



Sheer Heart Attack:

Why the Myocardial Infarction definition is
Critically flawed

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Current Heart Attack definition

ABI – Model Wording 2006 to date

Heart attack – *of specified severity*

Death of heart muscle, due to inadequate blood supply, that has resulted in all of the following evidence of acute myocardial infarction:

- Typical clinical symptoms (for example, characteristic chest pain).
- New characteristic electrocardiographic changes.
- The characteristic rise of cardiac enzymes *or* Troponins recorded at the following levels or higher;
 - Troponin T > 1.0 ng/ml
 - AccuTnI > 0.5 ng/ml or equivalent threshold with other Troponin I methods.

The evidence must show a definite acute myocardial infarction.

For the above definition, the following are not covered:

- Other acute coronary syndromes including but not limited to angina.

How effective is Troponin as a measurement of 'severity' in the context of the Myocardial Infarction definition?

- Emerging data clearly shows a definite correlation between the Troponin level and medical prognosis, even at very low levels....
- In a '**medical context**', Troponin is of significant value for diagnosis differentiation and patient risk assessment....

BUT, in an '**Insurance context**'

Troponin levels do not provide an effective measurement of “severity” for assessing MI critical illness claims because.....

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Troponin does not provide a very effective measurement of “severity” for MI claims because.....

- Claimants are exposed to significant variations in medical practice that are outside of their control, but may impact on the validity of their claim

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Troponin does not provide a very effective measurement of “severity” for MI claims because.....

- Claimants are exposed to significant variations in medical practice that are outside of their control; but may impact on the validity of their claim
- Those presenting with a likely STEMI where there is no Troponin reading may not be paid – Whereas, those with NSTEMI will more likely have a Troponin reading and be paid

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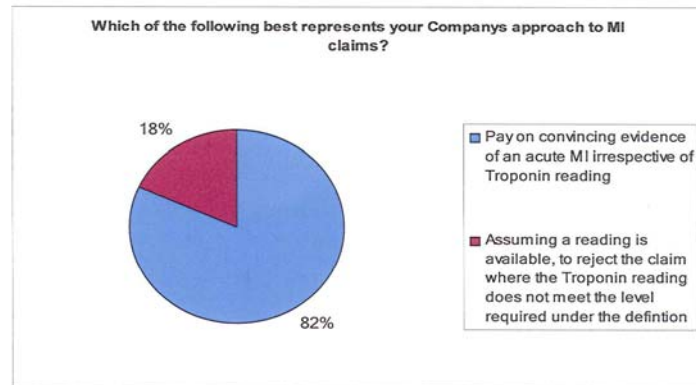
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Myocardial Infarction - Insurer's attitude to a "severity test"?



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- Those presenting with a likely STEMI where there is no Troponin reading may not be paid – whereas those with NSTEMI will more likely have a Troponin reading and be paid
- This inconsistency places pressure on insurers to pay claims that fail the contractual definition
- There is clear inconsistency with the Cardiomyopathy definition – Troponin is often elevated in cardiomyopathy but we don't use it for severity

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Troponin does not provide a very effective measurement of “severity” for MI claims because.....

- Troponin is more of a ‘diagnostic’ and ‘risk assessment’ tool rather than a severity indicator
- We don’t always receive the Troponin levels or know if they are ‘peak’ readings
- Relative to the insured’s overall situation, high value MI claims appear to generate ‘windfall’ payments
- As far as the claimant is concerned, they have had a heart attack

More problems in the future?

Future problems?

- Will a Troponin test always be performed - Changes to the clinical pathway
- Clinical STEMI presentation based on ECG = urgent surgical revascularisation or thrombolysis?
- Impact on Troponin level of thrombolysis or immediate surgical revascularisation? What level would it have reached without intervention?

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Future problems?

- Increasing development of hypersensitive assays will lead to increasing incidence of MI diagnosis – i.e. conversion of ACS (non-MI) to NSTEMI
- Results of March 2012 study – N L Mills. BHF/University Centre for Cardiovascular Science, University of Edinburgh
<http://www.bmj.com/content/344/bmj.e1533>

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Study findings

- 2092 suspected ACS patients
- Split into 3 groups based on Troponin I level of:

GROUP A	GROUP B	GROUP C
<0.012 ug/L (47%)	0.012ug/L – 0.049ugl (17%)	>0.050ug/L (36%)
- Against diagnostic threshold for this assay* of 0.050ug/L
- Lowering the diagnostic threshold = Increased diagnosis of MI from 752 to 1104 – a relative increase of 47% (42,000 patients per annum in the UK)
- Follow-up average 446 days – patients in GROUP B had a death or re-infarction rate 4 x higher than GROUP A patients

*Abbott ARCHITECT Troponin I assay

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Future problems?

- Rapid development of biochemical markers for diagnosing MI with a lack of standardisation – hard/impossible to create a sustainable fixed definition using Troponin values?
- Currently there are 24 commercially available Troponin assays (International Federation of Clinical Chemistry)
- Heart Fatty Acid binding Protein (H-FABP) – (in conjunction with Troponin)
- Myoglobin - (Rapid – but less cardiospecific)
- B-type natriuretic peptide (BNP) – (High value prognostic indicator)

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Future problems?

