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| ○ : 2021/2/17-2021/6/13に、副反応疑い報告が届けられたもの | 疾患名/症状名 | WHO_COVID-19 vaccine: Safety Surveillance Manual Module AESI_List of AESI defined for COVID-19 vaccines (May2020) | SPEAC; Safety Platform for Emergency vaccines CEPI (Coalition for Epidemic Preparedness Innovations)_Priority List of COVIER-19 Adverse events of special interest | 米国CDC (COVID-19 vaccine safety update),ACIP March 1, 2021資料、Rapid Cycle Analysis (RCA) to monitor the safety of COVID-19 vaccines in near real-time within the Vaccine Safety Datalink VSD Project March 3, 2021 | 医療機関報告 (2021/2/17-2021/6/13) 重複含む | 企業報告 (2021/2/17-2021/6/13) 重複含む |
|--|---------|---|--|--|-----------------------------------|---------------------------------|

| 既に報告義務対象疾患/症状、あるいは積極的に報告が求められている疾患/症状 | | | | | | |
|---------------------------------------|----------------------------------|--------------------------------------|--|--|------------------|------------------|
| ○ | アナフィラキシー | Anaphylaxis | Anaphylaxis | Anaphylaxis | 1,466 | 1,419 |
| ○ | c.急性散在性脳脊髄炎 (ADEM) | Acute disseminated encephalomyelitis | Acute disseminated encephalomyelitis(ADEM) | Acute disseminated encephalomyelitis(ADEM) | 6 | 8 |
| ○ | e.脳炎・脳症 | | Encephalitis | Encephalitis | 6 | 4 |
| | 高血圧性脳症 | | | | 0 | 1 |
| ○ | 低酸素性虚血性脳症 | | | | 2 | 0 |
| | 髄膜脳炎 | Meningoencephalitis | Meningoencephalitis | | 0 | 0 |
| ○ | f.脊髄炎 | | | Myelitis | 5 | 4 |
| | 脳脊髄炎 | | Encephalomyelitis | Encephalomyelitis | 0 | 0 |
| | 横断性脊髄炎 | | | Transverse myelitis (TM) | 0 | 0 |
| ○ | g.けいれん (強直性痙攣、全身性强直性間代性発作、間代性痙攣) | Generalized convulsion | Generalized convulsion | Convulsion/seizures | 60 | 65 |
| ○ | h.ギラン・バレー症候群 | Guillain Barre Syndrome | Guillain Barre Syndrome(GBS) | Guillain Barre Syndrome | 9 | 15 |
| ○ | j.顔面神経麻痺 | | | Bell's palsy | 39 | 30 |
| ○ | m.血小板減少性紫斑病 | | | | 13 | 7 |
| ○ | n.血管炎 | | Vasculitides/Vasculitis | | 6 | 5 |
| ○ | 微小血管炎 (毛細血管炎) | Microangiopathy | Microangiopathy | | 0 | 1 |
| | 単一臓器皮膚血管炎 | Single organ cutaneous vasculitis | Single organ cutaneous vasculitis | | 0 | 0 |
| ○ | u.関節炎 | Acute aseptic arthritis | Arthritis | | 48 | 10 |
| ○ | 無菌性髄膜炎 | | Aseptic meningitis | | 8 | 11 |
| ○ | 髄膜炎 | | | | 2 | 3 |
| ○ | 心筋炎 | Myocarditis | Myocarditis | Myocarditis | 9 | 10 |
| ○ | 血管迷走神経反射 (失神を伴うもの) | | | | 4 | 35 |
| ○ | 重篤な局所/全身性有害事象 | | Serious local/systemic AEFI | | 入院1,073 死亡249 | 入院1,205 死亡137 |

