Vaccine(s) administered In Past 30 Days

Clinical symptoms: chest pain, shortness of breath, palpitations, unexplained syncope, dry cough

#### **Initial Evaluation**

History: characterize symptoms <sup>1</sup> Detailed vaccination history & dates

· especially smallpox or other live vaccines

Past medical history

Cardiac risk factors 2

Pulmonary function testing with DLCO (diffusion limitation of carbon monoxide)

B. Symptoms + abnormality

of cardiac enzymes, ECG,

and/or echocardiogram

Physical examination <sup>3</sup> Chest X-ray: PA/Lateral

Electrocardiogram (ECG) 4 -

Laboratory <sup>5</sup>: Troponin, CK-MB

Echocardiogram

C. Progressive symptoms, LVEF < 40-45%, CK > 1,000, ventricular dysrhythmias, hemodynamic instability

SAVE

Plasma, Serum

(stored blood

protocol)

A. Symptoms Only

- A. Evaluate, treat, consult Evaluate as soon as possible
- · Document normal ECG, troponin, CK, CRP, other if indicated
- · Reclassify if any abnormality or if indicated by expert review
- Enter in VHC registry for FU monitoring
- Consider non-cardiac etiology
- Monitor if continued symptoms<sup>9</sup>
- Treat symptomatically<sup>10</sup>

#### Approach to new severe &/or persistent complaints

- Evaluate & treat with consultation as needed; FU 6-12 weeks
- New problem, vaccine temporal association, serious impact on quality of life, unremitting: Contact VHC via 866-210-6469

#### B. Cardiology evaluation, treat, consult

- Work up & treat for acute coronary syndrome, as indicated7
- Differential of myo-pericarditis <sup>6,6A</sup>
- Contact VHC + Cardiology Special studies<sup>5,8</sup>
- Serial daily enzymes for 5 days or normalization, and at 3 weeks
- Viral work-up (serology, PCR)
- · Establish functional impairment

Therapeutic options: NSAID, acetaminophen, COX2 inhibitor, other Rx such as steroids?

#### Management & Recovery<sup>10</sup>

- Profile (limited duty) until FU evaluation complete.
- VHC follow-up at 6-12 weeks and 6-12 months with repeat ECG, echocardiogram, enzymes, and exercise test, for clearance at home duty station

#### C. Cardiology evaluation, treat, consult

- Promptly work up & treat for acute coronary syndrome, as indicated<sup>7</sup>
- Differential of myo-pericarditis <sup>6,6A</sup>
- Contact VHC + Cardiology
- Viral work-up (serology, PCR)

**Transfer** to Tertiary Care Center: consider limitations of facility

- Apply elements outlined in B Individual case management
- **Monitor & document recovery**
- · VHC case management with tracking of 3-6 months and 12 month evaluation by cardiology
- Disability assessments annually x 2 years or until asymptomatic

A (as indicated), B &C: Refer to VHC Network for case management and second-level review (CISA/CDC/VHC): Echocardiograms, ECGs, cardiac isoenzyme results, copy of records and patient and provider contact information. All probable and confirmed cases<sup>6</sup>: disability assessments annually x 2 years or until asymptomatic, whichever is longer. Key VHC Consultant Sites: Brooke & Walter Reed Army Med Ctrs.

Consultation. Clinicians wishing to consult with Vaccine Healthcare Center and/or military cardiologists regarding optimal care should call the DoD Vaccine Clinical Call Center at 866-210-6469, to request a clinical cardiovascular consult. NOTE: Footnotes and additional information described on accompanying sheets. VHC will coordinate follow-up case management and outcomes data collection.

Footnote #	Topic	Documentation Categories	Documentation Details, Comments
1	Chest pain type	Category of patient's chest pain type if present (choose one):  I. Atypical chest pain: Pain, pressure, or discomfort in the chest, neck, or arms not clearly exertional or not otherwise consistent with pain or discomfort of myocardial ischemic origin.  II. Typical chest pain: Chest pain that is exertional and is relieved with rest or nitroglycerin. Often described as a pressure type of pain.  A. Stable chest pain: Chest pain without a change in frequency or pattern for the 2 weeks before this procedure.  B. Unstable chest pain: Chest pain that occurred at rest and was prolonged, usually lasting > 20 minutes, OR a recent acceleration of chest pain reflected by an increase in severity or frequency in the preceding 2 weeks.	
	Number of episodes of chest pain in last 72 hours	Number of distinct episodes of chest pa evaluation.	in that occurred in the last 72 hours before
	Secondary cause of chest pain (yes/no)		itated by a secondary factor such as known fever, anemia, hypoxemia, tachycardia, se.
	Reproducibility of symptoms	Note whether the chest pain is reproduct positional changes or pressure sensitive	cible by either deep respiration (pleuritic), e.
	Heart failure	Patient with complaint of dyspnea on exparoxysmal nocturnal dyspnea, orthopn	
	Dysrhythmia	Patient with complaint of palpitations, ra Documentation of concomitant sympton headedness associated with symptoms	ns of syncope (duration), dizziness or light

