	0
Vaccination site reaction	14	0
Vaccination site scab	1	0
Vaccination site swelling	101	0
Vaccination site urticaria	2	0
Vaccination site vesicles	1	0
Vaccination site warmth	53	0
General disorders SOC TOTAL	3862	5

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	1	0
Cholelithiasis	2	0
<i>Cholestasis and jaundice</i>		
Jaundice	3	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	1
Hepatic failure	1	0
Hepatorenal syndrome	2	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	1
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	2	0
Hepatitis chronic active	1	0
Hepatic disorders SOC TOTAL	17	2

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	53	0
Multiple allergies	1	0
Serum sickness	1	0
Serum sickness-like reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Drug hypersensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	13	0
Anaphylactic shock	6	1
Anaphylactoid reaction	3	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Blood isoimmune reactions</i>		
Alloimmunisation	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Immune system disorder	2	0
<i>Vasculitides</i>		
Eosinophilic granulomatosis with polyangiitis	1	0
Immune system disorders SOC TOTAL	88	1

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Administration site cellulitis	3	0
Arthritis bacterial	2	0
Bacterial infection	2	0
Bacterial sepsis	1	0
Cellulitis	149	0
Cellulitis gangrenous	1	0
Injection site cellulitis	29	0
Pneumonia bacterial	1	0
Post procedural cellulitis	1	0
Vaccination site cellulitis	24	0
<i>Bone and joint infections</i>		
Arthritis infective	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	5	0
Encephalomyelitis	1	0
Meningitis	1	0
Myelitis	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	1	0
Gas gangrene	1	1
<i>Dental and oral soft tissue infections</i>		
Parotitis	1	0
<i>Ear infections</i>		
Ear infection	1	0
Labyrinthitis	1	0
Otitis media	1	0
Otitis media acute	1	0
Otitis media chronic	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Haemophilus infections</i>		
Haemophilus infection	1	0
Haemophilus sepsis	1	0
Septic arthritis haemophilus	1	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
<i>Herpes viral infections</i>		
Herpes zoster	10	0
Oral herpes	1	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	6	0
Abscess limb	2	0
Administration site infection	1	0
Infection	9	0
Injection site abscess	2	0
Injection site infection	2	0
Localised infection	4	0
Respiratory tract infection	3	0
Systemic infection	1	0
Vaccination site abscess	1	0

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Infections Infections cont'd		
Vaccination site infection	3	0
<i>Influenza viral infections</i>		
Influenza	10	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	6	0
Lower respiratory tract infection	17	0
Pneumonia	32	8
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Neisseria infections</i>		
Meningitis meningococcal	1	0
Meningococcal sepsis	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Bacteraemia	1	0
Sepsis	13	0
Septic shock	2	0
<i>Skin structures and soft tissue infections</i>		
Carbuncle	1	0
Skin infection	1	0
Subcutaneous abscess	1	0
<i>Streptococcal infections</i>		
Bronchitis pneumococcal	1	0
Erysipelas	1	0
Meningitis pneumococcal	7	0
Pneumococcal infection	5	0
Pneumococcal sepsis	1	1
Pneumonia pneumococcal	1	0
Pneumonia streptococcal	1	1
Streptococcal sepsis	1	0
<i>Tuberculous infections</i>		
Erythema induratum	9	0
<i>Upper respiratory tract infections</i>		
Laryngitis	2	0
Nasopharyngitis	15	0
Rhinitis	1	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	4	0
<i>Vascular infections</i>		
Lymphangitis	4	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Post viral fatigue syndrome	2	0
Vestibular neuronitis	1	0
Viral infection	1	0
Viral rash	1	0
Infections SOC TOTAL	428	11

