

Case Series Drug Analysis Print

Name: FOI 21/877 - MMR Vaccine DAP 2020

Report Run Date: 09-Aug-2021

Data Lock Date: 08-Aug-2021 18:30:04

Earliest Reaction Date: 01-Jan-2015

MedDRA Version: MedDRA 24.0

FOI 21/877 - MMR Vaccine DAP 2020: All spontaneous suspected UK Adverse Drug Reaction (ADR) reports associated with the MMR vaccine in 2020

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenitis	1	0
Lymphadenopathy	10	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	2	0
Blood disorders SOC TOTAL	13	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	1	0
Cardiac disorders SOC TOTAL	1	0

Case Series Drug Analysis Print

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 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
Ear swelling	2	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>Hearing losses</i>		
Deafness	1	0
<i>Inner ear disorders NEC</i>		
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	3	0
Vertigo	2	0
Ear disorders SOC TOTAL	11	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Eye disorders		
<i>Eyelid movement disorders</i>		
Excessive eye blinking	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Swelling of eyelid	2	0
<i>Ocular disorders NEC</i>		
Eye pain	3	0
Eye swelling	2	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye inflammation	1	0
Eye irritation	1	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle disorder	1	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Refractive and accommodative disorders</i>		
Hypermetropia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness transient	1	0
Visual impairment	1	0
Eye disorders SOC TOTAL	19	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	17	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faecaloma	1	0
Faeces discoloured	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	3	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	2	0
Vomiting	18	0
Vomiting projectile	3	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
<i>Salivary gland enlargements</i>		
Salivary gland enlargement	1	0
Submaxillary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Stomatitis	1	0
<i>Tongue signs and symptoms</i>		
Strawberry tongue	1	0
Gastrointestinal disorders SOC TOTAL	59	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	2	0
Fatigue	14	0
Malaise	9	0
<i>Febrile disorders</i>		
Pyrexia	111	0
<i>Feelings and sensations NEC</i>		
Chills	1	0
Feeling cold	1	0
Feeling hot	2	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	3	0
Gait inability	5	0
<i>General signs and symptoms NEC</i>		
Crying	16	0
Developmental regression	3	0
High-pitched crying	1	0
Illness	2	0
Influenza like illness	1	0
Irritability postvaccinal	1	0
Multiple organ dysfunction syndrome	1	1
Peripheral swelling	8	0
Screaming	6	0
Swelling	4	0
Swelling face	5	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Injection site reactions</i>		
Injection site bruising	1	0
Injection site discomfort	1	0
Injection site erythema	6	0
Injection site inflammation	1	0
Injection site mass	3	0
Injection site pain	1	0
Injection site pruritus	1	0
Injection site swelling	7	0
Injection site warmth	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Discomfort	2	0
Pain	15	0
Tenderness	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse event	1	0
Post vaccination challenge strain shedding	1	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	4	0
Vaccination site discomfort	1	0
Vaccination site erythema	14	0
Vaccination site hypertrichosis	1	0

Case Series Drug Analysis Print

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 Earliest Reaction Date: 01-Jan-2015

Data Lock Date: 08-Aug-2021 18:30:04
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site inflammation	1	0
Vaccination site joint erythema	1	0
Vaccination site mass	4	0
Vaccination site pain	5	0
Vaccination site pruritus	1	0
Vaccination site rash	7	0
Vaccination site reaction	1	0
Vaccination site swelling	13	0
Vaccination site vesicles	1	0
Vaccination site warmth	4	0
General disorders SOC TOTAL	300	1

Case Series Drug Analysis Print

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Data Lock Date: 08-Aug-2021 18:30:04
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Haemophagocytic lymphohistiocytosis	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	6	0

Case Series Drug Analysis Print

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Data Lock Date: 08-Aug-2021 18:30:04
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Reaction Name	Total	Fatal
Infections		
<i>Adenoviral infections</i>		
Adenovirus infection	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	4	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	1	0
<i>Dental and oral soft tissue infections</i>		
Parotitis	2	0
<i>Ear infections</i>		
Otitis media	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
<i>Herpes viral infections</i>		
Herpes simplex	1	0
Human herpesvirus 6 infection reactivation	1	0
<i>Infections NEC</i>		
Vaccination site infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Pneumonia	1	0
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Respiratory syncytial viral infections</i>		
Respiratory syncytial virus infection	1	0
<i>Rubeola viral infections</i>		
Measles	6	0
Measles post vaccine	2	0
<i>Skin structures and soft tissue infections</i>		
Dermatitis infected	1	0
<i>Upper respiratory tract infections</i>		
Epiglottitis	1	0
Nasopharyngitis	4	0
Upper respiratory tract infection	1	0
Infections SOC TOTAL	34	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	1	0
<i>Pathways and sources of exposure</i>		
Exposure via skin contact	1	0
<i>Product administration errors and issues</i>		
Product administered at inappropriate site	1	0
<i>Skin injuries NEC</i>		
Scar	1	0
Injuries SOC TOTAL	7	0

