CARDIAC CHEST PAIN GUIDELINES FOR BIOCHEMICAL INVESTIGATION

Version:	2.0
Ratified by:	Clinical Biochemistry Senior Staff Group
Date ratified:	May 2020
Name of originator/author:	Mr Edward Kearney/Dr S Stock
Director responsible for implementation:	Dr E Lamb
Date issued:	May 2020
Review date:	May 2022
Target audience:	Clinical staff (medical, nursing and scientific), Trust wide and primary care

Version Control Schedule

Version	Date	Author	Status	Comment
1.0	1st Oct 2015	Edward Kearney	Archived	This replaces the previous policy BIO NO 004 Version 2.2
2.0	May 2020	Dr S Stock		This replaces version 1.0. If cTnI is undetectable on admission **AND** onset of chest pain occurred >1 h previously, then MI can effectively be excluded and patients considered for early discharge

WARNING: This is a controlled document

Contents

1 Policy Summary

This policy gives guidance on biochemical investigation of cardiac chest pain.

2 Introduction

In East Kent diagnostic testing for acute coronary syndrome is available using plasma measurement of the troponin I component of the cardiac contractile apparatus. High sensitive troponin I (hs TnI) is a sensitive and specific marker of cardiac muscle damage and is useful in risk stratification of patients with acute coronary syndromes. In particular, hs TnI is used in establishing the diagnosis of non ST-segment elevation myocardial infarction (NSTEMI).

Clinical classification of myocardial infarction

For the sake of immediate treatment strategies, such as reperfusion therapy, it is usual practice to designate MI in patients with chest discomfort, or other ischaemic symptoms that develop ST elevation in two contiguous leads of an electrocardiogram (ECG) as an 'ST elevation MI' (STEMI). In contrast, patients without ST elevation at presentation are usually designated as having a 'non-ST elevation MI' (NSTEMI). Many patients with MI develop Q waves (Q wave MI), but others do not (non-Q MI). Patients without elevated biomarker values can be diagnosed as having unstable angina. In addition to these categories, MI is classified into various types, based on pathological, clinical and prognostic differences, along with different treatment strategies.

The purpose of this protocol is to describe the use of the clinical biochemistry diagnostic service in the evaluation of patients with cardiac chest pain. It outlines the appropriate times at which hs TnI should be measured, the patients in whom it should be measured, and the situations in which its measurement is not appropriate. The protocol is informed by national policy documents supporting the use of troponin measurements. These include the National Institute for Health and Care Excellence (NICE) Clinical Guideline 94 "Unstable Angina and NSTEMI", NICE clinical guideline 95 "Chest Pain of Recent Onset", the NICE quality standard 68 "Acute coronary syndromes (including myocardial infarction)" and the NICE diagnostic guidance 15 "Myocardial infarction (acute): Early rule out using high-sensitive troponin tests". Further, the NICE technology appraisal guidance (TA47) states that raised plasma troponin concentrations should be used to identify patients with unstable angina who are at high risk of progression to MI or death.

This protocol should be used in conjunction with the clinical protocols for the management of myocardial infarction (MI) and acute coronary syndromes that have been developed and agreed by the cardiologists. It assumes that all patients with suspected cardiac chest pain have an ECG performed on admission and that the results of this test are used to influence subsequent decision making and test requesting.

WHEN TO MEASURE HIGH SENSITIVE TROPONIN I (SEE ALGORITHM APPENDIX A)

1. High sensitive troponin I should be measured at baseline in patients presenting with a suspected acute coronary syndrome (i.e. unstable angina or non-Q wave MI).
2. If the baseline hs TnI is < 2 ng/L, the patient is pain free, HEART score is ≤ 3 and it is > 1 hour since the onset of chest pain, consider early discharge. Discharge should not occur if the patient is considered at high risk of ACS, nor if the admission hs TnI sample is collected within 1 hour after the onset of chest pain. If < 1 hour since the onset of chest pain, then a repeat hs TnI should be taken 3 h after the first sample.