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	3	0
Foetal exposure during pregnancy	2	0
<i>Medication errors, product use errors and issues NEC</i>		
Circumstance or information capable of leading to medication error	1	0
Medication error	6	0
Product use in unapproved indication	1	0
Product use issue	1	0
Vaccination error	1	0
Wrong technique in product usage process	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	1	0
Wound decomposition	1	0
<i>Off label uses</i>		
Off label use	3	0
<i>Product administration errors and issues</i>		
Extra dose administered	2	0
Inappropriate schedule of product administration	6	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	4	0
Product administered to patient of inappropriate age	1	0
Product administration error	5	0
Wrong product administered	2	0
<i>Product prescribing errors and issues</i>		
Product prescribing error	1	0
<i>Skin injuries NEC</i>		
Contusion	22	0
Scar	2	0
<i>Vaccination related complications</i>		
Vaccination complication	6	0
Injuries SOC TOTAL	76	0

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Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Antinuclear antibody positive	1	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Streptococcus test positive	2	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	5	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	2	0
Blood glucose fluctuation	1	0
Blood glucose increased	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Cell marker analyses</i>		
Prostatic specific antigen increased	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	3	0
<i>Cholesterol analyses</i>		
High density lipoprotein decreased	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
International normalised ratio increased	2	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	18	0
Heart rate irregular	2	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin G decreased	1	0
<i>Immunology analyses NEC</i>		
Antibody test abnormal	1	0
Antibody test negative	2	0
<i>Investigations NEC</i>		
Blood test abnormal	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	1	0
Liver function test abnormal	1	0
<i>Microbiology and serology tests NEC</i>		
Seroconversion test negative	1	0
<i>Mineral and electrolyte analyses</i>		
Blood potassium increased	1	0
Blood sodium decreased	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
X-ray limb abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	2	0
Body temperature fluctuation	4	0
Body temperature increased	52	0
Grip strength decreased	1	0
Weight decreased	4	0
<i>Platelet analyses</i>		
Platelet count decreased	4	0
<i>Protein analyses NEC</i>		

Case Series Drug Analysis Print

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Report Run Date: 14-Feb-2022
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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
C-reactive protein increased	4	0
Red blood cell analyses		
Haematocrit abnormal	1	0
Red blood cell count decreased	1	0
Renal function analyses		
Blood creatinine increased	2	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	2	0
Urinalysis NEC		
Blood urine present	3	0
Protein urine present	1	0
Urinary tract function analyses NEC		
Urine output decreased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	2	0
Blood pressure decreased	4	0
Blood pressure increased	5	0
White blood cell analyses		
Eosinophil count increased	1	0
Neutrophil count increased	1	0
White blood cell count increased	6	0
Investigations SOC TOTAL	156	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	82	0
Hypophagia	1	0
Increased appetite	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
Diabetes mellitus inadequate control	6	0
<i>Disorders of purine metabolism</i>		
Gout	2	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	3	0
Feeding disorder	3	0
Food aversion	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	2	0
<i>Potassium imbalance</i>		
Hyperkalaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	5	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
Metabolic disorders SOC TOTAL	111	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	6	0
Arthropathy	3	0
Polyarthritis	6	0
Seronegative arthritis	1	0
<i>Bone disorders NEC</i>		
Jaw disorder	1	0
Osteonecrosis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	5	0
Bone swelling	1	0
Pain in jaw	3	0
<i>Bursal disorders</i>		
Bursitis	5	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Connective tissue disorders NEC</i>		
Myofascitis	1	0
Polymyalgia rheumatica	8	0
<i>Joint related disorders NEC</i>		
Joint lock	1	0
Periarthritis	16	0
Rotator cuff syndrome	2	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	160	0
Joint effusion	2	0
Joint range of motion decreased	1	0
Joint stiffness	6	0
Joint swelling	25	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle infections and inflammations</i>		
Myositis	7	0
<i>Muscle pains</i>		
Myalgia	148	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle disorder	1	0
Muscle fatigue	6	0
Muscle mass	1	0
Muscle spasms	12	0
Muscle swelling	3	0
Muscle tightness	1	0
Muscle twitching	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	34	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	1	0
Mobility decreased	10	0
Musculoskeletal stiffness	56	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Weight bearing difficulty	29	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	31	0
Limb discomfort	19	0
Musculoskeletal chest pain	5	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	4	0
Neck pain	21	0
Pain in extremity	402	0
Myopathies		
Myopathy	1	0
Rhabdomyolysis	1	0
Osteoarthropathies		
Osteoarthritis	2	0
Psoriatic arthropathies		
Psoriatic arthropathy	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	7	0
Soft tissue disorders NEC		
Axillary mass	1	0
Soft tissue disorder	1	0
Spondyloarthropathies		
Arthritis reactive	3	0
Synovial disorders		
Synovitis	1	0
Tendon disorders		
Tendon disorder	1	0
Muscle & tissue disorders SOC TOTAL	1073	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Intraductal proliferative breast lesion	1	0
Invasive ductal breast carcinoma	1	0
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	2	1
<i>Mesotheliomas malignant and unspecified</i>		
Mesothelioma	1	0
<i>Metastases to specified sites</i>		
Metastases to bone	1	0
<i>Non-small cell neoplasms malignant of the respiratory tract cell type specified</i>		
Lung adenocarcinoma stage IV	1	1
Neoplasms SOC TOTAL	8	2