Footnote	Prior angina	History of angina before the current admission. "Angina" refers to evidence or
2		knowledge of symptoms before this acute event described as chest pain or pressure, jaw pain, arm pain, or other equivalent discomfort suggestive of cardiac ischemia. Indicate if angina existed > 2 weeks before admission and/or within 2 weeks before admission.
	Previous myocardial infarction (MI)	The patient has had at least 1 documented previous MI before admission.
	Prior congestive heart failure (CHF)	History of CHF. "CHF" refers to evidence or knowledge of symptoms before this acute event described as dyspnea, fluid retention, or low cardiac output secondary to cardiac dysfunction, or the description of rales, jugular venous distension, or pulmonary edema before the current admission.
	Previous percutaneous coronary intervention (PCI)	Previous PCI of any type (balloon angioplasty, atherectomy, stent, or other) done before the current admission. Date should be noted.
	Previous coronary artery bypass graft (CABG)	Previous CABG done before the current admission. Date should be noted.
	Prior catheterization with stenosis > or = 50%	Documented coronary artery disease (CAD) at coronary angiography at any time before the current admission, with at least a 50% stenosis in a major coronary artery. If the patient had a cardiac catheterization before the index event that demonstrated a stenosis of 90% and that was successfully stented to a 0% residual, this should be coded as "yes," because a stenosis of > or = 50% was documented.
	History of stroke	Documented history of stroke or cerebrovascular accident (CVA). Typically, a patient has had a history of stroke if there was loss of neurological function caused by an ischemic event with residual symptoms at least 24 hours after onset. The year of the most recent stroke before the current admission should be noted.
	History of transient ischemic attack (TIA)	A focal neurological deficit (usually corresponding to the territory of a single vessel) that resolves spontaneously without evidence of residual symptoms at 24 hours
	Peripheral arterial disease	Peripheral arterial disease can include the following:  1. Claudication, either with exertion or at rest  2. Amputation for arterial vascular insufficiency  3. Vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities  4. Documented aortic aneurysm  5. Positive noninvasive test (e.g., ankle brachial index < 0.8)
	Diabetes	History of diabetes, regardless of duration of disease, need for antidiabetic agents, or a fasting blood sugar > 7 mmol/l or 126 mg/dl. If yes, the type of diabetic control should be noted (check all that apply):  1. None  2. Diet: Diet treatment  3. Oral: Oral agent treatment  4. Insulin: Insulin treatment (includes any combination of insulin)

