**Appendix Table 1. Pre-specified adverse events (AE) following vaccination.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Adverse events**  **(care setting)** | **Diagnosis** | **Risk window** | **ICD-9 Code\*** |
| **Group 1. Systemic reactions (inpatient, ED)** | Anaphylaxis | 0-6 days  (first episode in 30 days) | 995.0, 999.4 |
| **Group 2: Local reactions (outpatient, inpatient, ED)** | a) Cellulitis and infection  Cellulitis, upper arm and forearm  Cellulitis  Cellulitis, unspecified site  Pain in limb  Limb swelling  Complication of medical care  Lymphadenitis, unspecified, except mesenteric  Acute lymphadenitis  Enlargement of lymph nodes, lymphadenopathy  b) Allergic Reaction  Angioneurotic edema  Allergy unspecified  Allergic urticaria  Idiopathic urticaria  Urticaria, unspecified | 1-7 days  (first episode in 30 days) | 682.3  682.8  682.9  729.5  729.81  999.9  289.3  683  785.6  995.1  995.3  708.0  708.1  708.9 |
| **Group 3. Cardiovascular events (inpatient, ED)** | a) Acute and subacute myocardial infarction  Acute myocardial infarction  Other acute and subacute forms of ischemic heart disease  b) Acute pericarditis  Acute pericarditis  c) Acute myocarditis  Acute myocarditis in diseases classified elsewhere  Acute myocarditis NOS  Idiopathic myocarditis  Other and unspecified acute myocarditis  Myocarditis unspecified  d) Cardiomyopathy  Other primary cardiomyopathies  Cardiomyopathy in other diseases classified elsewhere  Secondary cardiomyopathy unspecified  Cardiomegaly – dilation, hypertrophy, ventricular dilation  e) Heart failure  Congestive heart failure unspecified  Left heart failure  Systolic heart failure  Combined systolic and diastolic heart failure  Heart failure unspecified | 1-42 days  (first episode in 12 months) | 410  411  420  422.0  422.90  422.91  422.99  429.0  425.4  425.8  425.9  429.3  428.0  428.1  428.2  428.4  428.9 |
| **Group 4. Stroke, cerebrovascular diseases, venous thromboembolism (VTE) (inpatient, ED)** | a) Stroke and cerebrovascular diseases  Occlusion and stenosis of precerebral arteries  Occlusion of cerebral arteries  Transient cerebral ischemia  Acute, ill-defined, cerebrovascular disease  Other and ill-defined cerebrovascular disease  b) VTE  pulmonary embolism and infarction  Deep vein thrombosis (DVT) | 1-42 days  (first episode in 12 months)  1-14 days  (first episode in 12 months) | 433  434  435  436  437.1,437.4,437.6,437.8,437.9  415.1  453.4 |
| **Group 5. Meningitis, encephalitis, and encephalopathy (inpatient, ED)** | Other specified viral meningitis  Unspecified viral meningitis, viral meningitis NOS, meningitis  Unspecified non-arthropod-borne viral diseases of central nervous system, viral encephalitis NOS  Meningitis due to viruses not elsewhere classified  Meningitis due to other nonbacterial organisms classified elsewhere  Meningitis of unspecified cause  Encephalitis, myelitis, and encephalomyelitis  Encephalopathy, not elsewhere classified | 1-42 days  (first episode in 12 months) | 047.8  047.9  049.9  321.2  321.8  322  323  348.3 |

\*ICD-9 codes include all additional fourth- or fifth- level digits where applicable.

ED: emergency department; NOS: not specified.

**Appendix Table 2. Characteristics of the chart review confirmed stroke/cerebrovascular cases among HIV-infected patients with a baseline viral load > 10,000 copies/ml, Vaccine Datalink Project, 2002-2013.**

|  |  |  |
| --- | --- | --- |
| **Characteristics** | **Number of Cases** | |
| **Risk window (n=4)** | **Control window (n=4)** |
| **New onset vs. recurrent** |  |  |
| **New onset** | 2 | 4 |
| **Recurrent cases** | 2 | 0 |
| **Confirmed diagnosis** |  |  |
| **Stroke** | 2 | 3 |
| **Transient Ischemic Attack (TIA )** | 2 | 1 |
| **Cluster pattern of onset date within the observation period** | 1 case on the day of vaccination; others on days 12, 36, and 39; | On days 70, 74, 95, and 105 |
| **Type of vaccine received** | 2 cases received influenza vaccine, 2 cases received hepatitis B vaccine | 3 cases received influenza vaccine, 1 case received hepatitis B vacine |
| **Documented potential risk factors** | 1 new onset TIA case: atherosclerotic plaque;  1 recurrent stroke case: type-2 diabetes, hyperlipidemia, AIDS. | 1 new onset stroke case: encephalitis, smoker in remission |