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	16	2
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	7	2
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
<i>Choreiform movements</i>		
Choreoathetosis	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Diabetic neuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	12	0
Coordination abnormal	1	0
Dysstasia	3	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
Primary progressive aphasia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	2	1
<i>Disturbances in consciousness NEC</i>		
Lethargy	42	0
Loss of consciousness	17	0
Somnolence	31	0
Stupor	2	0
Syncope	31	0
<i>Dyskinesias and movement disorders NEC</i>		
Hypokinesia	10	0
Movement disorder	5	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	1	0
Facial paresis	2	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	2	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	253	0
Sinus headache	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	3	0
Disturbance in attention	6	0
Mental impairment	1	0
<i>Migraine headaches</i>		
Migraine	7	0
Migraine with aura	1	0
<i>Mononeuropathies</i>		
Nerve compression	1	0
Peroneal nerve palsy	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Motor neurone diseases</i>		
Motor neurone disease	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	4	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	3	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	98	0
Dizziness postural	4	0
Head discomfort	2	0
Meningism	1	0
Myoclonus	1	0
Neurological symptom	1	0
Presyncope	7	0
Slow response to stimuli	1	0
<i>Olfactory nerve disorders</i>		
Parosmia	1	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	2	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	14	0
Hyperaesthesia	3	0
Hypoaesthesia	33	0
Paraesthesia	46	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	2	0
Hemiplegia	1	0
Monoplegia	9	0
Paralysis	3	0
<i>Parkinson's disease and parkinsonism</i>		
Cogwheel rigidity	1	0
Parkinson's disease	1	0
<i>Peripheral neuropathies NEC</i>		
Brachial plexopathy	1	0
Neuralgic amyotrophy	2	0
Neuritis	2	0
Neuropathy peripheral	1	0
Polyneuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	4	0
Febrile convulsion	1	0
Seizure	9	0
Status epilepticus	1	0
<i>Sensory abnormalities NEC</i>		
Allodynia	1	0
Dysgeusia	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Electric shock sensation	1	0
Neuralgia	4	0
Sensory disturbance	6	0
Sensory loss	2	0
Taste disorder	3	0
<i>Speech and language abnormalities</i>		
Dysarthria	5	0
Slow speech	1	0
Speech disorder	4	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	4	0
Radiculopathy	1	0
<i>Tremor (excl congenital)</i>		
Tremor	39	0
Nervous system disorders SOC TOTAL	808	5

