**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 infectionCellulitis, upper arm and forearmCellulitisCellulitis, unspecified sitePain in limbLimb swelling Complication of medical careLymphadenitis, unspecified, except mesentericAcute lymphadenitisEnlargement of lymph nodes, lymphadenopathyb) Allergic Reaction Angioneurotic edemaAllergy unspecifiedAllergic urticariaIdiopathic urticaria Urticaria, unspecified | 1-7 days (first episode in 30 days) | 682.3682.8682.9729.5729.81999.9289.3683785.6995.1995.3708.0708.1708.9 |
| **Group 3. Cardiovascular events (inpatient, ED)** | a) Acute and subacute myocardial infarctionAcute myocardial infarctionOther acute and subacute forms of ischemic heart diseaseb) Acute pericarditisAcute pericarditisc) Acute myocarditisAcute myocarditis in diseases classified elsewhereAcute myocarditis NOS Idiopathic myocarditis Other and unspecified acute myocarditisMyocarditis unspecifiedd) CardiomyopathyOther primary cardiomyopathiesCardiomyopathy in other diseases classified elsewhereSecondary cardiomyopathy unspecifiedCardiomegaly – dilation, hypertrophy, ventricular dilatione) Heart failureCongestive heart failure unspecifiedLeft heart failureSystolic heart failureCombined systolic and diastolic heart failureHeart failure unspecified | 1-42 days (first episode in 12 months) | 410411420422.0422.90422.91422.99429.0425.4425.8425.9429.3428.0428.1428.2428.4428.9 |
| **Group 4. Stroke, cerebrovascular diseases, venous thromboembolism (VTE) (inpatient, ED)** | a) Stroke and cerebrovascular diseasesOcclusion and stenosis of precerebral arteriesOcclusion of cerebral arteriesTransient cerebral ischemiaAcute, ill-defined, cerebrovascular diseaseOther and ill-defined cerebrovascular diseaseb) VTE pulmonary embolism and infarctionDeep vein thrombosis (DVT) | 1-42 days(first episode in 12 months)1-14 days(first episode in 12 months) | 433434435436437.1,437.4,437.6,437.8,437.9415.1453.4 |
| **Group 5. Meningitis, encephalitis, and encephalopathy (inpatient, ED)** | Other specified viral meningitisUnspecified viral meningitis, viral meningitis NOS, meningitisUnspecified non-arthropod-borne viral diseases of central nervous system, viral encephalitis NOSMeningitis due to viruses not elsewhere classifiedMeningitis due to other nonbacterial organisms classified elsewhereMeningitis of unspecified causeEncephalitis, myelitis, and encephalomyelitisEncephalopathy, not elsewhere classified | 1-42 days(first episode in 12 months) | 047.8047.9049.9321.2 321.8322323348.3 |

\*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 |