Hyn	ertension	Hypertension as documented by:
		History of hypertension diagnosed and treated with medication, diet, and/or
		exercise
		2. Blood pressure > 140 mm Hg systolic or 90 mm Hg diastolic on at least 2
		occasions
		Current use of antihypertensive pharmacological therapy
Smo	oking	History confirming cigarette smoking in the past. Choose from the following
	-	categories:
		Current: Smoking cigarettes within 1 month of this admission
		2. Recent: Stopped smoking cigarettes between 1 month and 1 year before this
		admission
		3. Former: Stopped smoking cigarettes > 1 year before this admission
		4. Never: Never smoked cigarettes
Dys	lipidemia	History of dyslipidemia diagnosed and/or treated by a physician. National
		Cholesterol Education Program criteria include documentation of the following:
		1. Total cholesterol > 200 mg/dl (5.18 mmol/l); or
		2. Low-density lipoprotein (LDL) > or = 130 mg/dl (3.37 mmol/l); or
		3. High-density lipoprotein (HDL) < 40 mg/dl (1.04 mmol/l).
		Treatment is also initiated if LDL is > 100 mg/dl (2.59 mmol/l) in patients with
F	aily history of CAD	known coronary artery disease, and this <i>would</i> qualify as hypercholesterolemia.
Fam	nily history of CAD	Any direct blood relatives (parents, siblings, children) who have had any of the
		following at age < 55 years:
		1. Angina 2. Myocardial infarction
		Sudden cardiac death without obvious cause
Lun	g disease	Documented history of chronic lung disease (i.e., chronic obstructive pulmonary
Lun	y uiscase	disease) or currently being treated with pharmacological therapy (e.g., inhalers,
		theophylline, aminophylline, or steroids) and/or has a forced expiratory volume in 1
		second (FEV1) < 70% of predicted, room air pO <sub>2</sub> < 60 mm Hg, room air pCO <sub>2</sub> > 50
		mm Hg, an FEV1/FVC ratio < 0.8, or an abnormal DLCO (diffusion limitation of
		carbon monoxide). Any history of acute lung injury to include pulmonary
		embolism/deep vein thrombophlebitis should be noted.
Gas	strointestinal disease	Documented history of gastroesophageal reflux disease, esophagitis, peptic ulcer
		disease, or currently being treated with pharmacologic therapy (e.g., H <sub>2</sub> -
		antagonistscimetidine, ranitidine), or proton pump inhibitors (e.g., omeprazole,
		lansoprazole). History of pancreatitis or cholelithiasis or other gallbladder disease.
Prio	r vaccination history and	Note made of all vaccinations received within 30 days of presentation, to include
adve	erse events	anatomic location of immunization.
		Note made of prior adverse events after vaccinations, including, but not limited to,
		arthralgias, myalgias, headache, shortness of breath, chest pain, febrile illness

Footnote	Gender	Patient's gender: male or female
3		
	Date of birth	Day, month, and year of the patient's birth
	Race	Patient's race or ethnicity:
		1. White
		2. Black
		3. Hispanic
		4. Asian
		5. Native American
		6. Other race not listed
		Note: These categories could be used in a "check all that apply" format to identify
		mixed races.
	Heart rate	Heart rate (beats per minute) should be the recording that was done closest to the
		time of presentation to the healthcare facility
	Systolic and diastolic blood	Supine systolic and diastolic blood pressure (mm Hg) should be the recording that
	pressure (at time of presentation	was done closest to the time of presentation to the healthcare facility and on
	and on discharge)	discharge
	Respiratory rate	Respiratory rate (breaths per minute)
	Temperature	Temperature (in Fahrenheit or Celsius) with indication as to method taken, i.e.,
		aural, oral, rectal, or non-invasive (skin probe). Should be the recording that was
		done closest to the time of presentation to the healthcare facility
	Height	Patient's height in centimeters or inches
	Weight	Patient's weight in kilograms or pounds
	Vaccination site	Vaccination site healing? For vaccinia, describe the vaccination response.
	Cardiac exam	Heart rate regular/irregular, absence/presence of S4, S3
		2. Absence/presence of murmur or rub

	3. Point of maximal impulse (PMI, apex) lateral
Jugular venous pressure	Normal/elevated
Lung exam	1. Rales, wheezes, etc.
	2. None (absence of rales over the lung fields)
	3. Mild CHF (rales over < or = 50% of the lung fields). Evidence of new pulmonary
	vascular congestion on chest radiograph also meets the definition.
	4. Severe CHF (rales over > 50% of the lung fields). Evidence of pulmonary edema
	on chest radiograph would also meet this definition.
Extremities	Edema on peripheral extremities, with notation as to evidence of sustained
	depression (pitting), and amount of depression (in millimeters, or 1-4+ scale)
Lymphatics	Adenopathy with documentation of anatomic location (ancillary, clavicular,
	submental, cervical, inguinal)

