Communication to Healthcare Professionals: reports of myocarditis/pericarditis after mRNA COVID-19 vaccination

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Summary

- Cases of myocarditis and pericarditis have been reported very rarely following vaccination with the COVID-19 mRNA vaccines Comirnaty™ (BioNTech/Pfizer) and Spikevax (Moderna).
- The cases to date have primarily occurred within 14 days after vaccination, more often after the second dose and in younger men.
- Available data indicates that cases to date have mostly experienced a mild course of illness which has responded well to conservative treatment.
- Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis and where clinically suspected, should refer individuals to the Emergency Department/Acute Medical Assessment Unit for investigations including ECG and troponin.
- Patients with a confirmed or probable myocarditis should not receive another dose of mRNA vaccine. If they are aged 18 years and over they may be given a non-mRNA vaccine(provided there are no contraindications) 28 days after the first dose.
- Following a diagnosis of confirmed pericarditis, the GP and patient/parent/guardian should liaise with the treating Cardiologist to make a joint decision as to whether the patient can attend for a subsequent dose of mRNA COVID-19 vaccine. This decision will need to be facilitated by easily available updated information on the factors pertinent to this decision provided by the National Immunisation Advisory Committee. This joint decision must occur in a timely manner so as to ensure the patient receives their subsequent dose of the vaccine within the recommended time period.
- Useful links to patient information are contained in the references. The National Immunisation Office (NIO) decision aid may be helpful for communication to parents: https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/prog1215/decisionaid.pdf

Background

Globally, an increased number of cases above an expected population rate of myocarditis and pericarditis have been reported in individuals who have received mRNA COVID-19 vaccines (Comirnaty™/BioNTech/Pfizer and Spikevax/Moderna).[1]

Available information to date indicates:

- Cases have most commonly been reported after the second dose of an mRNA COVID-19 vaccine;
- Symptom onset has most commonly been reported within 14 days of vaccination (range 0 – 40 days);

- Cases have more commonly been reported in young adults and adolescents, but less frequently in those aged 5-11 years old (although data is limited in this age group);[2]

- Cases to date have mostly experienced similar symptoms to the typical course of these illnesses, and have responded well to conservative treatment.[2]

Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the lining outside the heart. Symptoms can include chest pain, shortness of breath, or palpitations.

Diagnosis of pericarditis and/or myocarditis

Healthcare professionals should consider myocarditis and pericarditis in any individual who presents with new onset of shortness of breath, palpitations and (acute and persisting) chest pain and who has recently received a dose of an mRNA COVID-19 vaccination.[2] See Figure 1 for the diagnostic pathway.

Where there is clinical suspicion of pericarditis and/or myocarditis, individuals should be referred to the appropriate Emergency Department (ED) /Acute Medical Assessment Unit (AMAU) for an ECG and troponin blood test.

If the ECG and troponin investigations are within normal parameters, and a clinical diagnosis of pericarditis/myocarditis is not suspected, the individual may be discharged back to the care of their GP. The patient can proceed with the COVID-19 vaccine regime as normal.

If the ECG and/or troponin investigations return results outside of normal parameters, or there is a clinical suspicion of pericarditis/myocarditis, the treating physician (in ED or AMAU) should consult with a Cardiologist.

All cases of pericarditis and/or myocarditis should be managed in line with clinical hospital guidelines, under the advice of Cardiology.

Following treatment for a confirmed case of pericarditis and/or myocarditis:

- It is important that written communication is provided to the patient/parent/guardian and their GP with regard to the diagnosis of pericarditis and/or myocarditis by the discharging team.
- Patients/parents/guardians should be directed to the appropriate patient information so that they can make a decision about pursuing follow-up options for COVID-19 vaccination.[5-9]
- The individual can be discharged to the care of their GP when clinically appropriate.

Decision on the administration of second mRNA COVID-19 vaccines following a diagnosis of pericarditis and/or myocarditis

It is important to note that mRNA COVID-19 vaccinations are contraindicated where an individual has been diagnosed with myocarditis following vaccination with an mRNA COVID-19 vaccine.[2] Consideration may be given to the use of a non-mRNA vaccine for subsequent doses for anyone 18 and older,

including pregnant women. This should be given after an interval of at least 28 days and the person should then be considered fully vaccinated. A non-mRNA vaccine can also be considered for booster doses as per NIAC guidance.[2]

With regard to vaccination following a confirmed case of pericarditis, a timely joint decision between the treating Cardiologist, GP and patient/parent/guardian with regard to the appropriateness of subsequent mRNA COVID-19 vaccination administration should be made, where deemed clinically appropriate.[2] This timely decision will be facilitated by the ready availability of up to date information on the factors pertinent to this decision by the National Immunisation Advisory Committee, as the situation evolves.

The understanding of COVID-19 vaccination is constantly evolving as we continue to assimilate vast amounts of data and findings into clinical practice. An individual risk benefit analysis for each patient following a diagnosis of pericarditis must be undertaken on a case-by-case basis, taking into account the most up to date guidance from the National Immunisation Advisory Committee, the preference of the patient and their parent/guardian (where appropriate) and their risk factors for serious sequelae associated with COVID-19 infection. Factors that could influence the decision to continue with the subsequent dose of COVID-19 mRNA vaccine include: [3,4,12]

- Age
- Occupation
- The presence of co-morbidities or risk factors for severe COVID-19 illness (occupation and those at high or very high risk of COVID-19 due to co-morbidities)
- Laboratory-confirmed infection with SARS-CoV-2 in the previous nine months
- The severity of the pericarditis
- The views of the patient and their family.