3. If the baseline hs TnI is within the gender specific reference range and onset of pain was >6 h previously and the patient is now pain free the differential diagnosis is excluded and the patient is low risk. If there is still clinical suspicion of ACS then a repeat hs TnI should be taken 3 h after the first sample.
4. If the baseline hs TnI measurement is detectable and within the gender specific reference range and onset of pain is <6 h previously then a second sample for hs TnI measurement should be taken 3 h after the baseline sample. Interpretation will depend on the difference between the baseline and 3 h samples (see appendix A).
5. If the baseline hs TnI concentration is detectable and greater than the gender specific reference range but ≤ 170 ng/L (male) or ≤ 80 ng/L (female) irrespective of time of onset of chest pain a second sample for hs TnI measurement should be taken 3 h after the baseline sample. Interpretation will depend on the difference between the baseline and 3 h samples (see appendix A).
6. If the hs TnI is > 170 ng/L (male) or > 80 ng/L (female) (greater than five times the upper limit of the gender specific reference range) and there is a positive clinical presentation, the patient should be admitted and treated using local guidelines for ACS.
7. High sensitive TnI may also be measured in patients with a suspected late presentation of MI (although it should not be requested when the delay between suspected episode and presentation exceeds 7 days).
8. In patients in whom reinfarction is suspected from clinical signs or symptoms following the initial MI, an immediate measurement of hs TnI is recommended. A second sample should be obtained 3–6 h later. If the hs TnI concentration is elevated, but stable or decreasing at the time of suspected reinfarction, the diagnosis of reinfarction requires a 20% or greater change of the hs TnI value in the second sample. If the initial hs TnI concentration is normal, the criteria for new acute MI apply.

WHEN NOT TO MEASURE HIGH SENSITIVE TROPONIN I

1. High sensitive troponin I should not be measured in patients with chest pain that is clearly non-cardiac (e.g. musculoskeletal, pleuritic) or in medical admissions when the diagnosis is clearly non-cardiac (e.g. pneumonia). There are many causes of a raised troponin concentration that are not attributable to an ACS (Appendix B)

2. High sensitive troponin I testing is not generally available to primary care. Patients attending their GP with chest pain should be referred to their nearest A&E/ECC department, as recommended by NICE Clinical Guideline 95, Chest pain of recent onset. Should GPs wish to discuss exceptions to this policy they must contact the duty biochemist on 01233 616287.

INTERPRETATION (SEE ALGORITHMS APPENDIX A)

1. Patients demonstrating raised hs TnI concentration on the baseline sample or 3 h post-onset of chest pain should be managed according to Trust guidelines on acute coronary syndrome (see algorithm).

2. When a second sample is taken at more than 3 h after the first sample the result cannot be used to back-calculate the 3 h change.

TEST AVAILABILITY

1. High sensitive troponin I measurement will be provided by the clinical biochemistry laboratories at the three acute Trust sites on a 24 h per day basis with a 1 h turnaround time from receipt of the sample in the laboratory.

See Appendix A and B for algorithms.

3 Purpose and Scope

This policy gives guidance that is consistent with guidance developed by NICE.

4 Definitions

High sensitive troponin is used to describe a troponin assay that has a coefficient of variation of 10% or less at the 99th percentile (the upper limit of the reference population), and is able to detect cardiac troponin in at least 50% of the reference population.

The East Kent Hospitals laboratory measures hs TnI (Abbott *STAT* high sensitive Troponin I)

5 Duties

All staff involved in requesting, measuring or interpreting blood hs TnI concentrations must adhere to this policy.

6 Policy specific information

Not applicable.

7 Key Stakeholders, Consultation, Approval and Ratification Process

East Kent Hospitals University NHS Foundation Trust is the key stakeholder for this policy. This document was prepared by clinical biochemistry in consultation with Accident and Emergency Medicine and Cardiology, East Kent Hospitals University NHS Foundation Trust.
Correspondence can be found on S:\Path\SnrStaff\Comms with users\Clinical guidelines\Cardiac Chest Pain troponin

8 Review and Revision Arrangements

Three years from implementation date, by author.

9 Dissemination and Implementation

TrustNet, by proactive implementation through the Care Groups by appropriate clinical leads

10 Document Control including Archiving Arrangements

Archive of this document will be through Q-Pulse and TrustNet.

11 Monitoring Compliance

Within the Trust, responsibility for compliance with this policy must rest with the requesting Care Groups. Compliance will be assessed by retrospective audit.

12 References

1. National Institute for Health and Care Excellence (NICE) technology appraisal: Guidance on the use of glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes. http://www.nice.org.uk/Guidance/TA47 (accessed 12 March 2020).