Case Series Drug Analysis Print

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Data Lock Date: 08-Aug-2021 18:30:04
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Reaction Name	Total	Fatal
Investigations		
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	1	0
Heart rate increased	4	0
<i>Physical examination procedures and organ system status</i>		
Body temperature decreased	1	0
Body temperature fluctuation	1	0
Body temperature increased	2	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	1	0
Investigations SOC TOTAL	12	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	30	0
Food refusal	1	0
Hypophagia	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Food aversion	1	0
Metabolic disorders SOC TOTAL	34	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthropathy	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	4	0
Joint noise	1	0
<i>Muscle pains</i>		
Myalgia	4	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	5	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Toe walking	1	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	2	0
Neck pain	2	0
Pain in extremity	11	0
Muscle & tissue disorders SOC TOTAL	35	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Coordination and balance disturbances</i>		
Balance disorder	1	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	5	0
Loss of consciousness	1	0
Somnolence	5	0
Syncope	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akinesia	1	0
Hypokinesia	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
<i>Headaches NEC</i>		
Headache	5	0
<i>Muscle tone abnormal</i>		
Hypotonia	2	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	4	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	10	0
Inability to crawl	1	0
Infant irritability	3	0
Myoclonus	1	0
Unresponsive to stimuli	2	0
<i>Neuromuscular disorders NEC</i>		
Hypotonic-hyporesponsive episode	2	0
<i>Olfactory nerve disorders</i>		
Parosmia	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
Hypoaesthesia	1	0
Paraesthesia	2	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	1	0
Paralysis	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Febrile convulsion	3	0
Seizure	8	0
Seizure like phenomena	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	1	0
Sensory disturbance	2	0
Sensory loss	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	1	0
Speech disorder	1	0
Speech disorder developmental	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	79	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<i>Device physical property and chemical issues</i>		
Syringe issue	1	0
null SOC TOTAL	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	2	0
Breath holding	1	0
<i>Anxiety symptoms</i>		
Agitation	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Social avoidant behaviour	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
Disorientation	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	6	0
Middle insomnia	2	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	3	0
Irritability	17	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
<i>Increased physical activity levels</i>		
Restlessness	2	0
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Parasomnias</i>		
Sleep terror	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	3	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	1	0
<i>Stereotypies and automatisms</i>		
Head banging	1	0
<i>Thinking disturbances</i>		
Thinking abnormal	2	0
Psychiatric disorders SOC TOTAL	53	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Micturition frequency decreased	1	0
Urinary incontinence	1	0
Urinary retention	1	0
Renal & urinary disorders SOC TOTAL	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	4	0
Hyperventilation	1	0
Respiratory arrest	1	0
<i>Bronchospasm and obstruction</i>		
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	2	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	2	0
Pharyngeal swelling	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	1	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Oropharyngeal pain	3	0
Rhinorrhoea	5	0
Snoring	1	0
Respiratory disorders SOC TOTAL	28	0

Case Series Drug Analysis Print

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Skin disorders		
<i>Angioedemas</i>		
Angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	2	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Papule	8	0
Scab	1	0
Skin discolouration	3	0
Skin reaction	1	0
Skin tightness	1	0
Skin warm	5	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	2	0
Dermatitis diaper	2	0
Eczema	2	0
Skin irritation	1	0
<i>Erythemas</i>		
Erythema	13	0
<i>Pruritus NEC</i>		
Pruritus	7	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	97	0
Rash erythematous	5	0
Rash macular	2	0
Rash morbilliform	31	0
Rash papular	6	0
Rash pruritic	4	0
Rash rubelliform	3	0
Rash scarlatiniform	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Urticaria	11	0
Skin disorders SOC TOTAL	216	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	1	0
Social circumstances SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	4	0
Vascular disorders SOC TOTAL	5	0
TOTAL REACTIONS FOR DRUG	917	1
TOTAL REPORTS	299	
TOTAL FATAL OUTCOME REPORTS		1