DoD Clinical Guidelines for Post-Vaccination Associated Myopericarditis
DHA Immunization Healthcare Division

Vaccine(s) administered within past 30 days

Clinical symptoms: Chest pain without an alternative explanation, and/or shortness of breath, palpitations, syncope, cough, or suspected cardiopulmonary symptom(s)

Initial Evaluation

History: Characterize Symptoms
Past medical history
- Include detailed vaccination history
Risk factors for cardiac symptoms

Physical Examination

Laboratory (Troponin I/T, BNP/NT-proBNP, ESR, CRP, CK-MB, Viral surveillance) Diagnostics (CXR (PA/Lat) and EKG. Echocardiogram may require Pediatric Cardiology consultation for children), imaging studies (Cardiac MRI with t 1/2 mapping with contrast), and other testing as clinically indicated (see Footnote 6)

A. Symptoms only

A. Cardiology Consultation
- Document normal ECG, Troponin I/T, CK, CRP, other studies as indicated during acute symptoms
- Consider non-cardiac etiologies
Therapeutic options: NSAIDs, Colchicine (See Footnote 8)
Management & Recovery
- Activity based on exercise tolerance and clinical assessment
- Clinical F/U when asymptomatic with ECG, echocardiogram, and exercise stress test in adults to clear for return to unrestricted activity/full duty
- For ongoing or persistent symptoms, refer to cardiology (stress test not recommended)

B. Symptoms + objective abnormality

B. Cardiology Consultation
- Differential includes myopericarditis, acute coronary syndrome, and other cardiac etiologies
Special labs and diagnostics as indicated

B1. Symptoms with objective ECG abnormality but without positive cardiac enzymes or LV dysfunction

Therapeutic options: NSAIDs, Colchicine (See Footnote 8)
Management & Recovery
- No strenuous activity for 6 wks or until asymptomatic
- F/U when asymptomatic with ECG, echocardiogram, exercise stress test in adults as appropriate to clear for return to unrestricted activity/full duty; repeat any initial abnormal studies
- For ongoing or persistent symptoms, refer to cardiology (stress test not recommended)

B2. Symptoms with positive cardiac enzymes, depressed LV function, and/or imaging c/w myocarditis

Therapeutic options: NSAIDs based upon EF (See Footnote 8)
Management & Recovery
- No strenuous activity for 6 weeks
- 6 week clinical F/U visit, ECG, echocardiogram, exercise stress test in adults as clinically indicated; repeat abnormal studies (including cardiac enzymes). If normalized, may advance activity as tolerated.
- Deployment restriction for a minimum of 3 months
- Cardiology F/U at 3-6 months w/ consideration of repeat cMRI

B3. Includes B2 and any of the following: LVEF < 40%, sustained dysrhythmias, and/or hemodynamic instability

Therapeutic options & Management: see Footnotes 8 & 9

- Early Transfer to Tertiary Care Center - consider myocardial Biopsy
- No strenuous activity for 6 weeks
- Close clinical F/U as directed by cardiologists (echocardiogram, ECG, exercise stress test in adults)
- Activity as tolerated & deployment restriction for 3 to 6 months or longer as guided by clinical progress
- Cardiology F/U at 3-6 months for repeat evaluation (reassess deployability) w/ consideration of repeat cMRI

Refer post-immunization cases to IHD for clinical case review. Post-vaccinia cases will be assessed for entry into DoD Smallpox Vaccine Myopericarditis Registry and natural history surveillance study. With referral include: Patient and provider contact information, test results, and copies of pertinent records. Call the Immunization Healthcare Support Center at 877-438-8222 (DSN: 761-4245), and select Option 1 to request IHD and/or military Cardiology Consultation.
FOOTNOTES: The following guidance is for reference. Not every suggestion will be applicable to every patient. Recommendations are to be applied as diagnostic and therapeutic needs or questions arise and should be in conjunction with HHD staff consultation.

| Footnote | Characterize symptoms, including chest pain type | Specify symptom location, character, onset, duration, intensity/severity, frequency, accompanying/associated symptoms, and alleviating/aggravating factors. All associated clinical symptoms should be detailed. Categorize patient’s chest pain type if present (choose one):

1. Pericarditis chest pain: Chest pain that is typical and made worse by supine position, improved with leaning forward, pleuritic, constant
   a. Detailed history is critical to case definition of pericarditis – see case definitions, page 8
3. Atypical chest pain: Pain, pressure, or discomfort in the chest, neck, or arms not clearly exceptional or not otherwise consistent with pain or discomfort of myocardial ischemic origin.