Footnote	First 12-lead ECG: date and	Note date and time the first 12-lead ECG was performed for acute episode
	time	(whether in a prehospital setting, emergency department, or inpatient unit).
4		
	Location of ECG changes	The location of each type of ECG change listed below can be broken into 4
		categories:
		1. Inferior leads: II, III, aVF
		2. Anterior leads: V1 to V4
		3. Lateral leads: I, aVL, V5 to V6
		4. Diffuse leads: use if similar type of ECG changes identified in ≥ 9 of 12 leads.
	Type of ECG changes	ST-segment elevation indicates > or = 1 mm (0.1 mV) elevation in 2 or more contiguous leads
		2. ST-segment depression of at least 0.5 mm (0.05 mV) in 2 or more contiguous leads (includes reciprocal changes)
		3. T-wave inversion of at least 1 mm (0.1 mV) including inverted T waves that are not indicative of acute MI
		4. Q waves refer to the presence of Q waves that are > or = 0.03 seconds in width and > or = 1 mm (0.1 mV) in depth in at least 2 contiguous leads
	Conduction Abnormality,	The presence of left or right bundle branch block, ventricular pre-excitation, or 1st,
	including bundle branch block	2 <sup>nd</sup> , or 3 <sup>rd</sup> degree heart block should be noted, as well as whether it is new, old, or of uncertain timing.
	Rhythm	The categories of rhythm are as follows:
	,	1. Sinus rhythm
		2. Atrial fibrillation (or flutter)
		Atrial and/or ventricular electronically paced rhythm
		4. Ventricular tachycardia
		5. Supraventricular tachycardia
		6. Significant sinus arrhythmia
		7. Other (e.g., bigeminy, junctional)
		Premature ventricular complexes (PVC's),
	Ectopy	Premature supraventricular/atrial complexes (PAC's).
		3. Premature junctional complexes (PJC's)

Footnote 5		
Special Studies: All patients	Complete blood count	The presentation CBC, to include differential, with emphasis on eosinophil and lymphocyte count should be noted. The upper limit of normal of WBC, Hgb, Plt, and differential as determined by individual hospital laboratory standards should be reported.
	0	
	Cardiac enzymes	
	All values	All CK, CK-MB, and troponin values during the evaluation should be noted; include the units, date, and time. The upper limit of normal of CK-MB as defined by individual hospital laboratory standards should be noted. For troponin values, indicate which type: T or I.
	Inflammatory Markers	
	All values	All erythrocyte sedimentation rate and C-reactive protein values during the evaluation should be noted; include units, date, and time. Report the upper limit of normal as defined by individual hospital laboratory standards.

	1	
0		
Special Studies as		
Clincially		
indicated		
illulcateu	B-type natriuretic peptide	
	(BNP)	
	All values	All BNP values during the hospitalization should be noted; include units, date, and time
	Immune complex screening	
	All values	All C3, C4, CH50, Raji cell, C1q assay values during the evaluation should be noted; include units, date, and time. Report the upper limit of normal as defined by individual hospital laboratory standards.
	Cultures: Viral	
	All values	All viral cultures (nasal wash, urine, feces) for adenovirus, influenza viruses or
	All values	enterovirses should be noted to include date and time. Results of cerebrospinal fluid viral cultures including shell vial culture that looks specifically for enteroviruses, herpes simplex viruses, and cytomegalovirus should be noted to include date and time.
	Serologies: Viral	
	All values	All enterovirus, influenza, coxsackie B, Lyme, hepatitis B IgM and core IgG values and titers during the evaluation should be noted; include units, date, and time to differentiate between acute and convalescent sera.
	Collagen vascular screening	
	All values	Note all ANA, Anti-DS DNA, ENA, and similar values during the evaluation; include units, date, and time. Report the patterns associated with positive assays.
	Other labs	
	Total serum cholesterol level	The first total serum cholesterol level and type of units should be noted
	LDL	First serum low density lipoprotein (LDL) and units (either calculated or direct, if
		measured)
	HDL	First serum high density lipoprotein (HDL) level and units
		First serum C-reactive protein level and units
	Serum creatinine	First creatinine level and units
	Hemoglobin A1c	Documented laboratory value and units for patient's hemoglobin A1c