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
<i>Maternal complications of delivery NEC</i>		
Complication of delivery	1	0
<i>Maternal complications of pregnancy NEC</i>		
Hyperemesis gravidarum	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
Pregnancy conditions SOC TOTAL	6	0

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Reaction Name	Total	Fatal
<i>Product contamination and sterility issues</i>		
Product contamination microbial	1	0
<i>Product quality issues NEC</i>		
Product quality issue	2	0
null SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Anxiety symptoms</i>		
Agitation	2	0
Anxiety	3	0
Tension	1	0
<i>Behaviour and socialisation disturbances</i>		
Paranoia	1	0
Social avoidant behaviour	1	0
<i>Confusion and disorientation</i>		
Confusional state	11	0
Disorientation	8	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	5	0
Delirium tremens	1	0
<i>Depressive disorders</i>		
Depression	4	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	26	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Irritability	4	0
Mood altered	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	5	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressive symptom	1	0
Tearfulness	1	0
<i>Mood disorders NEC</i>		
Listless	4	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Parasomnias</i>		
Abnormal dreams	2	0
Nightmare	2	0
Sleep terror	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	10	0
<i>Thinking disturbances</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Thinking abnormal	1	0
Psychiatric disorders SOC TOTAL	106	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	4	0
Incontinence	1	0
Micturition urgency	1	0
Pollakiuria	5	0
Urinary incontinence	3	0
Urinary retention	1	0
<i>Bladder disorders NEC</i>		
Bladder obstruction	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Focal segmental glomerulosclerosis	1	0
Glomerulonephritis rapidly progressive	1	0
Nephrotic syndrome	3	0
<i>Nephritis NEC</i>		
Lupus nephritis	1	0
Tubulointerstitial nephritis	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	7	0
Chronic kidney disease	2	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
Proteinuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Polyuria	1	0
Renal pain	4	0
Renal & urinary disorders SOC TOTAL	39	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast enlargement	1	0
Breast mass	1	0
<i>Breast signs and symptoms</i>		
Breast pain	4	0
Breast swelling	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	1	0
Pelvic pain	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
<i>Vaginal and vulval infections and inflammations</i>		
Vulvovaginal inflammation	2	0
<i>Vulvovaginal disorders NEC</i>		
Vulval ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal burning sensation	1	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	61	0
Dyspnoea exertional	2	0
Hyperventilation	2	0
Respiratory arrest	1	0
Respiratory distress	2	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	15	2
Bronchospasm	4	0
Wheezing	15	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	66	0
Haemoptysis	2	0
Productive cough	8	0
Sputum discoloured	2	0
Sputum increased	2	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pulmonary eosinophilia	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Increased bronchial secretion	4	0
Pleuritic pain	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	5	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	1	0
<i>Parenchymal lung disorders NEC</i>		
Emphysema	1	0
Organising pneumonia	1	0
Pulmonary fibrosis	8	2
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal swelling	2	0
Tonsillar inflammation	1	0
<i>Pleural conditions NEC</i>		
Pleural thickening	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	6	0
Pneumothorax	1	0
<i>Pulmonary oedemas</i>		
Acute pulmonary oedema	1	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	1
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	0
Respiratory tract congestion	1	0
<i>Upper respiratory tract signs and symptoms</i>		

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Reaction Name	Total	Fatal
Respiratory disorders		
Respiratory disorders cont'd		
Aphonia	2	0
Catarrh	3	0
Dysphonia	3	0
Nasal discomfort	1	0
Oropharyngeal pain	26	0
Rhinorrhoea	10	0
Sneezing	7	0
Throat irritation	2	0
Throat tightness	5	0
Upper-airway cough syndrome	1	0
Respiratory disorders SOC TOTAL	286	5