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| WHO, SPEAC, CDCの資料にAEFIサーベイランス疾患として掲載されている疾患 | | | | | | |
|--|---------------------------|-------------------------------------|--|--|----|----|
| ○ | 急性呼吸窮迫症候群 (ARDS) | Acute respiratory distress syndrome | Acute respiratory distress syndrome (ARDS) | Acute respiratory distress syndrome (ARDS) | 2 | 2 |
| ○ | 急性心血管障害 | Acute cardiovascular injury | Acute cardiac injury | | 0 | 0 |
| ○ | 心不全 (急性心不全、うっ血性心不全、慢性心不全) | Heart failure | Heart failure | | 33 | 34 |
| ○ | 心原性ショック (心原性心停止) | | Cardiogenic shock | | 5 | 2 |
| ○ | 心膜炎 | | Pericarditis | Pericarditis | 4 | 3 |
| ○ | ストレス心筋症 (心筋症) | Stress cardiomyopathy | Stress cardiomyopathy | | 3 | 6 |
| ○ | 不整脈 | Arrhythmia | Arrhythmia | | 12 | 36 |
| ○ | 冠動脈疾患 | Coronary artery disease | Coronary artery disease | | — | — |
| ○ | 心筋梗塞 | | | Acute myocardial infarction | 26 | 35 |
| ○ | 狭心症 (不安定狭心症) | | | | 3 | 8 |
| ○ | 急性冠動脈症候群 (急性冠症候群) | | | | 1 | 3 |
| ○ | 冠動脈狭窄 | | | | 1 | 2 |
| ○ | 冠動脈閉塞 | | | | 1 | 2 |
| ○ | 冠動脈硬化症 | | | | 1 | 1 |
| ○ | 凝固障害 | Coagulation disorder | Coagulation disorder | | — | — |
| ○ | 血栓塞栓症 (血栓症、塞栓症) | Thromboembolism | | | 4 | — |

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|---|--|-----------------------|------------------------|--|----|----|
| ○ | 大脳静脈洞血栓症 | | | | 2 | 2 |
| ○ | 脳血栓症 | | | | 1 | 0 |
| ○ | 表在性血栓性静脈炎 | | | | 1 | 0 |
| ○ | 深部静脈血栓症 | | | Venous thromboembolism | 5 | 7 |
| ○ | 肺動脈塞栓 (肺塞栓症、肺動脈血栓症) | | Pulmonary embolus | Pulmonary embolism (subset of VTE) | 12 | 12 |
| ○ | 播種性血管内凝固症候群 (DIC) | | | Disseminated intravascular coagulation (DIC) | 2 | 2 |
| ○ | 門脈塞栓症 | | | | 1 | 1 |
| ○ | 腸間膜動脈血栓症 | | | | 1 | 1 |
| ○ | 血栓性血小板減少性紫斑病 | | | Thrombotic thrombocytopenic purpura | 0 | 1 |
| ○ | 動脈血栓症 (動脈塞栓症) | | | | 7 | 8 |
| | 静脈性血栓塞栓症 | | | Venous thromboembolism (VTE) | 0 | 0 |
| ○ | 肢虚血 (四肢静脈血栓症) | | Limb ischemia | | 2 | 1 |
| ○ | 虚血性大腸炎 | | | | 4 | 7 |
| ○ | 脳血管発作 (脳血管障害) | | Cerebrovascular stroke | | 2 | 3 |
| ○ | 一過性脳虚血発作 | | | Stroke, ischemic | 1 | 4 |
| ○ | 血栓性脳梗塞 | | | | 2 | 2 |
| ○ | 脳梗塞 (血栓性脳梗塞、塞栓性脳梗塞、出血性脳梗塞、ラクナ梗塞、大脳基底核梗塞) | | | | 63 | 60 |
| ○ | 脳幹梗塞 | | | | 3 | 3 |
| ○ | 小脳梗塞 | | | | 5 | 1 |
| ○ | 梗塞 | | | | 2 | 1 |
| ○ | 脳出血 | | | Stroke, hemorrhagic | 34 | 33 |
| ○ | 小脳出血 | | | | 2 | 1 |
| ○ | 脳幹出血 | | | | 2 | 3 |
| ○ | 脳室内出血 | | | | 2 | 2 |
| ○ | くも膜下出血 | | | | 30 | 28 |
| ○ | 視床出血 | | | | 4 | 2 |
| ○ | 被殻出血 | | | | 5 | 5 |
| ○ | 出血性疾患 | haemorrhage | | | — | — |
| ○ | 出血 | | | | 18 | 11 |
| ○ | 動脈出血 | | | | 1 | 0 |
| ○ | 鼻出血 | | | | 9 | 4 |
| ○ | 眼出血 (網膜出血、強膜出血、結膜出血) | | | | 5 | 14 |
| ○ | 口腔内出血 (歯肉出血) | | | | 7 | 3 |
| ○ | 肺出血 | | | | 2 | 0 |
| ○ | 喀血 | | | | 1 | 2 |
| ○ | 消化管出血 (下血・血便、メレナ、出血性胃潰瘍) | | | | 20 | 38 |
| ○ | 腹腔内出血 | | | | 1 | 1 |
| ○ | 接種部位出血 (皮下出血、接種部位内出血、内出血、点状出血) | | | | 32 | 72 |
| ○ | 出血性関節症 | | | | 0 | 2 |
| ○ | 性器出血 | | | | 6 | 12 |
| ○ | 血小板減少症 | Thrombocytopenia | Thrombocytopenia | Immune thrombocytopenia | 9 | 12 |
| ○ | 急性腎障害 (腎機能障害、腎不全) | Acute kidney injury | Acute kidney injury | | 9 | 9 |
| ○ | o.肝機能障害 (肝機能異常、肝酵素上昇) | Acute liver injury | Liver injury | | 34 | 29 |
| ○ | 嗅覚障害 (嗅覚錯誤) | Anosmia | Anosmia | | 4 | 4 |
| ○ | 味覚障害 (味覚不全、味覚消失、味覚障害) | Ageusia | Ageusia | | 20 | 13 |
| ○ | しもやけ様病変(凍瘡) | Chilblain-like lesion | Chilblain-like lesions | | 0 | 1 |
| ○ | 多形性紅斑(多形紅斑) | Erythema multiforme | Erythema multiforme | | 4 | 4 |
| ○ | 亜急性甲状腺炎 | | Subacute thyroiditis | | 3 | 2 |
| ○ | 急性甲状腺炎 | | | | 0 | 1 |