Myocarditis in children (< 12 yrs of age) shares features with that in adults. However, they may also present with irritability, vomiting, poor feeding, tachypnea, leathargy, ventricular arrhythmias, heart block, and other heart failure symptoms.

References:
1. Table 1, Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021 MMWR: Morbidity and Mortality Weekly Report 2021;70(27);977–982.

| Footnote | Assess past medical history | Detailed review of all systems, with attention to the following disorders:

- Lung disease
- Gastrointestinal disease
- Vascular disease (e.g., stroke, transient ischemic attack, peripheral arterial disease)
- Musculoskeletal disorders (e.g., impingement syndrome, thoracic outlet syndrome)
- Vaccination history and adverse events (with specific lot number, if available)

Reference: PMH study guide https://meded.ucsd.edu/clinicalmed/introduction.htm

| Footnote | Risk Factors for Cardiac Symptoms | Personal History of angina, myocardial infarction (MI), congestive heart failure (CHF), percutaneous coronary intervention (e.g., balloon angioplasty, stent, atherecetomy), coronary artery bypass graft (CABG), catheterization with stenosis ≥ 50%.
- Age, sex, race/ethnicity (ethnicity: Hispanic or Latino, Not Hispanic or Latino; Race: American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, Black or African American, White))
- Diabetes, hypertension, smoking, dyslipidemia, family history of CAD (especially prior to age 55), obesity, physical inactivity, stress, and excessive alcohol consumption.

Reference: https://www.cdc.gov/heartdisease/risk_factors.htm

| Footnote | Physical Examination | Perform a focused PE to include: gender and race/ethnicity, vital signs, ht, wt, detailed exam to include vaccination site, cardiac (jugular venous pressure if able), pulmonary, peripheral edema and lymphadenopathy.

Reference: http://meded.ucsd.edu/clinicalmed/introduction.htm

| Footnote | Laboratory studies | Report normal range as defined by individual hospital laboratory standards. Record units and normal range for laboratory.