Individuals aged 16 years and above, who have capacity, have the right to make the decision about whether they consent to receiving subsequent vaccines. Such individuals should be involved in the joint decision-making process and supported to make an informed decision by their parents/guardians and healthcare professionals.[10]

In the case of 12-15 year olds, a parent or guardian will need to be involved in the joint decision-making process as to whether their child can receive a subsequent dose of the vaccine. It is recommended that assent from the child to receive a subsequent vaccination, or otherwise, is also sought and that the child is supported to participate in this decision-making process.[11]

Any use of non-mRNA vaccines in those under 18 years of age are currently off-label and not recommended by NIAC.[12,13]

References

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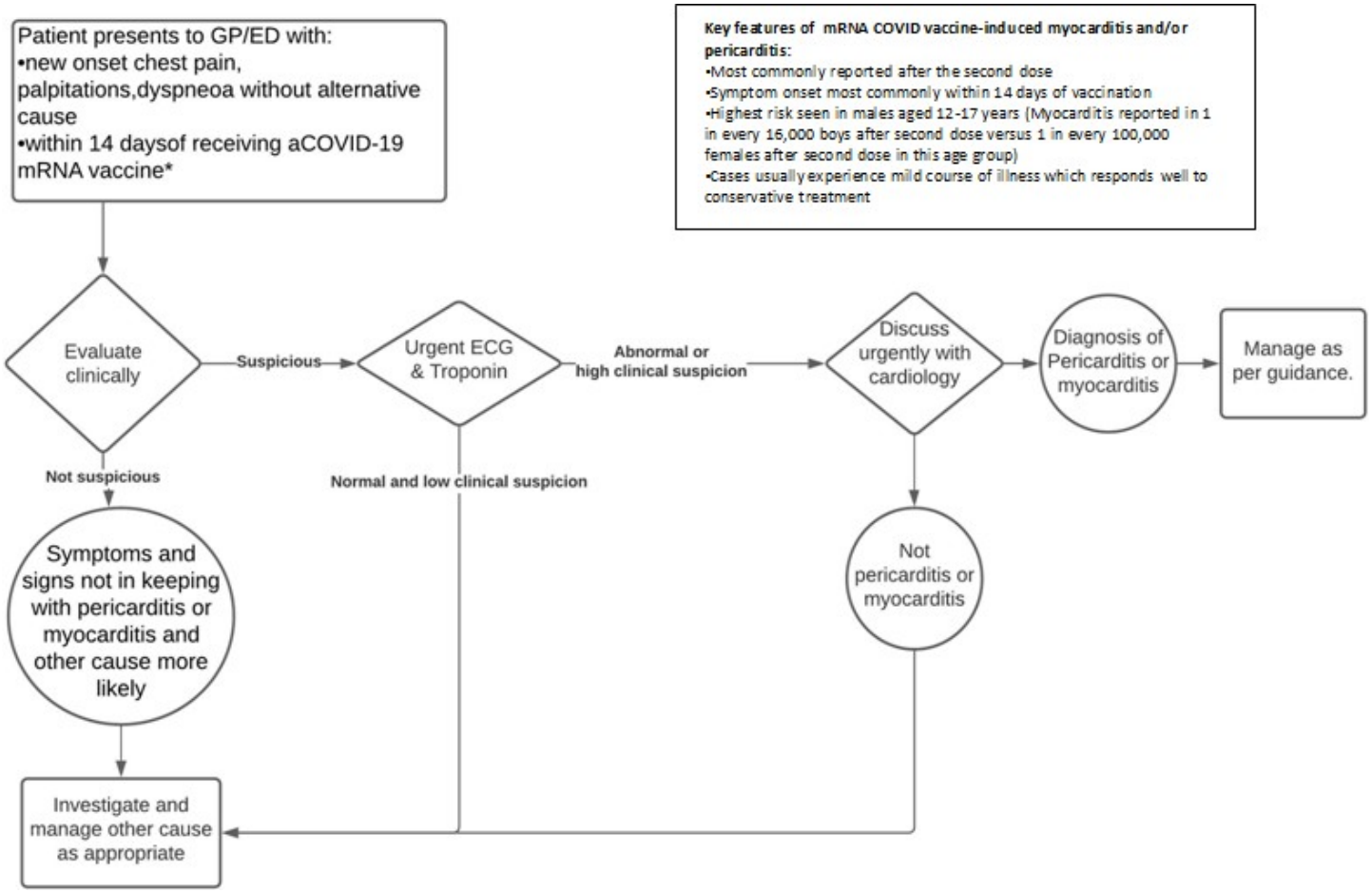
Figure 1. Diagnostic pathway for clinically suspected pericarditis and/or myocarditis post mRNA vaccinations



*Evidence to date indicates a range of 0-40 days for presentation with pericarditis/myocarditis post- mRNA vaccination. However, the EMA have concluded that the vast majority of cases to date have presented within 14 days of vaccination