2. National Institute for Health and Care Excellence (NICE) clinical guideline: Unstable angina and NSTEMI. http://www.nice.org.uk/guidance/cg94 (accessed 12 March 2020)

3. National Institute for Health and Care Excellence (NICE) clinical guideline: Recent onset Chest pain of suspected cardiac origin: assessment and diagnosis. http://www.nice.org.uk/guidance/cg95 (accessed 12 March 2020)

4. National Institute for Health and Care Excellence (NICE) quality standard: Acute coronary syndromes (including myocardial infarction) in adults. http://www.nice.org.uk/guidance/qs68 (accessed 12 March 2020)

5. National Institute for Health and Care Excellence (NICE) diagnostic guidance: Myocardial infarction (acute): Early rule out using high-sensitivity troponin tests (Elecsys Troponin T high-sensitive, ARCHITECT STAT High Sensitive Troponin-I and AccuTnI+3 assays) https://www.nice.org.uk/guidance/dg15 (accessed 29th July 2015)

6. Fourth universal definition of myocardial infarction. Kristian Thygesen, Joseph S. Alpert, Allan S. Jaffe, Bernard R. Chaitman, Jeroen J Bax, David A Morrow and Harvey D. White: the Executive Group on behalf of the Joint ESC/ACC/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction. European Heart Journal (2019) 40, 237 – 269.

7. 2015 ESC guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation.
   European Heart Journal Advance Access published August 29, 2015
   http://eurheartj.oxfordjournals.org/content/ehj/early/2015/08/28/eurheartj.ehv320.full.pdf

8. https://www.nice.org.uk/sharedlearning/adoption-of-high-sensitivity-cardiac-troponin-for-early-rule-out-of-acute-myocardial-infarction-ami-at-the-royal-wolverhampton-national-health-service-nhs-trust

9. Benefits of High Sensitivity Cardiac Troponin I at Admission. Ford, C. MedicalLab Management (2017), 20 – 24.

10. Application of high-sensitivity troponin in suspected myocardial infarction. Neumann JT, Twerenbold R, Ojeda F *et. al*. N Engl J Med (2019); 380:2529-40.

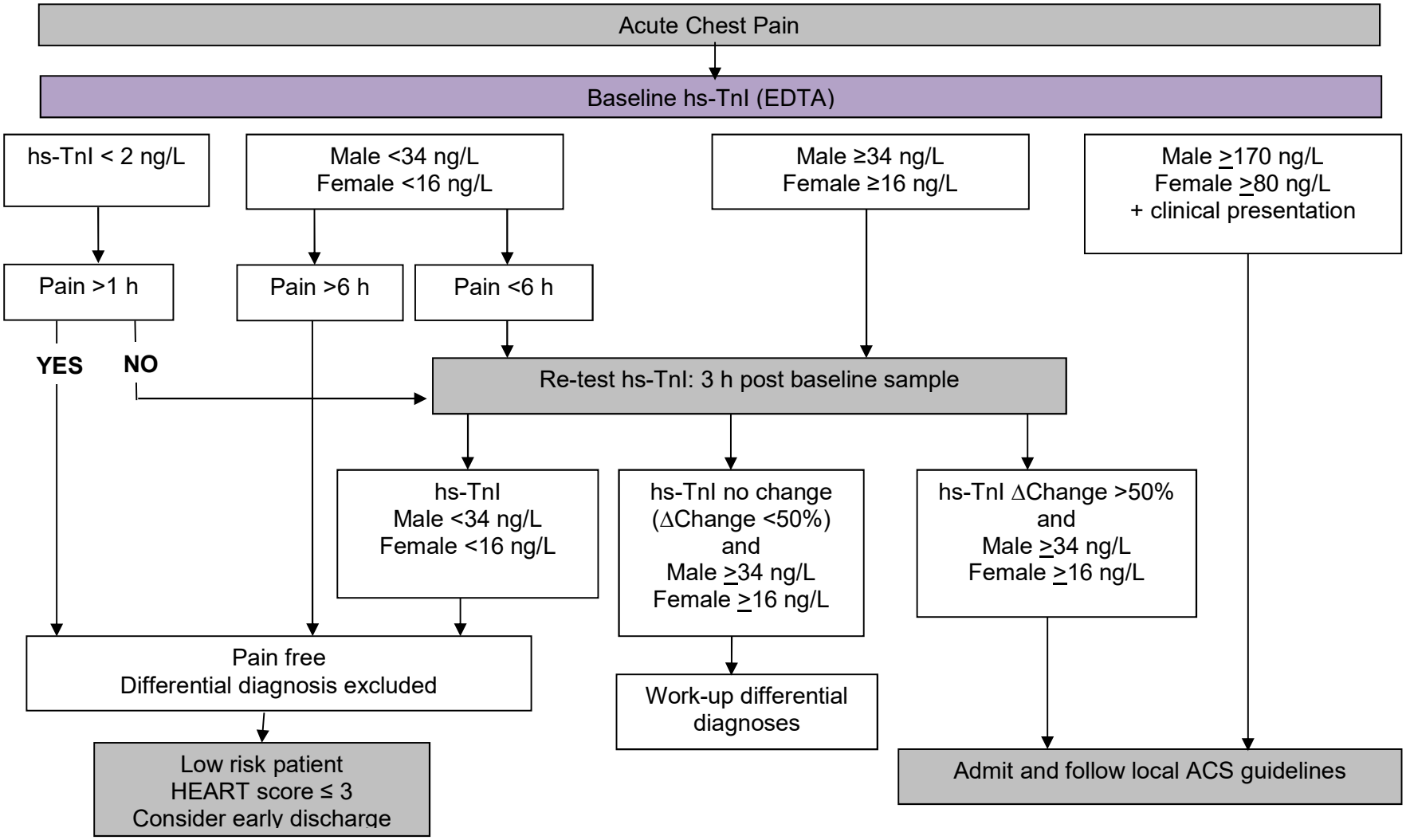
11. Immediate rule out of acute myocardial infarction using electrocardiogram and baseline high-sensitivity troponin I. Neumann, JT, Sorensen NA, Ojeda F *et. al.* Clinical Chemistry (2017);63:394-402.