Laboratory studies: All patients

| Laboratory studies | Complete blood count | CBC at presentation, to include differential, with emphasis on eosinophil and lymphocyte count should be noted.
| Laboratory studies | Cardiac enzymes | All CK-MB, troponin I/T (TnT) or high sensitivity troponin I/T values should be noted. For troponin T values, document 99th percentile cut-off for testing system used as well as name of testing system if available. For hs TnT, follow institutional hs TnT interpretation guidelines. hs TnT is the most accurate method for determining myocardial involvement (pericarditis vs epicarditis).
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<tr>
<th><strong>Inflammatory markers</strong></th>
<th>All erythrocyte sedimentation rate and C-reactive protein (CRP) (ultrasensitive, if available) values should be noted.</th>
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<tr>
<td><strong>Laboratory studies as clinically indicated:</strong></td>
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<td><strong>Immune complex screening</strong></td>
<td>All Complement related assay studies (including C3, C4, CH50, C1q &amp; C3D-binding assays) with values should be noted.</td>
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<td><strong>Brain natriuretic peptide</strong></td>
<td>Consider BNP if dyspnea is present. BNP or NT-proBNP are indicated for the evaluation of suspected heart failure or dyspnea of unknown cause. Higher-than-normal results suggest that you have some degree of heart failure, and the level of BNP or NT-proBNP in the blood may be related to its severity.</td>
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<td><strong>Viral surveillance</strong></td>
<td><strong>Vaccine-related myopericarditis is a diagnosis of exclusion.</strong> No smallpox or other live vaccine-related cases have exhibited an infectious etiology to date. When considering other etiologies, viral surveillance, including a history of recent SARS-CoV-2 infection, is prudent.</td>
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<td><strong>Other Cultures</strong></td>
<td>Consider ID consultation; all viral cultures (nasal wash, urine, feces) for COVID-19, adenovirus, influenza viruses, parvovirus B19 or enteroviruses should be noted.</td>
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<td><strong>Autoimmunity screening</strong></td>
<td>Note all ANA, Anti-DS DNA, ENA, and similar values during the evaluation. Consider additional special studies such as myocardial auto-antibodies. <strong>Consult Immunization Healthcare Division at 877-438-8222 (DSN: 761-4245), Option 1, for current information.</strong></td>
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<tr>
<td>Diagnostics</td>
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| **Electrocardiogram (ECG)** | Note date, time, rate, rhythm, the presence of ectopy and abnormalities in waves, intervals and segments. Provide copies of relevant ECGs to patient and incorporate in record. **Typical ECG manifestations:** **Pericarditis:**  
Acute  
1. Diffuse ST segment elevation, particularly leads I, II, III, aVF, aVL, and V5-V6  
2. Diffuse PR segment depression  
3. PR segment elevation in lead aVR  
Evolving  
1. T-wave changes: notched, biphasic, or low-voltage inversions. Differentiate from benign Early Repolarization  
1. Widespread concave ST elevation, most prominent in the mid- to left precordial leads (V2-5). ST elevation is usually < 2mm in precordial leads and < 0.5mm in the limb leads  
2. Notching or slurring at the J-point  
3. No reciprocal ST depression (except in aVR).  
4. ST changes stable over time (no progression on serial ECG tracings)  
**Myocarditis:**  
1. Diffuse T-wave inversions without ST segment abnormality  
2. Incomplete atrioventricular conduction blocks (usually transient)  
3. Intraventricular conduction blocks (usually transient)  
4. QRS / QT prolongation  
5. Sinus tachycardia  
6. Ventricular arrhythmias  
* With inflammation of the adjacent pericardium, ECG features of pericarditis (ST segment abnormalities) can also be seen.  
**References:**  
<p>| Chest X-ray | PA and Lateral |</p>
<table>
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<tr>
<th>Other diagnostics as clinically indicated:</th>
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<td><strong>Echocardiogram</strong></td>
<td>Echocardiography can be an important imaging modality for the evaluation of cardiac structure and function in patients suspected of myocarditis. Echocardiography reliably demonstrates the variable findings associated with myocarditis, including the following:</td>
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<td>- Subtle to profound changes in global left ventricular systolic function (LVEF), right ventricular function, and regional wall motion abnormalities</td>
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<td>- Variable degrees of LV enlargement</td>
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<td>- Thickened myocardium from wall edema</td>
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<td>- Pericardial effusion</td>
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<td></td>
<td>- Intracardiac thrombus</td>
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<td>- Functional valvar regurgitation</td>