If the diagnosis incidence of MI increases, depending on the Troponin level and type of severity test used in the definition we will;

- Have to significantly increase product cost to pay additional claims

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- Have to significantly increase product cost to pay additional claims
- Potentially expose any 'back book' of business written on the definition to significant risk of claims that were not priced for
- Risk increasing the proportion of declined claims for definition failure
- Risk an increase in commercial payments for definition failure that are not priced for

Myocardial Infarction (CI) definitions around the world

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Myocardial Infarction definitions around the world

- **South Africa** – Standardised wording / Tiered approach (25% -100%) / Severity based around EF / LVEDD / NYHA
Troponin to confirm diagnosis
- **Canada** – Definite diagnosis only / No tiering / No standard wording.
Troponin to confirm diagnosis (no levels included in wording)
- **Australia** – Definite diagnosis only / No standard wording / No tiering / EF used as qualifier if other criteria not met
Troponin to confirm diagnosis (Trop I >2.0ug/L or Trop T > 0.60ug/L)
- **Asia** – Mostly standardised wording / No tiering (in development) / Mostly severity based around EF
Troponin to confirm diagnosis

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Global differences

- South Africa, Asia, UK severity test – rest, definite diagnosis only
- Where severity test applied; based on reduced ejection fraction or other indicator of significant myocardial damage or impaired function (chamber size) or physical symptoms (NYHA)
- Use of Troponin in the definition is widespread – BUT mostly to confirm diagnosis and levels can differ from UK
- For tiered cover (South Africa) Troponins are a factor in determining severity (lower = less) at 25% / 50% payment level
- In Australia the thresholds vary from the UK ranges;
UK = Troponin T >1.00 ng/ml / Troponin I >0.50 ng/ml
Aus = Troponin T >0.60 ng/ml / Troponin I >2.00 ng/ml

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Time for a new approach?

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New approach?

- ABI workgroup creating a new definition
- Retain a severity approach? – but in a different form?
- Further details due soon.....

New approach?

100% Payment

Heart attack – *of specified severity*

A definite diagnosis of acute myocardial infarction resulting in death of heart muscle due to inadequate blood supply which is evidenced by all of the following:

- Typical clinical symptoms (for example chest pain)
- The characteristic evolution of new ECG changes
- **Elevation above the diagnostic threshold (for MI) of an appropriately validated cardiac biomarker**

where all of the above are consistent with a definite diagnosis of acute myocardial infarction, **and result in one or more of the following criteria being permanently present despite optimal therapy;**

- **Ejection Fraction of 40% or less**
- **Left Ventricular End diastolic Diameter (LVEDD) of 65mm or more**
- **Symptoms and limitation of physical activity that are consistent with and classified as stage III under the New York Heart Association (NYHA) criteria**

Payment will not be made for:

- *Other inflammatory heart conditions and acute coronary syndromes, including but not limited to unstable angina*
- **Elevation of any cardiac biomarker in the absence of a definite diagnosis of acute myocardial infarction**

50% or 25% Payment

Heart attack

• A definite diagnosis of acute myocardial infarction resulting in death of heart muscle due to inadequate blood supply which is evidenced by all of the following:

- Typical clinical symptoms (for example chest pain)
- The characteristic evolution of new ECG changes
- **Elevation above the diagnostic threshold of an appropriately validated cardiac biomarker**

where all of the above are consistent with a definite diagnosis of acute myocardial infarction.

Payment will not be made for:

Other inflammatory heart conditions and acute coronary syndromes, including but not limited to unstable angina

Elevation of any cardiac biomarker:

- **in the absence of a definite diagnosis of acute myocardial infarction, or**
- **resulting from the undergoing of a surgical procedure**

Benefits of this new approach?

- Severity test – BUT, based around evidence of impaired cardiac performance post event (aligned with Cardiomyopathy)
- Ejection Fraction set quite low at 40%
 - Allow for possible improvement after optimal therapy
 - Avoid (90 days+) delay in assessing/paying claim
- Pay **ALL** claims for a definite diagnosis of MI
- Pay reduced benefit as 'accelerated' – remaining 50% or 75% paid on re-infarction or other covered CI condition
- Likely reduction in overall claims cost for MI – fewer claims paid at 100% value
- Re-introduce a more appropriate 'criticality' element

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Introducing a two tier criteria could...

- Mean that in future, **ALL** definite MI claims would be paid
- Mean that, the more severe MI cases receive a full payment
- Mean that, cases of a less severe MI would still receive a significant level of payment
- Reduce the pressure on life offices to pay commercial claims
- Provide some 'future proofing' for claims costs against increasing MI diagnosis incidence

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In conclusion

- Persisting with Troponin as a sole test of severity in the Heart Attack definition is Critically flawed
- Introducing a two-tier approach that means that **all** claims are paid is a step forwards
- Revising the definition to include a more tangible test of severity will be more equitable, achieve greater consistency, align with other conditions and provide a significant level of price future proofing

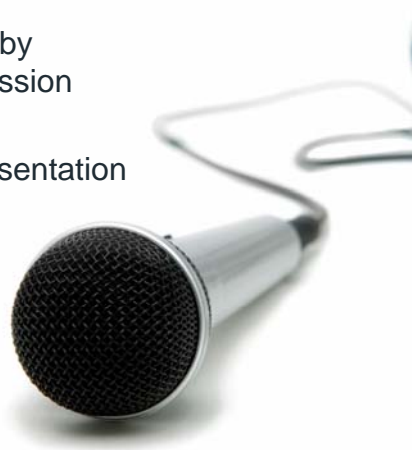
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Questions or comments?

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