12. Rapid rule-out of acute myocardial injury using a single high-sensitivity cardiac troponin I measurement. Sandoval Y, Smith SW, Shah ASV *et. al.* Clinical Chemistry (2017);63:369-376.

13 Associated Documentation

The Clinical Policy Board approved the original version of this protocol for the biochemical investigation of cardiac chest pain on 27th July 2001 (CPB/45/01/EL). The policy was introduced w.e.f. 1st October 2001. In April 2008 troponin I measurement replaced troponin T within the Trust. The original protocol was revised in September 2008. On 14th March 2011 the laboratory moved from reporting troponin in ug/L units to ng/L units. On July 1st 2014 the Trust switched from measurement of serum to measurement of plasma troponin. In October 2015 the Trust switched to measuring high sensitive troponin I (hsTnI). In March 2020 it was agreed that the Trust would introduce the use of a single undetectable hsTnI at presentation, to enable early and safe discharge in low risk patients.

Appendix A: Rule–out algorithm of non-ST-elevation acute coronary syndrome using high-sensitive cardiac Troponin I[7]



Appendix B - Reasons for the elevation of cardiac troponin values because of myocardial injury

Myocardial injury related to acute myocardial ischaemia
Atherosclerotic plaque disruption with thrombosis
Myocardial injury related to acute myocardial ischaemia because of oxygen supply/demand imbalance
Reduced myocardial perfusion, e.g.
• Coronary artery spasm, microvascular dysfunction
• Coronary embolism
• Coronary artery dissection
• Sustained bradyarrthythmia
• Hypotension or shock
• Respiratory failure
• Severe anaemia
Increased myocardial oxygen demand, e.g.
• Sustained tachyarrthythmia
• Severe hypertension with or without left ventricular hypertrophy
Other causes of myocardial injury
Cardiac conditions, e.g.
• Heart failure
• Myocarditis
• Cardiomyopathy (any type)
• Takotsubo syndrome
• Coronary revascularisation procedure
• Cardiac procedure other than revascularisation
• Catheter ablation
• Defibrillator shocks
• Cardiac contusion
Systemic conditions, e.g.
• Sepsis, infectious diseases
• Chronic kidney disease
• Stroke, subarachnoid haemorrhage
• Pulmonary embolism, pulmonary hypertension
• Infiltrative diseases, e.g. amyloidosis, sarcoidosis
• Chemotherapeutic agents
• Critically ill patients
• Strenuous exercise

Taken from :Fourth universal definition of myocardial infarction Kristian Thygesen, Joseph S. Alpert, Allan S. Jaffe, Bernard R. Chaitman, Jeroen J Bax, David A Morrow and Harvey D. White: the Executive Group on behalf of the Joint ESC/ACC/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction. European Heart Journal (2019) 40, 237 – 269.