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<td>Because an echocardiogram done in a child should also assess for congenital anomalies involving views different from the standard adult echo, pediatric echo-sonographers possess specific imaging skills. Pediatric echo-sonographers are therefore often embedded in a pediatric cardiology clinic/service. For this reason, in some institutions, a consultation with the Pediatric Cardiology Service may be required. Additionally, as the safety of NSAID use in adult myocarditis may be related to the degree of myocardial compromise (see Footnote 8), an initial echocardiogram is also recommended. If only a range is estimated for ejection fraction (LVEF), note the midpoint of the range. For pericardial effusions, record estimate of size and/or clinical significance (small effusions may not be diagnostic). Before returning to duty, Service Members who initially present with an acute clinical syndrome consistent with myocarditis should undergo a resting echocardiogram no less than 3 to 6 months after the initial illness.</td>
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<td><strong>Imaging</strong></td>
<td>Chest pain with elevated cardiac enzymes (TnT) may be caused by a variety of conditions including NSTEMI, myocarditis, Takotsubo cardiomyopathy, PE, renal disease, vigorous exercise, nonspecific cardiac demand from acute illness, as well as a false + TnT. If there is question as to the etiology of the individual’s symptoms, Cardiac MRI (CMR) with t1/t2 mapping is the test of choice. It possesses minimal risk and most accurately classifies the diagnosis and prognosis. Therefore, if logistically feasible at patient presentation, or at least within 2-4 weeks of symptom onset, CMR is recommended. If abnormal, then repeat at 6 week evaluation. If abnormal initially and at 6 week evaluation or if patient continues to be symptomatic, perform CMR at 3-6 months to assess for clearance for return to duty and deployment. See Footnote #9.</td>
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<td><strong>Pulmonary functions</strong></td>
<td>With DLCO if indicated; diffusion capacity corrected for hemoglobin is a sensitive measure of pulmonary interstitial disease and increased risk for hypoxia with activity.</td>
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<td><strong>Stress test</strong></td>
<td>Indicate whether an exercise tolerance, stress-echocardiogram, or nuclear/pharmacological stress test was performed during the hospital stay and the result of the testing, if performed. Clinical correlation is recommended in the cases of a negative stress test result. Before returning to duty, Service Members who initially present with an acute clinical syndrome consistent with myocarditis should undergo an exercise ECG no less than 3 to 6 months after the initial illness.</td>
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<td><strong>Cardiac catheterization/CTA</strong></td>
<td>Not routinely recommended, but may be considered in select cases where there exists a realistic question of acute coronary syndrome clinically and the troponin elevation and ECG ST-elevations and other clinical indications suggest an infarct pattern. If vessel occlusion is identified, note the anatomical region affected and the degree of stenosis present.</td>
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| **Holter & Event Monitor** | Before returning to duty, Service Members who initially present with an acute clinical syndrome consistent with myocarditis should undergo a 24-hour Holter monitoring no less than 3 to 6 months after the initial illness.  
| **Myocardial Biopsy** | Consider myocardial biopsy if heart failure is severe or worsening.  
| **Differential Diagnosis** | Consider viral myocarditis, acute coronary syndrome (myocardial infarction), NSTEMI, Takotsubo cardiomyopathy, aortic dissection, pneumothorax, pulmonary embolism, musculoskeletal pain, esophageal disorder (gastroesophageal reflux, esophageal spasm), systemic autoimmune disease. |
| **Therapeutic options** | Consult Immunization Healthcare Division at 877-438-8222 (DSN: 761-4245), Option 1, for current information.  
**Symptoms only (A) OR symptoms with objective findings, but with negative cardiac enzymes and no LV dysfunction (B1)**  
Non-steroidal anti-inflammatory agents are recommended (when non-cardiac etiologies are ruled out in category A). Colchicine, used with an NSAID, may reduce the risk of recurrence of pericarditis.  
**References:**  
**Symptoms w/ positive cardiac enzymes or depressed LV function or imaging c/w myocarditis (B2)**  
As Non-steroidal anti-inflammatory drugs (NSAIDs) may cause sodium and water retention, worsening heart failure, it is recommended that NSAID not be used if cardiac Ejection Fraction is < 40%. Clinical judgement regarding NSAID risks and benefits should be used for EFs between 40% and 49%. NSAIDs are safe and do provide significant symptomatic relief in uncomplicated pericarditis and may be protective, reducing myocardial damage in patients with myopericarditis and preserved LVEF (EF ≥ 50%). Other treatments to be considered in consultation with Cardiology and the IHD to include corticosteroid treatment (after biopsy if possible). Consider biopsy for viral PCR, culture and assessment of inflammation, and other histopathologic forms of deteriorating myocarditis. Consider corticosteroids with evidence of eosinophilic inflammation & clinical deterioration.  
