ESP-VAERS Working Document
Contact: mklompas@partners.org

ESP-VAERS Case Identification and Reporting Protocol

If patient administered a vaccine then monitor that patient for the next 30 days for the appearance of a new encounter with any of the following:

Vital sign entry
New Lab order
New Lab result (must be from lab ordered ≥1 day after vaccine encounter)
ICD9 code entry
Medication prescription
Allergy entry
Electrocardiogram

If none of the above appear within 30 days of the vaccine then stop.
If any of the above appears then continue:

Action Categories

Category	Interpretation	Action
One	Common, well described, low acuity adverse event	Report automatically
Two	Rare, high acuity adverse event on VDW list	1. Message to clinician to comment on adverse event 2. Automatically message CDC if no comment from clinician within 72 hours
Three	Possible novel adverse event not previously associated with vaccine	1. Message clinician to confirm or decline adverse event
Four	Routine health visit highly unlikely to be adverse event	Discard

***Alternatives for category two [PLEASE COMMENT*]:**

- Eliminate special distinction and treat as category three (clinician input event)
- Immediately message VAERS upon detection as well as send message to clinician to add optional comments

Significant findings:

Version: 1.0
Date: November 1, 2007

Vital signs

Component	Comparison	Value	Action Category
Temperature	None	>38 deg C	One

Lab result

Component name	CPT	Component	Trigger Value	Unit	Exclusion	Action Category
Hemoglobin			<10	g/L	X > (LKV*0.8)	Three
Total WBC count			<3.5	$x10^9$/L	X > (LKV*0.7)	Three
Neutrophils			<2000	$x10^9$/L	X > (LKV*0.7)	Three
Eosinophils			>600	$x10^9$/L	X < (LKV*1.2)	Three
Lymphocytes			<1000	$x10^9$/L	X > (LKV*0.7)	Three
Platelet count			<150	$x10^9$/L	X > (LKV*0.7)	Three
Platelet count			<100	$x10^9$/L	X > (LKV*0.7)	Two
Creatinine			>1.5	mg/dL	X < (LKV*1.3)	Three
ALT			>120	IU/L	X < (LKV*1.3)	Three
AST			>100	IU/L	X < (LKV*1.3)	Three
Bilirubin (total)			>2.0	mg/dL	X < (LKV*1.2)	Three
ALK			>200	IU/L	X < (LKV*1.3)	Three
PTT			>60	s	X < (LKV*1.3)	Three
Creatine kinase			>500	U/L	X < (LKV*1.3)	Three
Glucose			>200	mg/dL	X < (LKV*2.0)	Three
Potassium			>5.5	mmol/L	X < (LKV + 0.5)	Three
Sodium			>150	mmol/L	X < (LKV + 5)	Three
Sodium			<130	mmol/L	X > (LKV – 5)	Three

Abbreviations: X – current lab value; LKV – last known lab value

ICD9 code

Diagnosis	ICD9 codes	Exclusion	Action Category	VSD Source
Guillain-Barre	357.0	Same code within past 12 months	Two	Menactra
Bell's palsy	351.0	Same code within past 12 months	Two	Menactra
Seizures	345.*; 780.3	None	Two	Menactra
Seizures (RotaTeq)	779.0; 333.2	None	Two	RotaTeq
Febrile seizure	780.31	None	Two	MMR-V
Ataxia	052.7; 334.4; 781.2; 781.3	Same code within past 12 months	Two	MMR-V
Encephalitis	323.9; 323.5; 055.0; 052.0	Same code within past 12 months	Two	MMR-V
Arthritis	714.9; 716.9; 056.71	Same code within past 12 months	Two	MMR-V
Allergic urticaria	708.0	Same code within past 12 months	Two	MMR-V
Angioneurotic edema	995.1	Same code within past 12 months	Two	MMR-V
Anaphylactic shock due to serum	999.4	Same code within past 12 months	Two	MMR-V
Intussusception	543.9; 560.0	Same code within past 12 months	Two	RotaTeq
GI bleeding	569.3; 578.1; 578.9	004*, 008*, 204-208*, 286*, 287*, 558.3, 800-998* ever or same code within past 12 months	Two	RotaTeq
Meningitis / encephalitis	047.8; 047.9; 049.9; 321.2; 322*; 323.5; 323.9	047.0-047.1, 048*, 049.0-049.8, 053-056*, 320* ever or same code within past 12 months	Two	RotaTeq
Myocarditis	429.0, 422*	Same code within past 12 months	Two	RotaTeq
Hypersensitivity – drug, unspec	995.20	None	Three	
Pneumonitis – hypersensitivity	495.9	None	Three	
Upper respiratory tract hypersensitivity reaction	478.8	None	Three	
Poisoning – bacterial vaccine	978.8	None	Three	
Poisoning – mixed bacterial (non-pertussis) vaccine	978.9	None	Three	
Infection due to vaccine	999.39	None	Three	
Post-immunization reaction	999.5	None	Three	
Myelitis – post immunization	323.52	None	Three	
Encephalitis / encephalomyelitis – post immunization	323.51	None	Three	
Exclusion ICD9 diagnosis	see list	NA	Four	
Any other diagnosis		1. Same code on patient's current problem list *prior* to this encounter	Three	

Diagnosis	ICD9 codes	Exclusion	Action Category	VSD Source
		2. Encounter with same code in past 36 months 3. Past medical history list with same code		

[EXCLUSION CRITERIA – PLEASE COMMENT ON THE FOLLOWING:
1. SHOULD THERE BE ANY EXCLUSION CRITERIA FOR CATEGORY TWO EVENTS (TO TRY TO ELIMINATE FALSE POSITIVES FROM PATIENTS WHO WERE DIAGNOSED WITH THE PURPORTED EVENT PRIOR TO VACCINE ADMINISTRATION)?
2. IF THERE SHOULD BE EXCLUSION CRITERIA, SHOULD IT SIMPLY MIMIC CATEGORY THREE APPROACH (1. Same code on patient's current problem list prior to this encounter, 2. Encounter with same code in past 36 months, 3. Past medical history list with same code) OR SHOULD IT BE LESS RESTRICTIVE?]