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| ○ | 虫垂炎 | | | Appendicitis | 1 | 0 |
| | ワクチン関連疾患増悪 (VAED) | vaccine-associated enhanced disease | Enhanced disease following immunization | | 0 | 0 |
| | 多系統炎症性症候群 (MIS-C、MIS-A) | Multisystem inflammatory syndrome in children | Multisystem inflammatory syndrome in children | Multisystem inflammatory syndrome in children (MIS-C), Multisystem inflammatory syndrome in adults (MIS-A) | 0 | 0 |
| ○ | 横紋筋融解症 | | Rhabdomyolysis | | 3 | 2 |
| ○ | 急性膵炎 (膵炎、自己免疫性膵炎、壊死性膵炎) | | Pancreatitis | | 1 | 5 |
| | 川崎病 | | | Kawasaki disease | 0 | 0 |
| | ナルコレプシー/カタプレキシー (脱力発作) | | | Narcolepsy and cataplexy | 0 | 0 |

現行の予防接種副反応疑い報告書のa.~w.に含まれる疾患/症状

| | | | | | | |
|---|------------|--|--|--|-----|-----|
| ○ | a.無呼吸 | | | | 12 | 11 |
| ○ | b.気管支けいれん | | | | 15 | 13 |
| ○ | d.多発性硬化症 | | | | 3 | 3 |
| ○ | i.視神経炎 | | | | 4 | 2 |
| ○ | k.末梢神経障害 | | | | 87 | 86 |
| ○ | l.知覚異常 | | | | 76 | 4 |
| ○ | p.ネフローゼ症候群 | | | | 3 | 4 |
| ○ | q.喘息発作 | | | | 170 | 142 |
| ○ | r.間質性肺炎 | | | | 7 | 4 |
| ○ | s.皮膚粘膜眼症候群 | | | | 24 | 18 |
| ○ | t.ぶどう膜炎 | | | | 28* | 1 |
| ○ | v.蜂巣炎 | | | | 9 | 9 |
| ○ | w.血管迷走神経反射 | | | | 251 | 82 |

*取り下げ予定