**Reference:**  
**Progressive symptoms (LVEF < 40%, sustained dysrhythmias, hemodynamic instability) (B3)**  
- Conventional heart failure treatments (e.g., ACE inhibitors, nitrates, diuretics, select beta-blockers such as carvedilol or metoprolol succinate)  
- Strongly consider early referral for myocardial biopsy to guide optimal treatment.  
- Consider corticosteroids (preferably after biopsy) if no evidence of active infection and/or with evidence of eosinophilia in inflammatory infiltrate.  
- Consider Vaccinia Immune Globulin (VIG)/IVIG only with expert consultant case review via Immunization Healthcare Division.  
**Management and Recovery** | Whenever possible, standardized follow up should be coordinated with the Immunization Healthcare Division at 877-438-8222 (DSN 761-4245), Option 1.  
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<tr>
<th>Symptoms only (A) OR Symptoms with objective findings, but without positive cardiac enzymes or LV dysfunction (B1)</th>
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<tr>
<td>• Light physical activity at own pace until asymptomatic (A)</td>
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<tr>
<td>• No strenuous activity until asymptomatic (B1)</td>
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<tr>
<td>• Follow up when asymptomatic or in 4 weeks (A) to 6 weeks (B1)</td>
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<td><strong>Asymptomatic at follow-up</strong></td>
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<tr>
<td>• Repeat any previously abnormal studies</td>
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<tr>
<td>• Long-term follow-up will be completed by Immunization Healthcare Division</td>
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<tr>
<td><strong>Symptomatic and/or persistent/abnormal findings at follow-up</strong></td>
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<tr>
<td>• Repeat any previously abnormal studies</td>
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<tr>
<td>• Clinical evaluation to include stress test in adults (unless contraindicated)</td>
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<tr>
<td>• Repeat CMR if had previous enhancements or if symptomatic. Repeat at 12-18 months as indicated</td>
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<tr>
<td>• Consult cardiology for further recommendations</td>
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<tr>
<td>• Long-term follow-up will be completed by Immunization Healthcare Division</td>
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<tr>
<th>Symptoms with positive cardiac enzymes or mild depressed LV function or imaging c/w myocarditis (B2) OR Progressive symptoms (LVEF &lt; 40%, sustained dysrhythmias, hemodynamic instability) (B3)</th>
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<tr>
<td>• No strenuous activity for 6 weeks</td>
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<tr>
<td>• Clinical evaluation at 6 weeks</td>
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<tr>
<td>• Deployment restriction for 3-6 months depending upon whether:</td>
</tr>
<tr>
<td><strong>Asymptomatic at follow-up</strong></td>
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<tr>
<td>• Repeat any previously abnormal studies at 6 weeks and 3 months</td>
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<tr>
<td>• Stress test for adults at 6 weeks to assess exercise tolerance for rehabilitation; repeat at 3 months to assess exercise tolerance prior to clearance for deployment</td>
</tr>
<tr>
<td>• Long-term follow-up will be completed by the Immunization Healthcare Division</td>
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<tr>
<td><strong>Symptomatic and/or persistent/abnormal findings at 6 weeks and 3 month follow-up</strong></td>
</tr>
<tr>
<td>• Clinical evaluation to include enzymes (TnI/T or hsTnI/T), CRP, ECG, ECHO, 24 hour Holter Monitor, stress test (unless contraindicated)</td>
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<tr>
<td>• Repeat CMR if had previous enhancements or if symptomatic.</td>
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<tr>
<td>• Repeat clinical evaluation at 3-6 months to include repeat ECHO, stress test, 24 hour Holter monitor and CMR to assess for clearance for deployment.</td>
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<tr>
<td>• If normal and asymptomatic, clear for deployment/return to usual activity</td>
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<tr>
<td>• If normal and symptomatic, consult cardiology</td>
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<tr>
<td>• If abnormal studies with continued symptoms, not cleared for deployment, consult Cardiology</td>
</tr>
<tr>
<td>• Continue cardiology follow-up at 6 -12 month intervals until asymptomatic</td>
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<tr>
<td>• Long-term follow-up will be completed by Immunization Healthcare Division</td>
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**Return to Duty Criteria**

