Background. The Mini-Sentinel system was established in response to the FDA Amendments Act to monitor the safety of FDA-regulated medical products. We evaluated the positive predictive value (PPV) of ICD9-based algorithms to identify post-vaccination febrile seizures (FS). We also describe an adaptation of Brighton Collaboration (BC) definition for seizures for use in medical record review.

Methods. We identified ICD9 diagnosis (dx) codes for fever and seizures in the emergency or inpatient setting after influenza, diphtheria tetanus acellular pertussis-containing, and 13-valent conjugate pneumococcal vaccines from July 1, 2010 to June 30, 2011. We estimated the PPV for FS. BC criteria for seizures included documentation of loss of consciousness (LOC, defined as witnessing sudden LOC or history of unconsciousness) and generalized motor manifestations. Because medical record documentation may be insufficient for LOC, we included other consistent symptoms, including altered states of consciousness (ASC, e.g., documentation of eyes rolled back or unresponsiveness).

Results. Of 216 potential FS identified with ICD9 codes for seizures, 152 were chart-confirmed to have documentation of fever and seizure within 24 h or a clinician dx of FS (PPV = 0.70, 95% CI 0.64, 0.76). Two ICD9 codes (780.31, 780.32) specific for FS produced the highest PPV (PPV = 0.91, 95% CI 0.85, 0.95) and accounted for 140 (92%) of confirmed FS. In the absence of these codes, other non-specific seizure codes yielded much lower PPVs, regardless of the presence of same day codes for medically attended fever (PPVs ranging from 0.19 to 0.20).

Only 9 of the 152 confirmed FS met BC criteria for LOC and generalized motor manifestations. By including criteria for ASC, we captured an additional 101 confirmed FS. An additional 42 confirmed FS cases did not meet LOC/ASC and/or generalized motor manifestations criteria, but did have documentation of fever and seizure within 24 h or a clinician dx of FS.

Conclusion. Although ICD9 code algorithms based on any seizure code yielded a moderate PPV, restriction to specific FS codes yielded a higher PPV and accounted for a large proportion of confirmed FS. The use of ASC in validation criteria captured a larger number of cases beyond those meeting BC criteria.

Disclosures. C. McMahill-Walraven, Aetna: Employee, Salary