Appendix C - Equality Impact Assessment

Equality and Human Rights Impact Analysis (EHRIA)

Part One – Screening Tool

Name of the policy, strategy, function or methodology:	CARDIAC CHEST PAIN GUIDELINES FOR BIOCHEMICAL INVESTIGATION

Details of person completing the EHRIA	
Name	Dr Sally Stock
Job Title	Consultant Clinical Scientist
Directorate/Department	Pathology
Telephone Number	723 6025

1. Identify the policy, strategy, function or methodology aims

What are the main aims, purpose and outcomes of the policy, strategy, function or methodology?
To ensure a consistent and rational approach to the biochemical investigation of cardiac chest pain in East Kent ensuring best use of health service resources.
Does it relate to our role as a service provider and/or an employer?
Service provider.

2. Assess the likely impact on human rights and equality

Use this table to check if the policy, strategy, function or methodology:

- could have a negative impact on human rights or on any of the equality groups, or
- could have a positive impact on human rights, contribute to promoting equality, equal opportunities or improve relations.

It is not necessary to complete each box, nor to mark whether it is positive or negative, although you can do this if you find it helpful.

	Protected Characteristic								
	Race	**Sex**	**Disability**	**Sexual Orientation**	**Religion or belief**	**Age**	**Gender reassignment**	**Marriage & Civil Partnership**	**Pregnancy & Maternity**
Could this policy, procedure, project or service affect this group differently from others? **YES/NO**									
Could this policy, procedure, project or service promote equal opportunities for this group? **YES/NO**		**Y**							
Right to life *e.g. decisions about life-saving treatment, deaths through negligence in hospital*									
Right not to be tortured or treated in an inhuman or degrading way									
Right to respect for private and family life e.g. *respecting lgb relationships, confidentiality*									
Right to freedom of thought, conscience and religion *e.g. respect for cultural and religious requirements*									
Right to freedom of expression *e.g. access to appropriate communication aids*									
Right to freedom of assembly and association *e.g., right to representation, to socialise in care settings*									
Right to education *e.g. access to basic knowledge of hygiene and sanitation*									
Right to liberty e.g. informal detention of patients who do not have capacity									

3. How does it impact on people's human rights and equality?

Using the table above, explain anticipated impacts. If a full EHRIA is recommended, you can summarise the impacts - it is not necessary to set these out in detail,

Could people's human rights be impacted negatively? Could the policy, strategy, function or methodology result in inequality or discrimination?
No
Could this policy, strategy, function or methodology result in positive impacts on people's human rights or equality? Could it present opportunities to promote equality?
No

4. Recommendations

Is a full EHRIA recommended? If not, give reasons
No. The policy has equal impact.

5. Publication of EHRIA

Give details of where Screening Tool or the full EHRIA will be published and when this will take place
n/a.

Details of person completing the EHRIA	
Name	Dr Sally Stock

Signed

Date: 11 May 2020

Approval and sign-off	Name
Head of Department/Director	Dr E Lamb

Signed …… Date: ……

Appendix D – Author's Checklist of compliance with the Policy for the Development and Management of Organisation Wide Policies and Other Procedural Documents

POLICY:

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

	Requirement:	Compliant Yes/No/ Unsure	Comments
1.	**Style and format**	Yes	
2.	**An explanation of any terms used in documents developed**	Yes	
3.	**Consultation process**	Yes	
4.	**Ratification process**	Yes	
5.	**Review arrangements**	Yes	
6.	**Control of documents, including archiving arrangements**	Yes	
7.	**Associated documents**	n/a	
8.	**Supporting references**	Yes	
9.	**Relevant NHSLA criterion specific requirements**	n/a	
10.	**Any other requirements of external bodies**	n/a	
11.	**The process for monitoring compliance with NHSLA and any other external and/or internal requirements**	n/a	

Appendix E – Plan for Dissemination of Policies

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

Title of document:	CARDIAC CHEST PAIN GUIDELINES FOR BIOCHEMICAL INVESTIGATION		
Version Number:	2.0		
Approval Date:		**Dissemination lead:**	
Previous document already being used?	Yes		
If yes, in what format (paper / electronic) and where (e.g. Directorate / Trust wide)?	Electronic on Q-Pulse and the Pathology area of TrustNet		
Proposed instructions regarding previous document:	Remove previous document from controlled locations		

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Format (i.e. paper or electronic)**	**Comments:**
Trust clinical staff	TrustNet	electronic	
Trust clinical staff	Email and education and training	electronic	

Author's Dissemination Record - to be Used Once Document is Approved – to be kept with the master document

Date document forwarded to be put on the Trust's central register / in SharePoint:		**Date document put on Directorate register (if appropriate) / on Directorate webpage (if applicable)**	

Disseminated to: (either directly or via meetings, etc.)	**By Whom?**	**Format (i.e. paper or electronic)**	**Date Disseminated:**