**Category A or B1:**
Service Members (and adult and pediatric beneficiaries) with pericarditis should be on restricted duties (activity), including deployment, during the acute phase. Individuals can return to full duty/activities/deployment status when:
- There is complete absence of evidence for active disease, including effusion by echocardiography,
- When serum markers of inflammation have normalized.

For pericarditis associated with evidence of myocardial involvement, eligibility should also be based on the course of myocarditis (B2 or B3).

**Category B2 or B3:**
Service Members (and adult and pediatric beneficiaries) may return to full duty (unrestricted activity) and be deployment-eligible within 3 to 6 months if all of the following criteria are met:
- Ventricular systolic function has returned to the normal range.
- Serum markers of myocardial injury, inflammation, and heart failure have normalized.
- Clinically relevant arrhythmias such as frequent or complex repetitive forms of ventricular or supraventricular ectopic activity are absent on Holter monitor and graded exercise ECG.

**Footnote 10**

**Disability Assessment**

The majority of patients have recovered within 1 year. The natural history of this condition remains unknown. Careful functional assessment post-acute phase has not yielded definitive objective parameters. The long-term natural history of this condition (e.g., late onset arrhythmias, cardiomyopathy, recurrent myocarditis) has not been well defined. Development of new cardiac complications within 5 years following an episode of hypersensitivity myocarditis associated with immunization should be reported to the Immunization Healthcare Division clinical case management registry.
## Case Definitions for Myocarditis and Pericarditis

**MMWR: Morbidity and Mortality Weekly Report** 2021;70(27);977–982,  
https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm

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<th>Footnote 11</th>
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### Objective abnormalities

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<th>Probable</th>
<th>Confirmed</th>
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</table>
| **Acute Myocarditis** | Presence of $\geq 1$ new or worsening of the following clinical symptoms:*  
• chest pain, pressure, or discomfort  
• dyspnea, shortness of breath, or pain with breathing  
• palpitations  
• syncope  
**OR**, infants and children aged $<12$ years might instead have $\geq 2$ of the following symptoms:  
• irritability  
• vomiting  
• poor feeding  
• tachypnea  
• lethargy  
**AND**  
$\geq 1$ new finding of  
• troponin level above upper limit of normal (any type of troponin)  
• abnormal electrocardiogram (ECG or EKG) or rhythm monitoring findings consistent with myocarditis§  
• abnormal cardiac function or wall motion abnormalities on echocardiogram  
• cMRI findings consistent with myocarditis¶  
**AND**  
• No other identifiable cause of the symptoms and findings | Presence of $\geq 1$ new or worsening of the following clinical symptoms:*  
• chest pain, pressure, or discomfort  
• dyspnea, shortness of breath, or pain w/ breathing  
• palpitations  
• syncope  
**OR**, infants and children aged $<12$ years might instead have $\geq 2$ of the following symptoms:  
• irritability  
• vomiting  
• poor feeding  
• tachypnea  
• lethargy  
**AND**  
$\geq 1$ new finding of  
• Histopathologic confirmation of myocarditis†  
• cMRI findings consistent with myocarditis¶ in the presence of troponin level above upper limit of normal (any type of troponin)  
**AND**  
• No other identifiable cause of the symptoms and findings |
| **Acute Pericarditis** | Presence of $\geq 2$ new or worsening of the following clinical features:  
• acute chest pain††  
• pericardial rub on exam  
• new ST-elevation or PR-depression on EKG  
• new or worsening pericardial effusion on echocardiogram or MRI |  |
| **Myopericarditis** | This term may be used for patients who meet criteria for both myocarditis and pericarditis |  |

**Abbreviations:** AV = atrioventricular; cMRI = cardiac magnetic resonance imaging; ECG or EKG = electrocardiogram.

*Persons who lack the listed symptoms but who meet other criteria may be classified as subclinical myocarditis (probable or confirmed).
§ To meet the ECG or rhythm monitoring criterion, a probable case must include at least one of 1) ST-segment or T-wave abnormalities; 2) Paroxysmal or sustained atrial, supraventricular, or ventricular arrhythmias; or 3) AV nodal conduction delays or intraventricular conduction defects.
¶ Using either the original or the revised Lake Louise criteria. https://www.sciencedirect.com/science/article/pii/S0735109718388430?via%3Dihub
** Using either the original or the revised Lake Louise criteria. https://academic.oup.com/eurheartj/article/36/42/2921/2293375
†† Typically described as pain made worse by lying down, deep inspiration, or cough, and relieved by sitting up or leaning forward, although other types of chest pain might occur.
The Chair of the Myopericarditis Working Group gratefully acknowledges the contributions provided by:
The clinical staff of the Immunization Healthcare Division’s North Atlantic, South Atlantic, Central, and Pacific Region Vaccine Safety Hubs, and the Cardiology consultants from Walter Reed National Military Medical Center, Bethesda, MD, Fort Belvoir Community Hospital, Ft. Belvoir, VA, the Uniformed Services University of the Health Sciences, Bethesda MD, Womack Army Medical Center, Ft. Bragg, NC, and the Mayo Clinic, Jacksonville, FL.

DHA Immunization Healthcare Division
Web: https://health.mil/vaccines
24/7 Immunization Healthcare Support Center
(877-438-8222 or DSN 761-4245), Option 1