Medication prescription

Medication	Exclusion	Action Category
Medrol-pak	Same medication (any dose) within the past 12 months	Three
Prednisone	Same medication (any dose) within the past 12 months	Three
Benadryl	Same medication (any dose) within the past 12 months	Three
Epinephrine	None	Three

Allergies (vaccine specific)

Vaccine	Allergy Name	Exclusion	Action Category
Menactra	menactra	Allergy list prior to vaccine	Three
	mening*	Allergy list prior to vaccine	Three
MMR-V	MMR-V	Allergy list prior to vaccine	Three
	Measle*	Allergy list prior to vaccine	Three
	Mump*	Allergy list prior to vaccine	Three
	Rubel*	Allergy list prior to vaccine	Three
	Rubbel*	Allergy list prior to vaccine	Three
	Varicel*	Allergy list prior to vaccine	Three
RotaTeq	RotaTeq	Allergy list prior to vaccine	Three
	Rota*	Allergy list prior to vaccine	Three

Electrocardiogram

EKG finding	Value	Units	Exclusion	Action Category
QTcorr	>480	ms	X < (LKV + 40)	Three

Clinician Query Protocol

Action Category Two
(Rare, high acuity adverse event on VDW list)

Destination clinician: primary care provider *and* clinician who entered the trigger ICD9, ordered the trigger lab, prescribed the trigger med, or entered the trigger allergy / vital sign (if different from PCP).

Text:
Dear Dr. ("insert name")

Your patient ("patient name") may have suffered a serious adverse effect from a recent vaccine. ("Patient name") was recently noted to have ("ICD9 text" or "lab component name and value"). ("Patient name") was vaccinated with ("vaccine name(s)") "(trigger date minus vaccine date") days prior on ("date.") If you agree that this patient may have suffered a vaccine adverse effect, we will submit an electronic report to the CDC / FDA's Vaccine Adverse Event Reporting System on your behalf.

Please provide any additional clinical details on this event that you think might be helpful to CDC and FDA vaccine safety investigators:

Enter comments:
SEE REPORT SUBMIT

If you do not believe this new diagnosis is related to vaccination please provide details so that we can refine our adverse effect detection algorithms to minimize future inappropriate alerts:

Enter comments:
SUBMIT

This note was automatically generated by the Electronic Support for Public health system (ESP), a joint venture of Atrius Health, the Department of Ambulatory Care and Prevention at Harvard Medical School, and the Centers for Disease Control and Prevention. The project is funded by the Agency for Healthcare Research and Quality. If you have any questions about the project or this note please contact one of the following individuals:

Ross Lazarus MBBS, MPH, MMed	Principal investigator	ross.lazarus@channing.harvard.edu
Michael Klompas MD, MPH	Project manager	mklompas@partners.org
Francis X. Campion MD	Atrius physician liason	francis_campion@vmed.org

Action Category Three

Destination clinician: primary care provider

Text:

Dear Dr. ("insert name")

Your patient ("patient name") was recently noted to have ("ICD9 text" or "lab component name and value" or "prescription for 'drug name'" or "newly entered allergy to 'allergy name'" or "QT prolongation with corrected QT of 'QTcorr'"). "Patient name" was vaccinated with "vaccine name(s)" on "date." Do you think it is possible that ("ICD9 text 'is'" or "lab component name and value 'is'" or "this is due to") an adverse effect of a vaccine?

If so, we can automatically submit an electronic report to the FDA / CDC's Vaccine Adverse Event Reporting System (VAERS) on your behalf.

If you would like to submit an immediate electronic report with optional comments please enter comments below and click SUBMIT:

Enter comments:
SEE REPORT SUBMIT

If you do not believe this new diagnosis is related to vaccination please provide details so that we can refine our adverse effect detection algorithms to minimize future inappropriate alerts:

Enter comments:
SUBMIT

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Michael Klompas MD, MPH Project manager mklompas@partners.org
Francis X. Campion MD Atrius physician liason francis_campion@vmed.org

Reporting Elements

Demographic

Patient name	Last, first
Gender	
Date of birth	
Race	
Home address	
Telephone number	

Reporting clinician

Clinician name	Last, first
Practice address	
Practice phone number	

Vaccine data

Vaccine name	
Date of administration	
Vaccine lot number	
Additional vaccines 1	Vaccines administered during the same encounter as trigger vaccine
Additional vaccines 2	All additional vaccines administered within 30 days leading up to adverse event date

Clinical event

Event category	Vital sign, lab result, diagnosis, allergy, prescription, electrocardiogram
Event trigger	Specific test name or diagnosis that established the adverse event vital sign: "temperature" lab component name: "platelets" ICD9 text: "myocarditis" allergy name: "menactra" prescription: "prednisone" electrocardiogram: "QTcorr"
Event value	Temperature value, lab test result, ICD9 code number, allergy text, prescription dose + frequency + duration, QTcorr value
Event date	Date of trigger encounter (i.e. temperature encounter date, lab collected date, ICD9 encounter date, date allergy entered, prescription date, QTcorr date)
Time to onset	(event date) – (vaccine date of administration) in days
Clinician opinion	Probable vaccine adverse event – "yes" or "no" (note that for action category three this will be "yes" by default; the possibility of "no" only exists for action category two)
Clinician comment text	