Footnote		1.5 W. (AMAIA/D.0000.50.400.0	, (DDF/ 1/ 5004 II)
6	Myocarditis, Pericarditis cas	se definitions ( <i>MMWR</i> 2003;52:492-6, ww	w.cdc.gov/mmwr/PDF/wk/mm5221.pdf)
	Suspect (1) Symptoms (dyspnea,	Probable (1) Meets criteria for suspected	Confirmed
Myo- carditis	palpitations, or chest pain) (2) ECG abnormalities beyond normal variants, not documented previously (ST/T abnormality, paroxysmal supraventricular tachycardia, ventricular tachycardia, atrioventricular block, frequent atrial or ventricular ectopy) OR Focal or diffuse depressed LV function of uncertain age by an imaging study (3) Absence of evidence of any other likely cause	myocarditis (2) In addition, meets one of the following: Elevated levels of cardiac enzymes (Creatine Kinase-MB fraction, Troponin T or Troponin I), OR new onset of depressed LV function by imaging, OR abnormal imaging consistent with myocarditis (MRI with gadolinium, gallium-67 scanning, anti-myosin antibody scanning)	Histopathologic evidence of myocarditis by endomyocardial biopsy or on autopsy.
Peri- carditis	Suspect (1) Typical chest pain (made worse by supine position, improved with leaning forward, pleuritic, constant). (2) No evidence for alternative cause of such pain	Probable  (1) Meets criteria for suspected pericarditis (2) Has one or more of the following: Pericardial rub on auscultation OR ECG with diffuse ST-segment elevations or PR depressions not previously documented OR echocardiogram revealing an abnormal pericardial effusion	Confirmed Histopathologic evidence of pericardial inflammation in pericardial tissue from surgery or autopsy
6A	Differential Diagnosis	Consider acute coronary syndrome (myocardial infarction), aortic dissection, pneumothorax, pulmonary embolism, musculoskeletal pain, esophageal disorder (gastroesophageal reflux, esophageal spasm), systemic autoimmune disease.	

Footnote	Stress test	Indicate whether an exercise tolerance or pharmacological stress test was
		performed during the hospital stay. Date should be noted. Indicate if the test
7		involved ECG alone or either radionuclide imaging or echocardiogram.
	Ischemia result (positive,	Positive: On an exercise tolerance test, the patient developed:
	negative, equivocal)	a. Both ischemic discomfort and ST shift > or = 1 mm (0.1 mV) (horizontal or
		downsloping) or
		b. New ST shift > or = 2 mm (0.2 mV) (horizontal or downsloping) believed to
		represent ischemia even in the absence of ischemic discomfort.
		c. Definitive reversible perfusion defect on radionuclide imaging or inducible wall
		motion abnormality or failure of left ventricular augmentation on stress
		echocardiography should be considered a positive test.
		2. Negative: No evidence of ischemia (i.e., no typical angina pain and no ST shifts).
		3. Equivocal:
		a. Typical ischemic pain but no ST shift > or = 1 mm (0.1 mV) (horizontal or
		downsloping) or b. ST shift of 1 mm (0.1 mV) (horizontal or downsloping) but no ischemic
		discomfort
		Also, be sure to note any presence of a fixed defect on imaging study (indicating a
		probable area of previous myocardial infarction). Note that `fixed perfusion defects
		on radionuclide imaging may also be due to diaphragmatic or breast attenuation.
	Ejection fraction (EF)	The first EF obtained during hospital stay. It is the percent of blood emptied from
		the ventricle at the end of contraction and can be obtained, in preferred order, from
		a left ventriculogram, radionuclide ventriculography, or echocardiogram. If only a
		range is estimated for EF, note the midpoint of the range. Note type of test used for
		EF: contrast ventriculography, radionuclide ventriculography, echocardiography.
		Note also whether it was estimated or calculated.
	Cardiac catheterization	Diagnostic cardiac catheterization/angiography performed during the hospital stay.
		Date should be noted. Note percentage occlusion, from 0 to 100%, associated with
		the identified vessel systems. In instances where multiple lesions are present,
		enter the highest percentage stenosis noted. The systems of interest are as follows
		and should include major branch vessels of > 2 mm diameter: LAD or any major
		branch vessel, LCx or any major branch vessel, RCA or any major branch vessel,
		left main, bypass grafts.

Footnote	Other special studies	Auto-antibodies for myocardium Special studies on biopsy
8		
9	Normal tests but persistent symptoms	If symptoms persist > 3 months, consider further evaluation with specialty referrals, VHC referral.
10	Therapeutic options:  A: Mild to moderate – Chest pain with no LV dysfunction, +/- positive biomarkers	4 to 6 weeks limited exertion Aspirin or non-steroidal anti-inflammatory therapy such as ibuprofen (NSAIDS)
	B: Severe – Persistent symptoms, abnormal LV function, evidence of inflammation	As above for mild to moderate plus: Conventional heart failure treatments (e.g., ACE inhibitors, nitrates, diuretics, select beta-blockers such as carvedilol or metoprolol succinate) Consider corticosteroids if no evidence of active vaccinia/viral infection on endomyocardial biopsy. Vaccinia Immune Globulin (VIG) only if evidence of active vaccinia infection.