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Reaction Name	Total	Fatal
Skin disorders		
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	70	0
Miliaria	1	0
Night sweats	12	0
<i>Bullous conditions</i>		
Blister	6	0
Erythema multiforme	2	0
Stevens-Johnson syndrome	1	0
Toxic epidermal necrolysis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	4	0
Pain of skin	9	0
Scab	1	0
Sensitive skin	3	0
Skin burning sensation	3	0
Skin discolouration	7	0
Skin disorder	1	0
Skin induration	17	0
Skin lesion	3	0
Skin lesion inflammation	1	0
Skin necrosis	2	0
Skin reaction	16	0
Skin sensitisation	1	0
Skin swelling	2	0
Skin tightness	3	0
Skin warm	49	0
<i>Dermatitis and eczema</i>		
Dermatitis	4	0
Dermatitis allergic	11	0
Dermatitis contact	1	0
Eczema	4	0
Skin irritation	3	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	347	0
<i>Exfoliative conditions</i>		
Skin exfoliation	7	0
<i>Hyperpigmentation disorders</i>		
Skin hyperpigmentation	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail atrophy	1	0
<i>Panniculitides</i>		
Erythema nodosum	3	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pilar disorders NEC</i>		
Hair disorder	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Hair texture abnormal	1	0
Pruritus NEC		
Pruritus	48	0
Psoriatic conditions		
Erythrodermic psoriasis	1	0
Guttate psoriasis	1	0
Psoriasis	1	0
Purpura and related conditions		
Henoch-Schonlein purpura	4	0
Petechiae	3	0
Purpura	2	0
Rashes, eruptions and exanthems NEC		
Rash	76	0
Rash erythematous	29	0
Rash macular	23	0
Rash maculo-papular	3	0
Rash papular	10	0
Rash pruritic	9	0
Sebaceous gland disorders		
Fordyce spots	1	0
Skin dystrophies		
Skin wrinkling	2	0
Skin hypoplasias and atrophies		
Skin striae	1	0
Skin injuries and mechanical dermatoses		
Needle track marks	2	0
Skin vasculitides		
Vasculitic rash	5	0
Urticarias		
Urticaria	60	0
Urticaria papular	1	0
Urticarial vasculitis	1	0
Skin disorders SOC TOTAL	890	0

Case Series Drug Analysis Print

Name: FOI 22/404: Pneumococcal Polysaccharide Vaccine Adverse Reactions.

Report Run Date: 14-Feb-2022
Earliest Reaction Date: 23-Nov-1979

Data Lock Date: 02-Feb-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	5	0
Immobile	2	0
Loss of personal independence in daily activities	2	0
<i>Social issues NEC</i>		
Contraindication to vaccination	2	0
Social circumstances SOC TOTAL	11	0

Case Series Drug Analysis Print

Name: FOI 22/404: Pneumococcal Polysaccharide Vaccine Adverse Reactions.

Report Run Date: 14-Feb-2022
Earliest Reaction Date: 23-Nov-1979

Data Lock Date: 02-Feb-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Inner ear therapeutic procedures</i>		
Cochlea implant	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Medical device removal	1	0
Surgical & medical procedures SOC TOTAL	6	0

Case Series Drug Analysis Print

Name: FOI 22/404: Pneumococcal Polysaccharide Vaccine Adverse Reactions.

Report Run Date: 14-Feb-2022
Earliest Reaction Date: 23-Nov-1979

Data Lock Date: 02-Feb-2022 18:30:04
MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	11	1
Shock	2	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	2	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	1
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	5	0
Flushing	14	0
Hot flush	3	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	11	0
<i>Site specific vascular disorders NEC</i>		
Pallor	11	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	7	0
<i>Vascular hypotensive disorders</i>		
Hypotension	17	0
Orthostatic hypotension	2	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	1	0
Granulomatosis with polyangiitis	1	0
Vasculitis	5	0
Vasculitis necrotising	1	0
Vascular disorders SOC TOTAL	96	2
TOTAL REACTIONS FOR DRUG	8822	39
TOTAL REPORTS	2746	
TOTAL FATAL OUTCOME REPORTS		39