Recommended elements to include in an Acute Myocardial Infarction Event Case Report Form in trials including people receiving haemodialysis

A case report form is the tool used by clinical trialists to collect data from each participating patient. The case report form should be completed by the trial site. It enables efficient and complete data collection and together with appropriate source documents, allows for improved adjudication by a clinical events committee.

<table>
<tr><th>Recommended elements</th><th>Details to include</th></tr>
<tr><td>General event information</td><td>

Suspected/confirmed myocardial infarction
Date of event
Time of event
Was the event the primary reason for hospitalisation?
Was the event the primary cause of death? (separate CRF recommended for fatal events)

</td></tr>
<tr><td>Clinical presentation</td><td>Symptoms suspicious of acute myocardial ischemia including:

Chest pain/discomfort
Sweating
Arm/throat/neck/jaw pain or discomfort
Shortness of breath
Non-specific pain, discomfort or nausea, over and above or different to, usual background pain, discomfort or nausea.

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<tr><td>ECG</td><td>When available, ECGs should be provided, clearly labelled with date and time. Ideal timepoints might include as many of the following as possible:

ECG obtained at entry to study
ECG prior to event but at a time when patient was stable and asymptomatic
ECG at time of symptom presentation
Serial ECGs subsequent to initial presentation ECG
ECG post event when patient is stable

</td></tr>
<tr><td>Cardiac enzyme/markers</td><td>
<table>
<tr><th></th><th>Date</th><th>Time</th><th>Cardiac enzyme</th><th>Local lab URL</th><th>Result</th><th>Unit</th></tr>
<tr><td>Initial (at presentation with symptoms)</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Peak</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>*Subsequent 1</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>**Subsequent 2</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>**Subsequent 3</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="7">*If the initial cardiac enzyme result is above the sex specific 99th percentile URL and the delta from the initial result to the peak result is >20% then subsequent results are not required
** Any dynamic change in cTn or strong clinical suspicion should prompt further cTn samples so as not to miss a significant delta, eg at 2 hrs, 4hrs and 6hrs.</td></tr>
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<tr><td>Imaging evidence</td><td>

Is there Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality in a pattern consistent with an ischemic etiology?

</td></tr>
</table>

	• Modality of imaging • Date of imaging • Time of imaging
Identification/exclusion of coronary thrombus	• Yes/No • Procedure performed to identify a coronary occlusion thrombus • Date of procedure • Time of procedure
Recommended source documents	1. Admission summary 2. Discharge summary 3. ECGs as described above 4. Imaging reports 5. Angiography/PCI/CABG reports